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# Three-dimensional Echo-guided Suture of Atrial Septal Defect with Maniceps in an Experimental Model

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## ABSTRACT

Toward the establishment of suture closure procedures for atrial septal defect or patent foramen ovale under guidance of three-dimensional (3D) echocardiography but without use of cardiopulmonary bypass (off-pump surgery), an experimental study was conducted using a laparoscopic suture instrument, Maniceps. First, the panel setting of the 3D echo system which was optimal for precisely visualizing the surgical instruments on the image display with the least time delay was determined. The optimal setting was: 1) harmonic imaging, 2) no smoothing, 3) low scanning line density, and 4) a scanning range around 55°. Using an ex vivo model of atrial septal defect, 3D echo-guided surgical procedures were attempted in three steps. First, grasping of the edge of the defect with a forceps was attempted. It was feasible in every direction. Reverberation artifact occasionally disturbed imaging of the defect edge. Second, transfixion suture of the facing edges was attempted. Guided by 3D echo, serial sutures were feasible, but interlocking of the thread was a pitfall. Third, continuous suture of the defect was attempted under 3D echo guidance. Following the initial suture bite on one side, continuous suture could be performed under echo guidance. Deformity of the Maniceps needle after repeated sutures was a limitation. In conclusion, suture closure of the defect under 3D echo guidance using the Maniceps system is feasible in an *ex vivo* ASD model as visualization is optimized by panel setting for guiding surgical procedures.

***Key words:*** *Patent foramen ovale, Atrial septal defect, Echocardiography, Coronary artery bypass surgery*

Coronary artery bypass surgery without cardiopulmonary bypass (off-pump coronary artery bypass: OPCAB) has gained increased popularity and the percentage of off-pump surgery in total coronary artery bypass surgery exceeded 60% in Japan in 2008[6] and became 100% in our institute in the past two years. However, it has led to a dilemma. When patent foramen ovale (PFO) is diagnosed preoperatively or incidentally found intraoperatively in an OPCAB case, it is controversial whether to leave it untreated as a surgical strategy or to close it under cardiopulmonary bypass[9]. Since PFO is found in approximately one-fourth of the human population in transesophageal echocardiographic studies or autopsies[3,7], it is not a rare condition. The same problem is faced when atrial septal defect (ASD) is present in an OPCAB case. If PFO or ASD can be closed by off-pump surgery, this problem will be solved.

Previously we reported the three-dimensional (3D) echocardiography-guided suture of a defect in an ex vivo model with a commonly used needle holder and forceps[5]. However, the needle was barely visualized and it was difficult to capture with a forceps. It was a critical drawback of this method for proceeding to clinical application. Improvement in needle transfer or in needle visualization was anticipated.

In laparoscopic surgery, a needle transfer system, Maniceps, was devised by MANI INC., but was not widely used because a needle could be transferred without difficulty under an endoscopic view. We considered that such an instrument might potentially be used for echo-guided closure of PFO/ASD. However, there have been no literatures or data on the echo visualization of Maniceps. The purpose of this study was to examine: 1) the optimal panel setting of the 3D-echo system for visualizing the instruments and procedures; and 2) feasibility and problems of 3D echo-guided suture of a defect with Maniceps in an experimental model.

## MATERIALS AND METHODS

### *Surgical instruments*

A laparoscopic suture instrument, "Maniceps" (MANI, INC., Utsunomiya, Japan) for 7 mm needles was used (Fig. 1A). A straight needle with braided polyglycolate thread, Opepolyx-N (Alfresa Pharma Co., Tokyo, Japan) was attached to the holder and light tension was applied to the thread to securely seat the needle (Fig. 1B left). As the arms of the device were closed, the needle was captured by the needle catcher as it was released from the needle holder (Fig. 1B right). A laparoscopic forceps (RENEW IV Non-ratcheted hand piece, Micro-line PENTAX, Beverly, MA, USA) was used for grasping the object (Fig. 1C). The tip pieces of both the straight type and curved type were used in this study.

