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Original Article

Transcatheter closure of atrial septal defects within the oval fossa: medium-term results in children using the 'ASDOS'-technique

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Abstract *Objectives:* The purpose of this study was to evaluate the safety and efficacy of the ASDOS-technique (Sulzer-Osypka GmbH, Germany) for transcatheter closure of atrial septal defects within the oval fossa.

Background: Although several attempts have been made to occlude defects within the oval fossa by transcatheter techniques, none of these has gained general acceptance.

Methods: Patients with a defect in the oval fossa measuring equal to or less than 20 mm diameter, with a residual septal rim of 5mm or greater, body weight greater than 10 kg, with clinical indications for surgical closure were considered for transcatheter closure. Follow-up investigations were performed at discharge, after 1, 3, 6 and 9 months, as well as after 1 and 2 years.

Results: Of 78 patients considered for closure, a device was inserted in 41 patients (53%), with success being achieved in 40 patients (98%). The ages ranged from 1.1 to 15 years (7.8 ± 1.92 years), the 'stretched' diameter of the defect from 10 to 20 mm (14.7 ± 2.60 mm), and the diameters of the inserted devices from 25 to 45 mm (33.2 ± 5.43 mm). Transient impairment of atrioventricular conduction occured in 4 patients. During the follow-up of 23.0 ± 5.6 months elective surgical closure of a residual shunt was performed 26 months after insertion of the devcie in one patient. None of the other patients required surgery, hospitalisation or medical treatment, and none is requiring further treatment of the defect within the oval fossa. Fracture of one arm of the device occurred in 4 patients, but the fractured arms are in an unchanged and stable position after a period of at least 19 months.

Conclusions: Our medium-term data show that transcatheter closure in children of defects within the oval fossa can be performed with a high efficacy and safety using the ASDOS-device.

Keywords: Atrial septal defect, interventional cardiology, closure devices, biomaterials.

THE SURGICAL CLOSURE OF ATRIAL SEPTAL defects has, today, a negligable mortality and is still the procedure of choice.[1,2] It is, however, associated with a significant morbidity and risks inherent to the surgical techniques itself, including thoracotomy, cardiotomy and the need for extracorporal circulation.[2] Although further refinements of the surgical techniques have been developed,[3,4] several attempts have been made to occlude defects in the oval fossa by transcatheter techniques as an alternative approach.[5-15] Up to now, none of these techniques has gained general acceptance. The ASDOS-technique (ASDOS = Atrial-Septal-Defect-Occlusion-System; Sulzer-Osypka GmbH, Germany) was described originally by Babic.[12,14] The device consists of

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two separate umbrellas which are connected by a screwing mechanism and are thereby firmly attached to the rims of the deficient oval fossa (Fig.1). The device can be retrieved transvenously and repositioned after unscrewing both umbrellas.[14] In this report, we present our medium-term results (76.8 patient-years of follow-up) in 40 children in whom the device was inserted to close an atrial septal defect in the oval fossa, all patients having suitable indications for surgical closure.

Patients and methods

Between January 1995 and July 1996, 78 children with atrial septal defects in the oval fossa were considered for transcatheter closure using the ASDOS-technique at five institutions (Charité-Berlin (Germany); Universitätsklinik Essen (Germany); Christian Albrechts Universität , Kiel (Germany); Guy's Hospital, London (UK); University Hospital, Geneva (Switzerland)). Only patients with a defect in the oval fossa and normal pulmonary resistance, a body weight greater than 10 kg and clinical indications for surgical closure were considered for transcatheter intervention. For preinterventional imaging, transthoracic or transesophageal echocardiography was performed to measure the maximal diameter of the atrial septal defect and the minimal rim of tissue surrounding the defect. Additionally, the maximal 'length' of the residual interatrial septum was measured in the transthoracic echocardiogram from the apical four-chamber-view taking the distance between the septal insertion of the mitral valve to the origin of the right upper pulmonary vein as an estimate for the largest device which could be implanted. Only patients with a ratio between the diameter of the defect and the measured length of the interatrial septum of less than 2 were included.

Study protocol

The device was released for a limited clinical trial according to a study protocol approved by the authorized human subjects committee and by the local governmental authorities according to the european regulatory body for the approval of implantable devices. The study protocol was designed according to the declaration of Helsinki in its revised form of Tokyo. Informed consent was obtained from the patients, or the guardians, before implantation was attempted.

Criterions for inclusion into the study as obtained during cardiac catheterization were:

- Atrial septal defect within the oval fossa with normal pulmonary resistance
- Indication for surgical closure of the defect (pulmonic-to-systemic flow ratio greater than 1.5)
- Body weight greater than 10 kg
- Defect diameter less than 20 mm, residual rim greater than 5mm
- No major associated disease, which could interfere with implantation of the device.

