Initial Experience with the ATRIASEPT™:

A New Device for Transcatheter Closure of Secundum Atrial Septal Defect

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Abstract

Background: The ATRIASEPT™ (Cardia, Eagan, MN) is a low-profile, self-centering, fully retrievable and repositionable, double-umbrella device with a woven Nitinol frame and polyvinyl alcohol sails. It can be used for transcatheter closure of moderate-size secundum atrial septal defects (ASD) up to approximately 24 mm in stretched diameter. The diameter of the inner, self-centering ring is designed to closely match the stretched diameter of the ASD and the total arm length is 14 mm longer than the centering ring diameter. Device endothelialization is excellent. The ATRIASEPT™ contains significantly less metal than the Amplatzer Septal Occluder.

Methods: Device closure using the ATRIASEPT™ was performed at 6 different institutions using transesophageal echocardiography. Catheterization data were collected prospectively, but patients (pts) were not randomized. In the majority of pts, device size was chosen using balloon stretched diameter ("stop-flow" technique). Sheath size was 10-12 Fr. Follow-up (F/U) echocardiography (transthoracic or transesophageal) was performed at 1, 3, and 6 months.

Results: The ATRIASEPT™ was used in 39 pts (26 female), 37 with a single secundum ASD and 2 with additional ASDs. Median age was 25.7 yr (range 3-68 yr) and median weight was 45.3 kg (range 13-115 kg). In 37/39 pts, median ASD balloon stretched diameter was 17 mm (range 8-22 mm). Balloon sizing was not done in 2 pts. The median device centering ring diameter:ASD stretched diameter ratio was 1.06 (range 0.86-2) and the median device total arm length:ASD stretched diameter ratio was 1.86 (range 1.62-3.75). Small, < 2 mm residual left-to-right shunts were present in 5/39 patients (13%) immediately after device release. One pt required device retrieval with subsequent placement of a larger device. At a median F/U of 1 month (range 0-6 months), all pts had proper position of the ATRIASEPT™, sinus rhythm, and no mitral regurgitation. A 1.5 mm residual shunt was present in 1 pt (3%) at 1 mo F/U. In the smallest pt (13 kg) with a deficient anterior-superior rim, a 12 mm ATRIASEPT™ initially caused mild mitral regurgitation that resolved at 3 mo follow-up (F/U).

Summary: The ATRIASEPT™ is a new low-profile, self-centering, right-side retrievable and repositionable device for closure of moderate-size secundum ASD. Initial F/U shows the ATRIASEPT™ to be safe and effective in both children and adults. Further study of the ATRIASEPT™ is warranted.

Background

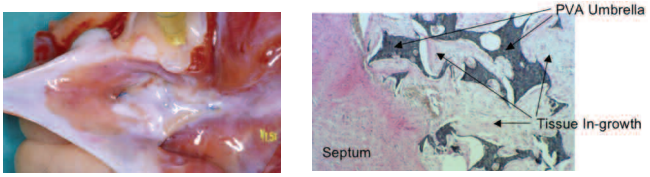
DEVICE CHARACTERISTICS

- Easy loading with locking bioptome delivery system
- Low-profile, self-centering, double-umbrella device design
- 6-arm, 19-strand woven Nitinol frame with polyvinyl alcohol (PVA) umbrellas that articulate individually to conform to septal anatomy before and after device release
- Centering ring sizes 12 – 34 mm diameter (2 mm increments)
  - 22 mm diameter device was the largest available in this series
- Total arm length is 14 mm greater than centering ring diameter
- Fully retrievable and repositionable without removing the device
- No exposed metal on the left atrial umbrella
- Excellent device endothelialization

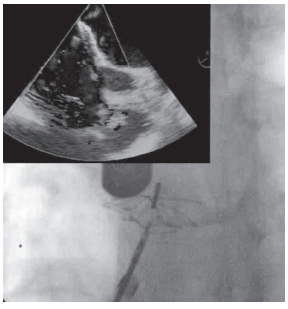
Results

ILLUSTRATIVE

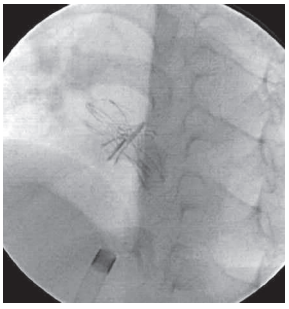
ATRIASEPT™ left atrial disk (left), centering mechanism (center) and appearance during delivery (right)



ATRIASEPT™ endothelialization (left) and microscopic appearance (right) at 137 days (lamb)



ATRIASEPT™ attached to delivery cable by TEE (top) and lateral fluoroscopy (bottom)



ATRIASEPT™ released from delivery cable, lateral fluoroscopy