

Figure. Edwards-SAPIEN 3 prostheses implanted, 23 (A), 26 (B) and 29 mm (C). Placement of the valve at the level of the ring (E) with elevation of the valve after inflation of the balloon (F). The solid line indicates the central zone of the prosthesis, marked by the radiopaque line of the balloon. The dotted line indicates the ideal final position that this marker should reach. Image of a 23 mm prosthesis before implantation, with polyethylene terephthalate outer skirt (D, arrow).

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NEW MODELS OF PERCUTANEOUS AORTIC VALVE PROSTHESIS

Initial Experience With the DirectFlow Percutaneous Aortic Valve in Spain



Experiencia inicial en España con la prótesis aórtica percutánea DirectFlow

To the Editor,

Percutaneous implantation of an aortic prosthesis in patients with severe aortic stenosis and high surgical risk has been proven to be more effective than medical treatment¹ and similar or superior² to conventional surgery according to the experience

gained with the Edwards-SAPIEN (Edwards Lifesciences; Irvine, California, United States) and Medtronic CoreValve (Medtronic; Minneapolis, Minnesota, United States) prostheses in clinical trials^{1,2} and clinical practice registers.³

The DirectFlow^{4,5} prosthesis (DirectFlow Medical; Santa Rosa, California, United States) has recently been marketed; its potential advantages over existing devices are the possibility of repositioning/recapturing the device, hemodynamic stability during the procedure, and a low rate of significant aortic failure.

The DirectFlow prosthesis (Figure) does not have any metal components and its structure is a system of communicating vessels, which when filled with liquid, make 2 rings (fluid entry via

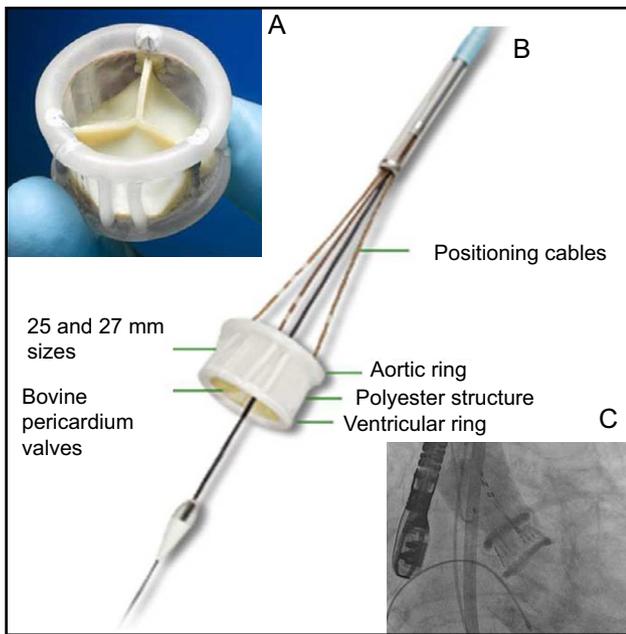


Figure. A: DirectFlow prosthesis seen from the aorta. B: Lateral view of the prosthesis and deployment system (positioning cables and internal lumen holding the support guide). C: Prosthesis in position with the 2 rings full of contrast medium; in this situation, the hemodynamic functionality and patency of the coronary arteries can be evaluated. At this time, it is still possible to reposition the prosthesis and recapture it if necessary.

the distal ring, exit via the proximal ring) connected by a polyester structure; the lower ring stabilises the prosthesis and the upper ring fixes the 3 bovine pericardium cusps. The deployment system comprises 3 cables that are attached to the lower ring and allow filling of the rings and positioning and deployment of the valve.

The valve fitted in its sheath (compatible with an 18 Fr introducer) is advanced up to the left ventricle, where both rings are filled with a mixture of contrast medium and water. The upper ring is then emptied and the lower ring is positioned just below the valve with the help of the 3 traction cables. The upper ring is then filled and the position, functionality, and coronary permeability are assessed. If the position is not optimal, the upper ring is deflated, the lower ring repositioned, and the upper ring reinflated. The result is then re-evaluated. When this is satisfactory, the contrast medium is replaced by a polymer that solidifies in 10 minutes and the fixation cables are released.

The selection criteria are: 20-26 mm ring (for 25 and 27 mm valves; size 23 is used for rings of 18 mm or more), ring-coronary ostia distance > 12 mm and absence of massive calcification. Previous valvuloplasty is essential in all cases.

We report our initial experience with this valve. Twelve patients were evaluated, of whom 7 were considered ineligible (5 due to small ring size, 1 due to ring-coronary distance < 12 mm, and 1 for both reasons). Finally, 5 patients were treated (Table) in whom a valve was correctly implanted, with mild or trivial aortic regurgitation in all cases. The hemodynamic result was good in 4 patients, although the gradients were slightly higher than those recorded with other percutaneous valves, but similar to

