First clinical use of bioabsorbable vascular grafts in children shows promise

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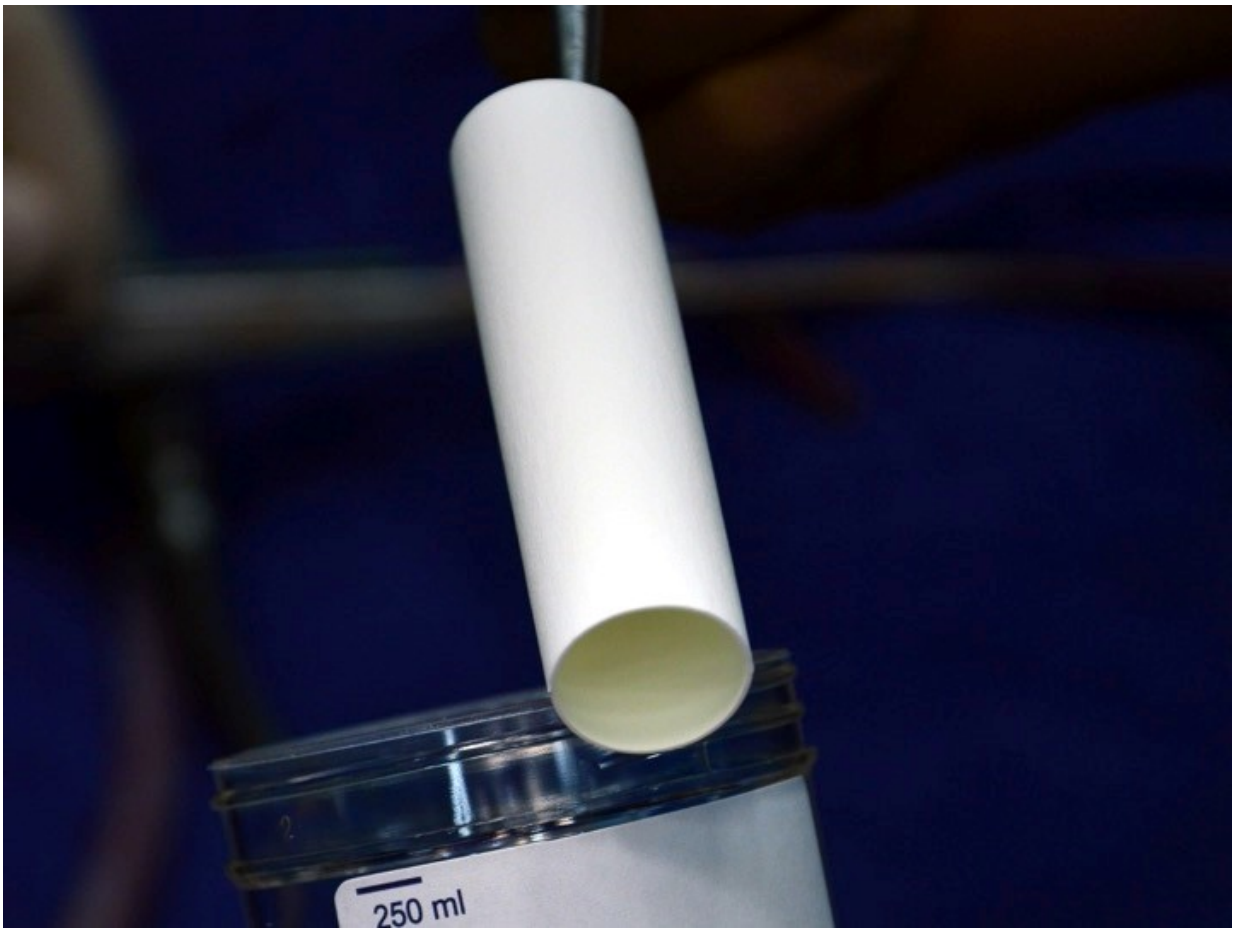
Professor Leo Bockeria with Dominika, the first patient implanted a bioasborbable graft. Credit: Xeltis

Current cardiovascular valve or blood vessel implants are generally associated with a number of complications, have limited efficacy over time, and may necessitate repeated interventions over a patient's lifetime, especially when implanted in a young child. In a presentation at the 96th AATS Annual Meeting, a team of surgeons from the Bakoulev Center for Cardiovascular Surgery, Moscow report their success with implantation of bioabsorbable vascular grafts used to correct a congenital cardiac malformation. Over time, the grafts are designed to biodegrade as a patient's own cells and proteins reconstitute natural functioning tissue, thus reducing permanent implant-related complications.

Bioabsorbable heart valves or blood vessels are designed to harness the body's innate healing process, enabling the natural restoration of complex body parts as the synthetic graft is absorbed. At the 96th AATS Annual Meeting, surgeons from the Bakoulev Center for Cardiovascular Surgery, Moscow report the results of implantation of bioabsorbable vascular grafts placed into five children born with serious cardiovascular anomalies. According to the investigators, this is the first-ever clinical trial of a bioabsorbable cardiovascular device.

"The positive results of the study provide hope for a new therapeutic approach in cardiovascular valve replacement called Endogenous Tissue Restoration (ETR). This is potentially a revolutionary approach to regenerative medicine in cardiovascular treatment," says lead investigator Leo Bockeria, MD.

The procedure was designed to help children born with single ventricle anomalies, a term used to describe a group of cardiac defects that shares the common feature that only one of two ventricles functions adequately. This can be due to lack of a heart valve, abnormal pumping ability of the heart, or other problems. The surgical procedure, known as a Fontan procedure, involves diverting the venous blood from the right atrium to the pulmonary arteries without passing through the area of the right ventricle.



The first ever bioabsorbable cardiac pulmonary graft. Credit: Bakoulev Scientific Center for Cardiovascular Surgery.

In this prospective, single-center feasibility study, five children aged 4.5 to 12.5 years born with a single-ventricle congenital malformation were implanted with a bioabsorbable graft connecting the inferior vena cava with the right pulmonary artery during an extracardiac Fontan procedure. Patients were followed for 12 months after surgery using echocardiography, CT-scan and MRI. No device-related adverse events were reported.

The grafts are composed of supramolecular bioabsorbable polymers,

manufactured using a proprietary electrospinning process by European medical device company Xeltis. The grafts have no size limitations, although this study used grafts that were 18 and 20 mm in diameter. Histological studies of the grafts in sheep have shown that graft implantation is followed by initial infiltration of inflammatory cells, which induces physiological healing and tissue formation. This is followed by degradation of the implant scaffold with eventual reduction of the inflammatory response.

The investigators report that all five patients successfully recovered from the procedure, with significant improvement noted in the patients' general condition. Imaging studies demonstrate anatomical and functional stability of the grafts.

Although longer follow-up is needed, the investigators say that the procedure has the potential to improve cardiac and vascular surgical procedures by reducing complications resulting from permanently-placed implants. This is especially important for a child who must live with the after-effects of surgery over his lifetime.

More information: "A Novel Bioabsorbable Vascular Graft in a Modified Fontan Procedure - the First Clinical Experience," by Leo Bockeria, Oleg Svanidze, Alex Kim, Konstantin Shatalov, Vladimir Makarenko. Late-Breaking Clinical Trial Presentation at the 96th AATS Annual Meeting, May 14-18, 2016, Baltimore, MD, during the Congenital Heart Disease Simultaneous Scientific Session on May 17, 2016. aats.org/annualmeeting

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