### *ASD model and 3D echo*

An ASD model was prepared for 3D echo-guided suture. We considered that the suture technique for ASD might be applied to closing PFO as well. A polyethylene sheet (1 mm thick) with a hole (1 cm in diameter) was fixed to a stainless wire frame basket (13 cm wide, 9 cm deep, 6 cm high) (Fig. 2A). This ASD model was immersed in water (Fig. 2B). A 3D echo system and an equipped 3D echo probe (iE33, X3-1, Philips Electronics Co., Netherland) were used for visualization. The echo probe was fixed with a holder so that the sheet and hole were scanned at a distance of approximately 5 cm from the transducer. This model simulated the intracardiac procedures of closing the ASD/PFO through the port trocars placed on the right atrial wall while being scanned by a nearby echo probe (Fig. 2C). The sheet with a hole was visualized in live 3D imaging (real time 3D imaging). By using a trackball, the surgeon's view orientation was displayed.

### *Optimal panel setting of echo system*

The optimal panel setting of the echo system for guiding the surgical procedures was examined with a focus on the precise visualization of instruments and real-time display of objects in motion. The candidate parameters which potentially affect the visualization included frequency of ultrasound, smoothing of 3D image, density of scanning lines, and size of scanning area for live 3D imaging. With Maniceps placed near the defect, the optimal panel settings were sought.

### *3D echo-guided surgical procedures*

Feasibility of 3D echo-guided procedures was evaluated in three steps.

1) secure grasping

Since it is essential to securely grasp the defect edge in any direction, echo-guided grasping was attempted at the edge in the 3, 6, 9, and 12 o'clock positions.

2) transfixion suture

In order to simulate an interrupted suture or figure-of-eight suture of the defect, serial transfixion sutures of the defect edge in the 6 and 12 o'clock positions were attempted.

3) continuous sutures

Continuous suture was started from the 9 o'clock position toward the 3 o'clock position. After the initial bite at the edge, the thread was tied and the next suture was applied while the thread at the edge was slightly pulled instead of grasping the defect edge.

### *Image recording*

Every echo image was recorded for later analysis in an S-VHS video tape with a video recorder attached to the echocardiographic system.

## RESULTS

### *Panel setting: imaging quality and frame rate*

1) ultrasound frequency

The 3D image of Maniceps with a needle was compared between non-harmonic imaging and harmonic imaging (Fig. 3). In the former, higher ultrasound frequency (around 3 MHz: resolution mode) and lower ultrasound frequency (around 1 MHz: penetration mode) were examined. The two arms of Maniceps were readily recognized in every mode but side lobe artifact blurred the image of the arms in non-harmonic imaging especially in resolution mode. The needle was recognized as an echogenic projection in every mode. In harmonic imaging, the needle as well as the arms were visualized most clearly (Fig. 3B).

2) smoothing

As smoothing was augmented from 0 to 9, the image became round but less discrete (Fig. 4). The edges of the defect and instruments were easily recognized, but the needle could be better visualized with smoothing at 0. Thus, imaging without smoothing was considered to be most suitable.

3) scanning line density

With high scanning line density, the image was clearer compared with that in low or medial density (Fig. 5), but the needle could be adequately recognized even in low density scanning. As the density was increased, the frame rate significantly decreased: 20 Hz, 14 Hz, and 9 Hz in high, medial, and low density, respectively.

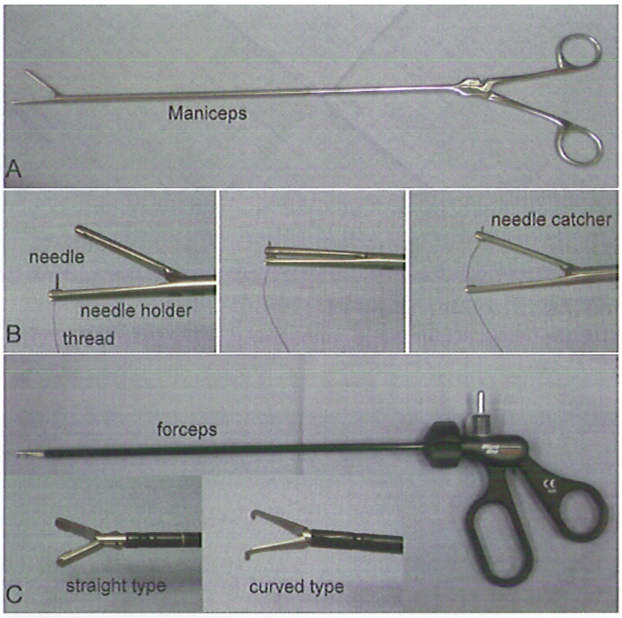


**Fig. 1.** Laparoscopic surgical instruments used in this study.
A: maniceps suture device. The diameter of the shaft is 3 mm. B: transfer of needle from the holder to the catcher. C: forceps with replaceable straight and rect-angularly curved tip pieces.

