Congenital Heart Disease

Tech Science Press

DOI: 10.32604/CHD.2020.012750

ARTICLE

Percutaneous Closure of Patent Foramen Ovale and Secundum Atrial Septal Defects with the GORE® CARDIOFORM Septal Occluder: Incidence and Implications of Device Wire Frame Fracture

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Received: 13 July 2020 Accepted: 20 August 2020

ABSTRACT

Background: Trans-catheter closure has become the treatment of choice for patent foramen ovale (PFO) and ostium secundum atrial septal defects (ASD). A wide variety of devices are commercially available, however, concerns have been raised about the risk of cardiac erosion associated with stiff/rigid devices. The GORE® CARDIOFORM Septal Occluder (GSO) is a double-disc, soft and conformable device with no reported incidence of cardiac erosions. However, wire frame fracture (WFF) have been reported. **Aim:** To assess the incidence and clinical significance of WFF after GSO implantation in paediatric patients. **Methods:** Seventy-seven consecutive patients were enrolled. Periprocedural and follow-up assessments included clinical, echocardiographic, and X-ray fluoroscopy examinations. **Results:** Mean patient age was 10.0 ± 3.9 years. In 7 patients the indication was PFO closure, in 70 patients ASD closure. Mean follow-up period was 3.1 ± 1.3 years. X-ray fluoroscopy evaluations were available for 60 patients. WFF was detected in a total of 22 (35.4%) GSO devices. Three WFF compromised the outer perimeter of the device. Incidence of WFF was higher for the 30 mm GSO device (58%; $p = 0.001$). A multivariate analysis confirmed that the GSO device diameter ($p = 0.013$; F = 6.7) and stretched ASD diameter ($p = 0.034$; F = 4.38) were independent factors related to WFF. WFF did not result in any clinical sequelae/patient harm. Residual shunt was observed in 4 patients (5%) at 24 hours following procedure. **Conclusion:** The GSO device is safe and effective for PFO and ASD closure. WFF was not associated with clinical sequelae or device instability. Device diameter strongly correlates with incidence of WFF.

KEYWORDS

Atrial septal defect; patent foramen ovale; percutaneous; transcatheter; catheterization; congenital heart disease; GORE®; CARDIOFORM Septal Occluder; wire frame fracture

1 Introduction

Trans-catheter closure of patent foramen ovale (PFO) and ostium secundum atrial septal defects (ASD) continue to increase as devices, delivery equipment, and implantation skills improve. Efficiency, procedural safety and positive clinical outcomes has also allowed for percutaneous treatment of challenging defects in paediatric/adolescent patients [1–3].

King and Mills first described percutaneous closure of an ostium secundum atrial septal defect in a human in 1976 using an umbrella-like device [4]. Advances in device technology and device options have now led to the majority of these procedures (5–90%) being closed percutaneously within the paediatric population with good long-term results [5–8]. Although, trans-catheter closure of PFO/ASD is recognised as a safe procedure, potential serious device-related adverse events can include cardiac erosion, device embolization, thromboembolic events, significant rhythm or conductance disturbance as well as device fractures or dysfunction resulting in instability and fragmentation [9–13]. Deficient septal rims, device movement, as well as rigidity of device have been reported as potential risk factors for cardiac erosions [13]. Arrhythmias and conduction complications may be explained by residual inflammation or by chronic mechanical irritation caused by the device [14,15]. The pathophysiology of device wire frame fracture (WFF) remains unclear [10,11,16].

GORE Occluder devices (W.L. Gore & Associates, Inc. Newark, DE) have progressively developed over the last two decades. The GORE® CARDIOFORM Septal Occluder (GSO) frame structure consists of five helically wound platinum-filled nitinol wires compared to the single wire frame design for its predecessor (GORE® HELEX® Septal Occluder). The GSO wire frame is also completely covered by expanded polytetrafluroethylene (ePTFE). The combination of the nitinol wire frame structure and FEP/ePTFE covering provide for a highly conformable device with less thrombotic and erosive potential. Despite significant improvements to the GSO device, there have been reports of GSO wire frame fractures in PFO/ASD procedures for adults as well as paediatric patients [16–18].

