

Baylor Scott & White cardiologists play critical role in determining how sonic waves may help treat advanced heart disease

Research in the Journal of the American College of Cardiology shows potential for 'shockwaves' to safely break up calcified plaque prior to stenting

October 16, 2020 -- Research for a new treatment for coronary artery disease that included participation by cardiologists on the medical staff at Baylor Scott & White Heart and Vascular Hospital – Dallas (BSWHVH) was recently published in the [*Journal of the American College of Cardiology \(JACC\)*](#). The article cites that patients with an advanced form of coronary artery disease (CAD) benefited from an investigational treatment that used sonic pressure waves to break up hardened blockages in the heart. The novel therapy not yet available to the general public is similar to the therapy used to break up kidney stones, and is known as Intravascular Lithotripsy (or IVL). It is currently being reviewed by the U.S. FDA for potential pre-market approval in the United States under a “Breakthrough” designation. One of the primary investigators was Robert Stoler, MD, FACC, FSCAI, co-medical director for cardiology and medical director for catheterization laboratory at BSWHVH – Dallas.

As people with CAD grow older and their disease progresses, plaque in the arterial wall evolves into calcium deposits, which narrow the artery. These bone-like structures make the artery rigid and more difficult to treat with current treatments, which can sometimes result in complications for patients. IVL is an innovative technology that generates sonic pressure waves – or shockwaves – on a conventional balloon catheter to fracture the problematic calcium so that the artery can be expanded, and blood flow restored with the placement of a stent.

“We were thrilled to be among the first centers in the United States to offer our study patients in North Texas access to this potential therapy as part of this important study,” said Dr. Stoler. “Hardened calcium within the heart is becoming more common as people are living longer and is very challenging to treat. From the new research just published, we now know that sonic pressure waves can modify the calcium in a predictable and safe manner and potentially help patients avoid unnecessary complications of previous treatments. If all goes well with the FDA, we will soon be able to offer this treatment to many more patients.”

The Disrupt CAD III study enrolled 384 patients at 47 sites in the United States, France, Germany, and the United Kingdom. The study met both the safety and effectiveness endpoints, and had high procedural success and few adverse events. With high procedural success, investigators were able to modify the calcium and expand the artery sufficiently to restore blood flow. This was complemented with a low rate of major adverse cardiac events, meaning there was limited damage to the heart muscle or need for a repeat procedure. The study also found a very low risk of complications that can be found with other technologies.

Shockwave C² Coronary IVL catheters are limited to investigational use in the United States by the FDA. The study, which was administered through Baylor Scott & White Research Institute. Learn more about [clinical trials](#) with Baylor Scott & White Research Institute.

About Calcified Coronary Artery Disease

Calcium slowly develops and progresses to its hardened, bone-like state over the course of several decades of cellular growth and death in diseased plaque within the heart arteries. While it is slow to develop, its impact is immediately encountered when performing procedures in calcified lesions. The calcium's hardened structure restricts normal artery movement and makes the rigid arterial tissue resistant to traditional balloon therapies that have been designed to compress the plaque within the artery wall to restore normal blood flow. For these reasons, the presence of calcium increases the complexity of most cases and decreases the effectiveness of most treatments.

How Intravascular Lithotripsy (IVL) Works

Intravascular Lithotripsy uses a small generator to produce therapeutic sonic pressure waves from a catheter that is threaded through the arterial system to the site of the heart blockage. The pressure waves pass through the soft arterial tissue, preferentially disrupting the hardened calcified plaque inside the arterial wall by creating a series of micro-fractures. After the calcium has been modified, the artery can be expanded using a low-pressure balloon and a stent, thereby enabling even historically challenging CAD patients to be treated effectively with minimal injury to the artery. For an animation of the procedure, visit www.intravascularlithotripsy.com.

About Baylor Scott & White Heart and Vascular Hospital - Dallas

Founded in a tradition of research and innovation, Baylor Scott & White Heart and Vascular Hospital – Dallas† opened in 2002 as the region's first and only dedicated hospital to heart and vascular care. The Dallas hospital is located adjacent to Baylor University Medical Center - Dallas, a part of Baylor Scott & White Health. Baylor Scott & White Heart and Vascular Hospital – Dallas has cardiology services available at Baylor Scott & White All Saints Medical Center – Fort Worth. With more than 43,000 patient registrations annually, a broad array of advanced cardiac interventional procedures and vascular surgeries are available, as well as diagnostic imaging and cardiac rehabilitative services. Programs on wellness and prevention are offered for the community. Additional information may be found at the hospital's website, BaylorHeartHospital.com or on the app, Baylor Heart Center, downloaded from the Apple store. To find a specialist, please call 1.844.BSW.DOCS.

About Baylor Scott & White Research Institute

Extending investigational expertise across more than 50 specialties areas, Baylor Scott & White Research Institute provides the business and regulatory infrastructure to accelerate medical breakthroughs and innovative new treatment models through clinical and translational activities. Baylor Scott & White Research Institute is present at sites and centers across Baylor Scott & White Health and maintains nearly 2,000 active trials each year.

† Joint ownership with physicians.

Notice Regarding Physician Ownership: Baylor Scott & White Heart and Vascular Hospital is a hospital in which physicians have an ownership or investment interest. The list of the physician owners or investors is available to you upon request. Physicians provide clinical services as members of the medical staff at one of Baylor Scott & White

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