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Benefits and medium-term outcome of the Sorin Pericarbon Freedom stentless aortic prosthesis in cases of acute bacterial endocarditis†

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Abstract

OBJECTIVES: The aim of this study is to evaluate the ease of use and the advantages of Sorin Pericarbon Freedom (SPF) stentless valve in cases of acute bacterial endocarditis and to check the intermediate-term results after the implant of SPF with respect to resistance to infection, valve deterioration and durability.

METHODS: Between June 2003 and February 2015, 26 patients with active aortic valve bacterial endocarditis underwent aortic valve replacement with SPF pericardial stentless aortic prosthesis. The mean age was 57 ± 18 years; 73% of the patients were in preoperative NYHA class III and VI. Mean Logistic EuroSCORE was 14.2 ± 12.7. Endocarditis occurred in 18 patients with native valves, and in 9 patients with prosthetic valves (4 mechanical aortic valve prostheses; 5 aortic bioprostheses). Aortic root abscesses were observed in 16 cases (61.5%). Surgery was emergent in 3 cases (11.5%). Redo surgery was performed in 9 cases (35%). Cumulative follow-up was 126.8 patient-years (mean 4.9 ± 3.3 years).

RESULTS: Operative hospital mortality was 0% for all patients. Residual mean prosthetic gradient at discharge was 9.4 ± 3.6 mmHg. Neither residual aortic incompetence nor residual abscess cavity was observed at discharge. Mean ejection fraction at discharge was 54 ± 8% (Min; Max: 35%; 65%). A total of 4 patients died at follow-up, all for non-cardiac causes. One patient was lost to follow-up. Two patients (8%) underwent non-valve-related reoperation with 0% mortality. Residual mean gradient at follow-up was 7.2 ± 2.1 mmHg. Three patients (17%) presented with mild/moderate aortic incompetence and 89% of patients were in NYHA Class I–II at follow-up. At 9 years, actuarial freedom from valve-related reoperation and from structural valve deterioration was 100%.

CONCLUSIONS: The SPF aortic prosthesis is a true pericardial stentless prosthesis suitable for the treatment of acute bacterial endocarditis. Intermediate-time results in terms of freedom from reoperation, structural valve deterioration and resistance to infections are satisfactory. Haemodynamic performances are excellent since a complete exclusion of aortic root abscesses is achieved without any reduction of the aortic annular diameter, usually due to marsupialization or patch closure of the infected cavities.

Keywords: Aortic valve replacement • Stentless aortic valve prosthesis • Acute bacterial endocarditis

INTRODUCTION

Acute bacterial endocarditis (ABE) of the aortic valve represents a life-threatening event which is often challenging for the cardiovascular surgeon. Valve replacement remains the most common approach to this serious disease. Unfortunately, in many cases, an aortic root abscess is associated with the aortic valve pathology, making necessary the reconstruction of the left ventricular outflow tract and the exclusion of the abscess cavity, besides the aortic valve replacement [1, 2].

An unresolved dispute concerning the prosthesis of choice for replacing an infected aortic valve alone or associated with a root abscess is ongoing. We report our 12-year experience of aortic valve replacement and aortic root reconstruction with the Sorin Pericarbon Freedom (SPF) stentless pericardial prosthesis in 26 patients with acute endocarditis of the aortic valve, alone or in association with aortic root abscesses (61% of cases).

Valve design

The SPF is a true stentless bioprosthesis made of two layers of bovine pericardium without any fabric reinforcement. The valve,

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which is treated with glutaraldehyde, is detoxified with homocysteic acid and stored in an aldehyde-free solution, with no need for rinsing before implantation [2].