This study reports findings of GSO device wire frame integrity for ostium secundum ASD/PFO closure in a paediatric cohort at mid- to long-term follow-up from the University Hospital of Padova, Italy. Secondary endpoints evaluated closure effectiveness and evidence of any device-related complications during follow-up.

2 Methods

2.1 Patients

In this prospective study, we enrolled all the patients that performed percutaneous ASD/PFO closure with a GSO device between January 1, 2012 and December 31, 2018 at the Paediatric Unit, Department of Women and Children's Health, University Hospital of Padova, Italy.

Inclusion criteria were an ostium secundum ASD of <17 mm in diameter, echocardiographic evidence of right ventricular (RV) volume overload, adequate septal rims (≥5 mm; except for the aortic rim), and patient body weight (BW) >15 kg. Exclusion criteria included ASD size >17 mm, absent interatrial septum or common atrium, proximity of ASD to important cardiac structures such as atrioventricular (AV) valves and pulmonary veins, and in the presence of other intracardiac associated anomalies.

The inclusion criteria for PFO closure was cardioembolic stroke in 3 patients and desaturation during exercise test as well as polyglobulia associated with corrected pulmonary stenosis/pulmonary atresia in 6 patients.

2.2 Study Device

The GSO device is a second generation septal occluder manufactured by W. L. Gore & Associates Inc. Newark, DE. The device consists of an implantable occluder and a 10 Fr catheter delivery system. The occluder is comprised of a platinum-filled nickel-titanium (Nitinol) five-wire frame design that is covered with an expanded polytetrafluoroethylene (ePTFE) membrane. The ePTFE includes a hydrophilic surface treatment to facilitate echocardiographic imaging of the device and surrounding tissue during implantation. When fully deployed, the device assumes a double-disc configuration.

Device deployment first involves deployment of the left disc into the left atrium (LA) towards the pulmonary veins by the extension of a rigid mandrel (whose length varies depending on device size). The LA must be capable of accommodating the length of the mandrel without causing injury to the atrial wall, the appendage, or the pulmonary veins. It is important to have good synergy between the interventionist and transesophageal echocardiographic (TOE) operator as the mandrel is extended [19]. The right disc is deployed after the left disc is fully deployed and pulled onto the surface of the left atrial septum. The device is locked by a simple intrinsic locking mechanism that passes through the centre of the device anchoring the discs once it is confirmed that both left and right discs appear planar and are apposed to the septum with septal tissue between the discs. The device is re-positionable prior to locking, and has a retrieval cord to allow for tension-free assessment after locking. If felt to be in sub-optimal position after locking, the retrieval cord can be used to remove the device from the body without the need for snaring.

The GSO device was available in diameters of 15, 20, 25, 30 mm at the time when the first patient in this study was implanted with the device. The platinum-filled Nitinol wire thickness increases with device diameter size and the platinum-filled core enhances fluoroscopic visibility. The five-wire frame design and ePTFE membrane serve to enhance the conformability and septal apposition of the GSO device. The device sizes/configurations limits use to defects less than 17 mm in size.

2.3 Study Procedure

The indication for closure and percutaneous feasibility was assessed by trans-thoracic echocardiography (TTE). Institutional indications for septal defect occlusion were applied. Written informed consent was obtained in all cases.

All procedures were performed under general anaesthesia with contemporary fluoroscopy and TOE guidance to minimize radiation exposure. All patients received 100 units/kg of heparin and antibiotic prophylaxis prior to the procedure. An 11 Fr Terumo sheath (Terumo Europe NV) was used for all procedures. The sizing of the defect of was performed for all cases with an Amplazter sizing balloon (Abbott Laboratories). Device type and size were chosen according to the stretched diameter during the sizing process. Factors such as tissue rims and defect size were also taken into consideration. A GSO device was considered for central ASDs with a stretch diameter <17 mm and for ASDs with deficient aortic rims with a stretched diameter of <15 mm. The GSO device was oversized when the operator felt that increased stability could be achieved by having the discs splayed around the aortic root. This also facilitated confident deployment in patients with deficient antero-superior rims. The device size was ultimately at the discretion of the implanter. Positioning of the device was guided by echocardiographic imaging and fluoroscopy.

