

# Using a 3D printer in cardiac valve surgery: a systematic review

 Liliansa Fortini Cavalheiro Boll<sup>1</sup>  
 Guilherme Oberto Rodrigues<sup>2</sup>  
 Clarissa Garcia Rodrigues<sup>1</sup>  
 Felipe Luiz Bertollo<sup>1</sup>  
 Maria Claudia Irigoyen<sup>3</sup>  
 Silvia Goldmeier<sup>1</sup>

**1.** Institute of Cardiology / University Foundation of Cardiology; Av. Princesa Isabel, 370 – Porto Alegre, RS, Brasil

**2.** College Method of São Paulo, São Paulo, SP, Brasil

**3.** School of Medicine of the University of Sao Paulo, SP, Brasil

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## SUMMARY

**BACKGROUND:** *The use of the 3D printer in complex cardiac surgery planning.*

**OBJECTIVES:** *To analyze the use and benefits of 3D printing in heart valve surgery through a systematic review of the literature.*

**METHODS:** *This systematic review was reported following the Preferred Reporting Items for Systematic Review and registered in the Prospero (International Prospective Register of Systematic Reviews) database under the number CRD42017059034. We used the following databases: PubMed, EMBASE, Scopus, Web of Science and Lilacs. We included articles about the keywords "Heart Valves", "Heart Valve Prosthesis Implantation", "Heart Valve Prosthesis", "Printing, Three-Dimensional", and related entry terms. Two reviewers independently conducted data extraction and a third reviewer solved disagreements. All tables used for data extraction are available at a separate website. We used the Cochrane Collaboration tool to assess the risk of bias of the studies included.*

**RESULTS:** *We identified 301 articles and 13 case reports and case series that met the inclusion criteria. Our studies included 34 patients aged from 3 months to 94 years.*

**CONCLUSIONS:** *Up to the present time, there are no studies including a considerable number of patients. A 3D-printed model produced based on the patient enables the surgeon to plan the surgical procedure and choose the best material, size, format, and thickness to be used. This planning leads to reduced surgery time, exposure, and consequently, lower risk of infection.*

**KEYWORDS:** *Heart Valves. Printing; Three-Dimensional. Cardiovascular Surgical Procedures.*

## INTRODUCTION

Cardiovascular diseases continue to be one of the primary causes of mortality, accounting for 40% of all deaths worldwide (WHO).<sup>1</sup> There are estimates that in 2030, this rate will reach 43.9%.<sup>2</sup> In addition to ischemic heart disease, valvular heart disease is one of the most prevalent cardiovascular diseases. Surgical repair of valvular lesions, however, have limitations depending on the patient's conditions,

congenital abnormalities, risk factors, comorbidities, and adverse immune responses.<sup>3</sup>

In a systematic review, the authors mention different techniques used by 3D printers, among them is *stereolithography*, which fabricates a solid object from a photopolymer resin, and then laser light is then used to harden the surface layer of the polymer liquid.

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CORRESPONDING AUTHOR: Silvia Goldmeier

Institute of Cardiology / University Foundation of Cardiology

Av. Princesa Isabel, 370 – Porto Alegre, RS / Brasil – Telephone and fax number: (51) 3230-3600

E-mail: [silvia.gold@cardiologia.org.br](mailto:silvia.gold@cardiologia.org.br)

*Fused deposition modeling* creates a 3D structure by extruding melted thermoplastic filaments layer by layer along with a physical support material that is later dissolved away. *PolyJet technology* creates 3D prints through a process of jetting thin layers of liquid photopolymers that are instantly hardened using UV light.<sup>4</sup>

In recent years, technological development has rapidly increased in cardiac surgery, contributing to the prevention of many complications.<sup>5</sup>

Advances in the surgical approach of valve diseases include progress in tissue engineering and the use of new surgical materials, improvement of mechanical and biological valves, and decreased use of thrombolytic and immunosuppressive drugs.<sup>6</sup>

In industrialized countries, the prevalence of chronic diseases, including degenerative valve disease has increased due to the aging of the population. By 2050, the number of people who require valve replacement may triple. Limitations to valve repair and remodeling in elderly patients include valve calcification due to aging.<sup>7</sup>

A strategy to deal with these limitations and that offers a promising future is three-dimensional (3D) rapid prototyping, which has emerged as an important tool for the guidance of preoperative and surgical planning.<sup>8</sup> The technique, developed in the 1980s, was initially used in the industry and has been increasingly used in health care for providing detailed information on preoperative diagnosis.<sup>5</sup>

