Closure of ASD’s using Devices Available Outside the US

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Co-Director of the Rush Adult Congenital Heart Disease Program

SCAI Fall Fellows Course, LV 2014

No Disclosures
Things I Have Learned...

“Good Judgment Comes From Experience...
Experience comes from bad judgment...”

“Always Tell the Truth and you’ll never have to remember anything”

If you are nice, generally people are nice back!

And....
The definition of a good talk is one that finishes on time!
Home...
First Non-Operative ASD Closure

Umbrella Device Keeps Heart Pumping
Non-Surgical Procedure Works For Boy

Kirk Hester releases after surgery to repair heart.

Suzette Creppel, the first to undergo new procedure, is now in stable condition.

The Society for Cardiovascular Angiography and Interventions
All Devices Have Advantages and Disadvantages....
Occlutech – Figulla-Flex II

• Titanium Oxide Coated Nitinol wire

• Ultrathin Non-woven PET fabric

• Single weld on the RA side

• Connecting ball on RA side to connect to delivery cable
Occlutech – Figulla-Flex II

- Flexible delivery cable
- Coupling mechanism similar to bioptome
- Allows device to conform to angle of atrial septum
Occlutech – Figulla-Flex II - Deployment
## Occlutech – Figulla-Flex II

### Device Sizes

<table>
<thead>
<tr>
<th>Article No.</th>
<th>Product Name</th>
<th>Waist Ø (mm)</th>
<th>Defect Size (mm)</th>
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<tbody>
<tr>
<td>29ASD04</td>
<td>Figulla® Flex II ASD</td>
<td>Size 4</td>
<td>D≤4</td>
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<tr>
<td>29ASD05</td>
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<td>4&lt;D≤5</td>
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</table>
Occlutech – Figulla-Flex II
Large ASD
Occlutech – Figulla-Flex II
Multiple ASD’s
Occlutech – Figulla-Flex II
Large ASD
Occlutech – Figulla-Flex II
Outcomes and Ongoing Trials

STRUCTURAL HEART DISEASE

**Figulla ASD Occluder versus Amplatzer Septal Occluder:** A Comparative Study on Validation of a Novel Device for Percutaneous Closure of Atrial Septal Defects

AYSENYUR PAC, M.D., TUGCIN BORA POLAT, M.D., ILKER CETIN, M.D., MEHMET BURHAN OFLAZ, M.D., and SEVKET BALLI, M.D.

From the Clinic of Pediatric Cardiology, Türkiye Yüksek İhtisas Education and Research Hospital, Ankara, Turkey

**Objectives:** Occlutech Figulla ASD Occluder (FSO) is an alternative device to Amplatzer Septal Occluder (ASO) with some structural innovations including increased flexibility, minimizing the amount of material implanted, and absence of the left atrial clamp. We aimed to report our experiences with FSO and compare the outcomes of this novel device versus ASO.

**Interventions:** Between December 2005 and February 2009, 75 patients diagnosed with secundum atrial septal defects underwent transcatheter closure. The FSO device was used in 33 patients, and the ASO was used in 42.

**Results:** Patient characteristics, stretch size of the defect, device left disc size, procedure, and fluoroscopy time were similar between the groups. However, the difference between device waist size and stretched diameter of the defect was significantly higher, and device delivery sheath was significantly larger in FSO group and device left disc size was significantly lower in the FSO group. In all subjects, the residual shunt was small to trivial during follow-up and the reduction in prevalence of residual shunt with time was similar in both groups \((P = 0.68)\). We found no differences in complication rate between the two devices; however, device embolization to the pulmonary bifurcation in one patient was recorded as major complication in FSO device group.

