

Aortic root reconstructive surgery

- new created technique for aortic stenosis

Academician d-r Zan Mitrev, T.Anguseva, E.Stoicovski, E Idoski

Special hospital for surgery
“Fillip II” Skopje - Macedonia

September, 2012

Reconstructive surgery for aortic stenosis

Symptoms/Signs

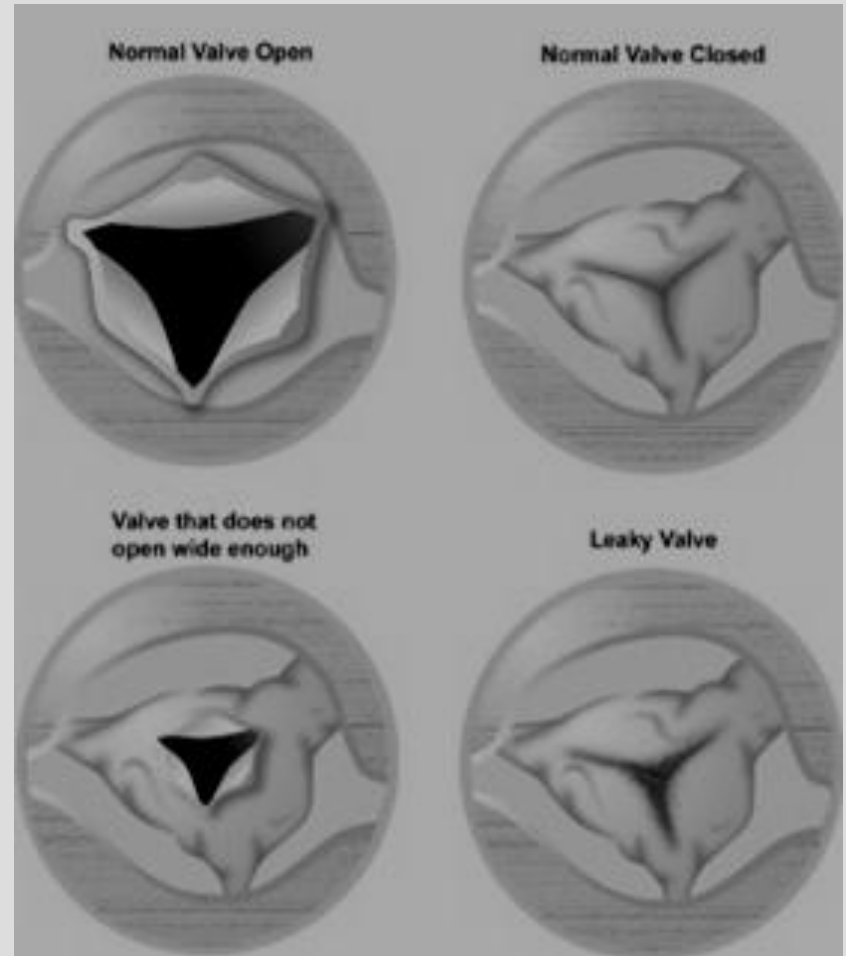
	Live expectancy
Angina	5 years
Syncope	2-3 years
Congestive Heart Failure	1-2 years

Therapy: Valve replacement for severe aortic stenosis

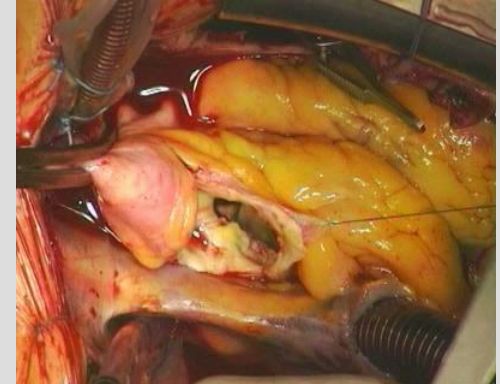
Operative mortality (elderly) 4-24%/

Morbidity 3-11%

Event rate in asymptomatic severe AS ~ 1%/year



Reconstructive surgery of the aortic root



Type I. Normal cusps with FAA dilatation

**Ia: Distal ascending aorta dilation (sino-tubular junction) –
atherosclerotic etiology**

**Ib: Proximal (Valsalva sinuses) and sino-tubular junction dilation-
Marfan Sy, sinus Valsalva ectasia...**

Ic: Isolated FAA dilation --- aortic ectasia

Id: Cusp perforation and FAA dilation

Type II. Cusp prolapsed: excess of cuspal tissue or commissural disruption / dissection

Type III. Cusp retraction, thickening and calcification.