Description of the device

The ASDOS-device (Sulzer-Osypka GmbH, Germany) basically consists of two umbrellas which are introduced into the left and right atrium over a guidewire-looped from the femoral vein to the femoral artery. The device, and the technique of implantation have been described previously in detail.[14] Briefly, both umbrellas consist of a central body and five arms, which are made of preshaped nitinol-wire, and are covered by a thin

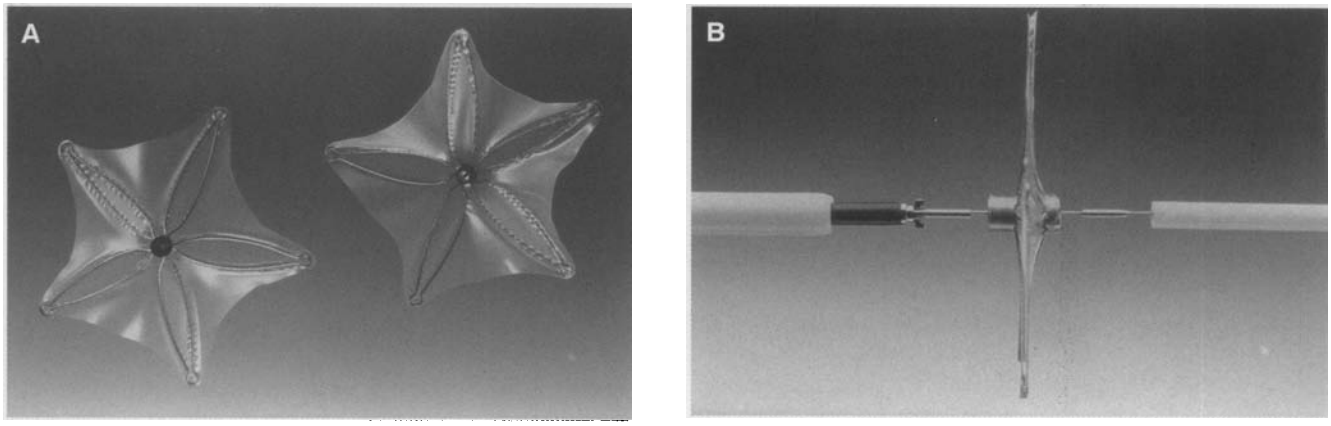

Figure 1.
The ASDOS-Device is shown en face (a) and en profile (b) after connecting the two umbrellas. The arms of the device which are made out of curved nitinol and covered by a thin polyurethan patch.

polyurethane-patch. The central body of the distal (left atrial) umbrella contains a thread, while the proximal (right atrial) umbrella contains a bolt (Fig.1a). Both umbrellas are inserted into the left and right atrium separately, and are connected by screwing the bolt on the threat using a screwdriver catheter (Fig.1b). Both umbrellas have a rounded shape due to the configuration of the five arms (Fig.1a). In subsequent descriptions the diameter at the tips of the arms will be referred to as the diameter of the device.

Technique of implantation

During cardiac catheterization, anomalous drainage of the pulmonary veins was excluded by right ventricular and, if necessary, by selective pulmonary angiography. The pulmonic-to-systemic-flow ratio was calculated from the oxymetric data. The 'stretched' diameter of the defect was assessed by balloon sizing using a compliant balloon catheter (modified Berman-catheter, special request, Arrows; occlusion balloon, Boston Scientific). The sizing balloon was advanced into the left atrium, slowely inflated, and pulled back to the interatrial septum. Using transthoracic or transesophageal colour-coded-doppler echocardiography, the smallest diameter was measured at the point where were the left-to-right-shunt ceased. In addition, the maximal diameter of the balloon which passed through the defect was measured.[16-18]

For the implantation of the ASDOS-device, a guidewire was looped from the femoral vein through the atrial septal defect to the femoral artery using a 0.014-in nitinol guidewire with a 0.035-in conus at its middle (450 cm, ASDOS-guidewire, Osypka-Sulzer GmbH, Germany). This lopp was immediately covered by a catheter (4F modified right Amplatz, Cordis) to protect the aortic and mitral valvar leaflets. An 11F long sheath was inserted over the guidewire into the femoral vein and its tip advanced into the left atrium. The diameter of the device was selected so that it doubled the diameter of the defect. The distal (left atrial) and proximal (right atrial) umbrellas were than inserted over the guidewire through this long-sheath. The left atrial umbrella was advanced using a 'pusher' (metalic 22G cannula with rounded tip) and retrieved by the conus on the guidewire-track. The right atrial umbrella was controlled by the screwdriver catheter, which was hooked into the thread by a counterclockwise rotation (Fig.2a). Cross-sectional echocardiography was performed to position the umbrellas on either side of the atrial septum, and color-coded-doppler echocardiography used to confirm cessation of left-to-right shunting across the atrial septal defect. To connect the umbrellas, the nitinol loop and screwdriver catheter were used to advance the bolt into the thread. Thereafter the screwdriver catheter was rotated clockwise, screwing the bolt firmly on the thread (Fig.2b). Adequate screwing was confirmed by observing the decreasing distance between the two umbrellas. Finally, complete closure of the atrial septal defect, normal flow within the systemic and pulmonary veins, competence of the atrioventricular valves, as well as an adequate position of the umbrellas on both sides of the atrial septum, was confirmed by echocardiography before relaesing the device by pulling the nitinol-wire throught the arterial catheter and out of the patient (Fig.2c).

Medication during and after implantation

Following the procedure heparin, was administered intravenously by continous infusion. Within the first 24 hours, 600 IU/kg heparin were administered. During the second 24 hours 400 IU/kg was given and than 200 IU/kg for an additional 24 hours. The antithrombin III levels were kept above 90%. Cefuroxim 50 mg/kg was administered in two doses 6 and 12 hours after termination of the procedure. Aspirin 2 to 3 mg/kg daily and dipyridamol 2 to 3 mg/kg daily were administered orally for 6 months thereafter. Endocarditis prophylaxis was recommended for 12 months.

