GORE® CARDIOFORM SEPTAL OCCLUDER SELECTED LITERATURE SUMMARY

GORE
Creative Technologies Worldwide

Objective and Glossary

Purpose

The intent of this summary is to provide practical information on patient outcomes using the GORE® CARDIOFORM Septal Occluder (previously known as GORE® Septal Occluder) in clinical practice. This summary is focused on published clinical performance and serious adverse event data associated with use of the device in transcatheter closure of atrial septal defects, such as ostium secundum and patent foramen ovale.

Scope

Publications that include fewer than ten patients have not been included. Serious adverse events for this report include clinical complications historically associated with septal occluder implantation resulting in further treatment or patient harm: arrhythmia requiring treatment, cardiac tamponade, frame fracture with clinical sequelae, post-procedural embolization, reintervention, stroke or TIA, or thrombus formation. For details of adverse events or other information beyond these summaries, please review the original publication.

Organization

Publications are organized according to the defect type being closed in the patients reported – PFO, ASD, or both. Within each group, publications are organized from largest to smallest size of the patient population being treated with a GORE® CARDIOFORM Septal Occluder.

Glossary

ASA – atrial septal aneurysm

ASD – atrial septal defect

Closure Success – completely occluded or a shunt described as trivial or small

PFO – patent foramen ovale

SD – standard deviation

Technical Success – defined as successful implantation of a GORE® CARDIOFORM Septal Occluder in patients where an attempt is made

TEE – transesophogeal echocardiography

TIA – transient ischemic attack

TTE – transthoracic echocardiography

Thomson 2014

Patent Foramen Ovale Closure with the GORE Septal Occluder**: Initial UK Experience

J.D. Thomson, et al.

Background

- Registry data from nine centers in the United Kingdom performing PFO closure with the GORE® Septal Occluder**
- 229 patients
- Indication for closure:
  - Stroke or TIA (n=191)
  - Migraine (n=5)
  - Platypnea-orthodeoxia (n=9)
  - Other (n=24)
- Median follow-up: 9 months

Population and Defect Characteristics

- Median age: 45 years (range 14–72)
- ASA: 89 / 229 (39%)
- Long tunnel PFO: 79 / 229 (34%)
- Median PFO balloon size: 8 mm (range 2–17)*

Results

Median Procedure Time (minutes)	32 (range 5–105)
Technical Success	100%
Closure Success	
Median 0 months	95% (with Valsalva)
Mean 3 months	100%

Serious Adverse Events	Number of Patients (%)
Arrhythmia Requiring Treatment	2 (0.9%)
Cardiac Tamponade	0 (0%)
Frame Fracture with Clinical Sequelae	0 (0%)
Post-Procedural Embolization	0 (0%)
Reintervention	0 (0%)
Thrombus Formation	1 (0.4%)
TIA / Stroke	0 (0%)

Conclusion

"In this registry series the GSO [GORE® CARDIOFORM Septal Occluder] was a reliable and effective device for closure of PFO of all types. Complications rates were in keeping with those reported for existing technology, which are already in use for this procedure. Clearly, further prospective data relating to device performance are required."

* GORE® CARDIOFORM Septal Occluder *Instructions for Use* recommend treating defects up to 17 mm, at time of publication the *Instructions for Use* recommended treating defects up to 15 mm.

** Now known as GORE® CARDIOFORM Septal Occluder.

Butera 2013

Transcatheter PFO Closure with GORE® Septal Occluder**: Early and Mid-Term Clinical Results

G. Butera, et. al.

Background

- Registry data from three Italian centers performing PFO closure with the GORE® Septal Occluder**
- 122 patients
- Indication for closure:
  - Stroke or TIA (n=110)
  - Migraine (n=12)
- Median follow-up: 9 months (range 1–18)

Population and Defect Characteristics

- Median age: 50 years (range 23–65)
- ASA: 38 / 122 (31%)

Results

Median Procedure Time (minutes ± SD)	30 ± 20
Mean Fluoroscopy Time (minutes ± SD)	5 ± 4
Technical Success	100%
Closure Success	
Procedure	84% (with Valsalva)
Mean 9 months	98% (with Valsalva)

