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REVIEW

Additive manufacturing applications in cardiology: A review

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A B S T R A C T

Background: Additive manufacturing (AM) has emerged as a serious planning, strategy, and education tool in cardiovascular medicine. This review describes and illustrates the application, development and associated limitation of additive manufacturing in the field of cardiology by studying research papers on AM in medicine/cardiology.

Methods: Relevant research papers till August 2018 were identified through Scopus and examined for strength, benefits, limitation, contribution and future potential of AM. With the help of the existing literature & bibliometric analysis, different applications of AM in cardiology are investigated.

Results: AM creates an accurate three-dimensional anatomical model to explain, understand and prepare for complex medical procedures. A prior study of patient's 3D heart model can help doctors understand the anatomy of the individual patient, which may also be used create training modules for institutions and surgeons for medical training.

Conclusion: AM has the potential to be of immense help to the cardiologists and cardiac surgeons for intervention and surgical planning, monitoring and analysis. Additive manufacturing creates a 3D model of the heart of a specific patient in lesser time and cost. This technology is used to create and analyse 3D model before starting actual surgery on the patient. It can improve the treatment outcomes for patients, besides saving their lives. Paper summarised additive manufacturing applications particularly in the area of cardiology, especially manufacturing of a patient-specific artificial heart or its component. Model printed by this technology reduces risk, improves the quality of diagnosis and preoperative planning and also enhanced team communication. In cardiology, patient data of heart varies from patient to patient, so AM technologies efficiently produce 3D models, through converting the predesigned virtual model into a tangible object. Companies explore additive manufacturing for commercial medical applications.

Contents

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1. Introduction

Regarding diseases, one of the biggest killers is cardiovascular disease, and millions of people required help in the issue of cardiovascular every year. Additive manufacturing helps to provide a better quality of life and speedy recovery of these patients.[1,2] It is an emerging and crucial adjunctive tool which can help cardiologists and cardiac surgeons for intervention and surgical planning, monitoring and analysis. Current applications of this technology are in device innovation, teaching tools, procedural planning and functional flow models.[3–5]

Additive manufacturing technologies are used to print 3D physical object from 3D digital file. A virtual design file is created from the CAD file using 3D modelling program/scanner or other scanning technologies like computed tomography (CT), magnetic resonance imaging (MRI). Further, Data is converted into a 3D physical model by using various AM technologies. The print material creates 3D model layer by layer, and this process is also called rapid prototyping.[6–8]

3D printed model has a unique purpose which allows the surgeon to envision and practice preoperatively. At all level of skill and experience, it is meaningful to surgeons depending on the specific circumstance. Imaging of the patient is done by using various scanning technologies that create the virtual 3D model and then importing the image file in a standard triangulate language (STL) format. The customised heart model is printed quickly by using various AM technologies which can be used further for clinical translation.[9,10] First, we make image acquisition and then go for virtual reconstruction and manufacturing.[11,12]

For preoperative evaluation, it is a promising tool that helps in medical education and hemodynamic simulation. It increases operative success and reduces operative risk. The decision of 3D cardiac model seems arbitrary because in interventional procedure cardiologist's perception can be different. In future practical clinical trials are possible by using AM in cardiovascular diseases treatment.[13,14]

Additive manufacturing has been revolutionising cardiovascular surgery, as in the new study taken by Texas A&M University; it combines Virtual reality (VR), high-resolution CT scan, vascular robotics systems and 3D printing for proper implementation in cardiology. This technology is used to provide a better standard of care and saves money. It supports treatment and creates holistic treatment plans.[15,16]

In patient-specific anatomies, it is used to evaluate stent placement. 3D printed models have some advantages over conventional platforms. In printing methods and materials; there is a rapid pace of advancement of principal drivers in the development.[17,18]

Additive manufacturing helps in creating a 3D model of the heart of a specific patient. Now treating doctor can understand the pathology and anatomic variations better which may be encountered during actual surgery or intervention. The scientists have manufactured an artificial heart which is made up of silicone, and it almost beats like a human heart but with a limited life. The step is closer to the replacement of a damaged human heart, and there will be no requirement of transplant. In worldwide, about 26 million people are suffering from heart failure, and there is a shortage of donors. Additive manufacturing technologies make custom artificial hearts that can solve the long-term problem.[19]