Follow-up investigations

Follow-up investigations were performed at all participating centers at discharge, after 1, 3, 6 and 9 months, as well as after 1 and 2 years. Follow-up investigations included clinical examination, standard electrocardiograms, transthoracic echocardiography, chest X-ray or fluoroscopy, and Holter monitoring. A residual shunt was classified as significant if it was greater than 2 mm as judged in the color-coded-doppler-echocardiogram, trivial if it was less than 2 mm, and as turbulance, if a flow disturbance was visible near the device which could not clearly be defined as trivial shunting.

Statistics

Students-t-test was performed for statistical comparisons between means.

Results

From January 1995 to July 1996, 78 patients were considered for closure using the ASDOS technique after screening with transthoracic or transesophageal echocardiography. During diagnostic cardiac catheterization and sizing of the defect, 37 patients

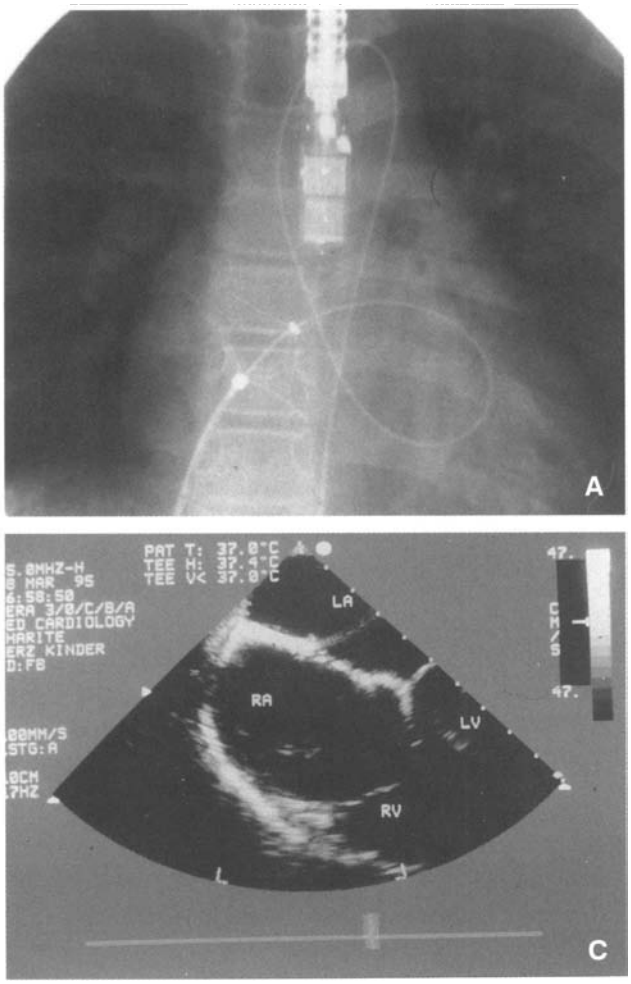

Figure 2.
Implantation of the ASDOS-Device.
a. The two umbrellas have been delivered on either side of the interatrial septum.
b. The umbrellas have been connected by screwing the bolt of the right atrial umbrella on the threat of the left atrial umbrella. Note the change of shape of both umbrellas before and after connecting them.
c. Transesophageal echocardiogram after release of the device, the device is firmly attached to the rims of the oval fossa.

(47%) were excluded from the study and no attempt was made interventionally to close the defect. The reasons for withdrawal of these patients from the study are summarized in Table 1. All of the patients requiring surgical closure were discharged the day after the cardiac catheterization, and were subsequently scheduled for elective surgical closure. Transcatheter closure of the defect was attempted in 41 patients (53%). The age of these patients ranged from 1.1 to 15 years (7.8 ± 1.92 years), the body weight varied from 11 to 56 kg (27.6 ± 12.65 kg). The diameter of the defect ranged from 8 to 22 mm (13.4 ± 3.33 mm) as judged in the echocardiogram, while the 'stretched' diameter evaluated during balloon sizing ranged from 10 to 20 mm (14.7 ± 2.60 mm) (Table 2). Thus, the 'stretched' diameter was significantly larger ($p < .0005$) than the estimated echocardiographic diameter. The ratio of pulmonary-to-systemic blood flow varied from 1.5:1 to 3.0:1 (1.9 ± 0.35), while the ratio of pulmonary-to-systemic resistance was lower than 0.015:1 in all patients. Mild Ebstein's malformation of the tricuspid valve without relevant tricuspid regurgitation was an associated finding in one patient. In another patient a small ('silent') arterial duct was found, which was occluded using a coil. General anesthesia was performed in 58 of the children for transesophageal echocardiography.