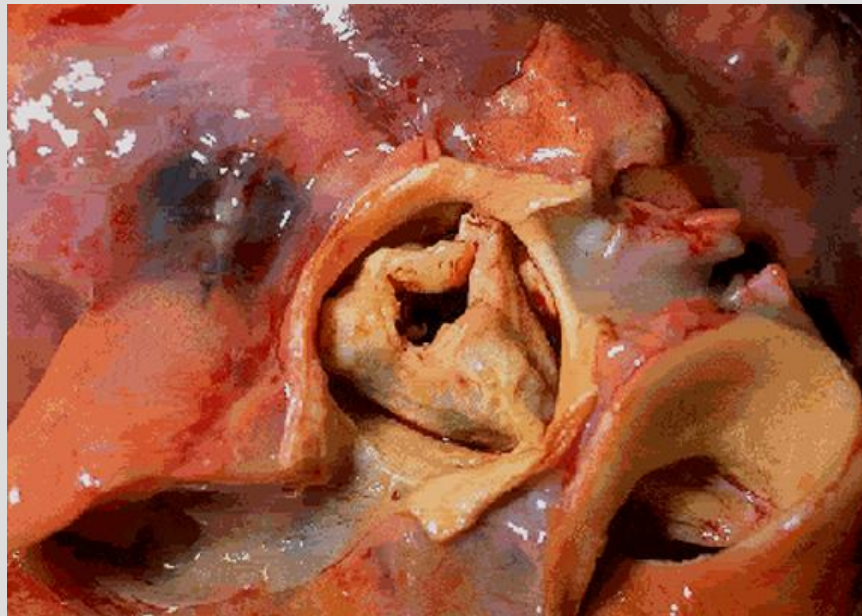
Reconstructive surgery of the aortic root

- in valvular stenosis still is ?????

Main task – restoration of normal aortic valve function

Two main techniques:

- reconstruction of aortic valve/root structures
- replacement of one or more leaflets



Aortic stenosis- calcification of the leaflets

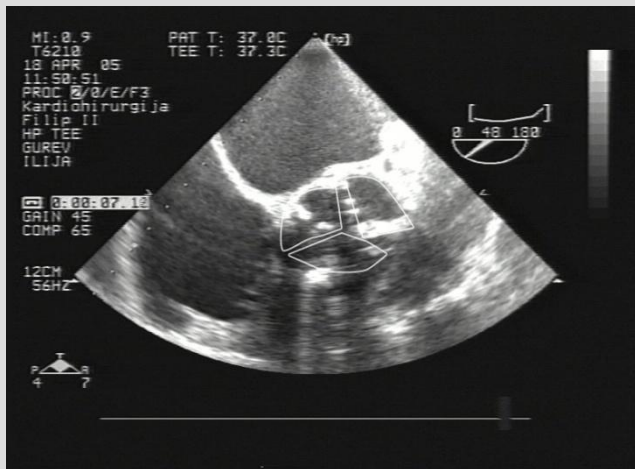


Reconstructive surgery of the aortic root

Type III. Cusp retraction, thickening and calcification.

Surgery:

- shaving of the nodes and free margin,
- cusp extension with pericardium
- calcium enucleation,
- **cusps replacement**

