

3D heart model printing for preparation of percutaneous structural interventions: description of the technology and case report

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Abstract

Background: Structural heart disease, including valvular disease as well as congenital defects, causes important alterations in heart anatomy. As a result, individualised planning for both surgical and percutaneous procedures is crucial for procedural optimisation. Three dimensional (3D) rapid prototyping techniques are being utilised to aid operators in planning structural heart procedures.

Aim: We intend to provide a description of 3D printing as a clinically applicable heart modelling technology for the planning of percutaneous structural heart procedures as well as to report our first clinical use of a 3D printed patient-specific heart model in preparation for a percutaneous mitral annuloplasty using the Mitralign percutaneous annuloplasty system.

Methods: Retrospectively gated, contrast enhanced, multi-slice computed tomography (MSCT) scans were obtained. MSCT DICOM data was analysed using software that creates 3D surface files of the blood volume of specific regions of interest in the heart. The surface files are rendered using a software package that creates a solid model that can be printed using commercially available stereolithography machines.

Results: The technique of direct percutaneous mitral annuloplasty requires advancement of a guiding catheter through the aorta, into the left ventricle, and requires the positioning of the tip of the catheter between the papillary muscles in close proximity to the mitral annulus. The 3D heart model was used to create a procedural plan to optimise potential device implantation. The size of the deflectable guiding catheter was selected on the basis of the patient's heart model. Target locations for annulus crossing wires were evaluated pre-procedurally using the individual patient's 3D heart model. In addition, the ability to position the Bident Catheter at the appropriate locations under the mitral annulus as well as the manoeuvrability between the papillary muscles were analysed on the heart model, enabling safe completion of the procedure, which resulted in a significant reduction in mitral regurgitation.

Conclusions: 3D printing is a helpful tool in individualised planning for percutaneous structural interventions. Future studies are warranted to assess its role in preparing for percutaneous and surgical heart procedures.

Key words: heart model, percutaneous techniques, structural disease, valvular repair, 3D printing

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INTRODUCTION

Moderate or severe mitral regurgitation (MR) is the most common valvular disease requiring surgical intervention in the United States [1] and the second most common in Europe [2].

Despite the established role of cardiac surgery in mitral valve repair [3], several percutaneous techniques are being developed to treat MR [4–6]. Since the operator has no ability to directly visualise the operated area, different imaging

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modalities, such as computed tomography (CT), magnetic resonance imaging (MRI), and especially echocardiography, play a significant role in the execution of percutaneous procedures [7].

In addition to two-dimensional (2D) views, all these methods can generate virtual three-dimensional (3D) images, which greatly facilitate understanding of the interrelationships of anatomical structures of the heart and great vessels. Advances in echocardiography have enabled the introduction of real-time 3D modality, which is now increasingly being applied during interventional procedures [8].

Despite the advantages of the 3D images, the result remains a 2D representation of a 3D anatomy, albeit with the addition of a virtual perspective view. The 2D virtual perspective view is not tangible, and does not allow for the preoperative adjustment of tools to be used during a procedure. The creation of a real physical model is helpful for the operator to plan and carry out a procedure without direct visual inspection of the target anatomy. Recently, this has become possible with the use of rapid prototyping (RP) techniques.

RP is a process by which a physical 3D model of an object is created from rendered computer-generated images.

The aim of this study was to provide a description of 3D printing as another clinically applicable modality for planning percutaneous structural heart procedures. We also report our first clinical use of a 3D RP heart model in the planning of a percutaneous mitral annuloplasty.

METHODS

Patient characteristics

A 41-year-old male patient with heart failure due to primary dilated cardiomyopathy, permanent atrial fibrillation and functional MR, was qualified for percutaneous mitral annuloplasty using the Mitralign system. The appropriate ethics committees approved the study. The patient gave written, informed consent before the procedure. Core lab adjudicated patient data is presented in Table 1.