METHODS

Patients

From June 2003 to February 2015, 26 patients underwent aortic valve replacement (AVR) for active aortic valve endocarditis with an SPF stentless prosthesis at our institution. In 61.5% of cases, a perian-nular aortic root abscess was associated with the valve pathology. There were 22 males (85%) and 4 females (15%), with a mean age of 57 ± 18 years (range: 15–82 years). In 12 patients (46%), the infection was mainly caused by *Staphylococcus* spp., by *Streptococcus* spp. in 8 cases (31%), by *Enterococcus* spp. in 8 cases (31%) and by *Micrococcus* spp. in 1 case (4%). In 15% of infections, more than one bacterial species was involved. Mean Logistic EuroSCORE was 14.2 ± 12.7; 73% of the patients were in NYHA class III or IV. Three patients (11%) were operated on an emergency base, according to the criteria reported in the current guidelines. Seven patients (27%) underwent concomitant procedures: mitral valve repair (4 patients), coronary artery bypass (2) and resection of subaortic stenosis (1). Indications for surgery were intractable sepsis, peripheral emboli and congestive heart failure. Preoperative characteristics of 26 patients with ABE are listed in Table 1.

Surgical technique

A standard full sternotomy incision was used in all cases, with moderately hypothermic extracorporeal circulation, cold crystalloid cardioplegia and topical cooling. Associated procedures such as coronary distal anastomoses or mitral valve surgery were carried out before aortic valve replacement. SPF is, in our opinion, an ideal valve substitute in case of bacterial endocarditis, allowing for left ventricular outflow reconstruction and abscess exclusion using the pericardial skirt in the inflow side of the prosthesis. Before implantation, a customized trimming of the inferior skirt and prosthetic sinuses of pericardial tissue is performed, according to the observed patient's aortic root anatomy and location of the abscess cavities. The valve was approached through a transverse aortotomy, 1.5–2 cm above the sinotubular junction. After excision of the native leaflets or of the infected prosthesis, accurate and complete annular tissue debridement was achieved. The

Table 1: Pre-, intra- and postoperative characteristics of 26 patients with acute bacterial endocarditis

	Pre-/intraoperative	Discharge	Last follow-up
Mean age ± SD [range]	57 ± 18 [15–82]		
NYHA			
I	1	–	9
II	6	–	9
III	16	–	1
IV	3	–	0
Missing	0	–	–
Mean Logistic EuroSCORE ± SD [range]	14.2 ± 12.7 [2.3–51.7]		
Mean EF (%) ± SD [range]	53.5 ± 8.5 [35–70]	53.6 ± 7.8 [35–65]	58.8 ± 5.9 [50–70]
Redo			
No	17		
Yes	9		
Presence of aortic abscess			
No	10		
Yes	16		
Emergency			
No	23		
Yes	3		
Concomitant procedures			
Mitral valve repair	4		
Coronary artery bypass	2		
Resection of subaortic stenosis	1		
Mean ECC time (h) ± SD [range]	139 ± 27 [94–102]		
Mean ACC time (h) ± SD [range]	106.5 ± 24 [63–151]		
Residual aortic incompetence (mild–moderate)		0/26	3/18
Size of implants			
21	1		
23	7		
25	5		
27	9		
29	4		
Mean PPG (mmHg) ± SD [range]		16.2 ± 5.6 [10–35]	16.6 ± 5.5 [11–30]
Mean MPG (mmHg) ± SD [range]		9.2 ± 3.5 [4–19]	8.5 ± 3.3 [5.0-15.0]
Residual abscess cavity			
No		26	
Yes		0	

NYHA: New York Heart Association; EF: ejection fraction; ECC: extracorporeal circulation; ACC: aortic cross-clamp; SD: standard deviation; PPG: pressure peak gradient; MPG: mean peak gradient.

