

## Original Article (Secondary Publication)

# Simulation using patient-specific hollow three-dimensional models for percutaneous closure of patent ductus arteriosus in adult : Complete republication

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## Abstract

**Background and Objective** : It is challenging to accurately predict the shape and stability of occlusion devices during percutaneous closure of patent ductus arteriosus (PDA) in adults. In this study, we evaluate the utility of percutaneous closure simulation of PDA in adults using patient-specific hollow three-dimensional (3D) models created from computed tomography data.

**Methods** : The study was conducted on four adult patients with PDA, whose age ranged from 54 to 75 years. While three were type E as per the Krichenko classification, one was type D. We created a transparent silicone hollow model using a solid model, which was printed by a personal 3D printer from contrast-enhanced multi-detector computed tomography data, as a mold. All processes were carried out at our institution. Before actually performing percutaneous closure of PDA, we simulated procedures using these models and investigated the shape and stability of AMPLATZER™ Duct Occluder/AMPLATZER™ Vascular Plug deployed in them.

**Results** : Briefly, the time and cost required to create a hollow 3D model were about 3 days and 10,000 Japanese Yen, respectively. It was very easy to recognize the shape and stability of deployed devices in these models because the devices were clearly visible from outside. In fact, these models could be picked up by hands and observed from various angles, which was helpful in selecting optimum devices for closure.

**Conclusions** : The transparent silicone hollow models are an excellent simulator of percutaneous closure of PDA, especially in adults.

(Keywords : simulation, three-dimensional printing, patent ductus arteriosus, percutaneous closure, adult)

## Introduction

In recent years, three-dimensional (3D) printing technology has remarkably advanced and has been applied in healthcare fields. In Japan, “additional reimbursement for imaging and other procedures” is available in the fields of neurosurgery and orthopedic surgery under the national health insurance scheme. This technology has already been in practical use. Regarding the treatment of congenital heart diseases, treatment simulation using 3D models printed with a 3D printer has been reported<sup>1-8)</sup>. However, because fabrication of 3D models based on data of individual patients is outsourced to specialized companies and is expensive<sup>3)</sup>, such models have still not been widely used in daily clinical practice<sup>9)</sup>.

In adults with patent ductus arteriosus (PDA), the arterial ducts are larger and longer than those in children, and the arterial wall is more frequently calcified<sup>10,11)</sup> and associated with aneurysm formation<sup>12)</sup>. For percutaneous closure, occlusion devices are selected on the basis of images acquired using angiography and computed tomography (CT)<sup>12,13)</sup>. In Japan, the available devices are limited. In addition, because the shape of a deployed occlusion device is difficult to predict accurately, procedural success inevitably depends on the experience of operators.

We developed a simple procedure to fabricate a silicone hollow 3D model from patient-specific data using a commercially available personal 3D printer at our institution. The objective of this study was to assess the usefulness of simulation of percutaneous closure of adult PDA with models fabricated using this procedure.

## Subjects and methods

### *Subjects and the simulation procedure*

The subjects were 4 adult patients with PDA who were between 54 and 75 years of age. They were all female (**Table**). At our institution, preoperative contrast-

**Table Characteristics in patient with patent ductus arteriosus**

| Case                                   | 1                              | 2    | 3                      | 4                       |
|----------------------------------------|--------------------------------|------|------------------------|-------------------------|
| Age (y.o.)                             | 54                             | 54   | 69                     | 75                      |
| Krichenko classification               | E                              | D    | E                      | E                       |
| Size of ampulla<br>Narrowest part (mm) | 4.3                            | 4.1  | 5.2                    | 4.1                     |
| Length (mm)                            | 26.0                           | 18.6 | 20.0                   | 18.1                    |
| Calcification                          | (-)                            | (-)  | (+)                    | (+)                     |
| Qp/Qs                                  | 1.4                            | 1.7  | 2.4                    | 1.5                     |
| AOP/PAP                                | 0.14                           | 0.15 | 0.30                   | 0.30                    |
| Comorbidities                          | Atrial flutter<br>Hypertension | (-)  | IE*<br>Liver cirrhosis | Valsalva sinus aneurysm |