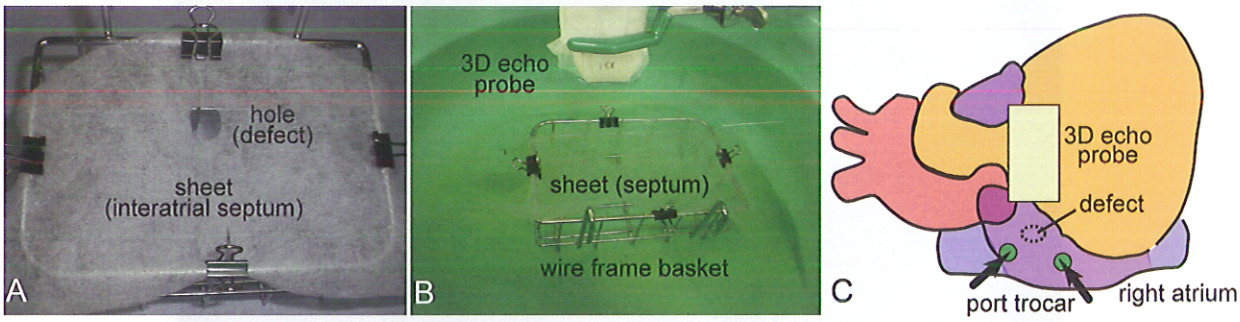


**Fig. 2.** An experimental model of atrial septal defect.
A: a sheet of polyethylene with a hole was attached to a wire frame basket, simulating an atrial septal defect. B: the model was immersed in water and scanned with a three-dimensional echo probe. C: schematic illustration of supposed set-up in the surgical field for echo-guided ASD closure.

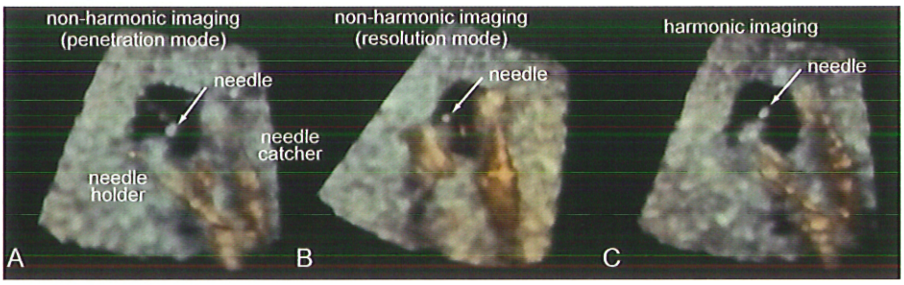


**Fig. 3.** Effect of ultrasound frequency on visualization of Maniceps.
A: non-harmonic imaging in low frequency (penetration mode). B: non-harmonic imaging in high frequency (resolution mode). C: harmonic imaging.

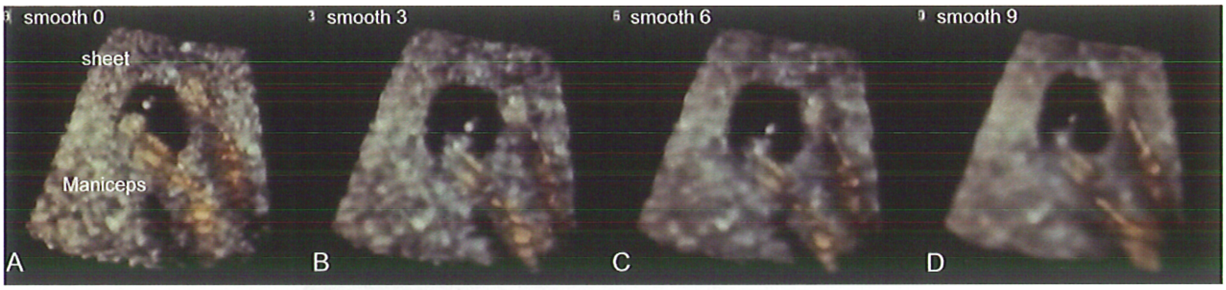


**Fig. 4.** Effect of smoothing on visualization.
A: no smoothing. B: grade 3 smoothing. C: grade 6 smoothing. D: grade 9 (maximal) smoothing.