Anti-platelet therapy (acetylsalicylic acid; 5 mg/kg/day; maximum 300 mg) and endocarditis prophylaxis was administered for 6 months following implantation.

2.4 Follow-up

Clinical follow-up included a TTE evaluation within 24 hours and serial outpatient clinical examinations with an EKG and TTE at 6, 12, and 24 months following implantation. TTE examination was performed by imaging the atrial septum from multiple planes to evaluate device position, with particular attention on visualization of the left and right atrial discs to rule out residual shunting, impingement of device on neighbouring structures (including systemic and pulmonary veins, AV valves, and aortic root), and intracardiac thrombus or vegetation formation. Estimation of right ventricle (RV) pressure was determined by tricuspid and pulmonary regurgitation jet velocities and by systolic ventricular septal configuration. The right ventricular end-diastolic diameter (RVEDD) was also measured [20].

Fluoroscopic evaluation to assess device integrity was performed in 60/77 at >12 months following implantation. A fluoroscopic frame rate of 15 frames per second was used. The device was interrogated in two projections: left and right caudal oblique at 60° and 30°, respectively. The angle (left-right and cranio-caudal) was adjusted in order to have the best alignment for en face view (right oblique) and orthogonal view (left oblique). Two single shots were collected for each patient and separately examined by two different interventional cardiologists. A score from 0 to 2 was related to the integrity of the wire frame structure of the device.

Adverse events were recorded post-procedure and during follow-up. A score of 0 was assigned to a device with no fractures; a score of 1 for a device with fracture(s) that did not occur in the outer periphery of the device, and a score of 2 for a device that had fracture(s) occurring in the outer perimeter of the device. All adverse events (AEs) that occurred after procedure or during clinical follow-up were recorded.

A database was created to report the following:

- Patient age
- Body surface area (at procedure, fluoroscopic follow-up and last clinical follow-up)
- Maximum ASD size (as measured by TEE)
- ASD stretch diameter (as measured by balloon sizing)
- Anterior and posterior rim quality (as determined by TEE)
- GSO device size
- Qp/Qs at diagnosis
- History of other cardiac anomalies
- Pulmonary hypertension
- Genetic syndromes
- RVEDD: M-mode (at procedure and last clinical follow-up)
- Fluoroscopy (at >12 months following implantation)
- AEs following procedure
- Presence of interatrial regurgitation with color Doppler on the day after closure and during follow-up
- Presence of device WFF

2.5 Statistical Methods

Patient and follow-up data was analysed descriptively. Statistical analysis was completed using SPSS version 25 (IBM SPSS Software). Continuous data was summarized by median and quartiles (interquartile range, IQR) or as mean ± standard deviation (SD). Categorical variables are presented as absolute numbers and percentages. Comparison between fractured and non-fractured devices was made by student's *t*-test for unpaired data. Comparison between device size and events was performed with the Mann-Whitney U test. Correlation between continuous data was performed with the Spearman test. Multivariate analysis was performed to include data with a significant *p* value at univariate analysis. A null hypothesis was rejected for *p* values less than 0.05.

3 Results

3.1 Patients' Characteristics

During the study period (January 1, 2012 to December 31, 2018), 77 patients were enrolled and underwent percutaneous trans-catheter PFO/ASD closure with the GSO device. Principle characteristics of the studied population and GSO device sizes implanted are reported in (Tab. 1).

Table 1: characteristics of the studied population

Patient characteristics	All patients (N = 77)
Male/female	37/40
Age (years)	
<10	41 (53%)
≥10	36 (47%)
Weight (kg)	
<15	0
≥15	77
Body Surface Area (kg/m^2)	1.19 ± 0.34
Diagnosis	
Isolated ASD	69 (89%)
ASD and others CHD	8 (11%)
Pulmonary hypertension	1
Genetic syndromes	3
Hemodynamic data	
Qp/Qs (AV ± SD)	1.7 ± 0.6
Mean RV/LV	0.7 ± 0.2
Number of implanted GSO per patient	
One	75
Two	2
GSO size (mm) (N = 79)	
20	8
25	34
30	37
Procedure characteristics	
Fluoroscopy time (Median & IQR)	6 min (5–8)
Adverse events (AE)	
Any AE	3
Any high severity AE	0

