Real stentless aortic valve new type of aortic root reconstructive surgery

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Aortic valve replacement

Standard:

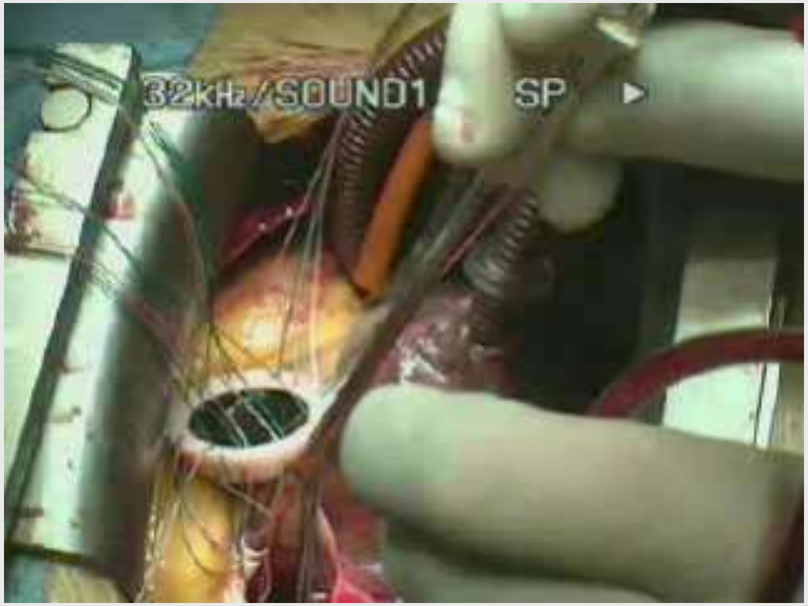
- mechanical valve prosthesis

- biologic valve prosthesis (stentled)
- stentless aortic bio-prosthesis

- Homograft (mini root, freestyle

  aortic root, xenograft)

- Ross procedure

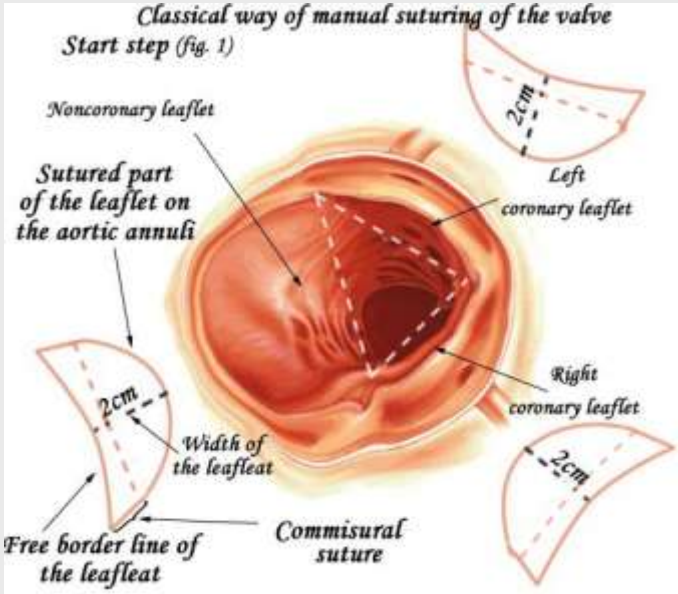


Ideal aortic valve prosthesis

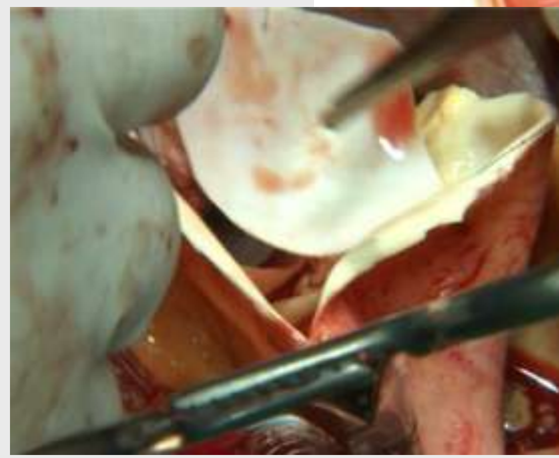
- no resistance to forward flow
- low stress gradient
- no leak when closed
- no damage to blood cells
- no thromboembolism
- should resist wear (durability)
- should not produce noise
- easy and simple way of implantation

