# Preliminary Experience in the Use of CERA Occluders for Closure of Different Intracardiac and Extracardiac Shunts

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**ABSTRACT: Background.** Transcatheter closure has become the method of choice for treatment of many heart defects. Recently, Lifetech Scientific introduced the Cera occluder (CO), a self-expandable nitinol wire-mesh device covered with ceramic coating. We present our preliminary experience in transcatheter closure of atrial septal defect (ASD), patent foramen ovale (PFO), patent ductus arteriosus (PDA), and postinfarction ventricular septal defect (PIVSD) with the CO. **Methods.** The study population consisted of 25 patients (17 female) ages 1.1-82 years (median age, 34.0 years) with either ASD (n = 7), PFO (n = 11), PDA (n = 6), or PIVSD (n = 1). All patients were treated percutaneously with appropriate CO devices, without any preliminary patient selection. The implantation technique applied in these procedures was the same as previously described for Amplatzer occluders. **Results.** All procedures were performed successfully. Complete shunt closure was achieved in all but 1 patient with PIVSD. No complications were observed during procedures or during follow-up of 0.5-4 months. **Conclusions.** Our preliminary experience in the clinical application of COs for transcatheter closure of ASD, PFO, PDA, and PIVSD has confirmed their utility, feasibility, and safety, at least in the short-term follow-up.

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**Key words:** Cera occluders, shunt closure

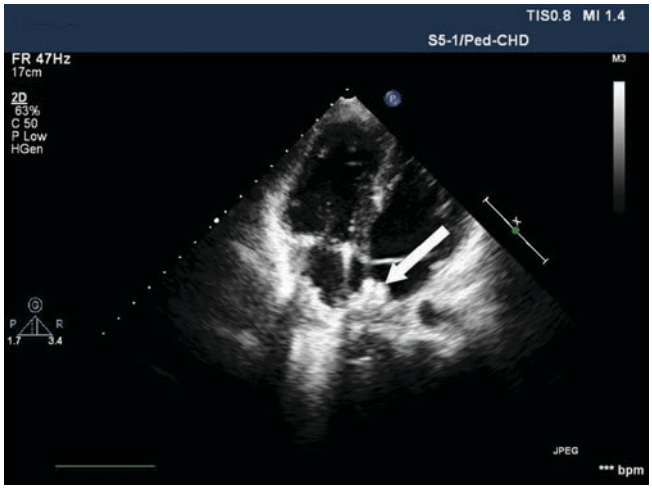


**Figure 1.** *Patient after heart transplantation, tricuspid annuloplasty (Carpentier ring) and ASD closure with Cera ASD occluder (white arrow) transthoracic echo 1 month after the procedure: 4-chamber view.*

The interventional approach has become increasingly preferred in the treatment of many congenital as well as structural heart defects, including type II atrial septal defect (ASD), patent foramen ovale (PFO) in young patients with cryptogenic stroke in anamnesis, selected patients with postinfarction ventricular septal defect (PIVSD), and patients with patent ductus arteriosus (PDA). Some severe sequelae that may affect the outcome of an interventional approach are receiving increasing attention from researchers.[1,2] Amplatzer devices (AGA Medical Corporation, now part of St. Jude Medical) have been the most popular occluding devices for many years. Good short- and intermediate-term results achieved with these devices have been documented.[3] Since the high cost of these devices can limit their widespread clinical use in some countries, there is a need for alternative lower-cost products that are safe and effective. We carried out a preliminary evaluation of the efficacy and safety of Cera occluders (Lifetech Scientific). These new devices are made of nitinol wire mesh and received CE approval (CE 0344). Although these devices are widely used in different parts of the world, there is a very limited number of publications regarding their clinical application. In this paper, we present our initial experience in the use of the Cera occluder (CO) for transcatheter closure of ASD, PFO, PIVSD, and PDA. To the best of our knowledge, this paper is the first to report the use of these devices for transcatheter ASD and PFO closure.