Mean patient age at implantation was 10.0 ± 3.9 years (range: 5–27). Mean body weight (BW) at implantation was 37.7 ± 17.3 kg (range: 18–94). Mean patient height at implantation was 138.2 ± 19.2 cm (range: 110–177). The mean ASD diameter measured by TEE was 9.7 ± 2.7 mm (range: 4–17; IQR: 8–11) with a stretched mean diameter as measured by stop-flow balloon sizing of 12.3 ± 3.3 mm (range: 7–30; IQR: 10–14).

In 69 (89%) patients the ASD or PFO was an isolated defect, while for 8 patients it was associated with different findings such as coronary anomaly (right coronary from left sinus, 1), ventricular septal defect (2),

bicuspid pulmonary valve (1), pulmonary dysplasia (1), critical pulmonary status post angioplasty and PDA stenting (1), and mitral valve (MV) prolapse with trivial regurgitation (1). One patient had a history of multiple cerebellar embolic strokes before the diagnosis of an ASD. Three patients were syndromic (DiGeorge, WAGR, and trisomy 21).

Pre-procedure TOE evaluations highlighted that 9 patients had deficient retro-aortic rims (<5 mm) and 2 patients had deficient posterior rims (<7 mm). ASD characteristics are reported in (Tab. 2).

Table 2: ASD characteristics

ASD features (N = 78)	
ASD size at echo (mm)	
PFO	7
<10	32
10–13	33
14–17	6
Aneurysmal oval fossa	4
Multi fenestrated ASD	9
ASD diameter (mm)	9.7 ± 2.7
ASD stretched diameter not including PFO (mm)	12.3 ± 3.3
GSO/ASD ratio	3.0 ± 0.9

3.2 Follow-up

The procedure was well tolerated without acute adverse events in 73 patients (95%). One patient had an intraoperative supraventricular tachycardia (SVT) that did not require cardioversion. In one patient the left disc of the GSO device prolapsed into the right atrium and was removed and replaced by another GSO device. One patient developed a haematoma at the site of venepuncture within 24 hours following implantation and, in another patient, an embolized 30 mm GSO device in pulmonary trunk was detected by a chest X-ray performed after 6 hours from the implantation. This patient underwent successful catheterization with removal of the embolized GSO device and subsequent implantation of a 21 mm Occlutech Figulla Flex device (Occlutech International AB). Four patients (54%), one of which included a multifenestrated defect, had residual inter-atrial shunt at 24 hours following implantation as determined by echocardiography (Tab. 3).

Median clinical follow-up was 1.27 years (IQR 0.8–2.3). Trivial inter-atrial shunt (2 mm width) persisted in 2/4 patients (50%). A patient without inter-atrial shunt in the first 24 hours following implantation was observed to have a trivial shunt during subsequent follow-up. None of these 3 patients had multiple fenestrated ASD; only one had a floppy fossa ovalis. Transient treatment with Flecainide was required for a case of recurrent SVT during early follow-up. Flecainide treatment was withdrawn after 6 months without recurrence of arrhythmias.

All patients were asymptomatic at last follow-up examination. A significant remodelling of the RV was detected by echocardiography at last follow-up, where the mean RV/LV ratio was 0.41 ± 0.1 *vs.* 0.7 ± 0.2 at implantation ($p < 0.001$).

Table 3: Acute adverse events (AE) after GSO implantation (could we include residual shunt info)

Relationship and event name Catheterization related	N°
Air embolus systemic	0
Atrial arrhythmia	1
Heart block (resolved)	0
Heart block (not resolved)	0
Access related trauma	
Hematoma	1
Re-bleed	0
Device related	
Atrial arrhythmia	1
Heart block (resolved)	0
Heart block (not resolved)	0
Device embolization	1
Device erosion	0
Residual shunt	3