Creation of 3D heart models

Retrospectively gated, contrast enhanced, multi-slice CT (MSCT) scans were obtained. The CT scan featured a slice thickness of 0.625 mm and had a field of view that contained the entire heart, including as much of the aortic arch as could reasonably be obtained. The CT scan otherwise followed relatively standard CT protocols. The MSCT DICOM data was analysed using software capable of highlighting voxels of the radiodensity (as measured in Hounsfield units) of contrast media. The software was then used to isolate cardiac structures of interest. The blood volume of the left atrium, left ventricle (LV) and aorta were highlighted throughout the stack of DICOM images. The highlighted blood volume was then converted by the software into a 3D surface. This surface represented the internal surface of the heart in the left

Table 1. Core lab echocardiographic parameters of the patient

Parameter	Baseline	Discharge
LV end diastolic diameter [cm]	7.20	7.00
LV end systolic diameter [cm]	5.90	5.10
LA volume [mL]	247	155
LV end diastolic volume [mL]	222	173
LV end systolic volume [mL]	149	108
LA diameter [cm]	7.30	6.60
LV ejection fraction [%]	32.9	37.6
MV annulus diameter S-L [cm]	4.6	3.3
MV annulus diameter A-P [cm]	4.3	3.8
Coaptation length [cm]	0.62	0.68
Vena contracta width [cm]	0.72	0.61
Tenting distance [cm]	1.10	0.96
Tenting area [cm ²]	3.60	2.80
Effective regurgitant orifice area [cm ²]	0.30	0.26

LA — left atrium; LV — left ventricular; MV — mitral valve

atrium, LV, and aorta. The 3D surface was then formatted as a STL file, which is a file type that can easily be recognised by commercial computer-aided designed software as well as 3D printing and stereolithography (SLA) machines.

Undesirable heart structures (e.g. deep branches of the pulmonary veins) were cropped and the resulting surface was thickened outward to a wall thickness of 3 mm. Finally, the software was used to slice the heart model into two sections (posterior and anterior) so that the inside of the model could be easily visualised for pre-procedural planning. In this case, the posterior half of the model included: the LV, all papillary muscles, left atrium, and posterior mitral valve annulus. The final virtual 3D model was then sent to a vendor for printing on a commercial SLA machine, utilising an additional manufacturing process which employs a vat of liquid ultraviolet curable photopolymer 'resin' and an ultraviolet laser to build respective model layers. For each layer, the laser beam traces a cross-section of the model pattern onto the surface of the liquid resin. Exposure to the ultraviolet laser light solidifies the pattern traced on the resin and joins it to the layer below.

RESULTS

CT scan and 3D model analysis

The analysis of the gated CT DICOM data focuses on a stack of slices of the heart during one portion of the cardiac phase at a time. The analysis for our case focused on the structure of the heart during diastole, as defined by 75% of the R-R interval. Alternative analysis may be reviewed during systole, at 40% of the R-R interval. The segmentation and separation of the regions of interest is typically done in the axial CT plane. The majority of this selection and separation is done