## Methods

From April 2013 to August 2013, a total of 25 patients (17 female) ages 1.1-82 years (median age, 34.0 years), weighing 9-107 kg (median weight, 62.0 kg) underwent transcatheter closure of different heart defects with Cera devices at our institution. These defects included ASD (n = 7), PFO (n = 11), PIVSD (n = 1), and PDA (n = 6). All patients had standard preoperative electrocardiogram, chest x-ray, and two-dimensional and color Doppler transthoracic echocardiogram (TTE). Patients with ASD had signs of right heart overload, while patients with PFO had a history of previous cryptogenic stroke (confirmed by cerebral computed tomography). All patients with PFO underwent transesophageal echocardiography (TEE) with bubble contrast administration during the Valsalva maneuver as well as transcranial Doppler (TCD) before and 3 months after the index procedure. In all these patients, right-to-left shunt through PFO

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**Table 1. Patient demographic data and procedural parameters.**

| Defect Type | Sex | Age (years) | Weight (kg) | Diameter (mm) | Device | Fluoro (min) | Follow-Up (months) |
|---|---|---|---|---|---|---|---|
| **ASD** | | | | | | | |
| 1. | F | 34 | 50 | 20 | 26 | 3.0 | 2.0 |
| 2. | F | 17 | 68 | 9 | 15 | 2.0 | 3.0 |
| 3. | M | 59 | 107 | 24 | 26 | 3.0 | 3.0 |
| 4. | F | 13 | 30 | 8 | 12 | 9.3* | 3.0 |
| 5. | F | 61 | 88 | 16 | 24 | 4.0 | 4.0 |
| 6. | F | 16 | 44 | 8 | 10 | 3.0 | 4.0 |
| 7. | M | 53 | 92 | 16 | 18 | 2.0 | 1.0 |
| **PFO** | | | | | | | |
| 8. | F | 34 | 56 | 7 | 25/18 | 2.0 | 2.5 |
| 9. | M | 52 | 52 | 15 | 25/18 | 1.6 | 3.0 |
| 10. | F | 46 | 85 | 5 | 16** | 3.4 | 3.0 |
| 11. | F | 42 | 54 | 13 | 13** | 3.0 | 4.0 |
| 12. | M | 31 | 71 | 8 | 18/18 | 2.1 | 4.0 |
| 13. | F | 48 | 98 | 7 | 25/18 | 2.0 | 4.0 |
| 14. | M | 26 | 105 | 9 | 18/18 | 3.0 | 4.0 |
| 15. | F | 34 | 69 | 7 | 25/18 | 3.0 | 1.0 |
| 16. | M | 50 | 103 | 10 | 35/25 | 1.0 | 1.0 |
| 17. | F | 31 | 75 | 7 | 25/18 | 3.0 | 0.5 |
| 18. | F | 49 | 62 | 6 | 25/18 | 1.0 | 0.5 |
| **PDA** | | | | | | | |
| 19. | M | 4 | 12 | 2.3 | 6/4 | 4.0 | 3.5 |
| 20. | M | 2 | 14 | 2.1 | 6/4 | 5.0 | 3.0 |
| 21. | F | 4 | 19.8 | 2.7 | 8/6 | 7.3 | 3.0 |
| 22. | F | 1.1 | 11.3 | 4.0 | 8/6 | 3.0 | 2.0 |
| 23. | F | 1.5 | 9.0 | 2.1 | 6/4 | 3.0 | 1.5 |
| 24. | F | 3.5 | 13 | 2.5 | 6/4 | 4.0 | 1.5 |
| **PIVSD** | | | | | | | |
| 25. | F | 82 | 72 | 10*** | 18**** | 44.0 | 0.5 |

*Legend: F = female; M = male; fluoro = fluoroscopy time; PIVSD = postinfarction VSD.*
**Patient after heart transplantation with surgically created ASD; **Patients with floppy PFO valves: ASD devise used; ***Multiple PIVSDs — biggest diameter given; ****ASD Cera device.*

was documented prior to the procedure. Similarly, all other patients with interatrial communication underwent TEE before the procedure. The patient with PIVSD suffered from myocardial infarction 4 weeks in advance and was in New York Heart Association class III/IV with important signs of worsening heart failure. All children with PDA had a continuous murmur heard in the 2nd-3rd left intercostal spaces, with left ventricular dilatation. Those with pulmonary hypertension or other conditions that made closure unsuitable/contraindicated, such as extremely large defects, were excluded from the study. We obtained written informed consent from all patients concerning the use of Cera occluders. The implantation protocol was approved by our hospital's medical Institutional Review Board.

