

Closing Remarks

INTERNATIONAL

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GORE® CARDIOFORM SEPTAL
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OUTCOMES IN YOUR PATIENTS

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The Gore REDUCE Clinical Study is being conducted through an FDA Investigational Device Exemption (IDE).

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CASE STUDY

GORE® CARDIOFORM Septal Occluder in challenging anatomies: A case series

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Percutaneous closure of patent foramen ovale (PFO) as a secondary prevention for cryptogenic stroke is emerging as a viable treatment option in patients with high likelihood of PFO related index event¹ and high risk of recurrence.^{2,3} The preliminary data of the randomized studies — CLOSE Trial⁴ and Gore REDUCE Clinical Study (shared in May 2017 at the European Stroke Organization Conference, ESOC in Prague) — are the most recent confirmation of this statement.

In the field of structural interventional cardiology, the percutaneous closure of PFO is a relatively easy procedure, but some challenging anatomies may make the procedure at risk of failure or complications, if a high level of technical experience and the most anatomically suitable closure device are not available.



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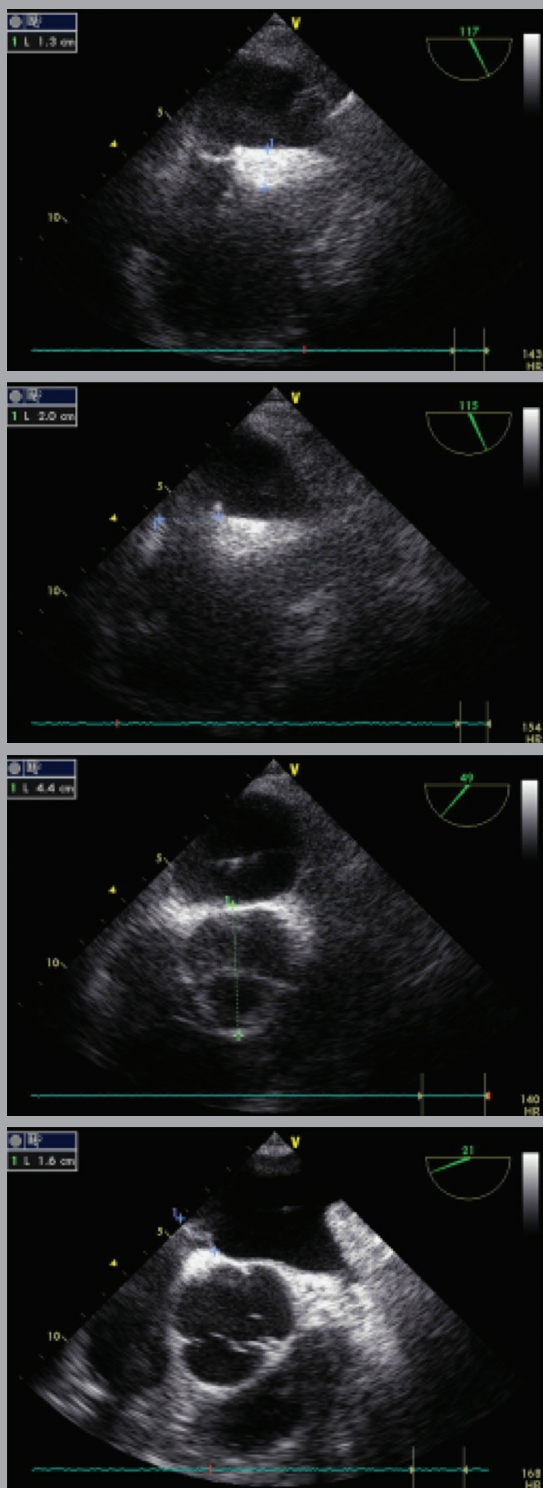


Figure 1.

