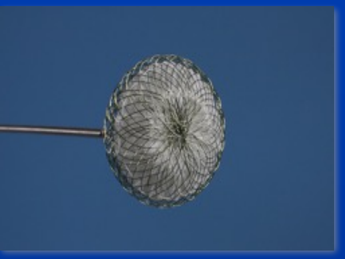


ASD Closure
Long-term Outcome

Ziyad M. Hijazi, MD, MSCAI, FACC

Professor of Pediatrics

Chair, Department of Pediatrics

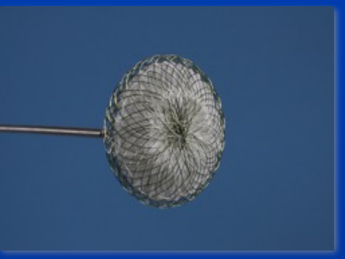
&

Director, Sidra Cardiovascular Center of Excellence

Sidra Medical & Research Center

Weill Cornell Medical College

Doha-Qatar

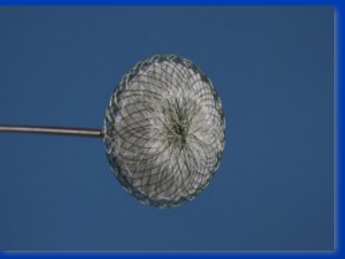


ASD Closure
Long-term Outcome

DISCLOSURE

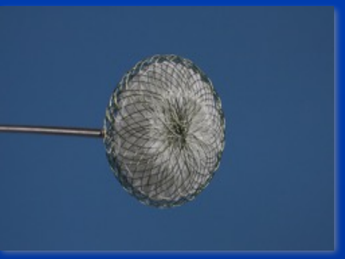
Consultant:

OCCLUTECH



ASD Closure
Long-term Outcome

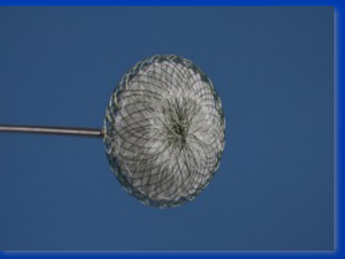
Sidra
Sidra Medical and Research Center
Qatar Foundation



ASD Closure
Long-term Outcome

Ideal Device For Catheter Closure

1. User friendly “Simple mechanics”
2. Retrievable or repositionable.
3. Effective/high complete closure rate.
4. Small delivery system.
5. Low profile within the heart.
6. Durability until full endothelialization.
7. Self-centering.
8. Preservation of flow & function despite embol.
9. Lack of ongoing morbidity.
10. Economical.

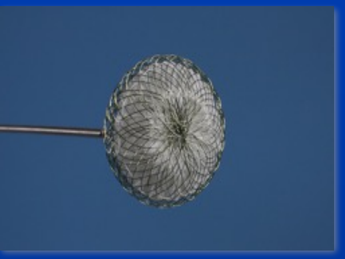


ASD Closure
Long-term Outcome

What Are The Available Devices?

US

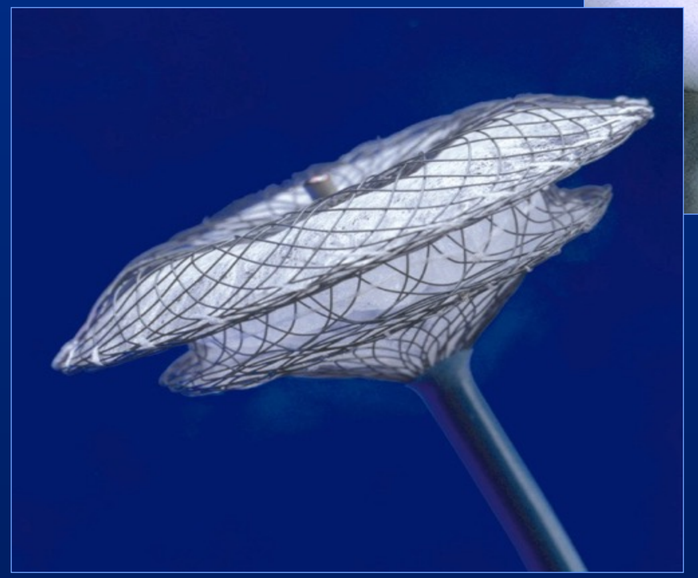
OUS

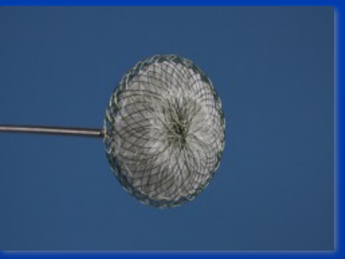


ASD Closure
Long-term Outcome

Amplatzer Septal Occluder

0.004-0.0075” Nitinol
Two Flat Disks
4mm Waist
Dacron Mesh
4-40 mm Sizes
Delivery Cable
7-12F





ASD Closure
Long-term Outcome

Gore Septal Occluder

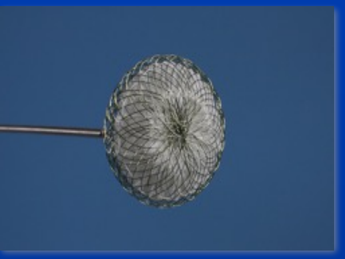
Nitinol Wire

15-30mm diameter

Good for ASD's/PFO's

<18mm (stretched) in diameter

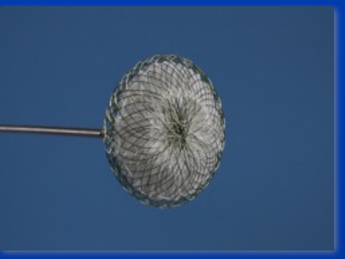
Retrievable and repositionable



ASD Closure
Long-term Outcome

Occlutech Figulla Flex II ASD Occluder

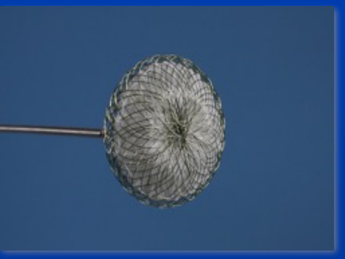
0.0047” Nitinol
Individual braiding
4mm Waist
Dacron Mesh
6-40 mm Sizes
Delivery Cable
7-14F



ASD Closure
Long-term Outcome

Cardia Devices

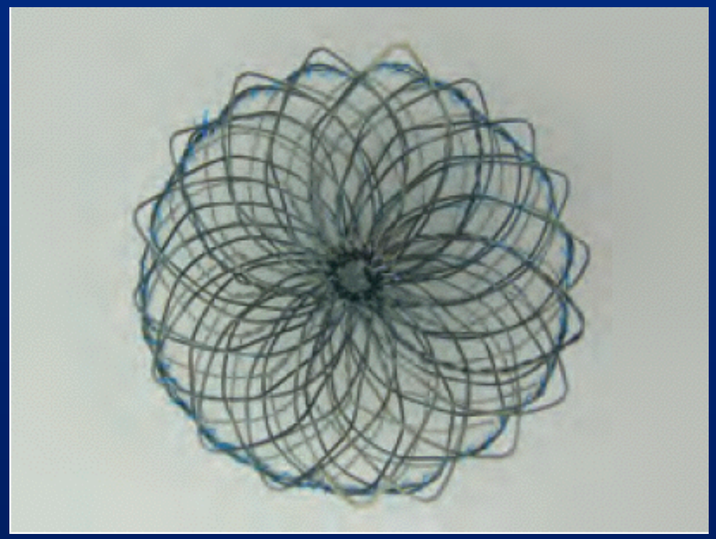
- **Six generations of devices!!! Generation VI: Ultrasept, round device, with no pointed ends.**

