TCT AP
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Initial Experience with a Bioresorbable ASD/PFO Occluder

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Disclosures

Physician name	Company	Relationship
Horst Sievert	Abbott, Access Closure, AGA, Angiomed, Aptus, Atrium, Avinger, Bard, Boston Scientific, Bridgepoint, Carag, Cardiac Dimensions, CardioKinetix, CardioMEMS, Cardiox, Celonova, CGuard, Coherex, Contego, Covidien, CSI, CVRx, EndoCross, ev3, FlowCardia, Gardia, Gore, Guided Delivery Systems, Hemoteq, InSeal Medical, Lumen Biomedical, HLT, Lifetech, Lutonix, Maya Medical, Medtronic, NDC, Occlutech, Osprey, Ostial, PendraCare, pfm Medical, Recor, ResMed, Rox Medical, SentreHeart, Spectranetics, SquareOne, Svelte Medical Systems, Trireme, Trivascular, Vascular Dynamics, Venus Medical, Veryan, Vessix	Consulting fees, Travel expenses, Study honoraria
	Cardiokinetix, Access Closure, Velocimed, Lumen Biomedical, Coherex, SMT	Stock options, Stocks
	Cook, St. Jude Medical	Grant Research Support

Why do we need a bioresorbable occluder?

- Because metal frameworks may cause
  - erosion
  - arrhythmia
  - thrombus formation
  - aortic valve leaflet distortion (1)
- For future transseptal access
  - EP
  - MV interventions
  - LAA closure
- Because patients prefer it

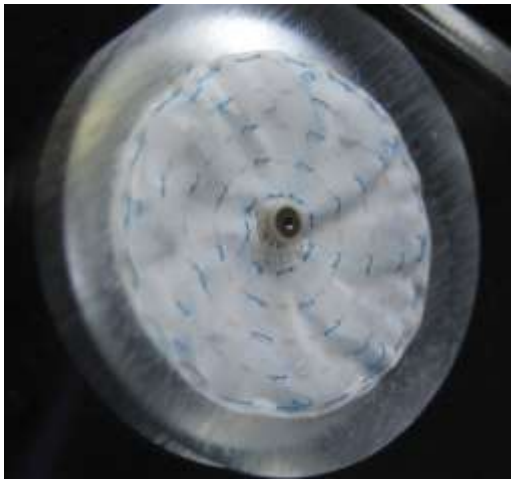
(1). Amin CCI 2008; Divchev EJEcho 2007; Chessa Int J Card 2004

CBSO evolved from Solysafe Occluder

- Solysafe CE marked 2007
- Design with metal wires (Phynox)
- Implanted in over 1000 pts with excellent results
- Voluntarily removed from market in 2010 due to metal frame fractures during FU
- CARAG Bioresorbable Septal Occluder is similar - but without wire framework

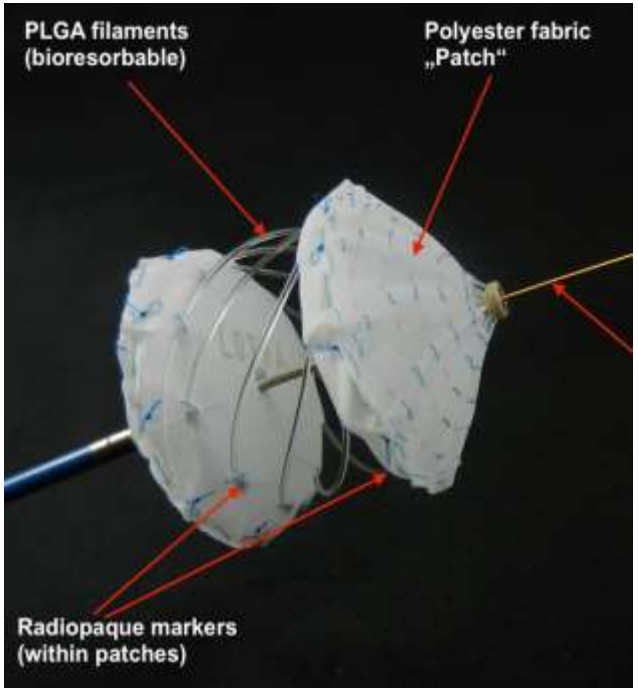
Similarities CBSO - Solysafe

- Same Delivery System
- Same OTW-technique
- Self centering
- Same flat double disc design
- Reattachable and resheathable after release