During the percutaneous PFO closure, the most challenging anatomies to deal with are the following, alone or in combination:

- Significant aneurysm of the septum primum (an aneurysm with an excursion of more than 15 mm)
- Fragile septum primum (a very thin and floating septum primum)
- Hypertrophic septum secundum (a “lipomatous” septum secundum thicker than 10 mm)
- Deficient aortic rim (an anterior aortic rim less than 5 mm)

A prominent eustachian valve (more than 10 mm) and an ectatic aortic root (more than 37 mm) are additional factors of difficulty.

In these particular anatomical settings, the metallic, self-centering devices, due to their rigid structure, may show some limitations in terms of incomplete apposition to the underlying structures with subsequent residual shunt. Moreover, a rigid device may lead to an erosion of a very thin septal structure.⁵

On the contrary, the GORE® CARDIOFORM Septal Occluder, due to its intrinsic characteristics of two independent conformable discs with minimal wire frame completely covered in thromboresistant ePTFE, may provide an optimal apposition even in these challenging anatomies.

The present article reports the clinical, anatomical, and procedural details of three cases with a challenging anatomy treated with Gore devices.

All three patients suffered an ischemic cryptogenic stroke within six months and presented a PFO associated to a severe right-to-left shunt. After a full clinical and instrumental evaluation aimed to exclude any other identifiable cause of stroke, a percutaneous treatment of PFO was scheduled.

In our institution, the patients undergo the percutaneous closure of PFO if they meet one or more of the following high-risk clinical and anatomical features: permanent right-to-left shunt, atrial septal aneurysm, prominent eustachian valve, recurrent brain ischemia, previous deep vein thrombosis or thrombophilia not requiring anticoagulation.⁶ The procedures are performed under

fluoroscopic and transesophageal echocardiographic (TEE) guidance. A six-month follow-up with transthoracic echocardiography (TTE) and transcranial Doppler is performed in order to evaluate any residual right-to-left shunt.

Case One

A 57-year-old male.

The intraoperative TEE showed a septum secundum diameter of 13 mm, a hypermobile thin septum primum, a 20 mm diameter fossa ovalis, an aortic root of 44 mm, an aortic rim of 2 mm, a PFO width of 6 mm, and a PFO length of 8 mm.

In this particular case, the challenging anatomy is represented by the contemporary presence of a hypertrophic septum secundum, a hypermobile and thin septum primum, a relatively small fossa ovalis, a dilated aortic root, and a minimal aortic rim (*Figure 1*).

A 30 mm GORE® CARDIOFORM Septal Occluder was selected and implanted. The 8 Fr femoral vein sheath was exchanged over a wire for an 11 Fr introducer sheath. The delivery catheter was then advanced through the introducer sheath and across the PFO. The left atrial disc was deployed by advancing the slider, and the device was then pulled back against the atrial septum. The right atrial disc was then deployed and subsequently imaged by TEE and fluoroscopy, the atrial septum and device were placed in a neutral position and the device was then unlocked. Fluoroscopy showed the three eyelets and the locking loop appropriately deployed. Echocardiography demonstrated a well positioned device.

It is noteworthy that the device perfectly fits to the aortic root anteriorly, the thick septum secundum superiorly, and the thin septum primum posteriorly and inferiorly (*Figure 2*). The final echo contrast test revealed no residual right-to-left shunt.

Case Two

A 39-year-old male.

The intraoperative TEE showed a regular septum secundum, a significant aneurysm of the septum primum, a fossa ovalis diameter of 30 mm, an aortic root of 42 mm, an aortic rim of 3 mm, a PFO width of 10 mm, a PFO length of 6 mm, and a prominent eustachian valve.