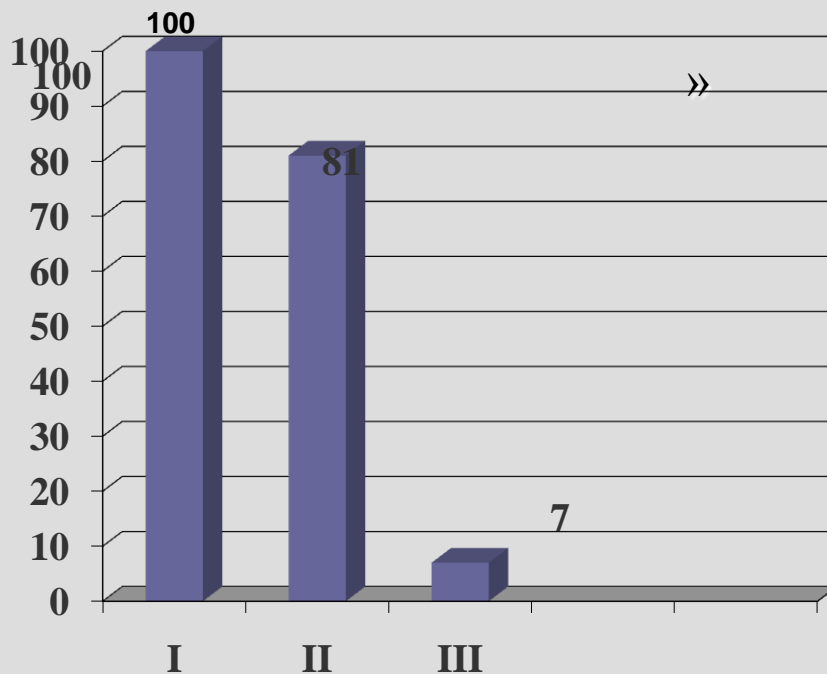


Aortic root reconstructive surgery for aortic stenosis - clinical approaches

- **Prospective study** **N = 188** pts Age (years) $56 \pm 7.6y$

Sex (f/m) 54 / 74

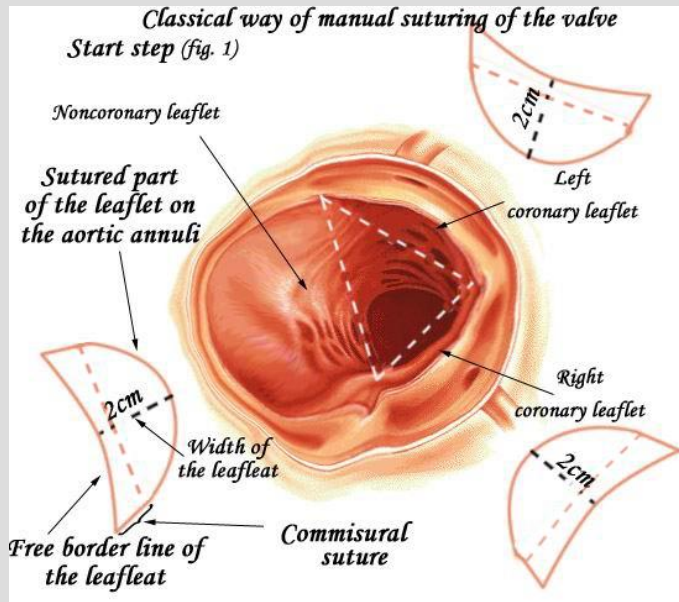
» The oldest patient – 72y



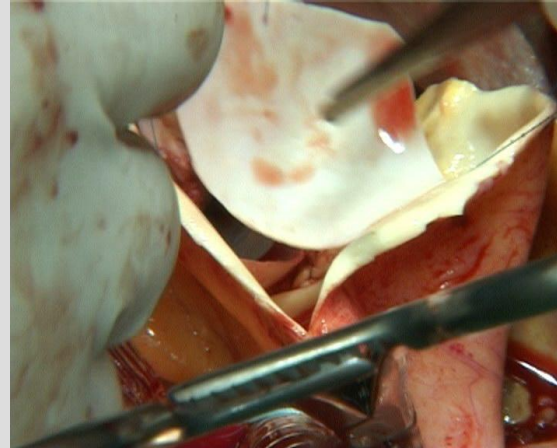
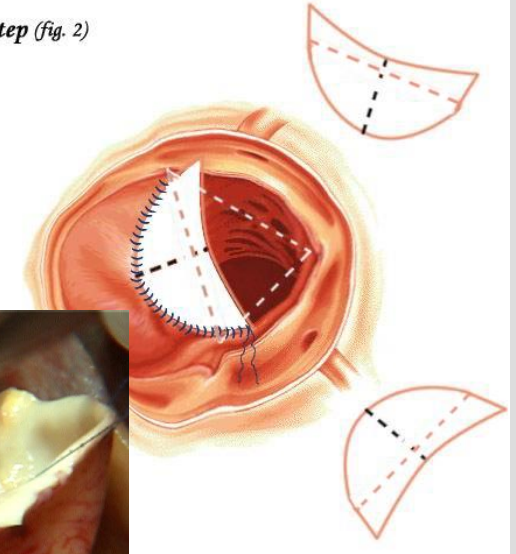
I=atherosclerotic etiology
II=rheumatic etiology
III=subacute endocarditis in patients on chronic haemodialysis



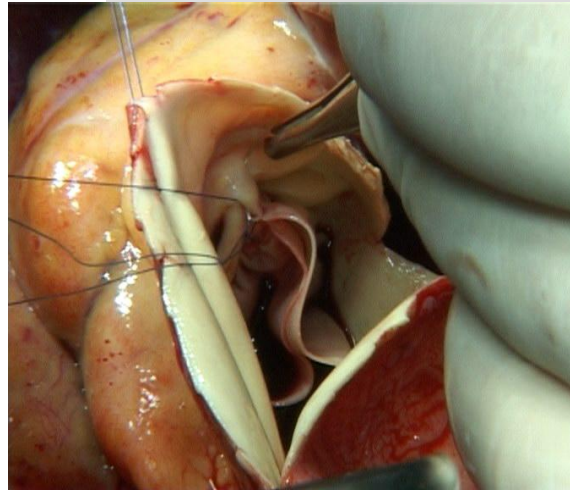
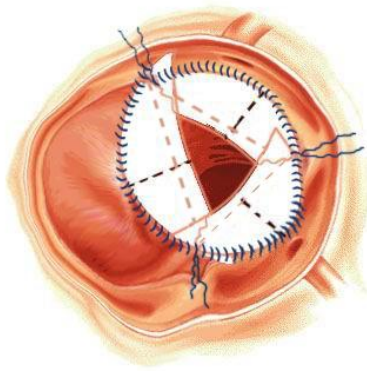
How to do it