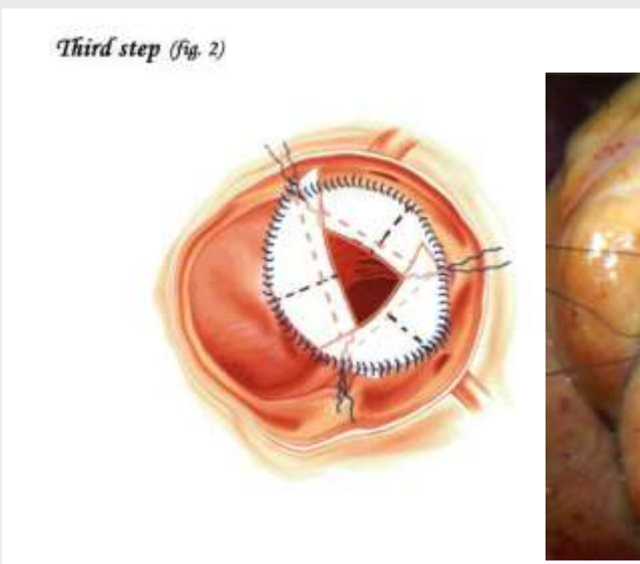
normal aortic valve

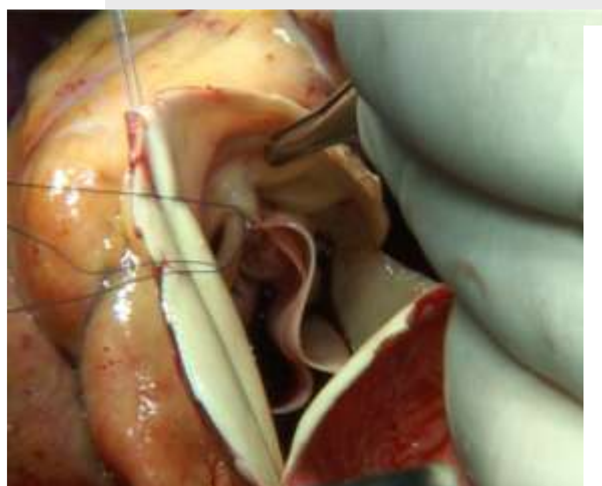
How to do it

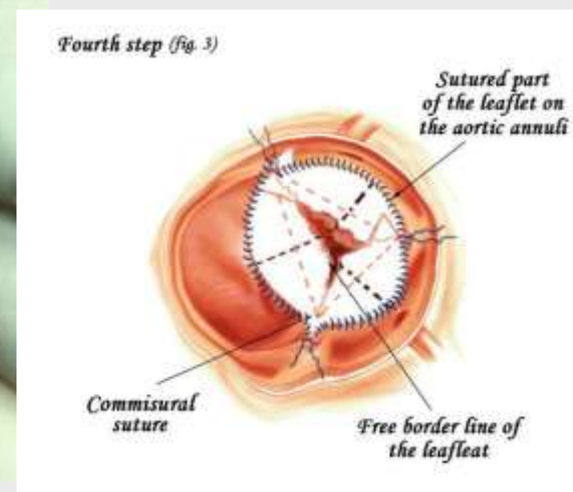

Classical way of manual suturing of the valve
Start step (fig. 1)
Noncoronary leaflet
Sutured part of the leaflet on the aortic annuli
Left coronary leaflet
2cm
Right coronary leaflet
2cm
Width of the leafleat
2cm
Free border line of the leafleat
Commisural suture