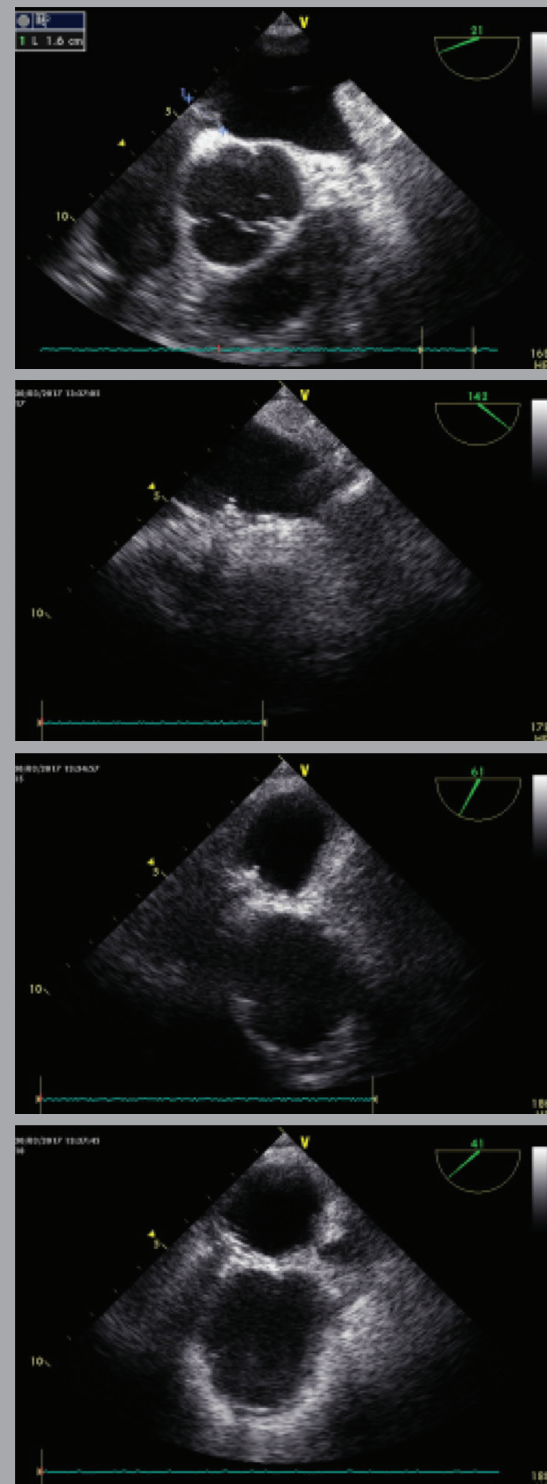


Figure 2.