A prospective case-crossover study involving 10 international centers analyzed 40 patients with complex CHD (mean age 3 years) and used an MRI scan and/or a CT scan to stratify the cardiovascular anatomy. Then, models were fabricated by fused deposition modeling with polyurethane filament. The images with their dimensions were compared with the 3D models, which accurately replicated the anatomy with a mean bias of  $-0.27 \pm 0.73$  mm. Of the total number of surgeons, only 4% did not agree that the 3D models provided a better understanding of the morphology of CHD and surgical planning. In conclusion, 3D models are precise replicas of cardiovascular anatomy and helped redefine the surgical approach.<sup>9</sup>

Printing physical models of the heart to be operated contributes to the careful planning of surgeries in adults and children with congenital abnormalities, thereby reducing the risk of error and complications.<sup>5</sup> Therefore, 3D printing enables accurate

measurement of the cardiac system, resulting in longer-term benefits to the patient.<sup>10</sup>

In the present study, we analyze the use and benefits of 3D printing in heart valve surgery by a systematic review of the literature.

## METHODS

### Protocol and Registration

This systematic review was reported following the Preferred Reporting Items for Systematic Review and registered in the Prospero (International Prospective Register of Systematic Reviews) database under the number CRD42017059034.

### Eligibility Criteria

The following inclusion criteria were considered: 3D printing and heart valve in humans; articles written in Portuguese, English or Spanish. We excluded studies limited to materials and devices, reviews, and conference abstracts.

### Information Sources

We searched the following electronic databases: PubMed, Embase, Web of Science, Scopus and LILACS. In addition, we manually searched the references of the articles selected and performed a citation analysis using Google Scholar.

