

Early Results with Stentless Mitral Valve Replacement

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Background and aim of the study: Implantation of a chordally supported stentless mitral valve (SMV) may be the strategy of choice for patients with severe degenerative mitral valve disease. Herein, the early clinical results of this surgical technique were analyzed.

Methods: Since August 1997, 52 patients (36 females, 16 males; mean age 68.0 ± 8.5 years) each received a SMV (Quattro™; St. Jude Medical Inc.) at the authors' institution. The underlying disease was predominant mitral stenosis ($n = 26$), incompetence ($n = 17$) and combined lesion ($n = 9$). The mean NYHA class was 3.1 ± 0.6 , left ventricular ejection fraction $64 \pm 13\%$, and cardiac index 2.1 ± 0.8 l/min/m².

Results: SMV implantation was performed using either a conventional sternotomy ($n = 33$) or a lateral minithoracotomy ($n = 19$). The mean implanted valve size was 29.2 ± 1.7 mm, and mean cross-clamp time 81

± 33 min. Reoperation was required in six patients: two for paravalvular leakage, two for functional stenosis (both 26 mm valves), in one patient for pannus formation with underlying collagenosis, and in one for papillary flap rupture at five years. One patient died perioperatively, one died after reoperation at one year, and five patients died at longer follow up, from non-cardiac causes. Hemodynamic function was shown to be normal on echocardiography.

Conclusion: Intermediate-term results after SMV implantation were promising. Preservation of annuloventricular continuity led to good left ventricular function, but long-term durability remains to be proven.

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The stentless mitral valve (SMV) has been designed to fulfil all the criteria of an ideal mitral valve prosthesis. Structurally, the valve is completely flexible, rectangular in shape, and consists of four leaflets, two of which are supported by papillary flaps (Fig. 1). During surgery, annuloventricular continuity can be preserved by fixation at the papillary muscles. The SMV is constructed from bovine pericardium, following polyol anticalcification treatment. At present, more than 200 patients have received this device at several study centers worldwide.

The early clinical results after SMV implantation have shown promise (1-8), with good patient outcome

and hemodynamic function compared to that achieved with conventional mitral valve repair or replacement (9). As yet, however, very few long-term data are available following SMV implantation. Hence, the study aim was to evaluate the intermediate-term results after SMV use.

Clinical material and methods

Patients

Since August 1997, a total of 52 patients (36 females, 16 males; mean age 68.0 ± 8.5 years) have undergone SMV implantation at the authors' institution. Preoperatively, the predominant mitral valve pathology was stenosis in 26 patients, severe incompetence in 17, and a combined disease in nine. The cause of mitral valve dysfunction was degenerative disease in most patients. The mean (\pm SD) preoperative NYHA functional class was 3.1 ± 0.6 , the ejection fraction $64 \pm 13\%$, body surface area 1.76 ± 0.2 m², left ventricular end-diastolic pressure 14 ± 5 mmHg, and cardiac index 2.1 ± 0.8 l/min/m².