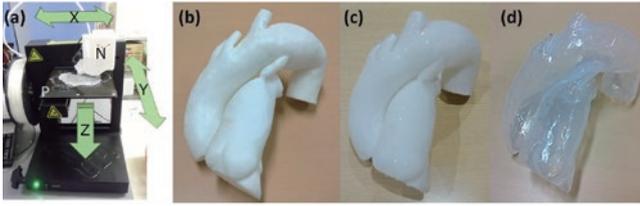
Qp/Qs, pulmonary blood flow/systemic blood flow ratio ; AOP/PAP, aortic pressure/pulmonary artery pressure ratio ; IE\*, past history of infectious endocarditis

enhanced CT is, in principle, performed in all adult patients with PDA to ascertain the vascular morphology. From 3 patients, excluding one who had undergone CT at another institution, written consent for CT was obtained after sufficient explanation. The morphology of their ductus arteriosus was classified as type E or D according to the Krichenko classification<sup>14)</sup>. On CT images, the narrowest diameter of the ductus arteriosus measured 4.1 to 5.2 mm, and their lengths ranged from 18.1 to 26.0 mm. Calcification was observed in 2 patients. The pulmonary-to-systemic flow ratio ranged from 1.4 to 2.4. None of the patients had concomitant pulmonary hypertension. All patients were in class II according to the New York Heart Association (NYHA) classification. After obtaining consent, the patients' CT data were used to fabricate transparent silicone hollow models, in accordance with the procedure described below. With these models, simulation was performed to predict the shape of the deployed AMPLATZER Duct Occluder (ADO ; St. Jude Medical, St. Paul, MN, USA) and AMPLATZER Vascular Plug II (AVP ; St. Jude Medical, St. Paul, MN, USA). Then, percutaneous closure was performed. ADO was deployed from the pulmonary artery and AVP, from the aorta. The use of AVP for closure of PDA was approved by the institutional ethics committee. To perform percutaneous closure, the models were brought to the catheterization laboratory, and the simulated shape of the deployed occlusion devices was referred to. To facilitate understanding of the disease and treatment, the models were shown to the patients during explanation of the treatment and to the staff members during conferences.

### *Model fabrication procedure*

In accordance with the procedure developed by Mashiko et al., 3D models were fabricated<sup>15)</sup>. Contrast-enhanced 64-row multi-detector CT (MDCT) was performed, and the Digital Imaging and Communication in Medicine data obtained were converted into the Standard and Triangulated Language format using Ziostation 2 (Amin, Tokyo, Japan) and OsiriX (Pixmeo, Geneva, Switzerland). The commercially available personal 3D printer UP Plus 2 (Tiertime Technology, Beijing, People's Republic of China) was used to fabricate acrylonitrile-butadiene-styrene (ABS) resin solid models. The CT scanner used was SOMATOM Definition FLASH (Siemens, Munich, Germany), and 350 or 370 mg/mL iohexol was administered as contrast medium at 1.8 mL/kg. CT was performed with a beam pitch of 3.0, and the bolus tracking technique was used to automatically trigger a scan at 100 Hounsfield units over the descending aorta and a voxel size of 512 × 512 × 512. Transparent silicone was applied onto the surface of the fabricated ABS resin solid models. After the silicone dried, the ABS resin was removed to create transparent silicone hollow models. To reduce the fabrication time and facilitate approach during

simulation, the area reproduced in the model was limited. For the patients with a calcified vascular wall, the narrowed vascular lumen due to calcification was also reproduced (Fig. 1).