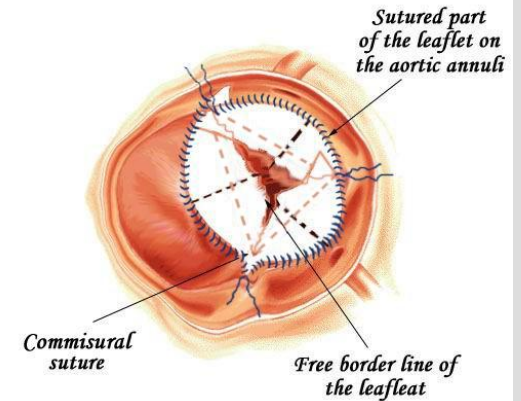
First step (fig. 2)



Third step (fig. 2)



Fourth step (fig. 3)



Aortic root reconstructive surgery for aortic stenosis

Reconstruction of aortic leaflets N= 188 pts.



surgery



Preop.echo 2D TEE



Postop.echo 2D TEE



Results

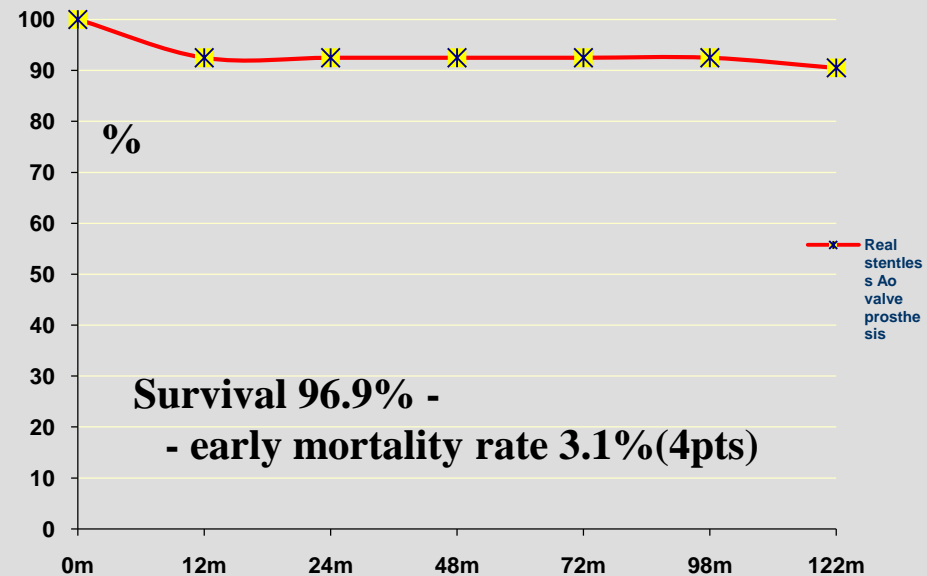
N= 188 pat

- ▶ **Early survival (30 days)** **96.9 %(6pts)**
- ▶ **Other main complication:**
- ▶ **Bleeding** **21 pat (5 surg. etiology)**
- ▶ **Ventilation time** **6.2h 2.13**
- ▶ **Stroke** **5 (1 with left side hemiparesis)**
- ▶ **4pts (with preoperative terminal renal failure) with CAVH 5 days in combination with bicarbonate haemodialysis**
- ▶ **Length of ICU stay** **4.2d 2.13**
- ▶ **Hospital stay** **13.2d 3.1**
- ▶ **Follow up period** **1-144 months**

Intra-operative TEE data

- ▶ $Dp/dt = 0.07 \pm 0.015$; $SS = 22 \pm 3.2$
- ▶ $EAO \text{ cm}^2 = 3.6 \pm 0.8$; $CO = 6.5 \pm 2.9 \text{ l}$
- ▶ *Average systolic valve gradient* $14 \pm 6.8 \text{ mmHg}$
- ▶ *Average mean valve gradient* $7 \pm 5.6 \text{ mmHg}$

Actuarial survival



Late complications and NYHA class N=182pts

5 patients re-operated (2,5%)