Serious Adverse Events	Number of Patients (%)
Arrhythmia Requiring Treatment	4 (3.3%)
Cardiac Tamponade	0 (0%)
Frame Fracture with Clinical Sequelae	0 (0%)
Post-Procedural Embolization	0 (0%)
Reintervention	0 (0%)
Thrombus Formation	0 (0%)
TIA / Stroke	2 (1.6%)*

* One patient had facial paresthesias and one complained of dysarthria and visual disturbances. No residual shunt or thrombus on the occluder was found.

Conclusion

"GORE® Septal Occluder [GORE® CARDIOFORM Septal Occluder] in our experience is an easy, safe, and effective device in closing PFO. We think that it achieves several steps forward to the 'ideal' device. Longer follow-up is needed to assess for device performance."

** Now known as GORE® CARDIOFORM Septal Occluder.

Knerr 2014

Results of Percutaneous Closure of Patent Foramen Ovale with the GORE® Septal Occluder**

M. Knerr, et. al.

Background

- Prospective, single-center experience performing PFO closure with the GORE® Septal Occluder**
- 60 patients
- Indication for closure included paradoxical embolism and dyspnea on exertion
- Patients were followed-up at 1, 6, and 12 months after implantation

Population and Defect Characteristics

- Mean age: 54 years (range 18–79)
- ASA: 48%

Results

Median Procedure Time (minutes ± SD)	35 ± 12.9
Mean Fluoroscopy Time (minutes ± SD)	6.0 ± 4.7
Technical Success	98%
Closure Success	
6 months	98%
9 months	100%

Serious Adverse Events	Number of Patients (%)
Arrhythmia Requiring Treatment	4 (6.7%)
Cardiac Tamponade	1 (1.7%)
Frame Fracture with Clinical Sequelae	0 (0%)
Post-Procedural Embolization	0 (0%)
Reintervention	0 (0%)
Thrombus Formation	1 (1.7%)
TIA / Stroke	2 (3.3%)*

* One patient described visual disturbances, paresthesia, and tremor of the left hand within 24 hours of implantation without brain infarct on imaging. A second patient had a stroke one month after implantation with no residual shunt or thrombus formation on the occluder detected.

Conclusion

"In patients with PFO, the GSO [GORE® CARDIOFORM Septal Occluder] can be implanted with a high technical success rate and similar closure rate compared with other devices. The incidence of AF was higher than reported after implantation of the most commonly used Amplatzer devices. However, this could not be confirmed in most other studies. Given the limited number of patients in our study, definitive conclusions regarding the risk of AF cannot be made."

** Now known as GORE® CARDIOFORM Septal Occluder.

Darsaklis 2014

A Novel System for Transcatheter Closure of Patent Foramen Ovale: Clinical and Echocardiographic Outcome Comparison with Other Contemporary Devices

D. Darsaklis, et. al.

Background

- A single-center experience comparing four different occluders for PFO closure
- The study included 48 GORE® Septal Occluder**, 34 GORE® HELEX® Septal Occluder, 74 AMPLATZER® PFO Occluder, and 37 BIOSTAR Occluder patients
- The mean follow-up for adverse event recording was between 5.6–32.4 months, and for closure assessment was between 3.4–4.4 months, depending on device group

Population and Defect Characteristics of GORE® Septal Occluder** Patients

- Mean age (± SD): 49.4 ± 10.9 years
- ASA: 9 / 48 (18.8%)
- Demographics and defect characteristics were not different between device groups

Results

- The GORE® Septal Occluder** showed statistically better closure performance than the GORE® HELEX® Septal Occluder and the AMPLATZER® PFO Occluder, and there was no difference compared with the BIOSTAR Occluder