3.3 Fluoroscopy Data

Fluoroscopy was performed on 60 patients (77%) at a mean follow-up time of 3.1 ± 1.3 year (Fig. 1), 7 patients after PFO closure (7/7) and 53 patients after ASD closure (53/70). A total of 62 GSO devices were analysed for wire frame integrity (2 patients had 2 GSO devices implanted, respectively). Twenty-two devices (35.4%) were observed to have wire fractures during fluoroscopic evaluation; there were 19 linear wire frame fracture (WFF) localized either near the device eyelet or peripherally at the transition to the outer loops (Fig. 2). Three WFF distorted the morphology of the device (Fig. 3); in these cases, echocardiography was unremarkable and no residual shunt was detected. Fractures occurred in 1/8 20 mm GSO devices (13%), 6/26 25 mm GSO devices (23%), and 15/28 30 mm GSO devices (54%). The 30 mm GSO device fractured more frequently than other device size configurations ($p = 0.001$). In all the cases the echocardiography did not show any device profile alteration. A multivariate analysis including patient age at implantation, ASD diameter, ASD stretched diameter, GSO device size, and GSO/ASD device size ratio indicated that the independent variables related to WFF were GSO diameter ($p = 0.013$; F = 6.7) and stretched ASD diameter ($p = 0.034$; F = 4.38) (Tab. 4). No clinical sequelae was associated with WFF for GSO.

4 Discussion

Technical progress and expertise have resulted in the widespread acceptance of percutaneous closure of PFO/ASDs [5–8]. Although, the procedure is recognised to be safe with similar outcomes to surgery [21–23], there are concerns with some potential serious device-related adverse events that include cardiac erosion, device embolization, thromboembolic events, rhythm or conductance disturbance, device fracture or dysfunction leading to instability and fragmentation [9–13].

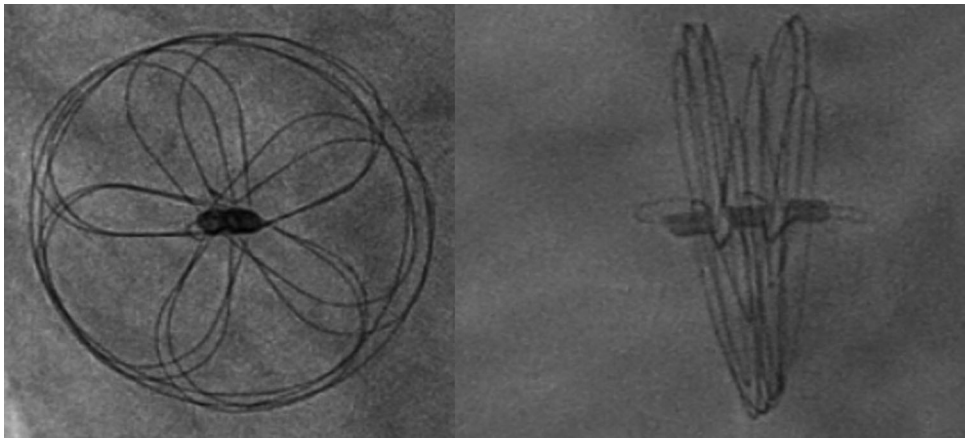

Figure 1: Right and left oblique views of a non-fractured GSO device

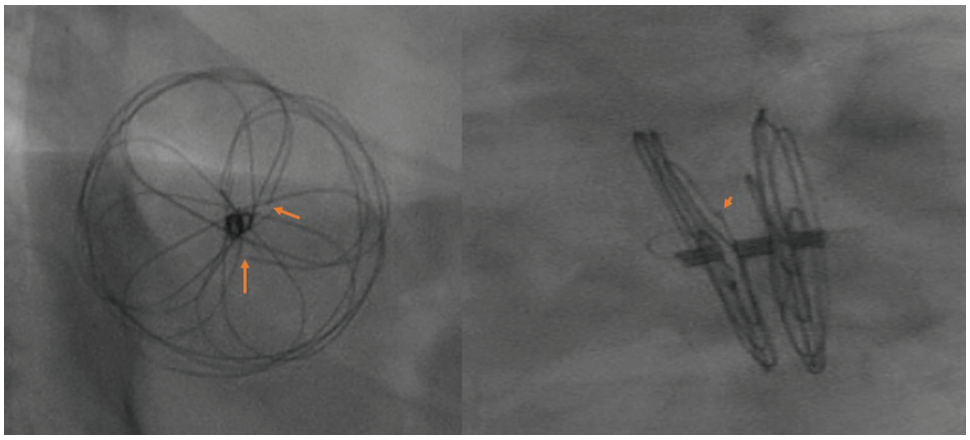

Figure 2: Right and left oblique views of a linear GSO WFF localized near the eyelet (arrow)