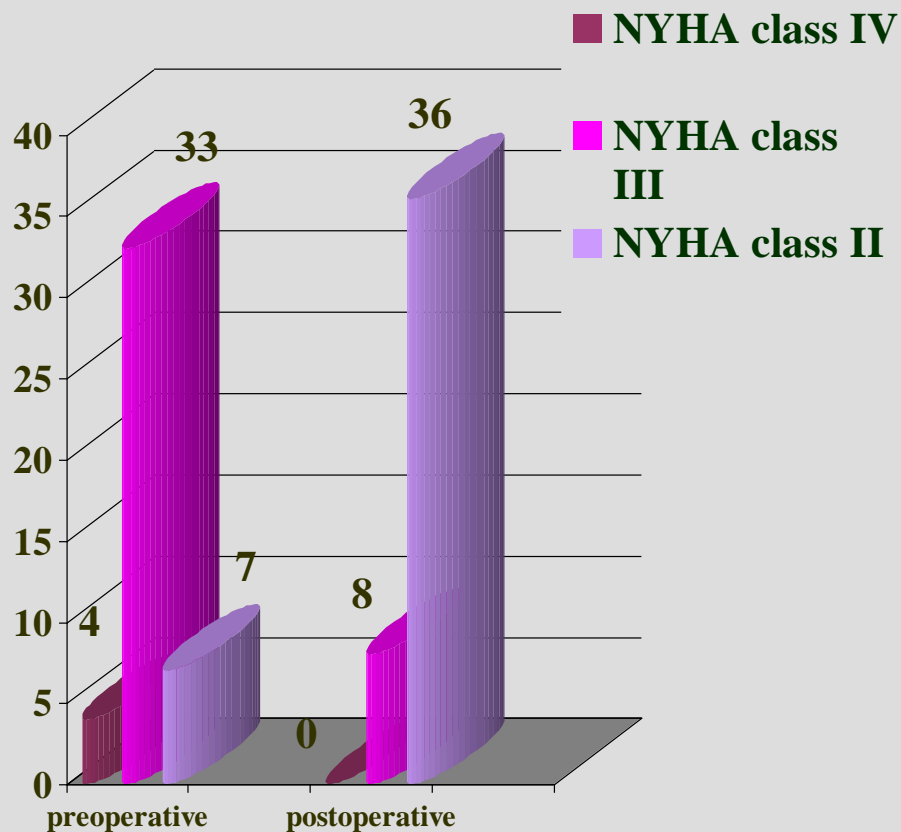
1-due to aortic regurgitation bigger than +2 as a result of dilatation of the aortic annulus

2-due to calcium degeneration of the leaflets

1-due to infective endocarditis

Late mortality 1% (2pts).

Follow up 1-144 months



Replacement of Aortic Valve Leaflets in a patient with a small root aorta – case report



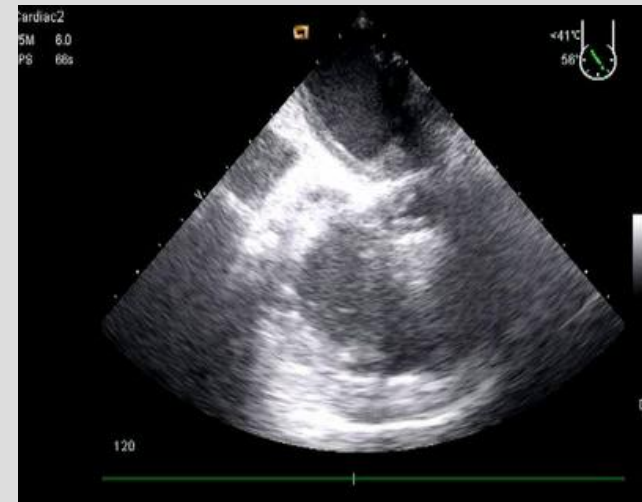
68y.old women
Severe symptomatic aortic stenosis
Small aortic root– 16,9mm
Severe calcification of the ascending aorta up to the aortic arch
Once delayed operation- because of her condition



Filip Vtori



Pre-operative echocardiography



Post-operative echocardiography

Replacement of Aortic Valve Leaflets in a patient with a bicuspid valve – case report

