

# Midterm follow-up after interventional closure of atrial septal defects using the Solysafe septal occluder

A. Koch, M. Glöckler, C. Breuer, O. Toka, S. Dittrich

## Objective:

The Solysafe septal occluders (Swissimplant®, fig. 1) is a self-centering device for interventional closure of secundum type atrial septal defects and patent foramen ovale which was first successfully implanted in 2005. Individual reports of wire fractures terminated the distribution and implantation of Solysafe septal occluders (SSO) in August 2010. Therefore, we contacted and evaluated all patients who underwent interventional closure of an atrial septal defect using this device at our institution.

## Methods:

From 7/2008 to 7/2010 interventional closure of an atrial septal defect using a SSO was performed in 23 patients (18 females, 5 males).

Mean age at the procedure was 8.0 years (2.9 to 16.2 years), the native defect size was mean 11mm (5 to 16mm) measured by transesophageal echocardiography. SSO types 15, 20, and 25 were used in 7, 13, and 3 patients, respectively. No SSO types 30 or 35 were used.

Between 09/2010 and 12/2010 all patients were re-evaluated carefully. In addition to transthoracic echocardiography and electrocardiogram the integrity of the wire frame was controlled by fluoroscopy.

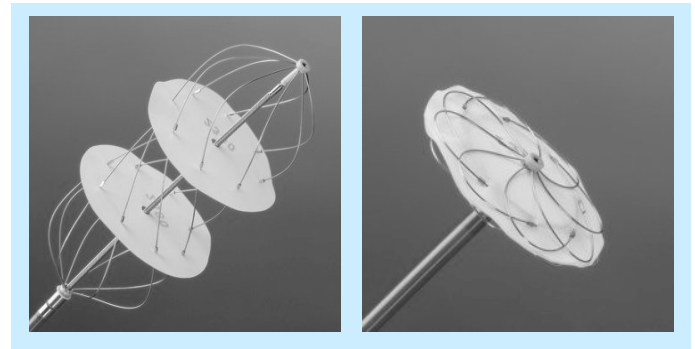


Fig. 1: Solysafe Septaloccluder

Patient	Defect size (mm)	Age (years)	SSO (mm)	Fluoroscopy (days after implantation)
1	13	3,8	20	109
2	8	7,2	15	158
3	13	4,1	25	75
4	10	13,4	20	69
5	10	10,9	20	298
6	12	5,5	20	252
7	5	16,1	15	250
8	8	12,8	15	187
9	8	7,5	20	188
10	13	2,9	20	397
11	7	10,8	20	391
12	9	5,4	20	274
13	16	11,7	25	391
14	14	6,7	20	519
15	5	4,5	15	433
16	9	6,0	15	464
17	16	4,9	25	593
18	13	14,5	20	640
19	12	5,8	20	590
20	14	4,5	20	491
21	10	7,9	15	774
22	14	10,1	20	609
23	8	5,7	15	799

## Results:

Mean 389 days (69 to 799 days) after the interventional procedure all patients were asymptomatic. Echocardiography (fig. 3) revealed a flat device in all patients without residual shunt. No wire fractures were detected by fluoroscopy (fig. 2).

## Conclusions:

Thorough check-up revealed no wire fracture or other device related problems in our patients treated with SSO types 15 to 25. However, mean follow-up was only 1 year.

Maybe larger devices or devices implanted in persistent foramen ovale are more susceptible to the reported wire fractures. Further careful follow-up evaluation is necessary.

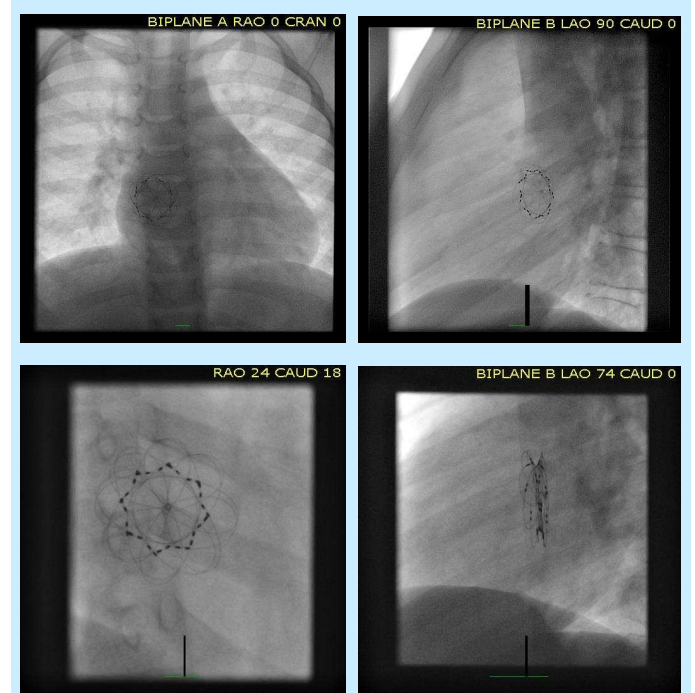


Fig. 2: Fluoroscopy

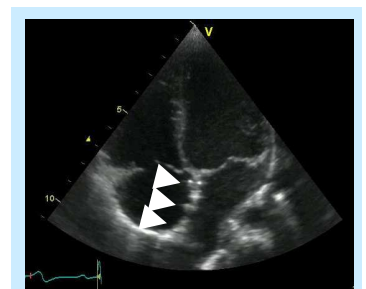


Fig. 3: Echocardiography