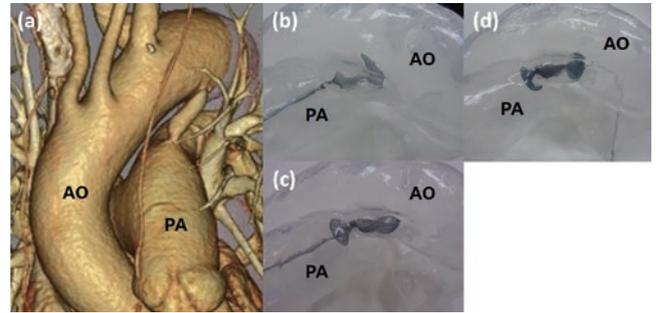
**Fig. 1** (a) Mechanism of three-dimensional (3D) model formed with 3D printer. Nozzle (N) for injecting acrylonitrile-butadiene-styrene (ABS) resin melted by heat moves in the X direction. Platform (P) moves in the Y direction, and pattern is drawn on the platform. After completion of one layer, the platform moves down in the Z direction to draw one higher layer. (b) - (d) A fabrication process of a silicone hollow model. (b) An ABS solid model is removed from the platform and the base and support are trimmed off the model. (c) ABS solid model is coated with transparent liquid silicone. (d) ABS is crushed and removed after silicone solidifies.

## Results

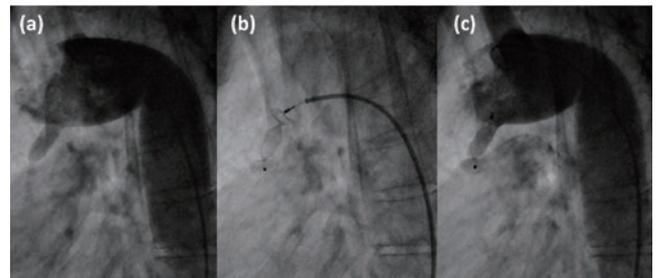
The time required to fabricate a model was approximately 7 hours for a solid model and 3 days for a hollow model. The fabrication cost (materials) was approximately 5,000 yen for a solid model and approximately 10,000 yen for fabricating a hollow model from a solid model. During the simulation, both the ADO and AVP deployed in the hollow models were clearly visible from the outside so that their shapes were easily ascertained (Figs. 2 and 4). Manipulating a model to observe it from various angles allowed us to select the optimal occlusion device. The devices selected in simulation and those actually deployed by percutaneous closure were identical in all patients. Specifically, 9-AVP2-012 was deployed in patients 1 and 2 and 9-PDA-009, in patients 3 and 4. In all patients, complete closure was achieved after deployment. The NYHA classification was improved from class II to class I. No complication was observed. The presented images show patients 1 and 2, for whom AVP was selected because deployment of ADO was determined to be difficult.

Patient 1 had Krichenko type E PDA with the narrowest diameter of 4.3 mm and an ampullary length of 26.0 mm. In simulation with a model, the largest ADO available in Japan (9-PDA-009 : aortic-side diameter, 16 mm ; device length, 8 mm) was too short to achieve a stable deployment. Although the 12-mm-diameter AVP (9-AVP2-012) measures 9 mm in length, its 3 parts were separately placed in the pulmonary artery, ampulla, and aorta in a stable form

(Fig. 2). In the actual closure process, AVP was also deployed in the shape observed in the simulation, and the ductus arteriosus was successfully closed (Fig. 3).