Immediate results

Successful implantation of the device was achieved in 40 of 41 patients (98%) in whom implantation was attempted. The size of the implanted devices ranged from 25 to 45 mm (33.2 ± 5.43 mm). The ratio of diameters of device to defect varied from 1.76 to 3.33 (2.3 ± 0.28) (Table 2). The 'length' of the interatrial septum as measured in the apical four-chamber-view was between 29 mm and 50 mm (37.7 ± 6.14 mm). The ratio between this measurement and the diameter of the device ranged from 0.91 to 2.0 (1.14 ± 0.19). All patients had a residual rim of atrial tissue of more than 5 mm (range 5 to 12 mm; 7.55 ± 1.92 mm). Occlusion of the defect with the initially selected device was successful in 36 of 41 patients (88%). In 4 patients, the device had to be retrieved and exchanged for a larger (n = 3) or smaller (n = 1) device, which was subsequently used successfully

Table 1. Reasons to withdraw patients from the study (37/78 patients)

Multiperforated and floppy interatrial septum	n = 4
'Stretched' defect size greater than 20 mm	n = 5
additional partial anomalous pulmonary venous return	n = 5
Rim of oval fossa less than 5 mm	n = 4
Pulmonary-to-systemic flow ratio < 1.5:1	n = 6
Defect size larger than 50% of the interatrial length	n = 13

Table 2. Implantation data

	Mean	SD	Range
Echocardiographic Diameter (maximal)	13.4 mm	3.3 mm	8 to 22 mm
'Stretched' Diameter	14.7 mm	2.6 mm	10 to 20 mm
Atrial Length	37.7 mm	6.1 mm	29 to 50 mm
Minimal Rim	7.6 mm	1.92 mm	5 to 12 mm
Diameter of Device	44.3 mm	5.43 mm	25 to 45 mm
Ratio of Device to Defect	2.3	0.28	1.76 to 3.3

for closure. Retrieval of the device was performed transvenously without complications. In all but one patient, the same venous access was used for the definitive closure of the atrial septal defect. In only one of 41 patients (2.4%) had the procedure to be abandoned. This was because complete closure of the defect could not be achieved with a 35-mm device, and a 40-mm device seemed not to fit into the atriums.

In none of the patients a significant shunt (greater than 2 mm) was observed after the procedure. A trivial residual shunt (less than 2 mm) was visible by colored-doppler-echocardiography in 4 of 40 patients immediately after closure. A turbulance near the device, which could not be clearly classified as a minimal residual shunt or disturbed flow due to the device, was observed in 5 additional patients (Table 3). The procedure time ranged from 67 min to 425 min (173 ± 99 min), the fluoroscopic time from 15.3 min to 77 min (36 ± 17 min).

Complications before discharge

In none of the patients did we encounter complications leading to death, surgery, morbidity or medical treatment other than treatment according to the study protocol. Transient impairment of atrioventricular conduction occured in 3 patients during the procedure, which normalized immediately after unscrewing both umbrellas and repositioning the device without acute or late sequels. Air embolism, thromboembolism or bleeding necessitating transfusion were not observed during or after the procedure. Transient deterioration of atrioventricular conduction occurred in one patient 6 hours after implantation. Brief periods of second and third degree atrioventricular block were noticed in this patient within the first three days following the implantation. As a stable escape rhythm with narrow QRS-complexes was present all the time, no specific therapy was required. Atrioventricular conduction normalized within 3 days. Repeated Holter-monitoring and standard-electrocardiograms revealed normal atrioventricular conduction with a PR-interval of 170 msec during a follow-up period of 26 months. In one additional patient, a small pericardial effusion was observed 3 days after the implantation, which required no therapy and resolved spontaneously within 4 weeks. The etiology remains speculative, as no diagnostic puncture of the effusion was performed.

Follow-up data

Duration of follow-up of the 40 patients with successful implantation of the device ranges from 13 to 32 months (23.0 ± 5.6 months). All patients have been followed for at least 12 months. The cumulative follow-up period is 921 patient-months, or 76.8 patient-years. In one patient with a residual shunt, elective surgical closure was performed 26 months after the initial intervention. None of the other patients required surgery, hospitalisation or a medical treatment other than endocarditis prophylaxis or supportive treatment for common cold. In none of the patients did we observe arrhythmias, thromboembolism, endocarditis, death, morbidity or other disorders. Trivial residual shunting was observed in one patient at 12 months follow-up. In another 4 patients flow disturbance near the device, which could not be differentiated from a minimal shunt, was detected echocardiographically. At 24 months follow-up only one patient had a trivial shunt. Surgical closure was performed after 26 months in this patient to achieve definite closure of the residual defect and exclude the risk for endocarditis. The device was completely covered by tissue. In none of the other patients is there any indication for further treatment of the atrial septal defect.

Fracture of one arm of the device occurred in 4 patients within the first 3 months after implantation (Fig. 3). No predeliction site was found for fractures. Two of them occurred at 4 o'clock, one at 9 o'clock and one at 7 o'clock in the en-face view. In all these patients, the fractured arms are still in an unchanged and stable position after 29, 27, 21 and 19 months respectively. In none of these patients did we observe residual shunting or disturbance in flow. The fractures were not visible in the

standard chest X-ray. Starting in April 1995, therefore fluoroscopic control of the integrity of the device was routinely performed. All fractures occurred within the first three months after the implantation.