Carag Bioresorbable Septal Occluder

- 0.018” guidewire
- 12 F sheath
- 2 opposing polyester covers
- Framework made of PLGA
- Resorption of PLGA
  - starts after 6 months
  - complete after 18-24 months



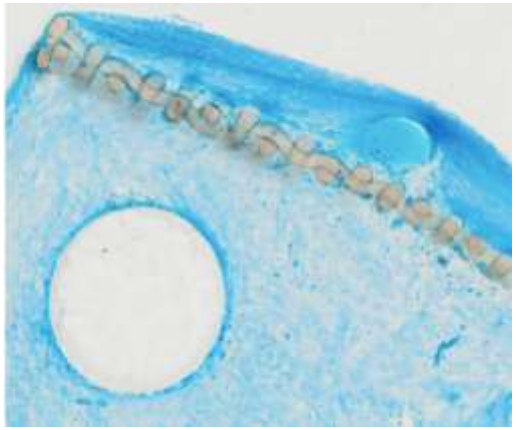
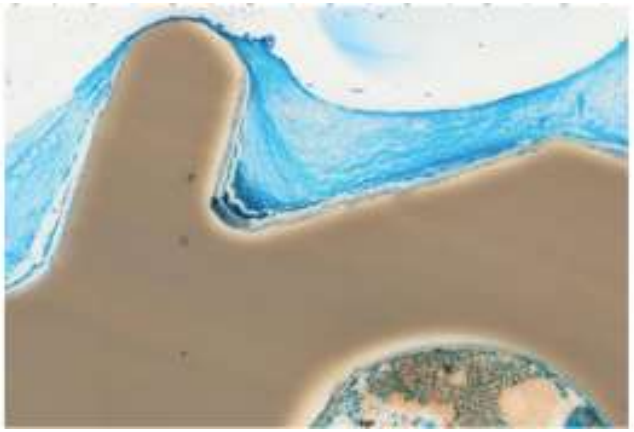
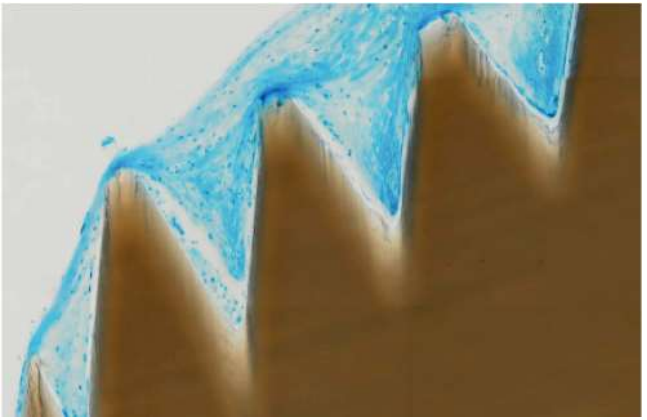
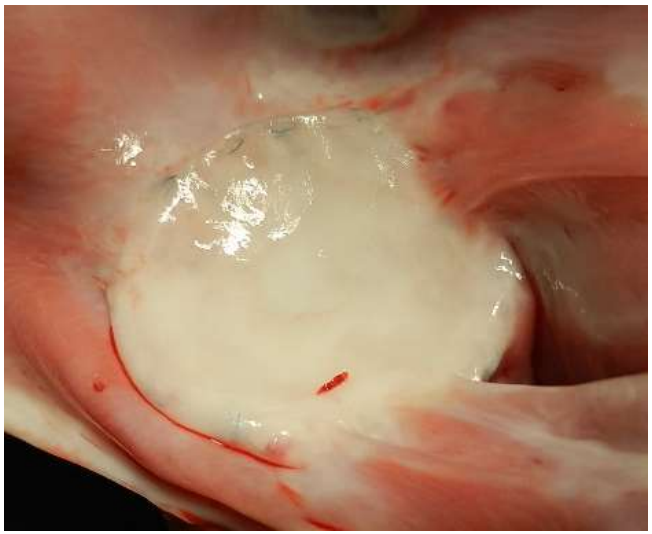
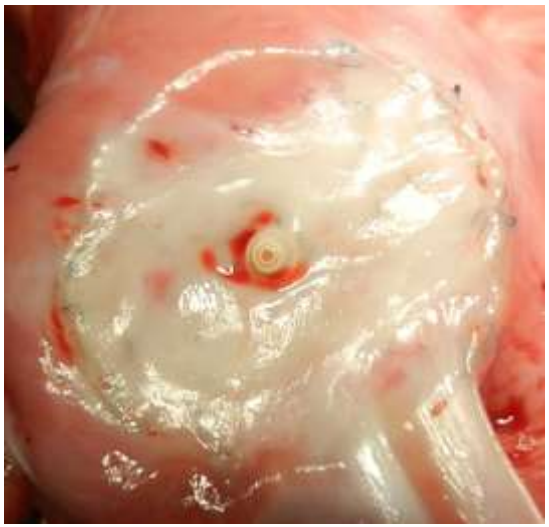
Preclinical studies

