

TCC ASD with Double Disc Device: **Any differences among different brands?**

Worakan Promphan, MD. FSCAI.
**Queen Sirikit National Institute of Child Health
(QSNICH)**
Bangkok-Thailand



I have presented at symposia sponsored by
Vascular Innovations (Cocoon™ ASD Device).

DISCLOSURE

SELF-CENTERING DOUBLE DISC DEVICES

Amplatzer™



Single hub design.

- Reduced material in LA
- Flat & low profile

Sizes: 6-36 mm

Larger sheath compared with ASO

Biocompatibility risk

1997

2003

2005

Self-expandable
Short-connecting waist
Nitinol wire mesh 0.004" -
0.008"
Polyester fabric fills the waist
and discs
Sizes: 4-40 mm

Heart-R™



Occlutech Figula™



SELF-CENTERING DOUBLE DISC DEVICES



2008

Cocoon™

Nanoplatinum-coated nitinol
wires

Sizes: 8-40 mm

SELF-CENTERING DOUBLE DISC DEVICES



TiN coated
Sizes: 8-42 mm

Cera™

2008

2009

Cocoon™

Nanoplatinum-coated nitinol
wires
Sizes: 8-40 mm



SELF-CENTERING DOUBLE DISC DEVICES



TiN coated
Sizes: 8-42 mm

Cera™



2008

2009

2010

Cocoon™

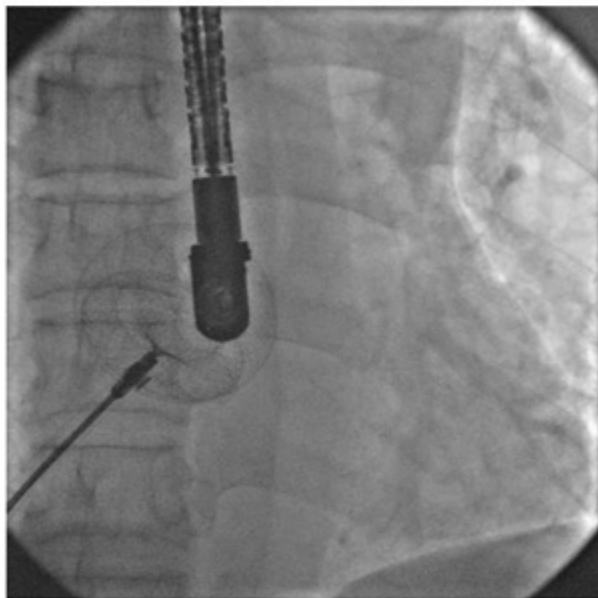
Nanoplatinum-coated nitinol
wires
Sizes: 4-40 mm



Figulla Flex™

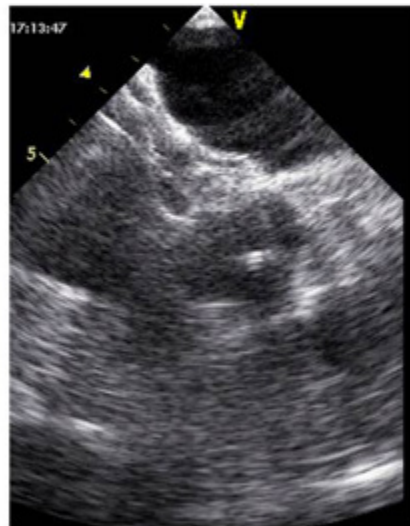
Sizes: 6-40 mm
Ball & socket delivery system
allows a tilt of 45 degree

HOW DOES FLEX DESIGN HELP?

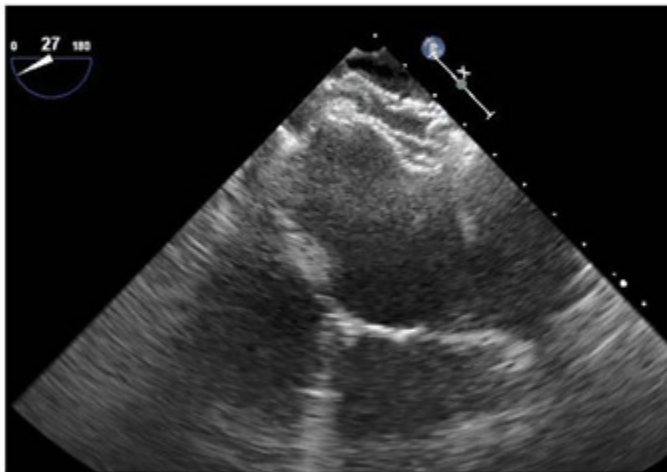


Occlutech Flex

HOW DOES FLEX DESIGN HELP?



Amplatzer



Occlutech Flex

SELF-CENTERING DOUBLE DISC DEVICES



Nit Occlud ASD-R

Made of one single wire
without shouldering joint. **(No Hub Design)**
Sizes: 3-30 mm.

Guide wire may facilitate PV approach for deployment.

