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M368 Advance in Mitral Valve Repair Using a Device Flexible in Three Dimensions: The St Jude Medical-Séguin Annuloplasty Ring
J. R. Séguin, R. Demaria, R. Rogier, and P. A. Chaptal

M372 The Inflexible Mitral Annulus After Valve Prosthesis: Inherent Risk of Dynamic Left Ventricular Outflow Tract Obstruction
Takeshi Komoda, Roland Hetzer, Johann Oellinger, Henryk Siniawski, Joseph Hofmeister, Michael Hübler, Roland Felix, Chikao Uyama, and Hajime Maeta

M375 Complement Activation Is Involved in the Structural Deterioration of Bovine Pericardial Bioprosthetic Heart Valves
M. Moczar, L. Lecerf, M. Ginat, and D. Loisance

M381 Transluminal Aortic Valve Placement: A Feasibility Study With a Newly Designed Collapsible Aortic Valve
Nader Moazami, Marc Bessler, Michael Argenziano, Asim F. Choudhri, Santos E. Cabreriza, John D. T. Allendorf, Eric A. Rose, and Mehmet C. Oz

SLIDE FORUM #3—ACCESS AND VASCULAR PROSTHESIS

M386 A Self-Expanding Bifurcated Endovascular Graft for Abdominal Aortic Aneurysm Repair: An Initial Study in a Canine Model
Gregory J. Wilson, Petr Klement, Yasushi P. Kato, John B. Martin, I. John Khan, Rysler Alcime, Jean-Pierre Dereume, David C. MacGregor, and Leonard Pinchuk

M394 Impregnation of Basic Fibroblast Growth Factor on a Microporous Small Caliber Graft Enhances Vascularization
Kiyoshi Doi, Shinichi Satoh, Takahiro Oka, and Takehisa Matsuda

M398 Penetrating Micropores Increase Patency and Achieve Extensive Endothelialization in Small Diameter Polymer Skin Coated Vascular Grafts
Takafumi Okoshi, Giorgio Soldani, Moses Goddard, and Pierre M. Galletti

POSTER SESSION #3—PERFUSION AND CIRCULATORY ASSISTANCE TECHNIQUES

M402 Ferromagnetic Artificial Cells for Artificial Circulation
Yoshinori Mitamura, Tatsuhiko Wada, and Eiji Okamoto

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Transluminal Aortic Valve Placement

A Feasibility Study With a Newly Designed Collapsible Aortic Valve

NADER MOAZAMI, MARC BESSLER, MICHAEL ARGENZIANO, ASIM F. CHOUDHRI, SANTOS E. CABRERIZA, JOHN D. F. ALLENDORF, ERIC A. ROSE, AND MEHMET C. OZ

Percutaneous stents are used in vascular applications in conjunction with angioplasty and in combination with graft material for repair of abdominal aneurysms. The authors have designed a collapsible bioprosthetic aortic valve for placement by a transluminal catheter technique. This trileaflet stent valve is composed of stainless steel and bovine pericardium. Stent valves, 23 and 29 mm, were tested in a pulse duplicator system with rigid rings from 21 to 31 mm in 2 mm increments. At a mean flow of 3.1 L/min (±0.7), normal systemic aortic pressure was generated with a transvalvular gradient of 14.9 ± 7 mmHg (mean ± SD). Regurgitation fraction ranged from 10 to 18% (mean 13.8 ± 3%) in the best ring size. Valves with the best hemodynamic profile were used for implantation in three 70 kg pigs in an open chest model. The valve was collapsed in a 24 Fr catheter designed to allow slow, controlled release. After resection of the native leaflets, the new valve was placed in the subcoronary position. No additional sutures were used for securing the valve. Two animals were successfully weaned from cardiopulmonary bypass and maintained systemic pressures of 100/45 (±10) and 116/70 (±15) mmHg, respectively. Intraoperative color echocardiography revealed minimal regurgitation, central flow, full apposition of all leaflets, and no interference with coronary blood flow. Both animals were sacrificed after being off bypass for 2 hr. Postmortem examination revealed the valves to be securely anchored. The third animal was weaned from cardiopulmonary bypass but developed refractory ventricular fibrillation because of valve dislodgment due to structural failure. Although long term survival data are needed, development of a hemodynamically acceptable prosthetic aortic valve for transluminal placement is feasible. *ASAIO Journal* 1996;42:M381–M385.

Intravascular stents have gradually obtained acceptance for peripheral and coronary vascular occlusive disease.[1–3] Combinations of stents with grafts have allowed for intraluminal bypass of aneurysms and long segment atherosclerotic lesions.[4] Transfemoral percutaneous aortic valve replacement is an extended application of this new technology that offers several new challenges. First, the valve needs to be accurately positioned without the benefit of direct open visualization. Second, the valve must remain firmly in the annulus under physiologic conditions. Finally, in the absence of sutures, the valve must provide a sufficient seal to minimize perivalvular regurgitation.

We have developed a novel sutureless bovine pericardial bioprosthetic aortic valve mounted on a collapsible stent. This prosthetic valve can be collapsed in a 24 Fr catheter for delivery. This report represents our initial characterization of this valve in a pulse duplicator system and in an open chest porcine model.