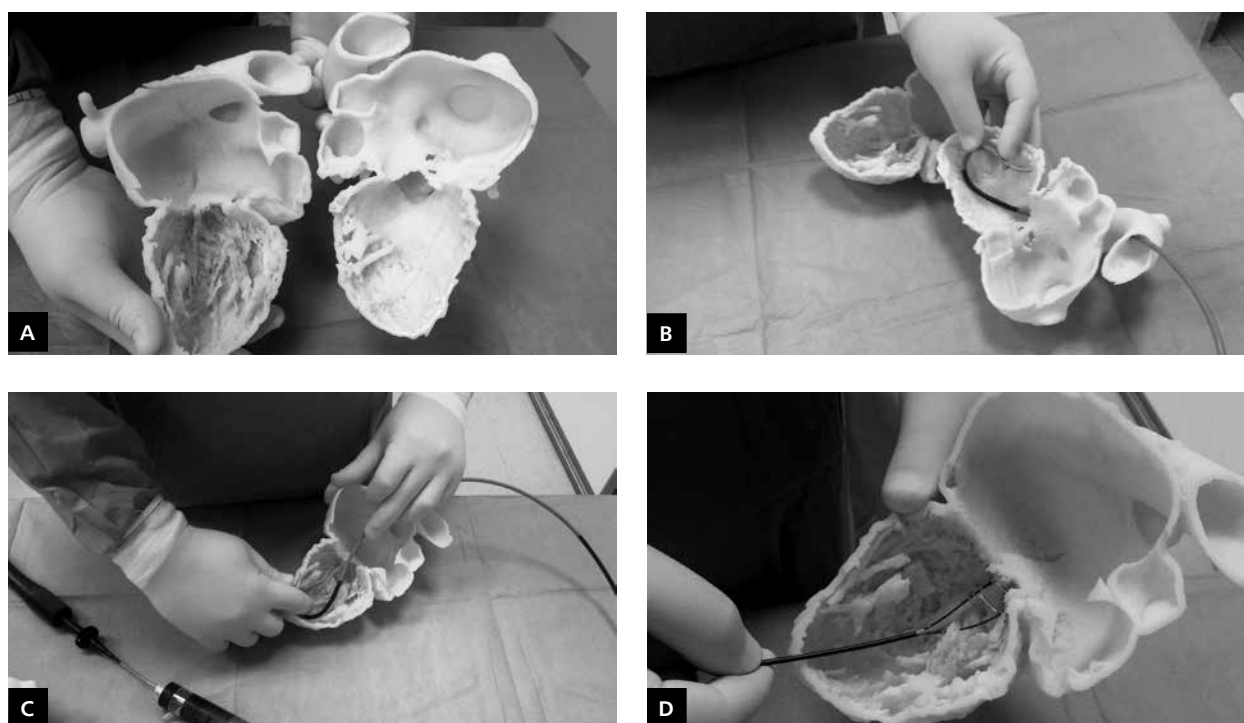


Figure 1. Individual three-dimensional heart model for planning a percutaneous direct mitral annuloplasty using the Mitralign Bident™ system; **A.** Heart model consisting of the posterior (left) and anterior (right) visualisation of left ventricle and atrium; **B, C.** Sizing the guiding catheter (containing the wire delivery catheter) curve within the left ventricle, between the papillary muscles; **D.** Sizing the Bident™ catheter size at the target zone below the mitral annulus

by automatic edge detection based on the radiodensity of the contrast. Some individual slices in the stack may require manual selection of the regions of interest. The raw CT data is used to look at gross anatomical features to identify subvalvular apparatus that includes large muscle bundles and ventricular trabeculations. The patient CT can also be used to identify calcification or ischaemic aneurysms.

The majority of the utility of the CT analysis for the Mitralign percutaneous annuloplasty system is attained by studying the 3D anatomy under the mitral valve and posterior surface of the LV. The precise location, number and sizes of the papillary muscles is readily apparent in the 3D model and is used to plan where the initial crossing wire placement will be optimal (Fig. 1). The amount of dilation at the base of the heart is analysed to determine the optimal placement of the Mitralign pledget implants. Significant dilation may guide the procedure to use wire delivery catheter articulation for crossing wires. Trabeculation and chordae in the subvalvular mitral apparatus are analysed to allow for placement of the Bident catheter safely and to determine the appropriate Bident sizes to use (Figs. 1B–D).

The 3D model generated by the CT analysis can be additionally used to accurately quantify the LV end diastolic diameter and LV height. The aortic entry angle into the LV can be measured in 3D and provides insight into the likely

manoeuvrability of the catheters under the mitral valve. In some cases, the location of the oesophagus relative to the left heart is reviewed, in order to ensure that appropriate transoesophageal echocardiography (TEE) views can be obtained without significant difficulty.

For descriptive purposes, we use the standard terminology for identifying mitral valve regions: the leaflets are divided into three segments, A1, A2 and A3 for the anterior leaflet, and P1, P2 and P3 for the posterior leaflet. The analysis of the individual 3D model showed a pronounced flattening of the medial LV wall under the P3 side of the posterior mitral annulus. The posterior medial papillary muscle was not well distended from the LV wall but was small and located on the far medial side of the LV. A muscle bundle was identified underneath the P2 region of mitral valve leaflet. The muscle bundle was not considered to be significant, as its location was not in any procedural location for implants. The anterior lateral papillary muscle was well distended from the LV wall and was of relatively normal size and shape. Some small chordae were noted below the mitral valve annulus in the P1 leaflet location, but these chordae connected to the LV wall below the mitral valve and would therefore not obstruct the wire delivery catheter or Bident catheter.