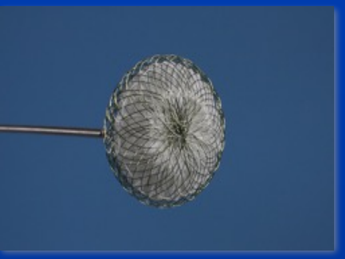


ASD Closure
Long-term Outcome

PFM Device-ASD-R

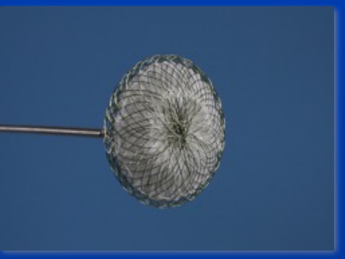
- **Newest kid on the block.**
- **Nitinol wire, no welding or hubs!**
- **Reverse configuration of the distal disk. Polyester fabric sutured to the border of the disk. Minimizing exposure of metal to blood….hence reduce clot formation.**





ASD Closure
Long-term Outcome

Pre Selection of Patients

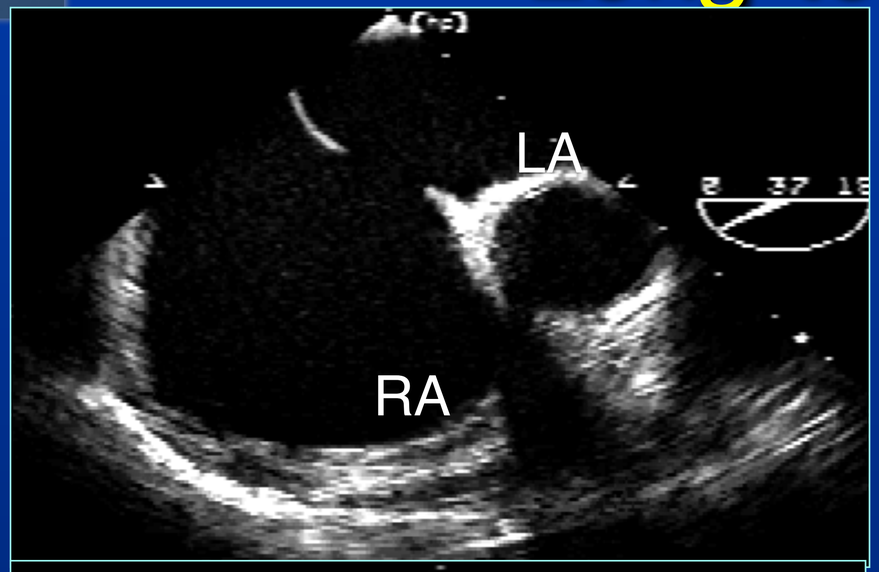


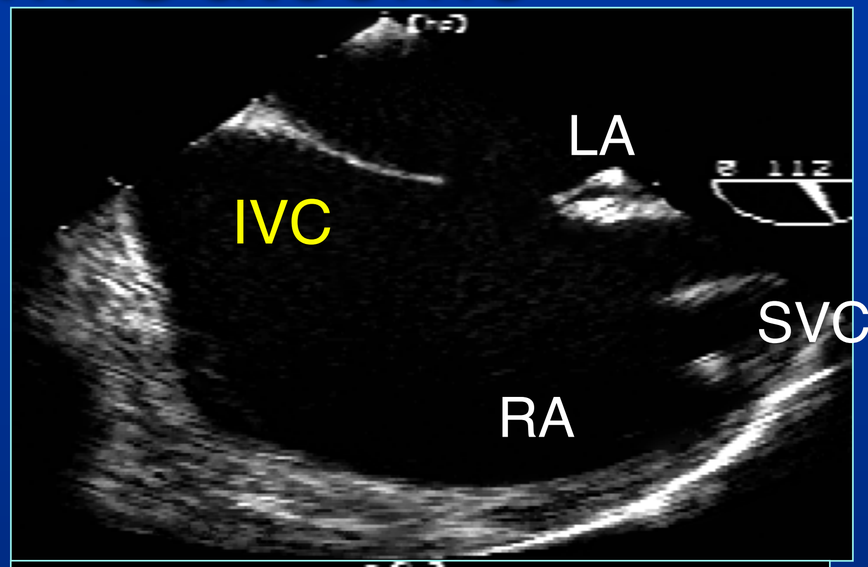
ASD Closure
Long-term Outcome

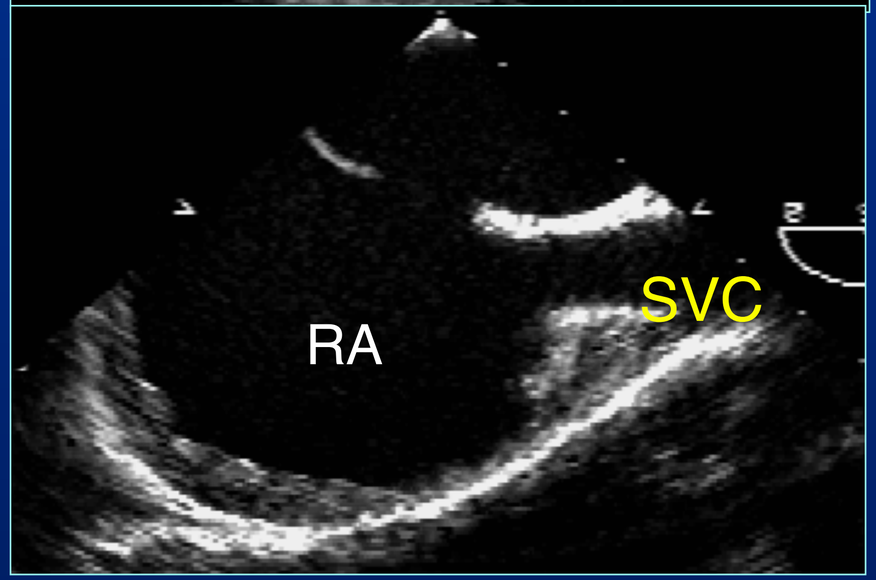