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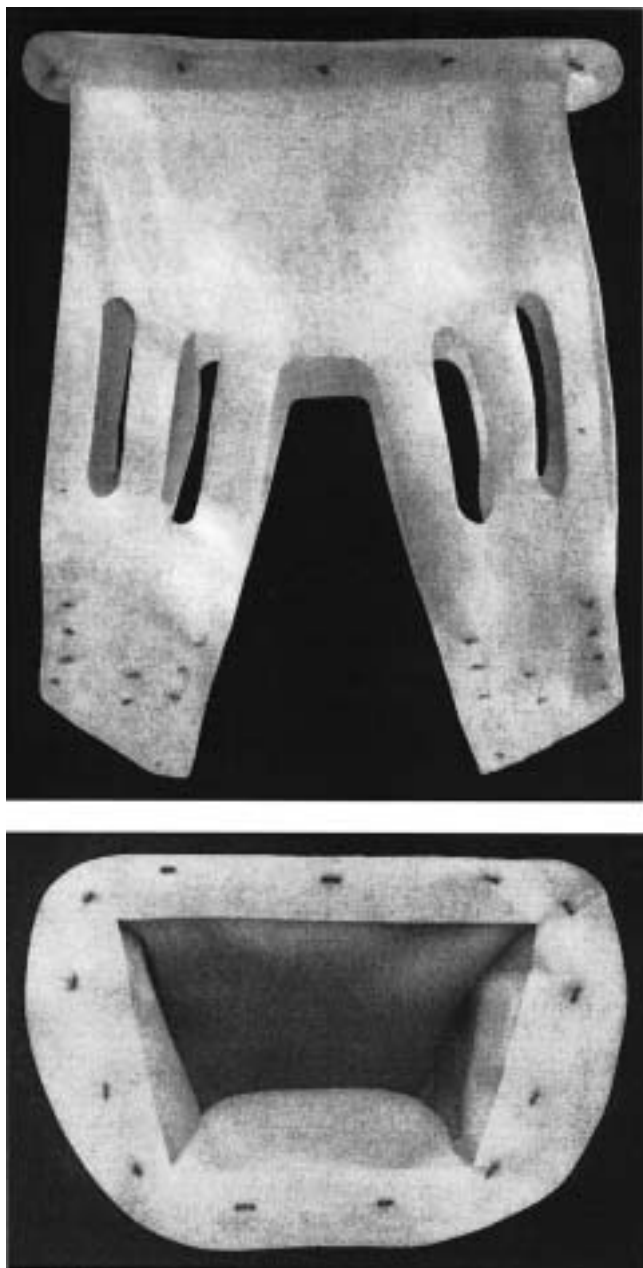


Figure 1: Stentless mitral valve (Quattro™). Lateral view, showing the anterior leaflet, papillary flaps and the inflow aspect.

Valve implantation

Implantation of the SMV (Quattro™; St. Jude Medical Inc., St. Paul, MN, USA) was approved by local and international ethical committees. Patients were only included after all details of the study protocol had been explained and they had provided their informed consent. The indications to implant a SMV were those applied normally to a patient with mitral valve disease. All patients were informed that their own valve would be repaired if possible; thus, only

patients with mitral valve stenosis or non-repairable mitral valve incompetence were included. The minimum patient age was 65 years unless contraindications were identified for the use of systemic anticoagulation, or the valve was chosen by special patient request.

Surgical technique

All operations were performed using a standard technique. The diseased mitral valve was completely excised using a straight line from just in front of the lateral to the medial commissure. The posterior leaflet was completely excised, leaving a small rim of the native valve. A stump of anterior leaflet chordae was left temporarily on each papillary muscle for traction during implantation. Appropriate sizing was carried out between the commissures and from the annulus to the tip of the papillary muscles. The papillary flaps were implanted using two Teflon-armed Tevdek II 3-0 sutures (Deknatel) in each case. The annulus was sutured using two or three continuous 3-0 Prolene sutures with four to six interruptions.

Follow up

Patients were followed up annually, including a physical examination and routine echocardiographic measurements at each visit (9). Both, the patient and their family physicians were instructed to contact the authors' clinic immediately in case of any other unexpected health conditions. No patient was lost to follow up.

Data analysis

Postoperative valve-related morbidity and mortality were evaluated according to standard guidelines (10). Results were reported as mean \pm SD. Absolute and relative frequencies were calculated. The Kolmogoroff-Smirnow test was used to assess normal distribution, after which Student's *t*-test for matched pairs was applied. A *p*-value <0.05 was considered to be statistically significant.

Results

Surgical outcome

Surgery was uneventful in all patients. Intraoperatively, the mean implanted valve size was 29.2 ± 1.7 mm; 27 patients received a large (30 mm) valve, 22 patients a medium (28 mm) valve, and three patients a small (26 mm) valve. The mean cross-clamp time was 81 ± 33 min. This included the time required for additional procedures, as five patients received bypass grafts, six underwent tricuspid valve repair according to the de Vega technique, and 20 had left atrial ablation therapy. The operations were performed using a standard median sternotomy in 33 patients, or

Table I: *Echocardiographic findings following stentless mitral valve implantation**

