

Real stentless aortic valve new type of aortic root reconstructive surgery



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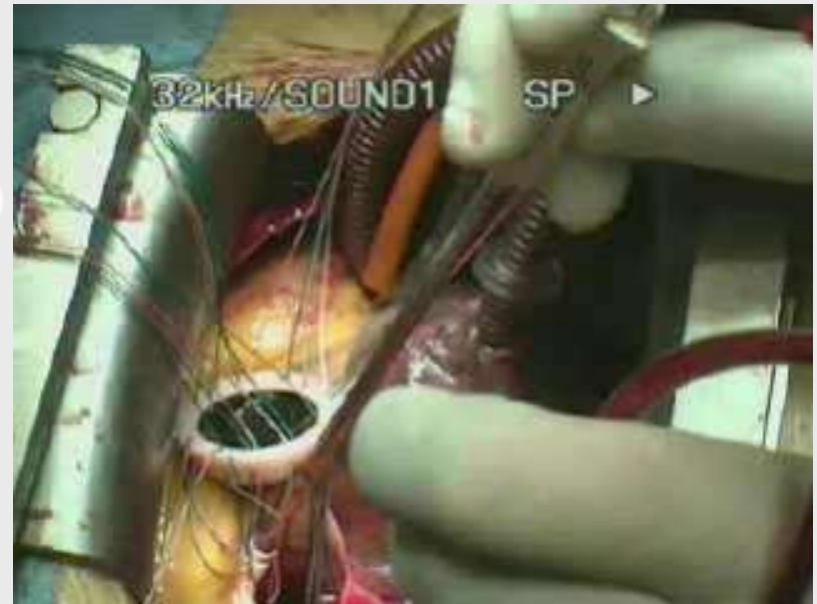
Cardiosurgery – Skopje



Aortic valve replacement

Standard:

- mechanical valve prosthesis
- biologic valve prosthesis (stentled)
- stentless aortic bio-prosthesis
- Homograft (mini root, freestyle aortic root, xenograft)
- Ross procedure



Ideal aortic valve prosthesis

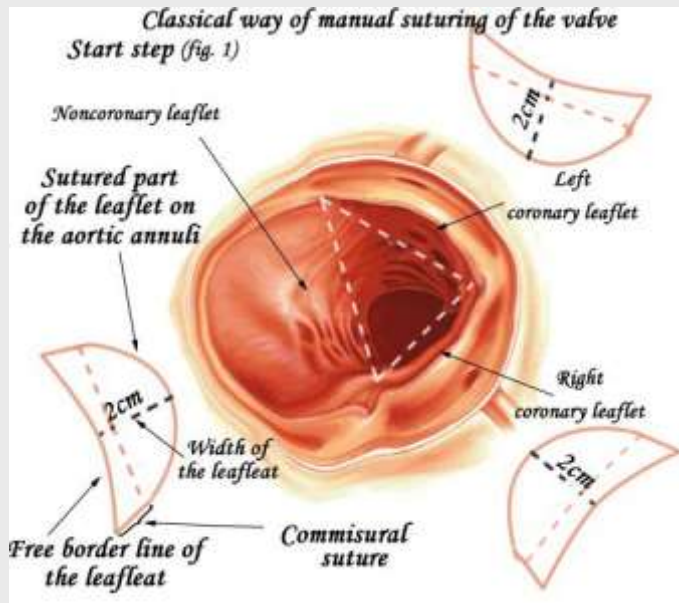
- ◆ no resistance to forward flow
- ◆ low stress gradient
- ◆ no leak when closed
- ◆ no damage to blood cells
- ◆ no thromboembolism
- ◆ should resist wear (durability)
- ◆ should not produce noise
- ◆ easy and simple way of implantation



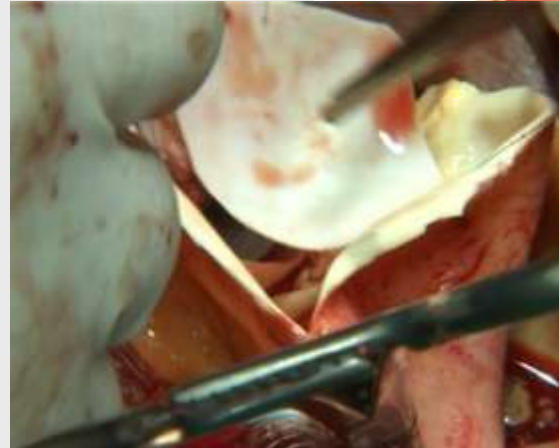
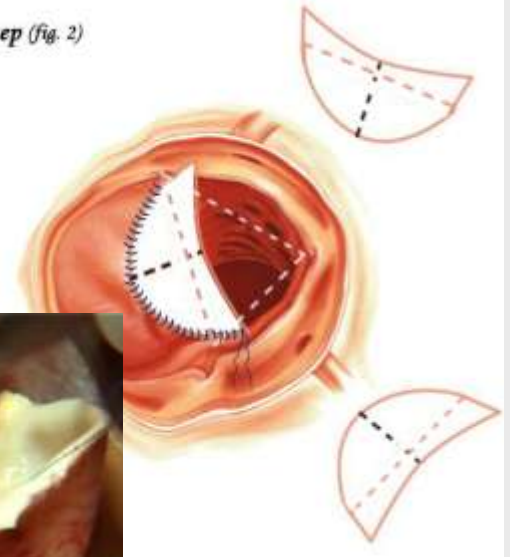
normal aortic valve



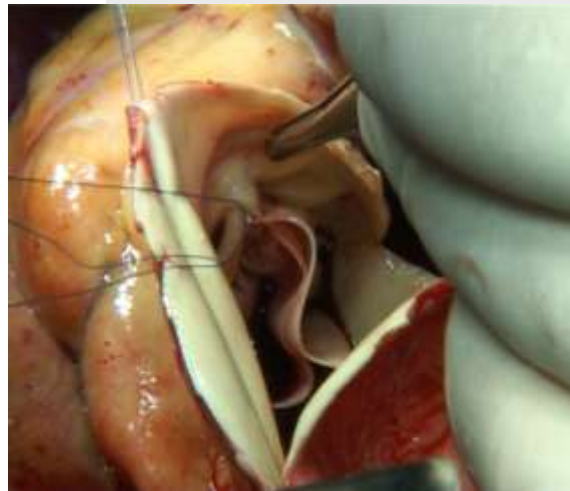
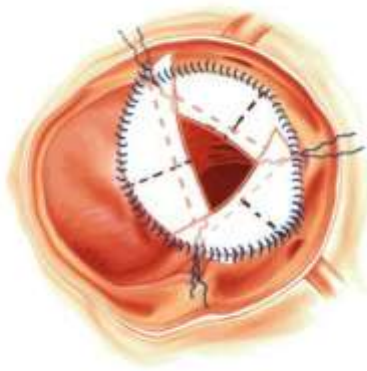
How to do it



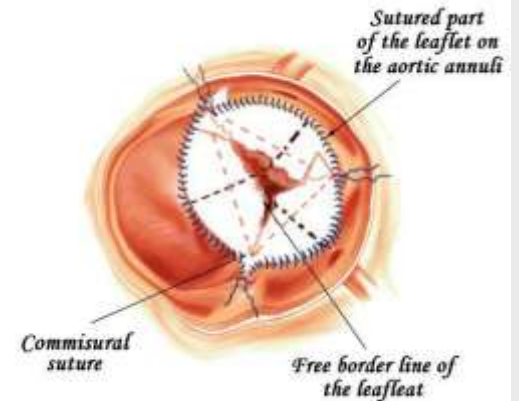
First step (fig. 2)