**Conclusions:** Both devices are clinically safe and effective in ASD closure. FSO device has similar outcomes when compared to ASO device. Difficulties in selecting the correct device size in larger defects and larger venous sheath requirement need to be evaluated in further studies. (J Interven Cardiol 2009;22:489–495)
Occlutech – Figulla-Flex II
Outcomes and Ongoing Trials

• Brazil (In Press)
• 122 patients
• Median age 24 (4-72)
• Successful implants 98.4%
• Median follow-up: 36 m
• No
  • Device embolization
  • Endocarditis
  • Thromboembolism
  • Erosion

• European Trial
  “A Randomized, Controlled, Multi-Centre Trial of the Efficacy and Safety of the Occlutech Septal Occluder (Figulla Flex II) Compared to the AGA Septal Occluder (Amplatzer ASO) for Transcatheter Closure of Secundum Atrial Septal Defects in Patients”

• Objectives
  – To determine the efficacy of the Figulla Flex II device compared to that of the Amplatzer ASO device for transcatheter closure of secundum atrial septal defects
  – To determine the safety of the Figulla Flex II device compared to that of the Amplatzer ASO device for transcatheter closure of secundum atrial septal defects

• 300 Patients
Lifetech – Ceraflex

2001 CE approved
1\textsuperscript{st} generation

2009 CE approved
2\textsuperscript{nd} generation

2011 CE approved
3\textsuperscript{rd} generation
Lifetech - Ceraflex

CeraFlex™ Features

- Minimizing the amount of material on the left atrial disc
  Avoid thrombotic complications.

CeraFlex™ Features

- Maximum flexibility - Pivot 360°
  Accurate positioning during procedure;
  Minimizing any unwanted drag or pull on the implant.

- Proprietary Titanium nitride coating technology
  Accelerates endothelialization;
  Prevents 93% of nickel release compared with uncoated occluders.
Proprietary Titanium Nitride (TiN) Coating

Faster Endothelialization

**Left Atrial Disc**

<table>
<thead>
<tr>
<th>TiN Coated Occluder</th>
<th>2 Months</th>
<th>4 Months</th>
<th>6 Months</th>
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<tr>
<td>Cera</td>
<td><img src="image1.png" alt="Image" /></td>
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<table>
<thead>
<tr>
<th>Uncoated Nitinol Occluder</th>
<th>2 Months</th>
<th>4 Months</th>
<th>6 Months</th>
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<tr>
<td></td>
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<td><img src="image5.png" alt="Image" /></td>
<td><img src="image6.png" alt="Image" /></td>
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</table>
Ceraflex ASD – Cable Connection
Flexible Delivery Cable

Soft cable, helps to minimize damage to heart or internal tissue structures
The CeraFlex wire loop connection system allows accurate final positioning with minimal tension, minimizing adverse tension or stress caused by the delivery cable, even in challenging anatomies!!!
CeraFlex Wire Loop Connection System

Accurate final positioning with minimal tension

Nitinol Loop Connection

$\Delta L = -1^\circ$
$\Delta R = -1^\circ$

Traditional Screw Connection

$\Delta L = 44^\circ$
$\Delta R = 30^\circ$
Ceraflex ASD – Release
# CeraFlex ASD and PFO Sizing Chart

## CeraFlex™ ASD

**Occluder Product Specification**

<table>
<thead>
<tr>
<th>Code</th>
<th>D Waist Diameter (mm)</th>
<th>D1 Right Disc Diameter (mm)</th>
<th>D2 Left Disc Diameter (mm)</th>
<th>L Waist Length (mm)</th>
<th>Minimum Sheath Size (Fr)</th>
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<tbody>
<tr>
<td>LT-ASDF-06</td>
<td>6</td>
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<td>18</td>
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<td>20</td>
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<td>8Fr</td>
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<tr>
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<td>22</td>
<td>26</td>
<td>4</td>
<td>9Fr</td>
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<tr>
<td>LT-ASDF-14</td>
<td>14</td>
<td>24</td>
<td>28</td>
<td>4</td>
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<tr>
<td>LT-ASDF-16</td>
<td>16</td>
<td>26</td>
<td>30</td>
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<tr>
<td>LT-ASDF-18</td>
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<td>4</td>
<td>10Fr</td>
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<tr>
<td>LT-ASDF-20</td>
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<td>34</td>
<td>4</td>
<td>12Fr</td>
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<tr>
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<td>36</td>
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<tr>
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<tr>
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<td>40</td>
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<tr>
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<td>LT-ASDF-30</td>
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<td>40</td>
<td>44</td>
<td>4</td>
<td>14Fr</td>
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<tr>
<td>LT-ASDF-32</td>
<td>32</td>
<td>42</td>
<td>46</td>
<td>4</td>
<td>14Fr</td>
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</table>