	Postoperative (n = 51)	12 months (n = 35)	48 months (n = 23)
EF (%)	55 ± 12	53 ± 11	57 ± 12
MV Vmax (m/s)	1.6 ± 0.2	1.8 ± 0.3	1.8 ± 0.2
MV Pmean (mmHg)	4.5 ± 1.7	4.6 ± 1.4	4.9 ± 1.4
MOA (cm ²)	2.7 ± 0.7	2.6 ± 0.6	2.6 ± 0.3
MI (grade 0-3)	0.4 ± 0.6	0.8 ± 0.6	0.7 ± 0.4

*Values are mean ± SD. EF: Ejection fraction; MI: Mitral valve incompetence; MOA: Mitral valve orifice area; MV Pmean: Mean mitral valve pressure gradient; MV Vmax: Maximum mitral valve blood flow velocity.

a lateral minithoracotomy in 19. In all patients the papillary muscles were sufficient to suspend the papillary flaps of the SMV. The intraoperative course was uneventful in all cases. Good valve function was confirmed using intraoperative transesophageal echocardiography. At discharge, 30 patients were in sinus rhythm, 13 were still in atrial fibrillation, and nine were fitted with a pacemaker. Among the latter group, six patients had a pacemaker preoperatively, while three required a new pacemaker to be inserted after surgery and left atrial ablation therapy. Following ablation, 14 patients were discharged in sinus rhythm and three had a DDD pacemaker.

Follow up

The mean follow up period was 35.1 ± 19.2 months (range: 5 to 63 months). All patients were seen either at the outpatient clinic or by their family physician. Overall, reoperation was required after 5-10 months in five patients (9.6%). In two cases this was for paravalvular leakage (9), in two for functional stenosis, and in one case for pannus formation with underlying collagenosis. The two patients with functional stenosis had both received a small-sized prosthesis (one after previous mitral valve surgery). One other patient presented with papillary flap rupture at the five-year follow up. Histological examination of the explanted valve revealed X-shaped collagen fibers in the papillary flaps. As this potential problem had been recognized previously, the SMV production has been completely changed since 1999, such that the collagen fibers are in a longitudinal direction, providing better stability. One positive finding in this explanted valve was that there was no calcification after five years of implantation.

With regard to in-hospital mortality one patient died perioperatively, as reported previously (9), and one died after reoperation for paravalvular leakage due to sepsis. During the follow up another five patients died from non-cardiac causes; these included spine fracture with renal failure, stroke with no evidence of thrombi, bronchial carcinoma, heart failure with a normally

functioning valve, and pneumonia. The most recent echocardiographic examinations had revealed good SMV function. In these five patients the preoperative cardiac index was 1.38 ± 0.1 l/min/m², and was significantly reduced in comparison to the other patients.

Echocardiographic measurements were carried out before discharge and at each visit to the hospital. Good valve function was seen in most patients, and trivial transvalvular refluxes - as are seen with most mechanical heart valve prostheses - were accepted. A typical laminar systolic transvalvular blood flow profile after SMV implantation was seen. Transthoracic echocardiography revealed normal mitral valve function in all patients postoperatively. The echocardiographic measurements taken postoperatively, and after 12 and 48 months follow up, are listed in Table I. The left ventricular ejection fraction was stable, and transvalvular blood flow velocities and pressure gradients were both normal. Mitral valve orifice areas were acceptable, and trivial transvalvular incompetence was identified in some patients.

Discussion

In time, stentless mitral valves may become the ideal mitral valve substitutes if their long-term durability can be proven. The SMV was designed in order to match all the complex functionality of the native mitral valve, as there is interaction between valve leaflets, annulus, chordae, papillary muscles and the left ventricle. Thus, although the SMV may be ideal for patients requiring mitral valve replacement, this promising new valve has still to stand the test of time.

At present, the intermediate-term results achieved with the SMV are - as seen in initial clinical reports (1-9) - quite acceptable. To date, the SMV has fulfilled some of the claims for an ideal prosthesis; namely, that it can be implanted at a low perioperative risk, and it is non-thrombogenic at follow up, despite no anticoagulation therapy being given to patients in sinus rhythm. As yet, no adverse immunological reactions have been documented, and the risk of endocarditis is

equally low as that with other prostheses. Based on its design features, the SMV offers a flexible annulus and is chordally supported. Hemodynamically, it has an adequate valve orifice area with central flow and acceptable gradients, there is low resistance to rapid opening, and there is complete closure and sufficient coaptation of the leaflets. All of these factors have contributed to the promising clinical results reported after three years.