2010

2011

2012

Figulla Flex™

Sizes: 6-40mm
Ball & socket delivery system
allows a tilt of 45 degree



distal view



lateral view



proximal view

SELF-CENTERING DOUBLE DISC DEVICES



2010

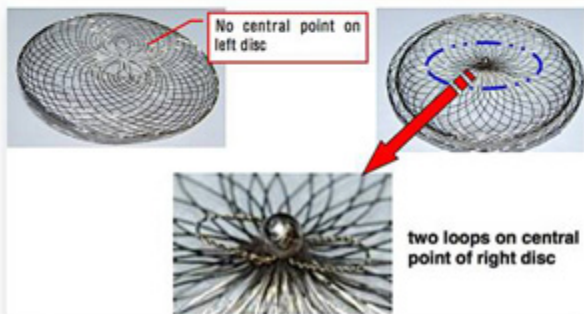
2011

2012

CeraFlex™

Figulla Flex™

Sizes: 6-40mm
Ball & socket delivery system
allows a tilt of 45 degree



SELF-CENTERING DOUBLE DISC DEVICES



2010

2011

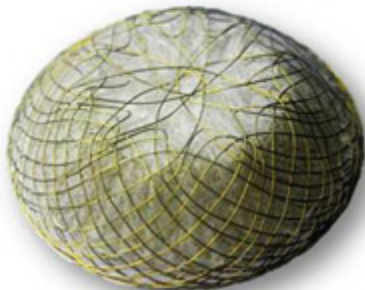
2012

Figula Flex II™

Figulla Flex™

Sizes: 6-40mm

Ball & socket delivery system
allows a tilt of 45 degree



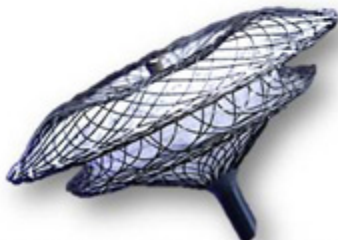
AVAILABLE DEVICES IN THAILAND



Occlutech Figula Occluder (OFO)
Occlutech Flex

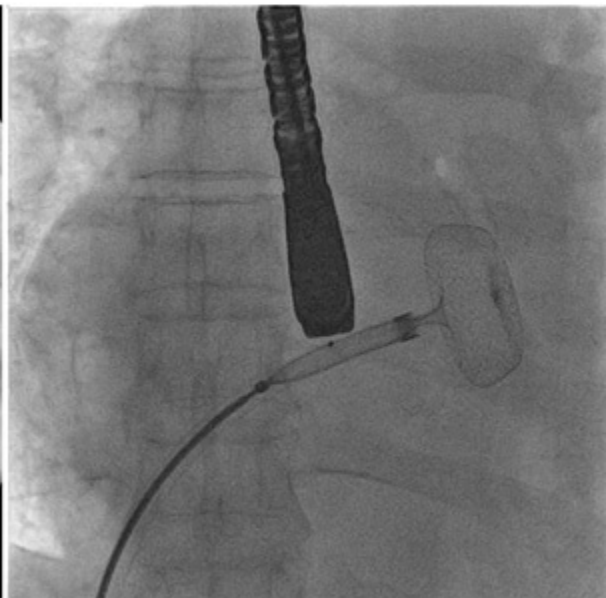
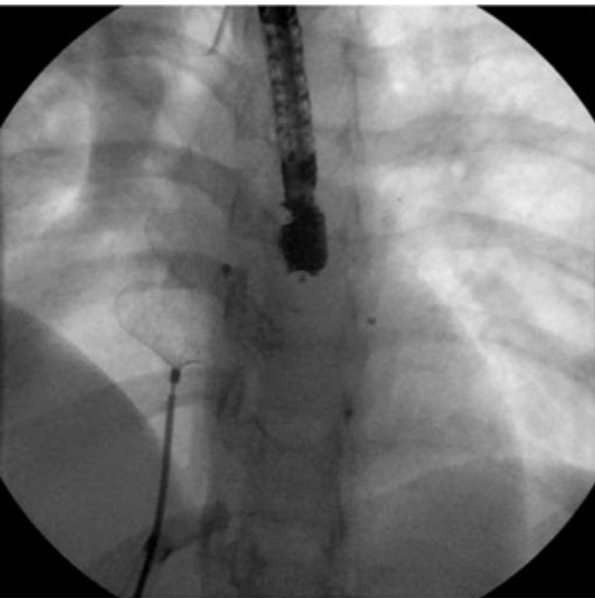


Cocoon Septal Occluder (CSO)



Amplatzer Septal Occluder (ASO)

Deployment



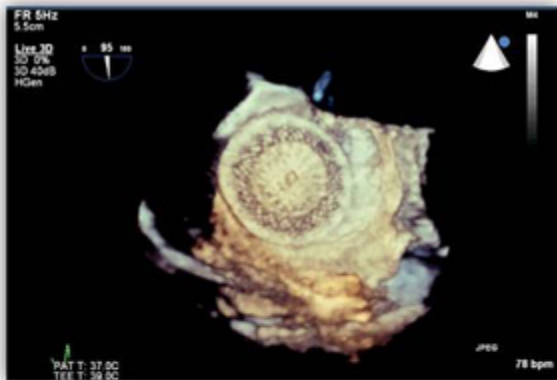
Amplatzer
TorqVue™ Delivery
Sheath(Braided)