abscess cavities, where present, were accurately debrided and curetted. Local disinfection was routinely carried out to remove the bacteria and the infected tissue. Sizing of the prosthesis is a crucial part of this procedure. Usually, the choice of the prosthesis is based on the size of the sinotubular junction rather than on the aortic annulus, particularly in cases of slightly dilated aortic root. In cases of bicuspid aortic valves, a tricuspid valve geometry was restored, paying attention to maintain a correct annular plane. Exclusion of aortic root abscesses was carried out in 16 patients (61%). In two cases of extensive damage of the aortic annulus extended to the aortic sinuses or to the mitro-aortic fibrous continuity, a patch of bovine pericardium was used in addition to valve replacement. In all cases, the prosthesis was completely inverted into the aortic root, and the inflow suture was carried out first using three 4-0 polypropylene stitches starting at the nadir of the removed aortic leaflets. Subsequently, the valve was everted and sutured to the aortic wall in a subcoronary position using three more continuous 4-0 polypropylene stitches (Fig. 1). The mean size of the implanted prostheses was 25.6 mm (in 70% of the cases bigger than size 23), the mean aortic cross-clamp time (ACC) was 106 min (range: 63–151 min) and the mean extracorporeal circulation (ECC) time was 139 min (range: 94–202 min). Intraoperative characteristics of patents with prosthetic valve endocarditis (PVE) are listed in Table 1.

Data collection

All patients were reached remotely through phone interview, mail questionnaire, referral cardiologists or family doctors. Clinical and echocardiographic examinations were obtained at our institution or by external cardiologists, according to a common evaluation protocol.

One patient was lost to follow-up (last follow-up time: June 2010).

Two patients underwent a cardiac reoperation. In both cases, redo surgery was not related to aortic prosthetic malfunction or degeneration, but to a supervening mitral valve or coronary artery pathology.

Statistical methods

Statistical analysis was performed according to the type of parameters. For quantitative variables, summary statistics are reported using mean, standard deviation, median, quartiles and extreme values. For qualitative variables, number of patients and occurrence (percentage) are reported. Percentages are calculated on the non-missing data.

Cumulative freedom from events was evaluated using the method of Kaplan–Meier for the death and reoperation.

The degree of uncertainty in each actuarial analysis is expressed with 95% confidence limits. The 95% confidence interval bounds for the cumulative freedom were calculated according to the method proposed by Greenwood. Statistical analyses were performed using SAS software (Release 9.2, by SAS Institute Inc., Cary, NC, USA).

RESULTS

Early mortality and patient status at discharge

Early 30-day hospital mortality was 0 (0%). The mean length of stay in intensive care unit was 62.3 h (range: 18–501 h), with a mean duration of mechanical ventilation of 20 ± 20 h (range: 1–312 h). All the patients discharged from our unit were admitted to the department of infectious disease for close observation and completion of the antibiotic therapy. At hospital discharge, all the patients were alive and in satisfactory clinical conditions. At the echo examination, the mean ejection fraction (EF) was 54 ± 8% (range: 35–65%).