Indications

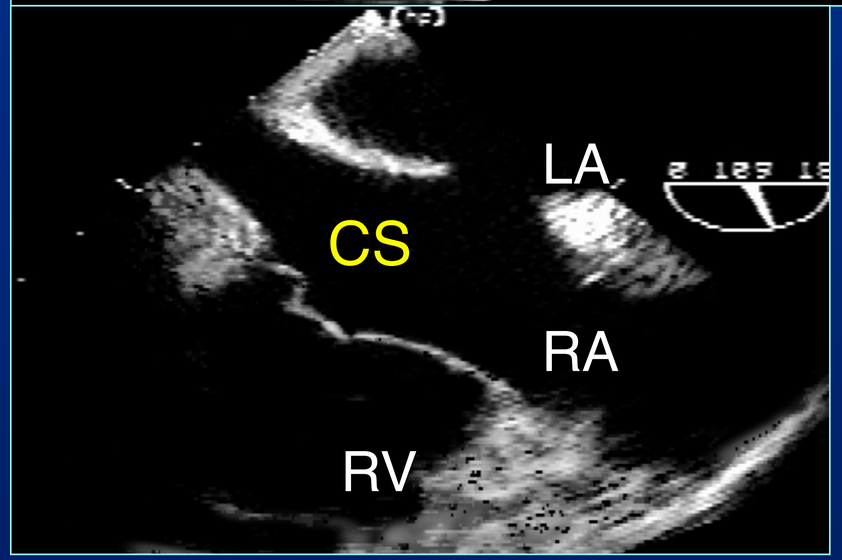
RVVO
Qp:Qs
Symptoms

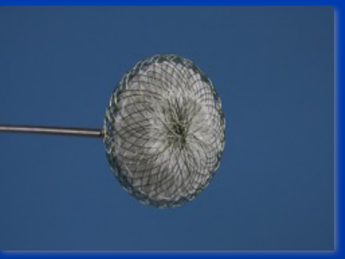
ASD Closure
Long-term Outcome



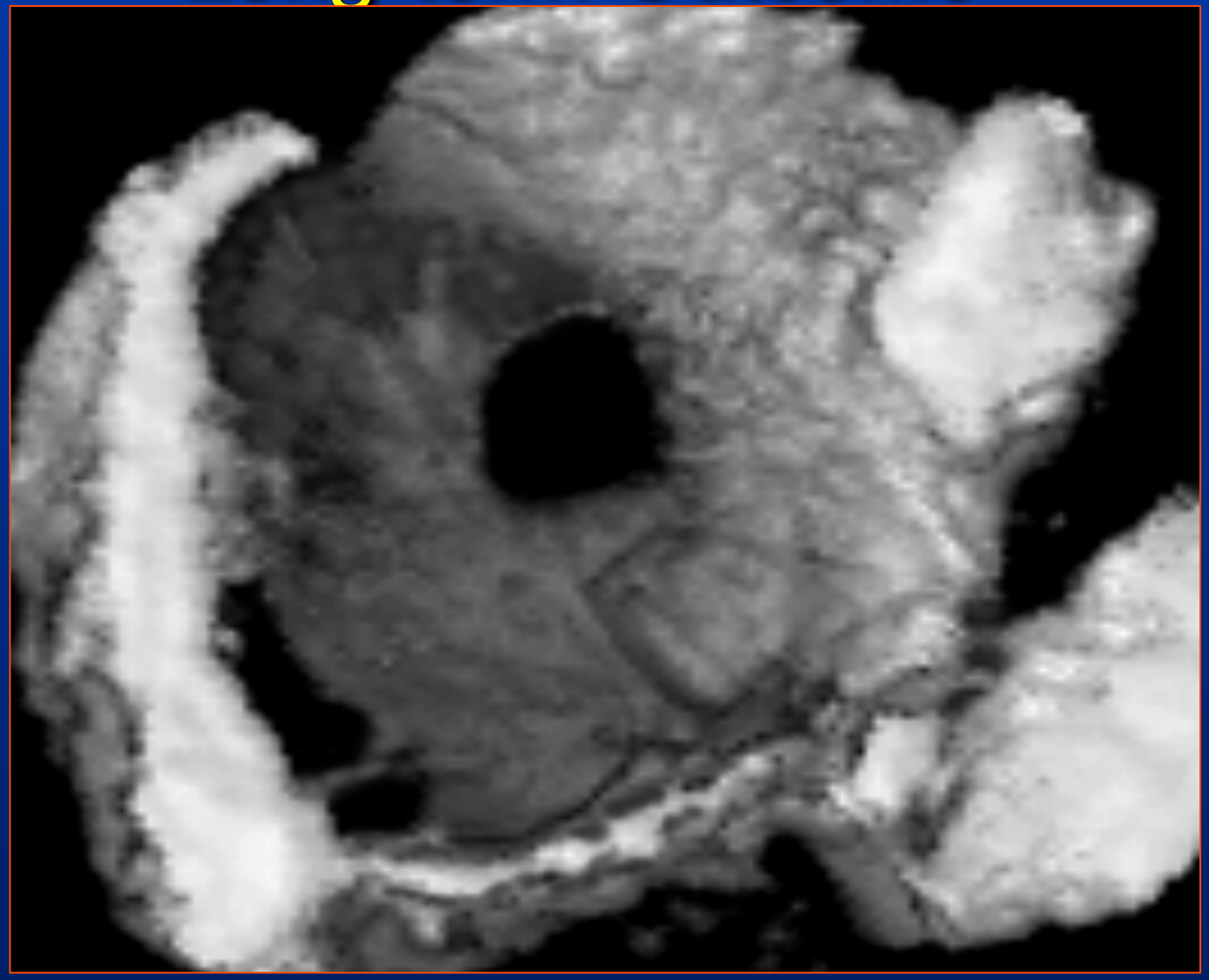


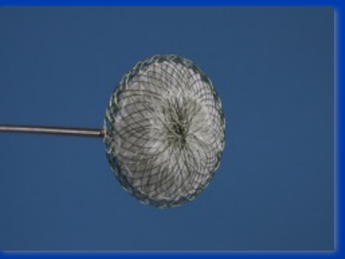






ASD Closure
Long-term Outcome

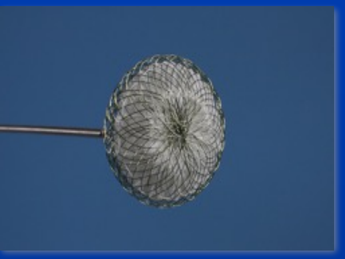




ASD Closure
Long-term Outcome

Pre Closure

Aspirin 81 mg starts 48 hours pre



ASD Closure
Long-term Outcome

Closure Protocol

General EA/TEE vs Conscious Sedation & ICE

R & L Heart Catheterization

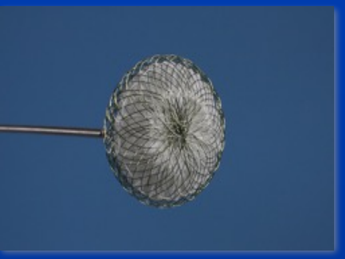
RUPV Angiogram (LAO/Cr)