Cocoon
Cocoon Delivery Sheath
(Braided)

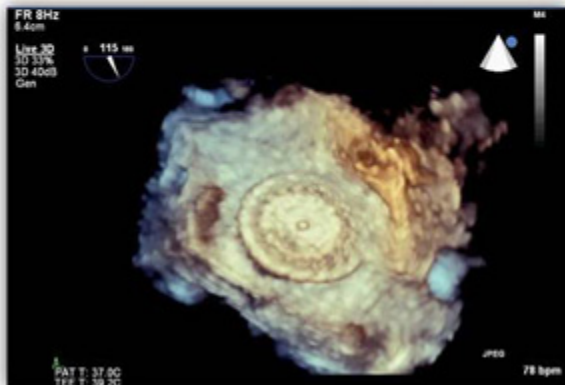
Occlutech
Mullins sheath

Appearance

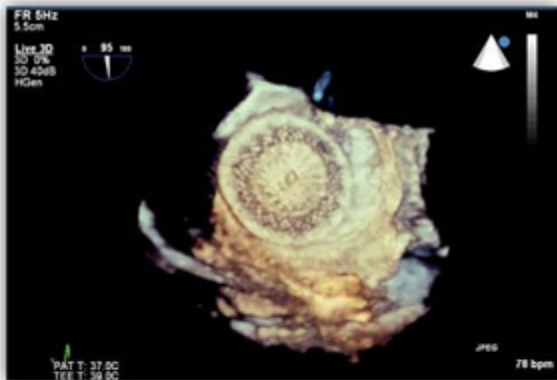
IMMEDIATE RESULTS



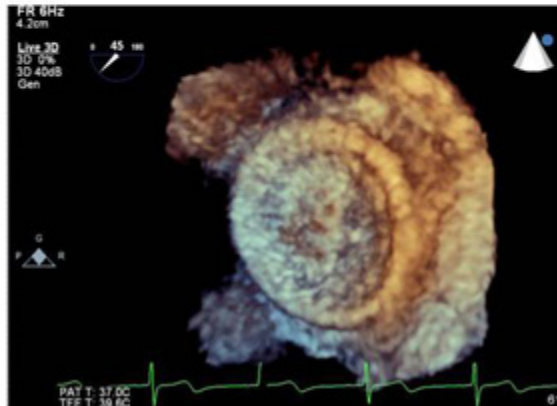
Amplatzer



Cocoon



Amplatzer



Figula
Occlutech



Courtesy of Jou Kou Wang

Success rate

IMMEDIATE RESULTS

Multi-center Study in Thailand*

*Sappasittiprasong Hospital
Khon Khen University
Rajvithi Hospital

	Amplatzer	Cocoon	Occlutech
Number	60	52	36
Mean Age (yr)	39.5 ± 16.4	40.9 ± 13.4	43.4 ± 14.4
Sex (M:F)	9:51	18:34	8:28
mPAP (mmHg)	18.2 ± 5.0	33.9 ± 4.3	21.9 ± 7.9
Rhythm			
NSR	60	48	36
AF	2	4	3
Rims			
Deficient aortic rim (%)	33.3	36.5	44.4
Diameter			
- TEE (mm)	21.9 ± 12.9	23.5 ± 4.3	19.1 ± 3.6
- Device implanted (mm)	28.5 ± 6.6	27.6 ± 7.8	24.1 ± 3.5
- Size different (mm)	5.2 ± 2.6	5.3 ± 2.8	4.9 ± 1.3

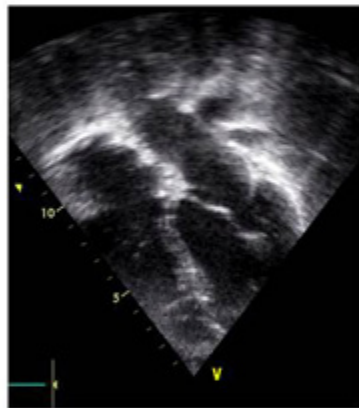
Multi-center Study in Thailand*

	Amplatzer	Cocoon	Occlutech
Procedural success rate (%)	93	94	100
Fluoro time (min)	16.1 ± 11.9	13.7 ± 6.5	9.57 ± 5.5
Number of device used	1.15 ± 0.44	1.18 ± 0.33	1.02 ± 0.16
Follow up time (mo)	31.3 ± 14.9	21.8 ± 10.3	19.4 ± 8.5
Residual shunt (%)			
- Day 1	41.7	42.1	42.9
- 1-3 months	0	0	0
- 12 months	0	0	0
Complication(s)			
- Embolization	1	1	1
- Pericardial effusion	1	1	0
- Stroke	0	1	0

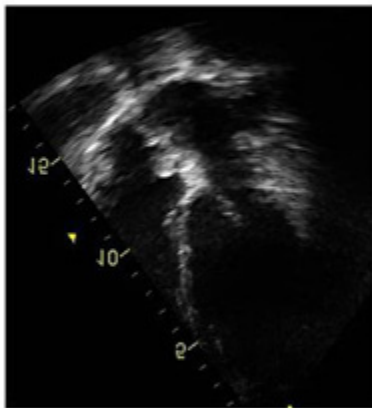
Appearance

MID & LONG TERM RESULTS

After 2 years.....