First step (fig. 2)




Third step (fig. 2)




Fourth step (fig. 3)
Sutured part of the leaflet on the aortic annuli
Commisural suture
Free border line of the leafleat

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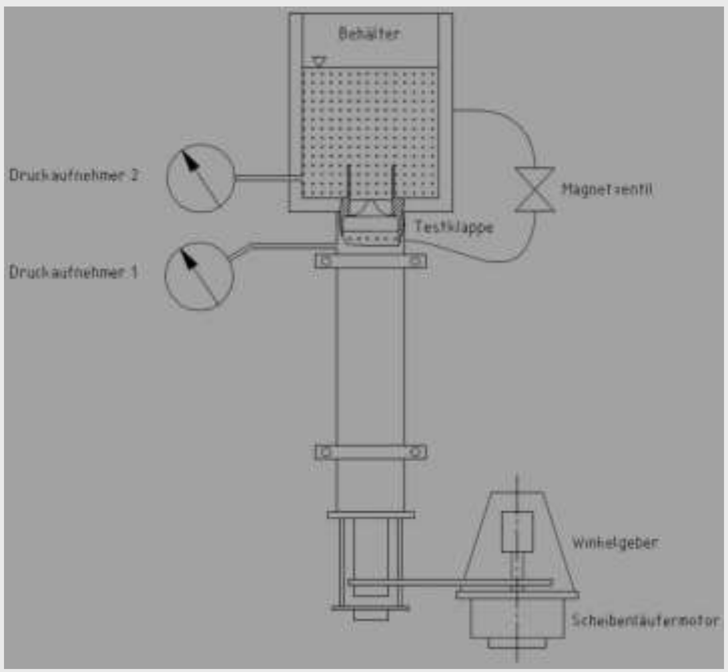
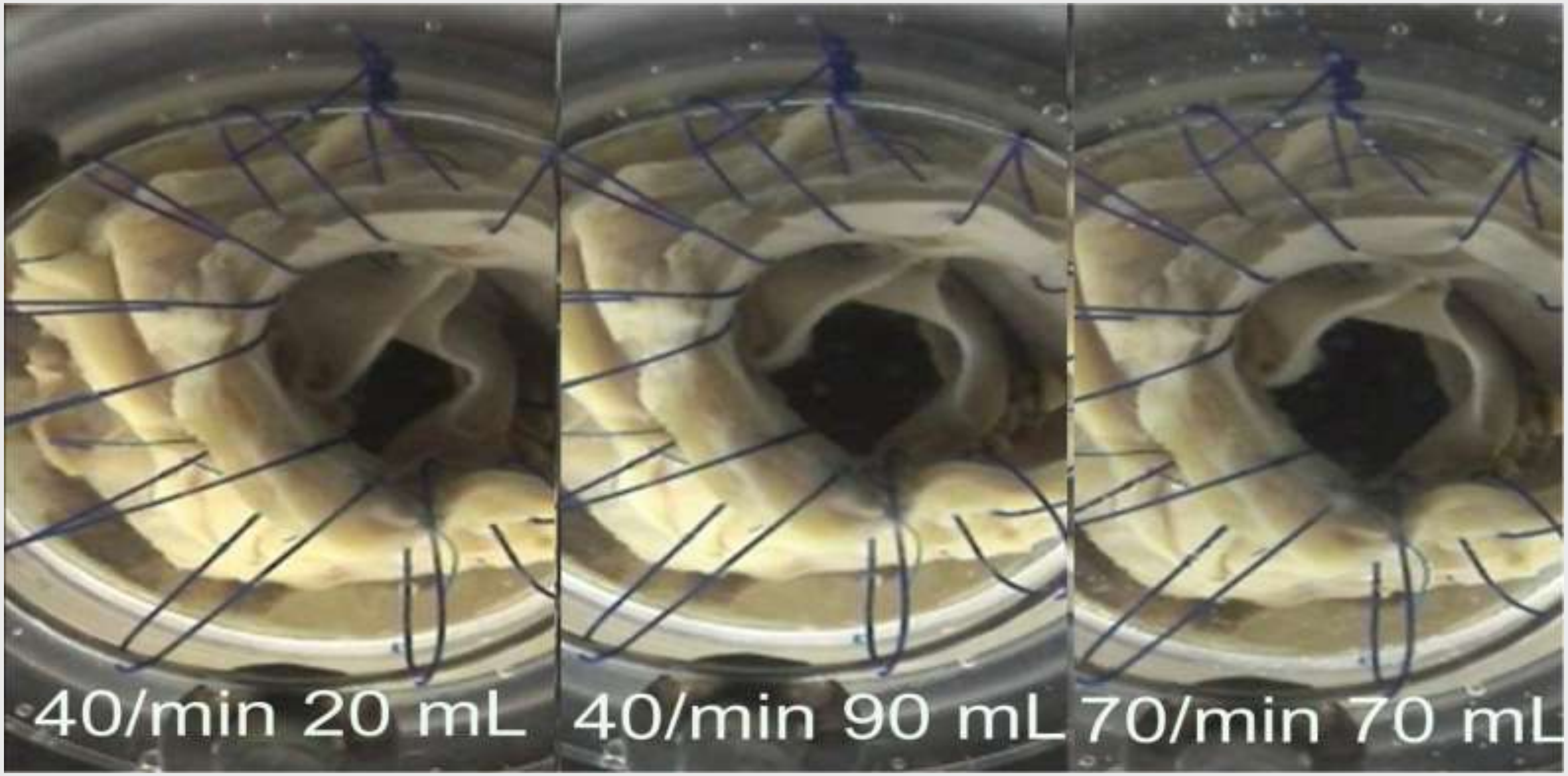
Labor für Biofluidmechanik
Prof. Dr.-Ing. K. Affeld
Berlin