- N = 24
- Implant success rate: 100%
- No procedural complications
- 1 animal died 1M post implant, not device related (animal was replaced)
- Histology showed
  - Complete endothelialization
  - No thrombus
  - No signs of calcification or metaplasia

Interventions by B.Söderberg/ B.Schmitt

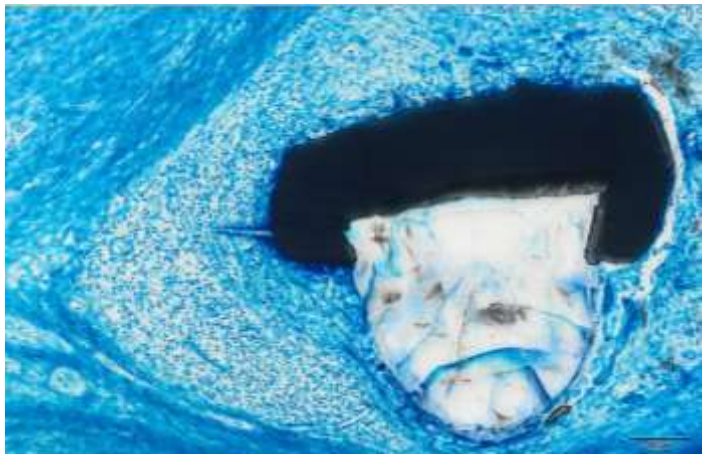
Endothelisation

Complete coverage/endothelialization of the occluder within 3 months even at exposed positions

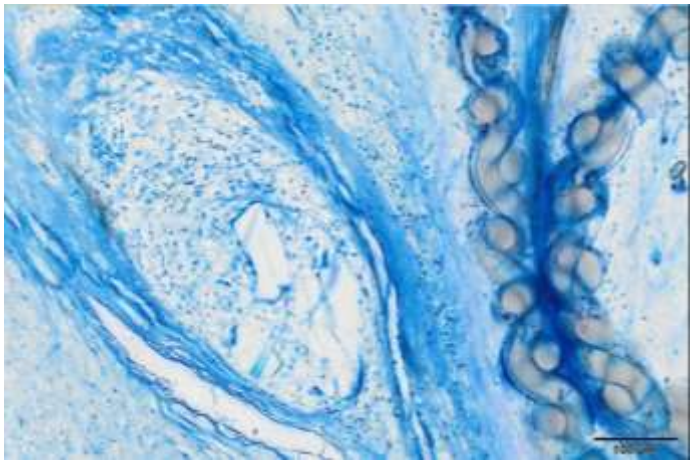






Resoption of the polymer

- Initially, the PLGA framework keeps the occluder in position
- After endothelialization the framework disappears
- No more metal framework related risks



Filament and Pt-Ir-Marker @ 8 months



Resorbed Filament and permanent membrane @ 15 months

What did we learn from the animal trials ?