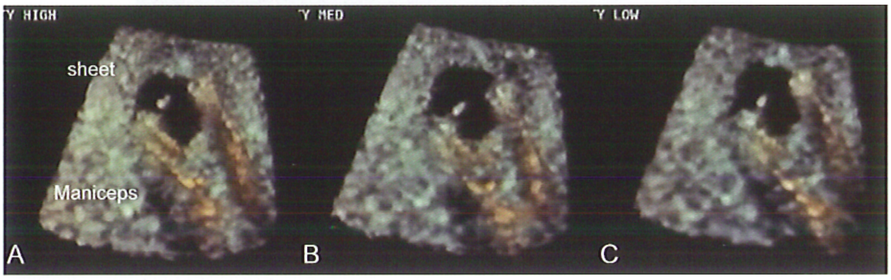


**Fig. 5.** Effect of scanning line density on visualization.
A: high density. B: medium density. C: low density. Although the image is sharp in high density, the frame rate is reduced.

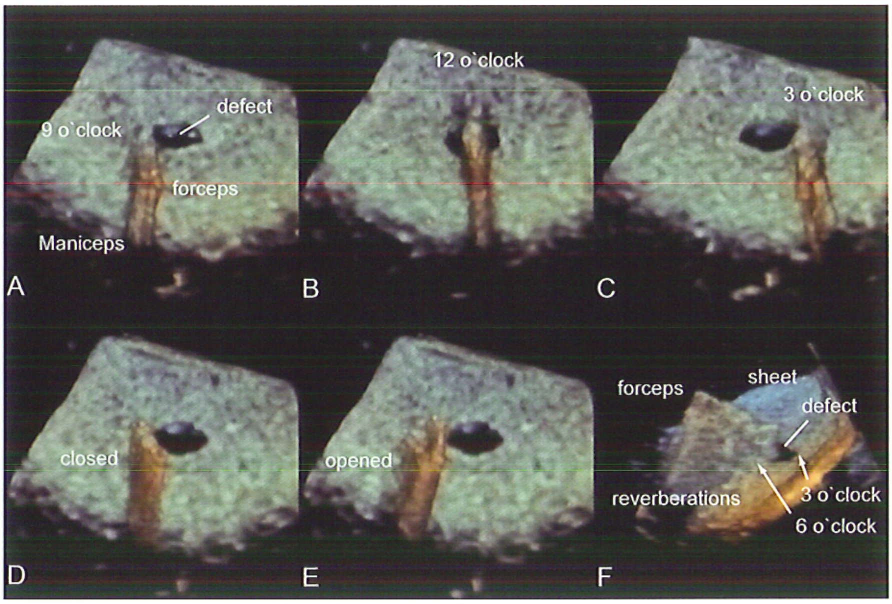


**Fig. 6.** Grasping of defect edge with a curved forceps.
A: 9 o'clock position. B: 12 o'clock position. C: 3 o'clock position. D: closed position. E: opened forceps. F: 6 o'clock position, interfered with by reverberations.

4) scanning range

When the scanning range for live 3D imaging was maximal (85°), the width of visualized area at 5 cm depth was maximal (9.2 cm) but the frame rate was 6 Hz even in low density and 4 Hz and 3 Hz in medial and high density, respectively. This frame rate was too low for guiding surgical procedures. As the scanning range was reduced to 35°, the frame rate increased to 33 Hz (low density), 24 Hz (medial density), and 15 Hz (high density), but the width of visualized area was only 3.2 cm, which was too narrow for visualizing the surgical procedures. With the scanning range of 55°, the visual field was 5.2 cm wide and the frame rate was higher than 10 Hz in low or medial density. This setting was acceptable for guiding the surgical procedures.