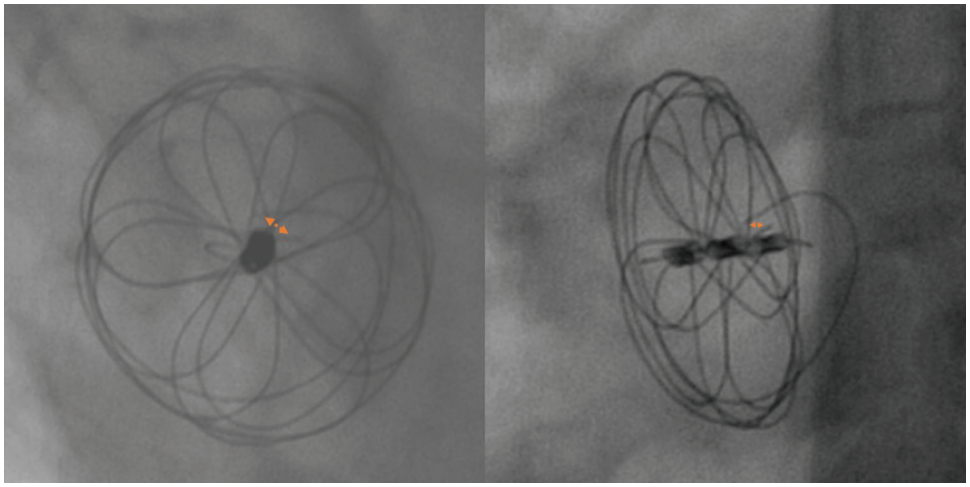

Figure 3: Right and left oblique views of GSO WFF distorting the morphology of device (arrow)

Table 4: Absolute and relative frequencies of GSO fractures

GSO analyzed (N = 62)	Wire frame fracture (%)	WFF with distorted morphology of GSO (%)
20 mm (8)	1 (12.5)	0 (0)
25 mm (26)	6 (23)	0 (0)
30 mm (28)	15 (54)	3 (11)

Trans-catheter closure of secundum ASD was first described by King and Mills using a 35 mm umbrella-like device [4]. Over time, a variety of transcatheter septal occluder devices with differing properties have become commercially available [8]. These occluders can generally be described as self-centering or non-self-centering. The AMPLATZER® Septal Occluder (ASO), Occlutech Figulla Flex II ASD Occluder, Ceraflex™ ASD Occluder, Cocoon Septal Occluder belong to the self-centering group and the defects amenable for closure are dependent on the available waist diameter of the different devices. The GORE® CARDIOFORM Septal Occluder (GSO) belongs to the non-self-centering device type and can treat defects up to 17 mm in size.

In our study, the GSO device demonstrated 95% ASD and PFO closure success which is in alignment with closure rates reported from previous multicentre, prospective studies for this device [16,24]. No adverse events were observed during follow-up. In particular, no cardiac erosions, cardiac tamponade, valve regurgitation, or chronic arrhythmias were observed. An early prolapse of the GSO left disc into the right atrium prior to the permanent release of the device was observed in one case, this patient had a deficient retro-aortic rim which is a known risk factor for this type of event [25].