In cardiology, it is difficult to predict the outcome of heart valve replacement for cardiovascular surgical procedures. There are four valves in the heart which are responsible for maintaining the unidirectional blood flow during opening and closing depending upon the pressure difference on each side. The entry of blood flow from atria to ventricles by two atrioventricular (AV) valves (tricuspid and mitral) and the two semilunar (SL) valves (pulmonary and aortic) are present in arteries leaving the heart.[20] Precise information about these valves is required. Through the applications of AM, it accurately communicates information about the status of the heart/valves and helps in several improvements.[7,21,22]

Thus, Additive manufacturing is used to improve patient-specific surgical planning with the help of data captured by CT and MRI. This technology saves time, improves surgical accuracy and outcomes. During complex surgical cases, model printed by this technology is helpful for the surgical team, teaching surgery practices and demonstration. For complex congenital heart disease, surgical planning is challenging due to the high variability of patients. It better understands the anatomical structures of the patient heart. It is a powerful tool before performing complicated surgery and interventions that play an important role in day-to-day clinical care.[23–25]

2. Need for the study

In today's globalised world, every industry needs customisation and innovation in products and services. In this study, we analyse and describe how the surgeon and patient can benefit by implementing this technology in the management of cardiovascular diseases. It has opened a new path to improve the golden hands of a heart surgeon. AM gives an idea about stabilising heart muscle during operation, short development time and care for the patient. It provides a good co-operation between surgeon and suture. This technology provides a possibility of physical manipulation of the cardiac model in vitro which improves safety and may reduce operating time for complex cardiac surgeries. It provides knowledge of customised cardiac valves and helps its printing using biological/adaptable materials. Doctors can check the status of an outer and inner layer of the heart wall and quickly determines the health of the heart. The study provides awareness to cardiology surgeon about preoperative evaluation, hemodynamic simulation and development of tools/devices. Heart operation becomes safer and faster.

3. Benefits of using additive manufacturing in cardiology

AM is used to design and print a customised heart. From a digital file, it directly fabricates graspable objects. The various benefits of AM for cardiologists are as follows:

I. Tangible heart model and its components are easily printed by AM technologies that are useful for the patient to review the heart and vessel anatomy.
II. For a complicated case, the benefit of 3D printed model is to see the anatomy of the heart from different angles and understand the anatomical positions of the vessels.
III. For explaining the planned procedure to patients, the anatomical 3D model is also beneficial to understand much better during invention that what will happen.
IV. In teaching, the 3D printed model becomes more accessible to explain. They can touch and turn it around. It is a most important educational tool because it gives more information as compared to 2D or 3D images on a screen.

V. 3D printed model is also beneficial for pre-surgical training which saves lives, improving outcomes and offering new treatments.

4. Research status

4.1. Research status of additive manufacturing in cardiology

Search using the keyword as "additive manufacturing" "cardiology", identified only six published articles. Three articles of 2017 and again three articles till August 2018 are published. Different Journals Academic radiology, Annals of biomedical engineering, International journal on interactive design and manufacturing, Journal of biomechanics, Netherlands heart Journal, Trends in biotechnology published one article each. Engineering and medical fields have an equal contribution of 30%. Biology field contributes 20%, chemical engineering contributes 10%, and Mathematics field again have the equal contribution of 10%. Additive manufacturing employs different 3D printing technologies to accomplish different types of requirements.

4.2. Research status of 3D printing in cardiology

In Cardiology, application of 3D printing is proliferating and is subject of intense research. We explored the research material using Scopus on the use of 3D printing in cardiology. Around 38 research articles were identified by searching keywords as "3D printing" "cardiology". The first article was published in 2000. Again, after a long gap, three articles were published in 2014, In the year 2015, one article published, and there is an increment of research publications in 2016 where eight articles are published. Sixteen articles published in 2017 and till August 2018, six articles were published in this ongoing year as shown in Fig. 1.

JACC cardiovascular imaging journal has highest publications of two articles and rests various other journals published one research articles by each.

Fig. 2 shows the area wise research on additive manufacturing in cardiology, and we found that the field of medicine has a significant contribution in this area which is 47%. Engineering contributes 11%, Biochemistry, Genetics and Molecular Biology contribute 7%, chemical engineering and materials science 8% contribution by each field, Again Computer science and health professions have an equal contribution of 4% by each field. Other fields also have 11% of the contribution, and this includes physics and astronomy, social sciences, chemistry and mathematics.

