

Atrial Septal Defect and the CardioSEAL™ Device

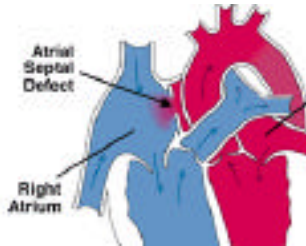
ELE282 Biomedical Engineering Seminar, April 3, 2000

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WHAT IS ASD?

Atrial Septal Defect is a congenital defect where the opening between the right and left atria, which is present during fetal development, does not close. This opening allows oxygenated and deoxygenated blood to mix,



causing certain parts of the heart to work harder to supply the body with the necessary amount of oxygen. There are approximately 4 out of every 100,000 people with ASD.

WHAT ARE THE LONG TERM EFFECTS OF ASD?

If an ASD is not detected in early childhood, the flow of blood from the left atrium to the right atrium causes the right ventricle and the lungs to work harder. Thus resulting in an enlargement of the right ventricle, and an increase in the pressure of the main arteries of the lungs. Sometimes an ASD can lead to shortness of breath and decrease in exercise tolerance. It is also common for an ASD to cause an abnormal heart rhythm, often the symptom that suggests ASD.

HOW DO YOU TREAT ASD?

Until recently, the only way to close the hole between the atria was with open-heart surgery. This procedure carries many risks as well as extensive scarring and recovery time. When closing the opening in open-heart surgery, a patch is sewn over the defect or the defects edges are pulled together and the hole is sewn closed. Now, with the CardioSEAL™ device, the defect can be closed using a catheter that is inserted in a vein in the leg and then directed through the body into the heart. This method involves the implantation of an umbrella shaped device,

which covers the defect and allows the heart to mend itself over the meshwork.

WHAT ARE THE ADVANTAGES OF THE CARDIAC CATHETERIZATION?

- Avoidance of deep general anesthesia
- Not necessary to be placed on a heart-lung machine
- No direct cutting or suturing of the heart.
- Short recovery (*Open heart*: 4-7 days in hospital and 4-6 weeks until normal activity, *Catheterization*: Overnight in hospital and resume normal activities within 2 days)



- Cosmetically better, no chest scar

WHAT IS THE CardioSEAL™ DEVICE?

OVERVIEW: The CardioSEAL™ is a catheter delivered implant device developed and manufactured by Nitinol Medical Technologies, Inc. It is a “double umbrella” with Dacron fabric attached to metal arms. These arms place the device over the defect and hold the device in place until tissue grows over it.

HISTORY: The CardioSEAL™ device is the second generation of the Clamshell Occluder. The Clamshell was tested in over 700 patients since 1989 and has successfully closed various heart defects, including ASD. Over time, it was discovered that one or more of the Clamshell’s metal arms would sometimes break. In order to fix this problem, the CardioSEAL™ was developed which altered the manufacturing of these arms. The new arms were tested and shown not to break if the device is used correctly, but some arm fractures have been reported. Based on all clinical trial experience, the fracture rate of the CardioSEAL™ arms is approximately 13%. There is actually a more recent version of the CardioSEAL™ called the STARFlex, also manufactured by Nitinol, but it has a self-centering capability. There are extra springs between the two umbrellas that allow the device to find a center position over the hole, producing a greater chance that the entire defect will be closed.

References:

Mike Landzberg, M.D. and the Cardiology Department, Children’s Hospital, Boston, MA
<http://www.childrenshospital.org/cardioseal/>

Nitinol Medical Technologies, Inc.
<http://www.nitinolmed.com>

Various Web Addresses: <http://www.heartpoint.com/congasd.html> and <http://www.cardio.com/articles/atri-sep.htm>