The right ventricular internal diameter, as measured in the M-Mode echocardiogram, was 21.3 ± 6.0 mm before occlusion of the defect. 6 months after closure it had decreased by 27.8 ± 18.0% to 15.5 ± 4.7 mm ($p < .0001$) (Table 4). At 1 year follow-up, the right ventricular internal diameter was 17.7 ± 5.2 mm. Although this is still significantly smaller than the diameter prior to implantation ($p < .0001$), there is a slight increase when compared with the diameter noted at 6 months-follow-up (n.s.). When the right ventricular diameter is 'corrected' for overall growth of the patient by calculating the ratio of right ventricular to left ventricular end-diastolic diameters, this ratio was .64 ± .18 before implantation, .44 ± .17 at 6-months follow-up ($p < .0001$) and .47 ± .17 ($p < .0001$) at 1-year follow-up. In none of the patients was paradoxical septal motion observed after occlusion of the defect.

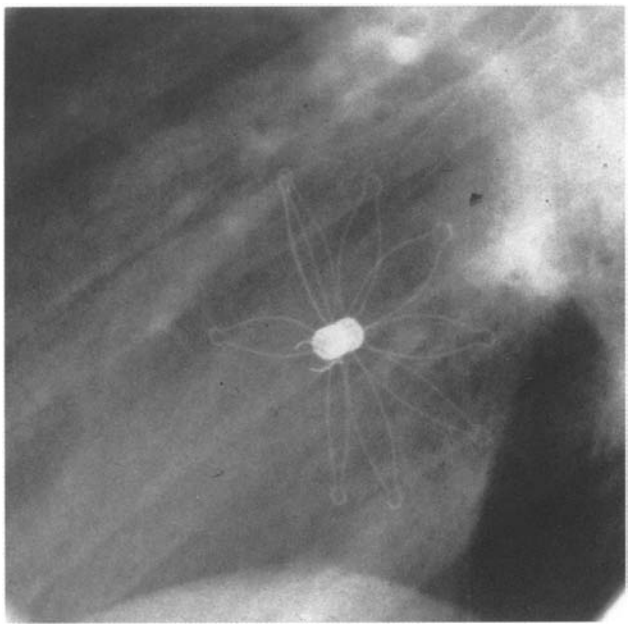

Figure 3.
Fluoroscopy of a fractured device after 3 months of follow-up. Although fractures of arms are a matter of concern, the fragment and the device are in stable and unchanged position for at least 19 months. Although there seems to be dislocation of one arm, this reflects a 'thick' interatrial septum in this particular patient.

Discussion

Transcatheter closure of defects in the oval fossa is a promising approach for at least some patients, as thoracotomy, cardiotomy and extracorporal circulation with ischemia of the heart can all be avoided. In this series we considered 78 patients for transcatheter closure, attempted closure in 41 patients, and achieved success 40 patients. Thus, in 53% of the preselected patients, and in 98% of patients in whom transcatheter closure was attempted, the atrial septal defect was occluded. Although the rate of successfull closure was high in those patients, in which it it had been attempted, we were able to achieve closure in only every second patient initially considered. Although a suboptimal preselection of patients cannot be excluded, another reason for this low rate of implantation was the caution of the investigators not to use oversized devices which might have resulted in friction lesions, or even perforation of the atrial wall, due to the stresses between the device and the walls of the heart. In only one of these patients was elective surgical closure needed because of a residual shunt. In none of the other patients was further treatment required related to the atrial septal defect within a cumulative follow-up of 76.8 patient-years. The right ventricular diameter decreased significantly after successfull closure (Table 4). Potential complications, such as embolization or dislocation of the device,[7,19-23] thromboembolic complications, endocarditis, pericardial effusion due to perforation or pressure necrosis,[21,22] tricuspid or mitral regurgitation,[7,24] alteration of venous return or significant residual shunting did not occur in this initial series. This lack of significant complications seems to be noteworthy when compared to other reports.[21,22] We speculate, that this may be due to the careful

Table 3. Residual shunt after transcatheter closure using the ASDOS-Device.

	Implantation	Discharge	6 months	1 year	2 years
n =	40	40	40	40	19
none	31	32	34	36	17
turbulance	5	5	5	4	2
trivial (< 2mm)	4	3	1	1	1
significant (> 2 mm)	0	0	0	0	0

Abbreviations: Implantation – immediately after implantation; Discharge – at discharge from hospital; 3,6 and 12 months – 3, 6 and 12 months after implantation.

Table 4. Change of echocardiographic right and left ventricular diameters 6 and 12 months after transcatheter closure using the ASDOS-device (n = 32).

	Before ASD-closure	6 months follow-up	12 months follow-up
RVID (mm)	21.3 ± 6.0	27.8 ± 18.0***	17.7 ± 5.2***
LVID (mm)	34.3 ± 5.7	37.0 ± 6.6**	38.2 ± 5.2**
RVID/LVID	0.64 ± 0.18	0.44 ± 0.17***	0.47 ± 0.17***

Abbreviations: RVID – diastolic right ventricular internal diameter (M-mode); LVID – diastolic left ventricular internal diameter (M-mode); * $p<.01$; ** $p<.001$; *** $p<.0001$

selection of patients, and strict adherence to the study protocol. Significant residual shunting was not observed in any patient, while trivial shunting being observed in only one by colored-doppler-echocardiography after 12 and 24 months of follow up (Table 3).