## CeraFlex™ PFO

**Occluder Product Specification**

<table>
<thead>
<tr>
<th>Code</th>
<th>D1 Right Disc Diameter (mm)</th>
<th>D2 Left Disc Diameter (mm)</th>
<th>L Waist Length (mm)</th>
<th>Minimum Sheath Size (Fr)</th>
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</thead>
<tbody>
<tr>
<td>LT-PFOF-1818</td>
<td>18</td>
<td>18</td>
<td>3</td>
<td>9Fr</td>
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<td>18</td>
<td>3</td>
<td>10Fr</td>
</tr>
<tr>
<td>LT-PFOF-2525</td>
<td>25</td>
<td>25</td>
<td>3</td>
<td>10Fr</td>
</tr>
<tr>
<td>LT-PFOF-3025</td>
<td>30</td>
<td>25</td>
<td>3</td>
<td>12Fr</td>
</tr>
<tr>
<td>LT-PFOF-3030</td>
<td>30</td>
<td>30</td>
<td>3</td>
<td>12Fr</td>
</tr>
<tr>
<td>LT-PFOF-3525</td>
<td>35</td>
<td>25</td>
<td>3</td>
<td>14Fr</td>
</tr>
</tbody>
</table>

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[RUSH UNIVERSITY MEDICAL CENTER](https://www.rush.edu)

[SCAI](https://www.scai.org)
Ceraflex ASD – Clinical Outcomes

• Although over 80,000 Lifetech devices implanted – limited clinical data with Ceraflex.

• One report describing 25 pts (ASD n=7)
Nit Occlud ASD-R

- *Device is knitted from a single nitinol wire*
  - low profile
  - no protruding clamps

- "Reverse" distal disc configuration

- "Pre-mounted" device

- "Snare like" release mechanism
Nit Occlud ASD-R

- Both discs are equal in size
- Polyester membranes in each disc
Nit-Occlud ASD-R Deployment
Nit-Occlud ASD-R Post Deployment Assessment
Nit Occlud ASD-R

**Release mechanism**

- "Lock wire" that goes through the device
- Pusher with a distal wire noose ("eyelet")
- Lock wire is attached to the right side of the implant by 4 subjetion wires connected to the pusher
Nit Occlud ASD-R

**Release mechanism**

- For release, the “security seal” is removed and the “lock wire” is retracted, dis-engaging the noose and freeing the implant

![Release mechanism](image)
### Nit Occlud ASD-R

Choosing the device = ASD d ( = or up to 2 mm)

<table>
<thead>
<tr>
<th>STENT (mm)</th>
<th>DISC (mm)</th>
<th>SHEATH (F)</th>
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<tbody>
<tr>
<td>8</td>
<td>16 (4 + 4)</td>
<td>7</td>
</tr>
<tr>
<td>10</td>
<td>19 (4.5 + 4.5)</td>
<td>8</td>
</tr>
<tr>
<td>12</td>
<td>22 (5 + 5)</td>
<td>8</td>
</tr>
<tr>
<td>14</td>
<td>24 (5 + 5)</td>
<td>10</td>
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<tr>
<td>16</td>
<td>28 (6 + 6)</td>
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<td>18</td>
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<td>22</td>
<td>35 (6.5 + 6.5)</td>
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<td>24</td>
<td>38 (7 + 7)</td>
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<td>26</td>
<td>42 (8 + 8)</td>
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<td>14</td>
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<td>30</td>
<td>47 (8.5 + 8.5)</td>
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Nit Occlud ASD-R – Clinical Experience