**Interventional procedure.** Depending on age, the patients received either general anesthesia (children and the PIVSD patient) or only local anesthesia (adults). Occlusion procedures were performed according to the guidelines provided in the manufacturer's product description and appropriate literature (similar to implantation of original Amplatzer devices). Monitoring of the implantation process was performed through continuous TEE in cases of ASD, PFO, and PIVSD closures and through fluoroscopy and angiography in cases of PDA closures. Before final device implantation, stretched diameters of particular defects were assessed with calibration balloons (Lifetech Scientific) in selected patients with ASD and PFO.

**Characteristics of the occluders.** Cera occluders are a family of different devices dedicated to ASD, PFO, PDA, and VSD closure. They are made of nitinol wire mesh coated with a ceramic deposition film. According to the manufacturer, this ceramic coating prevents nickel leaching (from nitinol wires), and promotes rapid endothelialization and complete defect closure.[4] Shapes and sizes of ASD, PFO, and PDA devices are similar to original Amplatzers. ASD and PFO occluders are self-expandable double-disc devices in the following sizes: ASD, 4-8 mm and then every 2 mm larger up to 42 mm (a given device size indicates its waist diameter, the left disc is wider than the right disc); and PFO, 18/18 mm, 25/18 mm, 30/30 mm, and 35/25 mm (right disc/left disc diameters). The PDA Cera occluder is a self-expandable, mushroom-shaped device with the following available sizes: 4/6 mm, 6/8 mm, 8/10 mm, 10/12 mm, 12/14 mm, 16/18 mm, 18/20 mm, 20/22 mm, and 22/24 mm. The Lifetech delivery system is generally 2 Fr bigger than the original AGA Medical system.

**Follow-up.** All patients had thorough clinical examination, electrocardiogram, and TTE performed before hospital discharge, at 1, 3, 6, and 12 months after the index procedure, and yearly thereafter in the outpatient clinic. The incidence of concomitant clinical-related or device-related adverse events, such as severe anemia or erythrocytosis, as well as the quality of life (subjective assessment) were also registered.

## Results

All procedures were performed successfully. Table 1 shows patient demographic and procedural parameters. The stretched diameter (with calibration balloon) was assessed in patients #1, #2, #3, #5, #7, #10, and #11 (Table 1).

The mean ASD diameter (assessed by TEE) was 14.4 ± 6.3 mm and the applied Cera ASD devices ranged from 10-26 mm. All