As evident through Scopus, this technology seems to have broad applications in the medical field, and the same is also helping in the specific area of cardiology.

5. Steps of Additive manufacturing towards its adoption

AM uses a 3D computer model to create a 3D physical model by adding layer by layer of material. Medical AM uses a 3D medical image to create solid replicas of patient heart/its parts. Significant steps used by AM in cardiology as discussed in Table 1:

Additive manufacturing is at the crossroads of CAD, non-invasive diagnostic imaging, structural heart intervention, printer and materials engineering. Cardiovascular applications of additive manufacturing development include the use of patient-specific 3D models for exploration of the valve, vessel function, surgical and catheter-based procedural planning.[40,41] 3D printed model is manufactured from various imaging that provides a direct manipulation, haptic feedback to enhance the understanding of underlying pathologies and cardiovascular anatomies. 3D printed heart/valves help surgeon for patient counselling. In heart surgery when valves replacement does not fit properly, the 3D printed model allows the surgeon to test for fit. Now the surgeon can practice the procedure to achieve successful operation.

6. Criteria's for adopting when using Additive manufacturing for the production of an artificial heart/components

In the current scenario, a 3D artificial heart model can be quite helpful for a cardiologist. Edition of scanned data is done according to the required shape and dimensions, and finally, one can obtain a printed model. This printed model is gainfully used towards solving the complex surgical problem and fulfils the deficiencies of the cardiology area with lesser time and cost. Table 2 discusses various criteria's regarding the printing of the heart or its components with its achievements and limitations. These issues can be taken up by using additive manufacturing in the printing of an artificial heart.

For design and development of a heart model, additive manufacturing is a useful tool which provides a better understanding of patient to the surgeon. A model can be well designed using scanning devices/supporting software which is ease of use and

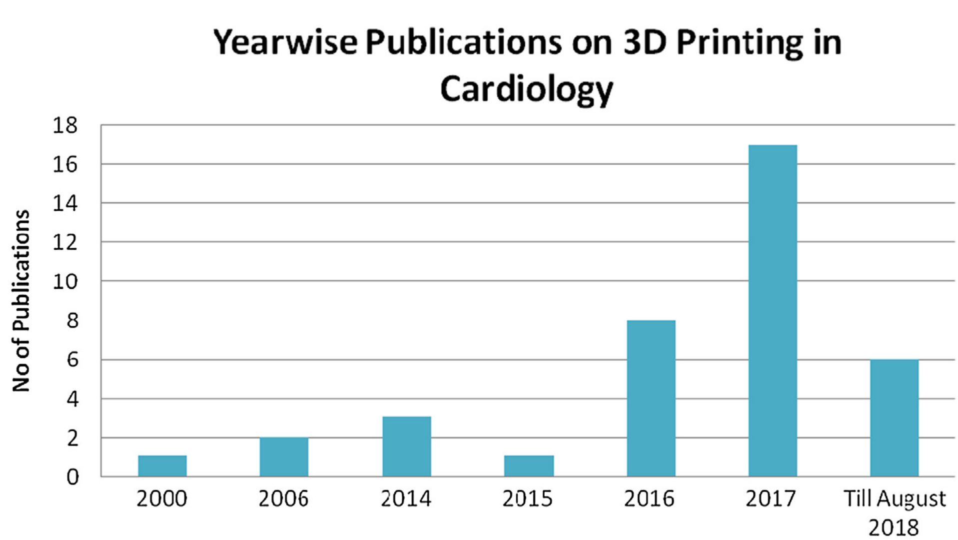

Fig. 1. 3D printing in cardiology: Year wise publication (Source: Scopus).