	GORE® Septal Occluder**	GORE® HELEX® Septal Occluder	AMPLATZER® PFO Occluder	BIOSTAR Occluder
Subjects Evaluated with TEE at First Follow-up	41	31	51	32
Mean Time to First Follow-up (months ± SD)	3.4 ± 0.8	3.5 ± 0.8	4.4 ± 2.1	4.3 ± 2.3
Closure Success	93%	74%	76%	94%

Serious Adverse Events

- A GORE® Septal Occluder** patient had an arrhythmia reported, but no treatment was described
- There were no cases of cardiac tamponade, frame fracture with clinical sequelae, post-procedural embolization, reintervention, thrombus formation, or TIA or stroke reported in any GORE® Septal Occluder** patient
- There were no differences in adverse event rates across all device types, though follow-up times were not similar between groups

Conclusion

"PFO closure in this population was safe as depicted by the absence of procedural complications and the low rate of clinical events at follow-up. The GSO [GORE® CARDIOFORM Septal Occluder] and BioSTAR Occluder had better closure performance compared with the HELEX [GORE® HELEX® Septal Occluder] and APO [AMPLATZER® PFO Occluder] devices at first follow-up TEE (mean of 3.5 months). Further studies with larger sample sizes and longer follow-up will be required to confirm the results of our study."

** Now known as GORE® CARDIOFORM Septal Occluder.

Musto 2013

Comparison Between the New GORE Septal Occluder** and Amplatzer Devices for Transcatheter Closure of Patent Foramen Ovale

C. Musto, et. al.

Background

- Single-center review of 45 consecutive patients undergoing PFO closure with the GORE® Septal Occluder** compared to 45 historical patients that received the AMPLATZER® PFO Occluder or the AMPLATZER® Cribriform Septal Occluder
- All patients were closed for paradoxical embolism
- Procedural results, right-to-left shunting at 6 months, and recurrent embolic events to 1 year were investigated

Population and Defect Characteristics for the GORE® Septal Occluder** Patients

- Mean age (± SD): 42 ± 9 years
- Mean tunnel length (± SD): 11 ± 4 mm
- Long tunnel (> 10 mm): 2 / 45 (4%)
- ASA: 3 / 45 (6%)
- All characteristics between the GORE® Septal Occluder** and AMPLATZER® Occluder patient groups were similar

Results

- Outcomes were statistically similar between patients who received the GORE® Septal Occluder** or an AMPLATZER® Occluder

Outcomes	GORE® Septal Occluder**	AMPLATZER® Occluders
Mean Procedure Time (minutes)	32.3 ± 9.3	27.5 ± 11.6
Mean Fluoroscopy Time (minutes)	3.5 ± 2.8	3.1 ± 2.6
Technical Success	100%	100%
Closure Success		
• Procedure	96%	98%
• 6 months	96%*	98%

* One patient persistently had a "late" (fifth-sixth cardiac cycle) shunt deemed probably independent of the device

Serious Adverse Events

- There were no cases of arrhythmia requiring treatment, cardiac tamponade, frame fracture with clinical sequelae, post-procedural embolization, reintervention, thrombus formation, or TIA or stroke reported in any patient.

Conclusion

"The GSO [GORE® CARDIOFORM Septal Occluder] device seems to be a valuable alternative to the Amplatzer occluders for percutaneous PFO closure. Device-and procedure-related complications are rare and mid-term clinical and echocardiographic results are encouraging. Moreover, GSO [GORE® CARDIOFORM Septal Occluder] is technically very easy to implant and has a short learning curve. Larger and randomized trials are needed in the future to establish the safety and the efficacy of the GSO [GORE® CARDIOFORM Septal Occluder] device."