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



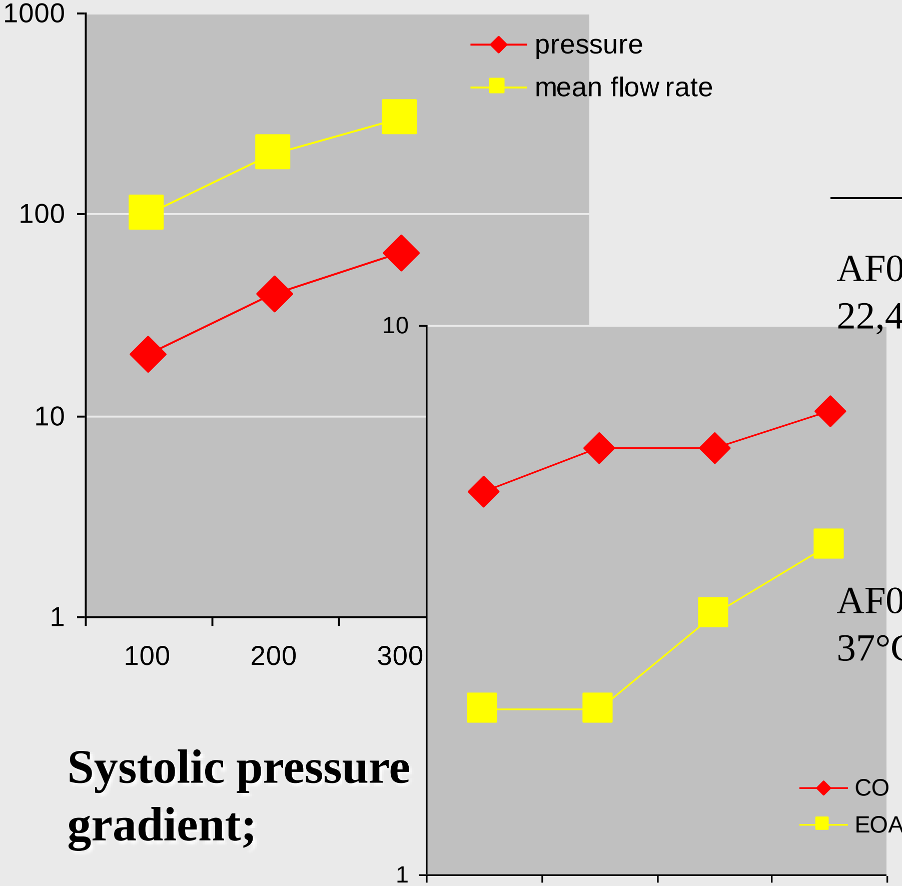
These valve parameters had been explored: 1.CO (cardiac output)