Third step (fig. 2)



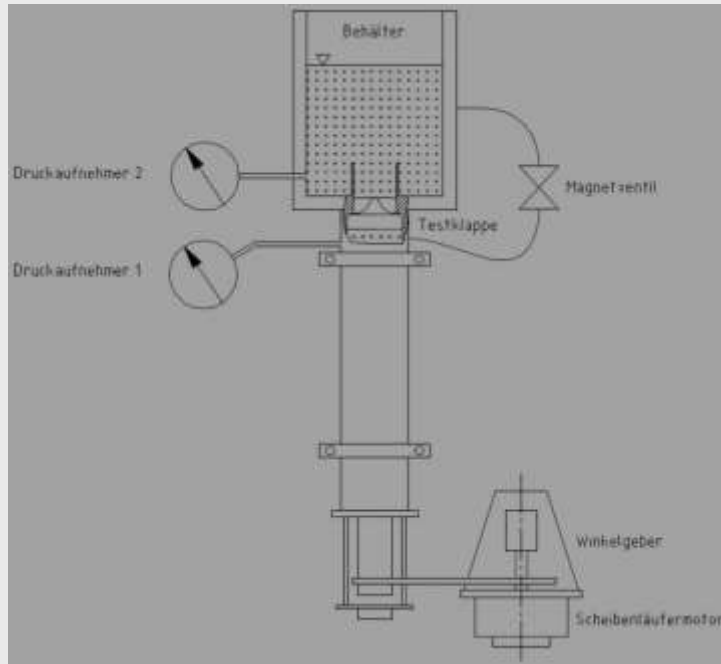
Fourth step (fig. 3)



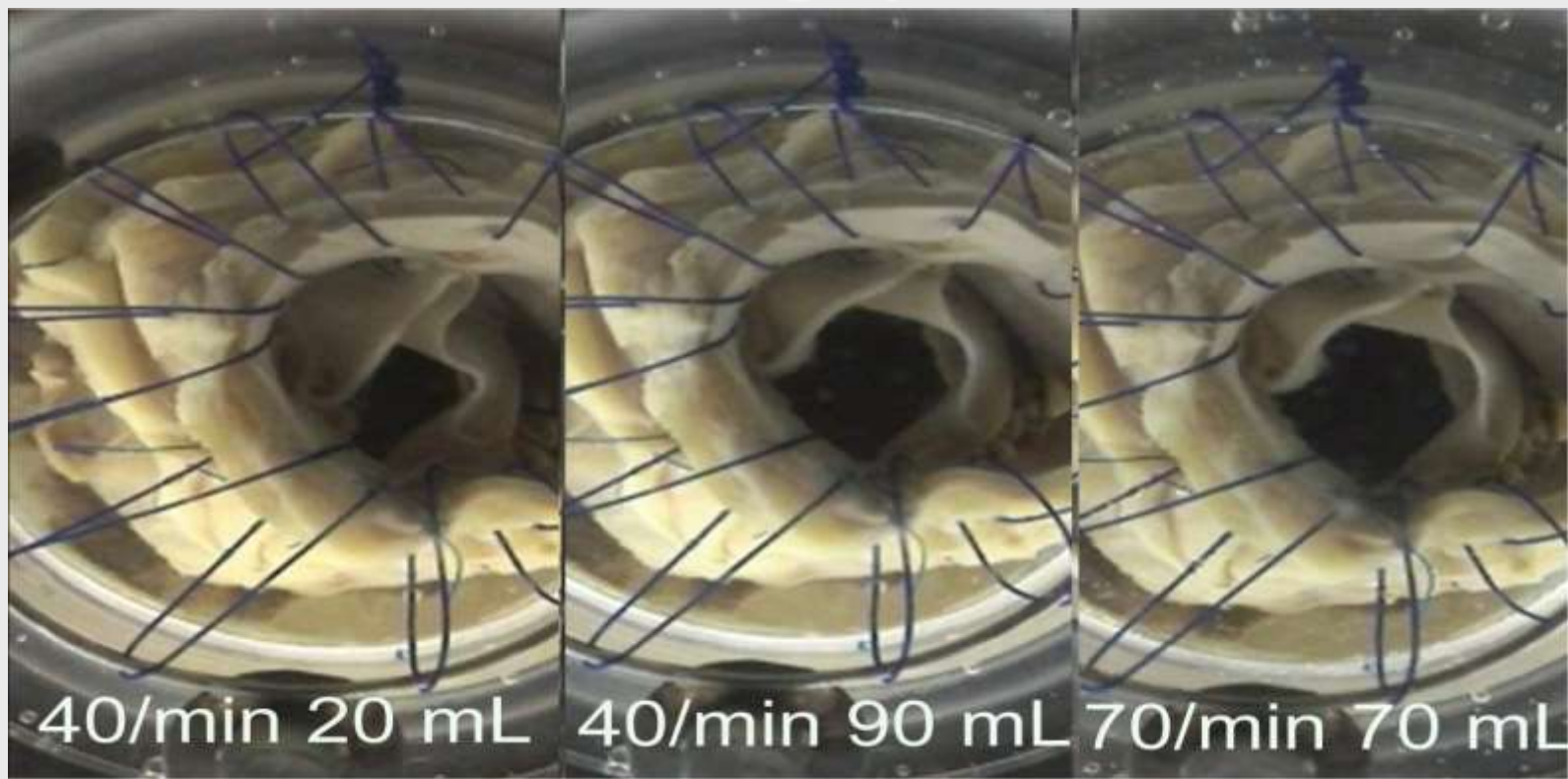
**Humboldt Universität zu Berlin
Charité Campus Virchow
Labor für Biofluidmechanik
Prof. Dr.-Ing. K. Affeld
Berlin**

Datum: 03.04.2003

**In vitro testing of the
real stentless aortic valve:**



Real stentless aortic valve new type of aortic root reconstructive surgery - in vitro test



These valve parameters had been explored: 1.CO (cardiac output)
2.Root mean square – in dependence of the ΔP , 3.leckage of volume,
4. elasticity of the leaflets, 5.pressure gradient, 6.resistance of the
flow