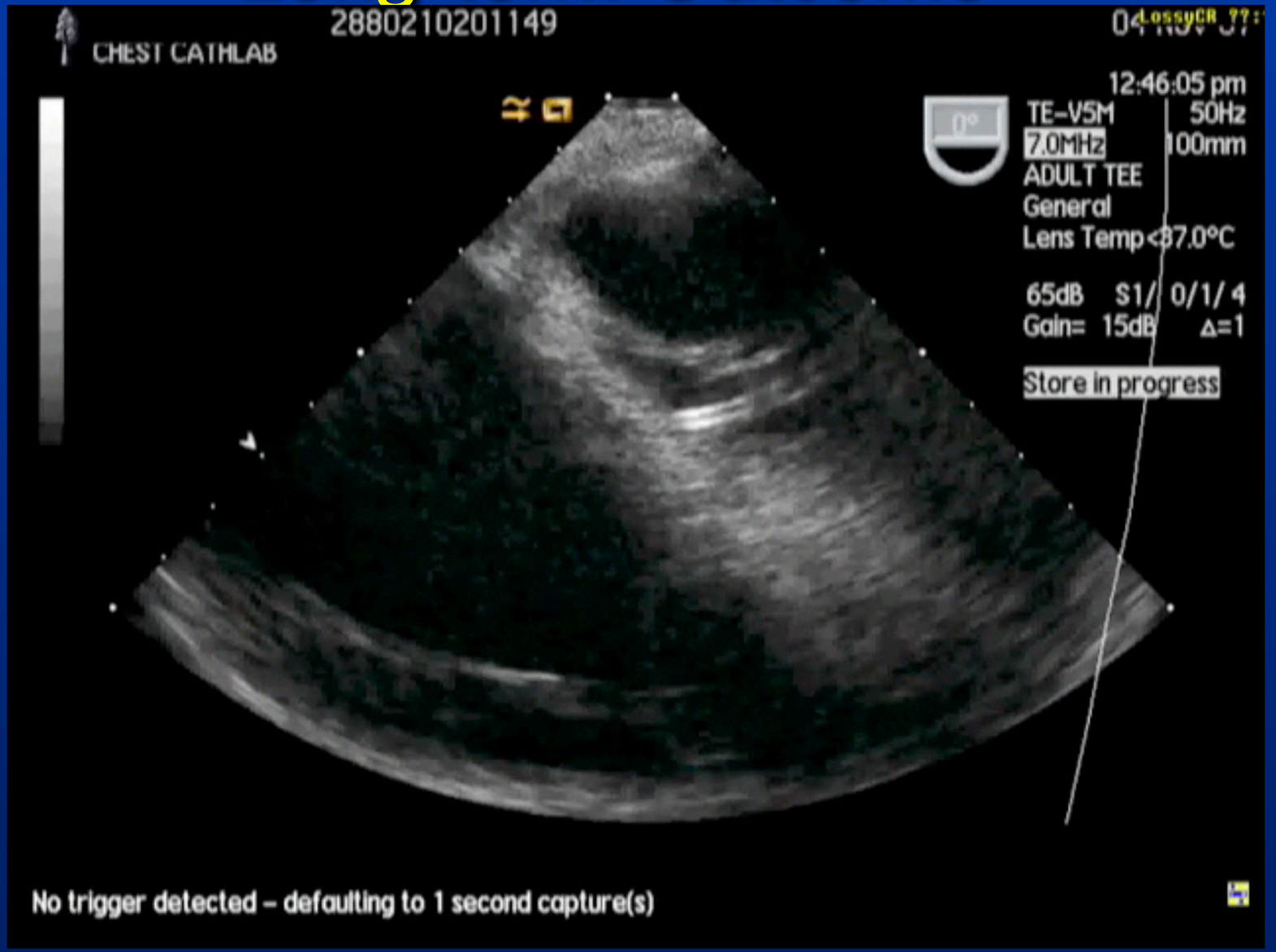
Balloon Sizing

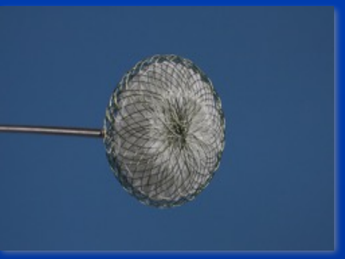
Closure

Assessment of closure

ASD Closure
Long-term Outcome



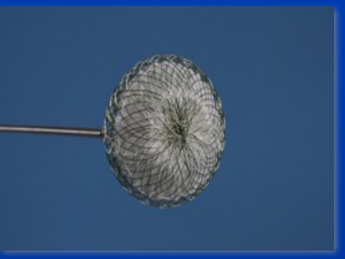




ASD Closure
Long-term Outcome

Post Closure

- **Aspirin 81 mg for 6-months**
- **Clopidegrol 75 mg for 2-3 months**
- **SBE prophylaxis for 6-months**

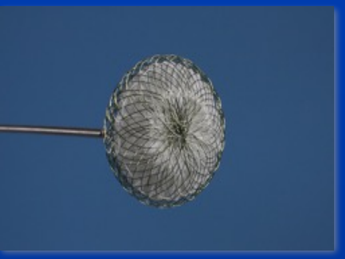


ASD Closure
Long-term Outcome

Possible Complications

- Embolization
- Arrhythmias/CHB
- Thrombus formation
- Air Embolism
- TIA/Stroke
- Erosions/PE/Tamponade/Death
- SBE
- Cobra formation
- Headaches/Migraines

ASD Closure
Long-term Outcome



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Comparison Between Transcatheter and Surgical Closure of Secundum Atrial Septal Defect in Children and Adults

Results of a Multicenter Nonrandomized Trial

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Chicago, Illinois; Orlando, Florida; San Francisco, California; and Minneapolis, Minnesota

OBJECTIVES This study sought to compare the safety, efficacy and clinical utility of the Amplatzer septal occluder (ASO) for closure of secundum atrial septal defect (ASD) with surgical closure.

BACKGROUND The clinical utility of a device such as the ASO can only be judged against the results of contemporaneous surgery.

METHODS A multicenter, nonrandomized concurrent study was performed in 29 pediatric cardiology centers from March 1998 to March 2000. The patients were assigned to either the device or surgical closure group according to the patients' option. Baseline physical exams and echocardiography were performed preprocedure and at follow-up (6 and 12 months for device group, 12 months for surgical group).

RESULTS A total of 442 patients were in the group undergoing device closure, whereas 154 patients were in the surgical group. The median age was 9.8 years for the device group and 4.1 years for the surgical group ($p < 0.001$). In the device group, 395 (89.4%) patients had a single ASD; in the surgical group, 124 (80.5%) ($p = 0.008$) had a single ASD. The size of the primary ASD was 13.3 ± 5.4 mm for the device group and 14.2 ± 6.3 mm for the surgery group ($p = 0.099$). The procedural attempt success rate was 95.7% for the device group and 100% for the surgical group ($p = 0.006$). The early, primary and secondary efficacy success rates were 94.8%, 98.5% and 91.6%, respectively, for the device group, and 96.1%, 100% and 89.0% for the surgical group (all $p \geq 0.05$). The complication rate was 7.2% for the device group and 24% for the surgical group ($p < 0.001$). The length of hospital stay was 1.0 ± 0.3 day for the device group and 3.4 ± 1.2 days for the surgical group ($p < 0.001$). [illegible] for the surgical group.

CONCLUSIONS The early, primary and secondary efficacy success rates for surgical versus device closure of ASD were not statistically different; however, the complication rate was lower and the length of hospital stay was shorter for device closure than for surgical repair. Appropriate patient selection is an important factor for successful device closure. Transcatheter closure of secundum ASD using the ASO is a safe and effective alternative to surgical repair. (J Am Coll Cardiol 2002;39:1836–44) © 2002 by the American College of Cardiology Foundation

Complication rate was 7.2% for the device Group and 24% for the surgical group (P<0.001)

Sidra Medical and Research Center

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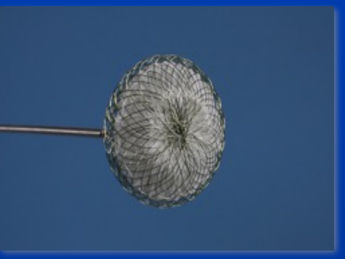


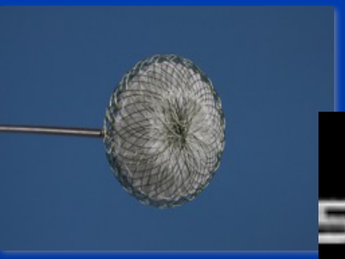
ASD Closure
Long-term Outcome

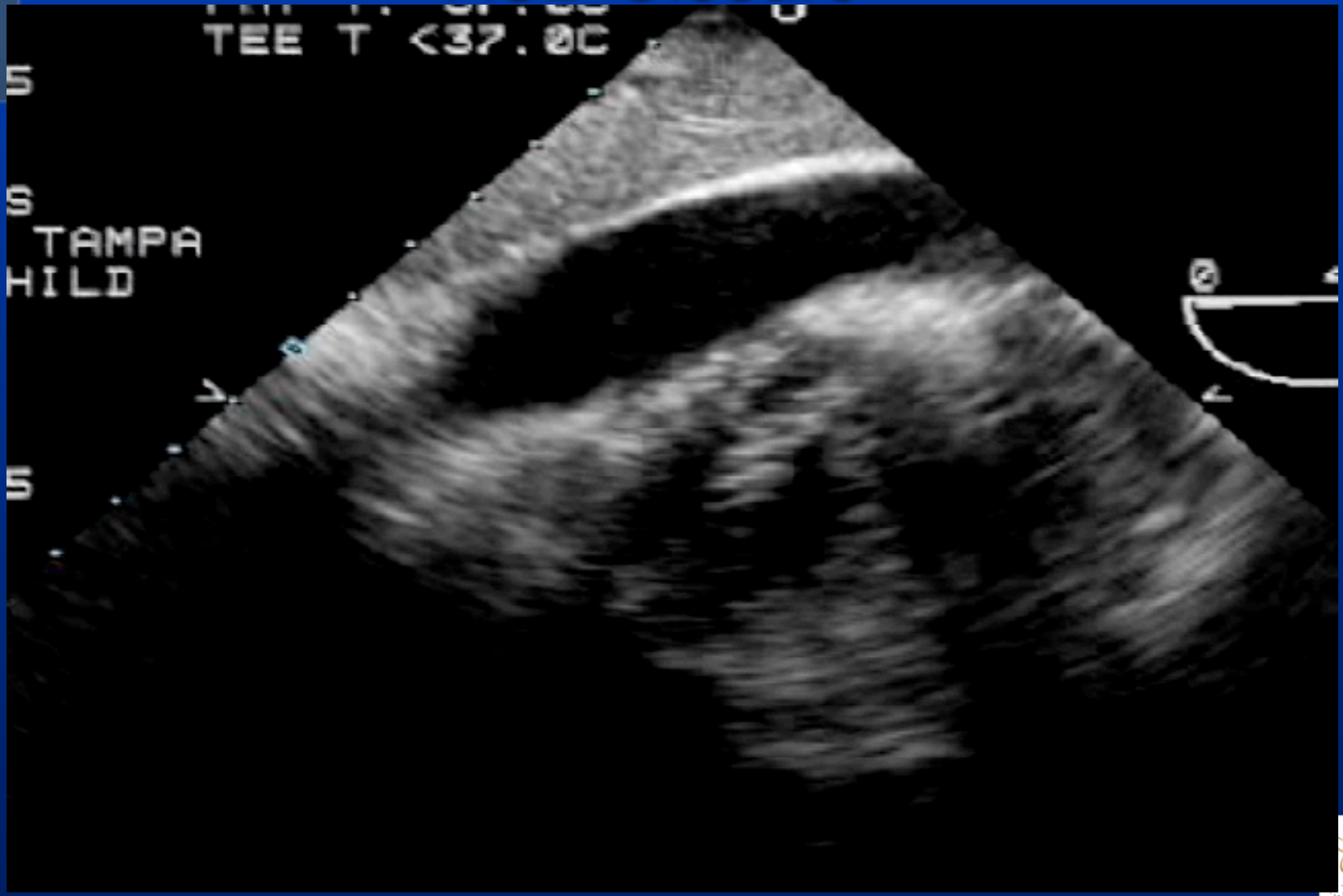
Mechanism of Erosion

Multi-factorial:

