

# A Novel One-Shot Circular Stapler Closure for Atrial Septal Defect in a Beating-Heart Porcine Model

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**Purpose.** In surgical atrial septal defect (ASD) closure, there are no techniques or devices that can close the ASD accurately in a short time under a beating heart. We have developed a simple and automatic ASD closure technique using a circular stapler. This study assessed the feasibility and efficacy of a new circular stapler closure for ASD.

**Description.** Under a continuous beating heart, hand-sewn patch plasty ASD closure was performed in 6 pigs (group A) and circular stapler ASD closure was performed in 6 pigs (group B). The time to close the ASD and the effectiveness of the closure were compared.

**Evaluation.** Closure was significantly faster in group B ( $10.5 \pm 1.0$  seconds) than in group A ( $664 \pm 10$  seconds;  $p < 0.05$ ). There was no leakage at the closure site, and sufficient tolerance was confirmed.

**Conclusions.** A circular stapler can be used to treat ASD faster than hand-sewn patch plasty, with sufficient pressure tolerance in a beating heart porcine model.

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For a secundum atrial septal defect (ASD), transcatheter ASD closure has gained widespread acceptance during the past few years. Approximately 80% of secundum ASDs are reported to be suitable for transcatheter closure [1]. The success rate of transcatheter closure is reported to be 95% to 98% [2–4]. However, the indications for transcatheter approaches are limited to small secundum ASDs [2, 5]. The presence of a large ASD or an insufficient rim ( $<5$  mm) to anchor the closure device decreases the success rate of the procedure and leads to severe complications [5]. The limited long-term follow-up of transcatheter closure and the lack of randomized studies comparing transcatheter and surgical closures make it imprudent to conclude that transcatheter closures are comparable or even preferable to the surgical approach, regardless of patient selection.

Therefore, surgical closure is still an important and necessary method in the treatment of ASD. Surgical closure of ASDs has excellent success rates and long-term outcomes [2]; however, there have not been any remarkable changes in surgical techniques, which involve direct closure or patch plasty by manual suture.

We have developed a simple and automatic ASD closure technique using a circular stapler. This novel

technique is different from all closure devices developed so far for surgical or transcatheter closure. This circular stapler closure (CSC) is designed to close the ASD as a completely alternative technique to the hand-sewn patch closure, which is a time-consuming procedure and requires direct vision. Compared with the transcatheter ASD closure device, the CSC staples the closure site to the atrial wall. This leads to the avoidance of the embolism of the device, which is the most severe complication of the transcatheter closure. The aim of this study was to assess the simplicity and feasibility of the ASD closure by comparing hand-sewn patch closure and CSC in a beating heart porcine model.

## Technique

### Circular Stapler Closure

The Proximate Intraluminal Stapler (Ethicon Endo-Surgery, Cincinnati, OH) was used for CSC. This mechanical circular stapler consists of a rigid applicator shaft and a staple cartridge with a circular knife blade (Fig 1) and is designed to transect, resect, and anastomose automatically. The outside diameter of the circular stapler is 29 mm, the knife diameter is 20.4 mm, and the circular stapler holds 24 titanium staples arranged in 2 circular lines.

The circular stapler was prepared for automatic ASD device closure. For closure preparation, the anvil head was wrapped with bovine pericardium (Edwards

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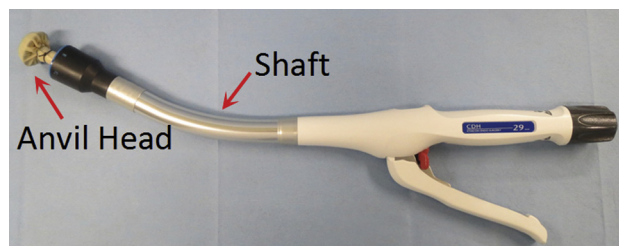


Fig 1. General view of the mechanical circular stapler.

Lifescience, LLC, Irvine, CA) and tied with a purse-string suture (Fig 1). The anvil head was attached to the shaft in the closing procedure. The process of CSC for the ASD had only three steps. First, the anvil head was passed through to the left atrium side via the ASD, and the shaft was kept on the right atrial side (Fig 2A). Second, stapling by the atrial wall and the bovine pericardium was performed, and the circular knife blade cut the inner tissue of the stapler line simultaneously (Fig. 2B). Finally, the anvil head was removed from the stapling site, and the procedure was completed (Fig. 2C).