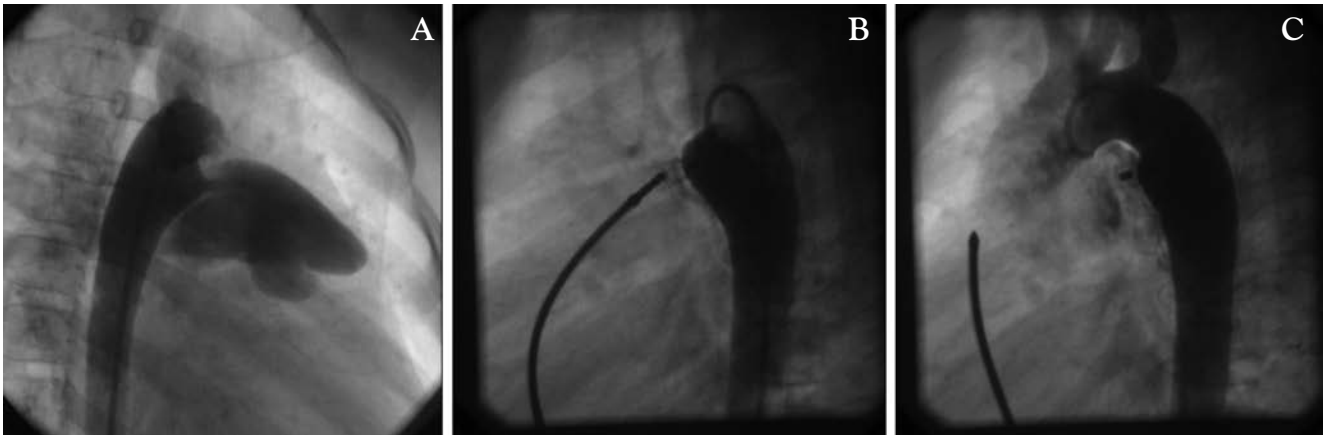


**Figure 2.** *Patent ductus arteriosus (PDA) aortographies.* **(A)** *Type A before closure: visible opacification of pulmonary artery (right anterior oblique 30° projection).* **(B)** *Cera PDA occluder in position still connected with delivery system (left anterior oblique 90°).* **(C)** *Almost complete closure of the shunt after release of the device (left anterior oblique 90°).*

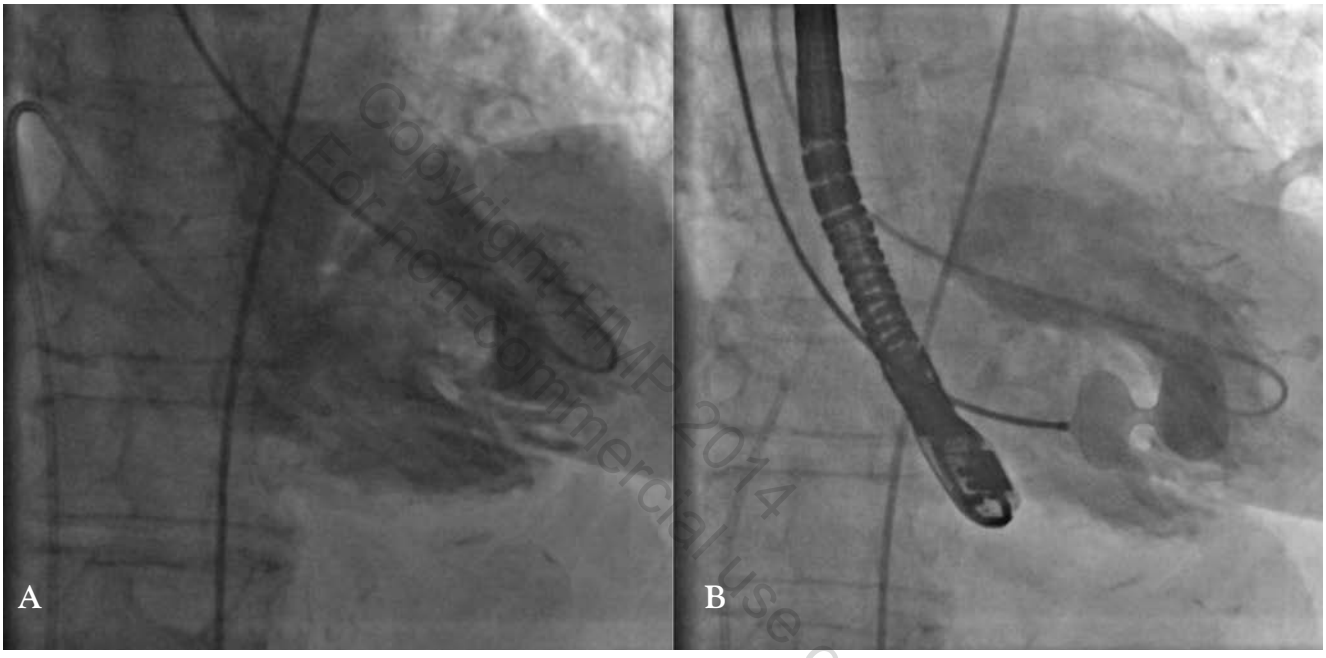




**Figure 3.** *Post-infarction ventricular septal defect: left ventriculographies in left anterior oblique 30° projection.* **(A)** *Before and* **(B)** *after transcatheter closure with atrial septal defect Cera occluder (device still attached to delivery system).*

but 1 ASD case were congenital and native in origin. A 13-year-old girl (patient #4; Table 1), 1 year after heart transplantation performed with the Shumway method, had a surgically created ASD (due to mild pulmonary hypertension before transplantation) and tricuspid valve annuloplasty (with the Carpentier ring, due to significant tricuspid regurgitation of the transplanted heart). She had her ASD closed with an 8 mm Cera ASD occluder, with the atypical localization of her device in the interatrial septum (Figure 1). In 3 patients under 18 years of age (#2, #4, and #6; Table 1) significant reduction of right ventricular dimension was seen in TTE performed at 1- and 3-month follow-up visits. No residual shunt through ASD was observed in any patient after 1-month follow-up exam.

