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Brief Report

Late-term development of an atrial defect and thrombus formation after device fracture following successful transcatheter closure of an atrial septal defect with a STARFlex device

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Abstract Development of a new defect following transcatheter closure of an atrial septal defect has yet to be reported. In this study, we present an acutely successful atrial septal defect closure with a STARFlex device, resulting in surgical explantation after discovery of device fracture, thrombus formation, and a second atrial defect 5 years after catheterisation. This case highlights the need for ongoing device surveillance, even in late follow-up.

Keywords: Thrombus formation; complications; late follow-up; atrial septal defect

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Case report

The STARFlex device was a third-generation umbrella device approved by the United States Food and Drug Administration in 2009 for transcatheter closure of secundum atrial septal defects, previously manufactured by NMT Medical Inc. in Boston, Massachusetts.[1] Use of the STARFlex device for atrial septal defect closure had a high procedural success rate, particularly in terms of long-term follow-up success.[2] Atrial thrombus formation after defect closure has been reported with the use of STARFlex devices (5.7%).[3] Following successful atrial septal defect closure, however, subsequent development of an atrial septal defect associated with a device fracture was not found in the literature.

In this report, we present a patient who underwent acutely successful atrial septal defect closure with a STARFlex device that resulted in surgical explantation after discovery of device fracture, thrombus formation, and shunting 5 years after catheterisation.

Initial presentation

The patient was diagnosed with an atrial septal defect at 6 months of age after discovery of a neonatal murmur. She was followed-up clinically for 4 years with minimal change in defect dimensions and was referred for transcatheter device closure after imaging revealed mild–moderate right ventricular volume overload. Before catheterisation, her echocardiogram demonstrated a 9.7 × 7-mm secundum atrial septal defect located posteriorly and inferiorly, with a deficient posterior rim and left-to-right flow.

Catheterisation procedure

The patient underwent catheterisation at 4.5 years of age. Her haemodynamics confirmed a significant left-to-right shunt through the atrial septal defect with a Qp:Qs of 3. Her right atrial pressure was mildly elevated with a mean of 7 mmHg and otherwise normal intra-cardiac pressures. The defect was balloon sized with a 20-mm PTS® Balloon Catheter (B. Braun Interventional Systems Inc., Bethlehem, Pennsylvania, United States of America) to 12 × 13 mm. The stop flow diameter was 15 mm by fluoroscopy and transoesophageal echocardiogram. A 33-mm STARFlex device was delivered without complication via a 10-F Hausdorf-Lock Atrial, Performer ™ Guiding Sheath (Cook® Medical, Bloomington, Indiana, United States of America), and the defect was closed successfully. Immediately after the procedure, an echocardiogram demonstrated properly positioned device arms, with a moderate

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residual atrial shunt through the central portion of the device via multiple small jets. The following day, a pre-discharge echocardiogram confirmed stable device positioning and reduction in the residual shunt.

Follow-up

At the 3-month follow-up, an electrocardiogram was within normal limits with a QRS axis of +90°. An echocardiogram was notable for resolution of right ventricle dilation and indicated a stabilised device with no residual left-to-right shunting. It was recommended that the patient return in 1 year for further follow-up.

The patient re-presented to the cardiology clinic 5 years after her 3-month follow-up visit. In the interim, she had been followed-up routinely by her paediatrician without further cardiac evaluation, hospitalisation, or significant illness. A new heart murmur was detected at the patient's annual checkup, prompting cardiac evaluation. Doppler imaging and two-dimensional echocardiography indicated either a shift in positioning of the device or loss of structural integrity compared with previous imaging. The echocardiogram showed a right atrial device arm on the left side of the septum and a left atrial device arm protruding within the left atrial lumen. A left-to-right shunt and a non-mobile, non-obstructive right atrial thrombus was detected on the posterior–inferior aspect of the device, with evidence of right ventricular volume overload (Fig 1). The patient was referred to the operating room for surgical removal of the device and thrombus. Preoperative imaging including an X-ray and intraoperative transoesophageal echocardiogram suggested a device arm fracture.

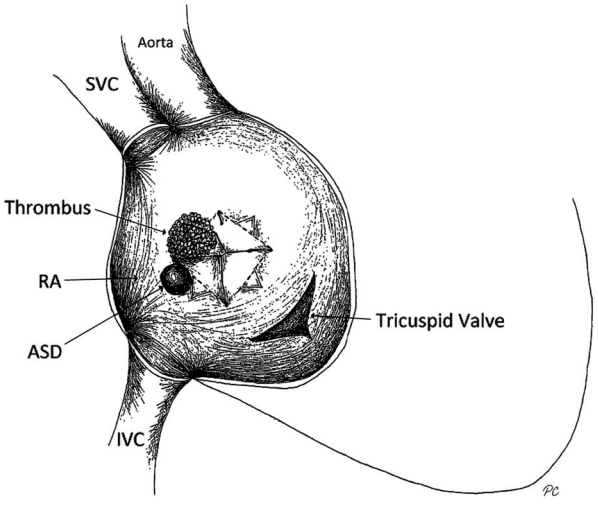

Figure 1.
Schematic of the STARFlex device, thrombus, and atrial septal defect (ASD) as they appeared before explantation. IVC = inferior vena cava; RA = right atrium; SVC = superior vena cava.

Operative procedure

Under general endotracheal anaesthesia, the right atrium was opened and inspected. A large, bland thrombus was visualised, affixed to the right atrial aspect of the STARFlex device, and centred upon a broken arm that was protruding into the right atrial free wall (Supplementary Fig S1). The fractured device and the atrial septal defect on the posterior–inferior aspect were confirmed (Supplementary Fig S2). There appeared to be erosion posteriorly through the right atrium, resulting in perforation upon device excision. After device removal, a pericardial patch was sewn onto the defect. The operation was completed with no complications, and the patient had an uneventful postoperative recovery with a normal echocardiogram on discharge.

Discussion

Owing to its less-invasive nature and low complication rate, transcatheter closure of atrial septal defects is often a preferred method compared with surgery, given suitable anatomy; however, transcatheter device closure is not without risks. Previous case reports have noted device problems in late follow-up, such as development of erosion with the AMPLATZER device and one reported case of dehiscence of an AMPLATZER device in an adult 14 years after implantation.[3–5] The most recent generation of the STARFlex device, no longer available but implanted in patients worldwide, resulted in excellent outcomes with a few complication;[2] however, this case underscores the importance of vigilant late follow-up, which may reveal device fracture, thrombus formation, and recurrent shunting.

The development of an atrial defect after catheterisation, particularly after confirmation of device stabilisation with no residual flow at the 3-month follow-up, is exceedingly rare. To our knowledge, this is the first case of this nature to be reported. Although the mechanism is unclear, there is evidence that the structural integrity of the device was compromised, resulting in an atrial-level shunt and formation of a large thrombus adherent to the device.

The late complication of device arm fracture and malposition, resulting in these complications, is clinically significant. This finding is important, as transthoracic closure of atrial septal defects is a relatively new procedure over the last two decades. This case highlights the need for ongoing and frequent device surveillance as we continue to learn more about long-term device performance in all transcatheter atrial septal defect closures.

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Conflicts of Interest

None.

Supplementary material

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