those reported with surgical biological prostheses[6]; 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 Lotus™ Valve: Initial Experience

Implante transcatéter de la válvula aórtica Lotus™: 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 Lotus™ (Boston Scientific, Natick, Massachusetts, United States),[5] which is a bovine pericardial tissue valve incorporated in a nitinol stent. The Lotus™ 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 Lotus™ 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 ProGlides™

Table
Characteristics of the 5 Patients, Procedure and Results After Transcatheter Implantation of the Lotus™ Valve

	Patients				
	1	2	3	4	5
Age, y	85	75	78	84	89
Sex	Male	Female	Male	Female	Female
EuroSCORE I, %	15.7	55	33	33	13.57
NYHA	III	IV	IV	III	II
Angina	No	No	No	No	No
Syncope	No	No	No	Yes	Yes
Maximum gradient pre-TAVI, mmHg	45	15	40	36	107
AVA, cm^2	0.5	0.8	1	0.5	0.42
LVEF	65	31	30	62	66
Ring diameter, by CT, mm	25.5	25.1	27.2	22.9	25.6
Access	Right femoral	Right femoral	Right femoral	Right femoral	Right femoral
Balloon valvuloplasty	22 × 40	22 × 40	22 × 40	22 × 40	22 × 40
Lotus™ n.º	23	23	27	23	23
TAVI duration, min	78	81	67	137	114
Maximum gradient at discharge*, mmHg	28	32	12	22	15
Residual AR	0	0	0	1 (central)	0

AR, aortic regurgitation; AVA, aortic valve area; CT, computed tomography; LVEF, left ventricular ejection fraction; TAVI, transcatheter aortic valve implantation.
* Maximum transvalvular gradient measured by transthoracic ultrasound.

(Abbot Vascular, United States), the 18Fr sheath was introduced until the descending aorta. The native aortic valve was crossed over with the standard technique, taking special care not to pass the mitral subvalvular apparatus with the guide. Once the passage was confirmed by transesophageal echocardiography, a super-stiff Safari™ guide (0.035″, 260 cm) (Boston Scientific) was introduced into the left ventricle and valvuloplasty was done with a NuCLEUS™ 22 × 40 mm balloon (NuMED Inc., Canada) in rapid stimulation at 180 bpm. Afterward, the Lotus™ valve was implanted in accordance with the recommended technique, without the need for overstimulation. Number 23 stents were implanted in 4 of the patients and a number 27 in 1. The size of the prosthesis was determined by the diameter of the area measured on computed tomography; in 2 patients, the final decision was supported by angiography at the time of the valvuloplasty. The implantation was successful in all patients, although 1 stent required repositioning. During implantation, the patients were hemodynamically stable at all times.

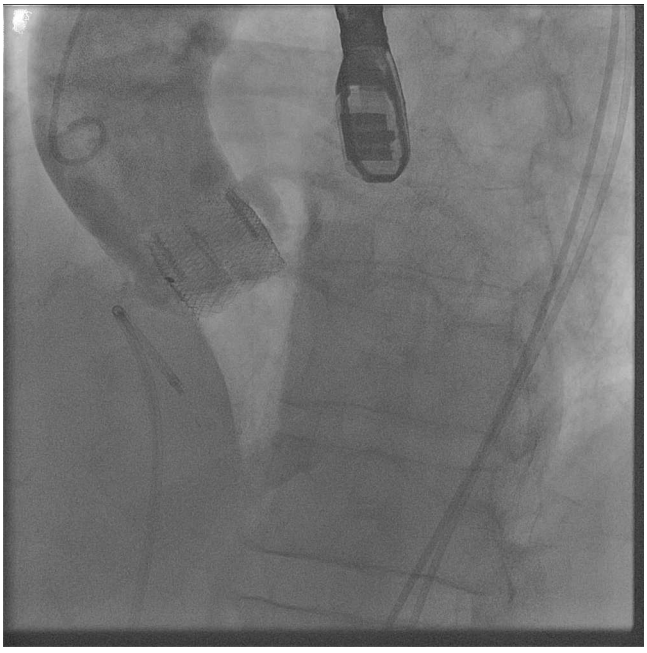

Figure. Absence of aortic insufficiency on aortography after transcatheter implantation of a 23-mm Lotus™.

The proper function of the prosthesis was immediately checked after the intervention by measuring the transvalvular gradient with hemodynamic and transesophageal echocardiography. The absence of aortic insufficiency was verified with transesophageal echocardiography and aortography (in patients without moderate-severe renal failure) (Figure).

The temporary pacemaker was withdrawn after 48 hours in all patients and the in-hospital clinical course transpired without incidences, with no need to implant permanent pacemakers and no appearance of clinical or clinically evident stroke. The patients were discharged from the hospital 4 (SD, 1.09) days after the procedure. On the TTE prior to discharge, we observed a mean maximum gradient of 21.8 (8.4) mmHg; only 1 patient had central mild aortic insufficiency (grade 1/4 by color Doppler), and none showed residual paravalvular aortic regurgitation.