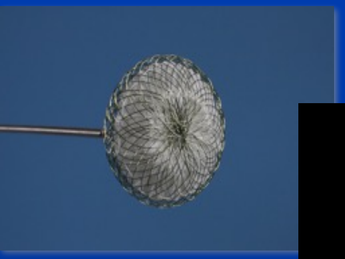
- **Rim deficiency**
- **Patient characteristics**
- **Defect shape**
- **Device size**
- **Septal malalignment**

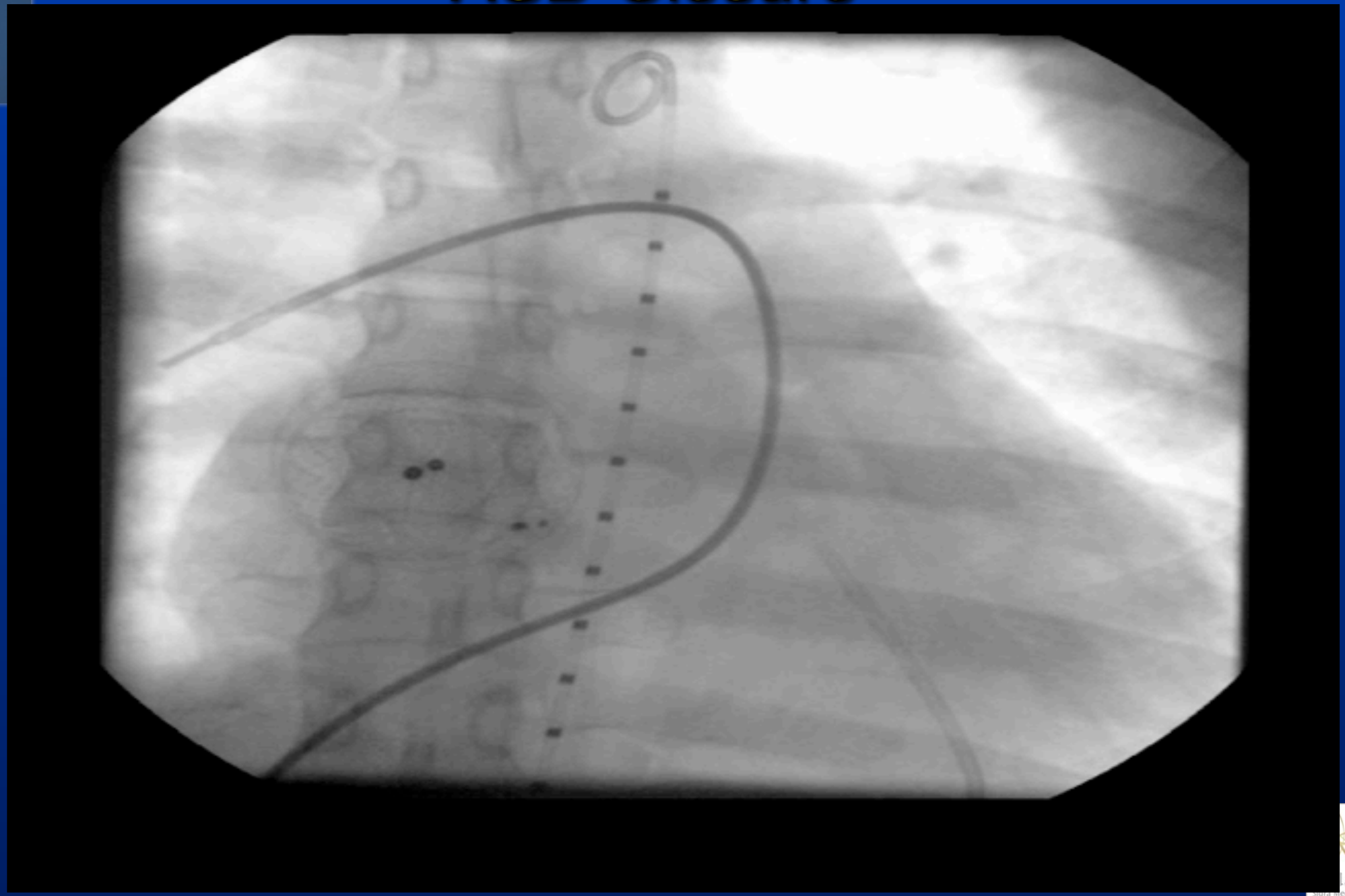
ASD Closure

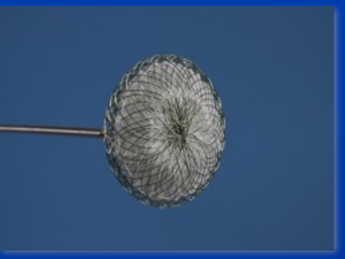




ASD Closure







ASD Closure
Long-term Outcome

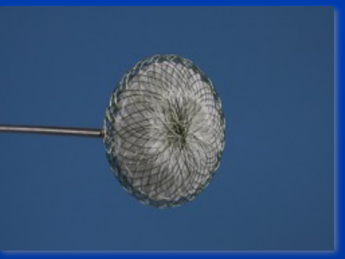
History of Erosions

First erosion case reported in US 2002

2004: IFU updated for device sizing

2009: IFU updated about sizing with additional warning.

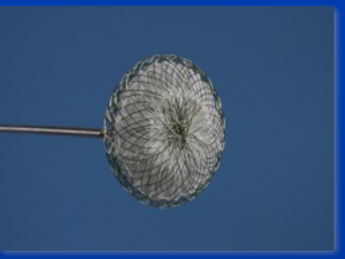
2011: SJM/FDA agreed to change IFU to include contra indications in patients with deficient ant/sup rim.



ASD Closure
Long-term Outcome

Numbers of Erosions as of 3/2012

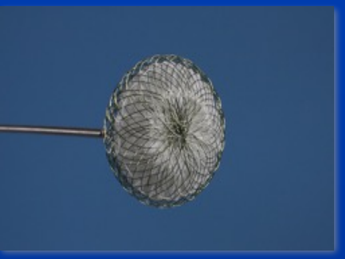
Source	Potential Erosions (n=202)	Confirmed -- Not Erosion Events (n=105)	Confirmed Erosions (n=97)
Literature	44	28	16
Field Event Report-MAUDE	122	46	76
PAS Investigator Query	10	7	3
PAS	26	24	2



ASD Closure
Long-term Outcome

Confirmed Erosion Events By Year

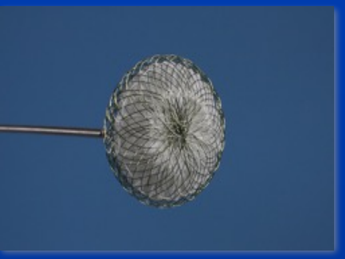
Year	US	OUS	Total
1998	0	1	1
1999	0	0	0
2000	0	1	1
2001	0	2	2
2002	6	4	10
2003	6	3	9
2004	1	6	7
2005	3	3	6
2006	5	5	10
2007	5	6	11
2008	4	4	8
2009	6	5	11
2010	6	6	12
2011	2	3	5
2012	2	0	2
unknown	2	0	2
total	48	49	97