** Now known as GORE® CARDIOFORM Septal Occluder.

Geis 2015

Using the GORE® Septal Occluder** (GSO) in Challenging Patent Foramen Ovale (PFO) Anatomies

N. A. Geis, et. al.

Background

- A single-center experience of 41 patients undergoing PFO closure with the GORE® Septal Occluder**
- All patients had challenging anatomy defined as atrial septal aneurysm (ASA), long PFO tunnel, or both
- Indication for closure:
  - Stroke or TIA (n=37)
  - Emboli to non-cerebral organs (n=2)
  - Neurosurgery in a sitting position (n=1)
  - Hemodynamic compromise and right heart volume overload (n=1)
- Follow-up occurred 6 weeks and 6 months after implantation

Population and Defect Characteristics

- Mean age (± SD): 46.1 ± 11.8 years
- ASA: 27 / 41 (66%)
- Long tunnel PFO (> 10 mm): 32 / 41 (78%)
- Tunnel length > 20 mm: 7 / 41 (17%)
- Both ASA and long tunnel PFO: 18 / 41 (44%)

Results

Mean Procedure Time (minutes ± SD)	37 ± 19
Mean Fluoroscopy Time (minutes ± SD)	5 ± 6
Technical Success	100%
Closure Success	
6 weeks	93%
6 months	98%
Serious Adverse Events	**Number of Patients (%)**
Arrhythmia Requiring Treatment	2 (4.9%)
Cardiac Tamponade	0 (0%)
Frame Fracture with Clinical Sequelae	0 (0%)
Post-Procedural Embolization	0 (0%)
Reintervention	0 (0%)
Thrombus Formation	1 (2.4%)
TIA / Stroke	2 (4.9%)*

* One patient with TIA was subsequently diagnosed with multiple sclerosis. One patient experienced perioperative spinal ischemia due to surgical complication.

Conclusion

"The GORE® Septal Occluder [GORE® CARDIOFORM Septal Occluder] is a suitable device for patent foramen ovale closure in challenging anatomies, including long-tunnel PFOs and atrial septal aneurysms."

** Now known as GORE® CARDIOFORM Septal Occluder.

Freixa 2013

Initial Clinical Experience with the GORE Septal Occluder** for the Treatment of Atrial Septal Defects and Patent Foramen Ovale

X. Freixa, et. al.

Background

- Single-center review of consecutive patients undergoing PFO or ASD closure with the GORE® Septal Occluder**
- 29 PFO patients closed for decompression illness or cryptogenic stroke
- Nine ASD patients closed for a significant left-to-right shunt
- Follow-up: 3 months

Population and Defect Characteristics

	PFO Patients	ASD Patients
Mean Age (years ± SD)	50.2 ± 10.4	45.8 ± 16.7
Mean Defect Size (mm)	9.0 (range 5–16)	12.2 (range 9–17)*
Aortic Rim < 5 mm	0 / 29 (0%)	4 / 9 (44.4%)
Fenestrated Septum	0 / 29 (0%)	2 / 9 (22.2%)
Septal Aneurysm	8 / 29 (27.6%)	3 / 9 (33.3%)
Tunnel PFO	6 / 29 (20.7%)	–

Results

Mean Fluoroscopy Time (minutes ± SD)	6.9 ± 2.7	12.7 ± 6.6
Technical Success	100%	100%
Closure Success 24 hours†	Complete: 97% Mild Shunt: 3%	Complete: 89% Mild Shunt: 11%
Closure Success 3 months ‡	Complete: 75% Shunt with Valsalva: 17% Shunt at Rest: 8%	Complete: 89% Mild Shunt: 11%

† Evaluation by TTE

‡ ASD patients evaluated by TTE, PFO patients evaluated by bubble study and TEE

Serious Adverse Events

- There were no cases of arrhythmia requiring treatment, cardiac tamponade, frame fracture with clinical sequelae, post-procedural embolization, reintervention, thrombus formation, or TIA or stroke reported in any patient.

Conclusion

"Clinical results demonstrated safety with no periprocedural complications, and efficacy with an acceptable rate of residual shunts immediately post implantation and at three-month follow-up. Further data with a larger number of patients and longer follow-up will be necessary to confirm these results, to evaluate the occurrence of device thrombosis and to compare the closure performance with other available devices."

* GORE® CARDIOFORM Septal Occluder *Instructions for Use* recommend treating defects up to 17 mm, at time of publication the *Instructions for Use* recommended treating defects up to 15 mm.