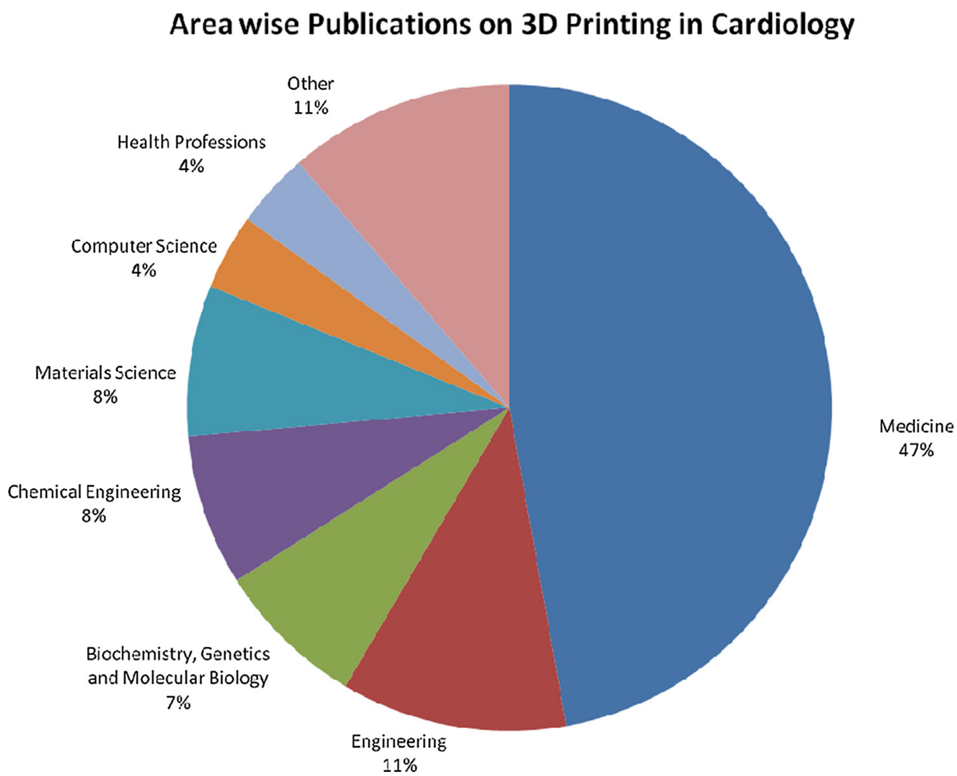

Fig. 2. 3D printing in cardiology: Area wise contribution (Source: Scopus).

Table 1
Steps of Additive Manufacturing toward making heart/its parts.

S No	Steps	Description	Benefits	References
1	Image acquisition	• It is an important process/technique to create a visual representation of internal parts of the body that is hidden by skin such as bones, heart as well as diagnosis and treats disease • Used to analyse and visual representation of some tissue and organs • Most crucial step in the design process • Capture accurate and precise virtual heart model • MRI and CT are useful for image acquisition	• Useful for delineating extra-cardiac and intra-cardiac vascular anatomy	Gómez-Ciriza, et al.[26], Giannopoulos et al.[27], Ripley et al.[28]
2	Segmentation	• It is a process to change the representation of the image into meaningful that collectively cover the entire image • Used to create the 3D virtual model as per requirement • Generated the cardiac structure from a medical image	• Measure tissue volume • Study anatomical structure, intra-surgery navigation, surgical planning and virtual surgery simulation	Dankowski et al.[29], Mosadegh et al.[30]
3	Computer-aided design	• CAD software develops a 3D virtual model, and the same is printed using AM technologies • Exported segmentation geometry into STL format which is used for printing of the 3D model by additive manufacturing technologies • Adjustment of layer thickness as per required strength	• Speed up for production of products/ medical implants /tools	Hu et al.[21], Haleem and Javaid[31], Jacobs et al.[32]
4	Rapid prototyping (3D printing)	• Various technologies are used to create a 3D model with different type of tissue, living cells and biomaterials • Medical is a fastest growing area of AM and now also implemented in cardiology • A better way of enabling or manufacture the patient-specific device • Built working models/prototype in a short time that is used to test various ideas, design features, functionality and performance	• High flexibility of this technology is to quickly make changes without any requirement of additional tools or equipment • Fabricates a device to match patient's anatomy or very complicated internal structure	Schrot et al.[33], Ngan et al.[34], Birbara et al.[35], Farooqi and Mahmood[36], Javaid and Haleem[37]
5	Clinical translation	• Technology is incorporated in routine clinical practice to address clinical translation that successfully creates good collaboration between doctor and patient • Play a vital role towards the understanding of molecular mechanism of disease • Leads to a better understanding of disease and development of new treatment and tests	• Helps in treatment/diagnoses of the disease • Analyse the human sample and match the genetic information of the patient	Campbell and Weiss[38], Hadeed et al.[39]

Table 2
Criteria's in using AM for the production of artificial heart/components.