ASD Closure
Long-term Outcome

EROSION ANALYSIS

- Hemodynamic presentation(n=97)
  - –Aortic atrial fistula – 16 (16.5%)
  - –Tamponade with a hemo PE -68 (70.1%)
  - –PE or Hemo PE or tamponade – 13(13.4%)
- Site of erosion
  - –LA – 47(28 involving the Ao)
  - –RA – 26(22 involving the Ao)
  - –RA & LA – 9
  - –Unknown - 15

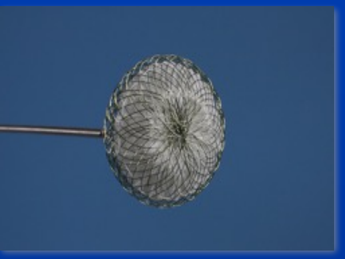


ASD Closure
Long-term Outcome

EROSION MORTALITY RATE

	Number of Deaths from Erosion	Mortality Rate
SJM (WW)	8	0.004-0.015%
SJM (US)	6	0.008-0.016%

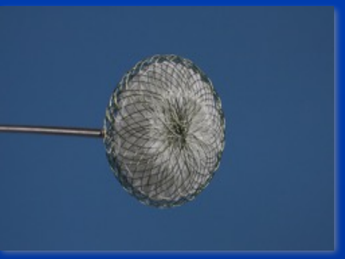
- No deaths occurred in patients younger than 15 years
- All reported deaths occurred within 16 months of implant.
- Each event confirmed presence of device oversizing, deficient anterior superior rim, or both



ASD Closure
Long-term Outcome

EROSION ANALYSIS

- **Management**
  - **–Explanted 74**
  - **–Not explanted 21**
    - **•Repair of the erosion site**
    - **•Pericardiocentesis alone**
  - **–Unknown – 2**

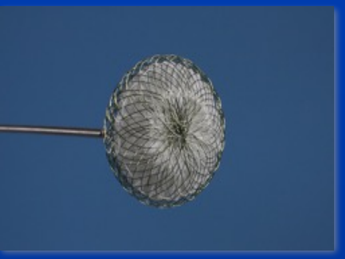


ASD Closure
Long-term Outcome

ROOT CAUSE ANALYSIS SUMMARY

97 Worldwide erosion cases have been identified in association with the on-label use of the AMPLATZER ASO device from December 1998 to March 2012:

- **48 US/49 OUS**
- **40% Pediatric**
- **70% Female**
- **75% involved device sizes > 18mm**
- **87.6% occurred within the first year of implants**
- **57% of pediatric erosion events occurred <72 hours**
- **35% of adult erosions occurred <72 hours**



ASD Closure
Long-term Outcome

ROOT CAUSE ANALYSIS SUMMARY

The most frequently observed relationship to erosion was oversizing and deficient anterior superior rims

- **40% of all erosion events were oversized**
  - **31% pediatric**
  - **46% adult**
  - **Declining from earlier reported 50%**
- **90% of all erosion cases had anterior-superior rim deficiency**
  - **100% pediatric**
  - **84% adult**
- **Every erosion case except 2 had either a deficient anterior superior rim or were oversized**

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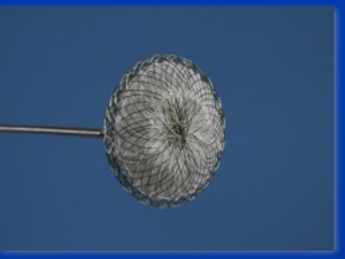
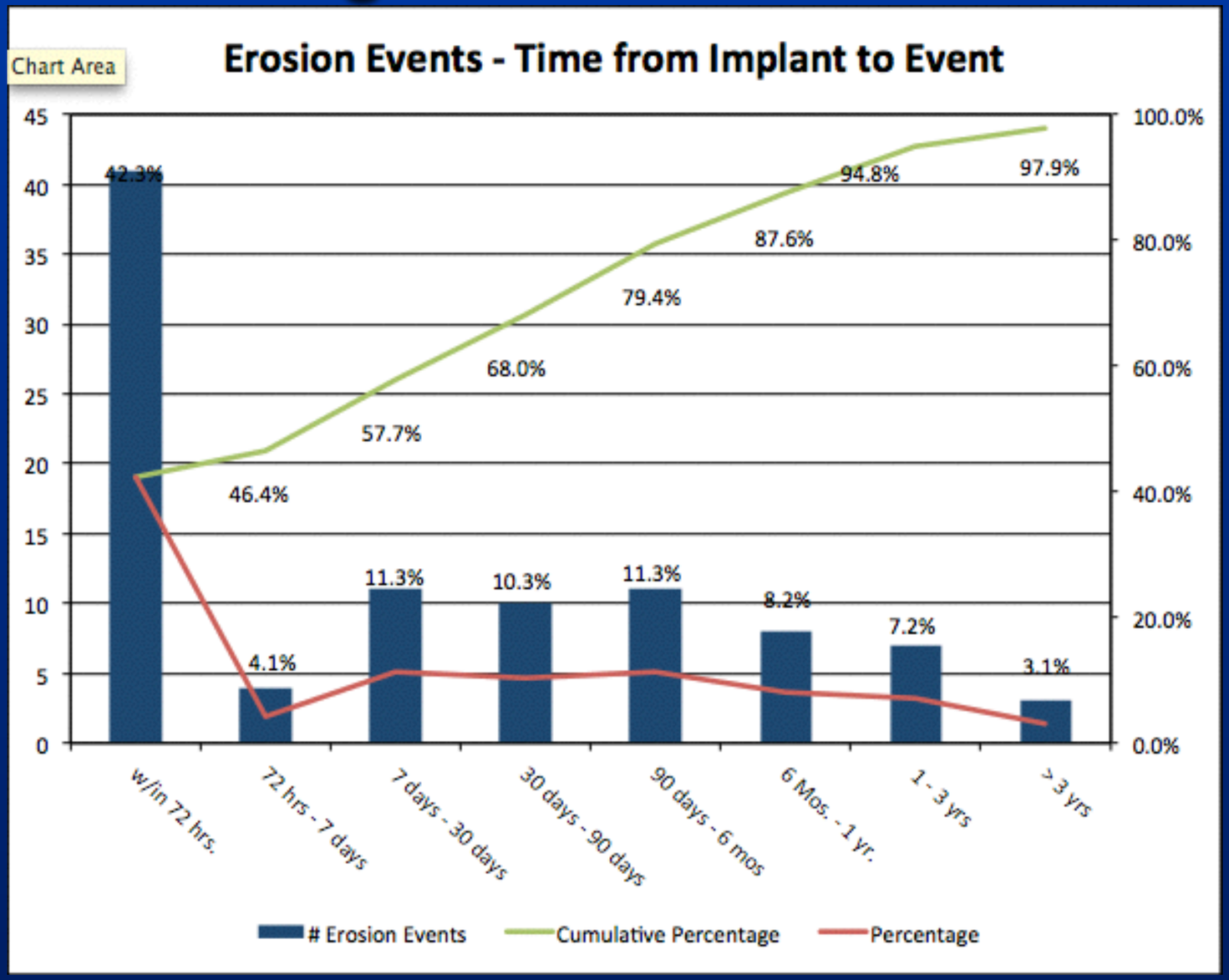
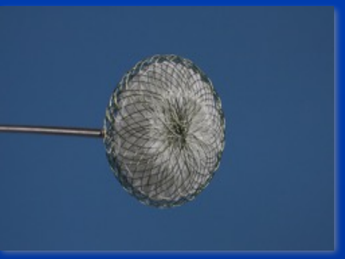


