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# Valve Leaflet Scoring Device for Aortic Stenosis Clears Feasibility Hurdle

## Investigators for the small study believe fracturing rigid leaflets can delay or augment TAVR. One surgeon isn't convinced.

*By* **Michael O'Riordan** *May 23, 2019*


PARIS, France—In a small, feasibility study, a new percutaneous device used to fracture calcium deposits in patients with degenerative calcified aortic stenosis to improve leaflet mobility had a significant effect on aortic valve area and lowered the mean pressure gradient.

The Leaflex Performer catheter system (Pi-Cardia) was used to treat 16 patients scheduled to undergo TAVR, but investigators speculate the technology could be used not only to prep patients with heavily calcified aortic valves before the procedure, but even as a solo treatment, one that might push back the need for transcatheter valve replacement.

Baumbach, MD (Queen Mary University of London and Barts Heart Center, London, England), during a late-breaking clinical trials session at EuroPCR 2019. “Where is this going? I think the Leaflex as a stand-alone procedure has the potential to fill a gap and expand treatment options for patients with aortic stenosis.”

The Leaflex device scores the leaflets to create multiple fractures at areas of valve calcification. By cracking the calcium and creating space in the calcium deposit, the technology improves flexibility and restores leaflet mobility while preserving the native valve, investigators say. The catheter includes expandable nitinol elements that, when placed across the valve, are compressed to score the calcium from the aortic side.

The device was successfully introduced into all 16 patients and device scoring performed in 11 patients. Aortic valve area increased from 0.7 cm2 prior to scoring to 1.2 cm2 after the procedure was performed. Mean pressure gradient decreased from 34 to 18 mm Hg while the peak-to-peak pressure gradient decreased from 51 to 21 mm Hg. All changes from baseline were statistically significant.

“We were selective in this early group,” said Baumbach. “We wanted to prove the principle. This was not an all-comers study and patients with prohibitively large calcium ‘blobs’ on the leaflets were excluded. Every patient was screened with CT. The next generation of the device will be able to cut through larger chunks of calcium and I think the selectiveness will be less.” He noted that the first-generation device comes in one size and is designed for aortic annulus diameters between 23 and 26 mm, but future devices are expected to come in three sizes.

In terms of safety, there was one noncardiac death not related to the procedure at 16 days. As for stroke, there were two events, neither embolic, with one related to a prolonged procedure and the other related to emergency surgery following perforation of the left ventricle. Baumbach said they did not capture any large emboli in the cerebral protection devices. He added that the Leaflex Performer is “very reminiscent” of the first-generation transcatheter heart valves in the way it moves through the aortic arch. “There was no problem bringing it into position,” he said. “The procedure itself takes about 20 minutes.”

## Unmet Need or Unneeded Work

Cardiothoracic surgeon Olaf Wendler, MD (King’s College Hospital, London, England), who was not involved in the trial, said decalcification of the aortic valve has been performed during surgery, but it’s no longer regularly done because the process has the unintended effect of promoting calcium deposits. While the Leaflex device fractures the calcification, which differs from decalcification performed in surgery

Aside from such biological considerations, Baumbach believes there is an unmet clinical need for the device in patients with aortic stenosis. He pointed out the scoring device differs substantially from balloon aortic valvuloplasty (BAV), which is also a temporary measure but one no longer recommended because the results aren't particularly durable.

"With balloon valvuloplasty, you stretch more than you crack, and there is immediate recoil," he said. "In some individual cases you might get a better result, and maybe even a lasting result, but usually these effects don't last. This procedure is entirely different in that it selectively cuts into the bridges of calcium that are the reason the leaflets actually don't move. It restores leaflet mobility and creates a much larger aortic valve area than balloon valvuloplasty. There is no reason to think there is any recoil because nothing is stretched."

Wendler, however, isn't particularly convinced. "At what point in the [disease process] of the patient with aortic stenosis would you use this device?" he asked. "I don't know if there's an advantage to delay future TAVR implantations by 1 or 2 years."

BAV has largely been left behind, said Wendler, because TAVR is such a successful treatment and has a low rate of complications. "You might as well just do one procedure and do it right the first time," he said. "If you do two procedures, you double the risk of stroke. That's why I have doubts about the indication."

Baumbach agreed that long-term results are lacking so they simply don't know how the procedure will be used. "Is this a procedure that will create a larger aortic valve area indefinitely, or can it push out the next procedure for the next 3, 4, or 5 years? Maybe yes," he said. "In this case, the procedure will have a role in environments where TAVR is still prohibitively expensive, and we will find roles in patients where we don't want to implant a valve at that point in time."



## Sources

Baumbach A, Hildick-Smith D, Mylotte D, et al. Safety, feasibility, and acute performance of the Leaflex Performer when used pre-TAVI in aortic stenosis patients: the Leaflex feasibility study. Presented at: EuroPCR 2019. May 22, 2019. Paris, France.

Baumbach reports receiving institutional research support from Abbott Vascular and consulting/speaker fees from AstraZeneca, Sinomed, MicroPort, Abbott Vascular, Cardinal Health, and KSH.