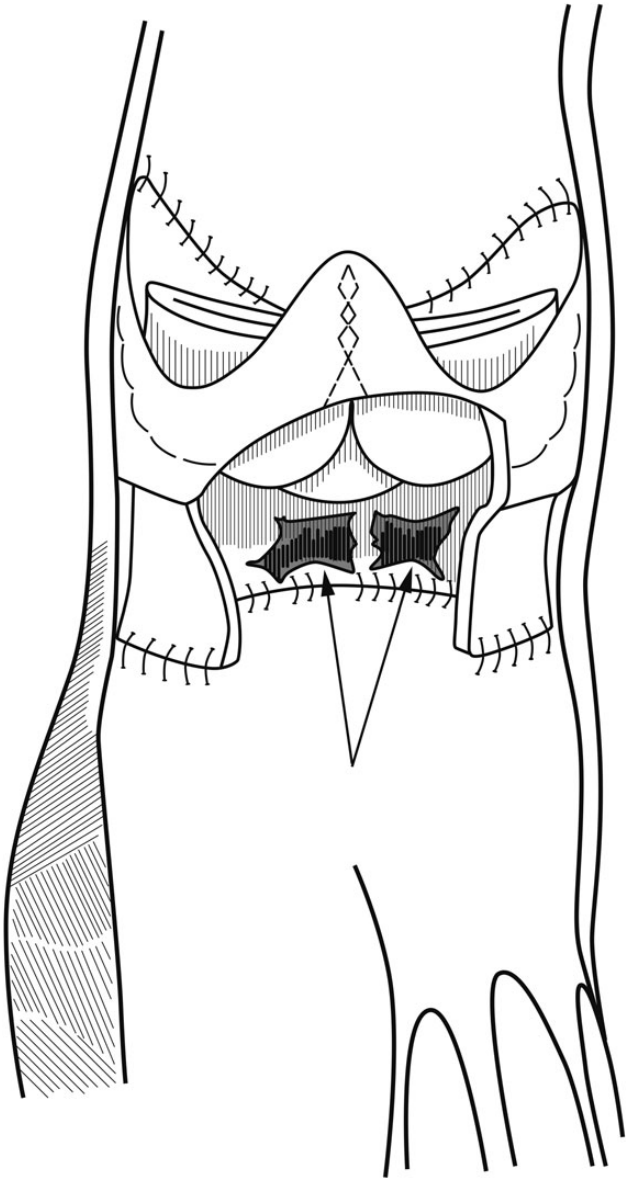

Figure 1: Exclusion of the abscess cavity by using the prosthetic inferior skirt (arrow).

The residual peak and mean transvalvular gradient were 17 mmHg (range: 11–30 mmHg) and 8 mmHg (range: 5–15 mmHg), respectively. There was no residual aortic incompetence at discharge, with complete exclusion of the abscess cavities, when present.

Late mortality

There were four late deaths (15.4%), all for non-cardiac causes. At 9 years, freedom from cardiac death was 100% and is reported in Fig. 2.

Reoperations and valve-related complications

There were two cardiac reoperations (8%). Freedom from valve-related reoperation is reported in Fig. 3. In these two cases, surgery was not related to the first operation for ABE and did not involve the aortic valve. Freedom from recurrent infection is illustrated in Fig. 4.

Intermediate-time results

Follow-up time ranged between 3 months and 12 years (mean: 4.9 ± 3.3 years). One patient was lost to follow-up. The remaining patients are in excellent clinical conditions. At the time of the last follow-up control, 87% of the patients were in Class NYHA I–II. At last echocardiographic examination, the mean EF was 59 ± 5% (50–70%), the transaortic peak gradient was 17 mmHg (11–30 mmHg) and the mean gradient was 8 mmHg (5–15 mmHg). Aortic valve insufficiency was absent in 83% of cases and mild to moderate in 17% (mild in two cases, moderate in one). In all instances, it was related to late dilatation of the aortic root.

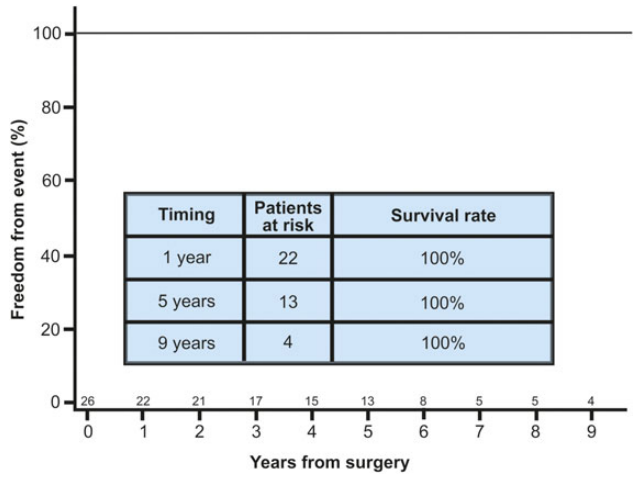

Figure 2: Freedom from cardiac death.