ASD Closure
Long-term Outcome



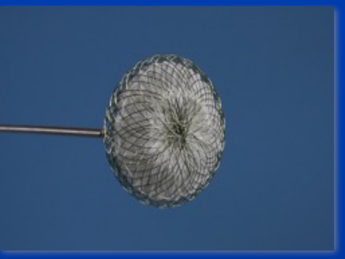


ASD Closure
Long-term Outcome

EROSION INCIDENCE RATE

	# of Erosions	Sales	With Cards	Incidene
SJM (WW)	97	223,965	55,000	0.04-0.17%
SJM (US)	48	72,566	38,000	0.07- 0.11%
	Number of Erosions	Number of Implants	Incidence	
Pivotal Trial	0	452	0%	
PAS	2	970	0.23%	

Note: PAS erosion events are included in the 48 US erosion events



ASD Closure
Long-term Outcome

Recommendations by the FDA

1. Retro aortic rim deficiency-warning vs contra indications
2. Record keeping of any device implanted
3. Work with ASE to come up with guidelines for device implantation and follow up.
4. Notify all patients of potential erosions
5. TTE within a week from implant
6. A letter to all cardiologists

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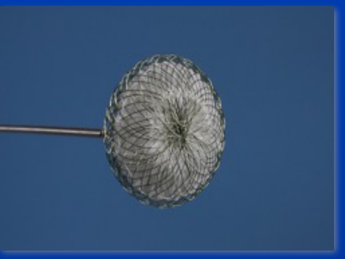
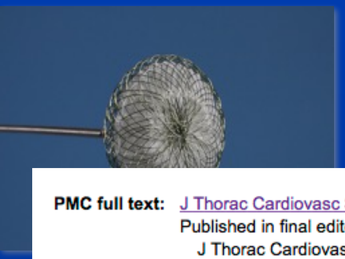


ASD Closure
Long-term Outcome

Surgical Closure-STS Data

ASD Closure
Long-term Outcomes



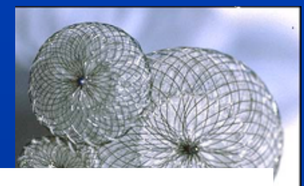


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Table 3

Outcomes

	Overall(n=5265)	Pulmonary valve replacement (n=574)	ASD repair (n=365)	Conduit operation (n=328)	Aortic aneurysm repair (n=136)	Mitral valvuloplasty (n=135)	Ross operation (n=108)	Fontan revision/conversion (n=105)
In-hospital mortality	109 (2.1%)	4 (0.7%)	0 (0%)	8 (2.4%)	3 (2.2%)	1 (0.7%)	2 (1.9%)	11(11%)
Length of stay (days)	5 [3–7]	5 [4–6]	4 [3–5]	5 [4–7]	6 [4–8]	5 [4–8]	5 [4–6]	10 [7–13]
Postoperative complication								
Any	1446 (28%)	135 (24%)	72 (20%)	96 (29%)	35 (26%)	48 (36%)	43 (40%)	54 (51%)
Arrhythmia	496 (9.4%)	39 (6.8%)	28 (7.7%)	26 (7.9%)	8 (5.9%)	22 (16%)	11 (10%)	24 (23%)
Low cardiac output	87 (1.7%)	4 (0.7%)	3 (0.8%)	5 (1.5%)	2 (1.5%)	4 (3.0%)	4 (3.7%)	9 (8.6%)
AV block requiring permanent pacer	69 (1.3%)	0 (0%)	0 (0%)	1 (0.3%)	3 (2.2%)	1 (0.7%)	2 (1.9%)	1 (1.0%)
Cardiac arrest	52 (1.0%)	2 (0.4%)	0 (0%)	7 (2.1%)	3 (2.2%)	1 (0.7%)	0 (0%)	3 (2.9%)
Pleural effusion	162 (3.1%)	6 (1.1%)	6 (1.6%)	12 (3.7%)	4 (2.9%)	11 (8.2%)	4 (3.7%)	7 (6.7%)
Pneumonia	124 (2.4%)	19 (3.3%)	12 (3.3%)	3 (0.9%)	0 (0%)	0 (0%)0 (0%)	1 (1.0%)	
Reintubation	71 (1.4%)	1 (0.2%)	1 (0.3%)	8 (2.4%)	1 (0.7%)	2 (1.5%)	1 (0.9%)	6 (5.7%)
Mechanical ventilation>7days	52 (1.0%)	0 (0%)	2 (0.6%)	7 (2.1%)	1 (0.7%)	0 (0%)	0 (0%)	6 (5.7%)
Unplanned reop	111 (2.1%)	4 (0.7%)	2 (0.6%)	6 (1.8%)	4 (2.9%)	3 (2.2%)	1 (0.9%)	5 (4.8%)
Bleeding requiringreop	100 (1.9%)	7 (1.2%)	2 (0.6%)	6 (1.8%)	4 (2.9%)	1 (0.7%)	9 (8.3%)	4 (3.8%)
Renal failure requiring temporary dialysis	56 (1.1%)	3 (0.5%)	0 (0%)	4 (1.2%)	0 (0%)	0 (0%)	0 (0%)	9 (8.6%)

Continuous variables are presented as median [interquartile range]

Postoperative complications occurring in >1.0% of the study population are displayed.

ASD=atrial septal defect; AV=atrioventricular; reop=reoperation

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ASD Closure
Long-term Outcome

STS Adult Cardiac Surgery Database

	ASD repair(n=26,117)	Congenital defect repair(n=10,133)	Pulmonary valve replacement(n=3622)
Isolated procedure	9602(37%)	2835(28%)	1738(48%)
Age (years)	48 [36–59]	44 [32–58]	38 [28–49]
In-hospital mortality	2.1%	3.7%	2.8%
Concomitant procedure*	16,515(63%)	7298(72%)	1884(52%)
Age (years)	66 [56–75]	65 [54–74]	47 [37–56]
In-hospital mortality	5.0%	4.5%	3.5%

*Concomitant procedure=procedure performed in association with coronary artery bypass grafting, aortic valve procedure, and/or mitral valve procedure

Continuous variables are presented as median [interquartile range]

ASD=atrial septal defect

Percutaneous ASD Closure in a Large Australian Series: Short- and Long-Term Outcomes

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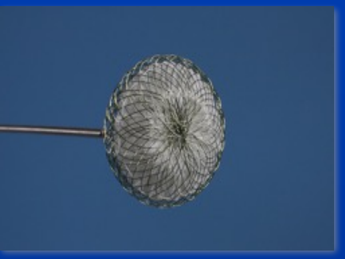
Aim: To assess the clinical and echocardiographic outcomes in patients referred for device closure of atrial septal defects in a tertiary referral hospital in Australia.

Methods: A prospective follow-up study was performed on all patients who had device closure of a secundum atrial septal defect (ASD) from June 1999 to December 2007. Clinical and echocardiographic data at the time of implantation and follow-up is presented.

Results: 176 patients were referred for shunt closure of ASD. All patients had a significant shunt defined as a shunt with right heart dilatation and/or a shunt ratio of at least 1.5:1. The majority were female (67%) and the average age was 36.5 ± 22.7 years; age range 3–84. The average hospital admission time was 2.5 ± 1.7 days. The average follow-up occurred at 3.7 ± 3.6 months for the first follow-up and 26.3 ± 18.2 months (range 3 months–7.8 years) for the long-term follow-up. Baseline echocardiogram findings showed the majority had a normal left ventricular ejection fraction (99%); average LVEF = 63.2 ± 7.2% while the right ventricle was dilated in 61% of patients. Procedure information: The average procedure time was 94.8 ± 36.4 min. Procedural imaging was performed using Transoesophageal echocardiography (TOE) in 107 cases (61%); Intracardiac Echocardiography (ICE) in 69 (39%). Device use was as follows: Amplatzer = 156 cases, Helex = 18, and Starflex = 2. Postprocedure shunt assessment by transthoracic echocardiography showed successful closure (no shunt or trivial shunt) in 99% cases. Two patients were referred for inpatient surgery due to a significant residual shunt in one case and an unstable device in another. One patient who had an unstable device had their device repositioned successfully. Atrial arrhythmia was the most common complication occurring in the peri-implantation period in 12 cases (6%) with four further cases at final up. The high prevalence of right ventricular dilatation in 65% patients at baseline had improved significantly at the first and long term follow-up to 2% ($p = 0.0001$).

