Deployed Edwards Sapien prosthesis is always deformed

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Data regarding stent geometry of the deployed Sapien prosthesis (Edwards Lifesciences, Irvine, Calif) are lacking. We report here the fluoroscopic morphologic analysis of the stent shape after implantation of this prosthesis through a retrograde transfemoral approach in high-risk surgical patients with severe symptomatic aortic stenosis.

PATIENTS AND METHODS

We reviewed the fluoroscopic data of 19 patients in whom a Sapien prosthesis has been implanted. The study was approved by the local institutional review board and all patients gave their informed consent. Main preoperative clinical and echocardiographic data were reported in [Tables 1 and 2](#).

The size of the implanted Sapien Edwards valves was 23 mm (n = 13) or 26 mm (n = 6). At the end of each procedure, 2 perpendicular fluoroscopic views of the implanted valve were obtained: the profile (or long axis) and front (or short axis) view ([Figure 1](#)). The 3 points of the stent frame to which the leaflets are attached at their commissural level were here designated as “commissural bands.”

The proximal and distal diameters were measured on the profile view. Measurements made on the short-axis view are depicted in [Figure 2](#).

Data were expressed as median (range) for continuous variables and as percentages for categorical variables.

RESULTS

On the profile view, the stent shape was never rectangular. The distal diameter was always larger than the proximal diameter (median distal to proximal diameter ratio, 1.08; range, 1.04–1.13). Two types of stent profiles were identified ([Figure 3](#)). The stent frame had a biconic or a truncated conic aspect in 84% and 16% of cases, respectively.

On the front view, the rim of the projected image of the stent was never strictly linear. In fact, a more or less extended segment of the rim was linear (reflecting good alignment with x-ray films) whereas the remaining was crescent-like ([Figure 1](#)). This aspect was due to the stent eversion that mainly

TABLE 1. Preoperative clinical characteristics and main risk factors of the study population

Baseline characteristics	n (%) or median (range)
Age (y)	81 (62–96)
Gender (M/F)	10 (53)/9 (47)
NYHA functional class: II/III/IV	11/7/1
Cardiac rhythm: sinus/AF/pacing	16/2/1
Coronary artery disease	11 (58)
Chronic renal failure (creatinine clearance < 50 mL/min)	8 (42)
Cerebrovascular disease	7 (37)
Previous cardiac surgery	5 (26)
Chronic obstructive pulmonary disease	3 (16)
History of chest irradiation	2 (10)
Hepatic cirrhosis	1 (5)
Logistic EuroSCORE (%)	20.6 (8–52)

M/F, Male/female; NYHA, New York Heart Association; AF, atrial fibrillation.

involved the distal stent extremity, as revealed by the profile analysis. The stent projection was usually grossly circular or elliptic.

The 3 projections of the commissural bands described an easily identifiable triangle. The median relative difference between the longest and the shortest side (or L value) within a same triangle was 2.9% (range, 0%–16.4%). The shape of this triangle was considered as grossly equilateral in all but 3 cases (17.5%), where this difference exceeded 10%. The L/2H ratio was significantly higher than the theoretical value (median, 2.04 [range, 1.73–2.47] vs 1.73; $P < .0001$), thus implying the noncircularity of the distal part of the stent.

TABLE 2. Preoperative echocardiographic data of the study population

	n (%) or median (range)
Aortic valve area (cm ²)	0.53 (0.24–0.8)
Mean aortic gradient (mm Hg)	62 (24–110)
Aortic annulus diameter (mm)	21 (19–23)
Bicuspid aortic valve	0
Ejection fraction (%)	55 (17–77)
Ejection fraction ≤ 30%	1 (5)
Left ventricular end-diastolic diameter (mm)	54 (34–60)
Septal thickness (mm)	12 (10–20)

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FIGURE 1. Fluoroscopic long-axis (*left*) and short-axis (*right*) views of an implanted Sapien Edwards valve. Note the crescent like zone (*arrows*) of the stent projection on the short-axis view.