S No	Criteria	Achievements	Limitation	References
1	Ease of design	• Design software plays a significant role in product design and development for the creation of design as per requirement • The design also creates from scanning devices such as CT, MRI and 3D scanners which help to generate a product in a lesser time	• Highly design skills are required	Cheng et al.[42], Zhang and Joshi[43], Olivier et al.[44]
2	Material	• Used to print various types of material such as plastic, powder, metal, composite, wood and allied materials. • By changing material, it creates the model as per required strength	• In some technologies of Additive manufacturing material changing options are limited	Cunico and Carvalho[45], Fahad et al.[46]
3	Colour	• In cardiology, one can undertake a study on full-colour of 3D heart model before starting actual surgery • Through this one can also see the overall heart vane, the flow of blood and blockage in the heart • Colour-Jet 3D printer can easily print full-colour model, and full fill this required criteria	• Some technologies are monochrome	Chromy and Zalud[47], Dahake et al.[48]
4	Efficiency	• AM improve sustainability aspects and resource efficiency • It improves the efficiency of material input processing, product and process design, and component manufacturing	• Affected by the quality of raw material that decreases the overall performance of the system	Gibson et al.[49], Rengier et al.[50], Salmi et al.[51]
5	Speed	• This technology has a fast-built-in speed option by changing the print orientation of the product. • Used to produce make-to-order models • Cardiologist require 3D printed model in very less time before operating the patient	• Processing speed seems sufficient during fabrication of a customised model but not suitable for mass production	Swann[52], Tukuru et al.[53], O'Malley et al.[54], Schievano et al.[55]
6	Model Dimensions	• Print any shape and size product as per geometry of the implant • A sophisticated shape can also be manufactured efficiently	• Some technologies print standard dimension product depending upon the size of the built bed	Negi et al.[56], Vaezi et al.[57], Wang et al.[58]
7	Cost	• For a medical implant or model, AM successfully produces at a lower cost • Medical implant's fabrication is easy as compared to another machining process as each medical data of each patient is different	• Only efficient for customisation	Yap et al.[59]; Zhang et al.[60], Melchels et al.[61], Tuomi et al.[62]
8	Accuracy	• Improve accuracy through changes in layer thickness and resolution in the 3D digital file • Changing in the specification of raw material affects the accuracy of the model because medical case accuracy is a significant factor	• Sometimes a product is not so accurately fabricated as compared to another machining process	Arrieta et al.[63], Balazic and Kopac[64], Mallepree and Bergers[65], Kernan and Wimsatt[66]
9	Ease of use	• This technology comfortably captures a medical image and convert it into the 3D model • The model produced by AM technology is ease of use because no tooling and fixtures are required	• Required educated human resources for operating these machines	Chimento et al.[67], Hieu et al.[68], Salmi et al.[69]
10	Simulation before or after medication	• AM can assist towards advanced simulation in cardiology for healthcare solution • Simulation train doctors and give virtual reality for the surgeon to expect, predict the change after surgery and medication • It presents a critical/innovative way to communicate and interact	• Sometimes it is not reliable	Pandit et al.[70], Chiumenti et al.[71]

improved efficiency/accuracy. Heart model shows real understanding regarding actual pathology in the heart/associated body components. This knowledge can help in reduced time spent on invasive surgery and develops a clear communication among the surgical team members. Thus, a printed model can allow cardiologists learn about the problem on the structure of hearts and deliver better treatment.

7. Types of applications of additive manufacturing in cardiology

In many cases, there is a requirement of customised 3D heart model of the patient. AM fulfils this requirement at an economical price. This novel technology is also medically used in various areas of medicine like maxillofacial and orthopaedic surgery that helps to reduce surgical time. In cardiology, surgeons can study and practice their hands on the 3D printed patient anatomy. Thus, AM has various applications in interventional structural heart disease as discussed in Table 3.