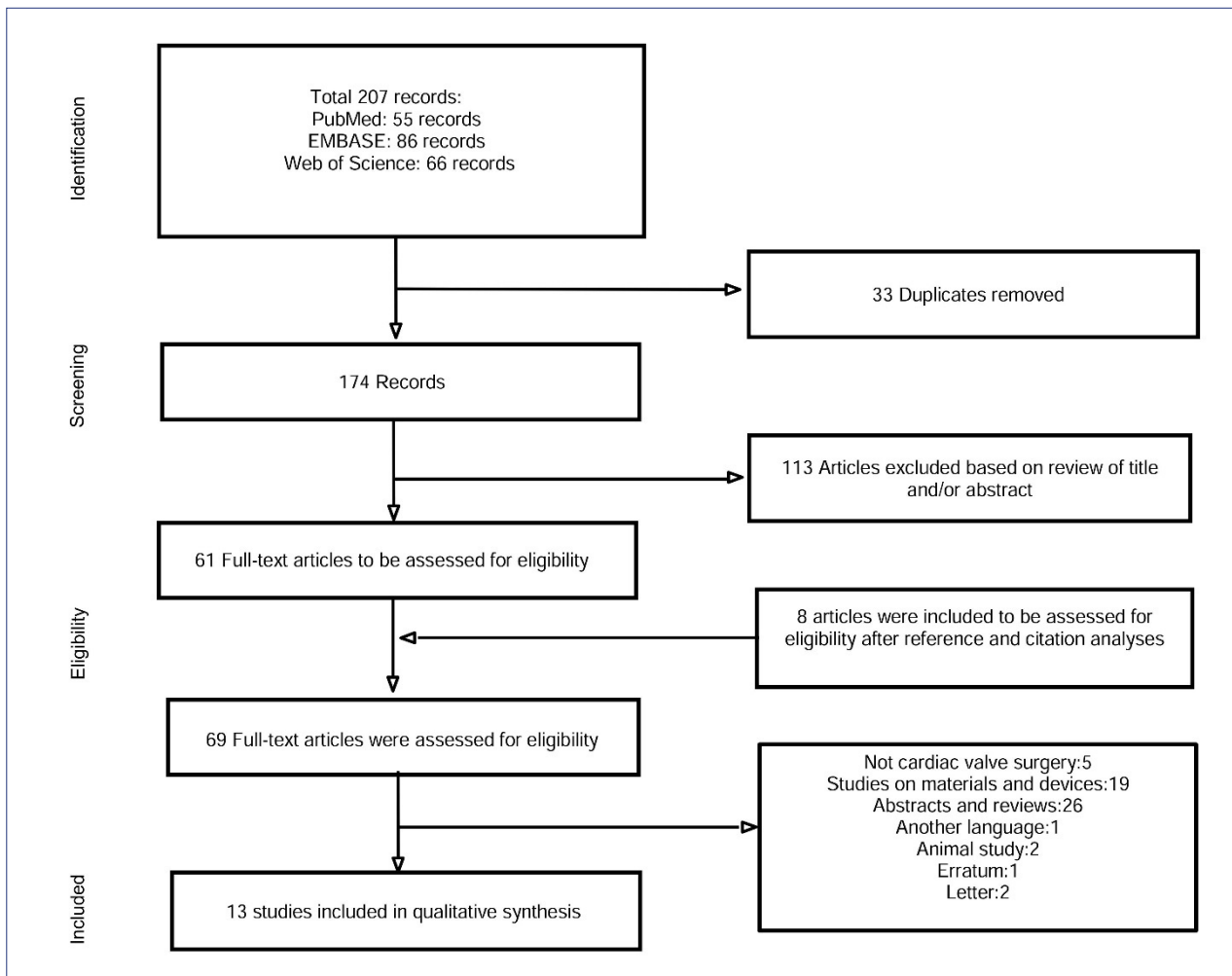
### Search

The initial search comprised the keywords “Heart Valves”, “Heart Valve Prosthesis Implantation”, “Heart Valve Prosthesis”, “Printing, Three-Dimensional”, and related entry terms. The complete strategy was used for the search in PubMed. Searches were conducted in August 2018 and, initially, 301 articles were identified in the electronic databases. After removing duplicates, 268 articles were left to be evaluated by title and abstract. From those, 75 articles were selected for full-text analysis, and 10 met the inclusion criteria. After reference and citation analysis, 3 additional articles were included for full-text analysis. Thirteen articles were included in the systematic review. Figure 1 shows the flow diagram of the study selection process of this review.

### Study Selection

The titles and abstracts of the retrieved articles were independently evaluated by 3 reviewers (LB, GR, and FB). Abstracts which did not provide enough

**FIGURE 1:** FLOW DIAGRAM OF THE STUDY SELECTION PROCESS.



information regarding the eligibility criteria were kept for full-text evaluation. Reviewers independently evaluated full-text articles and determined study eligibility. Disagreements were solved by consensus, and if any disagreement persisted, they sought a fourth reviewer’s opinion (SG).

**Data Extraction**

Three reviewers (LB, GR, and FB) independently conducted the data extraction, and disagreements were solved by the fourth reviewer (SG). First, the general characteristics of the studies were collected, such as 3D printing and cardiac valves. Then, the type of valve, image acquisition method, type of patient, manufacturing material and 3d printing evaluation method.

**Data Analysis**

The analysis of the articles retrieved was performed in a descriptive manner, in two stages. In the

first one, we analyzed the year, authorship, place of study, type of study, target population, study design, assessment of outcomes regarding the question addressed and the given answer options. In the second stage, we analyzed the prevalence of the outcome measure and the factors associated with this outcome.

**RESULTS**

**Study Characteristics**

The studies included were published between 2008 and 2018, and the sample size varied from 1 to 8 individuals. The studies included 4 children, 2 teenagers, 8 adults, 16 elderly, and 4 had no age records. There was no post-surgical follow-up. The surveys were conducted in the United States, Poland, Spain, Germany, Japan, and France. The study designs were case report and retrospective analysis. The descriptive data of the studies included are presented in Table 1.

## Synthesis of Results

Some methodological aspects varied among the reviewed studies and may affect the synthesis of results, including the instruments used to assess 3D, the type of valve and its manufacturing material, and imaging methods. Data about the quality of results from each study are described in Table 2.

## DISCUSSION

This systematic review evaluated the use of 3D rapid prototyping, which provides very accurate information in highly complex cardiovascular diseases. We identified 13 articles on this technique, which included a small number of patients (report of isolated cases) aged between 3 months to 94 years. The studies were conducted in the USA (n=6), Europe (n=6), and Japan (n=1).