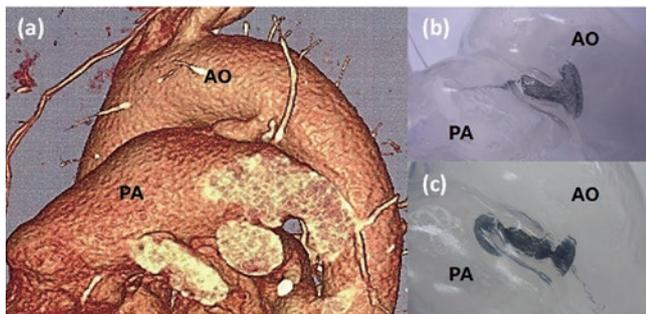
**Fig. 2** (a) Three-dimensional-MDCT image of Case 1 shows long ductus arteriosus or type E PDA in Krichenko classification. (b), (c) Simulation of closure of PDA with ADO (9-PDA-009) . Because the length of ADO is too short, stable deployment is impossible. (d) In the same simulation with AVP (9-AVP2-012) , the three parts of the device are placed in PA, ampulla, AO respectively. AO, aorta ; PA, pulmonary artery ; MDCT, multi-detector computed tomography ; PDA, patent ductus arteriosus ; ADO, AMPLATZER™ Duct Occluder ; AVP, AMPLATZER™ Vascular Plug.



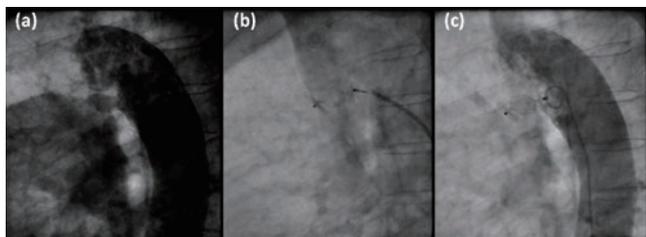
**Fig. 3** (a) Aortography in lateral view of Case 1 shows long ductus arteriosus or type E PDA. (b) AVP (9-AVP2-012) is deployed but not released yet. Three parts of the device are placed in pulmonary artery, ampulla, aorta respectively, as in the previous simulation. (c) Post-deployment aortography shows good position of the device and small residual shunt. The shunt disappeared next day. PDA, patent ductus arteriosus; AVP, AMPLATZER™ Vascular Plug.

Patient 2 had Krichenko type D PDA, or aneurysmal ductus arteriosus, with the narrowest diameter of 4.1 mm and an ampullary length of 18.6 mm. In the simulation with ADO (9-PDA-009), the shape of the device did not fit in the aneurysm-like ampulla ; thus, stable deployment could not be achieved. However, the central part of AVP (9-AVP2-012) fitted well into the shape of the aneurysm-like

ampulla (**Fig. 4**). In the actual closure process, AVP was also deployed in the shape observed in the simulation, and the ductus arteriosus was successfully closed (**Fig. 5**).



**Fig. 4** (a) Three-dimensional-MDCT image of Case 2 shows type D PDA in Krichenko classification. (b) Simulation of closure of PDA with ADO (9-PDA-009). Because the shape of ADO does not fit the aneurysm-like ductus, stable deployment is impossible. (c) In the same simulation with AVP (9-AVP2-012), the three parts of the device are placed in PA, ampulla, AO respectively. The center part fits the aneurysm-like ampulla. AO, aorta.; PA, pulmonary artery; MDCT, multi-detector computed tomography; PDA, patent ductus arteriosus; ADO, AMPLATZER™ Duct Occluder; AVP, AMPLATZER™ Vascular Plug.



**Fig. 5** (a) Aortography in lateral view of Case 2 shows aneurysmal ductus arteriosus or type D PDA. (b) AVP (9-AVP2-012) is deployed but not released yet. Three parts of the device are placed in pulmonary artery, ampulla, aorta respectively, as in the previous simulation. The center part of AVP fits well with the shape of the aneurysmal ampulla. (c) Post-deployment aortography shows good position of the device and small residual shunt. The shunt disappeared next day. PDA, patent ductus arteriosus; AVP, AMPLATZER™ Vascular Plug.