Self-centering wire mesh devices, like the ASO device, tend to be stiff and have been reported to pose an increased risk of cardiac erosion (a condition where abrasion of the atrial cardiac tissue occurs due to the device) in adult as well as paediatric patients. El Said et al. [26] reported an erosion rate as high as 0.5% for the ASO device and more recently a prospective, multicentre study reported an erosion rate of 0.3% with the ASO device [27]. Similarly, cardiac erosions have been reported for the Occlutech Figulla Flex generation of occluders [28], Cardia Ultrasept II ASD Occluder® device [29], and the Nit-Occlude ASD-R® device [30]. Erosions in surrounding cardiac structures can occur as late as 12 years following implantation [31] and can lead to cardiac perforation with pericardial effusion, cardiac tamponade, or death [32–34]. Cardiac erosion remains poorly understood and a number of factors have been postulated for the occurrence of device-related cardiac erosion. These include deficient aortic and/or superior rim, movement of the device within the heart, implantation of an over-sized/under-sized device, and device stiffness [13]. An eroded septum can also lead to device dislodgement and potential late embolization or reoccurrence of atrial shunting.

A further limitation of wire mesh occluder devices (such as the ASO) is that the wire frame structure of these devices is not covered with a biomaterial and is in direct contact with the blood stream increasing thrombogenecity [35]; moreover, its permanent stiff metallic structure causes significant artefacts during MRI and can interfere with septal dynamics and functional problems in later years [25,36]

The GSO is a soft and conformable device with low metallic content. The device remains soft to the touch with no rough edges in contact with the cardiac tissue. The relatively soft and compliant properties of these devices has resulted in no reported cardiac erosions associated for GSO and HLX. Furthermore, the 5 wire platinum-filled nitinol frame for GSO is entirely covered with a biocompatible ePTFE membrane that reduces thrombogenicity due to its microstructure and absence of exposed metal to the blood stream. The minimal metallic frame structure also preserves the future opportunity of trans-septal access via perforation through the GSO membrane [37] if required.

In addition to cardiac erosions, a perceived concern with septal occluder devices is the incidence and potential long-term implications of device wire frame fracture (WFF). Device WFF can lead to thrombus formation, device instability, complete/partial device embolization, and perforation of the atrial wall leading to pericardial tamponade [11,12,29,38]. Rezaian et al. [12] reported a case of WFF associated with left atrial endocardial damage and thrombus formation in an adult with the ASO device. In contrast, Kumar et al. [38] reported two adult PFO cases of pericardial tamponade due to WFF with Gore Occluder devices.

Incidence of WFF with Gore's first generation septal occluder, HLX, has been reported to range from 6.4% to 11.7% with almost half of the fractures occurring in the first 6 months following implantation [10,17,39]. The presence of an atrial aneurysmal septum was also related to an increased incidence of WFF for HLX by predisposing its left atrial disc to "funnel" into the aneurysm, thus, distorting its profile and stressing the nitinol frame. Fagan et al. [10] reported a WFF rate of 31.5% when HLX was used to close a defect with an atrial septal aneurysm. Similar to our experience, the larger diameter HLX devices were shown to be an independent predictor of WFF [10]. The second generation GSO device features a more robust frame design that includes 5 helically wound metallic wires compared to the single wire frame design of HLX. The frame thickness for GSO progressively increases with device size. Procedural and mid-long term follow-up data has shown GSO to be effective and safe for ASD/PFO closure [16,25]. Despite improvements in design, there are several reported incidences of WFF for GSO. Butera et al. [17] reported a WFF rate of 1.6% (2/122 patients) for PFO closure with GSO at 6 months from chest X-ray imaging with no reported incidence of associated clinical sequelae and device instability. A WFF rate of 6.8% (5/74 patients) as assessed by chest X-ray imaging was reported by Kubicki et al. [18] for ASD closure with GSO in children/adolescents at a median follow-up of 3.5 years with no reported incidence of clinical sequelae and device instability associated with WFF. More recently, Gillespie et al., evaluated the results of the single-arm multicenter U.S. IDE trial for GSO for closure of ASDs. A total of 400 patients (paediatric and adult) were enrolled in this study and fluoroscopy was performed on 134 patients at 6 months and on 148 patients overall (that include later time-points). A fracture rate of 6.1% (9/148 patients) was reported with no associated clinical sequelae or device instability [16].