- 74 patients – successful implant in 73 (98.6%)
- Median age 17.2 years (2-74)
- Complete occlusion in 72/73
- Mean follow-up 11.4 months
  - No Embolization
  - Cardiac Perforation
  - Endocarditis
  - Wire fracture

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
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<tbody>
<tr>
<td>Age mean ± SD (range)</td>
<td>17.2 ± 17.9 years (2–74)</td>
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<tr>
<td>Weight mean ± SD (range)</td>
<td>40.2 ± 22.2 kg (9–97)</td>
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<tr>
<td>Sex F/M</td>
<td>79.5%/20.5%</td>
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<tr>
<td>ASD-OS TTE size mean ± SD (range)</td>
<td>12.6 ± 3.3 mm (7–22)</td>
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<tr>
<td>ASD-OS TEE size ± SD (range)</td>
<td>14.9 ± 3.8 mm (7–26)</td>
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<tr>
<td>ASD-OS balloon sizing size mean ± SD (range)</td>
<td>18.6 ± 3.5 mm (12–28)</td>
</tr>
<tr>
<td>Median pulmonary artery pressure mean ± SD (range)</td>
<td>21.2 ± 6.2 mm Hg (12–34)</td>
</tr>
<tr>
<td>Successful interventions</td>
<td>98.6%</td>
</tr>
<tr>
<td>Device size mean ± SD (range)</td>
<td>18.9 ± 4.5 mm (10–30)</td>
</tr>
<tr>
<td>Fluoroscopy time mean ± SD (range)</td>
<td>10.1 ± 3.3 min (4–20.8)</td>
</tr>
<tr>
<td>Follow up time mean ± SD (range)</td>
<td>11.4 ± 6.8 months (1–24)</td>
</tr>
<tr>
<td>Closure 7 days–1 months</td>
<td>97.2%</td>
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<tr>
<td>Closure 3–6 months</td>
<td>98.6%</td>
</tr>
<tr>
<td>Hospital admission time mean ± SD (range)</td>
<td>24.9 ± 6.2 h (24–72)</td>
</tr>
</tbody>
</table>

RUSH UNIVERSITY MEDICAL CENTER

Catheterization and Cardiovascular Interventions 84:464–470 (2014)

The Society for Cardiovascular Angiography and Interventions
Cardia ASD Device

- Numerous iterations
  - Atriasept (Cardiac Perforation)
  - Atriasept II
  - Ultrasert
- Nitinol frame (foam fabric)
- Dual articulating sails
- Self-centering mechanism
- 6-34 (48)mm waist sizes (9-11Fr sheaths)
- Loaded via bioptome
- Limited data with new occluder
- Marketed for Fontan fenestration occlusion

12mm Device in 5 year old
Biostar

- Based on Starflex
- Double Stainless steel arms
- Nitinol wire
- 2 discs of acellular porcine collagen
- Resorbs within 6 months
- Heparin Sulfate coating
- 23, 28 and 33mm diameters
- ? Future
Sideris Button Device

- Used since 1999
- Initial design – 48hrs release
- New device IRP (3 parts)
  - Supporting balloon cath
  - Patch (Polyurethane foam) – no wires
  - Safety thread
- Surgical adhesive
- 3 sizes
- Cross defect – inflate balloon – detach balloon – immobilized with safety thread
- Biodegradable
- Animal data
- Some safety concerns
Solysafe ASD Occluder

• Self-Centering
• Two foldable Polyester patches
• 8 Metal wires (Cobalt Alloy)
• Two wire holders
• Introduced over 0.018”
• 10Fr Short sheath
• Deployment – pulling distal and pushing proximal
• Minimal clinical data
• Safety concerns – 20% wire fracture

PICES

• Pediatric Interventional Cardiology Early Career Society
  • SCAI Committee
  • Promote development of younger interventionists
  • Multiple ongoing projects
  • Listserve pices@googlegroups.com,
  • Meet twice yearly at SCAI and PICS
  • Free!

PICES secretary: Gareth J. Morgan can be reached at drgarethjmorgan@gmail.com