DISCUSSION

The present fluoroscopic study revealed that, once deployed, the Sapien prosthesis not only did not have a rectangular aspect on the long-axis view but also that its distal extremity (supporting the free edge of the leaflets) was never strictly circular.

Although there are different ways to investigate stent geometry, the question of its utility may be raised. There is a wide belief that valve durability is critically dependent on stress distribution on leaflets.^{1,2} Stress on leaflets is dependent on prosthesis design. One may assume that stress distribution on leaflets in a “nondeformed” prosthesis as provided by valve manufacturers has been minimized. In a previous study, we³ have clearly shown that even a minor stent deformation might be responsible for leaflet distortion. Abnormal stent shape of the deployed Sapien prosthesis was shown to be constant in the present study. We may therefore assume that there

is an increase in stress on leaflets in these valves. Computer modeling studies should confirm this hypothesis. The impact of stent deformation on valve durability should also be investigated in ex vivo studies using pulse duplicators.

In the present fluoroscopic study, the stent shape was particularly investigated at the level of its distal extremity, that one supporting the free edge of the leaflets. Leaflet to stent mismatch was demonstrated in at least 17.5% of cases (3/17), where the relative difference between the largest and smallest intercommissural distance within a same stent exceeded 10%. Leaflet to stent mismatch may be responsible for either leaflet restriction or leaflet prolapse in the most severe forms. In both cases, intraprosthetic regurgitation may occur as it has previously been reported.⁴

In summary, the present fluoroscopic study of the Sapien prosthesis revealed that this prosthesis did not have a cylindrical deployment after full expansion. It also showed

FIGURE 2. Schematic representation of the main measurements of stent deployment performed on the long-axis and short-axis views. In case of circular stent deployment, this ratio is independent of the stent diameter and should be equal to $\tan(\pi/3) \approx 1.73$. Conversely, alteration in this ratio would imply a non-circular deployment of the stent. PD, Proximal diameter; ID, intermediate diameter; DD, distal diameter; L, intercommissural distance.

FIGURE 3. Two stent profiles were seen on the long-axis view. Fully deployed stents had a biconic (*left*) or a conic (*right*) aspect. Note the waist zone (*) on the left.

indirect evidence of leaflet tissue to stent mismatch in at least 17.5% of cases. The clinical impact of these new data will have to be determined.

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Novel use of plasmapheresis in a patient with heparin-induced thrombocytopenia requiring urgent insertion of a left ventricular assist device under cardiopulmonary bypass

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The management of heparin-induced thrombocytopenia (HIT) remains a major clinical challenge in adults requiring cardiac surgery, especially when present preoperatively. Patients with end-stage heart failure are particularly vulnerable to the development of HIT owing to their frequent and long-term exposure to heparin. We report a case in which plasmapheresis was successfully used to eliminate the circulating antiheparin platelet factor 4 (PF4) antibodies (Ab) to implant a left ventricular assist device (LVAD) under cardiopulmo-

nary bypass (CPB) with full heparinization, as routinely performed.

CLINICAL SUMMARY

The patient was a 47-year-old man with mild chronic obstructive pulmonary disease and no significant medical history except for multiple recent hospitalizations for respiratory decompensation, presumed to be secondary to exacerbation of chronic obstructive pulmonary disease as well as pneumonia. He was admitted to an outside institution with acute cardiogenic shock, presumed to be secondary to acute viral myocarditis, without any evidence of myocardial ischemia (negative electrocardiographic findings, negative troponin levels). He also had acute renal failure, hepatic ischemia with significantly elevated transaminase levels, and rapid development of respiratory failure necessitating emergency intubation. He was started on inotropic support. An echocardiogram revealed severe global biventricular hypokinesis with a left ventricular ejection fraction of 7%, severe mitral and tricuspid

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