## Discussion

In recent years, 3D printing technology has been applied in healthcare fields. In Japan, reimbursement for a “procedure using a full-scale organ three-dimensional model” as part of the “additional reimbursement for imaging and other procedures” is available in the fields of neurosurgery and orthopedic surgery under the national health insurance scheme. Regarding surgical treatment of congenital heart diseases, 3D models are increasingly reported to be useful for simulation, explanation to patients, and educational purposes. They are greatly useful for simulation of surgery for rare congenital and morphologically complex heart diseases.<sup>4,7,8,16-22)</sup>

PDA is common among congenital heart diseases, and cases of PDA in adults, particularly elderly people, are not uncommon<sup>12)</sup>. Adult PDA manifests characteristics different from those of pediatric PDA. With advancing age, the vascular wall is often calcified and becomes hard and fragile<sup>13)</sup>. When surgery is performed for adult patients, PDA cannot be closed by simple ligation, unlike that in children, and more invasive cardiotomy with cardiopulmonary bypass is frequently required<sup>10,12,23)</sup>. Percutaneous closure, which is considered less invasive than open surgery, is greatly useful<sup>12)</sup>. As the body constitution becomes larger, the absolute values of blood vessels increase and lesions became larger and longer. Thus, closure with ADO or coils is sometimes unsuitable. For selection of occlusion devices, precise morphological assessment of the ductus arteriosus and measurement of its size are essential. In many cases of adult PDA, aortography makes it difficult to ascertain the detailed morphology of the ductus arteriosus because it overlaps with the aortic arch or because contrast media are diluted. Consequently, contrast-enhanced CT is often performed to assess the morphology before percutaneous closure<sup>12)</sup>. At our institution, contrast-enhanced CT is performed in all patients. In this study, data obtained from these CT images were used to fabricate 3D models.

### Accuracy of the fabricated models

Fabrication of 3D models from CT images is often outsourced to specialized companies in which models are fabricated with advanced techniques through complex processes. Thus, fabrication takes many days and is expensive. The long fabrication time and high cost seem to be factors that prevent wide adoption of 3D models in daily clinical practice. Various 3D printing methods are available, including stereolithography, fused deposition modeling, selective laser sintering, and ink-jet printing. As greater precision is demanded, more-expensive equipment is required<sup>3)</sup>. The 3D printer used in this study uses fused deposition modeling, which is generally considered inferior to other methods in terms of accuracy. Furthermore, MDCT data, from which 3D models are fabricated, are affected

by a certain degree of error because of the mechanisms of scanning and image reconstruction. In the case of PDA, the morphology and size of the ductus arteriosus presumably change in different time phases, that is, the systolic and diastolic phases. In this study, CT scans were not electrocardiography (ECG)-gated and the time phases were not taken into account. Although these factors might have affected the accuracy of the fabricated models, appropriate devices were selected on the basis of simulation without any problems. The shape of a deployed occlusion device was also well reproduced by simulation. When models were fabricated, the narrowed vascular lumen due to calcification was also reproduced. On the basis of the shape of the deployed occlusion devices, the hardness of silicone appeared to be appropriate for reproducing calcified arterial ducts. For simulation of percutaneous closure of adult PDA, the models fabricated in this study were sufficiently accurate and excellent simulators in terms of selection of occlusion devices.

#### *Imaging examination*

From the perspective of preventing radiation exposure from CT, fabrication of 3D models based on magnetic resonance imaging (MRI)/magnetic resonance angiography (MRA) is also frequently reported overseas. Several reports have also described 3D models fabricated from echocardiographic data<sup>24,25</sup>. Contrast-enhanced CT provides extremely good data for model fabrication because the stark contrast between different signal intensities clearly depicts the border between the walls and the lumens of the heart and blood vessels. In Japan, because of the high prevalence of CT devices, the relative ease of performing CT is an advantage. At present, contrast-enhanced CT more clearly depicts the border between the walls and the lumens of the heart and blood vessels and provides more accurate data than MRI, MRA, and ultrasonography. In this study, data obtained from CT scans routinely performed at our institution were used to fabricate models of adult patients with PDA, and no new CT scans were performed for model fabrication. We consider that ECG gating is not required for CT scans of ductus arteriosus, unlike scans performed to ascertain the morphology of the intracardiac structures, and radiation exposure can be reduced by non-ECG-gated CT<sup>26</sup>. Moreover, if preoperative simulation reduces the duration of the actual catheterization, the simulation may contribute to the reduction in the radiation exposure associated with catheterization for examination and treatment.

