

Late complications after Interventional Closure of Atrial Septal Defect with the Solysafe® Septal Occluder

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Objectives

To evaluate long term results of ASD closure by Solysafe septal occluder (SSO fig.1) and potential complications, such as: device deformation (DD), device fracture (DF), wire embolization (WE), device thrombosis (DT), and others.

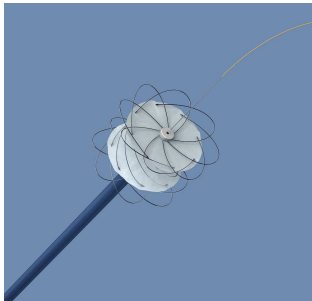


Fig.1 SSO

Methods

Extended follow-up examination was performed in all patients after implantation of SSO, including transthoracic echocardiography (TTE), standardized fluoroscopy (SF) and in pts with complications transesophageal echocardiography (TEE) as well.



Fig 2. Defice fractures and wire embolizations

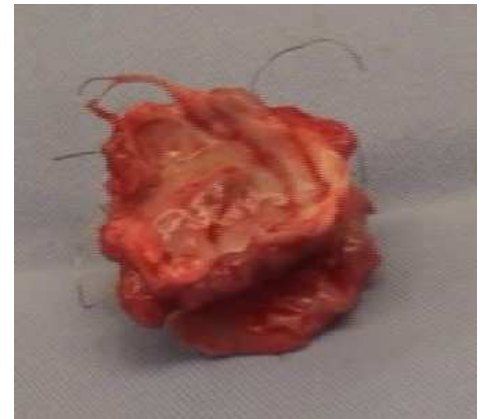


Fig 3. Surgically explanted SSO

Results

Number of pts	57
Median age	15.9 (4.5 - 53)

Complete follow up	49 pts (85.9%)
Median follow up	3.2 yrs (2.2 - 3.7)

Complications 15/49 (30.6%)

	Device Deformation	Device Fracture	Wire Embolization	Device Thrombosis
Group A n=12 small SSO 15 mm	∅	∅	∅	∅
Group B n=25 medium SSO 20, 25 mm	2 pts 8 %	1 pt 4 %		
Group C n=12 large SSO 30, 35 mm	3 pts 25 %	9pts 75%	3 pts 25%	1 pt 8.3%

Device was surgically explanted in 3 pts. Unfortunately one pt died after surgery due to massive pulmonary embolism, but there is no hard evidence to blame it to the device.

Conclusion

The incidence of late complications after ASD closure by Solysafe Septal Occluder is extremely high, particularly in pts with large occluder. Standardized fluoroscopy is imperative for accurate diagnosis of device fracture and wire embolisation. Close monitoring is necessary for all pts with SSO.