Doctors can use a 3D heart model to guide a tricky heart valve replacement. This technology helps simulate the procedure and rapid development of new medical tools/devices that are helpful for individual patients. Heart model allows preoperative simulation of a specific patient. It holds educational promise for a high-risk operation which was a challenge to teach. 3D printed models are rigid, semi-rigid, single- colour and having multi-colour that easily fulfils the needs of the clinical team. We can section a heart in any plane and can rotate in all axes on screen. By using AM technology, we can see heart precisely and analyse it before an interventional procedure/actual surgery.[94,95] Patient 3D heart models can be stored in a follow-up appointment/records.[96] Surgeons take advantages of additive manufacturing technologies to solve complex medical problems due to its flexibilities of design and manufacturing.

Table 3
Different types of applications of AM in the area of cardiology.

S No	Clinical Applications	Description	References
1	Aortic pathology	• For patient anatomy, 3D printed model is an accurate replica which is helpful in the planning of endovascular stenting in transverse arch hypoplasia, specifically in determining stent length, balloon size and optimal position • 3D printed model has great potential to guide the delivery of the covered stent • Helpful in several diseases like under-treated and under-diagnosed which caused the wall enlargement of the aorta and localised weakness	Gosnell et al.[72], Wolf et al.[73]
2	Atrial septal defect closure	• The atrial septal defect is the hole in the valve which separates the upper chambers of the heart, from left to right side of the heart hole causes oxygen-rich blood to leak • AM has the potential to develop new medical devices for preclinical and it closure the atrial septal defect	Mathur et al.[74]; Perez-Arjona[75]
3	Stent angioplasty in pulmonary venous baffle obstruction	• For the planning of the interventional procedure, 3D models are utilised and trialled 3D model in advance • Helpful for planning and selection of the appropriate device • 3D printed model guide to open blocked or narrowed blood vessel that supply to the heart	Gosnell et al.[72]; Shiraishi et al.[76], Dickinson et al.[77]
4	Percutaneous mitral annuloplasty	• Used for development of treat mitral regurgitation and effective role of cardiac surgery for mitral valve repair • It prints patient replica and carries out percutaneous mitral annuloplasty procedure • Improved the success of intervention such as guide catheter that requires additional torque • 3D model is suitably used to treat valvular heart disease and followed applications in mitral and aortic valves	Sodian et al.[78], Noecker et al.[79], Pellegrino et al.[80]
5	Pulmonary valve implantation	• For pulmonary valve implantation, 3D models have the right pulmonary artery and ventricular outflow tract • Appropriately used for patients with pulmonary valve implantation • Potential to aid in the design of future devices used during heart surgery	Kim et al.[81], Sodian et al.[82]
6	Transcatheter aortic valve implantation	• Used for preoperative planning of transcatheter valve replacement of patient and know the exact position of the critical structures which reduce the perioperative risk • This technology is used for repairs the valve without removing the damaged/old valve	Otton et al.[83], Kiraly et al.[84]
7	Structural interventional cardiology training	• Used for interventional cardiology that is efficiently applicable for congenital heart disease • Its potential applications are to fellow training and its revalidation • Helpful during the integrative treatment of a patient for structural heart disease, atherosclerosis and heart valve disease • It provides patients with the highest quality of care and achieves successful outcomes for patients	Farooqi et al.[85], Costello et al.[15]
8	Teaching tools	• Creates models for anatomic teachings like the plastic heart models and healthcare professionals • Artificial 3D heart model conveys a complex anatomic arrangement depicting patient-specific anatomic pathology • Used for the education of medical professionals such as understanding the relationship of normal and abnormal structure	Torres et al.[86], Javaid and Haleem[87]
9	Procedural planning	• 3D printed heart model provides a comprehensive understanding and evaluates various congenital heart conditions • It includes interventional preoperative planning and simulations • Use sterilised models during surgical procedures and pre-procedural planning of specific patient	Jacobs et al.[32], Shiraishi et al.[88], Schmauss et al.[89]
10	Functional flow models	• Quickly create a 3 D model of patient-specific like aortic valvenology • Functional evaluation performance of the model can be checked under various vitro flow condition because the area of the aortic valve is not in fixed value, there is variation in valve orifice area of some patient due to the increase of flow volume • Functional model can provide controlled testing of flow under pre-specified conditions	Sacks et al.[20], Vukicevic et al.[23]
11	Device innovation	• It can easily redesign new structural heart repair devices/ tools/devices • Creating 3D models with innovation in material, software and the hardware • Technology can give impetus towards innovation of surgical devices/instruments • Used for product development, research and development, design validation, planning, regulatory filings, intellectual property assessment and clinical trials	Lazkani et al.[90], Green et al.[91], Olivieri et al.[92]
12	Treatment of arrhythmia	• 3D imaging and printing help cardiologists for a better understanding of arrhythmias • The risk is involved in the treatment of arrhythmia because everyone's heart anatomy is different • AM is the perfect technique for this treatment by taking data from CT and MRI scan and print a 3D model	Miller[93], Farooqi et al.[36]

