

# Stented bioprostheses in aortic position

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#### ABSTRACT

**Introduction:** Biological stented prostheses are currently the main type of prosthetic valve used for aortic valve replacement. The ratio of bioprotheses to mechanical prostheses has switched in the last 15 years; the percentage of biological prostheses implanted has risen from 30 % to 85 %. Moreover the total number of implanted stented bioprostheses remained stable over the last years despite competing procedures like stentless prostheses or transcatheter aortic valve implantation.

**Methods:** A literature search of all published aortic valve replacement studies was performed from January 2000 through May 2012.

**Results:** The recommendations guiding the type of heart valve replacement have been revised in recent years. Of particular interest are the new generation of biological prostheses with extended durability, a decrease in mortality of reoperation and an increase in life expectancy. Comorbidities such as chronic renal insufficiency or chronic atrial fibrillation are no longer contraindications to bioprostheses.

**Conclusion:** Overall, even in face of more innovative biological alternatives the implantation of stented bioprostheses is still a very interesting option and represents actually the most frequent valve implantation technique for aortic stenosis.

**Keywords:** aortic valve replacement, stented bioprostheses, effective orifice area, quality of life, patient-prosthesis mismatch.

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#### INTRODUCTION

For the invasive treatment of symptomatic aortic stenosis several attractive options became available beyond conventional cardiosurgical implantation of stented bioprostheses or mechanical valves. Besides stentless prostheses, in particular transcatheter procedures are of growing importance.

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Nevertheless the number of implanted stented bioprostheses in Germany expanded or at least remained stable over the last years. Thus, 9.704 bioprostheses were implanted in Germany in 2010, according to 84% of all implanted prostheses in aortic position (1). This proportion has dramatically switched in favor of bioprostheses during the last 15 years. Implantation of bioprostheses was associated with a 30-daymortality of 3,3%, which is higher than for mechanical valves (1,5%) due to the fact that patients for bioprostheses are significantly older or suffer from more complex co-morbidities (2).

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The purpose of this review is to summarize the features of the currently available bioprostheses in the light of competing procedures.

## Stented bioprostheses and implantation technique There has been a continuous development

to improve the design of stented bioprostheses with respect to hemodynamic profile, biological durability and ease of implantation. Various designs are available, allowing a valve selection according to individual patient factors or anatomical criteria including techniques for intra-annular and supra-annular positioning (3, 4). Nevertheless the ideal valvular prosthesis has yet to be built. It would have the same biological and hemodynamic properties as a normal valve and would not undergo degeneration. Still none of the currently available biological prostheses meet these specifications. Stented bioprostheses have proven to be effective even in small aortic roots regarding hemodynamic improvement, left ventricular mass reduction and improvement of the patient's quality of life (5). In vitro examinations showed pericardial valves to be slightly superior to porcine valves with regard to gradient and orifice area (6). Associated with the scalloped designs of stented bioprostheses a tension-free implantation with avoidance of paravalvular leaks can

Implantation techniques evolved over the last decades which resulted in short cross-clamp times in normal findings. Surgeons learned that meticulous care in decalcifying the aortic annulus and sizing helps to prevent paravalvular leaks. Additionally, accurate sizing prevents a patients-prosthesis-mismatch which could result in poor postoperative clinical performance (7). Avoiding the use of running suture for stented valve implantation was also proven to lower the rate of this complication

be expected.

(8). The evolvement of low profile valves reduces the risk of coronary occlusion in patients with a small distance between annulus and coronary ostia.

### Long term results of stented bioprostheses

The currently available and established bioprostheses show rates of degeneration at 20 years around 15% in patients aged 65 or higher (9-12). The freedom from repeat aortic valve replacement reaches over 85% after 20 years in patients older than 60 years and 65% in all age groups. Along with these convincing results of durability and freedom of re-implantation stented bioprostheses became also attractive for younger patients. If a repeated valve replacement is necessary due to functional deterioration the operative mortality is acceptable with 4 to 6% and is mainly due to active endocarditis and comorbidities (13). Lately transcatheter aortic valve implantation (TAVI) with valve-in-valve implantation into the degenerated xenograft showed to be an additional option in high risk patients with the need for redo valve replacement (14).

### Comparison with stentless prostheses and autografts

Stentless porcine valves were initially believed to have superior hemodynamic properties resulting in more effective reduction of left ventricular mass and better clinical performance according to NYHA class. These findings couldn't be yet approved by long-term follow up investigations (15, 16). Currently used stented bioprostheses exhibit equal results in the midterm postoperative course. Bearing this in mind calls the more demanding implantation technique of stentless prostheses in question. Stented bioprostheses are still used more commonly than stentless ones because of their relative ease of implantation, their extensively

documented long-term results, and the low risk associated with reoperation.