However, several additional aspects should be considered when evaluating the present results. Technically, SMV implantation is not difficult, though exact sizing is crucial, as described previously (9). In this respect, transesophageal echocardiography should be available to assist the sizing procedure with measurements under hemodynamically stable conditions.

It must be borne in mind that all patients with chronic mitral valve disease carry a considerable preoperative risk profile. This includes a relatively higher patient age, additional conditions (as detailed above), a rather low cardiac index preoperatively, and myocardial remodeling due to chronic valvular heart disease. Consequently, the perioperative and follow up morbidity and mortality reported throughout the present study can be deemed acceptable.

Among the present patients, two required SMV explantation due to functional stenosis. Both patients had received a small size prosthesis, and both had a relatively small left ventricular cavity. Before reoperation, high transvalvular pressure gradients without any restricted motion of the SMV, fusion of the cusps or signs of calcification were diagnosed. Upon reintervention, no intrinsic valvular stenosis was seen, and it was confirmed that the small ventricular cavities had caused the need for reoperation. Under such circumstances, the implantation of a SMV should therefore be considered with great care.

The preservation of annuloventricular continuity has been shown previously to be beneficial in mitral valve surgery (11). The SMV is the first prosthetic heart valve to be developed in which full preservation of this continuity can be achieved by attaching the valve to both papillary muscles. Furthermore, with the valve's flexibility, any restriction to ventricular performance should be excluded. Most certainly, the preservation of annuloventricular continuity is the main reason for the well-preserved left ventricular function seen in the present patients at follow up (Table I).

The results of echocardiography investigations among the present patients have demonstrated consistently good hemodynamic function over the years, with the stabilization of left ventricular function, as well as adequate transvalvular blood flow velocities and gradients, being documented. These results com-

pared favorably to the hemodynamic function of other conventional prostheses as reported elsewhere (9). Some trivial transvalvular incompetence was seen, but this also is quite common with other prostheses. Thus, at present the SMV, when implanted in the mitral position, was seen to be functioning in line with current standards.

In summary, the intermediate-term results obtained after SMV implantation were acceptable, and the morbidity and mortality - though considerable - may in part have been influenced by the poor preoperative functional condition of the patients, and by the surgeons' steep learning curve during the early stages of the series. However, most patients achieved a good hemodynamic and functional outcome that led to a significant improvement in their quality of life. It appears that, although the concept of an ideal mitral valve substitute may be close at hand, the long-term performance of these prostheses remains to be proven.

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Meeting discussion

DR. JOSE POMAR (Spain): When working on mitral repair, the area of coaptation is very important, because the bigger the area, the bigger the compliance with changes in the ventricle. How large is the area of coaptation in the valve, and how do you calculate when to implant the flaps on the papillary muscles? Do you try to obtain a large area of coaptation?

DR. THOMAS WALTHER (Leipzig, Germany): Basically, it is important to implant the valve at the optimal position, with not too much prolapse, but not too stiff. The region of coaptation is 1.5 cm long, which is sufficient even if there is some reverse remodeling of the ventricle postoperatively. Sizing is very tricky, but there are two ways of doing this. First, we measure the distance to the papillary muscles directly, and second we use transesophageal echocardiography before going on-pump to measure the distance under normal hemodynamic conditions.

DR. RADU DEAC (Romania): I am concerned that the rupture which presented at 5.1 years was late. I note that you studied the tissue histologically, but did you also consider tissue calcification? My second question is about paravalvular leaks, because if the valve has a pericardium collar reinforcement at the circumference, this should not happen. Can you explain this?

DR. WALTHER: That occurred early in the series, in two patients, where there was a calcified annulus, and tension from the whole contraction of the ventricles caused a suture to tear out of the annulus at that point. There was no calcification of the explanted valve. The valve appeared quite curved, and very soft. In particular, we examined the collagen fibers and found an X-shape. But we must evaluate those patients who received this prosthesis between 1997 and 1999 very carefully, because it could happen again.

