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.

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 Transient Ischemic Attack (TIA), or thrombus formation. The published reports may not have adverse events described by the serious or non-serious description that has been adopted here. For details of non-serious adverse events or other information beyond these summaries, please review the original publication.

Organization
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
SD – standard deviation
Technical Success – defined as successful implantation of a GORE® CARDIOFORM Septal Occluder in patients where an attempt is made
TEE – transesophageal echocardiography
TIA – transient ischemic attack
TTE – transthoracic echocardiography
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: four months (range 0.2–22)

Population and Defect Characteristics for Successful GORE® Septal Occluder** Implants
• Median age: 6 years (range 3–14)
• Median bodyweight: 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

<table>
<thead>
<tr>
<th>Median Fluoroscopy Time (minutes)</th>
<th>9 (range 0–19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success</td>
<td>91%†</td>
</tr>
<tr>
<td>Closure Success</td>
<td></td>
</tr>
<tr>
<td>Procedure</td>
<td>100%</td>
</tr>
<tr>
<td>Median 4 months</td>
<td>100%</td>
</tr>
</tbody>
</table>

† 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® 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® 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® 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.
** Now known as GORE® CARDIOFORM Septal Occluder.
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: three 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" 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."

* Current GORE® CARDIOFORM Septal Occluder Instructions for Use recommendations allow treating defects up to 17 mm.
** Now known as GORE® CARDIOFORM Septal Occluder.
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: six 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

<table>
<thead>
<tr>
<th>Mean Fluoroscopy Time (minutes)</th>
<th>8 (range 5–43)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success</td>
<td>95%†</td>
</tr>
<tr>
<td><strong>Closure Success</strong></td>
<td></td>
</tr>
<tr>
<td>Procedure</td>
<td>100%</td>
</tr>
<tr>
<td>6 months</td>
<td>100%</td>
</tr>
</tbody>
</table>

† 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® 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."

** Now known as GORE® CARDIOFORM Septal Occluder.
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: one year

Population and Defect Characteristics
• Mean age: 8.3 years (range 4–14)
• Mean body surface area: 1.08 m² (range 0.69–1.39)
• Mean defect size: 10.5 mm (range 7–14.5)

Results

<table>
<thead>
<tr>
<th>Mean Fluoroscopy Time (minutes)</th>
<th>8.6 (range 5.5–12.1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success</td>
<td>80%*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Closure Success</th>
<th>24 hours</th>
<th>1 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

* 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** 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.
### ASD Closure Outcomes Summary

<table>
<thead>
<tr>
<th>OUTCOMES</th>
<th>Grohmann 2014</th>
<th>Nyboe 2013</th>
<th>Smith 2014</th>
<th>Lombardi In Press</th>
<th>All Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects</td>
<td>45</td>
<td>22</td>
<td>22</td>
<td>10</td>
<td>99</td>
</tr>
<tr>
<td>Technical Success</td>
<td>91%</td>
<td>100%</td>
<td>95%</td>
<td>80%</td>
<td>93%</td>
</tr>
<tr>
<td>Closure Success within 24 hours</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Closure Success at Follow-up (time point)</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Serious Adverse Events</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arrhythmia Requiring Treatment</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Cardiac Tamponade</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Frame Fracture with Clinical Sequelae</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Post-Procedural Embolization</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Reintervention</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Thrombus Formation</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>TIA / Stroke</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>
References