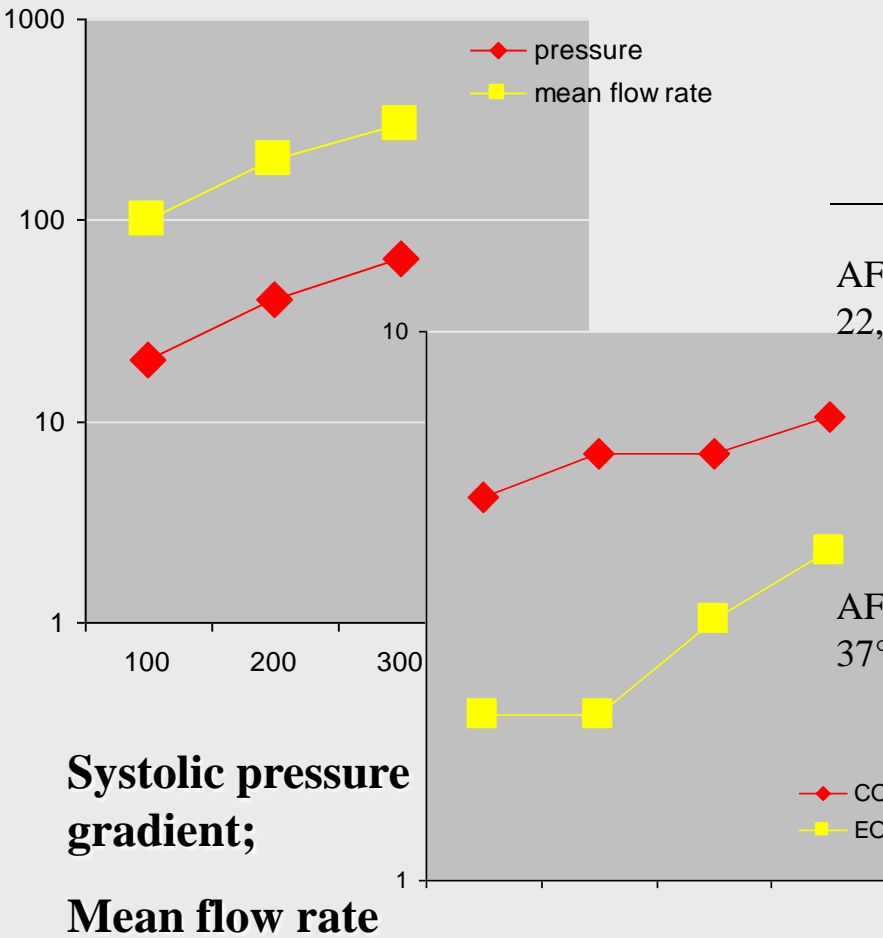
Real stentless aortic valve new type of aortic root reconstructive surgery – in vitro test



Root mean square (EOA) in dependence of CO and systolic pressure through the valve ; $EOA = RMS / (51,6 * \Delta p^{1/2})$; $R = 1333 * \Delta p / MF$ (mean flow)



Real stentless aortic valve new type of aortic root reconstructive surgery – in vitro test



	HF 1/min	SV mL	CO L/min	MF mL/s	RMS mL/s	ΔP mmHg
AF04-030403-03	40	20	0,8	53	58	10,7
22,4°C	40	30	1,2	80	86	14,2
	70	30	2,1	104	112	17,9
	100	30	2,9	125	136	22,0
	40	50	2,0	131	143	23,4
	70	40	2,8	136	148	24,3
AF04-030403-04	40	20	0,8	53	58	10,5
37°C	40	30	1,2	80	86	13,8
	70	30	2,1	103	112	17,9
	100	30	2,9	126	137	21,6
	40	50	2,0	132	143	23,2
	70	40	2,8	137	149	23,9
	70	49	3,5	169	185	32,7

Systolic pressure gradient;
Mean flow rate

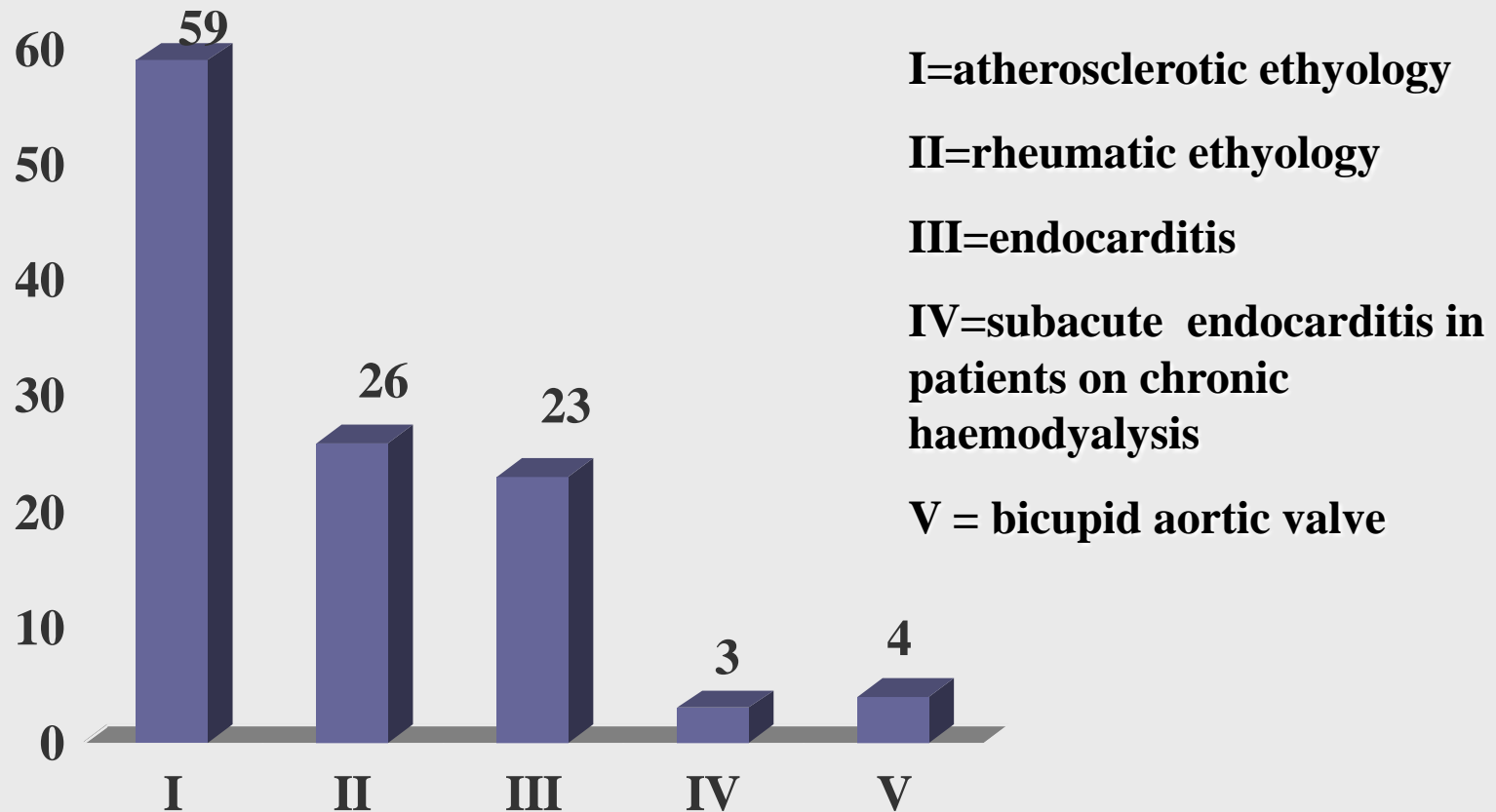
Cardiac output

Effective orifice area-aorta



Real stentless aortic valve new type of aortic root reconstructive surgery - our early clinical approaches

▼ Prospective study N = 115pts with severe aortic stenosis



Patients demographics data N = 115 pts

Age (years) $56 \pm 7.6y$

Sex (f/m) 34 / 81 **The oldest patient – 72y**

Including criteria:

Severe aortic valve stenosis, with aortic root not bigger than 3,5cm

Trans-aortic middle pressure gradient $>65\text{mmHg}$

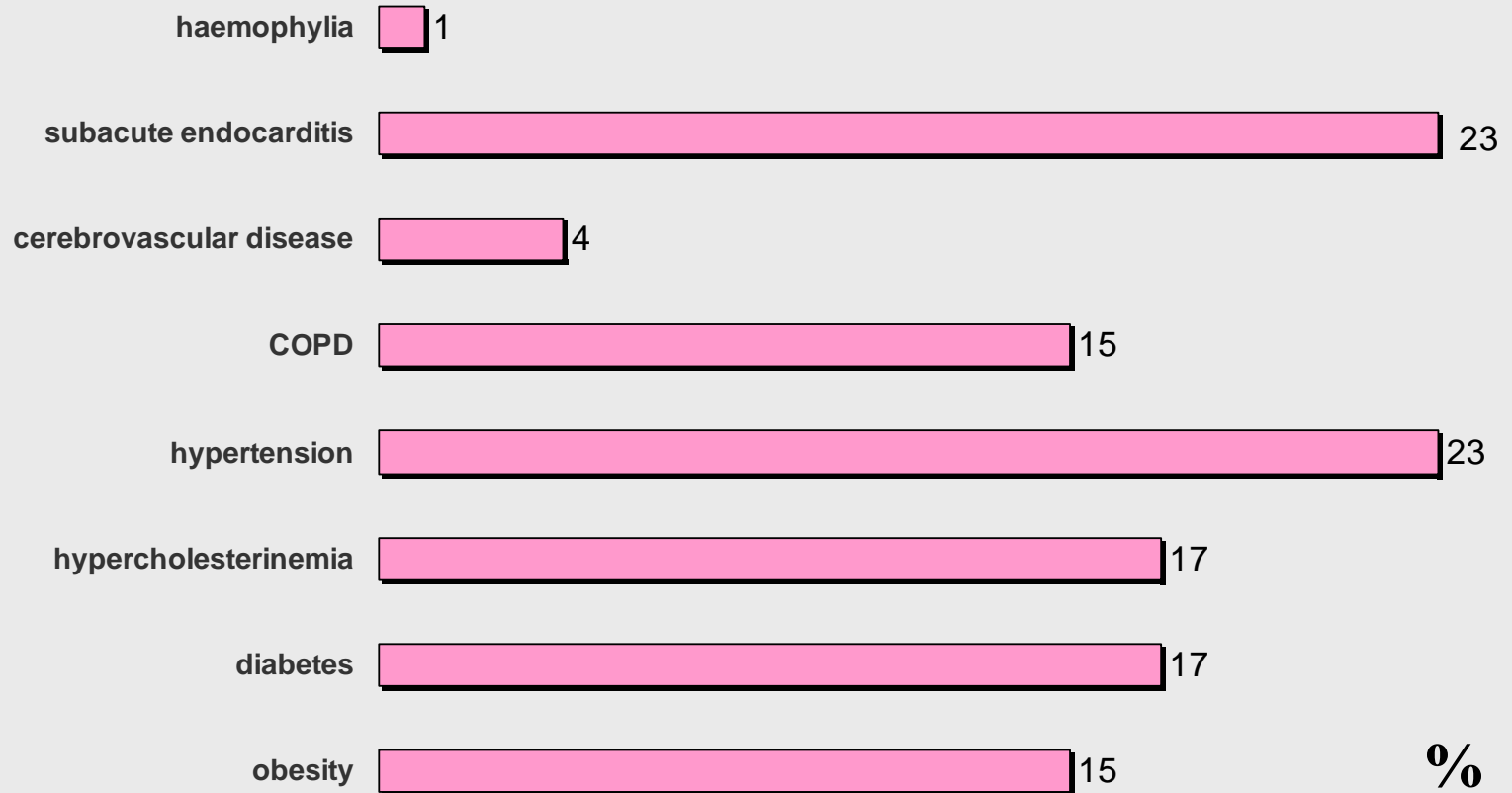
Performed investigations

- Trans-thoracic echocardiography
- Catheterisation
- Trans-esophageal echocardiography pre and intra-operatively



Preoperative co-morbidity

N=115pts



Real stentless aortic valve ultrasound evaluation bicuspid valve

Preoperative echo

Postoperative echo

Pre-op.evaluation

Post-op.evaluation



Results I

N= 115 pat.