Table

Baseline Data on the Procedure and Follow-up of the 5 Patients Treated

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
Sex, age, y	Male, 86	Male, 66	Female, 87	Male, 90	Male, 84
EuroSCORE	8.4	10.3	22.8	10.8	7.5
Comorbidities	Coronary disease, right coronary artery stent	Severe COPD, severe liver disease, APO requiring prior valvuloplasty	Severe pulmonary hypertension, atrial fibrillation		Atrial fibrillation
Evaluation prior to the procedure					
<i>Echocardiography</i>					
Valve area, cm ²	0.8	0.95	0.46	0.64	0.65
Mean gradient, mmHg	36	28	50	52	51
Aortic regurgitation	Mild	Severe	Mild	No	No
LVEF, %	61	25	63	69	70
<i>CT</i>					
Ring diameter*, mm	25.6	23.4	21.6	21.8	23.5
Distance RC/LC, mm	13/17	17/20	13/15	15/11	17/20
Procedure					
Valve size	27	27	25	25	25
Number of positions	3	3	6	3	2
Positioning time, min	10	12	15	8	5
Complications	Vascular surgery	No	Femoral pseudoaneurysm, bleeding	No	No
Results at day 30					
Area, cm ²	1.7	0.72	1.6	1.7	
Mean gradient, mmHg	18	35	17	19	10
Regurgitation	Grade 1	Grade 1	Grade 1	Grade 1	Grade 1
Functional situation	Better	Better	Better	Better	Better
Last follow-up					
Follow-up time, months	11	9	7	5	3
Vital situation	Alive	Alive	Alive	Alive	Alive
Functional situation	Better	Better	Better	Better	Better

RC, right coronary; LC, left coronary; APO, acute pulmonary oedema; COPD, chronic obstructive pulmonary disease; LVEF, left ventricle ejection fraction; CT, computed tomography.

* Diameter calculated from the area measured by CT at the level of the valve ring.

those reported with surgical biological prostheses⁶; in 1 patient with a functionally bicuspid valve due to fusion and calcification of the commissure between the right sinus and the noncoronary sinus, the initial postoperative gradient rose from 12 to 35 mmHg by the third day and a geometrical deformity of the polyester structure was observed via computed tomography and fluoroscopy. Despite the residual gradient (stable since then), and probably due to a reduction in the degree of aortic failure (from grade 3 to grade 1), the patient improved clinically and still has good functional status. Both prosthetic function and clinical outcome were favourable in the other patients.

The main advantages of the DirectFlow prosthesis over the Edwards-SAPIEN and Medtronic CoreValve prostheses are as follows:

- Greater flexibility
- Better hemodynamic stability during deployment (valve operative during implantation, does not require high-frequency stimulation)
- Possibility of evaluating the prosthesis prior to its deployment.
- Possibility of repositioning/recapturing the device.
- Low rate of aortic failure.

The disadvantages include:

- Less radial strength
- Slightly higher transvalvular gradient

The information available on this valve is still limited. The results presented at the 2014 EuroPCR congress seem to confirm the stability of the hemodynamic results after 1 year in the first 100 patients treated. Nonetheless, there are aspects, such as the impact of the residual gradient or the selection criteria, that require studies in larger samples and with longer follow-up periods. There are currently no data comparing the clinical results with those of the Edwards-SAPIEN and Medtronic CoreValve prostheses.

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NEW MODELS OF PERCUTANEOUS AORTIC VALVE PROSTHESIS

Transcatheter Aortic Valve Replacement With LotusTM Valve: Initial Experience



Implante transcáteter de la válvula aórtica LotusTM: serie inicial de 5 casos

To the Editor,

Currently, transcatheter aortic valve implantation is a well-established therapeutic option for the treatment of patients with inoperable symptomatic and severe aortic stenosis or with high risk for surgery.¹ Although the midterm results in this type of patient are good, moderate-severe residual paravalvular aortic regurgitation (6%) or stroke (3%), and their prognostic implications, have been observed in recent years.^{2,3}

Paravalvular aortic regurgitation can be caused by the implantation of a smaller-sized prosthesis, its inadequate expansion or intense calcification of the ring, which impedes correct stent apposition. The incidence of this complication has been reduced by more precise measurement of the aortic ring by using computed tomography and posterior balloon dilatation of the stent.⁴

At the same time, industry has developed second-generation valves that minimize the risk of residual paravalvular aortic

regurgitation. Among them is the LotusTM (Boston Scientific, Natick, Massachusetts, United States),⁵ which is a bovine pericardial tissue valve incorporated in a nitinol stent. The LotusTM is preloaded and designed to provide more precise release and the possibility of its repositioning or recovery after implantation. This stent also minimizes the risk of paravalvular aortic regurgitation with its new-age sealing system (urethane membrane) that adapts to the irregular surface of the ring.

This article presents 5 consecutive cases of severe degenerative aortic stenosis treated with the LotusTM aortic stent. Average patient age was 84 (SD, 5.63) years, and the EuroSCORE was 33% (SD, 16.7%) (Table).

The severity of the stenosis was assessed by transthoracic echocardiography and a hemodynamics study with left-right catheterization. The indication for implantation was discussed and accepted in all patients except 1, who underwent urgent implantation due to hemodynamic instability.

The procedures were done under general anesthesia with transesophageal echocardiography. Before valvuloplasty, a provisional active-fixation pacemaker for ventricular overstimulation was implanted in the septum of all patients. Right femoral access was created in all patients; the puncture was guided by fluoroscopy and, after preparing the area with 2 ProGlidesTM