** Now known as GORE® CARDIOFORM Septal Occluder.

Sganzerla 2015

Clinical Performance of the New Gore Septal Occluder** in Patent Foramen Ovale Closure: A Single-Center Experience

P. Sganzerla, et. al.

Background

- The first 22 PFO closure patients, all consecutive, of a single-center experience using the GORE® Septal Occluder**
- All patients had PFO closure for one or more documented cerebral thromboembolic events related to paradoxical embolism
- All patient's shunts were assessed using transcranical Doppler at baseline, 6, and 12 months after implantation

Population and Defect Characteristics

- Mean age (± SD): 52 ± 14 years
- Shunt status at baseline:
  - Moderate to Large: 22 / 22 (100%)
  - Shunt at rest: 15 / 22 (68%)
  - Shunt on Valsalva: 7 / 22 (32%)
- ASA: 9 / 22 (41%)
- Prominent eustachian valve: 2 / 22 (9%)
- Chiari network: 1 / 22 (5%)

Results

Mean Procedure Time (minutes)	41 (range 22–92)
Mean Fluoroscopy Time (minutes)	7 (range 3–16)
Technical Success	100%
Closure Success	
6 months	100%
12 months	100%
Serious Adverse Events	**Number of Patients (%)**
Arrhythmia Requiring Treatment	2 (9.1%)
Cardiac Tamponade	0 (0%)
Frame Fracture with Clinical Sequelae	0 (0%)
Post-Procedural Embolization	0 (0%)
Reintervention	0 (0%)
Thrombus Formation	0 (0%)
TIA / Stroke	0 (0%)

Conclusion

"The initial experience on this single-center, small series of consecutive patients with PFO and previous acute cerebral ischemic disease suggests that the GSO [GORE® CARDIOFORM Septal Occluder] is a safe and effective closure device, straightforward to implant with quick deployment and minimal imaging, and suitable for a range of atrial septal anatomies. Mid-term follow-up results are reassuring in terms of residual shunts, but long-term GSO [GORE® CARDIOFORM Septal Occluder] safety and efficacy must be evaluated over a longer follow-up period in future studies."

** Now known as GORE® CARDIOFORM Septal Occluder.

Søndergaard 2013

The First Clinical Experience with the New GORE® Septal Occluder (GSO)**

Søndergaard, et. al.

Background

- First human experience of the GORE® Septal Occluder** for ASD or PFO closure
- One ASD and 10 PFO patients were included
- Mean follow-up: 70 ± 33 days

Population and Defect Characteristics

- Mean age (± SD): 53 ± 9 years
- Mean defect size: 9.4 mm
- PFO Tunnel > 10 mm: 3 / 10 (30%)

Results

Mean Fluoroscopy Time (minutes)	8.6 (range 5.5–12.1)
Technical Success	100%
Closure Success	
Procedure	91%
Mean 70 days	100%

Serious Adverse Events

- There were no cases of arrhythmia requiring treatment, cardiac tamponade, frame fracture with clinical sequelae, post-procedural embolization, reintervention, thrombus formation, or TIA or stroke reported in any patient.

Conclusion

"This paper documents the first-in-man use of the GORE Septal Occluder [GORE® CARDIOFORM Septal Occluder] and shows promise in handling, occlusion rate and biocompatibility. These early data will require substantiation with anticipated increase of use of the device in Europe and the rest of the world."

** Now known as GORE® CARDIOFORM Septal Occluder.

Grohmann 2014

Transcatheter Closure of Atrial Septal Defects in Children and Adolescents: Single-Center Experience with the GORE® Septal Occluder**

J. Grohmann, et. al.

Background

- Single-center experience with the GORE® Septal Occluder** for ASD closure
- 45 patients
- Indication for closure: significant left-to-right shunt
- Median follow up: 4 months (range 0.2–22)

Population and Defect Characteristics for Successful GORE® Septal Occluder** Implants

- Median age: 6 years (range 3–14)
- Median body weight: 20 kg (range 13–95)
- Median balloon-sized diameter: 12 mm (range 8–18)*
- Deficient retro-aortic rim (< 3 mm): 10 / 41 pts (24%)

Results

Median Fluoroscopy Time (minutes)	9 (range 0–19)
Technical Success	91%†
Closure Success	
Procedure	100%
Median 4 months	100%

† Technical failures: one patient had a defect diameter outside the sizing recommendations, and three had multiple defects that were treated surgically.