For successful transcatheter closure with this technique it seems necessary to have an adequate rim of tissue surrounding the oval fossa as the implanted device has to cover not only the defect but also its rims to obtain a firm attachment and produce secure occlusion of the defect.[17,18,25,26] A firm attachment of the device to the margins of the oval fossa seems to be of additional importance for complete endothelization of the device, which starts at the site where the rims of the device are in conjunction with the atrial walls.[8,10,11,13] In this series, the residual rim ranged from 5 to 12 mm (7.55 ± 1.92 mm) (Table 2). The ratio between the measured length of the interatrial septum and the maximal diameter of the device ranged from 0.91 to 2.0 (1.14 ± 0.19), indicating that, in most patients (median 1.1), the device covered the oval fossa almost completely (Table 2). The device was usually twice the diameter of the defect with a ratio of 2.3 ± .28 (median 2.3). During this series, no attempt was made to use smaller devices. The device itself is not self-centering, but repositioning can be achieved by use of the guidewire and the individually preshaped pusher. Careful repositioning of the device under echocardiographic guidance was necessary in the majority of our patients to achieve adequate positioning and complete occlusion. Echocardiography allows the precise assessment of the position of the device within the oval fossa, and its relation to adjacent structures as the pulmonary and systemic veins, the eustachian and atrioventricular valves, as well the ascending aorta and the triangle of Koch containg the atrioventricular node. Thus, in contrast to self-centering devices, where the self-centering mechanism defines the final position of the device, the ASDOS-technique permits positioning and repositioning as determined by the operator.

The diameter of the implanted devices varied from 25 to 45 mm. For the implantation of such large devices it is important to be able to retrieve the device transvenously without the need for surgery.[20] Retrieval was needed in 4 patients, because it was obviously too small, while in one patient it was too large to fit into the atriums. Retrieval of all devices was performed interventionally without complications, as previously described.[14] Due to the 'memory' of the nitinol arms, the devices were intact after retrieval. In three of these patients, complete occlusion of the defect was subsequently achieved after implantation of a larger device, in one patient after implantation of a smaller device, while in the other patient the attempted transcatheter closure was abandoned because the defect seemed to be unsuitable. The option to release the device from the delivery system while still on the guidewire circuit seems to be an advantage of the ASDOS-technique, as the adequate position of the device can be controlled, while repositioning and retrieval is still possible.Due to the tension between the guidewire circuit and the device, 'trivial' shunting between the tips of the arms was observed immediately prior to release in several patients. After release from the guidewire circuit this 'trivial' shunt disappeared immediately in most patients. In one-tenth of patients, a trivial residual shunt was visible at discharge. Turbulance near the device, which could not be clearly differentiated from a minimal residual shunt, was observed in 5 additional patients.

While no rhythm disturbances occurred during the period of follow-up, a transient alteration of atrioventricular conduction was observed in 3 patients during the procedure, which resolved immediately after unscrewing and repositioning of the device. This impairment of atrioventricular conduction seems to be due to mechanical desturbance of the atrioventricular node, which is compressed between the umbrellas. The possibility to relieve this mechanical alteration by unscrewing and repositioning of the device seems to be an advantage of the ASDOS-technique. In one additional patient, atrioventricular conduction deteriorated 6 hours after implantation, resulting in

transient second to third degree atrioventricular block. Although this resolved completely within 3 days, and remained normal during a follow-up period of 26 months, this is potentially a serious complication. Thus, care must be taken not to implant oversized devices. In addition, we would suggest, that in the region of the atrioventricular node a residual rim of atrial tissue of at least 7 mm should be present. As an estimate for the size of the atrial septum, we measured the depth of the atriums in the apical four chamber view. These data, however, do not show wether this measure is adequate for the selection of the largest possible device. Rather careful echocardiographic monitoring of the device during implantation and elucidation of its relation to adjacent structures, is mandatory.

As has been reported with other devices,[19,27-29] one arm of the device fractured in four of our patients (Fig.3). As it was impossible to visualize fractures in the chest X-ray, the integrity of all devices was controlled by fluoroscopy. This should also be recommended for the follow up of other devices. The fractured arms, and the device itself, remained in an unchanged and stable position for at least 19 months. In none of these patients did residual shunting occur. This stability of the fractured arms can be attributed to their curved shape, which had been designed to prevent migration of fragments in case of fractures. All of the fractures occurred in the center of the device, where the stresses are highest. It can be suggested that some of these fractures resulted from overdistension of the arms by a 'thick' muscular interatrial septum, resulting in a concave deformation of the device. Although nitinol, from which the arms of the ASDOS-device are made, has a high flexibility, overdistension can result in fatigue fractures (Figs 3 & 4). Bench testing of the device in an overdistended configuration showed that the incidence of fractures increases with the angle of overdistension of the nitinol. As overdistension of the device depends on the thickness of the atrial septum, elongation of the thread could be a solution to prevent such overdistension. The need for a variable distance between the umbrellas according to the individual anatomy of the interatrial septum seems to be an important observation, as the stresses which occur between the device and a 'thick' interatrial septum or the aortic root have not been recognized as a potential problem for design of devices.