DR. DEAC: I did not mean macroscopic calcification because that is obvious, but the calcium content of the tissue would be interesting. Also, have you made any studies on ventricular performance?

DR. WALTHER: Other than echocardiography measurements and ejection fraction, we have not made any other studies.

DR. FRIEDRICH W. MOHR (Leipzig, Germany): A comment about papillary muscle attachment. The original disease must be taken into account, and what will

happen to the ventricle. For example, a cardiomyopathy patient may not be the right candidate because of the diverting papillary muscles. But in a patient with severe mitral insufficiency you can expect a reduction of ventricular size in time - that should be taken into consideration and the valve stretched slightly, because there will be some billowing later on. The valve will not be incompetent, but the distance between the papillary muscle attachment and the annular side may change if the ventricular size changes.

DR. POMAR: I have a question about the flaps. When using artificial chordae, such as Gore-Tex, it has been shown that after some time the endothelium covered the whole artificial tissue. Do you see this with pericardium and papillary muscle attachment, or there is tissue growing up from both sides?

DR. WALTHER: On that explant we didn't see any tissue growing up - it was only at the tip of the papillary muscles.

DR. POMAR: Were you able to see any type of endothelial layers?

DR. WALTHER: We couldn't prove the existence of a complete endothelial layer, but there was a type of smooth surface mimicking that.

DR. CHRISTOPHE ACAR (Paris, France): Can the Quattro valve be used in all patients, whatever the shape or the anatomy of the papillary muscle? Can it also be used in redo patients?

DR. WALTHER: As Professor Mohr pointed out, any very dilated ventricle would be a problem, and if the papillary muscles are too close to the annulus it is also difficult. You may get functional stenosis - so not all patients are suitable.

DR. ACAR: What about reoperations?

DR. WALTHER: If the papillary muscles are still available, yes. But if they are retracted, or if the patient had a mechanical valve before and a surgeon had cut all the chordae, it may be difficult. It depends on the intraoperative findings.

DR. ACAR: One of the main difficulties we had with the mitral homograft was valve sizing. You don't seem to have this kind of problem with this valve. Do you just calibrate the valve using an obturator as you would for any valve replacement?

DR. WALTHER: We take the usual size at the annulus, and measure the distance of the commissures. But I think that the distance of the papillary flaps is more important. It is not easy - as was seen in the patient where the annulus was torn and a paravalvular leak occurred. It is also a question of experience.

DR. CHUNG SEN KO (Malaysia): When you implant the valve, do you preserve the leaflets and the chordae? If you excised them, you would jeopardize the chance of preserving ventricular chordae continuity. Also, I can't really see the benefit of stentless mitral

valve replacement? It is clear in the aortic position because when you remove the stent you reduce the gradient, but that's not the case in the mitral valve?

DR. WALTHER: To answer your second question, it is intriguing to achieve a mitral prosthesis that mimics the physiological native healthy mitral valve, and this is a step forward in comparison to all conventional prostheses available for the mitral position. But you are correct - the results are not better than with conventional prostheses. With regard to your first question, I should point out that we excise the leaflets completely. There is a straight line from the commissures at the anterior leaflet - you excise the posterior, and keep one or two strong chordae initially to seize them with a forceps to get a hold on the papillary muscles. You then stitch through the papillary muscles and fix the prosthesis there. Afterwards, of course, you cut those chordae as well.

DR. LAWRENCE BURR (Canada): You showed that when the flaps come down they are attached to the papillary muscle, and therefore you maintain that annular base of the papillary muscle dimension. Does that contribute to the ventricular function staying in the mid-50% region, or actually improving slightly?

DR. WALTHER: It's not just cross-related - I hope that in the long-term the ventricular function will be maintained.

DR. BURR: Because that seemed to be logical. As I progressed with mitral valve replacement when the valve couldn't be repaired, I have increasingly used Gore-Tex resuspension of the papillary muscles. And those patients seemed a lot better in the 5- to 10-year follow up. So I think that's an important aspect of the surgery.