Preoperative echo

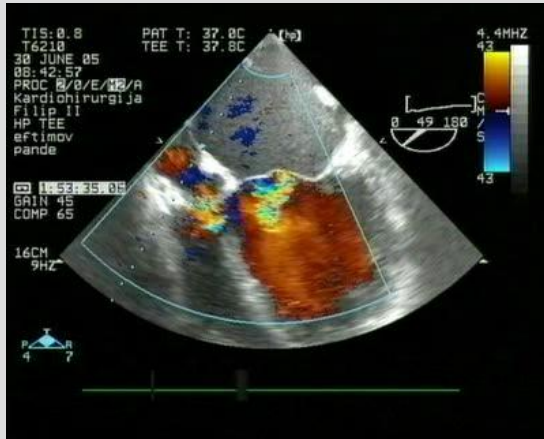
Postoperative echo

Pre-op.evaluation

Post-op.evaluation



Reconstruction of the unileaflet aortic disease in a patient – case report



Pre-op.evaluation



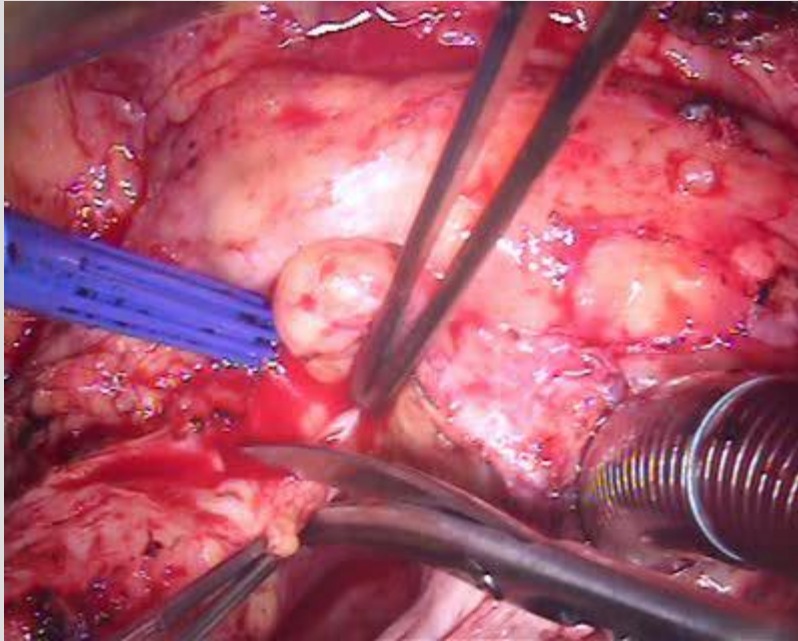
Operation technique



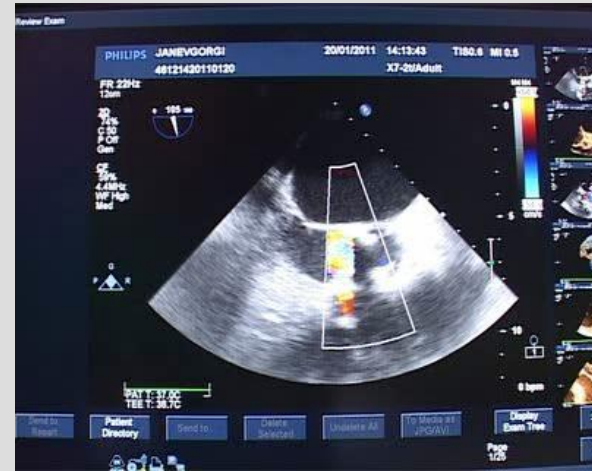
Post-op. evaluation



Re-operation-replacement of Aortic Valve Leaflets in a patient with prosthetic endocarditis – case report



64y.old men; 04/2007 biologic aortic valve prosthesis
09/2010 Pseudomonas pneumonia with severe symptomatic
prosthetic endocarditis
Peri-annular abscess
Positive haemoculture- Pseudomonas aurogenosa
ICV- aphasio
3months after ICV re-operation



Pre-operative echocardiography



Post-operative echocardiography



Techno College Award Nominee 2010 • Techno College Award Nominee 2010 • Techno College Award Nominee 2010 • Techno College Award Nominee 2010

PHOENIX combines tissue stimulation and bone marrow cell therapy

AVT Pasallo
Principal Engineer, Cardiogenesis Corp., CA, USA

Coronary artery disease (CAD) is a manifestation of atherosclerosis which often results in patients suffering from angina, myocardial infarction, congestive heart failure and ultimately death. Currently available options for treating CAD include lifestyle changes in conjunction with drug therapy, percutaneous coronary intervention (PCI) including techniques such as stent placement, and coronary artery bypass graft surgery (CABG). The objective of each of these approaches is to improve blood flow to the heart and prevent the complications related to myocardial ischemia.