Methods

Stent Valve Construction

Stainless steel wire, size 0.020″, was used to construct all stents, and size 0.022″ was soldered on the ring to serve as the anchoring fixation point in the aortic annulus. For constructing the stent valves at different sizes, because of the collapsible nature of the design, all valves were placed in a ring of predetermined size. Subsequently, bovine pericardium stabilized by a photooxidation process[5] was sewn on the stent from a single sheet to construct trileaflet valves constrained to different sizes.

In Vitro Measurements

A total of 16 stent valves were constructed. The four that were acceptable in terms of overall symmetry were subjected to further studies. A pulse duplicator similar to a pre-

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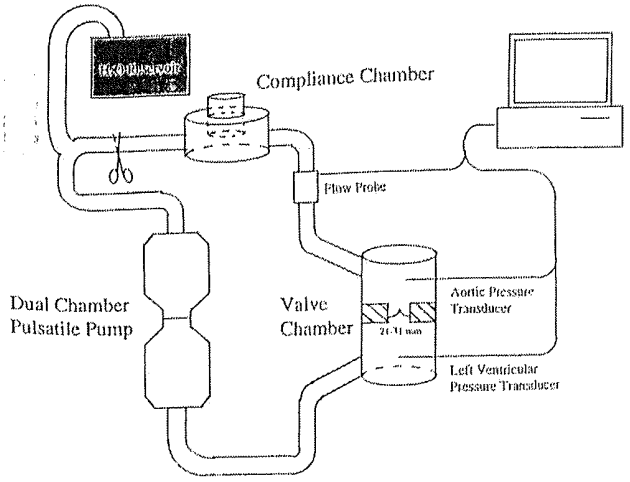

Figure 1. Diagram of the mock circulatory loop used for *in vitro* testing of valves. The chamber allows for adjustment of compliance and resistance.

(Figure 1). This system uses an Abiomed BVS 5000 dual chamber (Abiomed, Inc., Danvers, MA) to generate pulsatile flow. Each stroke ejects 80–85 ml of saline into the circuit. The system possesses an open reservoir to simulate the venous and atrial systems. In addition, a piston–cylinder–spring arrangement functions as an adjustable compliance chamber. Peripheral vascular resistance could be adjusted by application of a clamp to the circuit partially to impede forward flow. The valve was placed on a ring in a rigid chamber made of Plexiglas. The ring size in the chamber could be changed to a diameter ranging from 21 to 31 mm in 2 mm increments. A 5 Fr Millar catheter (Millar Instruments, Houston, TX) was placed on the ventricular side and the aortic side of the valve to measure transvalvular pressures gradients. An ultrasonic flow probe (Transonics, Ithaca, NY) was placed on the outflow tubing to monitor forward and backward flow. All data were digitized at 200 Hz using a 12 bit A-D board (AD Instruments, Milford, MA) recorded with the MacLab system and stored on the hard drive for subsequent analysis. Regurgitant fraction was calculated by the ratio of the integral of backward flow to the integral of total flow (forward and backward) using customized wave analysis software (IGOR; Wavemetrics, Inc., Lake Oswego, OR).

Animal Care

Animals received humane care in compliance with the *Principles of Laboratory Animal Care* formulated by the Institute of Laboratory Animal Resources and the *Guide for the Care and Use of Laboratory Animals* published by the National Institutes of Health (NIH Publication No. 86-23, revised 1985).

Experimental Procedure

Pigs weighing 60–70 kg were anesthetized with ketamine (20 mg/kg) and thiamylal sodium (4.5 mg/kg). After endotracheal intubation, anesthesia was maintained with isoflurane (1.5–2.5%) mixed with 100% oxygen. Lidocaine 2 mg/kg and bretyllium 5 mg/kg were given as a loading dose, and a continuous drip of 1 mg/kg/hr for each was maintained throughout the experiment. Standard concentrations of phenylephrine (Neo-Synephrine; Winthrop Pharmaceuticals, New York, NY), norepinephrine bitartrate (Levophed; Winthrop Pharmaceuticals), and epinephrine drips were used as needed to maintain a mean blood pressure of 60 while on cardiopulmonary bypass (CPB). Internal paddles charged up to 50 V were used for defibrillation as needed.

Surgical Procedure

Sternotomy was performed, and the pericardium was opened. Heparin (300 μg/kg) was administered and adequate anticoagulation was verified by an activated clotting time of greater than 400 sec. A 14 Fr cannula was inserted in the aorta and a 36 Fr dual stage venous cannula was inserted in the right atrium for CPB. The aorta was dissected proxi-

Table 1. Hemodynamic Characterization of the Stent Valves in the Mock Circulatory System

Valve Size (mm)	Ring Size (mm)	VP (mmHg)	AoP (mmHg)	Regurgitant Fx (%)	Flow (L/min)
Empty chamber (no valve)	25	177	167	100	3.3
	27	158	149	100	3.3
	29	165	156	100	3.3
	31	157	152	100	3.3
23	21	173/20	163/70	10	2.7
	23	188/23	178/70	14	3.2
	25	160/25	150/33	26	2.2
	27	193/35	184/36	50	2.1
23	21	130/15	120/60	14	2
	23	174/9	169/52	18	2.1
	25	153/25	145/37	27	2.1
29	27	161/10	146/63	13	3.71
	29	163/12	149/52	15	3.67
	31	169/18	147/46	20	4.5
29	27	137/9	122/60	10	3.24
	29	145/18	120/42	17	3.46
	31	144/25	114/30	27	3.28

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