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Hemodynamic Evaluation of a New Stentless Autologous Pericardial Mitral Valve

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Background. There is no satisfactory mitral valve prosthesis. An ideal mitral valve substitute should be biologic, nonantigenic, and anatomically correct.

Methods. We developed a stentless, chordal-supported (including anterior basal stay chords) mitral valve made with glutaraldehyde-treated autologous pericardium. Eight such prostheses were implanted in sheep.

Results. Seven animals survived the operation and were studied postoperatively immediately, at 1 week, and at 1 month. Simultaneous left ventricular and left atrial pressures showed peak and mean transvalvular pressure gradients of 6 ± 2 mm Hg and 1 ± 1 mm Hg, respectively. Echocardiography performed intraoperatively and then 1 week and 1 month postoperatively showed normal valve leaflet movements. Color and pulsed Doppler echocardiography showed no sign of

transvalvular stenosis or regurgitation. Effective orifice area was 5.39 ± 0.35 cm² at intraoperative, 5.51 ± 0.29 cm² 1 week after operation (n = 5), and 5.51 ± 0.28 cm² 1 month after operation (n = 3). Three animals were sacrificed at 19 days and at 1 and 3 months. One animal is alive at 10 months.

Conclusions. This new stentless pericardial mitral valve performed satisfactorily with low gradients and no regurgitation. Possible advantages of this pericardial valve are excellent hemodynamics, ease of construction and implantation, lack of immunogenicity, and low cost. Similarly designed valves but with a shorter nonglutaraldehyde treatment time have been used in 3 sheep monitored for more than 3 months.

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The mitral valve is a complex structure closely related to the left ventricle (LV). Present-day available mitral substitutes are not anatomically correct and therefore can be expected to have limited durability and interfere with the normal function of the LV. Given the limited success of mitral homografts and heterografts, attention has been directed toward the use of pericardium more or less fashioned as a mitral valve [1-5]. On the basis of a previous morphometric study of the normal mitral valve, we designed a stentless, chordal-supported (including anterior basal chords) valve made of glutaraldehyde-treated autologous pericardium. This report describes the in vivo hemodynamic behavior of this valve implanted in sheep.

Material and Methods

Eight Targhee sheep weighing 31 to 52 kg were used. The animals were anesthetized with intravenous ketamine (1.0 mg/kg), atropine (0.03 mg/kg), and propofol (Diprivan, 4.0 mg/kg), then were intubated and mechanically ventilated with oxygen and isoflurane gas. A left thoracotomy through the fourth intercostal space exposed the pericardium. After cleaning its mediastinal

surface, a rectangular 10 × 5-cm piece of pericardium was excised. The pericardium was then placed on a special template (Fig 1) corresponding to mitral orifices of 25, 27, and 29 mm. Two types of templates were used. One corresponded to an open mitral valve split at a commissure, and the other to an open mitral valve opened through the center of the posterior leaflet. The template and pericardium were immersed in 0.5% buffered glutaraldehyde solution for 10 minutes, followed by rinsing in saline solution for 15 minutes. The pericardium was trimmed, and its lateral margins were sutured so that a truncated cone resulted in a larger anterior and smaller posterior leaflets tapered into two long prolongations to be used to anchor it to the papillary muscles of the host. Initially, two 4-0 polypropylene sutures replicating the length of the strut chords were placed between the extremities of the chord prolongations and the base of the anterior leaflet. To reduce the valve construction time, the template was modified to include two pericardial extensions that when bent downward onto the pericardial chords become the anterior strut chords (Figs 1 and 2). This modification reduced the total preparation time (including glutaraldehyde treatment) from 70 to 80 minutes to 40 to 50 minutes.

Heparin sodium (3.5 mg/kg) was administered, the aortic arch was cannulated (20 F straight tip, flexible arch arterial cannula dlp-70420; Medtronic, Inc, Grand Rapids, MI), followed by the right atrium with a dual-stage venous cannula (32 × 40 F TR-3240-L; Research Medical,

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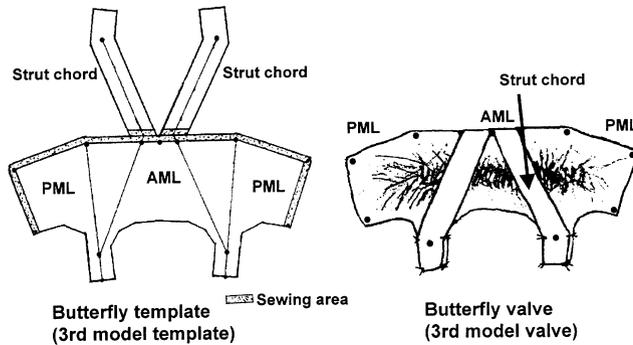


Fig 1. Template designed for the intraoperative construction of the autologous pericardial mitral valve. (AML = anterior mitral leaflet; PML = posterior mitral leaflet.)