Unfortunately an increasing number of patients have exhausted surgical or percutaneous options and continue to have severe angina despite maximal medical therapy. These patients are characterized by moderately compromised ejection fractions, triple vessel coronary artery disease and a history of failed prior interventions, including previous bypass surgery. The hallmark of this patient population is the presence of diffuse coronary artery disease which makes traditional surgical and percutaneous treatment options more less likely to provide optimal, durable results.

Transmyocardial revascularization (TMV) is an approved surgical procedure to treat refractory angina patients with advanced CAD in which 1mm transmural laser channels are created in ischemic myocardium which cannot be conventionally revascularized due to diffuse CAD or small vessel disease. TMV provides



Figure 1: PHOENIX Handpiece Delivery System

durable angina relief and has been shown to improve exercise tolerance¹ and a long-term survival benefit compared to medical management². The therapy has been utilized in over 40,000 patients in the treatment of severe angina symptoms.

The mechanism of TMV has been shown to be multi-factorial. The diversion from the laser energy provides acute effect, with the angiogenic response resulting from the local and systemic wound healing process providing longer term effect³. Cardiogenesis has developed an advanced delivery system (PHOENIX) to combine the laser tissue stimulation and the delivery of autologous bone marrow cells. This combination treatment is expected to increase the angiogenic effect achieved with TMV to improve patient outcomes⁴. Early experience with the PHOENIX utilizing autologous bone marrow cells has been encouraging⁵. The results of the STAR-heart study of



Figure 2: Sequence of delivery of laser energy and therapeutic material

bone marrow derived cells in the treatment of ischemic cardiomyopathy demonstrates the potential of bone marrow cells to enhance hemodynamic performance, exercise tolerance and long term survival⁶.

The PHOENIX handpiece is the first device specifically designed to allow physician-directed injection of biologic or pharmacologic agents to pre-determined areas of myocardium with reversible ischemia in conjunction with delivery of TMV. The PHOENIX is designed for use with the Cardiogenesis Ho-VAG TMV laser console. Laser energy is delivered to the myocardium through the fiberoptic component of the handpiece. The fiberoptic consists of 3 fibers, 100 µm

in diameter with an overall diameter of approximately 1mm. Immediately after channel creation, these needles are advanced distally into the surrounding tissue for fluid delivery. These injection needles are incorporated within the distal guide shaft, surrounding the fiberoptic bundle at the distal-most tip. Proximal to the handle is an injection port to permit introduction of the fluid.

An Investigative Device Exemption has been submitted for combining laser stimulation and bone marrow derived cells using the PHOENIX delivery system. A multi-center randomized trial of the combination therapy is pending.

References
1. Bhattarai D, Sander S, Sridharan SB et al. Transmyocardial laser revascularization compared with optimal medical therapy for treatment of refractory angina pectoris: a prospective randomized trial. *Lancet*. 1998; Sep 5; 352(9122):1654-60.
2. Alon R, Dvir E, Harel Y, et al. Transmyocardial revascularization results: long-term follow-up of a prospective, randomized, multicenter trial. *Ann Thorac Surg*. 2004; Aug; 78(8):1224-4.
3. Albert R, Pahlitzsch UA, Lin WB et al. Transmyocardial revascularization by Balloon-Catheter-Assisted Transmyocardial Laser and Hemostatic Resection. *Thorac Cardiovasc Surg*. 2003; 51(2):121-7.
4. Patel VJ, Sridharan S, Sridharan M, Patel S, Patel D, Patel S, Sridharan C, Saha C. Improved cell survival in irradiated myocardial infarcted animal model using transmyocardial laser and cell delivery system. *Cell Ther*. 2002; 3(2):123-34.
5. Rayor G, Harel Y, Aggudo B, Dvir E. Bone marrow cell revascularization for treating refractory angina pectoris: three coronary heart disease. *Br J Cardiol*. 2009; 111(12):174.
6. Sridharan S, Patel V, Sridharan M, et al. The Acute and Long-Term Effect of Transmyocardial Laser Revascularization in 101 Patients with Obstructive Coronary Artery Disease. *Am J Cardiol*. 2010; 105(12):1721-7.

Techno College Award Nominee 2010 • Techno College Award Nominee 2010 • Techno College Award Nominee 2010 • Techno College Award Nominee 2010

Zan Adrev
Special Hospital for Surgery Filip 7
Srege, Metkovich

Replacement aortic valve leaflets

The Replacement Aortic Valve Leaflets is technique for replacing one or more diseased or dysfunctional leaflets in an aortic heart valve. These unique leaflets are attached directly onto a patient's native aortic ring to provide good haemodynamic performance without tamias negative haemodynamics associated with artificial aortic valves. This real stenosis aortic valve bioprosthesis ensures haemodynamic improvement with a normal transvalvular gradient in patients it can even be successfully implanted in children patients with a small root or bicuspid valve.