8. Major finding through the study

Additive Manufacturing provides a useful contribution in the area of cardiology, starting from imaging to clinical translation, it has a useful role, and the same is presented below:

i. Research on applications of this technology in cardiology is increasing; Search of the literature showed that medicine is the most common field where research on AM is rapidly progressing.
ii. AM helps converting a predesigned virtual model into a physical object and acts as an efficient, supportive tool for medical education that reduces operative risk.
iii. Additive manufacturing follows five steps in cardiology by its application, i.e. image acquisition, segmentation, computer-aided design, rapid prototyping and clinical translation to create an artificial 3D heart.
iv. 3D printed model provides excellent communication between patient and health professionals. The patient can understand the illness better and take a more informed and empowered decision.

v. AM helps provide a walk-through planning tool to the cardiac surgeon before complicated surgery that can make the procedure safer and faster.
vi. AM helps the surgeons to create a customised action plan which gives an idea of what to expect by studying patient's accurate replica of cardiovascular tissue.
vii. AM can potentially help in designing an artificial heart that will closely resemble the human heart. It is at a nascent stage and requires innovation in medical tools/ devices to fabricate customised artificial heart rapidly.
viii. Additive manufacturing has various applications in Aortic pathology, Atrial septal defect closure, proper patients for pulmonary valve implantation, procedural planning, teaching tool and device innovation.
ix. Due to various attributes of AM such as design, colour, efficiency, speed, cost and accuracy, it has the potential to revolutionise the practice of cardiac intervention and surgery.

9. Limitations and future directions

AM provides less tangible benefits in specific areas. It does not provide information about blood loss, blood clot; chest wound infection, and metabolic abnormalities. Before the printed 3D model, an accurate and precise medical image is required. The technology involves cost and time in addition to the standard care of patients.

However, the future growth of technology will overcome present-day challenges. AM has the potential for congenital heart disease and simulation of structural interventions. In the broadest sense, it will enhance multidisciplinary collaboration involving clinical cardiologists, radiologists, cardiac catheterisation specialists, and surgeons. AM may become a ubiquitous and essential tool to fabricate customised implantable medical devices that improve existing therapeutic interventions. In future, these 3D printing technologies could print a 3D heart model by using smart materials which can change their shape and functionalities concerning time. These are called 4D printing technologies. These technologies can easily print heart, kidney and liver by the input of smart material with high flexibility with perfect fit and matches genetically. These models can grow in the patient body as per patient growth. It could also manufacture smart cardiac tube that can grow in patient body with the help of body heat concerning time. This new rapidly growing technology can well be used in continuous quality control, perform precise surgery and expands frontiers of modern medicine.

10. Conclusion

Additive manufacturing is emerging as an important tool in the field of medicine especially cardiology. It easily fabricates a three-dimensional physical model of the heart of a specific patient in a short time, using various specialised technologies from previously acquired scanned virtual image. Three-dimensional scanned images created by CT and MRI can be examined in the form of a realistic and tangible object. This can be used to examine the complexity of diseased anatomy in a given patient. This technology easily fulfils various requirements of cardiology due to its flexibility in design and manufacturing of specific patient 3D models. Research in this field is continuously increasing and will take over various challenges which were not previously possible by other conventional manufacturing technologies. It has the potential to be of immense help to the cardiologists and cardiac surgeons for intervention and surgical planning, monitoring and analysis. A prior study of the patient's heart model can lead to better pre-procedure planning, enhanced team communication, and improved outcomes. In future, these technologies can use the smart material as input and could take over the challenge of heart replacement of patient and save millions of lives. The paper summarised additive manufacturing applications particularly in cardiology, especially manufacturing of a patient-specific model of heart or its components.

Conflict of interest

The authors declared that there is no conflict of interest.

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