The patient was regarded as having a high probability of procedural success, according to the previously described

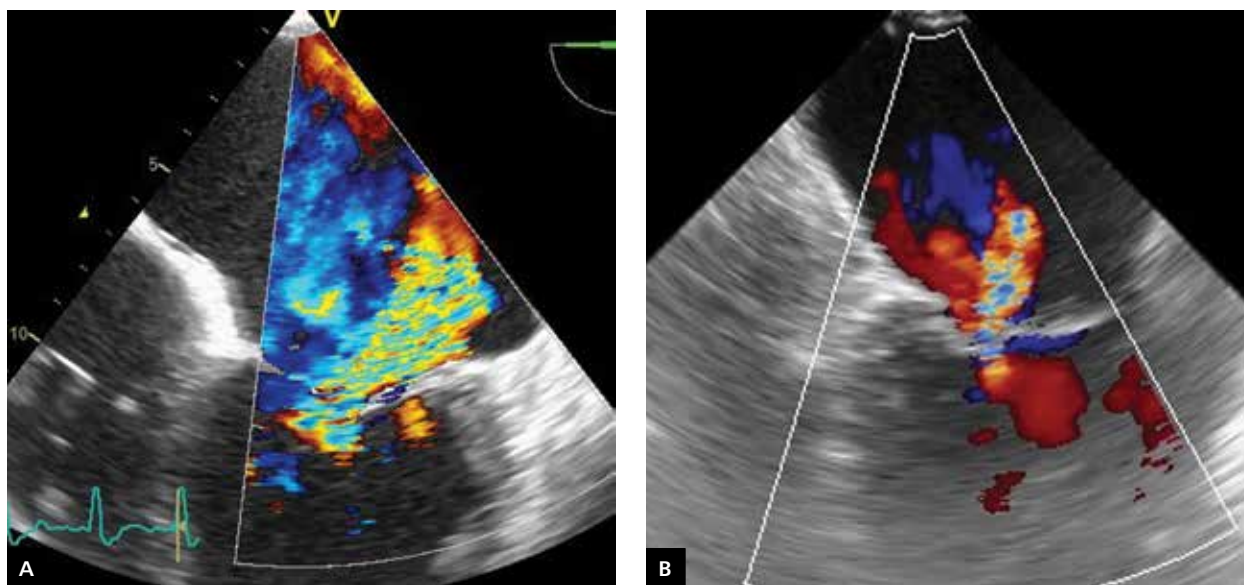


Figure 2. Transoesophageal echocardiography images obtained before the procedure (A) and after (B) direct percutaneous mitral annuloplasty using the Mitralign Bident™ system. The procedure was prepared using an individual three-dimensional heart model of the patient, as described in the text

technique [5]. Prior to the start of the case, a few potential observations were discussed. Firstly, the guide catheter would need to be torqued towards the medial side of the LV more than usually because of the flattened LV wall in this area. This additional torque would help to ensure optimal Bident placement. Secondly, the flatness of the medial wall of the LV, combined with the relative flatness of the atrium near the atrial septum, was noted as a potential challenge for TEE imaging. Thirdly, it was noted that it would be most desirable to cross the annulus by using the wire delivery catheter to facilitate wire crossing closest to the P1 commissure.

The percutaneous mitral annuloplasty procedure was carried out successfully (Fig. 2). A significant decrease in multiple quantitative parameters of MR was noticed (Table 1).

DISCUSSION

In this study, we have demonstrated that the creation of a real physical model of the heart could be a useful imaging modality that could have a significant impact on the planning and practical preparation for a catheter-based structural heart procedure. Secondly, to the best of our knowledge, this is the first report describing the application of 3D printing techniques in planning a percutaneous valvuloplasty procedure. Although our experience with 3D heart models is very promising, the advantages and current limitations of its use must be acknowledged.

Currently, several imaging techniques, such as echocardiography, MRI and CT, can create a satisfactory 2D image of the heart and vessels. An obvious next step that allows better visualisation and understanding of the spatial relations

would be the transition from 2D to 3D imaging. Real-time 3D echocardiography is currently entering mainstream clinical practice [9]. MRI techniques allow for 3D reconstruction [10] and new X-ray-based imaging referred to as 3D rotational angiography and C-arm CT are emerging as valuable tools in the interventional cardiology field [11]. Although these imaging advances permit assessment that is more accurate, and allow for better spatial orientation, there is however only a virtual 3rd dimension, which is unlikely to represent complex 3D relationships faithfully. RP is a technology that could overcome the inadequacy of existing 2D and 3D imaging methods and allow for the generation of real physical, fully tangible, models of the required organ.