### Surgical Protocols

To evaluate the circular stapler for ASD closure, 12 healthy adult pigs (female, approximately 50–60 kg) were used in the experiment. Treatment of pigs was based on the Guide for the Care and Use of Laboratory Animals, prepared by the National Academy of Sciences and published by the National Institutes of Health (revised 1996) and the Guideline for the Care and Use of Laboratory Animals in Takaramachi Campus of Kanazawa University. The protocols in this study were approved by

the animal experimentation committee of Kanazawa University.

Pigs were placed supine, and a median sternotomy was performed to access the heart. After the median sternotomy, the left-to-right shunt ratio ( $Q_p/Q_s$ ) was measured before the ASD was created (pre-ASD state).  $Q_p/Q_s$  was calculated according to the formula:  $Q_p/Q_s = (\text{SatArt} - \text{SatMv})/(\text{SatArt} - \text{SatPA})$ . With SatArt indicating arterial oxygen saturation, SatMV indicating mixed venous saturation, SatPA indicating pulmonary artery oxygen saturation, and SatPV indicating pulmonary venous oxygen saturation. SatMV was calculated according to the formula:  $\text{SatMV} = (\text{SatSVC} + \text{SatIVC})/2$ . SatSVC and SatIVC were the oxygen saturation in the SVC and the IVC, respectively.

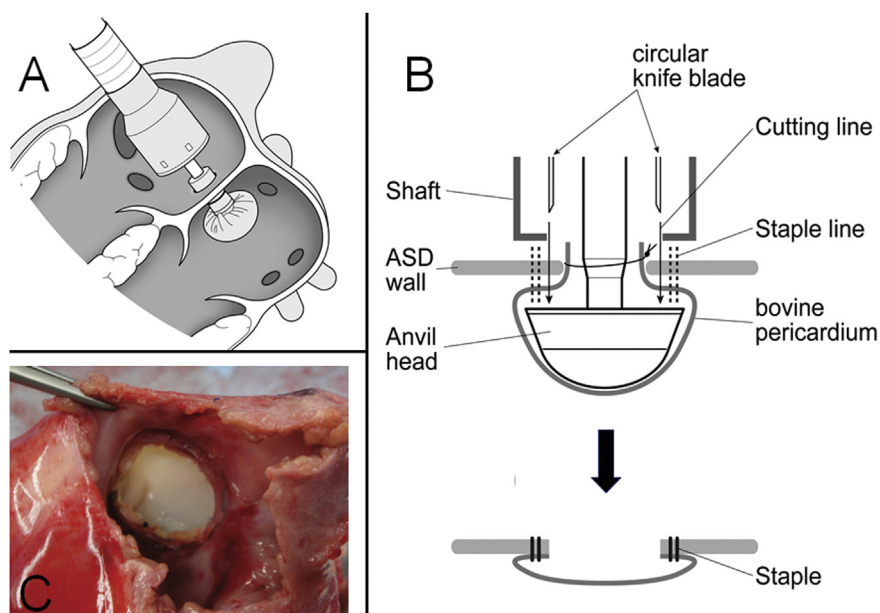
Cardiopulmonary bypass (CPB) was established, and a 15-mm circular ASD was created through the fossa ovalis under direct vision. After the ASD was created, the atriotomy was closed and the pigs were weaned from CPB. Hemodynamic status was confirmed to be stable for 30 minutes for the assessment of the left-to-right shunt by epicardial transapical echocardiography, and the  $Q_p/Q_s$  was measured (ASD state).

CPB was resumed for the closure of the ASD. In group A, the ASD was closed by hand-sewn patch plasty in 6 pigs, and in group B, the ASD was closed using the circular stapler in 6 pigs. After the atriotomy was closed, the pigs were weaned from CPB. Left-to-right shunt and the  $Q_p/Q_s$  were measured (ASD closure state) with the same method used before the closure.

### Postoperative Pressure Study

After the procedure was completed, the pigs were euthanized under deep anesthesia. The heart was excised, and a pressure study was used to assess the

Fig 2. (A) General view of circular stapler closure. (B) Schematic of atrial septal defect (ASD) closure by the circular stapler. (C) Image of the anastomotic site from the right atrium.