Although fractures seem to be a matter of concern, they could also be an advantage, as they relieve the stresses between the device and the heart. If these stresses are not relieved, they can result in friction lesions, pressure necrosis, and in perforation of the atrial wall. When oversized devices are used, laceration of the ascending aorta can lead to hemopericardium, with pericardial tamponade even months after the implantation.[19-22] These stresses seem to be a particular problem of devices made from nitinol, as this metal will tend to retain its original shape independent of the individual anatomy of the heart. Although fractures can be an advantage by relieving potential stresses between heart and device, it is important that the device remains in stable position when fractures occur, and that the resulting fragments do not migrate, perforate or lacerate adjacent structures and embolize.[7,19]

Although repositioning, retrieval and firm attachment of the device within the oval fossa are advantages of the ASDOS-technique, the possibility of fatigue fractures, and of mechanical alterations due to the tension between the two umbrellas, have to be mentioned as possible disadvantages. A clear disadvantage of the ASDOS-technique is the complex procedure required for implantation using an veno-arterial guidewire circuit. On the other hand, this allows release of the device from the delivery system while it is still secured by the guidewire circuit. Establishing this veno-arterial guidewire-circuit is a complex maneuver, with the risk of an arterial puncture and

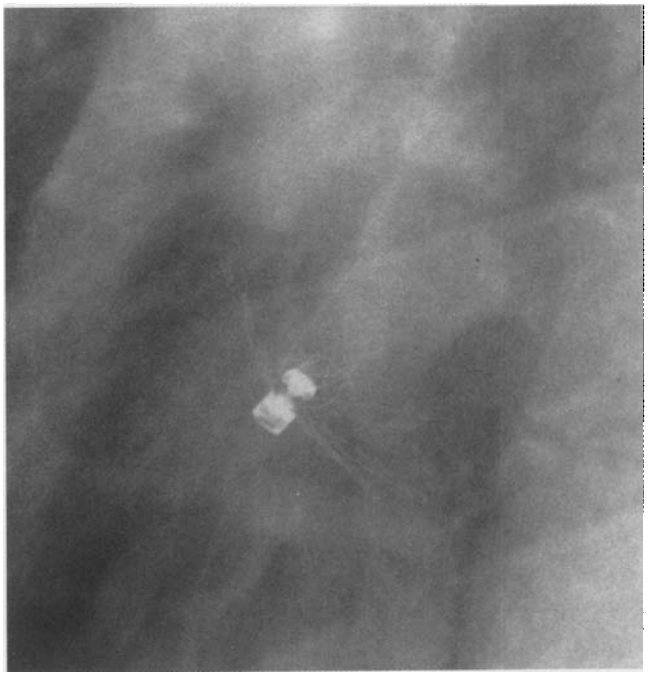

Figure 4.
Overdistension of the device due to a 'thick' muscular interatrial septum. The concave deformation of the device can result in fatigue fractures of the arms. Bench testing showed that the fracture rate of the nitinol arms increases with the overdistension.

the potential risk of lacerating the mitral or aortic valve. No complications due to this maneuver, however, were observed in this series. The fluoroscopic time of 36 ± 17.0 min, and a total procedure time of 173 ± 100 min, seem to be acceptable during the initial phase for a complex interventional procedure, but seem to be rather long for a routine procedure.

In conclusion, our medium-term data show that the ASDOS-technique can be used with a high efficacy and safety for the trancatheter closure of defects in the oval fossa in a carefully selected group of children. As with other transcatheter techniques, a residual rim of atrial tissue surrounding the defect is necessary for succes, limiting the application of this particular technique. The distance between the umbrellas should be adjustable to prevent stresses between the device and the heart, stresses which can result in fractures of arms due to overdistension of the nitinol. The technique of implantation is complex and time consuming, but offers additional safety as unscrewing and repositioning of the device is possible after release from the delivery system so that overdistension of the device and direct contact with critical structures can be avoided. Although our follow-up covers 76.8 patient-years, with a mean follow-up period of 23.0 ± 5.6 months (13 to 32 months), further experience is needed with this, to assess ist long-term safety, any possible long-term problems, and the limitations of the technique.