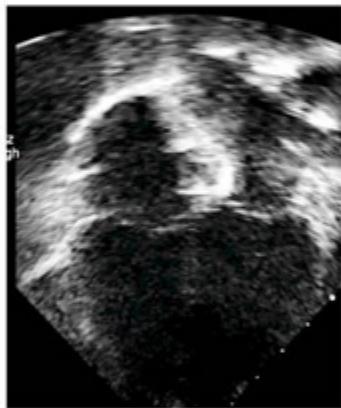


Amplatzer



Courtesy of C. Wongvipaporn

Cocoon

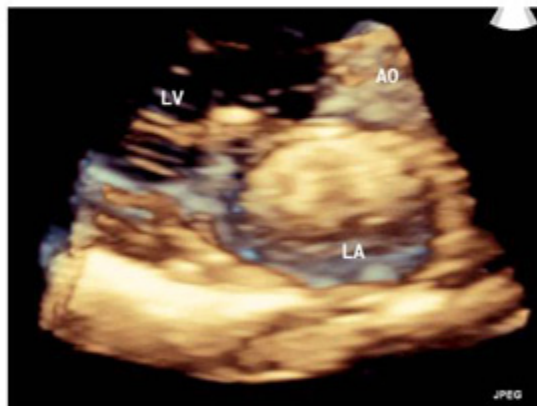


Occlutech

3D Imaging



Amplatzer 3 yrs after implantation.



Occlutech 2.5 yrs after implantation.

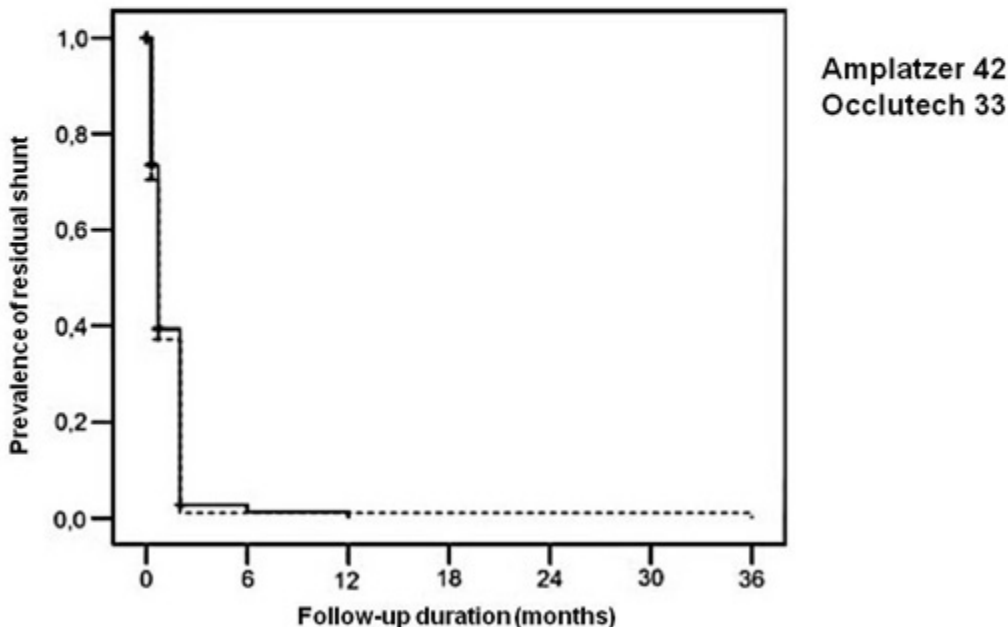
Residual shunt

Residual shunt

MID & LONG TERM RESULTS

MID & LONG TERM RESULTS

Kaplan-Meier analysis of residual shunt in Figulla ASD Occluder group (solid line) and in Amplatzer Septal Occluder group (dashed line).



Percutaneous Transcatheter Closure of Interatrial Septal Defect in Adults: Procedural Outcome and Long-Term Results

Joelle Kefer,^{1*} MD, PHD, Thierry Sluysmans,² MD, PHD, Cedric Hermans,³ MD PHD, Rames El Khoury,¹ MD, Catherine Lambert,³ MD, Françoise Van de Wyngaert,⁴ MD, Caroline Ovaert,² MD, PHD, and Agnes Pasquet,¹ MD, PHD