DISCUSSION

Two well-known key factors in the treatment of ABE involving the aortic valve are the timing of surgery and the extent of resection of the infected tissue, particularly when an abscess cavity is present. Delay in surgical treatment has a great influence on mortality and morbidity; incomplete eradication of bacterial debris is responsible for recurrent infections. Furthermore, the type of bacterial agent should drive the therapeutic decision towards an earlier and aggressive medical and surgical therapy, before aortic root abscess develops.

As far as the best surgical approach, the choice of the aortic prosthesis (mechanical, biological stented and stentless, and homografts) and the complete exclusion of the abscess cavities are two crucial points. In younger patients, with aortic root abscesses, the Ross operation can be an option [2, 3].

The aortic homograft is considered by many authors as the gold standard for the treatment of aortic ABE [1, 4–6]. Yankah *et al.* [7] reported 91% freedom from reinfection and 70% survival at 17 years in a series of 161 patients with PVE treated with homograft. Sabik *et al.* [8] reported a freedom from reinfection at 17 years of 95% in a cohort of 103 consecutive patients. Grinda *et al.* [9] reported a freedom from reinfection at 10 years of 93% in a series of 104 patients. The reinfection rate in all the reported series of PVE treated with homograft is low, ranging between 3.8 and 6.8%.

Similar results, however, have been reported by many authors with the use of stentless Dacron-free aortic prostheses. In particular, Siniawski *et al.* [10] compared two groups of patients treated with stentless prosthesis and aortic homograft, without finding any difference in terms of reinfection rate (4% in both) and mortality (12 vs 16%, in the stentless prosthesis vs aortic homograft group, respectively).

In 2008 and 2010, Musci *et al.* [11, 12] studied two large series of 255 and 221 patients with PVE with a reinfection rate of 8.6 and 5.4%, respectively. In the second study, the freedom from reoperation and reinfection was 92% at 10 years.

Less satisfactory results are reported when a stentless Dacron-covered aortic valve is used. In a series of 32 patients with PVE receiving a Freestyle implant, Heinz *et al.* [13] reported a 10-year actuarial survival and freedom from reoperation for prosthetic dysfunction and recurrent infection of 54.2% and of 53.1%, respectively.

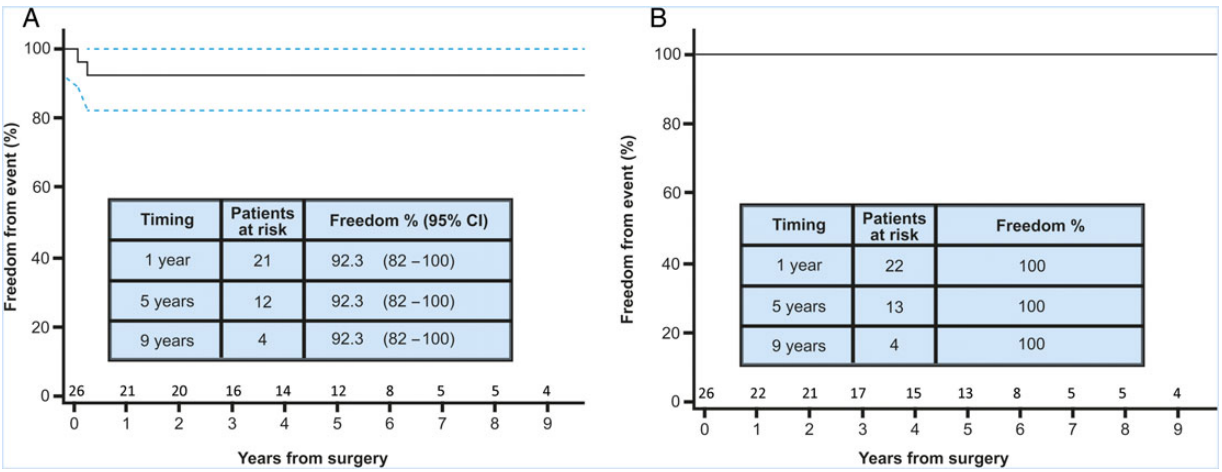

Figure 3: Freedom from reoperation (**A**) and valve-related reoperation (**B**).