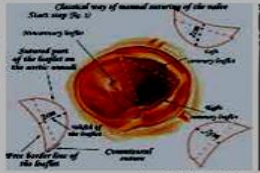


Figure 1: Schematic view



Figure 2: In vivo ultrasound measurement

un (72 pts) and replacing valve cusps on the aortic fibrous ring of the patient. This innovative aortic valve is called realy stenosis, because the newly created leaflets are directly sutured onto the patient's native aortic ring. This valve was created from the same pericardium which other biologic valve prosthesis are made. The di-

ameter is measured between two commissures and leaflet is created in a semi-circular shape in such configuration the three elements contact and overlap in closed valve similar to the closing of a native heart aortic valve. This allows the surgeon to replace the aortic leaflets separately, creating new commissures.

Features and benefits replace mitral aortic valve leaflets
• Is close to native aortic valve morphology
• Real stenosis valve ring leaflets are directly sutured to the aortic annulus
• Created from the same pericardium from which other biologic valve prosthesis are made

Separable leaflets may be used according to the native dimension of the valve
• In vivo results, confirmed with initial clinical results showed proportional loading of haemodynamic parameters CO mean flow rate systolic pressure gradient as in normal valve.
• Adequate increasing of aortic valve area and cardiac output during physical stress confirmed by dobutamine stress echocardiography
• Decreases aortic wall stress resulting not for low transvalvular pressure gradient in patients
• Insures haemodynamic improvement signs for stenosis
• Adequate for usage even in patients with small root or bicuspid aortic valve
• Easy for implantation in patients with an aortic valve disease when surgeon has to change both valves mitral and aortic one. There will be no geo-

metrical disposition of the aortic mitral annulus.
• No mitral regurgitation
• No need for anticoagulant therapy
• Potential to be used in patients with endocarditis
• Potential usage for patients with previous implanted prosthesis
• Potential use in patients who are with physically active way of living
• Low cost
• Potential to be implanted using mechanical device cutters techniques
• In case of need for re-operation it is possible to implant percutaneous aortic valve or if it is performed classic transaortic way
• It is easy to explain the valve and to replace the prosthesis
• Potential for implantation in the pulmonary artery position
Research indicates there are no products on the market comparable in design or function to the Replacement Aortic Valve Leaflets. Basic parameters SPG: 14 ± 2.5; SV: 6 ± 0.5; SF: 70 ± 9.8



Figure 3: Suturing of the second new created leaflet



Figure 4: Suturing of the first leaflet

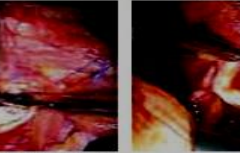


Figure 5: Newly created valve

metical disposition of the aortic mitral annulus.
• No mitral regurgitation
• No need for anticoagulant therapy
• Potential to be used in patients with endocarditis
• Potential usage for patients with previous implanted prosthesis
• Potential use in patients who are with physically active way of living
• Low cost
• Potential to be implanted using mechanical device cutters techniques
• In case of need for re-operation it is possible to implant percutaneous aortic valve or if it is performed classic transaortic way
• It is easy to explain the valve and to replace the prosthesis
• Potential for implantation in the pulmonary artery position
Research indicates there are no products on the market comparable in design or function to the Replacement Aortic Valve Leaflets. Basic parameters SPG: 14 ± 2.5; SV: 6 ± 0.5; SF: 70 ± 9.8



Figure 6: Postoperative (newer Ao valve stenosis)

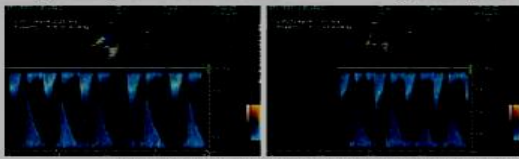


Figure 7: Postoperative. In implanted real stenosis Ao valve. EAO 3.6cm²

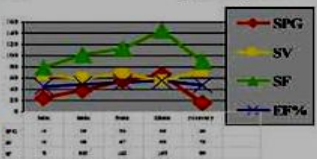


Figure 9: Postoperative. In implanted real stenosis Ao valve. EAO 3.6cm²

EACTS 2010 Techno-colleague Award nominee (printed Daily News)

Conclusion:

This technique is:

- method of choice for small root aortic stenosis**
- patients do not need anticoagulation therapy**
- restores the aortic root geometry , because every leaflet is sized according to patient's natural dimensions of sinus Valsalva**
- ensures bigger orificium area with a smaller transvalvular gradient compare with standard procedure**

Reconstructive surgery of the aortic stenosis is not that complex surgical technique and could be routine and applicable for every cardio surgeon