Background: Percutaneous transcatheter closure of patent foramen ovale (PFO) and atrial septal defect (ASD) has been shown to be feasible. **Aim:** The aim of this study was to evaluate the safety and efficacy of transcatheter interatrial septal shunt closure with prosthesis implantation in adults patients during long-term follow-up. In addition, the impact of thrombophilia and pulmonary hypertension on the outcome were investigated. **Methods:** Between June 1999 and November 2009, 287 patients (112 males, 43 ± 14 years) were treated in our institution by transcatheter closure of PFO (N = 175) or ASD (N = 112). Clinical and echocardiographic follow-up were prospectively performed at 1, 6 and 12 months followed by a 1 once a year evaluation. **Results:** All procedures were successful with eight procedural complications (2.7%): one stroke, two femoral pseudoaneurysms, three transient atrial fibrillation, two minors pericardial effusions. Among patients with presumed paradoxical embolism, thrombophilia was observed in 29 patients (17%); only one of them experienced a recurrent stroke. Among patients with ASD, pulmonary hypertension was observed in 32 cases (28%) and significantly reduced (47 ± 7 to 31 ± 11 mm Hg, P < 0.0001). 99% Follow up , up to 11 years. v-up. Clinical improvement was observed in 93%. Freedom from death, cardiac surgery or recurrent embolism was 98 ± 1% at 5 years. **Conclusion:** Percutaneous transcatheter interatrial septal defect closure is a safe and effective treatment in adults patients, even in case of thrombophilia or pulmonary hypertension, during a long-term follow-up, up to 11 years.

Characteristics of the 18 residual shunts 6 months after implantation.

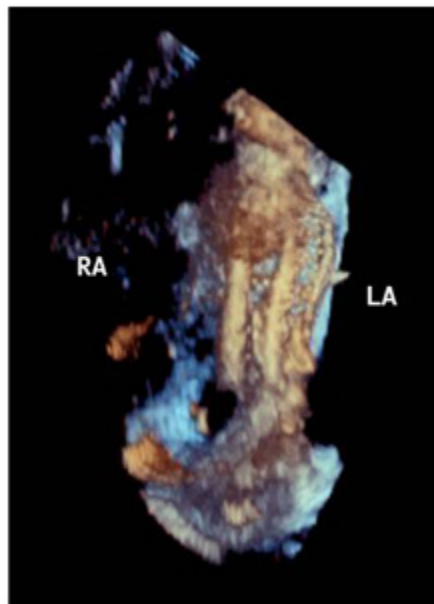
Type of primary defect	Type of prosthesis	Quantification of shunt	Mechanism of shunt at 6 m	Resolution of shunt at 18 m
PFO	Cardia	Trivial or small	Through prosthesis	Yes
PFO + ASA	Cardia	Trivial or small	Malapposition right disk	Yes
PFO + ASA	Cardia	Trivial or small	Malapposition right disk	Yes
PFO + ASA	Cardia	Trivial or small	Malapposition right disk	Yes
PFO + ASA	Starflex	Trivial or small	Through prosthesis	Yes
PFO + ASA	Cardia	Moderate or large	Malapposition right disk	No, moderate or large
PFO + ASA	Cardia	Trivial or small	Through prosthesis	No, trivial or small
PFO + ASA	Amplatzer	Trivial or small	Additional ASD	Unknown
PFO + ASA	Cardia	Trivial or small	Malapposition right disk	Yes
PFO + ASA	Starflex	Trivial or small	Through prosthesis	No, trivial or small
PFO + ASA	Starflex	Moderate or large	Additional ASD	Yes
PFO + ASA	Starflex	Moderate or large	Additional ASD	No, trivial or small
PFO + ASA	Premere	Moderate or large	Additional ASD	Yes
ASD	Cardia	Trivial or small	Through prosthesis	No, trivial or small
ASD	Occlutech	Trivial or small	Through prosthesis	Yes
ASD	Amplatzer	Trivial or small	Surgical patch muliperforated	No, trivial or small
ASD	Amplatzer	Moderate or large	Additional ASD	No, trivial or small
ASD + ASA	Cardia	Moderate or large	Additional ASD	No, trivial or small

PFO = patent foramen ovale; ASD = atrial septal defect; 6 m = six months; 18 m = 18 months; ASA = atrial septal aneurysm.

Cardia	118
Amplatzer	101
Starflex	24
Occlutech	19
Premere	15
Helex	10

Residual shunt (6/18 mo):	
Amplatzer	3/0 (1 N/A)
Occlutech	1/1

Cocoon Device (n=31)



- **Residual shunt**
 - 1 day: 41.4%
 - 1 week: 17.2%
 - 1 month: 0%

Erosion
EROSION

MID & LONG TERM RESULTS
MID & LONG TERM RESULTS

Amplatzer ASD and PFO occluder device is estimated to be approximately **0.1%**^{1,2}.