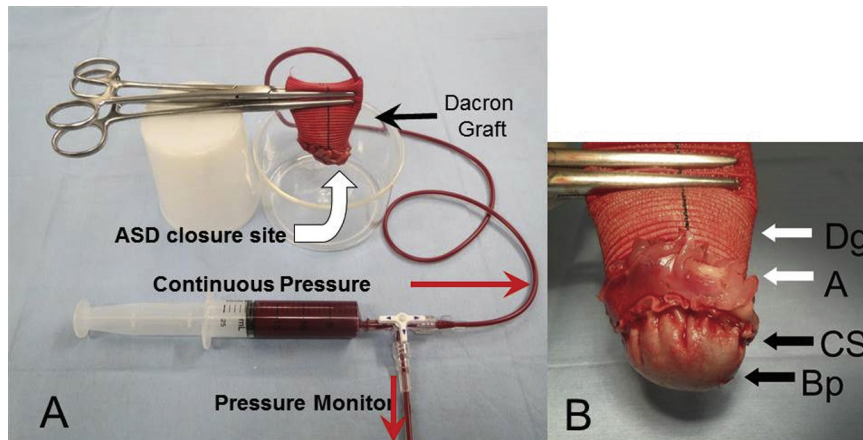


Fig 3. (A). Photograph of the postoperative pressure study shows a pressure level of 100 mm Hg. (B) General view of the postoperative pressure study shows the anastomosis (A) of and the atrial wall (white arrows) and the bovine pericardium (Bp) and the circular stapler the Dacron graft (Dg; DuPont, Wilmington, DE) closure site (CS) (black arrows).

ASD closure site. The atrial septal wall with the ASD closure site was anastomosed with a Dacron (DuPont, Wilmington, DE) graft from the side of the left atrium. Forceps were used to close the opposite end of the Dacron graft. This closed system was filled with heparinized porcine blood, and external pressure was manually applied while monitoring the interior pressure of the system (Figs 3A and 3B). The amounts of bleeding from the closure site under continuous pressure for 3 minutes were measured in groups A and B. Continuous pressure was applied to the closure site at 10, 25, 50, 75, and 100 mm Hg. The porcine blood that leaked at each pressure was collected and measured.

#### Statistical Analysis

All data are expressed as means  $\pm$  standard deviation. Stata MP 13.1 software (StataCorp LP, College Station, TX) was used for analysis. Comparative analysis for closure time was performed using the Mann-Whitney *U* test. For  $Q_p/Q_s$  and leakage at each level of pressure, values were subjected to two-way factorial repeated-measures analysis of variance. Prior tests of differences in means of  $Q_p/Q_s$  ratios at of each three states (pre-ASD, ASD, and ASD closed) were performed by Student's *t* test. A prior test of differences in means of leakage at each of the three levels of pressure was

performed by Student *t* test. Results were considered significant at  $p < 0.05$ .

#### Clinical Experience

Closure was significantly faster in group B ( $10.5 \pm 1.0$  seconds) than in group A ( $664 \pm 10$  seconds;  $p < 0.05$ ).

Epicardial transapical echocardiography showed there was no left-to-right shunt at the closure site in either group (Figs 4A and 4B). Cardiac function was good, and there was no obstruction or regurgitation of any valve. Flow from the coronary sinus was good in every pig. During the operation, there were no significant arrhythmias.  $Q_p/Q_s$  increased from the pre-ASD state to the ASD state and then decreased in the ASD closure state ( $1.00 \pm 0.10$  to  $2.08 \pm 0.28$  and decreased to  $1.01 \pm 0.20$  in group A;  $1.00 \pm 0.10$  to  $1.98 \pm 0.17$  and decreased to  $1.01 \pm 0.22$  in group B). There were no significant differences between groups A and B in each of the three states ( $p = 0.63$ ). There was a significant difference between the pre-ASD state and the ASD state and between the ASD state and the ASD closure state ( $p < 0.05$ ).

The amounts of leakage from the anastomotic site under continuous pressure for 3 minutes in groups A and B, respectively, were  $0 \pm 0$  mL and  $0 \pm 0$  mL at 10 mm Hg and 25 mm Hg,  $1.7 \pm 2.1$  mL and  $0.5 \pm 0.8$  mL at 50 mm Hg,  $15.1 \pm 3.9$  mL and  $2.3 \pm 4.8$  mL at 75 mm Hg, and 26.7