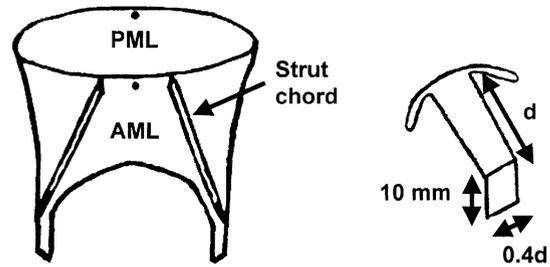


Fig 2. Overall view of the stentless pericardial mitral valve bioprosthesis and locator instrument. (AML = anterior mitral leaflet; PML = posterior mitral leaflet; d = annulus diameter in millimeters.)

Inc, Midvale, UT). Moderate hypothermic cardiopulmonary bypass was established, and the heart was arrested with cold crystalloid cardioplegic solution. The mitral valve was exposed through a left atriotomy, and the mitral valve leaflets and chords were excised. A chordal locator instrument (Fig 2) was developed to determine where the two new pericardial chords should be sutured to the papillary muscles. The curved part of the instrument was placed against the mitral annulus at the level corresponding to the mid scallop of the posterior leaflet. The distal end of the instrument indicated where the anchoring sutures should be placed in both papillary muscles. Three mattress-pledgeted 4-0 polypropylene sutures were passed through the body of each papillary muscle at the level determined by the locator. These sutures were then passed through the extremity of the pericardial chord. The valve was lowered into the LV, and the sutures were tied. The inflow orifice of the pericardial valve was sewn to the mitral annulus with four 4-0 polypropylene running sutures. The left atriotomy was closed, air was evacuated, the aortic clamp was released, and the heart was defibrillated. Cardiopulmonary bypass was discontinued, followed by removal of the cannulas and the administration of protamine sulfate.

Once the animal was hemodynamically stable, the function of the pericardial valve was analyzed. Left atrial and LV pressures were measured simultaneously, and the transvalvular pressure gradients were calculated. Epicardial echocardiography was performed (Ultramark 9, Ultrasound System; Advanced Technology Laboratories Inc, Bothell, WA) using a 5.0-MHz transducer. Two-dimensional echocardiography provided a view of the mitral area, leaflet motion, and LV function. The pulsed Doppler cursor was placed at the tip of the leaflets to

record mitral flow patterns and to detect signs of mitral stenosis. Peak and mean velocity and pressure half time were obtained. Peak and mean pressure gradients were calculated using $4 \times (\text{velocity squared})$. Effective orifice area was calculated by 220 divided by pressure half time using the standard pressure half time method. Color Doppler echocardiography was also used to search for valve regurgitation. The mitral regurgitation was graded quantitatively according to the method described by Czer and associates [6].

The animals were allowed to recover and were kept under observation in our facility. The function of the prosthesis was checked using transthoracic echocardiography under conscious conditions following the same protocol at 1 week and then at 1 month after operation.

Each animal was cared for in accordance with the "Principles of Laboratory Animal Care" formulated by the National Society of Medical Research and the "Guide for the Care and Use of Laboratory Animals" prepared by the Institute of Laboratory Animal Resources and published by the National Institutes of Health (NIH publication 85-23, revised 1996). This research was also reviewed and approved by the Institutional Animal Care and Use Committee of The University of Montana.

