CARDIOVASCULAR FLASHLIGHT

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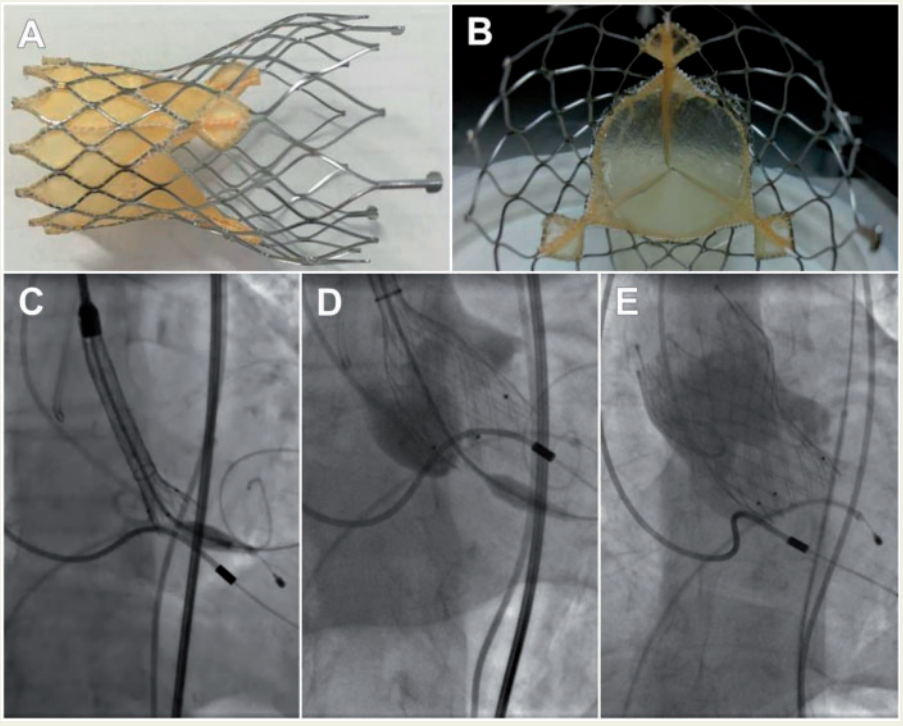
First-in-man implantation of a pre-packaged self-expandable dry-tissue transcatheter aortic valve

Yuan Feng[1†], Zhen-Gang Zhao[1†], Jorge Baccaro[2], Min Frank Zeng[3], R. David Fish[4], and Mao Chen[1*]

[1]Department of Cardiology, West China Hospital, Sichuan University, 37 Guoxue Road, Chengdu 610041, People's Republic of China; [2]Corrientes Institute of Cardiology, Corrientes, Argentina; [3]Venus MedTech Inc., Hangzhou, China; and [4]Texas Heart Institute, Houston, USA

* Corresponding author. Tel: 86-28-85423362, Fax: 86-28-85423169, Email: hmaochen@foxmail.com

† The first two authors contributed equally to the study.



Transcatheter aortic valve implantation (TAVI) has become the mainstay of treatment for aortic stenosis. Reasonable extension of TAVI utilization into a broader group, however, would mandate further device refinement.

The Venibri Valve is designed for outcome optimization and procedural simplification of TAVI by incorporating advantages of the self-expandable Venus A-Valve frame (Venus Medtech Inc., Hangzhou, China) and the proprietary 'dry' tissue technology (Colibri Heart Valve LLC, Broomfield, CO, USA). The inflow of the multi-level support nitinol frame has been strengthened for bicuspid and severely calcified valve with radiopaque markers indicating the landing zone. The trileaflet porcine pericardial leaflets, which has been processed with the proprietary 'dry' tissue technology, are sutured in a supra-annular position (*Panels A* and *B*). Briefly, the pericardial tissue undergoes the following procedures before it could be cut into specified dimension for suturing: (i) excess fat trimmed off; (ii) mounted on a frame and fixed in glutaraldehyde solution; (iii) placed in glutaraldehyde solution plus 20% isopropyl alcohol for bioburden reduction; (iv) rinsed with saline; (v) immersed in special chemical solution for final chemical treatment; and (vi) laid on a flat surface under an air purifying hood and air dried for 72 h at room temperature. With proven freedom of glutaraldehyde residuals, biocompatibility, resistance to calcification, and tolerance to accelerated wear and fatigue tests, the dry-tissue prosthetic valve is expected to carry favourable durability. The valve has been pre-mounted, pre-packaged, and sterilized at manufacturer, thus is ready for use off the shelf and does not need on-site valve preparation.

The first-in-man implantation of the Venibri Valve was performed in an 82-year-old female with severe aortic stenosis at Corrientes Institute of Cardiology, Argentina. Patient informed consent and institutional review board approval were obtained in advance. The procedure was performed via transfemoral access. Immediately upon package removal, a 29-mm pre-mounted Venibri Valve was ready for use. After purging the system of air, it was inserted over the guidewire. The processes and techniques of valve insertion, advancement, and deployment were generally similar to those engaged in a typical self-expandable TAVI procedure (*Panels C* and *D*), except that slower controlled release at the initial stage was intended to allow full hydration and early functioning of the dry-tissue leaflets. It took approximately 15 min from package opening to delivery system retrieval. The mean pressure gradient was 4 mmHg post-deployment with no paravalvular leak (*Panel E*). She was fully ambulant (NYHA functional class I) at 6-month follow-up.

Rapid wait-free TAVI, which could be life-saving in the setting of haemodynamic instability or under other emergent circumstances, is demonstrated possible in this Venibri first-in-man case. Besides, as the device can be easily transported and stored, it also confers the potential of facilitating TAVI dissemination to resource-poor regions. The innovation will help promote TAVI efficiency and accessibility.