Conclusion: Device closure of secundum atrial septal defects in this large Australian cohort demonstrates a high procedural success rate with a low incidence of complications in the short and long term.

(Heart, Lung and Circulation 2012;21:572–575)



Intermediate and long-term followup of percutaneous device closure of fossa ovalis atrial septal defect by the Amplatzer septal occluder in a cohort of 529 patients

Munesh Tomar, Sanjay Khatri, Sitaraman Radhakrishnan, Savitri Shrivastava
Department of Congenital and Pediatric Heart Diseases, Fortis Escorts Heart Institute, New Delhi, India

ABSTRACT

Objectives : The aim of present study is to analyze the intermediate and long-term follow up results of percutaneous closure of fossa ovalis atrial septal defect (ASD) with Amplatzer septal occluder (ASO) in a large cohort of patients including children and adults.

Methods : Between May 1998 and July 2008, 529 patients (age group 2-77 years, median 28 years) underwent successful device closure with an ASO at single tertiary referral cardiac center in India.. This was out of an attempted 543 cases. The procedure was carried out in catheterization laboratory under transesophageal echocardiographic and fluoroscopy guidance. The mean size of ASD was 20 mm (7-40 mm) while size of septal occluder was 10-40 mm (mean 24 mm). Two devices were deployed in four patients. Three patients developed transitory pulmonary edema in immediate postprocedure period requiring ICU care for 48 hrs. All patients were advised for Aspirin (3-5 mg/kg, maximum 150 mg) once daily for 6 months. In patients with device 30 mm or larger, Clopidogril (75 mg once daily) was given for 3 months in addition to Aspirin. Clinical evaluation, echocardiogram were done on 3 months, 6 months and then at 1, 3, 5, 7 and 10 years of follow up. Transesophageal echocardiography (TEE) was performed in case of any doubt on clinical evaluation or on transthoracic echocardiography (n=10).

Results : Followup data is available for 496 patients (93.7%). Followup period is from 12 months to 120 months (median 56 months). On followup, device was in position in all patients, no residual shunt and no evidence of thrombosis. Interventricular septal motion normalized on day of procedure in 89% patients, in 6% over 3 months while flat septal motion persisted in 5% (n=25, all in age group > 40 years) of cases, though right ventricular dilatation persisted in 10% (n=50, age more than 40 years) of patients. Symptom-free survival was 96.7 % (480/496) in patients who came for followup. Only one 68 year old patient with preexistent tricuspid regurgitation developed congestive heart failure, and one patient (58 years old) had a history of hemiparesis after 1 year of device on telephonic interview. Ten patients were in atrial fibrillation (AF) before the procedure and remained in AF on followup.

Conclusions : Our study showed that percutaneous closure of fossa ovalis ASD is a safe and effective procedure on intermediate and long-term followup in both the children as well as adults. both. Technical factors during the procedure and proper follow up are important. Our single centre intermediate and long term experience in a large number of patients support the use of device closure as an alternative to surgery.

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Transcatheter Closure of Large Atrial Septal Defects

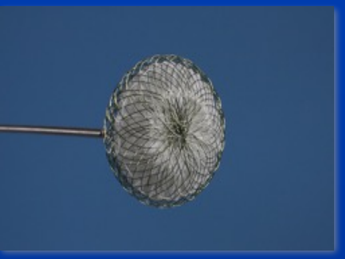
Feasibility and Safety in a Large Adult and Pediatric Population

Alban-Elouen Baruteau, MD; Jérôme Petit, MD; Virginie Lambert, MD, PhD; Marielle Gouton, MD; Dominique Piot, MD; Philippe Brenot, MD; Claude-Yves Angel, MD; Lucile Houyel, MD; Emmanuel Le Bret, MD, PhD; Régine Roussin, MD; Mohamedou Ly, MD; André Capderou, MD, PhD; Emre Belli, MD

Background—Data are needed on the safety and efficacy of device closure of large atrial septal defects.

Methods and Results—Between 1998 and 2013, 336 patients (161 children <15 years) with large, isolated, secundum atrial septal defects (balloon-stretched diameter ≥34 mm in adults or echocardiographic diameter >15 mm/m² in children) were managed using the Amplatzer device, at the Marie Lannelongue Hospital. Transthoracic echocardiographic guidance was used starting in 2005 (n=219; 65.2%). Balloon-stretched diameter was >40 mm in 36 adults; mean values were 37.6±3.3 mm in other adults and 26.3±6.3 mm/m² in children. Amplatzer closure was successful in 311 (92.6%; 95% confidence interval, 89%–95%) patients. Superior and posterior rim deficiencies were more common in failed than in successful procedures (superior, 24.0% versus 4.8%; P=0.002; and posterior, 32.0% versus 4.2%; P<0.001). Device migration occurred in 4 adults (2 cases each of surgical and transcatheter retrieval); in the 21 remaining failures, the device was unreleased and withdrawn. After a median follow-up of 10.0 years (2.5–17 years), all patients were alive with no history of late complications.

Conclusions—Closure of large atrial septal defects using the Amplatzer device is safe and effective in both adults and children. Superior and posterior rim deficiencies are associated with procedural failure. Closure can be performed under transthoracic echocardiographic guidance in experienced centers. Early device migration is rare and can be safely managed by device extraction. Long-term follow-up showed no deaths or major late complications in our population of 311 patients. **(*Circ Cardiovasc Interv*. 2014;7:837-843.)**



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Long-term cost-effectiveness of transcatheter versus surgical closure of secundum atrial septal defect in adults ☆

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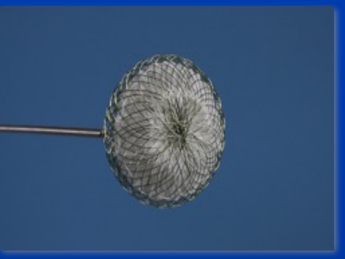
ABSTRACT

Background: The most common congenital anomaly in adults is secundum atrial septal defect (ASD), which can be closed using a surgical or transcatheter approach. Despite the growing use of transcatheter ASD closure, few studies have examined the cost-effectiveness of this strategy. We sought to compare the long-term cost effectiveness of transcatheter and surgical closure of secundum ASD in adults.

Methods: A decision-analytic model was used with all clinical outcome parameter estimates obtained from the province-wide Québec Congenital Heart Disease Database. Costs were obtained from a single academic centre (Canadian dollars). A cost-effectiveness analysis using a discrete event Monte Carlo simulation model from the perspective of a single third party payer and multiple sensitivity analyses were performed. Patients were followed for a maximum of 5 years after ASD closure.

Results: Between l998 and 2005, we identified 718 adults (n = 335 transcatheter; n = 383 surgical) who underwent ASD closure in Quebec. The 5-year cost of surgical closure was $15,304 SD $4581 versus $11,060 SD $5169 for the transcatheter alternative. At 5 years, transcatheter closure was marginally more effective than surgery (4.683 SD 0.379 life-years versus 4.618 SD 0.638 life-years). Probabilistic sensitivity analyses demonstrated that transcatheter ASD closure was a dominant strategy with an 80% probability of cost savings and equal or greater efficacy compared to surgical treatment.

Conclusion: Although definitive conclusions are limited given the observational nature of the primary data sources, transcatheter ASD closure appeared to be a cost-effective strategy associated with slightly improved clinical outcomes and reduced costs compared to surgical closure at 5-years follow-up.



ASD Closure
Long-term Outcome
Conclusion

Transcatheter ASD closure using various devices offers a safe, effective

and

less invasive treatment option. Complications are uncommon. Mortality

of device closure compares very favorably with that of surgery

Long-term outcome seems to be good

For appropriate secundum ASD, catheter closure should be the first option

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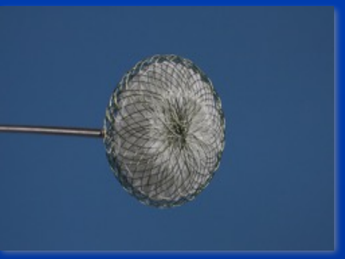

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