With the improvement of technology, RP methods have been used in the production of models to whole devices with full functionality and have been utilised in medicine [12]. To the best of our knowledge, there has been no documented use of RP methods in the planning of percutaneous mitral annuloplasty.

3D printing has experienced significant growth in recent years. Manufacturing technologies such as SLA, extrudate deposition modelling, and selective laser sintering allow for building complex 3D shapes with increasingly impressive detail resolution. In SLA, layers are built from a photochemically curable resin and are selectively cured by an ultraviolet laser. Layer thicknesses as small as 0.05 mm are achievable with modern SLA machines.

Based on our experience with RP techniques, we can state that pre-procedural planning using a 3D heart model represents an exciting new tool for the visualisation of anatomical variability. The 3D heart model provides echocardiologists and

interventional cardiologists with anatomical awareness similar to that of a cardiac surgeon. The heart team involved in the case can discuss patient therapeutic options while holding the heart model in their hands. The team then can co-ordinate efforts to allow for an efficient procedure. They can note, for example, a large muscle bundle under the annulus. The echocardiologist would therefore go into the case prepared to monitor the distance between the wire delivery catheter and the muscle bundle, while the interventional cardiologist would go into the case prepared to watch out for the muscle bundle altering the motion of the wire delivery catheter with the beating of the heart. In this way, the clinical team can together determine the best locations on the mitral valve annulus to treat the patient and reduce the MR.

There are more examples of the use of RP models of heart and vessels in cardiology. Schievano et al. [13] described the use of 3D models of the right ventricular outflow tract and pulmonary trunk which allowed for more accurate selection of patients for percutaneous pulmonary valve implantation when compared to MRI images alone. Kim et al. [14], in a very elegant paper with a description of RP technical aspects, presented four cases of adult patients referred for percutaneous procedures (ventricular septal defect, atrial septal defect, prosthetic mitral valve perivalvular leak, and thoracic aortic pseudoaneurysm). RP models of the heart and/or vessels helped to define the precise anatomy of the defects and allowed for more accurate procedure planning and adjusting the catheters used during intervention. 3D heart models are also useful in cardiac surgery. In the paper by Jacobs et al. [15], RP models were used to plan the resection of an LV aneurysm and right ventricular tumour. In another study, heart models made from a rubber-like urethane allowed simulation of a surgical operation [16].

Limitations of the study

The above-mentioned studies, including ours, are limited to at most a few cases and represent mainly preliminary data. The main limitation is the lack of validation in a randomised manner that will allow for the evaluation of the real feasibility and value of this imaging technique. In addition, while the SLA process is inherently accurate, the accuracy of a medical model depends on many factors, especially the operator performing the virtual segmentation correctly. The technique of percutaneous mitral annuloplasty described above is still in the early stages of development, and therefore no comparisons to procedures done without the use of 3D models for planning have been performed. Currently, 3D printers are just becoming widely available at more affordable cost, and the use of 3D printed models in medicine is expected to rapidly increase [14–16].

CONCLUSIONS

3D heart printing may be a helpful tool for percutaneous structural interventions for facilitating preoperative planning,

adjustment of procedural tools, and intraoperative supervision of the target structures. For interventional procedures that treat complex structural heart disease, 3D printing represents an emerging modality for understanding the anatomical nuances of the cardiac structures being treated. RP techniques, which allow for the rapid creation of 3D models, can be used for individualised procedural planning, which in turn can improve procedural outcomes. We have shown, for example, that the creation of an individual 3D model can be used to optimise the implantation of the Mitraalign percutaneous annuloplasty system. Future studies are warranted to assess its role in the area of percutaneous and surgical heart procedures.

Conflict of interest: MS, LF and AG are employees of Mitraalign Inc, Tewksbury, MA, USA. TS is a principal investigator in a clinical trial supported by Mitraalign Inc, Tewksbury, MA, USA and is receiving investigator honoraria.