▶ Middle aorta cross-clamping time

61±9.6min

▶ Middle bypass time

82±12.5min

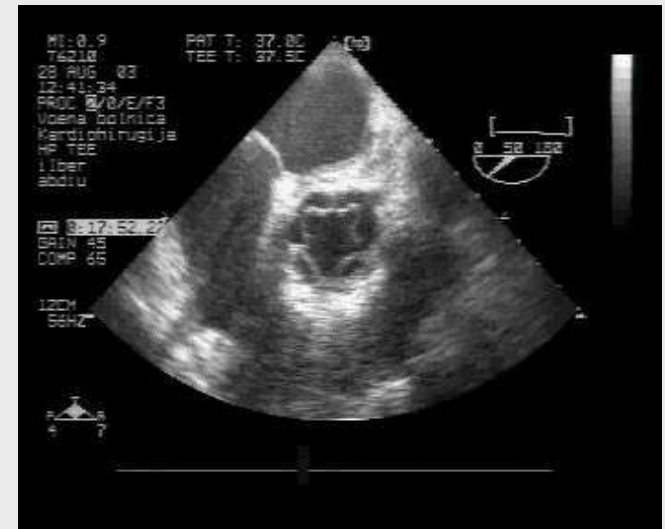
Intra-operative TEE data

▶ $Dp/dt = 0.07 \text{ } 0,015$; $SS = 22 \pm 3.2$

▶ $EAO \text{ cm}^2 = 3.6 \pm 0,8$; $CO = 6,5 \pm 2.91$

▶ Average systolic valve gradient $14 \pm 6.8 \text{ mmHg}$

▶ Average mean valve gradient $7 \pm 5.6 \text{ mmHg}$



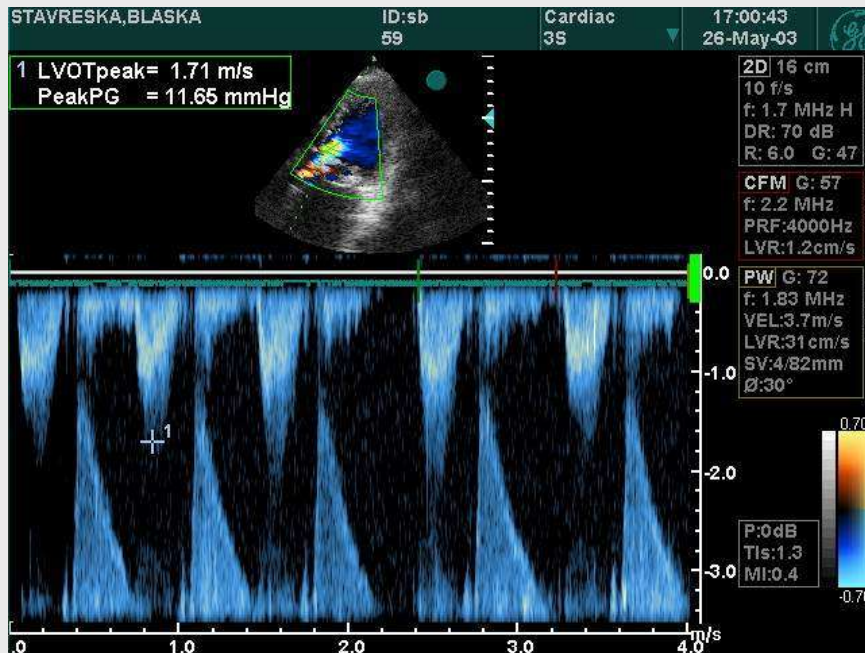
Results II

N= 115 pts

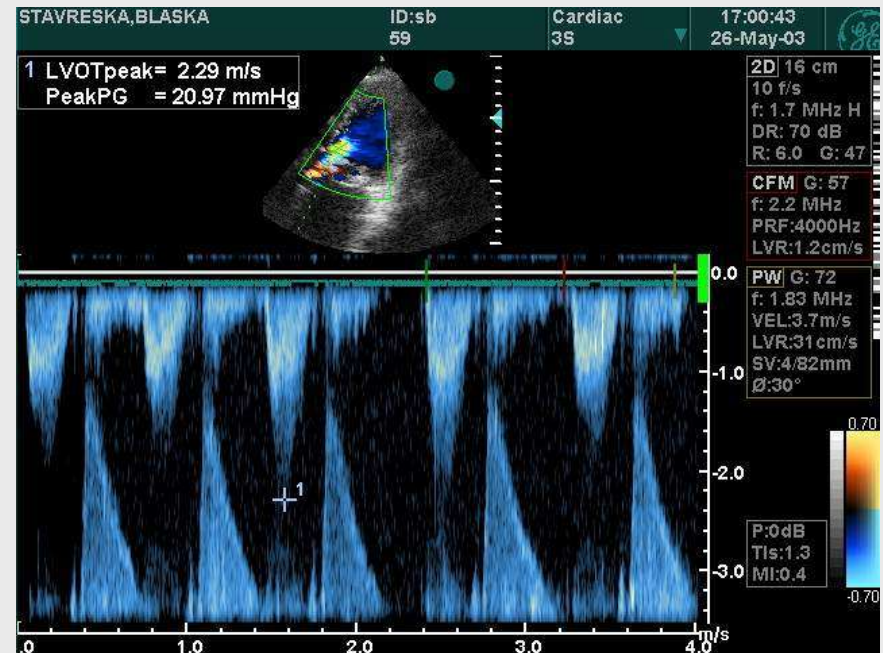
- ▶ Early survival (30 days) 94.8% (8pts)
- ▶ Other main complication:
 - ▶ Bleeding 5 pat (3 surg. etiology)
 - ▶ Ventilation time 6.8h±2.2
 - ▶ Stroke 2 (1 with left side hemiparesis)
 - ▶ 3pts (with preoperative terminal renal failure) with CVVHD (Prismaflex Gambro) 5 days
 - ▶ Length of ICU stay 8.6d ±2.1
 - ▶ Hospital stay 14.4 ±3.2
- ▶ Patients have been treated with anti-aggregates (Tbl. Aspirin 0,1 1x1)
- ▶ Simvastatin
- ▶ Follow up period 4-84 months



Dobutamin stress echo n = 36pts



0-stadium



I-stadium

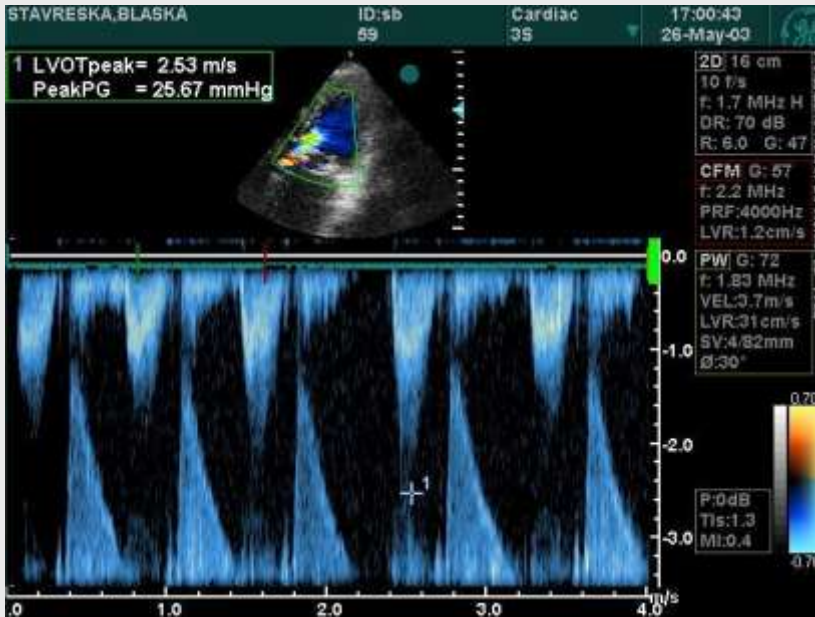
Protocol:- (5µg/kg/min)dobutamin

-dosage was doubled on every 3 min-up to 12min

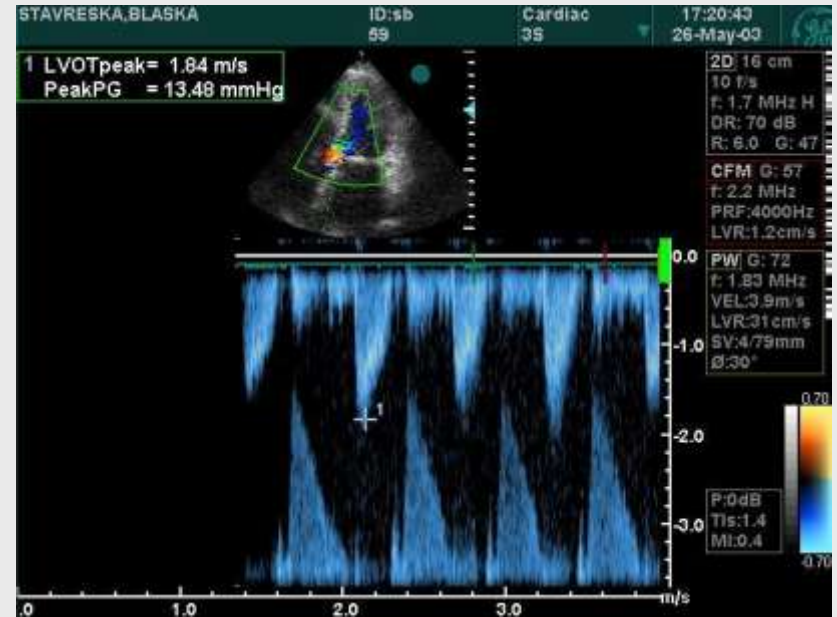
-followed parameters: CO,PG syst. and mean through the aortic valve, dp/dt, and systolic separation (SS).