Based on these results, the panel setting for the

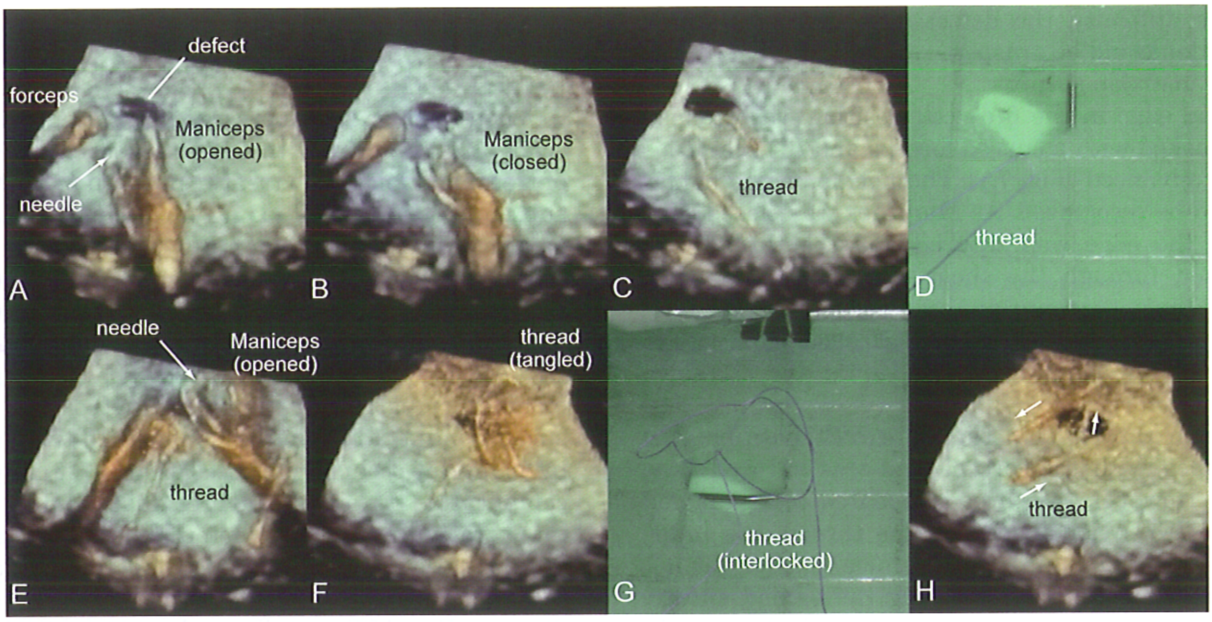


**Fig. 7.** Serial sutures of defect.
A: the edge grasped in the 6 o'clock position. B: suture bite. C: thread after suture. D: inspection of first suture. E: the edge grasped in the 12 o'clock position. F: tangled thread after second suture. G: interlocking of thread on inspection. H: interlocking released.