The 3-D printing technique was used in aortic, mitral, tricuspid and pulmonary valve repair, either combined or isolated. However, there was no post-operative follow-up in any of the cases. Mitral repair was reported in three articles,<sup>12-14</sup> aortic repair in five,<sup>11,15,17,19,20</sup> tricuspid valve repair in one,<sup>18</sup> pulmonary valve repair in one,<sup>23</sup> tricuspid/mitral repair in two,<sup>16,21</sup> and aortic/mitral repair in one article.<sup>22</sup>

Due to the high complexity of the cardiac valve replacement surgery and recommendation, the inclusion criteria varied between the studies. The case reports described 3D printing technology as an accurate tool for replication of cardiac prosthesis in implantation surgeries.

A multi-slice computed tomography (MSCT) scanner is provided with a software package that turns images into a printable file that is sent to a 3D printer. This method is used for acquisition and precise

**TABLE 1:** DESCRIPTIVE DATA OF THE STUDIES INCLUDED

Study, Year	Country	Study design	Number of subjects	Age	Gender	Basic Diseases	Type of valve
Duan et al. <sup>11</sup> /2013	USA	Case report	1	12	male	Congenital malformations	Aortic valve
Dankowski et al. <sup>12</sup> /2014	Poland	Case study	1	41	male	Dilated cardiomyopathy	Mitral valve
Little et al. <sup>13</sup> /2016	USA	Case report	1	62	male	Bacterial endocarditis	Mitral valve
Vukicevic et al. <sup>14</sup> /2017	USA	Case report	2			1-Mitral valve regurgitation 2- Tissue infection	Mitral valve
Gallo et al. <sup>15</sup> /2016	Italy	Case report	1	79		Hypertension, diabetes mellitus, chronic kidney disease, dyslipidemia, atrial fibrillation, epilepsy, thalassemia minor, and monoclonal gammopathy	Aortic valve
Maragiannis et al. <sup>16</sup> /2016	USA	Case report	8	84, 92, 94, 70, 91, 64, 81, 55	5- male 3- female	Severe degenerative aortic stenosis	6-Tricuspid and 2-Mitral valve
Sodian et al. <sup>17</sup> /2008	Germany	Case report	1	81	female	Aortic valve stenosis, after coronary artery bypass grafting (CABG)	Aortic valve
Bauch et al. <sup>18</sup> /2015	USA	Case report	2			Atrial fibrillation	Tricuspid valve
Schmauss et al. <sup>19</sup> /2015	Germany	Case report	8	16, 3m, 2, 14, 81, 43, 50, 70	4- female, 4- male	1-Congenital malformations 2- Congenital malformations 3- Congenital malformations 4- Congenital malformations 5- Aortic stenosis 6- Heart insufficiency 7- HIV, a type A Aortic dissection 8- Aortic valve stenosis, calcified ascending aorta	Aortic valve
Fujita et al. <sup>20</sup> /2017	Japan	Case report	1	82	female	Previously undergone mitral valve replacement	Aortic valve
Jacobs et al. <sup>21</sup> / 2008	Germany	Case report	3	50, 81, 50	2- female, 1- male	Malignant tumor and ventricular aneurysm	Mitral and Tricuspid valve
Kim et al. <sup>22</sup> / 2008	USA	Case report	4	30, 50, 72, 69	1- female, 3- male	Congenital VSD Atrial septal aneurysm Periprosthetic valvular defect. Thoracic aortic pseudoaneurysm	Aortic and Mitral valve
Hadeed et al. <sup>23</sup> / 2016	France	Case report	1	5m		Congenital malformations (systolic heart murmur)	