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Drukowanie trójwymiarowego indywidualnego modelu serca pacjenta w planowaniu zabiegów przezskórnych w chorobach strukturalnych serca: opis technologii i prezentacja przypadku

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Streszczenie

Wstęp: Wady zastawkowe, a zwłaszcza wady wrodzone serca, mogą prowadzić do istotnych zmian w jego anatomii. Uwidoczenie wzajemnych relacji przestrzennych zmienionych struktur jest kluczowym elementem przygotowania do zabiegów chirurgicznych i przezskórnych z punktu widzenia zarówno bezpieczeństwa pacjenta, jak i optymalizacji wyników. Mimo rozwoju technik obrazowych, w tym technik obrazowania trójwymiarowego w czasie rzeczywistym (np. echokardiografii), uzyskiwane obrazy są jedynie rekonstrukcjami, które są rzutowane na płaszczyznę ekranów komputerów. Techniki tzw. szybkiego prototypowania (*rapid prototyping*), nazywane potocznie drukiem trójwymiarowym (druk 3D), są coraz powszechniej stosowane w medycynie. Umożliwiają one stworzenie trójwymiarowych, rzeczywistych, fizycznych modeli organów, a to może znacznie ułatwić przygotowanie do operacji wad strukturalnych serca.

Cel: Celem pracy było przedstawienie zastosowania klinicznego druku 3D jako jednej z technik obrazowania struktur serca oraz opisanie wykorzystania modelu serca wykonanego z użyciem druku 3D przy planowaniu zabiegu przezskórnej plastyki pierścienia zastawki mitralnej z wykorzystaniem systemu Mitralign.

Metody: Do stworzenia trójwymiarowego modelu serca wykorzystano obrazy serca uzyskane przy użyciu wielorzędowej tomografii komputerowej. Dane w formacie DICOM poddano dalszej obróbce z zastosowaniem oprogramowania Mimics® (firma Materialise). Na podstawie analizy objętości krwi stworzono wirtualny, trójwymiarowy model wewnętrznej powierzchni lewej komory, lewego przedsionka i początkowego odcinka aorty, stanowiące obszar zainteresowania. Pliki poddano dalszej obróbce z zastosowaniem oprogramowania Magics® (firma Materialise), aby dodać żądaną grubość ścianki. Uzyskano trójwymiarowe odwzorowanie wewnętrznych powierzchni struktur serca pacjenta, bez konieczności uwzględniania grubości ścian jam serca i struktur niebędących w obszarze zainteresowania operatora. Stworzono w ten sposób plik danych opisujący model serca, który można wydrukować za pomocą komercyjnie dostępnej drukarki 3D wykorzystującej technikę stereolitografii.

Wyniki: Technika bezpośredniej przezskórnej plastyki pierścienia zastawki dwudzielnej wymaga wprowadzenia cewnika do lewej komory przez aortę i umieszczenia jego końcówki między mięśniami brodawkowatymi w okolicy pierścienia zastawki. Trójwymiarowy model serca został wykorzystany na etapie przygotowania do zabiegu, aby zwiększyć szanse jego powodzenia. Rozmiar cewnika prowadzącego został określony na podstawie jego dopasowania do indywidualnego modelu serca pacjenta tak, aby zapewnić swobodne manewrowanie wewnątrz komory. Na podstawie modelu określono również optymalną lokalizację przewodników przechodzących przez pierścień zastawki. Ponadto sprawdzono możliwości ułożenia cewnika Bident™ w odpowiednich miejscach docelowych, jak również możliwości manewrowania cewnikiem między mięśniami brodawkowatymi. Zastosowanie modelu 3D znacznie ułatwiło bezpieczne przeprowadzenie zabiegu, w wyniku którego uzyskano redukcję niedomykalności zastawki mitralnej.

Wnioski: Model serca stworzony przy użyciu technik druku 3D może być pomocnym narzędziem wykorzystywanym na etapie przygotowania do zabiegów przezskórnych u pacjentów z chorobami strukturalnymi serca. Należy przeprowadzić dalsze badania oceniające jego rolę w przygotowaniu zarówno do operacji przezskórnych, jak i chirurgicznych.

Słowa kluczowe: model serca, techniki przezskórne, choroby strukturalne, naprawa zastawki, druk 3D

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