Serious Adverse Events

- There were no cases of arrhythmia requiring treatment, cardiac tamponade, frame fracture with clinical sequelae, post-procedural embolization, reintervention, thrombus formation, or TIA or stroke reported in any patient.

Conclusion

"The GSO [GORE® CARDIOFORM Septal Occluder] is an effective device for ASD closure in children and adolescents, even in ASDs not presenting sufficient retro-aortic rims, and in multiple ASDs. Limitations associated with the non-self-centering GSO [GORE® CARDIOFORM Septal Occluder] are larger ASDs with diameters beyond 18 mm. The device's flat profile and conformability enable close septal alignment with high closure-rates—easily visible and verifiable on echocardiography. Nonetheless, there can be no scientific evidence of the GSO's [GORE® CARDIOFORM Septal Occluder] safety until long-term follow-up data from larger series of patients are forthcoming."

* GORE® CARDIOFORM Septal Occluder *Instructions for Use* recommend treating defects up to 17 mm, at time of publication the *Instructions for Use* recommended treating defects up to 15 mm.

** Now known as GORE® CARDIOFORM Septal Occluder.

Nyboe C 2013

First Experiences with the GORE® Septal Occluder** in Children and Adults with Atrial Septal Defects

C. Nyboe, et. al.

Background

- ASD closure in 22 patients (10 children and 12 adults)
- Indications for closure were: clinical symptoms, dilated right ventricle, or significant left-to-right shunt
- Median follow-up: 3 months

Population and Defect Characteristics

- Mean child age (± SD): 6.6 ± 0.9 years
- Mean adult age (± SD): 41.8 ± 4.7 years
- Mean defect size (± SD): 11.4 ± 0.4 mm
- Deficient retro-aortic rim (0–2 mm): 12 / 22 (55%)
- Multiple defects: 6 / 22 (27%)
- ASA: 4 / 22 (18%)

Results

Mean Procedure Time (minutes ± SD)	37.3 ± 4.4
Mean Fluoroscopy Time (minutes ± SD)	11.0 ± 1.6
Technical Success	100 %
Closure Success	
Procedure	100%
Mean 4 months	100%

Serious Adverse Events

- There were no cases of arrhythmia requiring treatment, cardiac tamponade, frame fracture with clinical sequelae, post-procedural embolization, reintervention, thrombus formation, or TIA or stroke reported in any patient.

Conclusion

"The new GORE® Septal Occluder [GORE® CARDIOFORM Septal Occluder] was used successfully for transcatheter closure of ASDs with a diameter ≤ 15 mm in both children (n=10) and adults (n=12). The occluder conformed to different types of septal anatomy including deficient aortic rim, aneurysm, and multiple defects. There were no complications during the procedure or at a mean follow-up at 3.7 ± 0.4 months. Fluoroscopy and procedure times were considerably less than previously reported for closure of ASDs using the GORE® HELEX® Septal Occluder."

** Now known as GORE® CARDIOFORM Septal Occluder.

Smith 2014

UK Multicenter Experience Using the GORE® Septal Occluder (GSO™)** for Atrial Septal Defect Closure in Children and Adults

B. Smith, et. al.

Background

- Multicenter UK experience of GORE® Septal Occluder** closure for ASD
- Inclusion criteria: secundum ASD < 18 mm diameter*
- 22 patients attempted closure with GORE® Septal Occluder** were compared to 22 retrospective AMPLATZER® Septal Occluder patients
- Follow-up: 6 months

Population and Defect Characteristics for GORE® Septal Occluder** Patients

- Mean age: 17 years (range 3–48)
- Mean defect size: 11.2 mm (range 4–16)*
- One patient had concomitant pulmonary balloon valvoplasty

Results for GORE® Septal Occluder** Patients

Mean Fluoroscopy Time (minutes)	8 (range 5–43)
Technical Success	95%†
Closure Success	
Procedure	100%
6 months	100%

† Technical failures: Procedural embolization occurred in one case and the device was successfully retrieved. Patient received a 17 mm AMPLATZER® Septal Occluder.