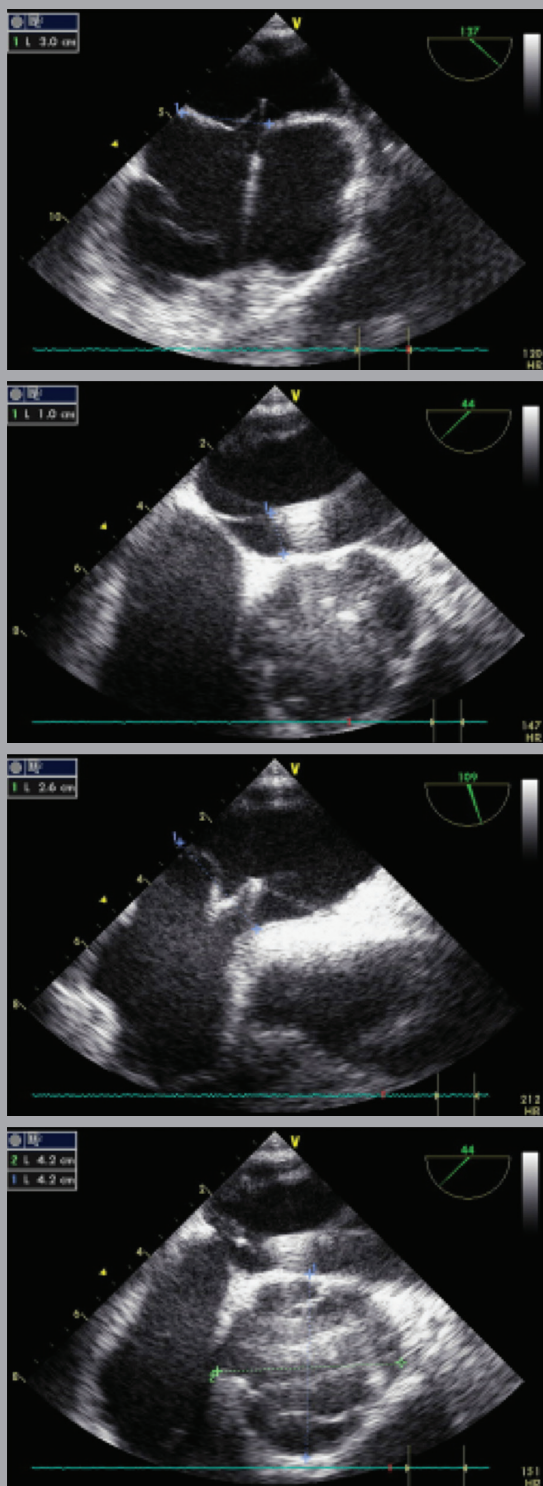


Figure 3.

In this particular case, the challenging anatomy is represented by the contemporary presence of a significant aneurysm of the septum primum, an ectatic aortic root, a minimal aortic rim, and a prominent eustachian valve (*Figure 3*).

A 30 mm GORE® CARDIOFORM Septal Occluder was selected and implanted, according to the standard procedure. It is of interest that, after the left atrial disc forming, a clockwise rotation before the pullback was necessary to achieve an optimal contact with the septal structures. The subsequent opening of the right disc allowed a complete fixation of the significant aneurysm (*Figure 4*), without any interference with the prominent eustachian valve. The final echo contrast test revealed a trivial residual right-to-left shunt.

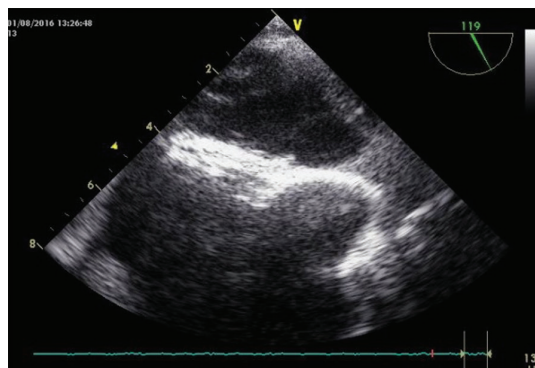


Figure 4.

Case Three

A 42-year-old female.

The intraprocedural TEE showed a septum secundum of 11 mm, an aneurysm of the septum primum, a fossa ovalis diameter of 24 mm, a regular aortic root, an aortic rim of 6 mm, a PFO width of 4 mm and a length of 14 mm, and a prominent eustachian valve. In this particular case, the challenging anatomy is represented by the contemporary presence of a hypertrophic septum secundum, an aneurysm of the septum primum, a long (but compliant) tunnel, and a prominent eustachian valve (*Figure 5*).

A 25 mm GORE® CARDIOFORM Septal Occluder was selected and implanted according to the standard procedure. Even in this case, the device fit perfectly to the aortic root anteriorly, the thick septum secundum superiorly, and the thin septum primum posteriorly and inferiorly. The long compliant tunnel

was not a limitation to the use of the device. The eustachian valve did not interfere with the device (*Figure 6*). The final echo contrast test revealed no residual right-to-left shunt.

The following clinical course was uneventful and the six-month echocardiography follow-up showed no or trivial residual shunt in all three cases. This case series shows that GORE® CARDIOFORM Septal Occluder performs well in not only conventional septal anatomies, but also in complex or very complex septal anatomies and may overcome the limitations of self-centering metal devices in particular situations such as the hypertrophic septum secundum and the deficient aortic rim.