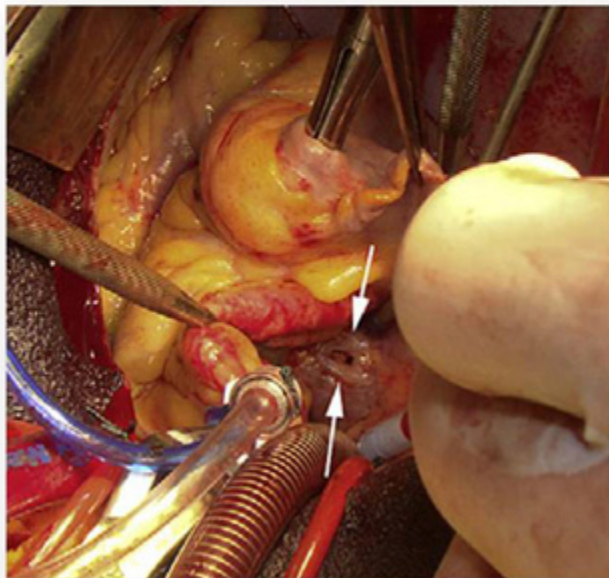
1. Amin Z, et al. CCI 2008.

2. Amin Z, et al. CCI 2004.

Late erosion of an Amplatzer septal occluder device 6 years after placement

Nathaniel W. Taggart, MD,^a Joseph A. Dearani, MD,^b and Donald J. Hagler, MD,^a Rochester, Minn

46 years old man, PFO.
ASO 14 mm implanted.



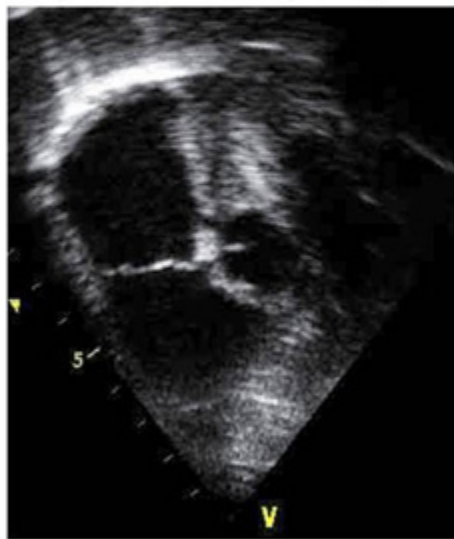
Other devices: **No Erosion**

or **No Information!**

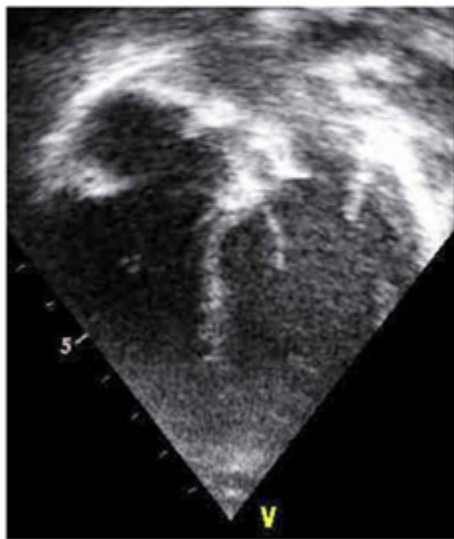
1. Volume of case.
2. Registration difficulty.
3. Time after implantation.

No late Erosion reported in Children.....

Amplatzer 26 mm in 6 yrs old girl



Immediate after deployment



3 yrs after deployment

Thrombosis

MID & LONG TERM RESULTS

Animal Study

Tissue ingrowths (3 month)



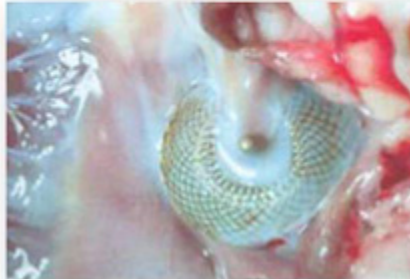
Amplatzer : Right Disk



Cera I : Right Disk



Amplatzer : Left Disk



Cera I : Left Disk

Thrombus Formation at 4-Week TEE and 6-Month TEE After Closure

Occluder	n	TEE Due (n)		TEE Performed (%)		Thrombus (% , n)	
		6 Months	4 Weeks	6 Months	4 Weeks	6 Months	
Rashkind	1	1	100%	100%	0%	0%	
Buttoned Device	52	52	67%	69%	0%	0%	
ASDOS	42	42	66%	83%	3.6% (n = 1)	0%	
Angel Wings	30	30	0%	97%	0%	3.3% (n = 1)	
CardioSEAL	27	27	52%	93%	7.1% (n = 1)*	0%	
StarFLEX	142	111	74%	70%	5.7% (n = 6)*	0%	
Amplatzer	418	375	78%	70%	0%*	0.3% (n = 1)	
PFO-Star	127	127	60%	66%	6.6% (n = 5)*	1.5% (n = 1)	
Helex	161	138	76%	80%	0.8% (n = 1)	0%	

*The difference between the Amplatzer occluder against the CardioSEAL occluder, the StarFLEX occluder, and the PFO-Star occluder was significant ($p < 0.05$).

TEE = transesophageal echocardiography.

Percutaneous atrial shunt closure using the novel Occlutech Figulla device: 6-month efficacy and safety.

Van Den Branden BJ, Post MC, Plokker HW, Ten Berg JM, Suttorp MJ.