- There were no statistical differences in clinical outcomes between the GORE® Septal Occluder** and AMPLATZER® Septal Occluder.

Serious Adverse Events

- There were no cases of arrhythmia requiring treatment, cardiac tamponade, frame fracture with clinical sequelae, post-procedural embolization, reintervention thrombus formation, or TIA or stroke reported in any patient.

Conclusion

"This study demonstrates that GSO™ [GORE® CARDIOFORM Septal Occluder] device implantation is feasible and safe in the closure of secundum type atrial defects up to 17 mm in diameter, with excellent early term outcomes. This technology highlights the need for these procedures to be performed by operators with comprehensive knowledge of device design and the variations in the anatomy of the atrial septum and its relations. Given the familiarity of most operators with the HELEX™ [GORE® HELEX® Septal Occluder] implant, it would be anticipated that centers will be able to safely and smoothly introduce this promising device into their practice."

* GORE® CARDIOFORM Septal Occluder *Instructions for Use* recommend treating defects up to 17 mm, at time of publication the *Instructions for Use* recommended treating defects up to 15 mm.

** Now known as GORE® CARDIOFORM Septal Occluder.

Abu-Tair 2016

Transcatheter Closure of Atrial Septal Defects Using the GORE® Septal Occluder** in Children Less Than 10 kg of Body Weight

T. Abu-Tair, et. al.

Background

- All patients weighing less than 10 kg who were closed with the GORE® Septal Occluder** at a single center
- The indication for closure was congestive heart failure where at least 3 of the 4 following criteria had to be present for each patient. The number of patients exhibiting each criteria is listed in parentheses
  - Tachypnea (n=12)
  - Failure to thrive defined as body weight below the fifth percentile (n=6)
  - Increased rate of pulmonary infections (n=13)
  - Right atrial and / or right ventricular enlargement (n=14)
- Median follow-up: 1.6 years (range 0.5–4.2)
- Comparisons were made between left disc diameters of the GORE® Septal Occluder** (GSO) that was implanted and the comparable AMPLATZER® Septal Occluder (ASO) that would otherwise have been recommended

Population and Defect Characteristics

- Median weight: 8900 grams (range 6350–9650)
- Median age: 378 days (range 258–1036)
- Median ASD diameter: 11 mm (range 5–17)
- Median septal length: 30 mm (range 25–35)
- Multifenestrated defect: 5 / 14 (36%)
- Deficient retro-aortic rim (< 5mm): 2 / 14 (14%)

Results

Technical Success	100%
Closure Success	
Median 1.6 years	100%

- Color-coded duplex sonography of the femoral, iliacal, and lower inferior caval veins at 1 month post-procedure showed regular venous flow in all patients.
- The diameter of the left atrial disc of the GSO implanted was significantly smaller than the left atrial disc of the ASO that would have been recommended (mean 21.8 vs 24.3 mm, p=0.035).
- There were no cases of arrhythmia requiring treatment, cardiac tamponade, frame fracture with clinical sequelae, post-procedural embolization, reintervention, thrombus formation, or TIA or stroke reported in any patient.

Conclusion

"Our data suggest that the GSO [GORE® CARDIOFORM Septal Occluder] is even applicable in infants and children with a body weight of less than 10 kg. We report on 14 successfully closed ASDs without vascular access complications despite the use of a 10-Fr introducer sheath. Due to its flexible design, light weight, and the possibility to use significantly smaller occluders, the GSO [GORE® CARDIOFORM Septal Occluder] seems to be a suitable device to close ASDs in small children with insufficient and unstable rims, a small atrial septum, and soft surrounding tissue. Despite the small number of patients included, the results of this and previous reports [12, 23, 26] suggest positive expectations for a low rate of complications in this younger patient group."