References

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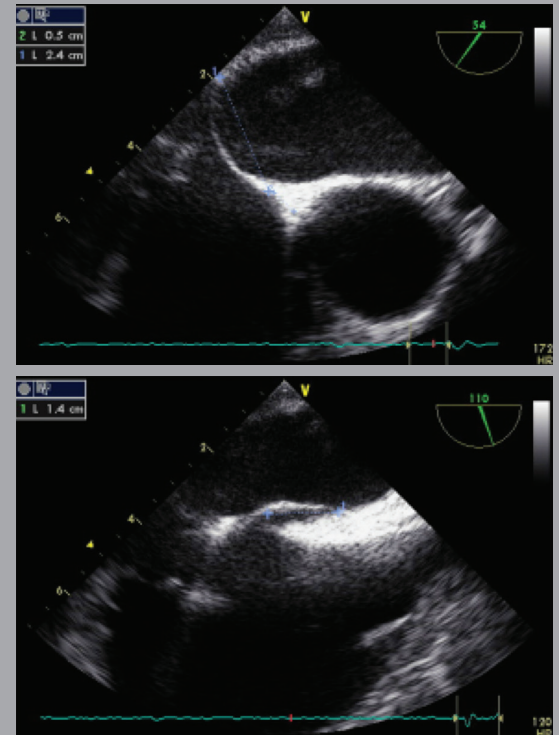


Figure 5.

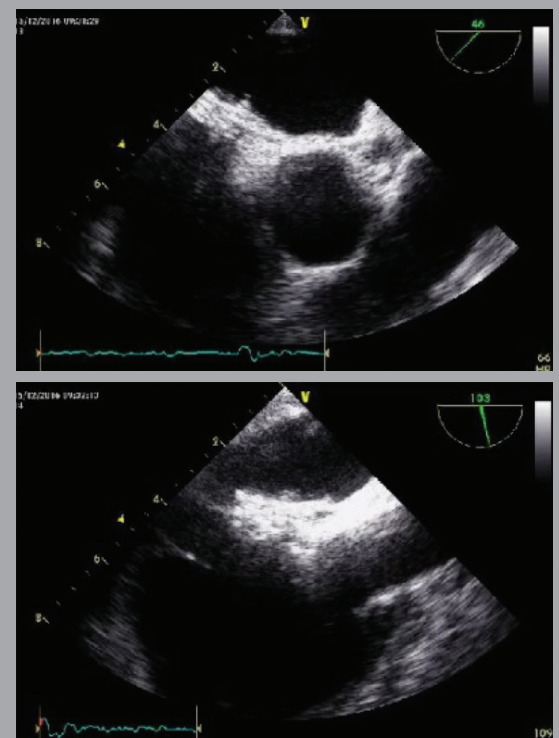


Figure 6.

CLINICAL SUMMARY

Multicenter mid-term follow-up results using the GORE® Septal Occluder* for atrial septal defect closure in pediatric patients

Grohmann J, Wildberg C, Zartner P, *et al.*

Objectives

The authors' objective was to assess the safety and efficacy of the GORE® CARDIOFORM Septal Occluder used for device closure of significant secundum-type atrial septal defects focusing on pediatric patients.

Methods: Multicenter retrospective analysis of 173 consecutive patients implanted with a GORE® CARDIOFORM Septal Occluder for at least 12 months (one- to four-year mid-term follow-up).

