Figure 2. Pulmonary Regurgitation at 1 Year: 100% Improvement

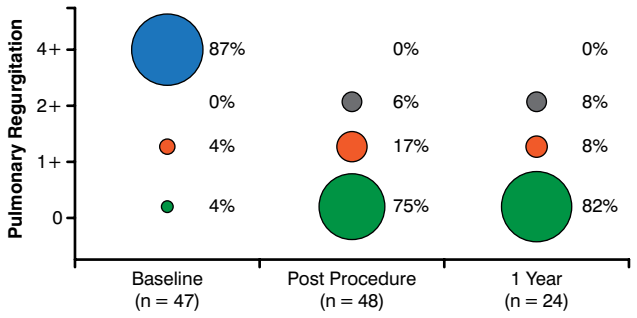

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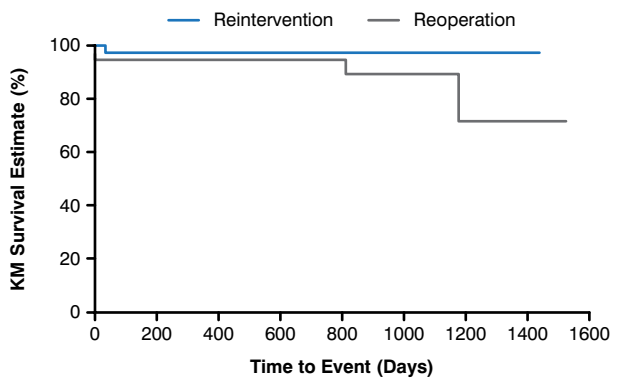
Figure 3. Freedom From Reintervention



KM=Kaplan–Meier.

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Table 2. Clinical Outcomes at 1 Year: PREMIER Registry.

Events (%)	1 Year
Mortality	0%
Reoperation	0%
Reintervention	0%
Arrhythmia or conduction system injury (defect)	3.8%
Bleeding or hemorrhage	2.3%
Infection or respiratory infection	0.8%
Vascular or arteriovenous fistula	1.5%
Device performance	
Valve stent fracture	0%
Device migration/malposition requiring intervention	3.1%
Valve stenosis or restenosis	0.8%

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SAPIEN pulmonic valve for treating patients with conduit failure in the right ventricular outflow tract, or moderate to severe pulmonary regurgitation with or without stenosis. Objectives of the study are to observe the use of the device in routine clinical practice of percutaneous pulmonary valve implantation and to evaluate its efficacy and safety in a real-world situation.

Currently, 131 patients are enrolled in the study, and 130 patients have completed both 6- and 12-month follow-up. Clinical outcomes at 1 year are shown in Table 2.

The study also found significant improvements ($p < .0001$) in pulmonary regurgitation and hemodynamics at both 6 months and 1 year compared to baseline.

Dr. Kenny concluded by stating that in assessing these 2 studies, there is momentum to complete the COMPASSION trial.

Early Data Show Benefits of New Device for Closing Congenital Heart Defects

Written by Mary Beth Nierengarten

A new-generation device used in the treatment of transcatheter closure of congenital heart defects provides easier delivery, better septal apposition, and faster endothelialization than an older version of the device. Early clinical experience showed the device to be efficient and successful in closing both atrial septal defects (ASDs) and patent foramen ovales (PFOs).

Joseph Paolillo, MD, Sanger Heart and Vascular Institute, Levine Children's Hospital, Charlotte, North Carolina, USA, presented information on the GORE Septal Occluder device, early clinical trial data, and experience with using the device for closure of ASDs and PFOs.

Similar to its earlier version—the GORE HELEX Septal Occluder—the design of the GORE Septal Occluder maintains a number of advantages. Both devices are soft and conformable, have a flattened profile, are easily repositioned, and include a retrieval cord concept.

Additional advantages of the new design include an improved delivery system for ease of use and a 5-wire design that provides enhanced disc conformability for rapid closure.

Early clinical data from a number of international trials show a high level of technical success and a high percentage of occlusion rates with the use of the device for closure of both PFO and ASD [Grohmann J et al. *Catheter Cardiovasc Interv* 2014; Smith B et al. *Catheter Cardiovasc Interv* 2014; Nyboe C et al. *Catheter Cardiovasc Interv* 2013].