** Now known as GORE® CARDIOFORM Septal Occluder.

Lombardi 2013

Feasibility and Safety of a New Generation of Gore Septal Occluder** Device in Children

Lombardi, et. al.

Background

- Single-center experience of pediatric ASD patients with GORE® Septal Occluder** Closure attempted
- 10 pediatric patients, all with evidence of right heart volume overload, were included
- Follow-up: 1 year

Population and Defect Characteristics

- Mean age: 8.3 years (range 4–14)
- Mean body surface area: 1.08 m^2 (range 0.69–1.39)
- Mean defect size: 10.5 mm (range 7–14.5)

Results

Mean Fluoroscopy Time (minutes)	8.6 (range 5.5–12.1)
Technical Success	80%*
Closure Success	
24 hours	100%
1 year	100%

* Technical failures were related to limited septal tissue and device instability. In one patient no ASD closure was performed, in the other a 15 mm AMPLATZER® Septal Occluder was successfully implanted.

Serious Adverse Events

- There were no cases of arrhythmia requiring treatment, cardiac tamponade, frame fracture with clinical sequelae, post-procedural embolization, reintervention, thrombus formation, or TIA or stroke reported in any patient.

Conclusion

"The new GORE Septal Occluder [GORE® CARDIOFORM Septal Occluder] device appears to be a feasible, well-tolerated and successful tool for the closure of an ASD of 15 mm or less in childhood."

** Now known as GORE® CARDIOFORM Septal Occluder.

PFO Closure Outcomes Summary

Outcomes	Thomson 2013	Butera 2013	Knerr 2013	Darsaklis 2013	Musto 2013	Geis 2015	Frexia 2014	Sganzerla 2015	Søndergaard 2013	All Combined
Subjects	229	122	60	48	45	41	29	22	10	606
Technical Success	100%	100%	98%	100%	100%	100%	100%	100%	100%	99.8%
Closure Success at Follow-up (time point)	100% (3 months)	98% (9 months)	100% (12 months)	93% (4 months)	96% (6 months)	98% (6 months)	75% (3 months)	100% (12 months)	100% (70 days)	97.3%
Serious Adverse Events										
Arrhythmia Requiring Treatment	2 (0.9%)	4 (3.3%)	4 (6.7%)	0 (0%)*	0 (0%)	2 (4.9%)	0 (0%)	2 (9.1%)	0 (0%)	14 (2.3%)
Cardiac Tamponade	0 (0%)	0 (0%)	1 (1.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.2%)
Frame Fracture with Clinical Sequelae	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Post-Procedural Embolization	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Reintervention	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Thrombus Formation	1 (0.4%)	0 (0%)	1 (1.7%)	0 (0%)	0 (0%)	1 (2.4%)	0 (0%)	0 (0%)	0 (0%)	3 (0.5%)
TIA / Stroke	0 (0%)	2 (1.6%)	2 (3.3%)	0 (0%)	0 (0%)	2 (4.9%)	0 (0%)	0 (0%)	0 (0%)	4 (1.0%)

* One patient had a documented arrhythmia, however no treatment was described.

ASD Closure Outcomes Summary

Outcomes	Grohmann 2014	Nyboe 2013	Smith 2013	Abu-Tair 2016	Lombardi 2013	Frexia 2014	Søndergaard 2013	All Combined
Subjects	45	22	22	14	10	9	1	123
Technical Success	91%	100%	95%	100%	80%	100%	100%	94.3%
Closure Success within 24 hours	100%	100%	100%	N / A	100%	89%	100%	99.0%
Closure Success at Follow-up (time point)	100% (4 months)	100% (4 months)	100% (6 months)	100% (1.6 years)	100% (1 year)	89% (3 months)	100% (70 days)	99.2%
Serious Adverse Events								
Arrhythmia Requiring Treatment	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Cardiac Tamponade	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Frame Fracture with Clinical Sequelae	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Post-Procedural Embolization	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Reintervention	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Thrombus Formation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
TIA / Stroke	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

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