BACKGROUND:

The **Occlutech Figulla Occluder** is a new innovative device for percutaneous closure of a patent foramen ovale (PFO) and an atrial septum defect (ASD). We describe the safety and efficacy of this new device at **6-month follow-up**.

METHODS:

All **82** consecutive patients (51% female, mean age 49.0 ± 13.6 years) who underwent percutaneous **PFO (n = 48) or ASD (n = 34)** closure between October 2008 and October 2009 were included.

RESULTS:

Implantation success was 100%. The in-hospital complications were two new onset supraventricular tachycardia (SVT) (2.4%, both ASD patients), nine minimal groin hematoma's (11.0%, 4 PFO and 5 ASD patients), and one transient ST elevation during the procedure (1.2%, ASD patient). During 6 months follow-up (n = 79), **no major complications or reoccurrences of cerebral thrombo-embolic events did occur**. Seven patients (8.9%, 6 PFO and 1 ASD patient) experienced a new SVT. One patient developed a recurrent cerebral hemorrhage 5 months after ASD closure, which appeared not to be related to the procedure. Using contrast transthoracic echocardiography 6 months after PFO closure (n = 45), a residual shunt was present in 30.2% of the patients (small 25.6%, moderate 4.6%, severe 0%). In the ASD group (n = 34), a residual shunt was observed in 32.5% (small 17.7%, moderate 14.7%, severe 2.9%).

CONCLUSION:

The Occlutech Figulla Occluder appears to be easy to use, effective, and safe for percutaneous closure of PFO and ASD. We report a low complication rate but a relative high percentage of small residual shunts 6 months after closure.

Stroke Due to Late Device Thrombosis Following Successful Percutaneous Patent Foramen Ovale Closure

Ravikiran Korabathina,¹ MD, David E. Thaler,² MD, PhD, and Carey Kimmelstiel,^{1*} MD

52 years old male,
PFO closed by ASO for stroke prevention.
3 yr later: confusion + mild hemiparesis.

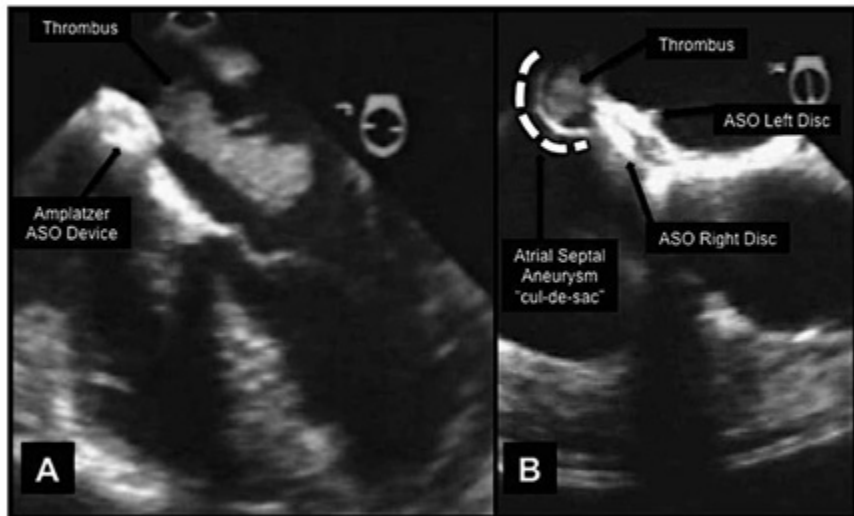


Fig. 1. TEE long-axis view showing a well-seated ASO device with a 4 cm mobile thrombus adherent to the left atrial disc and prolapsing through the mitral valve into the left ventricle (panel A). TEE short-axis view showing thrombus located within a "cul-de-sac" created by the superior rim of the ASA and the superior portion of the left atrial ASO disc (panel B).

Stroke Due to Late Device Thrombosis Following Successful Percutaneous Patent Foramen Ovale Closure

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52 years old male,
PFO closed by ASO for stroke prevention.
3 yr later: confusion + mild hemiparesis.



INCOMPLETE ENDOTHELIALIZATION

- Device (material, profile)
- Atrial septal anatomy (aneurysm)
- Host



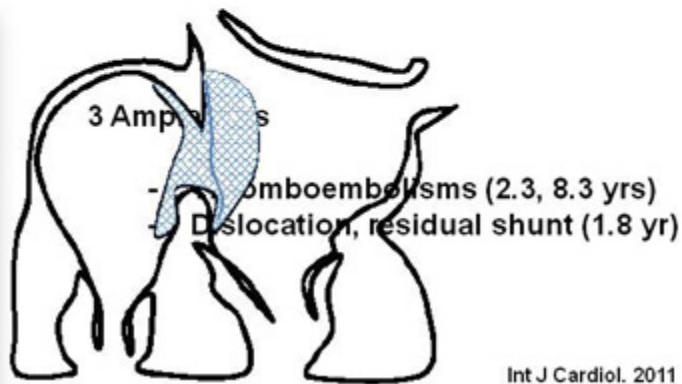
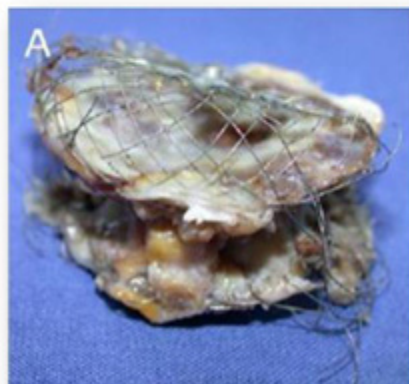
Clinical, echocardiographic and histopathologic findings in nine patients with surgically explanted ASD/PFO devices: do we know enough about the healing process in humans?

