

EMBOLIC FILTERING METHOD AND APPARATUS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part (CIP) of U.S. patent application Ser. No. 10,847,909, filed May 19, 2004, which is based on and claims priority to U.S. Provisional Patent Application No. 60/471,555, May 19, 2003, the entire disclosures of which are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates generally to a device and method for preventing the undesired passage of emboli from a venous blood pool to an arterial blood pool. The invention relates especially to a device and method for treating certain cardiac defects, especially patent foramen ovals and other septal defects through the use of an embolic filtering device capable of instantaneously deterring the passage of emboli from the moment of implantation.

[0004] 2. Description of Related Art

[0005] The fetal circulation is vastly different than the normal adult circulation. The blood circulating in a fetus is oxygenated by the placenta, not the developing lungs. Therefore, the fetal circulation directs only a small percentage of the circulating blood to the fetal lungs. Most of the circulating blood is shunted away from the lungs to the peripheral tissues through specialized vessels and foramina that are open ("patent" during fetal life. In most people these specialized structures quickly close after birth. Unfortunately, they sometimes fail to close and create hemodynamic problems that can be fatal if left untreated.

[0006] A diagram showing the blood circulation of a human fetus is illustrated in **FIG. 1**. The umbilical arteries branch off of the iliac arteries and deliver unoxygenated blood to the placenta. The fetal blood travels through the capillary bed in the placenta and transfers carbon dioxide to the maternal blood and takes oxygen and other nutrients from the maternal blood. The umbilical vein returns oxygenated blood to the fetus. Most of the oxygenated blood from the umbilical vein bypasses the developing liver and travels through a specialized vessel called the ductus venosus to the inferior vena cava and then into the right atrium. A good portion of the oxygenated blood from the inferior vena cava is directed across the right atrium and into the left atrium through a specialized curtain like opening in the heart called the foramen ovale. The blood from the left atrium then enters the left ventricle and then into the aorta where it travels to the head and other body tissues delivering the needed oxygen and nutrients.

[0007] The small amount of blood entering the right atrium that does not pass through the foramen ovale, most of which comes from the superior vena cava, flows into the right ventricle and then gets pumped into the pulmonary trunk and pulmonary arteries. Some of this blood is pumped into the developing lungs. However, the fetal lungs are collapsed which causes a high resistance to blood flow. Another specialized vessel, called the ductus arteriosus, is a vessel that connects the high pressure pulmonary artery to

the lower pressure aorta. Therefore, most of the blood in the pulmonary artery flows into the lower pressure aorta through this specialized vessel.

[0008] Upon birth, the circulatory system goes through profound changes. The flow through the umbilical arteries and umbilical vein stops and consequently the flow through the musculature around the ductus venosus constricts and the blood flow through the ductus venosus stops. The lungs fill with air and the resistance to blood flow into the lungs drastically decreases. The corresponding pressure in the right atrium, right ventricle, and pulmonary arteries also decrease. The decrease in pressure in the right atrium causes the curtain like opening of the foramen ovale to close, driving more blood into the right ventricle and then to the lungs for oxygenation. Over time, the foramen ovale is replaced with a membrane called the fossa ovalis. Similarly, the decrease in pressure in the pulmonary arteries reduced the pulmonary arterial pressure to the same as or slightly less than the pressure in the aorta, which stops or reverses the flow through the ductus arteriosus. Once the muscular tissue of the ductus arteriosus is perfused with well oxygenated blood, the muscle begins to constrict and close the ductus arteriosus. The ductus arteriosus normally closes within about one week of life.

[0009] Usually over time, the unique openings of the fetal circulation become obliterated and a solid mass of tissue forms where these opening once were. However, in some people the opening remain. A patent ductus venosus after birth is very rare and almost always fatal. A patent ductus arteriosus occurs in about 1 out of every 5000 births. The patent ductus arteriosus once diagnosed is either medically treated or surgically ligated to close the ductus. In about one of four people, the foramen ovale does not seal shut, instead it remains patent. Such defects usually measure 10 mm or more in diameter and occupy one third or more of the length of the atrial septum in echocardiographic four chamber sections. Since the pressure in the left atrium is about two to four mm Hg greater than the pressure in the right atrium, the curtain like opening usually remains shut. However, if the pressure in the right atrium increases, such as upon heavy lifting or while performing a Valsalva type maneuver, the curtain like fold of tissue opens and the blood flows from the right atrium to the left atrium.

[0010] Studies have shown that adults with strokes of unknown origin, i.e., cryptogenic strokes, have about twice the normal rate of patent foramen ovals than the normal population. Although there is a correlation between strokes and patent foramen ovals, it is currently unknown why this correlation exists. It is theorized that blood clots and plaque that have formed in the peripheral venous circulation (in the legs for example) break off and travel to the heart. Normally, the clots and plaque get delivered to the lungs where it is trapped and usually cause no harm to the patient. Patients with a patent foramen ovale, however, have a potential opening that the clots or plaque can pass through the venous circulation and into the arterial circulation and then into the brain or other tissues to cause a thromboembolic event like a stroke. The clots may pass to the arterial side when there is an increase in the pressure in the right atrium. Then the clots travel through the left side of the heart, to the aorta, and then to the brain via the carotid arteries where they cause a stroke and the associated neurological deficits.