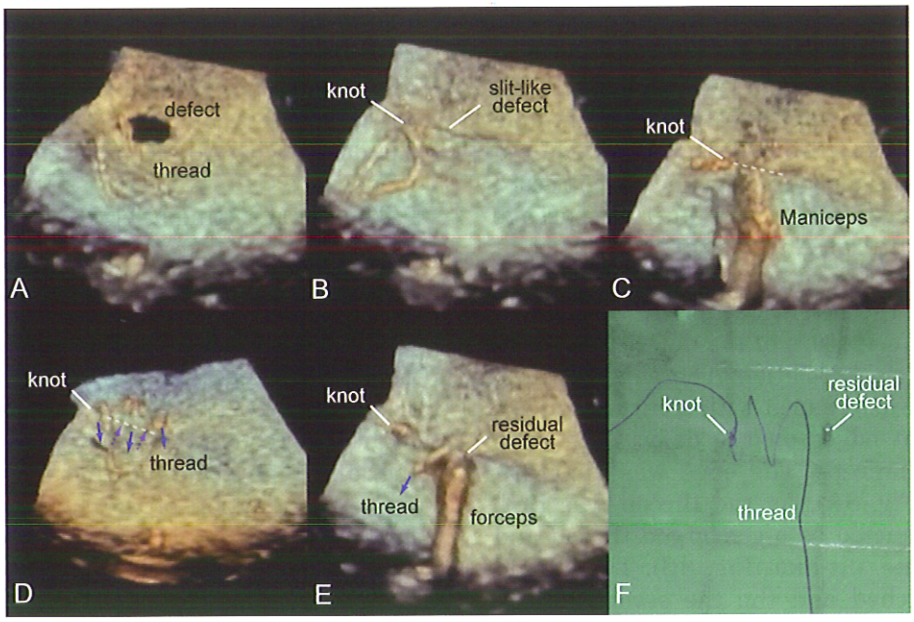


**Fig. 8.** Continuous suture of defect.
A: the 9 o'clock end of defect sutured. B: after ligation of thread showing convergence of thread. C: the second suture bite. D: spiral course of thread after three suture bites. E: the thread pulled but with residual defect. F: inspected view after three suture bites with residual defect.

subsequent echo-guided procedures was determined as: 1) low density, 2) no smoothing, 3) harmonic imaging, and 4) scanning range around 55°.

***Echo-guided surgical procedures***

1) grasping

The defect edge in the 9, 12, and 3 o'clock positions could be easily grasped with a straight forceps under 3D echo guidance (Fig. 6A-C). The acoustic shadow and the movement of the septum were helpful for locating the forceps. Opening and closing of the forceps was readily recognized in the echo views (Fig. 6 D, E). When the 6 o'clock position of the edge was masked by the forceps from the surgeon's view, the view point was changed with a trackball (Fig. 6F). However, visualization of the edge was interfered with by reverberation artifact which originated from the forceps. Despite some difficulty, the defect edge in the 6 o'clock position could be grasped.

2) transfixion suture

The edge in the 6 o'clock position was grasped or hooked with a curved forceps and the Maniceps was advanced (Fig. 7A). The needle on the holder could be recognized. As Maniceps was closed (Fig. 7B), the edge was sutured and the thread was passed through the sheet (Fig. 7C). On inspection, the suture margin was appropriate (Fig. 7D). Suture bite adjacent to the grasped portion was helpful for avoiding an inadequate or excessive suture margin.

Then the edge in the 12 o'clock position was grasped with the forceps and was sutured (Fig. 7E). However, the thread appeared to be tangled (Fig. 7F). When inspected, the thread was interlocked (Fig. 7G), probably because tension was not applied on the thread during the second suture. When the interlocking was released, the margin of the suture was appropriate (Fig. 7H). By taking up the slack during the second suture bite, interlocking could be avoided.

3) edge suture

To practice the initial bite of continuous suture, the edge in the 3 o'clock position was grasped with a straight forceps and the adjacent septum was sutured with Maniceps. The position and margin of the suture was appropriate. This technique was repeatedly attempted and the time required for one suture was measured on the video record (from starting to grasp the edge until the passage of thread after suture). Although it took 60 sec at the first attempt, the time was gradually shortened to 24 sec at the seventh attempt.

Next, continuous suture of the defect was started from the 9 o'clock position. The edge in the 9 o'clock position was grasped with a curved forceps and the adjacent edges on the defect side were sutured with Maniceps. The edge was appropriately sutured (Fig. 8A). As the thread was tied, the knot was depicted as a converged thread and the defect became slit-like (Fig. 8B). The thread was slightly hitched and the the second suture was applied adjacent to the knot (Fig. 8C). After three suture bites, the thread was depicted as spiral with the portion behind the sheet not visualized (Fig. 8D). As the thread was pulled, the loop was tightened but there was still a residual defect, which was evidenced by inserting the forceps into the defect (Fig. 8E). On inspection, three sutures were appropriately done and there was a residual defect (Fig. 8F). Continuous suture was interrupted at this moment because the needle was deformed by repeated sutures and could not be captured by the needle catcher.

