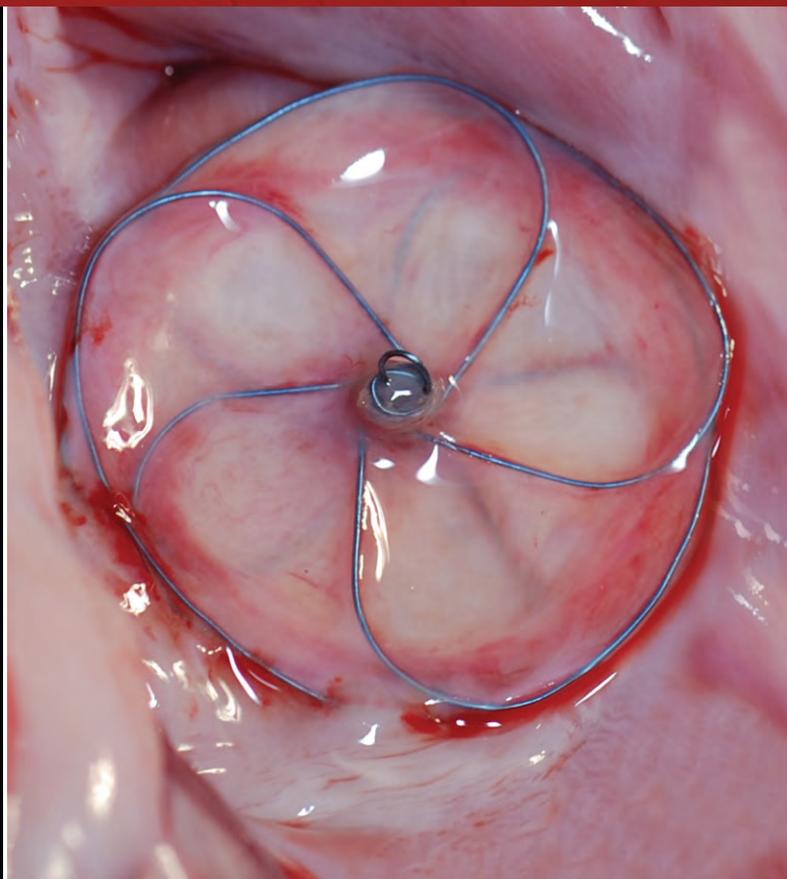


Case Study



► Closure of a Secundum Atrial Septal Defect with a GORE® CARDIOFORM Septal Occluder in a Small Infant with Chronic Lung Disease



PERFORMANCE
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CASE STUDY

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The patient is a 5-month-old male born at 28 weeks estimated gestational age with a birth weight of 840 grams. He was transferred to our hospital at 4-days-old due to concerns for interventricular hemorrhage and respiratory distress. An initial echocardiogram showed an atrial septal defect and normal ventricular size and systolic function so the patient was extubated that day and transitioned to non-invasive ventilation. However, he was reintubated from days 13 to 17 due to increased work of breathing, with non-invasive ventilation maintained until day 39 when he was transitioned to high flow nasal cannula. LASIX® (furosemide) was administered throughout his care due to pulmonary edema discovered on his chest X-ray.

On day 58 the patient was again reintubated due to increased work of breathing. A repeat echocardiogram showed severe pulmonary hypertension with estimated supersystemic right ventricular systolic pressure, so he was placed on inhaled nitric oxide with subsequent improvement in his clinical condition. With this improvement, he was extubated, weaned from nitric oxide, and started on oral ADCIRCA® (tadalafil). Echocardiogram demonstrated improved right ventricular pressure of 50% systemic, with a persistent atrial septal defect measuring 6 to 7 mm in diameter. He remained on high-flow nasal cannula due to increased work of breathing, and fed continuously through a nasoduodenal tube as he had emesis with gastric feeds. There was also progressive right ventricular dilation and a persistent left-to-right shunt through the atrial septal defect. After a multi-specialty

discussion, he was referred to the catheterization laboratory to evaluate his pulmonary vascular resistance, assess the pulmonary to systemic flow ratio, and possibly perform transcatheter occlusion of the secundum atrial septal defect if felt to be clinically indicated.