Dr. Paolillo provided further early evidence of the highly technical success and closure rates with the new device from his experience at the Levine Children's Hospital. Since the first implant in January 2013, 22 devices have been implanted: 19 in an ASD trial and 3 in a PFO trial. Current outcomes show technical success with all 3 devices in the PFO trial with immediate complete closure and technical success in 95% (19 of 20 attempts) of the ASD trial with 100% closure by 1 month. He noted that the ASD trial included patients with multifenestrated defects and those with deficient retroaortic tissue.

Further evidence is expected from the GORE Septal Occluder European Union Clinical Evaluation: A Study to Evaluate Clinical Success and Performance in the Treatment of Transcatheter Closure of PFO [NCT01605851], a clinical trial that began in 2012.

Device for Closing Small to Moderate PDA Is Safe and Effective

Written by Mary Beth Nierengarten

The AMPLATZER Duct Occluder II [ADO II] device is safe and effective for the closure of small- to moderate-sized patent ductus arteriosus (PDA). The ADO II's small diameter, delivery systems, and device symmetry allows for a more flexible approach than ADO I and may broaden the use of this device in potential patient populations.

Daniel Gruenstein, MD, University of Minnesota Children's Hospital, Minneapolis, Minnesota, USA, presented the results of the ADO II prospective, single-arm, open-label, multicenter investigational device exemption clinical trial conducted to evaluate the clinical safety and efficacy of the ADO II device [NCT00713700].

In 2006, the ADO I device was shown to be effective in the closure of medium to large PDA diameters [Wang JK et al. *Int J Cardiol* 2006]. The ADO II device was designed for smaller PDA diameters. Figure 1 shows the distinctive design features of the ADO I and ADO II devices.

The current study assessed the safety and efficacy of the ADO II device using a primary safety end point of freedom from device- and procedure-related serious adverse events at 6 months and a primary efficacy end point of an absence of residual PDA shunt at 6 months. The study compared the performance of the ADO II device against the performance goals based on the original ADO clinical trial.

A total of 192 patients met the inclusion criteria and were enrolled in the study between August 2008 and April 2011. Patients were eligible if they were aged 6 months to 18 years and weighed >6 kg [AGA Medical Corporation. AMPLATZER Duct Occluder II Instructions for Use. St. Jude Medical. 2013]. Inclusion criteria also included an anatomy with a PDA diameter of <5.5 mm and PDA length of 3 to 12 mm. Patients were excluded from the study if they had a descending aorta <10 mm, a right-to-left shunt, high pulmonary vascular resistance, or medical comorbidities.

Figure 1. ADO I Versus ADO II Design


	ADO	ADO II
Ductal diameters:	2–12 mm	< 5.5 mm
Delivery system:	5F–7F (sheath)	4F–5F (catheter)
Retention discs:	1	2
Approach:	Venous	Arterial or venous
Flexibility:	"Rigid" design; may distort PDA	"Articulating" design; conforms to PDA
Design:	Single braid; polyester fabric	Double braid; no fabric

ADO=AMPLATZER Duct Occluder; PDA=patent ductus arteriosus.
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Table 1. Safety and Efficacy Results

End Point	Performance Goal	% (95% CI)	p Value[a]
Primary safety	5.34%	1.60% (0.33 to 4.59)	.0113
Primary efficacy	94.60%	98.19% (94.81 to 99.63)	.0201

[a]p value was based on a one-sided Exact Fisher's test (significance level of 0.025).

The enrolled patients had a mean age of 4.4 years and mean weight of 19.35 kg. Of the 192 patients, 178 (92.7%) were successfully implanted with the device and an attempt at implantation was done in the remaining 14 patients. Safety data at 6 months was obtained for all 192 patients, with continual follow-up for up to 5 years planned for the 178 patients successfully implanted.

The results of the study showed the ADO II device to be safe and effective at 6 months (Table 1).

The study also showed that the mean fluoroscopy time was 14 minutes (range, 2 to 89 minutes), with an average fluoroscopy time of 15.2 minutes when using an antegrade approach for device implantation, and 11.6 minutes using a retrograde approach.

According to Dr. Gruenstein, this provides preliminary evidence that the flexibility of the ADO II approach may reduce radiation exposure by reducing fluoroscopy times.