

Affordable stent graft and its delivery system developed for treating aorta enlargement

A team of Scientists from Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) an autonomous Institute under the Department of Science and Technology (DST), have developed a new affordable stent graft and its delivery system for the treatment of thoracic aortic aneurysm a potentially fatal condition if left untreated.

Thoracic aortic aneurysm is the ballooning or enlargement of the aorta, the main artery that carries blood away from the heart to the rest of the body. In India currently, Thoracic surgeons use the imported stent-grafts for the Endovascular Aortic Repair (EVAR), a minimally invasive technique which involves the insertion of stent-grafts in the diseased vessel, by a delivery catheter which enters the central circulatory system through the femoral artery (artery in the groin area), as there is no indigenous device available in the market.

The imported stent-graft, along with its delivery system, costs at least 3.5 lakhs. Besides, they are designed for the anatomy of the aorta of Europeans and have a larger diameter catheter, which is difficult to insert and pass through the femoral artery of Indian patients (Asian Population in general) and often injuries to the blood vessels.

This led Dr. Sujesh Sreedharan and his team from SCTIMST to develop an indigenous affordable stent graft and its delivery system that costs lower and is suitable for the anatomy of the Asian population.

Aortic aneurysm is a disease affecting about 5% of the population in their late sixties and can be fatal in case of rupture. Most patients with aortic aneurysms do not have any symptoms at all. The aneurysm is usually discovered by X-ray during a routine health exam for some other, unrelated condition. When symptoms do occur, pain in the chest or abdomen is most common, depending on the aneurysm's location. Some people describe a pulsing sensation in the abdomen as a symptom of an abdominal aortic aneurysm. A thoracic aortic aneurysm may cause back pain, shortness of breath, or difficulty swallowing. Smoking, High blood pressure, High Cholesterol, Old age, Hardening of the arteries, Diabetes, and Hereditary factors are the major causes of Aortic aneurysm.

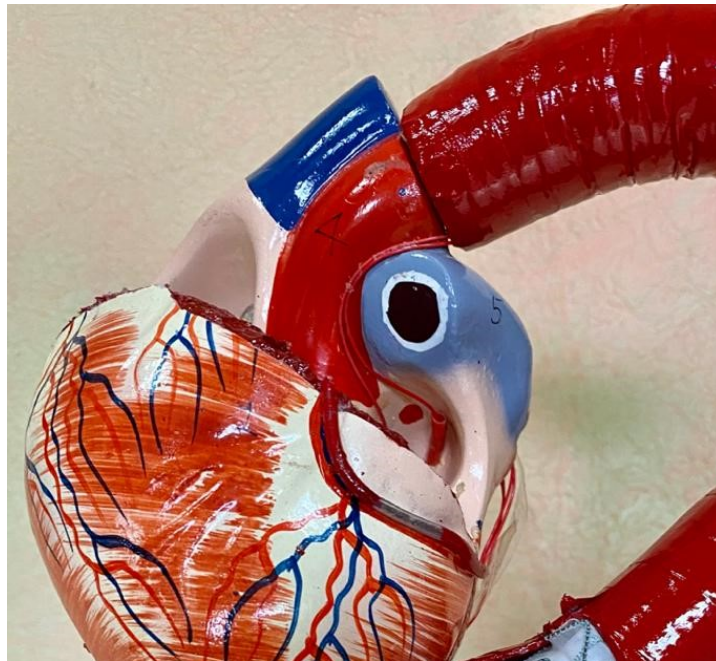
SCTIMST developed a new asymmetric design for the NiTi (Nickel Titanium Alloy) rings (stents- a tube consisting of a fabric supported by a reinforcing metallic mesh), which redirects the blood flow through it. The principle of aneurysm treatment in endovascular repair is to produce a sealed conduit for blood to pass through the affected segment of the aorta without leaking into (and pressurizing) the aneurysm sac, preventing the aneurysm wall from rupturing.

NiTi rings (stents) can be compressed to a lower diameter and can be inserted into a lower diameter catheter sheath. This asymmetric design helps the stent graft to affix itself to the inner aortic wall, thereby resisting the displacement of stent-graft during the flow of blood.

Endoleak(Type-1) is a defect which occurs after the deployment of the stent-graft in the aneurysm area. Blood enters through the gap between the inner aortic wall and the upper end of the graft fabric.

To prevent this defect, SCTIMST developed a braided 'end cuff' made of NiTi, which when sewed at the proximal end of the tubular graft eradicates the gap between the inner aortic wall and prevents the occurrence of Endoleak (Type-1).

A tip capture mechanism is also provided at the end of the delivery catheter, which helps in positioning the stent-graft in aorta and releases while deploying the stent-graft. This helps accurate positioning of the stent-graft during delivery. The delivery system incorporates a new feature for the fast release of the stent-graft and accurately deploys the device during the EVAR procedure.



The stent-graft developed by SCTIMST is made up of polyester fabric sewed in tubular form and are scaffolded by NiTi (Nickel Titanium Alloy) rings (stents), which are sewed into the tubular fabric. The NiTi rings were made in collaboration with National Aerospace Laboratories, Bangalore (CSIR-NAL).

The stent-graft is compressed to a lower diameter and is inserted into the Catheter Sheath (small diameter delivery tube) of the delivery system. During the EVAR procedure, the sheath, along with the compressed stent graft, is inserted through the artery in the groin area and to reach the aneurysm. The catheter sheath is then retrieved using a mechanism provided in the delivery system after deploying the stent-graft at the correct position. The stent-graft expands and fixes firmly on the inner aortic wall because of the superelastic property exerted by the NiTi rings. Once the stent-graft is in place, blood flow occurs only through the conduit created by the stent graft, excluding the aneurysm and preventing its rupture.

Six patent applications and five design registrations were filed for the developed technology.