## DISCUSSION

When PFO or ASD is present in a patient who is scheduled for OPCAB, there are several strategies of treatment: either no treatment (with or without subsequent treatment using an occluder device) or conversion to an on-pump bypass thereby forsaking the benefit of off-pump surgery[9]. Although PEO or ASD may be left untreated unless there is significant right-to-left shunt flow at the time of OPCAB, the shunt flow may increase with aging or by other pathologies later and necessitate closure of shunt. PFO can be non-surgically treated by using an occluder device. However, it may be complicated by significant residual shunt[4,8] or interfere with future catheter ablation for atrial fibrillation which may develop during long-term follow-up in patients with ischemic heart disease. For ASD, totally endoscopic or robotic surgeries have been reported as less invasive treatments[1,2,10]. However, they necessitate a cardiopulmonary bypass. If off-pump ASD/PFO closure in the beating heart were available, it would certainly be desirable. This study was conducted as the second step toward this goal. The results indicated that 1) panel settings can be optimized for visualizing instruments and guiding surgical procedures, and 2) 3D echo-guided suture of the defect with Maniceps is feasible in an *ex vivo* model.

The panel setting affects the sharpness of images, artifacts, and frame rate, which substantially determine the feasibility of echo-guided surgical procedures. There are two important points for guiding procedures: 1) clear and precise visualization of the objects, and 2) minimal time delay in image display. The former can be optimized by a higher ultrasound frequency, no image smoothing, and high scanning line density. To obtain a wide visualization of the surgical working space for facilitating the procedures, the maximal scanning range is helpful. However, the image display is delayed because of the time required for data acquisition and data processing. For guiding the surgical procedures, a frame rate of higher than 10 Hz is mandatory because the time delay exceeds 0.1 sec at a frame rate below 10 Hz. Thus, a compromise needs to be reached. Since the delay is increased according to the number of scanning lines for one frame of image, it is necessary to limit the line density and scanning area. The conclusive setting for 3D echo-guided procedure in this study was: 1) harmonic imaging; 2) no image smoothing; 3) low line density, and 4) moderate scanning range (around 55°) for live 3D imaging. At this setting, a surgical field of 5 to 6 cm width can be visualized at a frame rate of 10 to 15 Hz.

Maniceps enables 3D echo-guided surgical procedures including single edge suture and continuous suture, although there is a learning curve for mastering the procedures. Several tips and pitfalls were elucidated in this study. The width of suture bite can be inadequate or excessive. Since undoing of the suture is not desirable in a beating heart, the suture bite should be precise. This pitfall may be resolved by repeated practice and careful location of Maniceps by reference to the movement of septum or the position of forceps. In serial or continuous suture, the slack of the thread should be taken up to avoid an interlocking of the suture (Fig. 7F, G) because it is difficult to release the interlocking in a beating heart. After several sutures, the defect becomes slit-like and the residual defect may be overlooked. It can be detected either by shunt flow in color Doppler imaging or by insertion of the forceps into the defect (Fig. 8E, F). Additional sutures may be placed under echo guidance.

The next step toward the clinical application of 3D echo-guided off-pump closure of PFO/ASD in OPCAB patients is "standardization" of this procedure. It is essential to assess the precision and certainty of echo-guided procedures, including the width of suture margin and distance between sutures as well as the rate of technical failure. For this purpose, an assessment using a standardized ASD model is necessary, preferably using an *ex vivo* ASD model with movement like a beating heart.

This study has clarified two problems to be solved. One is reverberation artifact, which masks the image behind the forceps and makes it difficult to grasp the defect edge (Fig. 6F). To reduce an interference by reverberations, the surface materials of the instruments need to be renovated. Alternatively, this problem may be solved by relocating the echo probe and changing the direction of scanning. Another problem is deformity of the needle after repeated sutures by Maniceps (5 to 10 times). A deviated needle tip cannot be captured by the needle catcher. Because of this limitation, continuous suture with the Maniceps system is not recommended but interrupted suture is appropriate. Figure-of-eight suture for closing PFO may be safely done with one suture.

Technological advancement will solve some of these problems and further facilitate echo guidance with more clearest images. This technique may be further developed to 3D echo-guided closure using robotic surgical instruments such as the da Vinci system, endoscopic technique through the intercostal space, or possibly endovascular fashion.

In conclusion, suture closure of defects under 3D echo guidance using the Maniceps system is feasible in an ex vivo ASD model as visualization is optimized by panel setting for guiding surgical procedures.

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