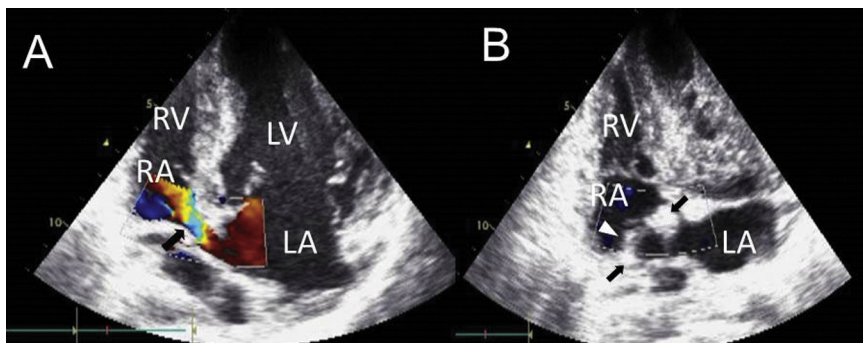


Fig 4. Echocardiography before and after atrial septal defect closure. (A) The arrow shows shunt flow from the left atrium (LA) to the right atrium (RA) by color Doppler. (B) Arrows show the staplers, and the arrowhead shows the bovine pericardium of the circular stapler closure. (LV = left ventricle; RV = right ventricle.)



$\pm 9.8$  mL and  $9.0 \pm 3.5$  mL at 100 mm Hg. Leakage at the ASD closure site did not differ significantly in either group below 50 mm Hg. However, at pressures of 75 mm Hg and 100 mm Hg, the amount of leakage was significantly less in group B ( $p < 0.05$ ).

## Comments

To the best of our knowledge, this is the first study to report staple device for intracardiac operations, such as atrial and ventricular septal defects. The present study found that compared with hand-sewn closure, CSC was faster with low residual shunts on echocardiography and  $Q_p/Q_s$  measurements. In the postoperative pressure study, CSC showed sufficient tolerance. This result suggests that this novel CSC technique leads to simple and feasible intracardiac operations compared with conventional hand-sewn closure.

The development of stapling devices has been remarkable in recent years. Many studies, especially in gastrointestinal and thoracic operations, have reported the superiority of the stapling device over hand-sewn sutures [6, 7]. It is said that not only shorter anastomosis time but also more precise anastomosis led to the reduction of anastomotic complications, such as bleeding and leakage of the anastomotic site. The theoretic benefit of staple-line reinforcement is that it reduces tension by spreading force evenly, decreasing the space between the staples, and thereby preventing tearing of the staples through the tissue [8]. Thus, surgical staplers have the ability for fast and accurate anastomosis or suturing compared with manual hand suturing.

Moreover, compared with transcatheter ASD closure devices that require sufficient rims, this technique can be performed in cases of insufficient rims of at least 1 to 2 mm. This is because the distance from the edge of the anvil to the staple line is 1 mm. For the cases without rims, we are planning to make rims by suture retracting. Thus, this closure technique has a great advantage from transcatheter ASD closure in cases of ASDs with a short rim.

In the present study, hand-sewn closure required longer closure time because of the movement of the beating heart and the blood flow due to the left-to-right shunt flow. On the other hand, every closure with CSC took only 10 seconds. This is accomplished because the stapler is designed to staple at once. This mechanism also contributes to equal tension to the anastomotic site and led to closure with no leakage.

The echocardiographic findings,  $Q_p/Q_s$ , and pressure leak test revealed complete closure, which demonstrated the feasibility of the closure. The pressure study showed no significant difference at low pressure levels, but at high pressure levels, the CSC showed significant tolerance of the closure site compared with hand-sewn closure. This result suggests that the CSC has the potential of better tolerance compared with hand-sewn closure in high-pressure sites such as ventricular septal defects. More investigation can lead to its use for ventricular septal defects, valve repairs, and other intracardiac operations.

Surgical closure for ASD treatment has excellent success rates and long-term outcomes [2]; however, it is widely performed under full sternotomy, CPB, and cardiac arrest. The results of the present study suggest that surgical ASD closure under a beating heart can be accomplished with a circular stapler, although the closure was performed under direct vision and CPB. Further refinements of this platform toward a minimally invasive approach will include the use of echocardiographic guidance closure, either transthoracic or transesophageal, and without CPB. Not all ASDs are in a completely circular form. Closure of asymmetric ASDs can be performed by using larger circular staplers or by using 2 devices. Furthermore, we are making an oval-type stapler for asymmetric ASDs. The present study is the initial step, and future studies will be aimed for more precision and safety of CSC under a beating heart without CPB.

## Disclosures and Freedom of Investigation

The source of all funds in the study was from the authors' department, Kanazawa University, Department of General and Cardiothoracic Surgery. The authors had full control of the design of the study, methods used, outcome parameters, analysis of data, and production of the written report.

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