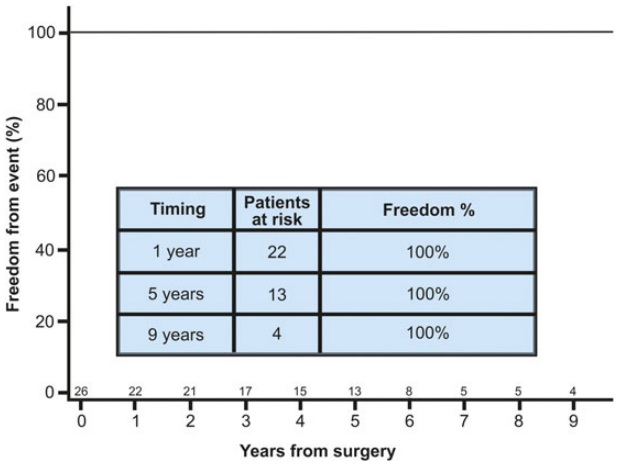

Figure 4: Freedom from recurrent infection.

The SPF is a Dacron-free stentless valve made of two layers of bovine pericardium, stabilized in glutaraldehyde, detoxified and stored in an aldehyde-free solution. Since 2003, 320 patients underwent aortic valve replacement with SPF in our institution, of these 26 patients presented with aortic ABE. In 17 cases, the infection involved the native aortic valve, and the prosthesis in the remaining ones. An abscess cavity of the aortic root was found in 16 cases. Three patients (11%) required an emergent surgery. Concomitant procedures were carried out in 7 patients (27%).

SPF valve is a user-friendly valve. A possible drawback of SPF could be related to the implantation technique, similar to homograft that requires a greater surgical expertise and the slightly longer cross-clamp time. The pericardial tissue of the inflow skirt and of the prosthetic sinuses can be trimmed and adapted to the anatomy of the patient. This prosthesis is suitable to the treatment and replacement of prosthetic aortic valves with endocarditis, with or without destructive abscesses of the aortic root, and it is particularly indicated when these abscesses extend to the aortic-mitral fibrous continuity. It is possible in the majority of the cases to completely exclude the infected tissues, after accurate curettage, local disinfection and complete reconstruction of the ventricular-aortic junction.

In our opinion, besides the remarkable resistance to infections, the main benefit from the use of the SPF stentless valve is the lack of need for any patch material or interrupted, pledgeted stitches, which are necessary to exclude abscesses. This way larger size prosthetic implants and a more linear aortic flow are achieved along with shorter cross-clamping time. This is particularly important since the use of undersized prostheses was identified as an incremental risk factor for reoperation [14]. No patient–prosthesis mismatch was observed in our series and actually 70% of patients received an implant larger than 23 mm, and 50% larger than 25 mm [mean implant size: 25.6 ± 2.3 mm (range: 21–29 mm)]. The residual aortic mean and peak gradients at discharge and at follow-up were close to physiological findings, and the average length of aortic cross-clamp was comparable with the one from routine procedure of aortic valve replacement. No patient in this series required pacemaker implantation.

Sponga *et al.* [15] have recently reported a similar experience of aortic root reconstruction with the SPF valve. A series of 40 patients affected by PVE were operated between 2007 and 2015, using SPF stentless valve to reconstruct the aortic root. They reported a 10% early mortality and a survival rate of 85% at 1 year, and 76% at 5 years, with 100% freedom from reoperation and reinfection at 5 years. The haemodynamic outcome was satisfactory, with very low residual aortic gradients, and normalized EF.