A telephone follow-up was done 30 days after implantation. All patients reported functional class improvement: 3 were in functional class I/IV, and 2 in class II/IV. One of the patients was readmitted 28 days after the procedure due to chest pain, although the valve was observed to be functioning properly and there was no coronary arterial disease.

These are the first 5 patients treated with the Lotus™ transcatheter aortic valves reported in our country. We consider that the advances made in prostheses will enable us to achieve better results. The new sealing system for Lotus™ valves reduces residual paravalvular aortic regurgitation without the need to oversize the prosthesis relative to the ring, which could reduce complications such as ring rupture and thus allow expansion of the indications for transcatheter aortic valve implantation.

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Mid-term Clinical Outcome of Titanium-nitride-oxide-coated Cobalt-chromium Stents in Patients With de Novo Coronary Lesions: OPTIMAX First-in-man Study

Resultados clínicos a medio plazo de los stents de cobalto–cromo recubiertos de oxinitruro de titanio en pacientes con lesiones coronarias de novo: primer estudio humano de OPTIMAX

To the Editor,

Concerns have been raised about higher rates of late stent thrombosis (ST) following implantation of drug-eluting stents.[1] Localized hypersensitivity reactions were demonstrated in the vessel wall at autopsy in patients with late ST after implantation of first-generation drug-eluting stents. Hence, stents with a biocompatible coating were developed to minimize the vessel wall inflammation responsible for late events.[2] The safety of titanium-nitride-oxide-coated stents based on a 316L stainless-steel platform has been demonstrated in unselected populations[3] and in randomized clinical trials in acute coronary syndrome.[4] Cobalt-chromium alloy has a superior radial strength that allows the development of ultra-thin struts but preserved radial force. In a prospective first-in-man observational study, we explored the 6-month clinical outcome of a titanium-nitride-oxide-coated stent based on a cobalt-chromium platform in *de novo* coronary lesions.

We enrolled 184 symptomatic patients with significant stenosis of a *de novo* lesion in a native coronary artery or a coronary bypass graft. Clinical presentation included stable angina and acute coronary syndrome. We excluded patients with heart failure, left ventricular ejection fraction $<$ 30%, cardiogenic shock, renal impairment, prior target vessel revascularization, allergy to antithrombotic medications, active bleeding, and life expectancy $<$ 12 months. The study was conducted according to the 1964 Declaration of Helsinki. Informed consent was obtained from all patients. The protocol was approved by our Ethics Committee. The OPTIMAX™ stent (Hexacath, Paris, France) is a thin-strut (81 μm) stent, based on a cobalt-chromium platform with a twin helicoidal design. Titanium-nitride-oxide is coated on all surfaces of the stent. The stent is available in lengths of 7, 10, 13, 16, 19, 22, and 28 mm, and in diameters of 2.25, 2.50, 2.75, 3.0, 3.5, and 4.0 mm. Procedural success was defined as successful implantation of the stent with residual stenosis $<$ 20% and final TIMI 3 flow, without dissection or thrombosis. Clinical success was defined as procedural success without in-hospital major adverse cardiac events (MACE). The primary endpoint was MACE at 6-months' follow-up, defined as cardiac death, nonfatal myocardial infarction (MI), or ischemia-driven target lesion revascularization (TLR). Cardiac death was defined as death from cardiovascular causes or unknown cause. Myocardial infarction was diagnosed by persistent chest pain with an increase of CK-MB and/or troponin $\geq$ twice the upper reference limit. Target lesion revascularization was defined as a repeat intervention to treat significant (>50%) in-stent restenosis. Secondary endpoints included individual components of the primary endpoint, noncardiac death, ischemia-driven target vessel revascularization, and definite ST at 6-months' follow-up. Stent thrombosis was adjudicated according to the Academic Research Consortium. Patients were prospectively followed up for 6 months. Follow-up coronary angiography was performed in patients developing recurrent symptoms during follow-up. An independent clinical event committee adjudicated all clinical events. Because of the observational design of the current study, no formal power calculation was performed.

The mean age of the cohort was 69 (SD, 9) years; 70.1% were men. Patients presented with acute coronary syndrome in 57.1%, radial access was used in 90.2%, and complex (type B and C) lesions were treated in 80.5%. Baseline clinical and procedural characteristics are shown in Table 1. Procedural and clinical success occurred in 100% of the patients. All patients completed the 6-month clinical follow-up. The mean duration of follow-up was 198 (SD, 18) days. At 6-month follow-up, the primary endpoint of MACE occurred in 4.3%. No ST was observed. Clinical outcome at 6 months is summarized in Table 2.

Over the past decade, titanium-nitride-oxide-coated stents based on 316L stainless-steel platform have shown a satisfactory clinical outcome in observational studies and randomized clinical trials.[3,4] In a report by Karjalainen et al on 193 patients (212 Titan® stents), the 6-month rate of MACE was 6.7%, nonfatal MI 2.1%, and target vessel revascularization 6.2%; the TLR rate was 3.6%.[5] Nevertheless, 46% of patients had a prior MI (vs 8.5% in the current study). Interestingly, no ST occurred at 6-months' follow-up.[5] In the TIBET registry, which enrolled 156 diabetic patients (197 Titan®