Vogt MO, Kühn A, Hörer J, Schreiber C, Schneider H, Foth R, Eicken A, Hess J, Sigler M.

Table 1
Clinical data of patients before implantation and explantation of ASD/PFO occluder.

Patient	IAS morphology	Indication for closure	Date of implantation	Type of device	Indication for explantation	Date of explantation	Years since implantation
1	ASD II	Hemodynamic	01/2000	Amplatzer ASD 34	Cerebral (recurrent) and coronary embolism Thrombus (LA+RA)	06/2008	8.3
4	PFO + ASA	Cerebral embolism	03/2001	Cardiosafe 33 mm	Thrombus (RA + LA); strut fracture	03/2004	2.9
5	PFO	Cerebral embolism	06/2001	Starflex 28 mm	Cerebral embolism (recurrent); Thrombus (RA, between device and IAS)	05/2005	3.9
6	PFO	Cerebral embolism	06/2004	Cardia PFO 30 mm	Cerebral embolism; thrombus (LA)	09/2007	3.2
7	ASD II	Hemodynamic	08/2004	Amplatzer ASD 32 mm	Dislocation; residual shunt	05/2006	1.8
8	PFO + ASA	Cerebral embolism	07/2005	Cardia PFO 35 mm	Perforation of IAS (within ASA); residual shunt	06/2006	0.9
9	ASD II	Hemodynamic	12/2005	Amplatzer ASD 20 mm	Coronary embolism; recurrent Thrombus (LA + RA)	05/2008	2.3

ASD II = atrial septal defect, PFO = patent foramen ovale, ASA = atrial septum aneurysm, LA = left atrium, RA = right atrium, IAS = interatrial septum.



Multi-Center Study in Thailand*

	Amplatzer	Cocoon	Occlutech
Procedural Success rate (%)	93	94	100
Fluoro time (min)	16.1 ± 11.9	13.7 ± 6.5	9.57 ± 5.5
Number of device used	1.15 ± 0.44	1.18 ± 0.33	1.02 ± 0.16
Follow up time (mo)	31.3 ± 14.9	21.8 ± 10.3	19.4 ± 8.5
Residual shunt (%)			
- Day 1	41.7	42.1	42.9
- 1-3 months	0	0	0
- 12 months	0	0	0
Complication(s)			
- Embolization	1	1	1
- Pericardial effusion	1	1	0
- Stroke	0	1	0

**Any differences among
different brands?**

In short term.....

Not really.

In long term.....

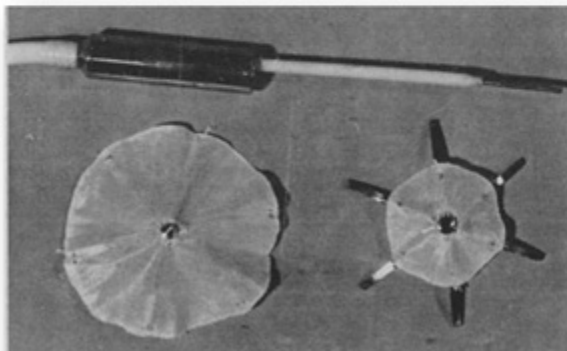
**Need more registration
Need more follow up time**

Too early to tell!!

Late follow-up of nonoperative closure of secundum atrial septal defects using the King-Mills double-umbrella device

Noel L. Mills, MD, Terry D. King, MD

There has been a marked increase in device closure of secundum atrial septal defects (ASDs) in the last decade. No clinical reports of late results have been forthcoming until now. The purpose of this report was to provide very long-term follow-up of nonoperative closure of secundum ASDs using the King-Mills Umbrella device. ASD closure using this technique did not appear to protect against the known secundum ASD complication of atrial arrhythmia. **Twenty-seven-year follow-up** of the umbrella ASD closure via the femoral vein shows effective occlusion, **absence of device complications, and no reinterventions.**



- 1. User friendly.**
- 2. High occlusion rate.**
- 3. Appear in a low profile shape (as early as possible).**
- 4. Not too soft/ not too stiff.**
- 5. Tailor made for each individuals. (septal aneurysm/ AF/ large defect & small rims)**

The right Device.....

Acknowledgement

- **Chaiyasith Wongvipaporn**, Khon Khen University.
- **Napa Siriwiwattana**, Rajvithi Hospital.
- **Worawut Tassanawiwat**, Sappasittiprasong Hospital.