#### *Advantages of the 3D models and usefulness of the simulation*

The 3D CT images that have been widely adopted in recent years are only “virtual 3D images” and definitely different from directly tangible 3D models<sup>1</sup>. The hollow 3D models in this study were made of transparent silicone ;

therefore, the shape of the deployed devices were visible from the outside, and the models can be manipulated and observed from any angle. Another advantage is the portability of the models<sup>8</sup>). In other words, they can be brought to the catheterization laboratory and compared with actual fluoroscopic images during deployment of the occlusion devices. Performing preoperative simulation to ascertain devices to be used and procedures to be performed appears to contribute to safer and more effective treatment. This study was conducted with the promotional occlusion devices provided by Abbott Japan (formerly St. Jude Medical). When simulation is performed, procurement of the necessary devices is also an issue. Showing 3D models during explanation to patients and conferences with staff members facilitates understanding of treatment, and the models are also useful for stimulating discussions among staff members and educating them<sup>27-31</sup> .

The use of a commercially available personal 3D printer limited the initial investment cost to approximately 200,000 yen. As the models were fabricated at our institution, the fabrication cost was lower than the cost of outsourcing to external companies. All processes of our procedure from data collection to model fabrication could be completed at our institution, so the fabrication time was shortened. Another possible advantage was that our models facilitated cooperation between radiological technologists and physicians who perform catheterization<sup>9</sup>). As commercially available or free data conversion software and a commercially available printer were used to fabricate the models, no technical knowledge of computers was required. Although the 3D printer used in this study limits the size of the model that can be printed, full-scale models could be fabricated even for adult patients by limiting the area to be reproduced, which contributed to the reduction in fabrication time and had an advantage of facilitating ascertainment of approaches and the shape of an occlusion device during simulation.

#### **Conclusion**

We developed a simple procedure to fabricate a silicone hollow 3D model from patient-specific data by using a commercially available personal 3D printer. The fabricated models allowed clear visualization of the shape of the deployed occlusion devices, were portable enough to bring to the laboratory, and were excellent simulators for percutaneous closure of adult PDA. As the devices selected for the simulation were actually used for percutaneous closure, the shape of the deployed occlusion devices was well reproduced by the models. Simulation using models fabricated by our procedure for percutaneous closure of adult PDA is useful for a more safely and effectively performing the procedure.

## Declaration of interest

The authors have no conflict of interest to declare.

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This article is based on the study first reported in Japanese to journal of JPIC<sup>31)</sup>.

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# 患者データから自施設で作製した中空立体模型を用いた，成人動脈管開存の経皮的閉鎖術シミュレーション

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## 和文要約

【背景と目的】動脈管開存（PDA）の経皮的閉鎖術に際し，閉鎖栓留置形状の正確な予測は困難である。中空立体模型による成人PDA経皮的閉鎖術シミュレーションの有用性を検討する。【対象と方法】対象は成人PDA 4症例。年齢54～75歳，Krichenko E 3症例，D 1症例。患者CT画像データから3Dプリンターで造形した実体模型を元に透明シリコン製中空模型を作製し，AMPLATZER™ Duct Occluder，AMPLATZER™ Vascular Plug IIの留置形状をシミュレーションして閉鎖術に臨んだ。【結果】中空模型の作製時間は3日，費用は約1万円であった。留置した閉鎖栓は良好に透見でき，手にとって様々な角度から観察することで，最適な閉鎖栓を選択しえた。【考察と結論】透明シリコン製中空立体模型はPDAの経皮的閉鎖術シミュレーターとして優れ，特に成人症例で有用性が高い。

（キーワード：シミュレーション，3Dプリント，動脈管開存，経皮的閉鎖術，成人）