- PLGA bioresorbable framework can be placed safely and effectively
- Endothelialization complete by 1-3 months
- Bioresorption in progress at 8 and 15 months
- Bioresorption expected to be completed between 18 and 24 months

First in Human

- Single center
- 15 Patients
- ASD & PFO
- Endpoints
  - Effective Closure @ 6 months
  - Safety @ 6M
- Follow-up
  - 1, 6, 12, 24M

Inclusion Criteria

- >18 years
- Body weight > 40 kg
- isolated ASD or PFO
- In ASD's
  - RV overload
  - defect between 4 -25 mm
- In PFO's

  tunnel length ≤ 4 mm

Exclusion criteria

- Defects unsuitable for percutaneous closure
- Multiple or fenestrated ASD
- Any significant cardiac valve dysfunction
- Anomalous pulmonary veins
- Defects with inadequate margins

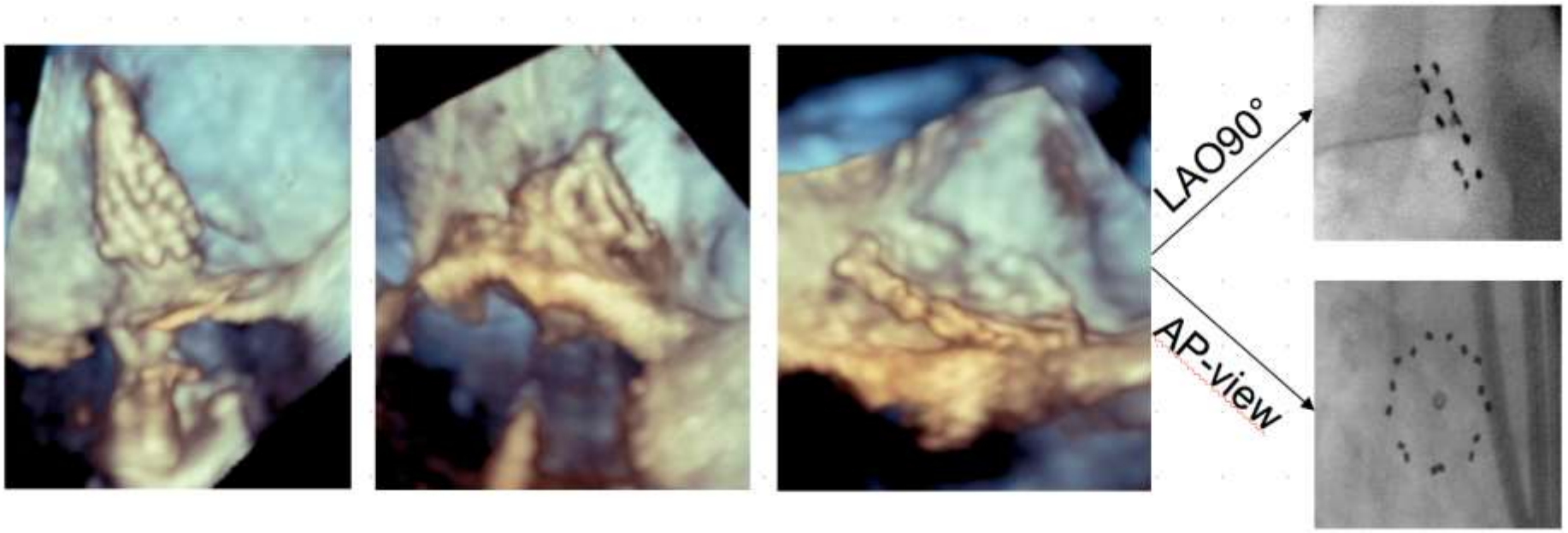
CBSO - Sizing

- Based on balloon sizing

Defect Size	Occluder Type
4 – 12mm	S
13 – 20mm	M
21 – 25mm	L

CBSO - Visibility

Easily visible under fluoroscopy and echo
Platinum-iridium (Pt-Ir) markers, attached to fabric



Results

- 14 patients (female=7 / male=7)
- Age 48.3 ± 10.9
- enrollment ongoing

- Procedure time 33 ± 25 min
- No procedure or device related adverse events

Results

- ASD (n=8)
  - diameter = 17.5 mm (13 mm – 21 mm)
  - FU 1-12 months
  - Complete closure at last FU in 6/8
    - <3mm residual shunt in 2
- PFO (n=6)
  - diameter = 8.7 mm (5.4 mm -10.8 mm)
  - FU 12 months
  - Complete closure at last FU in 4/6

Thank You!

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