Results

Seven sheep survived the surgical procedure. Three died within 1 week after the operation; 2 because of severe regurgitation secondary to partial dehiscence of the annulus suture, and 1 of infective endocarditis. Four survived and 3 were sacrificed at 19 days, 1 month, and 3 months. One sheep is still alive 10 months after operation. The postoperative hemodynamic study was performed in 7 animals. Left atrial pressure, LV pressure, and peak and mean pressure gradients were 15 ± 5 , $5 \pm$

Table 1. Hemodynamic Data

	LAP (mm Hg)		LVP (mm Hg)		PG (mm Hg)	
	Systolic	Diastolic	Systolic	Diastolic	Peak	Mean
Mean	15 ± 5 (9-21)	5 ± 4 (0-10)	89 ± 18 (70-112)	4 ± 3 (-1-7)	6 ± 2 (3-8)	1 ± 1 (0-3)

Values are presented as mean \pm standard deviation with range in parentheses.

LAP = left atrial pressure; LVP = left ventricular pressure; PG = pressure gradient.

Table 2. Echocardiographic Data

LVEDD (mm)	LVESD (mm)	EF (%)	PG (mm Hg)		EOA (cm ²)	Grade of MR
			Peak	Mean		
36.3 ± 2.1 (34.0–38.9)	24.5 ± 1.7 (22.2–26.5)	63.2 ± 5.3 (58.4–71.2)	3.5 ± 2.0 (1.0–5.1)	1.2 ± 1.3 (0.0–3.0)	5.39 ± 0.43 (4.89–5.95)	0 ± 0 (0)

Values are presented as mean ± standard deviation with range in parentheses.

EF = ejection fraction; EOA = effective orifice area; LVEDD = left ventricular end-diastolic diameter; LVESD = left ventricular end-systolic diameter; MR = mitral regurgitation; PG = pressure gradient.

4, 89 ± 18, 4 ± 3, 6 ± 2, and 1 ± 1 mm Hg, respectively. Simultaneous pressure tracings showed a very low transvalvular pressure gradient (Table 1). All echocardiograms clearly showed the valve. Two-dimensional echocardiography demonstrated physiologic mitral areas and leaflet motion that hardly differed from a normal mitral valve. The long-axis view revealed proper valve positioning and good attachment of the pericardial chords. The new strut chords could be noted as straight lines during the entire cardiac cycle. Color and pulsed Doppler echocardiography showed no signs of stenosis or regurgitation. Left ventricular end-systolic and end-diastolic diameters, ejection fraction, peak and mean pressure gradients, effective orifice area, and grade of mitral valve regurgitation at the operative day are shown in Table 2. The effective orifice area was 5.39 ± 0.43 cm² at intraoperative, 5.51 ± 0.29 cm² at 1 week (n = 5), and 5.51 ± 0.28 cm² 1 month after operation (n = 3).

Comment

The mitral valve is an integral part of the LV, and its presence plays an important role in LV geometry. Present-day mitral replacement is not physiologic because all mitral substitutes do not resemble the normal mitral valve. Not only are their opening and closing mechanisms completely different from normal, but they also interfere with the mobility of the annulus and ignore the annulopapillary continuity that is essential for LV function. Our interest was to develop a tissue valve that would (as much as possible) incorporate all components of the mitral valve, not require permanent anticoagulation, and be available in the developing world. Autologous pericardium was selected because of its availability and lack of antigenicity, and the possibility to fashion it as a mitral valve with enough extra tissue to compensate for inevitable surgical inaccuracies.

Several stentless pericardial valves with an anatomic configuration have been described in the literature [1–5]. All models attempt to balance an anatomic design with a simple surgical implantation technique. Only the cone-shaped autologous valve described by Deac and colleagues [4] and the bovine quadricuspid bioprosthesis described by Liao and associates [5] have reached clinical application. We have developed a mitral substitute that imitates the normal mitral valve as much as possible in

terms of its being stentless and without a sewing ring, and incorporating two strut chords to maintain annulopapillary continuity and reduce the tension on the marginal chords. The insertion technique is simple because the critical sutures anchoring the valve to the papillary muscles are placed without the prosthesis in the field, and a simple instrument directs their location. The hemodynamic behavior of the pericardial valve has been excellent. Unexpectedly, the main problem encountered was early annular level dehiscence. Although the excuse of the friability of the annulus tissue in sheep is valid, reinforcement at this level seemed warranted. A new series of animals has been started with the addition of a Duran flexible ring placed at the end of the procedure. Also, to reduce the pericardial treatment time to 5 minutes and hopefully encourage cell rehabilitation, these grafts have been treated with an ethanol-based solution [7]. Three animals of this series have been alive for more than 3 months. Longer follow-up is required before suggesting its possible clinical application.

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