The mean PDA diameter (assessed in angiography) was 2.6 ± 0.7 mm. In all patients with PDA, devices were implanted through the femoral vein and the subsequent control aortography confirmed their appropriate position (Figure 2). Cera PDA devices (6/4 mm and 6/8 mm) were applied (Table 1). Total PDA occlusion was seen the day after the procedure in all patients.

The mean PFO tunnel length was 8.5 ± 3.0 mm. Cera PFO occluders (25/18 mm and 18/18 mm) were applied (Table 1). In 2 PFO cases with very floppy valves (#9 and #10; Table 1), PFO assessment with calibration balloons was performed and Cera ASD devices were applied according to the stretched diameters (16 mm and 13 mm devices). TCD study performed 3 months after the procedure was negative in 6 patients. No new neurological events were observed during the follow-up of 0.5-4 months.

PIVSDs were multiple in origin with the aneurysmatic tissue located close to the apex (Figure 3). The biggest hole (seen

in TEE) was 10 mm in diameter and was closed with an 18 mm Cera ASD device. After the procedure, the patient's arterial pressure increased from 65/30/45 mm Hg to 130/80/92 mm Hg; however, residual shunt through additional communications was diagnosed with TTE. Nevertheless, significant shunt reduction and clinical improvement (New York Heart Association class II/III) were observed.

The mean fluoroscopy time of all procedures in all defects (except the PIVSD patient) was 3.2 ± 1.8 minutes. The PIVSD patient, who required three device repositions with arteriovenous loop creation, had a fluoroscopy time of 44 minutes due to the high complexity of the procedure.

Complications were observed during the procedures in only 1 patient. In the patient with PIVSD, pulmonary edema occurred due to low cardiac output. No other new-onset sequelae (eg, rhythm disturbances, headache) were recorded in any patient.

## Discussion

Our initial experience indicates that Cera implants are a safe and effective option for transcatheter closure of common congenital heart diseases (PDA and ASD) as well as PFO and PIVSD. Our team has had good experience with the use of Amplatzer, Figulla (Occlutech), and other implants (Cardio-O-Fix; Starway Medical) for ASD, PDA, PFO, PIVSD, and ruptured sinus of Valsalva aneurysm.[5,6] A comparative study of Cardio-O-Fix versus Amplatzer septal occluder suggested their similar effectiveness in ASD closure.[7] Also, our last study on transcatheter closure of PFO with the Amplatzer versus Cardio-O-Fix PFO occluder demonstrated their comparable efficacy.[8]

Published papers describing clinical experience with Cera occluders are limited. We have found data on the percutaneous closure of perimembranous ventricular septal defect (VSD),[9] postinfarction VSD,[10] PDA,[11] and aorta-right atrial fistula.[12] Results presented in these clinical reports indicated good effectiveness and mid-term results of Cera devices. Last year, during the Congenital and Structural Interventions Symposium in Frankfurt, Germany, Dr Shakeel Qureshi expressed his favorable opinion on Cera implants. His lecture mostly concentrated on the closure of VSDs with Lifetech implants. Our experience confirms their usefulness in the closure of simple defects such as0 ASD, PFO, and PDA, but also in complex lesions such as surgically created ASD in a heart transplant recipient (with initially increased pulmonary pressure) or postinfarct VSD. We have observed no technical complications during the implantation of Cera occluders (such as tulip malformation, which was described recently by Hayes and Rosenthal).[13]

**Study limitations.** Our study has its limitations. First of all, it was a retrospective analysis concerning a relatively small number of patients. Secondly, a longer follow-up as well as prospective comparative studies with other devices are necessary to evaluate these devices properly.

## Conclusion

Our preliminary experience in the clinical application of Cera occluders for transcatheter closure of ASD, PFO, and PDA has confirmed their utility, feasibility, and safety. Percutaneous closure of postinfarction VSD with these devices may also be safe.

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