Dobutamin stress echo n = 36pts



IV-stadium



recovery

Remarkable: in all pts CO increased in a linear module with a pressure gradient . 56mmHg, was the highest measured systolic pressure gradient in the IVth stadium, with a CO 7-9l/min, and dp/dt as in normal valve, with a good SS

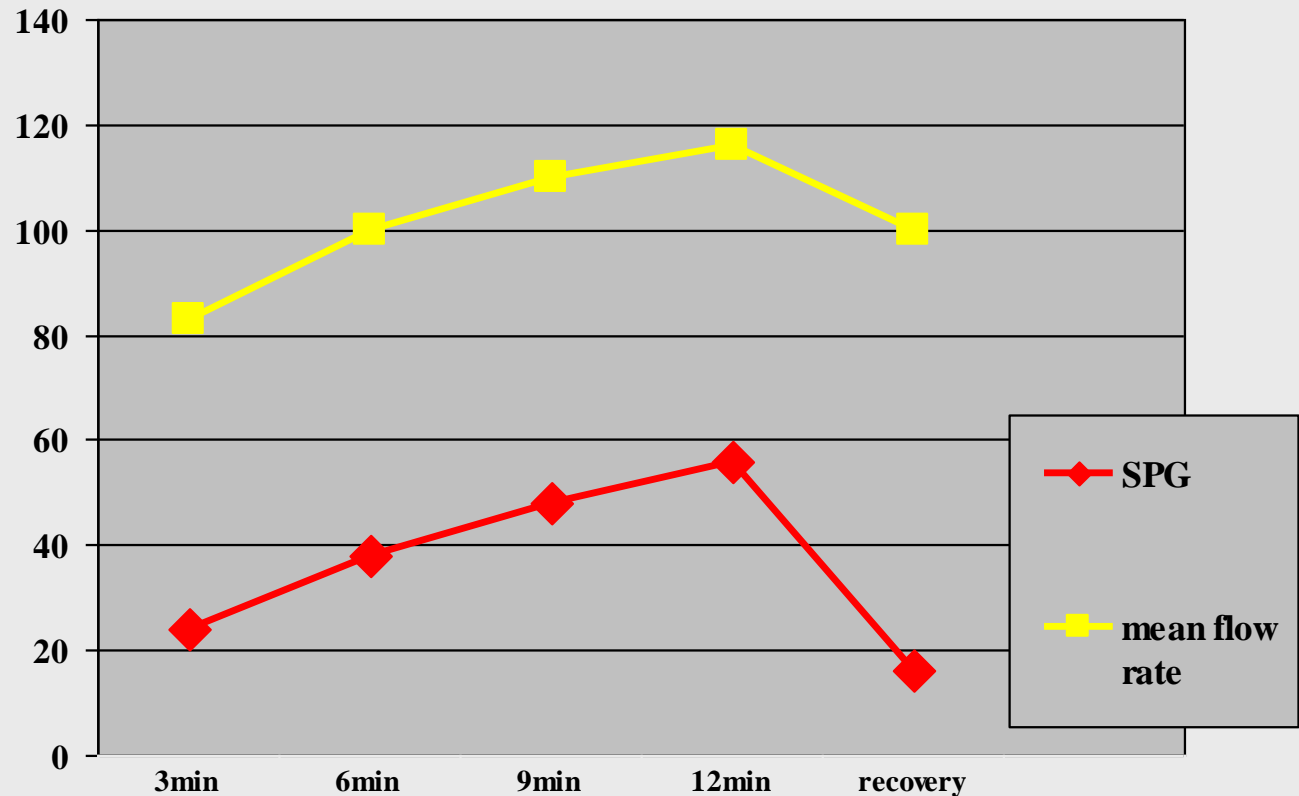


Proportional ratio of Systolic pressure gradient and mean flow rate n = 36pts

Basic parameters

SPG=14 ± 3.5

**mean flow
rate=64 ± 9.5**



SPG

24

38

48

56

16

mean flow rate

83

100

110

116

100



Proportional ratio of EAO and CO during dobutamin stress echo