At 140 days the patient was taken to the catheterization laboratory, intubated, and given general endotracheal tube anesthesia. His weight was 4.26 kilograms. Using ultrasound guidance, a 5 Fr sheath was placed in the right femoral vein, and a 20 Gauge catheter was placed in the right femoral artery for invasive blood pressure monitoring during the procedure. Intravenous Heparin of 100 units / kg were administered. The baseline catheterization data, intubated with FiO2 of 25%, revealed a Qp:Qs of 1.6 with systolic pulmonary artery pressure of 35 mm Hg with an arterial pressure of 86 mm Hg, and an indexed pulmonary vascular resistance of 3.2 Wood units. Repeat right heart catheterization on 100% oxygen showed an increased Qp:Qs of 2.3 and decreased pulmonary vascular resistance to 2.4 Wood units. Therefore, we felt that transcatheter occlusion of his atrial septal defect would decrease pulmonary blood flow and right heart volume overload. In addition, we felt continued management with pulmonary vasodilators in the presence of an intracardiac shunt would likely be detrimental.

A transthoracic echocardiogram (TTE) demonstrated a secundum atrial septal defect measuring 5.7 mm x 8.1 mm in diameter with adequate tissue rims around the defect. The total septal length measured 23 mm (*Figure 1*). Based on prior experience with the GORE® HELEX® Device, we chose to use GORE® CARDIOFORM Septal Occluder for this case. A 15 mm device was selected based on the atrial septal defect dimensions. The femoral vein sheath was exchanged over a



Figure 2. TTE of left atrial Occluder disc being formed in the left atrium.

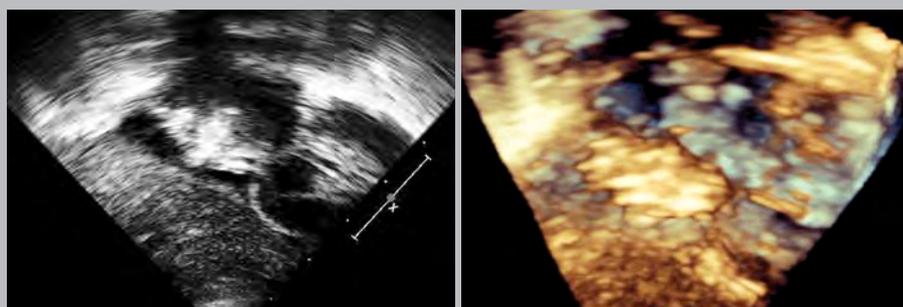


Figure 3. Immediately after device placement 2D (left) and 3D (right) TTE confirm appropriate device appearance and positioning.

wire for a 10 Fr TERUMO GLIDESHEATH Introducer Sheath. The GORE® CARDIOFORM Septal Occluder delivery catheter was then advanced through the introducer sheath and across the atrial septal defect under TTE guidance. The left atrial disc (Figure 2.) was deployed by advancing the slider, and the device was then pulled back against the atrial septum. The right atrial disc was then deployed and subsequently imaged by TTE and fluoroscopy, which confirmed the device was well positioned. The atrial septum and device were placed in a neutral position by relieving any downward tension on the delivery catheter, and the device was then locked. Fluoroscopy showed the lock had deployed appropriately. Echocardiography demonstrated a well-positioned device with no residual left-to-right shunt. The retrieval cord was subsequently removed. Two and three-dimensional imaging (Figure 3.) and fluoroscopy (Figure 4.) confirmed the device was well positioned. An angiogram with 1 cc of contrast showed no evidence of injury to the iliac vein or inferior vena cava, and the 10 Fr sheath was subsequently removed and hemostasis was achieved with manual pressure and subsequent application of a MERIT MEDICAL SAFEGUARD® Pressure Assisted Device. The patient was extubated and was transported back to the neonatal intensive care unit in stable condition. The following day, a repeat echocardiogram showed stable device position with no residual left to right shunt (Figure 5.). Over the next five weeks, the patient showed gradual clinical improvement. He advanced to full nasogastric feeds, and then transitioned to oral feeding. He gained 39 grams per day following his procedure. Chest x-ray showed significant improvement with decreased pulmonary edema, and he was weaned from nasal cannula oxygen. LASIX® (furosemide) was discontinued and he was transitioned to DIURIL® (chlorothiazide) for chronic lung



Figure 1. TTE of the atrial septal defect with color flow Doppler. The defect was centrally located and measured 5.7 mm x 8.1 mm.

disease management. A follow-up echocardiogram 29 days post procedure showed a well-positioned device with no residual atrial level shunt, normal right ventricular size and systolic function, and no evidence of pulmonary hypertension. Thirty-seven days after closure of his atrial septal defect he was discharged home. A follow-up TTE five-months post-procedure continued to show a well-positioned device and successful treatment of the patient (Figure 6.).