References

1. Pastorek JS, Allen HD, Davis JT. Current outcomes of surgical closure of secundum atrial septal defect. Am J Cardiol. 1994, 74: 75-77.
2. Galal MO, Wobst A, Halees Z, Hatle L, Schmaltz AA, Khougeer F, De Vol E, Fawzy ME, Abbag F, Fadley F, Duran CMG. Peri operative complications following surgical closure of atrial septal defect type II in 232 patients- a baseline study. Eur Heart J. 1994, 15: 1381-1384.
3. Massetti M, Babatasi G, Rossi A, Neri E, Bhoyroo S, Zitouni S, Maragnes P, Khayat A Operation for atrial septal defect through a right anterolateral thoracotomy: current outcome. Ann Thorac Surg. 1996, 62: 1100-1103.
4. Chang CH, Lin PJ, Chu JJ, Liu HP, Tsai FC, Lin FC, Chiang CW, Su WJ, Yang MW, Tan PP Video assisted cardiac surgery in closure of atrial septal defect. Ann Thorac Surg. 1996, 62: 697-701.
5. King TD, Thompson SL, Steiner C, Mills NL. Secundum atrial septal defect: nonoperative closure during cardiac catheterization. JAMA 1976, 235: 2506-2509.
6. Rashkind WJ. Transcatheter treatment of congenital heart disease. Circulation 1983, 67: 711-717.
7. Rao PS, Sideris EB, Hausdorf G, Rey Ch, Lloyd TR, Beekman RH, Worms AM, Bourlon F, Onorato E, Khalilullah M, Haddad J. International experience with secundum atrial septal defect occlusion by the buttoned device. Am Heart J 1994, 128: 1022-1035.
8. Sideris EB, Sideris SE, Fowlkes JP, Ehly RL, Smith JE, Gulde RE. Transvenous atrial septal defect occlusion in piglets with a 'buttoned' double-disk device. Circulation 1990, 81: 312-318.
9. Rome JJ, Keane JF, Perry SB, Spevak PJ, Lock JE. Double-umbrella closure of atrial defects. Initial clinical applications. Circulation 1990, 82: 751-758.
10. Lock JE, Rome JJ, Davis R, Van Praagh S, Perry SB, Van Praagh R, Keane JF. Transcatheter closure of atrial septal defects. Experimental studies. Circulation 1989, 79: 1091-1099.
11. Das GS, Voss G, Jarvis G, Wyche K, Gunther R, Wilson RF. Experimental atrial septal defect closure with a new, transcatheter, self-centering device. Circulation 1993, 88: 1754-1764.
12. Babic UU, Grujicic S, Popovic Z, Djurisic Z, Vacinic M, Pejcic P. Double-umbrella device for transvenous closure of patent ductus arteriosus and atrial septal defect. First experience. J Interven Cardiol 1991, 4: 283-294.
13. Sharafuddin MJA, Gu X, Titus JL, Urness M, Cervera-Ceballos JJ, Amplatz K. Transvenous closure of secundum atrial septal defects. Preliminary results with a new self-expanding nitinol prothesis in a swine model. Circulation 1997, 95: 2172-2178.
14. Hausdorf G, Schneider M, Franzbach B, Kampmann C, Kargus K, Goeldner B. Transcatheter closure of secundum atrial septal defects with the atrial septal defect occlusion system (ASDOS): initial experience in children. Heart 1996, 75: 83-88.
15. Masura J, Gavora P, Formanek A, Hijazi ZMTranscatheter closure of secundum atrial septal defects using the new self-centering amplatzer septal occluder: initial human experience. Cathet Cardiovasc Diagn. 1997, 42: 388-393.
16. King TD, Thompson SL, Mills NL. Measurement of atrial septal defect during cardiac catheterization: experimental and clinical trials. Am J Cardiol 1978, 41: 537-542.
17. Hellenbrand WE, Fahey JT, McGowan FX, Weltin GG, Kleinman CS. Transesophageal echocardiographic guidance of transcatheter closure of atrial septal defect. Am J Cardiol. 1990, 66: 207-213.
18. Rao PS, Langhough R, Beekman RH, Lloyd TR, Sideris EB. Echocardiographic estimation of balloon-stretched diameter of secundum atrial septal defect for transcatheter occlusion. Am Heart J. 1992, 124: 172-175.
19. Worms AM, Rey C, Bourlon F, Losay J, Marcon F, Godart F, Coullet JM. French experience in the closure of atrial septal defects of the ostium secundum type with the Sideris button occluder. Arch Mal Coeur Vaiss. 1996, 89: 509-515.
20. Agarwal SK, Ghosh PK, Mittal PK. Failure of devices used for closure of atrial septal defects: mechanisms and management. J Thorac Cardiovasc Surg 1996, 112: 21-26.
21. Bohm J, Bittigau K, Kohler F, Baumann G, Konertz WSurgical removal of atrial septal defect occlusion system-devices.Eur J Cardiothorac Surg 1997, 12: 869-872.
22. Sievert H, Babic UU, Ensslen R, Scherer D, Spies H, Wiederspahn T, Zeplin HE. Transcatheter closure of large atrial septal defects with the Babic system. Cathet Cardiovasc Diagn 1995, 36: 232-240.
23. Rao PS, Ende DJ, Wilson AD, Smith PA, Chopra PS. Follow-up results of transcatheter occlusion of atrial septal defects with buttoned device. Can J Cardiol. 1995, 11: 695-701.
24. Arora R, Trehan VK, Kalra GS, Chawla R, Jhamb U, Nigam M, Kenchaiah KS, Bhardwaj S, Khalilullah M. Transcatheter closure of atrial septal defect using buttoned device -Indian experience. Indian Heart J 1996, 48: 145-149.
25. Rosenfeld HM, van der Velde ME, Sanders SP, Colan SD, Parness IA, Lock JE, Spevak PJ. Echocardiographic predictors of candidacy for successful transcatheter atrial septal defect closure. Cathet Cardiovasc Diagn 1995, 34: 29-34.

26. Reddy SC, Rao PS, Ewenko J, Koscik R, Wilson AD. Echocardiographic predictors of success of catheter closure of atrial septal defect with the buttoned device. Am Heart J 1995, 129: 76-82.
27. Koike K, Echigo S, Kumate M, Kobayashi T, Isoda T, Ishii M, Ishizawa A, Kamiya T, Kato H. Transcatheter closure of atrial septal defect with a prototype clamshell septal umbrella: one year follow-up. J Cardiol 1994, 24: 53-60.
28. Justo RN, Nykanen DG, Boutin C, McCrindle BW, Freedom RM, Benson LN. Clinical impact of transcatheter closure of secundum atrial septal defects with the double umbrella device. Am J Cardiol 1996, 77: 889-892.
29. Prieto LR, Foreman CK, Cheatham JP, Latson LA. Intermediate-term outcome of transcatheter secundum atrial septal defect closure using the Bard Clamshell Septal Umbrella. Am J Cardiol 1996, 78: 1310-1312.