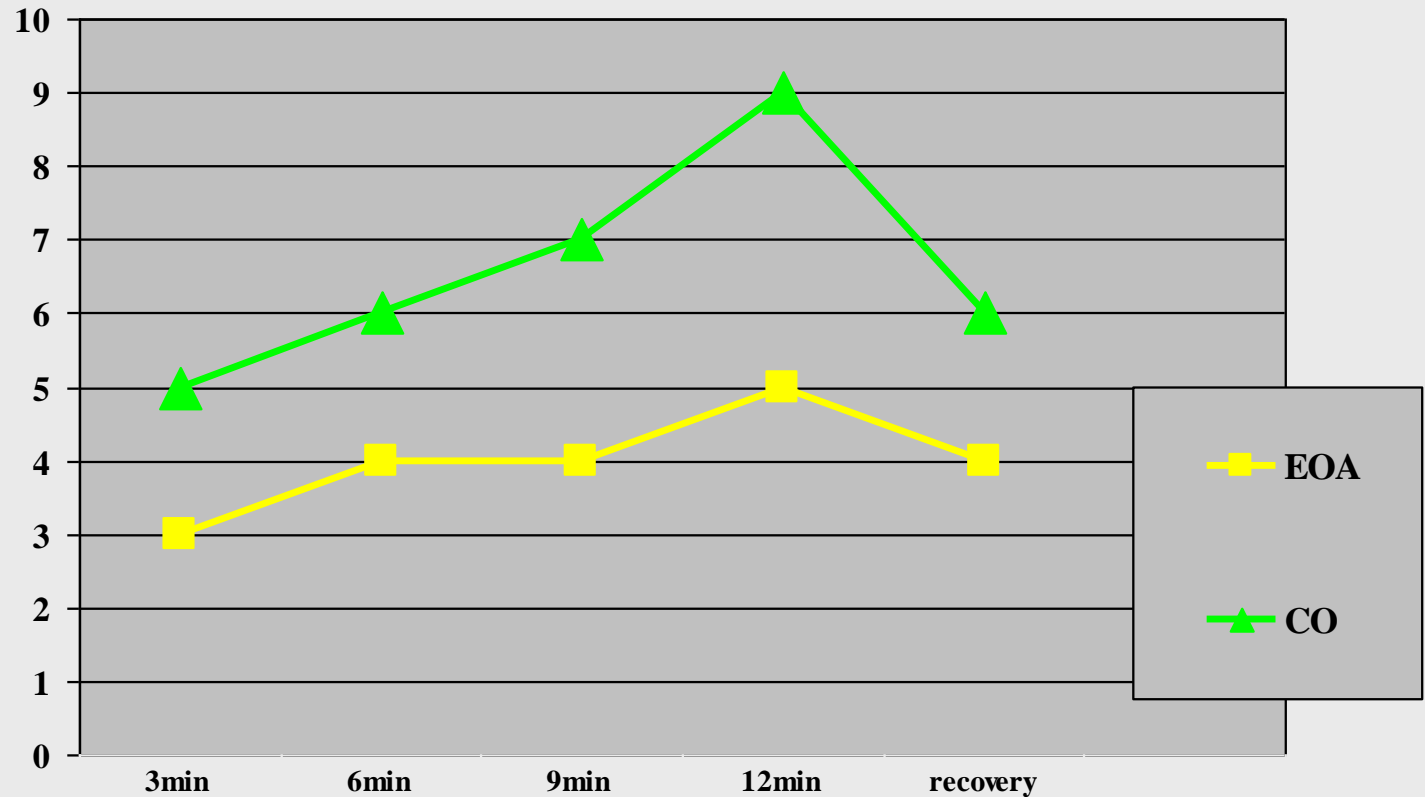
n = 36pts

Basic parameters

EOA = 3.2 ± 1.5

CO = 6.2 ± 2.5

EOA = $CO / \sqrt{\text{sist. mean press. gradient}}$



EOA

3min

3

6min

4

9min

4

12min

5

recovery

4

CO

5

6

7

9

6



Late complications and NYHA class

3 patient re-operated

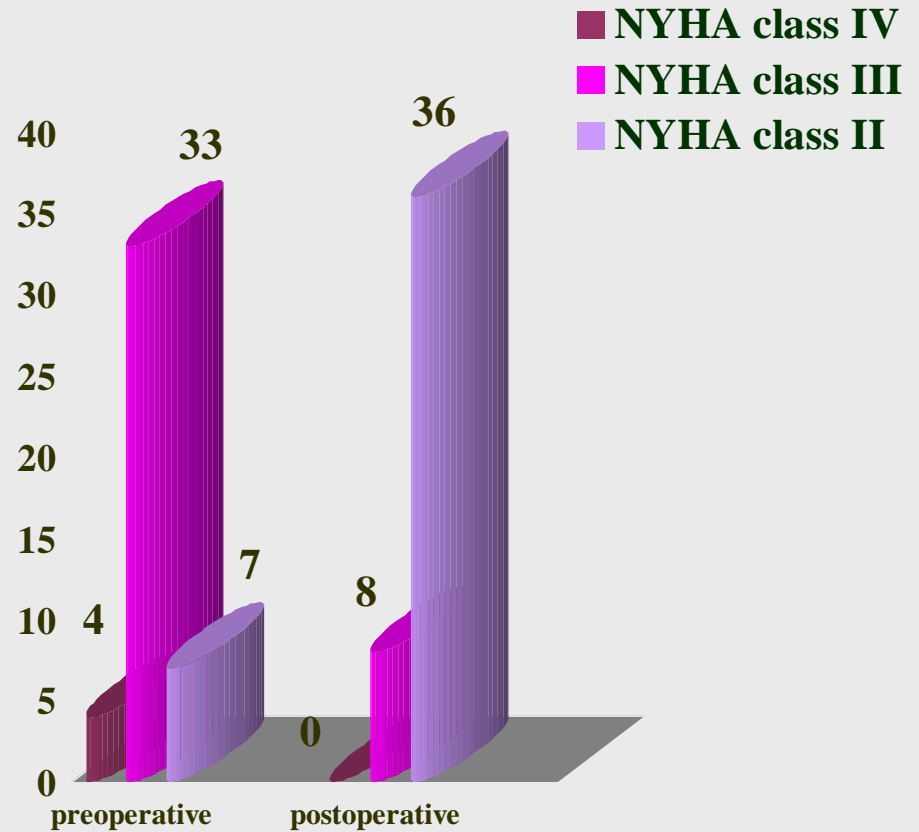
1-due to aortic regurgitation bigger than +2 as a result of dilatation of the aortic annulus

1-due to calcium degeneration of the leaflets

1-due to infective endocarditis

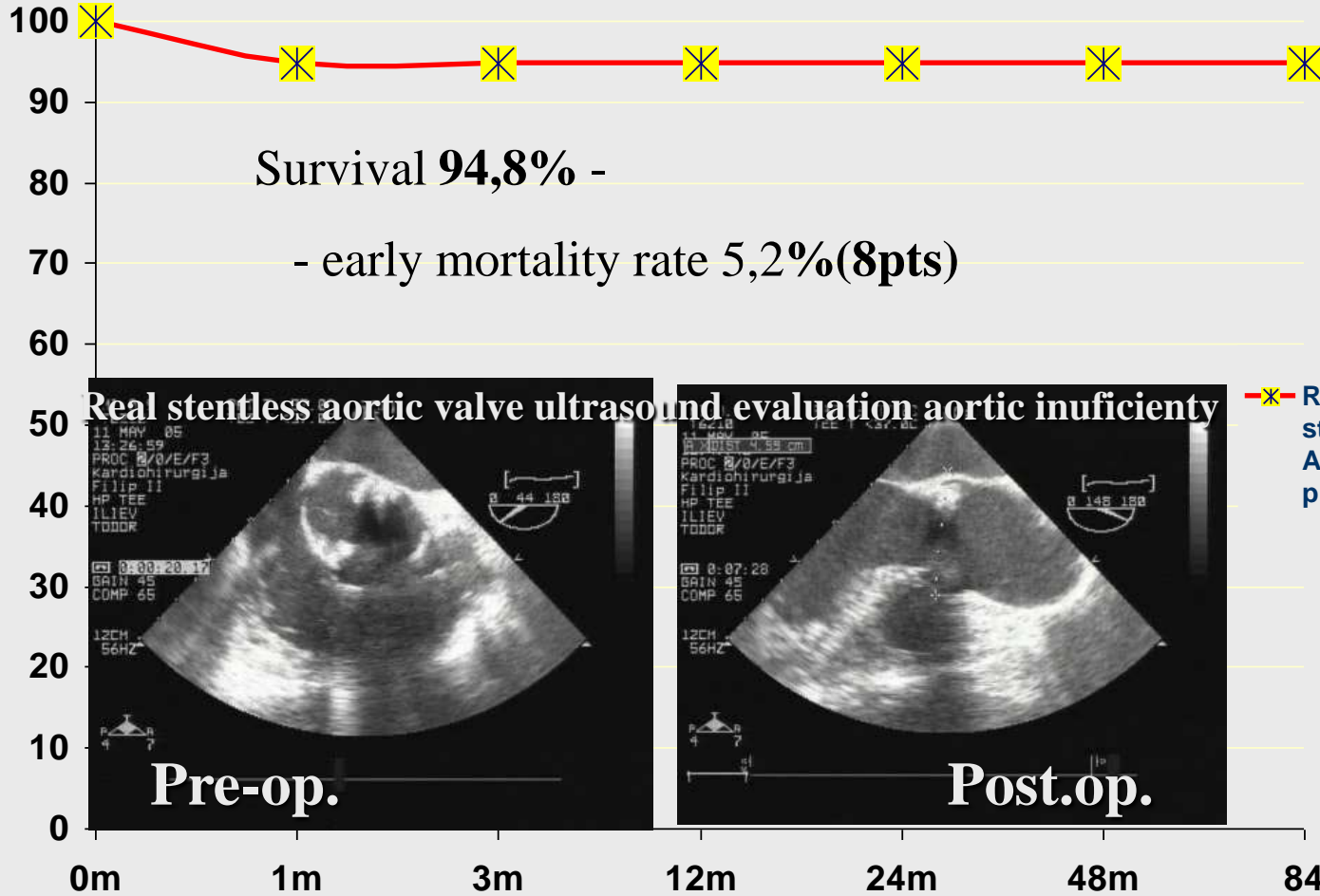
Late mortality 0%.