In our study the rate of WFF (35.4%; 22/62 device) for GSO at a median follow of 3.1 ± 1.3 years was significantly higher to that reported from other studies [16–18]. The higher rate of WFF could be attributed to the use of fluoroscopy at appropriately angled projections to obtain multiple views of the device with the specific intent to image for the presence of localized WFF. The factors which were observed to independently predict WFF were GSO device size and ASD stretched diameter, this correlation was confirmed by multivariate analysis including age, ASD diameter, ASD stretched diameter, GSO/ASD size ratio, and GSO device size. Ninety-five percent of all WFF occurred in the two largest GSO configurations (25 mm and 30 mm) and 68% of WFF occurred in the largest, 30 mm, GSO configuration. A similar correlation was also reported from the GSO multicentre U.S. IDE trial for ASD closure [16] and for HLX occluders [10]. Theoretically, the risk of WFF could be reduced with the use of smaller sized GSO devices, however, a more detailed understanding of the dynamic and pulsatile forces of the ASD and surrounding cardiac structures may better clarify the mechanisms associated with WFF. A consideration that may provide an explanation for the occurrence of WFF with GSO is attributed to the soft and conformable properties of the device. In contrast to exhibiting stiff/abrasive properties (which is a risk factor for cardiac erosion) [13], the soft and conformable GSO device adapts and conforms to the dynamic and pulsatile forces exerted by the heart which may cause device WFF.

Despite the high incidence of WFF reported for GSO in our study, there were no incidence of clinical sequelae or device instability associated with device fractures at a median follow-up of 3.1 ± 1.3 years. The risk of patient harm associated with GSO WFF is mitigated by the design, construct, and material composition of the device. The GSO frame is completely covered with an ePTFE membrane which

reduces the risk of wire frame fragment protrusion in the event of fractures. In addition, the ePTFE membrane for GSO utilizes an open microstructure that facilitates tissue ingrowth/endothelialisation which provides rapid stabilization of the device against the septal tissue, including in the presence of WFF. In our study, one acute case of device embolization occurred but no post-procedure or late emerging device embolizations were observed, confirming that covering of the metallic frame of the device with a biocompatible ePTFE membrane reduces the risk of wire fragment embolization [10].

The long-term implications of WFF are unknown and longer follow-up may be necessary to evaluate potential device instability associated with WFF. The incidence of patient harm/clinical sequelae associated with WFF for GSO appear to be very low compared to the reported incidence of cardiac erosions for stiff/abrasive wire mesh occluder devices [26,27]. Only two cases of acute cardiac tamponade secondary to atrial perforation by WFF of Gore septal occluders have been reported in literature [38] from a total of >40,000 devices implanted worldwide with almost 10 years of clinical use.

4.1 Device Limitations

The GSO configurations are limited in their ability to treat defects larger than 17 mm, requiring a different device to treat larger defects. Gore's latest addition to its Cardioform family of occluders is the GORE® CARDIOFORM ASD Occluder device which available in five configurations, treating a defect range of 8–35 mm. This treatment range is comparable to the range (3 to 38 mm) that can effectively be treated with Amplatzer occluders. A WFF rate of 35.6% (as determined by fluoroscopy at 6 months) has been reported for the GORE® CARDIOFORM ASD Occluder with no associated clinical sequelae or device instability [40].

4.2 Study Limitations

This series has limitations typical of a single-centre study. This study did not determine when exactly device WFF occurred. In addition, longer follow-up to include more patients may be required to determine the safety profile for GSO in the paediatric/adolescent population and to further clarify the mechanisms/factors associated with WFF.

5 Conclusion

GSO is a safe and effective device for secundum ASD closure in paediatric/adolescent patients. The design, construct, and material construct combine to provide a soft and conformable device that reduces the risk of cardiac erosion and thrombogenicity. Incidence of WFF for GSO is relatively high compared to stiff wire-mesh devices, however, clinical sequelae and device instability associated with WFF for GSO is very low. Mechanisms/factors associated with WFF have yet to be clarified and longer-term follow up to determine impact of WFF on device stability is required. Large GSO configurations have a higher incidence of WFF. However, this do not imply any safety warning. In our opinion, fluoroscopy is the best technique to detect WFF and periodic follow-up by echocardiography is recommended to assess device stability in the presence of WFF.

Funding Statement: The authors received no specific funding for this study.

Conflicts of Interest: The authors declare that they have no conflicts of interest to report regarding the present study.

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