Patient Characteristics

Age: Median 6 years (range 0.7–17.9)

Weight: Median 21 kg (range 6.4–95)

Defect characteristics:

- Single ASD II: 131 (76%)
- Multiple defects: 42 (24%)
- Atrial septal aneurysm: 25 (14%)
- Small retro-aortic rim: 33 (19%)

Conclusions

- Longer term follow up demonstrated GORE® CARDIOFORM Septal Occluder to be an efficient device for ASD closure in children
- No erosion or perforation were reported

“We maintain that GSO [GORE® CARDIOFORM Septal Occluder] may be considered the ASD closure-device of choice to implant in deficient retroaortic rims and / or when most of the atrial septum requires covering in conjunction with relatively large and / or multiple defects.”¹



GORE® CARDIOFORM Septal Occluder

Results

Median follow-up period, months (range)	20 (12–51)
Fluoroscopy, median (IQR, range), minutes	10 (6.9–14.2, 0–46)
ASD size** (IQR, range), mm	12 (10–14, 6–20)
ASD native† median (IQR, range), mm	9.5 (7–11, 5–18)

Closure results

Closure success (n = 173)	
Complete closure	95.1%
Residual shunt < 3 mm	4.6%

Safety

Adverse events	Procedural	Follow-up 20 months
Arrhythmia	5 (2.8%)	6 (3.4%)
Arrhythmia with treatment	0 (0%)	0 (0%)
Embolization	1 (0.5%)	0 (0%)
Migraine	0 (0%)	3 (1.8%)

** ASD balloon sizing performed in 133 patients (77%).

† ASD's native diameter recorded in 40 patients (23%).

* Now known as GORE® CARDIOFORM Septal Occluder.

1. Grohmann J, Wildberg C, Zartner P, *et al.* Multicenter midterm follow-up results using the gore septal occluder for atrial septal defect closure in pediatric patients. *Catheterization & Cardiovascular Interventions* 2017;89(7):E226-E232.

CLINICAL EVIDENCE

Gore® Cardioform Septal Occluder

Clinical evidence in ASD treatment

Increase in anatomical complexity 

Multi-fenestrated defects

Grohmann J, Wildberg C, Zartner P, *et al.* Multicenter midterm follow-up results using the gore septal occluder for atrial septal defect closure in pediatric patients. *Catheterization & Cardiovascular Interventions* 2017;89(7):E226-E232.

Grohmann J, Höhn R, Fleck T, Schmoor C, Stiller B. Transcatheter closure of atrial septal defects in children and adolescents: single-center experience with the GORE® septal occluder. *Catheterization & Cardiovascular Interventions* 2014;84(6):E51-E57.

Freixa X, Ibrahim R, Chan J, *et al.* Initial clinical experience with the GORE septal occluder for the treatment of atrial septal defects and patent foramen ovale. *EuroIntervention* 2013;9(5):629-635.

Søndergaard L, Loh PH, Franzen O, Ihlemann N, Vejlsstrup N. The first clinical experience with the new GORE® septal occluder (GSO). *Eurointervention* 2013;9(8):959-963.

Low mean body weight < 35 kg

Lombardi M, Tagliente MR, Pirolo T, Massari E, Milella L, Vairo U. Feasibility and safety of a new generation of gore septal occluder device in children. *Journal of Cardiovascular Medicine* 2016;17(Supplement 2):e249-e251

< 12 kg

Grohmann J, Höhn R, Fleck T, Schmoor C, Stiller B. Transcatheter closure of atrial septal defects in children and adolescents: single-center experience with the GORE® septal occluder. *Catheterization & Cardiovascular Interventions* 2014;84(6):E51-E57.

< 10 kg

Abu-Tair T, Wiethoff CM, Kehr J, Kuroczynski W, Kampmann C. Transcatheter closure of atrial septal defects using the GORE® Septal Occluder in children less than 10 kg of body weight. *Pediatric Cardiology* 2016;37(4):778-783.

RIM deficiency

Grohmann J, Wildberg C, Zartner P, *et al.* Multicenter midterm follow-up results using the gore septal occluder for atrial septal defect closure in pediatric patients. *Catheterization & Cardiovascular Interventions* 2017;89(7):E226-E232.

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Freixa X, Ibrahim R, Chan J, *et al.* Initial clinical experience with the GORE septal occluder for the treatment of atrial septal defects and patent foramen ovale. *EuroIntervention* 2013;9(5):629-635.

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