In conclusion, the stentless aortic Dacron-free prostheses can be considered a valid alternative to aortic homografts in cases of ABE of the aortic valve, also considering that aortic homografts are not available in most cardiac centres. Our experience has demonstrated along with other authors [15] that SPF represents a valid solution for aortic valve replacement in cases of ABE of the aortic valve, particularly when complicated by aortic root or annular abscesses. One of the main advantages of this versatile and user-friendly prosthesis is the possibility of tailoring the valve to the anatomy of the patient's aortic root, with the possibility of excluding all abscesses and infected tissue using the inferior valve skirt. Furthermore, the excellent haemodynamic behaviour is maintained over the time along with an adequate resistance to infections. However, a longer follow-up time is required to drop reliable information about the durability and the freedom from recurrent endocarditis and thromboembolic events of SPF aortic prosthesis.

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Conflict of interest: none declared.

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APPENDIX. CONFERENCE DISCUSSION

Dr Sádaba *(Pamplona, Spain)*: Congratulations because your results in a very complex group of patients have been excellent. We have been seeing mortalities around 10% and you have zero mortality, so just very good results.

I have two questions. Firstly have you referred to it already and is it the 15% prevalence of at least mild aortic regurgitation. Now, we would see this in transcatheter aortic valve implantation patients and we say that's not good enough. Would you have any particular concerns about this?

Dr Stefanelli: As I said, in all of the cases, the residual incompetence was due to aortic root dilatation. Maybe, in those patients we would have had to replace the ascending aorta just to avoid the problem in the future. Even though this valve has a very high coaptation area, with the progressive dilatation of the sinotubular junction this could be insufficient to guarantee the competence of the valve.

Dr Sádaba: Just following on this, I mean I understand that the Freedom is a supra-annular prosthesis normally. But in these cases you implanted it in a subannular position, isn't it?

Dr Stefanelli: Yes.

Dr Sádaba: Do you think that that could have an impact, be responsible for aortic regurgitations, or not?

Dr Stefanelli: Well, actually it's not really supra-annular. In the majority of cases I didn't use the entire inferior skirt, but I was able to tailor the prosthesis according to the amount of pericardium which I needed to exclude the abscess. This is a prosthesis that I've implanted in more than 330 cases. In the normal cases, I try to cut away all the inferior skirt in order to lower the implant of the prosthesis.

Dr Sádaba: And just a second question. According to your Kaplan-Meier curve, you only had 2 patients at risk at 10 years. So, as far as I understand, there are only 2 patients who have had a follow-up of 10 years and then you refer to 2 patients who required reoperation at 10 years. So is there any concerns about the long-term durability of this prosthesis? Do you have any data on other studies?

Dr Stefanelli: Well, in spite of the fact that this prosthesis has been on the market for 25 years, there are only a few studies reporting long-term results. The longer follow-up time, as reported by a paper from Mazzucco is 10 years, and they reported a 96% freedom from re-operation due to structural valve deterioration. We are collecting the data of 330 patients who received a Freedom aortic valve, and we have reached almost 14 years follow-up.

As far as these 2 cases reported with structural deterioration, one case was the only case where I had to implant a 21 prosthesis, so maybe this could be the reason of early failure. The second was a case where there was a fracture, located at the commissure between the left coronary and the non-coronary cusp, probably related to a technical error, as you know, in stentless valve, when the implant is not symmetrical, abnormal shear stresses develop, influencing the long-term results of these valves.

Dr M. Musci *(Berlin, Germany)*: One comment, Dr Stefanelli. I think that with your small amount of data, multivariate analysis is not allowed and you should use another statistical tool. Because you only have 26 patients, in my opinion only univariate analysis is allowed.

Dr Stefanelli: You're right. I think you're right.

Dr El Khoury: I missed your indications. All your endocarditis were acute or healed endocarditis? Because your results are excellent really, better than aortic valve replacement standard.

Dr Stefanelli: Maybe this could be related to the small number of patients, almost two patients per year. In the total number of patients operated for acute bacterial endocarditis, of course, the numbers are different. Besides, we are very accurate when we do this operation.