Follow up 4-84 months



Actuarial survival

%



Follow up 4 to 84months



Replacement Aortic Valve

Leaflets in a patient with a small aortic root case report



**Pre-operative
echocardiography**

68y.old women

**Severe symptomatic aortic
stenosis**

Small aortic root – 16,9mm

**Severe calcificated
ascending aorta up to
aortic arch**

**Once deleted operation-
because of her condition**



Small-root case report



operation



6 months follow up

Excellent haemodynamic

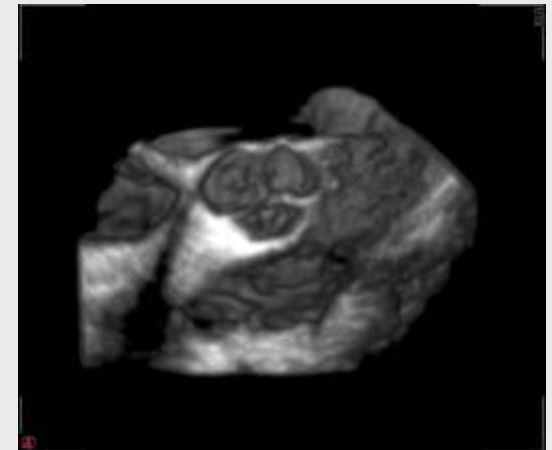
Normal quality of life



Small-root case report 3D TEE approach



Post operative



Pre operative



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PHOENIX combines tissue stimulation and bone marrow cell therapy

PHOENIX
Principal Engineer: CardioGenics 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 therapies, 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 advanced anginal or percutaneous options and continue to have severe angina despite maximal medical therapy. These patients are characterized by road-way compromised epicardial arteries, type-II 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 less likely to provide optimal, durable results.

Transcatheter revascularization (TCR) is an approved surgical procedure to treat refractory angina patients with an advanced CAD in which, from within a low catheter, are created in ischemic myocardium which cannot be conveniently revascularized due to diffuse CAD or small vessel disease. TCR provides



Figure 1: PHOENIX Handpiece Delivery System

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

The mechanism of TCR has been shown to be multi-factorial. The observation from the laser energy provides acute effect, with the angiogenic response resulting from the local and systemic wound healing process providing longer term effect. CardioGenics has developed an advanced delivery system (PHOENIX) to combine the laser tissue stimulation and the delivery of autologous bone marrow cells. The combination treatment is theorized to increase the angiogenic effect achieved with TCR to improve patient outcomes. Early experience with the PHOENIX utilizing autologous bone marrow cells has been encouraging. The results of the STENTless study of



Figure 2: Separation of delivery of laser energy and therapeutic cells

bone marrow derived cells in the treatment of ischemic cardiomyopathy document also the potential of bone marrow cells to enhance hemodynamic performance, exercise tolerance and long term survival.¹

The PHOENIX handpiece is the first device specifically designed to allow physician-directed separation of biologic or pharmacologic agents to pre-determined areas of myocardium with remote ischemia in conjunction with delivery of both therapies. The PHOENIX is designed for use with the CardioGenics HAVING™ TCR laser console. Laser energy is delivered to the myocardium through the fiberoptic component of the handpiece. The fiberoptic consists of 2 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 blood delivery. These injection needles are incorporated within the distal glide shaft, surrounding the fiberoptic bundle at the distal-most tip. Incorporated in the handle is an injection port to permit introduction of the BMA.

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. Bhatt DL, Hassel III, Skolnick ST et al. Transcatheter laser myocardial revascularization with autologous bone marrow cells for treatment of refractory angina pectoris: a prospective randomized trial. *Circulation*. 2009; 119:1010-1018.
 2. Bhatt DL, Hassel III, Skolnick ST et al. Transcatheter laser revascularization of coronary artery disease: a prospective, randomized multi-center trial. *Am J Med*. 2009; 122:100-108.
 3. Aylward J, et al. *Am J Med*. 2009; 122:100-108.
 4. Aylward J, et al. *Am J Med*. 2009; 122:100-108.
 5. Aylward J, et al. *Am J Med*. 2009; 122:100-108.
 6. Aylward J, et al. *Am J Med*. 2009; 122:100-108.
 7. Aylward J, et al. *Am J Med*. 2009; 122:100-108.
 8. Aylward J, et al. *Am J Med*. 2009; 122:100-108.
 9. Aylward J, et al. *Am J Med*. 2009; 122:100-108.
 10. Aylward J, et al. *Am J Med*. 2009; 122:100-108.

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Replacement aortic valve leaflets

The Replacement Aortic Valve Leaflets (RAL) technique for replacing one or more diseased or dysfunctional leaflets in an aortic heart valve. These valve leaflets are attached directly onto a patient's native aortic ring to provide good haemodynamic performance with out further negative haemodynamic associated with artificial aortic valves. This real bioactive aortic valve provides aneurysm haemodynamic improvement with a natural frame made of adenin. In patients it can even be successfully implanted in children patients with a small root or bicuspid valve.

The Replacement Aortic Valve Leaflets is used in vivo tested in Laboratory for Bioactive Characterisation (Leeds) and in vivo tested in Clinical practice performed on 132 patients, using bovine (91.6%) of equine pericardium (7.2%) and replacing valve cusps on the aortic fibrous ring of the patient. This bioactive aortic valve is called real bioactive, 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 products are made. The dis-

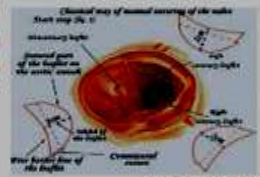


Figure 1: Schematic view



Figure 2: An vivo ultrasound measures valve

section is measured between two commissures and leaflet is created in a rectangular shape in such way around the three elements contact and overlap in closed valve similar to the closing of a native heart valve. This allows the surgeon to replace the aortic leaflets easily, creating new coronary ostia.

- When both valve biologic valve provided and made
- Separate biologic may be used according to the native dimension of the valve
- In vivo results confirmed with in vivo clinical results showed potential increasing of haemodynamic parameters CO, Stroke Volume, aortic pressure gradient as in normal valve.
- Adequate opening of aortic valve area and cardiac output during physical stress confirmed by Doppler flow echo results
- Decreased aortic wall shear stress due to low transvalvular pressure gradient in patients
- Insures haemodynamic improvement in aortic regurgitation
- Adequate for usage even in patients with small root or bicuspid aortic valve
- Low risk for embolism in patients with an aortic root at disease when surgery has to change both aortic root and aortic valve. There will be no geometric disproportion of the neo-aortic root at aortic valve
- No need for anticoagulant therapy
- Potential for implantation in patients with endocarditis
- Potential usage for patients with postoperative aortic regurgitation
- Potential use in patients who are with physically active way of leaflet
- Low cost
- Potential to be implanted using mechanical device (catheter) technology
- In case of need for re-implantation it is possible to implant percutaneous aortic valve (if it is performed classic transcatheter way)
- It is easy to replace the valve and to implant new pericardium
- 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. (Bioactive pericardium) (91.6 + 7.2) (98.8)

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



Figure 3: Suture of the second neo-created leaflet



Figure 4: Suture of the first leaflet



Figure 5: Newly created valve



Figure 6: Postoperative (Leeds Aortic Valve)



Figure 7: In vivo flow recovery

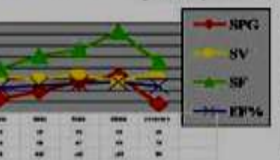
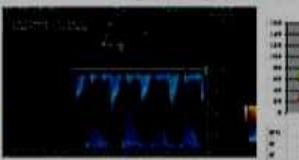


Figure 10: Postoperative (Leeds Aortic Valve)



Cardiosurgery - Skopje