**TABLE 2.** QUALITY OF RESULTS FROM EACH STUDY

Study, Year	Imaging Modality / Technique	Printer details	Manufacturing material	Endpoints of printers
Duan et al. <sup>11</sup> /2013	Computed tomography	Micro-CT (GE eXplore CT120; GE Health Care, Milwaukee, WI) at 100 µm resolution, 80keV, 30 mA, 800 angles, 30 ms exposure time, 30 gain, and 20 offset.30	Alginate/gelatin hydrogel	Living aortic valve conduits with anatomical resemblance to the native valve based on alginate/gelatin hydrogel system
Dankowski et al. <sup>12</sup> /2014	Multi-slice computed tomography (MSCT)	3D printing as a clinically applicable heart modeling technology	Rubber-like urethane	
Little et al. <sup>13</sup> / 2016	Echocardiography and tomography	A multimaterial patient-specific 3D model	Multimaterial TangoPlus	Replicate the mitral valve leaflet geometry, regional calcium deposition (yellow) and pathology.
Vukicevic et al. <sup>14</sup> /2017	Clinical 3D transesophageal echocardiography and computed tomography	Multi-material 3D printing technology and addition 3D TEE	Multi-material, TangoPlus-Shore 3	Specific mitral leaflet geometry and the mitral valve apparatus can be digitally reconstructed from currently available clinical imaging tools
Gallo et al. <sup>15</sup> /2016	A 64-row multi-detector computed tomography (MDCT)	Three-dimensional (3D) model	Stereolithography	Was useful to rule out the risk of occlusion of the brachiocephalic trunk during the stent-valve deployment and is a useful tool to plan complex transcatheter
Maragiannis et al. <sup>16</sup> /2016	ECG-gated and 64-slice multi-detector CT	Multimaterial 3D printed	The rubber-like material TangoPlus	Replicate the anatomic and functional properties of severe degenerative aortic valve stenosis.
Sodian et al. <sup>17</sup> /2008	128-slice computed tomography	3D printing techniques	Stereolithographic model, Stereolithographic prototyping	Proving benefit in complex anatomy
Bauch et al. <sup>18</sup> /2015	Computed tomography (CT)64 slice	Three- dimensional (3D) printing technology	Poly-actic acid filament	Research to minimize detrimental interactions between permanent pacing leads(His) and the tricuspid valve apparatus
Schmauss et al. <sup>19</sup> /2015	CT 64 or 128 slices or MRI scans	3D printing models in collaboration with theInstitute of Micro-Technology and Medical Device Technology,	A starch/cellulose powder (zp 15e) bound with polymer (zb 60). Using different types of material enables the production of rigid and flexible parts.	Perioperative planning and simulation in a variety of complex cases in pediatric and adult cardiac surgery
Fujita et al. <sup>20</sup> /2017	Multislice computed tomography (MSCT)	3D reconstruction of computed tomography image.	Stereolithography	Simulation was performed using a patient-specific heart prototype to evaluate the safety and efficacy of TAVI guidewire use.
Jacobs et al. <sup>21</sup> / 2008	Computer tomography (CT) and magnetic resonance imaging (MRI) images	3-dimensional (3D) printed multi-material	Plaster model	Planning and improved orientation to resection of ventricular aneurysm and malignant cardiac tumors may facilitate the surgical procedure due to better.
Kim et al. <sup>22</sup> / 2008	Multidetector CT	3D image processing software.	Polymerization of a photosensitive resin	Plan the operative approach for a 2.5-year-old child with single ventricle and single AV valve
Hadeed et al. <sup>23</sup> / 2016	Multi-detector-CT using 64-slice	Printed using a three-dimensional printer with HeartPrint® flex material (Materialise).	Flex material (Materialise)	Allows better understanding regard to size, position of ventricular septal defect, and its relationships with the great arteries.

reproduction of anatomical structures<sup>24-26</sup> and, despite limitations of diagnostic imaging techniques associated with cardiac and vascular movement, MSCT provides accurate and reliable data of the organ size and localization of structural and/or valve abnormality. This high-resolution method allows the images to be reconstructed, processed and printed as a dig-

ital model, from which an individualized, geometric prototype is constructed. This technique facilitates surgery planning, leading to higher accuracy of the surgical procedure<sup>12,13</sup> and shorter surgery time.

The complexity of cardiovascular diseases may be exemplified by the fact that tricuspid valve dysfunction may also be directly related to signs of

transvenous stimulation.<sup>18</sup> According to Vukicevic et al.<sup>14</sup>, MSCT images were able to describe functional elements of the mitral valve leaflets and subvalvular apparatus, including the myocardial structure, papillary muscles, chordae tendineae, and pathologic calcium deposits.