Another "biological" approach is the use of an autograft like the Ross procedure, where the patient's pulmonic valve is transferred to the aortic position. These pulmonic autografts have excellent hemodynamic properties as well as low rates of thrombosis. degeneration, and endocarditis. The Ross procedure is suitable for children and young adults because it is compatible with further growth of the aortic root. Experienced centers report larger series with satisfying midterm results (17). Nevertheless since the pulmonary valve has to been replaced by a bioprosthesis it is a demanding two valve procedure with prolonged cross clamping times. Aside from this, special means are necessary for pulmonary autograft stabilization to prevent its degeneration (18).

### Comparison with mechanical valve prostheses

There are only a few current randomized trials comparing the long-term results of biological and mechanical valves. A large-scale review revealed no difference in survival rates at 10 years and a slightly higher survival rate at 15 years for patients with mechanical prostheses (19). The bioprostheses had higher rates of degeneration and reoperation. The reoperation rate for mechanical valves in the aortic position is less than 5% at 10 years and less than 10% at 15 years, while the corresponding figures for bioprostheses are 10% and 30%, respectively. Hemorrhagic complications are significantly more common in patients with mechanical valves because of anticoagulation (20).

Chronic atrial fibrillation is no longer a contraindication to bioprostheses since permanent oral anticoagulation can be avoided if concomitant ablative surgery results in permanent conversion to sinus rhythm. End stage renal failure was also defined a contraindication to bioprostheses since a rapid

degeneration was feared due to altered metabolism in these patients. It has been found that life expectancy is already curtailed to such an extent that bioprosthesis degeneration often does not occur in the remaining lifetime. The supposed advantage of the longer durability of a mechanical valve is also offset by the potential complications of oral anticoagulation, especially because anticoagulation is more difficult to manage in dialysis patients than in others.

Nevertheless aortic valve replacement using a tissue valve remains controversial for patients younger than 60 years since there are studies reporting reduced mid-term results (21). Some younger patients are averse to oral anticoagulation and therefore prefer a biological valvular prosthesis. The operative risk of a second valve replacement has significantly decreased. Thus, younger patients opting for a bioprosthesis can enjoy a normal quality of life without anticoagulation for many years but may need to undergo a second valve replacement procedure with an acceptable degree of risk (22).

### Comparison with minimally invasive aortic valve replacement

Implantation of conventional prostheses can be performed through a limited direct access like a hemi-sternotomy or a lateral access. Reported large series show that aortic valve operations can be safely performed in experienced centers (23). Substantial progress in valve technology led to the development of self-expanding valves. Since a few years a number of bioprostheses are available for suture-less implantation which is usually combined with a limited surgical access. First publications report encouraging midterm results in high risk patients (24, 25).

Future will show the benefits of this procedure characterized by short cross clamping times and whether it can coexist with TAVI procedures.

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### Options in high risk patients in the TAVI-era

After its clinical inauguration by Cribier in 2002 the transcatheter aortic valve implantation gained widespread use in high risk patients with aortic stenosis. In Germany a massive increase of its application can be observed; in 2010 nearly every fourth aortic valve replacement was performed as a TAVI procedure (26). The PARTNER trial was a randomized trial comparing TAVI with standard-of-care therapies in high risk patients. A 2-year follow-up of patients in the PARTNER trial supports lately TAVI as an alternative to surgery in high-risk patients.

The two treatments were similar with respect to mortality, reduction in symptoms, and improved valve hemodynamics, but paravalvular regurgitation was more frequent after TAVI and was associated with increased late mortality (27).

There are a growing number of publications reporting promising short term results in high risk patients (28). Nevertheless there is still a lack of evidence that TAVI is superior to open valvular replacement as the gold standard regarding long-term results. Current guidelines recommend the use of TAVI restricted to patients with contraindications for open surgery or inacceptable perioperative risks.

#### **CONCLUSION**

Current studies reveal that bioprostheses of the most recent generation last longer than earlier types. Furthermore, reoperation rates have declined. Because life expectancies in general have risen, more and more elderly patients are presenting for valve replacement and for these patients a bioprosthesis is usually chosen. In addition the cost effectiveness of stented bioprostheses appears unbeatable and the surgical ease of implantation allows for cross-clamp times between 30 and 60 minutes.

Overall, even in face of more innovative biological alternatives the implantation of stented bioprostheses is still a very interesting option and represents actually the most frequent valve implantation technique for aortic stenosis.

Especially in the light of growing use of interventional valve replacement there is the urgent need for complete nationwide registry with adequate long term follow up, quality of life information and relevant subgroup analysis to define new standards in the treatment of patients with aortic stenosis.

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