Discussion

This case demonstrates the feasibility of closing a secundum atrial septal defect with the GORE® CARDIOFORM Septal Occluder in a small infant. In some infants with chronic lung disease from prematurity, the additive effect of left-to-right shunt through an atrial septal defect can have a deleterious effect due to increased pulmonary blood flow and volume loading of the right ventricle. Previous reports have shown a benefit of transcatheter atrial septal defect closure in infants

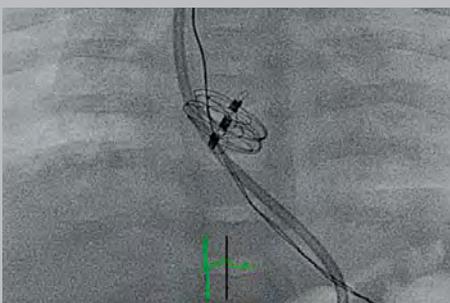


Figure 4. Fluoroscopy of the Occluder at the end of the implantation procedure. The device is locked and the discs take a flat profile.

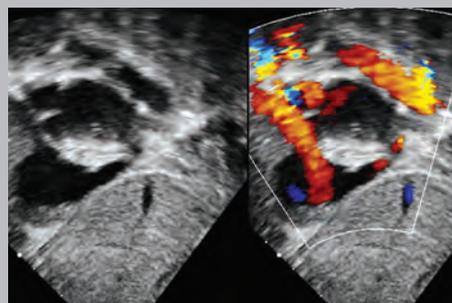


Figure 5. Subcostal long axis image from TTE the day after device placement. The device is well-positioned with no residual shunt seen by color Doppler.

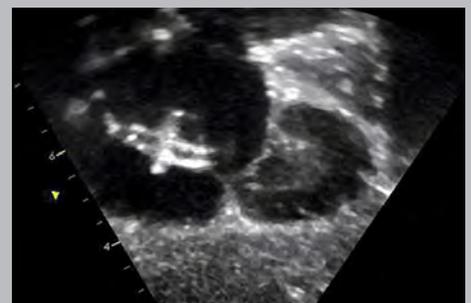


Figure 6. Follow-up TTE five-months post-procedure demonstrating stable device position and defect closure.

with chronic lung disease,¹⁻⁴ and we previously reported our experience with the GORE® HELEX® Device in these patients.⁵ Based on our experiences with the GORE® HELEX® Device, we chose to try the GORE® CARDIOFORM Septal Occluder for this patient.

There were some technical aspects using the GORE® CARDIOFORM Septal Occluder that differed from our experience with the GORE® HELEX® Device. We found that the GORE® CARDIOFORM Septal Occluder delivery catheter generally will not advance through a 9 Fr TERUMO GLIDESHEATH Introducer Sheath and had to use a 10 Fr sheath when not using a guidewire to advance the catheter into the left atrium, which is in agreement with the manufacturer's *Instructions for Use*. By using serial dilation of the femoral vein, we found a 10 Fr sheath advanced very easily. We did not have any difficulty achieving hemostasis after sheath removal, and there was no clinical evidence of venous stasis or vascular occlusion following the procedure. This technical difference will need to be considered when using this device in smaller patients and alternate access sites such as transhepatic may need to be considered in some patients. The delivery catheter for the GORE® CARDIOFORM Septal Occluder is somewhat stiffer than that of the GORE® HELEX® Device, and we found it was easier to manipulate and position the device in a small infant. Deployment of the Occluder was simple because of the slider. Keeping the septum neutral and making sure there was no tension on the delivery catheter, there was very little repositioning when locking the device; this was much different than our experience with the GORE® HELEX® Device in infants. The recommended device to defect ratio for the

GORE® CARDIOFORM Septal Occluder is 1.75:1 which is less than that recommended for the GORE® HELEX® Device. With a maximum atrial septal defect diameter of 8.1 mm, we felt a 15 mm GORE® CARDIOFORM Septal Occluder was appropriate to use in our patient. It is recommended the device diameter is less than 90 percent of the total septal length. The atrial septum in our patient measured 23 mm in length, and we felt we could use the 20 mm GORE® CARDIOFORM Septal Occluder if we were not satisfied with the stability of the 15 mm device.

In summary, we have shown that transcatheter occlusion of a secundum atrial septal defect with a GORE® CARDIOFORM Septal Occluder using the femoral venous approach is technically feasible in a small infant, can be performed safely, and may be beneficial in infants with chronic lung disease.

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