Title

Long-term follow-up of the Starflex device for closure of secundum atrial septal defect

Journal

Catheterization and Cardiovascular Interventions, 73(2)

ISSN

1522-1946

Author

Tobis, Jonathan

Publication Date

2009-02-01

DOI

10.1002/ccd.21956

Editorial Comment

Long-Term Follow-Up of the Starflex Device for Closure of Secundum Atrial Septal Defect

Jonathan Tobis,* MD
Professor of Medicine, David Geffen School of Medicine at UCLA, Los Angeles, CA

The accompanying article from Texas Children's Hospital describes the 7–9-year follow-up in 27 patients who had a secundum atrial septal defect (ASD) closure attempted with the Starflex ASD occluder device. The procedural success was 85% (23 patients). Two cases of device embolization occurred with the largest size 40-mm device. The other two unsuccessful cases where primarily because of insufficient aortic rim. At one year, there was 96% complete closure in the 23 patients with only one small <2 mm residual defect.

One of the main questions that patients ask who are considering having a percutaneous closure of an ASD or PFO is what is the long term results with these devices? It is reassuring to know that the long-term follow-up was good in this cohort of 23 patients. There were no late complications, and the right ventricular size normalized in 90% of the patients. Although there were five cases identified of fractured metal spring arms, this did not cause any clinical complications presumably because of the likelihood that there was effective endothelialization of the device by the time that the spring arms fractured.

Despite these reassuring observations with the Starflex ASD device, there are currently much better devices for closure of atrial septal defects. The newer devices are more effective, easier to use, and non-thrombogenic. The Starflex device is limited to ASDs with a maximum balloon stretch diameter of 19-mm. This device requires adequate centering, and therefore, a device that is twice the diameter of the defect needs to be chosen. This report demonstrates the complications associated with the larger devices. In addition, we have reported a 20% incidence of thrombus on the first generation CardioSeal device. Reisman et al. report a 3% incidence of thromboembolism when this device is used to close patent foramen ovale. Other devices that are currently available have a 0% thromboembolism rate, and essentially a 0% rate of device embolization. The manufacturer of the Starflex device, NMT, made significant contributions to the development of percutaneous closure of structural heart defects and should be given appropriate recognition for their pioneering work. However, with the development of newer devices that are associated with a higher success rate and lower complications, my conclusion is that the CardioSeal or Starflex atrial septal defect device should not be used for ASD or PFO closure and should be graciously retired from use.

Conflict of interest: Nothing to report.

*Correspondence to: Jonathan Tobis, David Geffen School of Medicine at UCLA, 10833 Le Cote Ave, Factor Building, Room B-976, Los Angeles, CA 90095, PU-87. E-mail: jtobis@mednet.ucla.edu

Received 8 December 2008; Revision accepted 10 December 2008

DOI 10.1002/ccd.21956
Published online 26 January 2009 in Wiley InterScience (www.interscience.wiley.com).