

Unusual deformity of a Starflex atrial septal defect occluder

Matthias Sigler,¹ Shakeel Qureshi²

¹Department of Paediatric Cardiology and Intensive Care Medicine, Georg-August-University, Goettingen, Germany;

²Department of Paediatric Cardiology, Evelina Children's Hospital, Guy's & St Thomas Trust, London, United Kingdom

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WE PRESENT IMAGES OF A SURGICALLY REMOVED 40 millimetre Starflex device used to attempt occlusion of an atrial septal defect (NMT Medical Inc., Boston, MA, USA). The device had been implanted 44 months previously in a 9 year old female patient with an interatrial communication within the oval fossa, Noonan's syndrome with mild valvar pulmonary stenosis, and Von Willebrand's disease. Removal was indicated because of a large residual shunt and an abnormal deformity, with the device protruding into both atriums, albeit without significant obstruction to flow on colour-Doppler echocardiography. The excised specimen (Fig. 1) was fixed in formalin and embedded in the hard resin methyl-methacrylate (Technovit 9100 new, KULZER & Co, Wehrheim, Germany). Sections of the resin block were prepared using a diamond cutter and subsequent grinding as described previously.¹

On gross examination, the implant was completely covered by smooth-shining, whitish tissue without exposure of foreign material to the blood stream, save for the self-centring springs. Specifically, we found no evidence of fractured arms, nor formation of superficial thrombus. Histologically, the section, stained with Richardson blue (Fig. 2) showed the metal struts and polyester fabric to be entirely surrounded by fibromuscular cells and

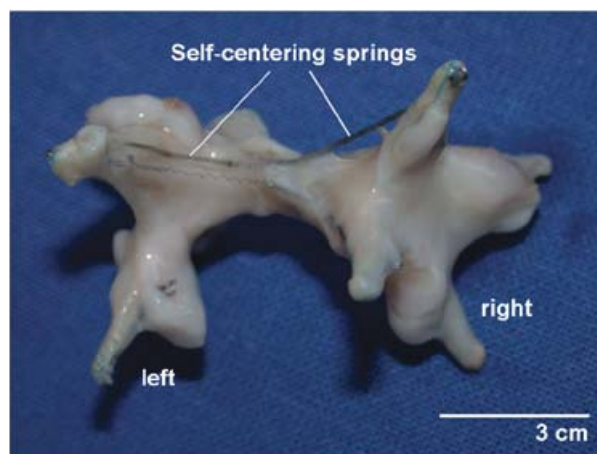


Figure 1.

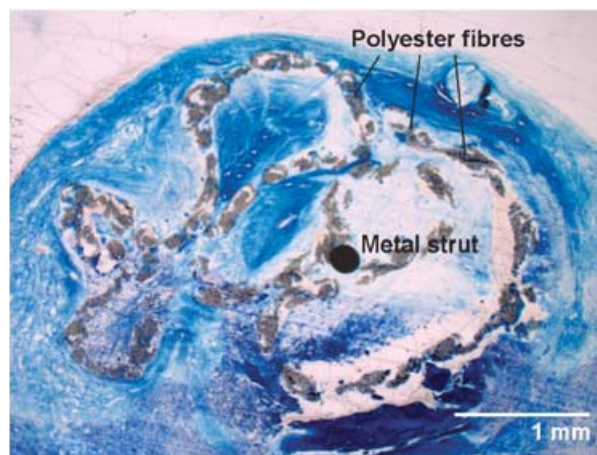


Figure 2.

Correspondence to: Dr Matthias Sigler, Georg-August-University Goettingen, Department of Paediatric Cardiology and Intensive Care Medicine, Robert-Koch-Str 40, D-37075 Goettingen, Germany. Tel: ++49 551 396204; Fax: ++49 551 392561; E-mail: msigler@gwdg.de

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connective tissue. Implant-related inflammatory reaction was only mild, with few foreign body giant cells related to the polyester fibres. A marked meandering infolding of the polyester texture was visible around the arms of the device.

Late protrusion of one or both umbrellas of a Cardioseal Starflex septal occluder is a rare complication. It has occurred with or without residual shunting, and has been associated with recurrence of stroke in one reported case. In our own series of 9 explanted Cardioseal/Starflex devices examined histopathologically, the anomalous arrangement was present in 3. Its aetiology has yet to be identified, either in the literature or in our own

series. Neither local inflammatory reactions nor quality or quantity of tissue formation differed from specimens without this deformity, nor were alterations detected in the metal frame or the polytetrafluorethylene membrane. Since this complication clearly limits the therapeutic benefit of the device, larger series of explants should be analyzed to elucidate the underlying mechanisms of failure, which might then guide improvement in the design of the occluder.

Reference

1. Sigler M, Paul T, Grabitz RG. Biocompatibility screening in cardiovascular implants. *Z. Kardiol.* 2005; 94: 383–391.