Our main findings were: a) both 3D transesophageal echocardiographic and MSCT can be used to replicate the morphology of mitral leaflets, papillary muscles, and left ventricle; however, MSCT is more effective in replicating the chordae tendineae and pathologic calcium deposits. b) Multi-material 3D printers can be used to replicate the mitral valve leaflet material properties with sufficient precision for device implantation. It has been shown that the mitral valve can be digitally reconstructed by both MSCT and 3D printing technologies.<sup>14</sup>

Nowadays, 3D printing is performed using stereolithography apparatus, which solidifies photocurable resins by laser technology and polymerization reaction.<sup>11</sup> The models created by this printing process accurately replicate the aortic valve anatomy, with excellent visual correlation with MSCT images.<sup>16</sup> Therefore, digital reconstruction is performed from a set of unique images that are transformed into specific anatomic models.<sup>14</sup> Patients with severe anatomical changes, valve calcification, ischemic aneurysms, previous surgery, and vascular dysfunction may benefit from the method<sup>12</sup> and the tactile feedback provided by 3D printed models.<sup>15</sup>

This example may be extended to patients with previous myocardial revascularization surgery who benefited from stereolithographic models obtained by preoperative tomography<sup>17</sup> and newborns and children with congenital heart diseases.<sup>19,23</sup>

For patients with severe aortic valve stenosis, simulation using a 3D heart model contributed to the planning of transcatheter aortic valve implantation (TAVI), considering the prohibitive surgical risk.<sup>20</sup> The use of 3D rapid prototyping models to identify structures at risk and during resection of ventricular aneurysm and malignant cardiac tumors may facilitate the surgical procedure and lead to better results.<sup>21</sup>

Some structures may have constitutional and functional failures such as fissures or cavities, which may be corrected by surgical intervention. However, while these abnormalities are not precisely seen or noticed by imaging techniques, 3D printed models could be studied in detail by the surgeons. Currently, the surgeon needs to expose the operative field and instantly decide on the area to be corrected and the best procedure to be adopted.

The use of 3D printer as a supportive tool in surgical planning, when performed using high-quality imaging, benefits patients with several heart diseases, since the 3D-printed heart model is similar to the exposed heart. In addition, as prototyping technology becomes more usual, its manufacturing time and cost will be reduced.

## CONCLUSION

With a 3D printed models of the patient's heart, the surgeon can plan and perform some processes before the surgical procedure or operation *per se*. Simulations enable the planning and selection of the best material, size, format, and thickness to be used. This results in a reduction in surgery time, lower exposure of the operative field, reduced risk of infection and earlier rehabilitation.

Our results suggest that 3D printed physical models may be superior to conventional teaching materials such as printed and computed images for providing better specific vision and understanding complex anatomy. The use of 3D printed models in the future will facilitate the investigation of permanent electrical stimulation of tricuspid valve using electrodes, and thereby improve the understanding of cardiac anatomy complexity and the planning of surgical procedures.

## Conflict of Interest

The authors declare no conflict of interest

## Funding Source

None

## RESUMO

**INTRODUÇÃO:** A impressora 3D é utilizada como coadjuvante no planejamento de cirurgias de cardiopatias complexas.

**OBJETIVOS:** Analisar o uso e os benefícios da impressão 3D em cirurgias de válvula cardíaca por meio de revisão sistemática da literatura.

**MÉTODOS:** Esta revisão sistemática foi conduzida de acordo com os itens do Preferred Reporting for Systematic Reviews e registrada no banco de dados Prospero (Registro Prospectivo Internacional de Revisão Sistemática) sob o número CRD42017059034. Foram utilizados os seguintes bancos de dados: PubMed, Embase, Scopus, Web of Science e Lilacs. Incluídos artigos com os termos de busca



"Heart Valves", "Heart Valve Prosthesis Implantation", "Heart Valve Prosthesis", "Printing, Three-Dimensional" e termos relacionados. Dois revisores independentes conduziram a extração dos dados e um terceiro (revisor) solucionou as discordâncias. Todas as tabelas usadas para a extração de dados estão disponibilizadas em site próprio. A ferramenta Cochrane Collaboration foi utilizada para avaliar o risco de viés na inclusão de estudos.

**RESULTADOS:** Identificados 301 artigos e 13 relatos de casos e séries de casos que atenderam aos critérios de inclusão. A amostra envolveu 34 pacientes, com idade de 3 meses a 94 anos.

**CONCLUSÃO:** Até o presente momento, não há estudos que contemplem um número considerável de pacientes. A impressão de um modelo 3D produzida a partir do protótipo do paciente permitirá ao cirurgião planejar a cirurgia, bem como escolher o melhor material, tamanho, formato e espessura da válvula a ser utilizada. Esse planejamento reduz o tempo de cirurgia, a exposição e, conseqüentemente, a redução do risco de infecção.

**PALAVRAS-CHAVE:** Valvas cardíacas. Impressão tridimensional. Procedimentos cirúrgicos cardiovasculares.

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