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*Δp/MF(mean flow)

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



Systolic pressure gradient;

Mean flow rate

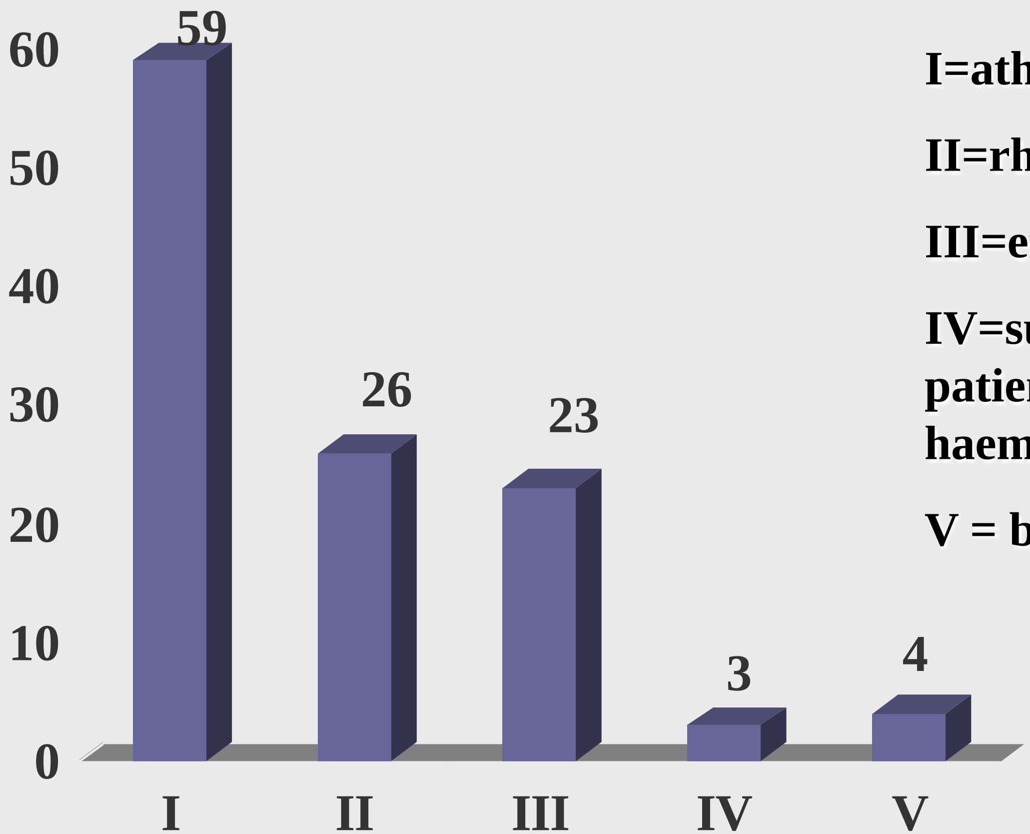
Cardiac output

Effective orifice area-aorta

	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

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

- Prospective study N = 115pts with severe aortic stenosis



I=atherosclerotic ethyology

II=rheumatic ethyology

III=endocarditis

IV=subacute endocarditis in patients on chronic haemodyalysis

V = bicupid aortic valve

Patients demographics data   N = 115 pts

Age (years)   56 ± 7.6y

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

Including criteria:

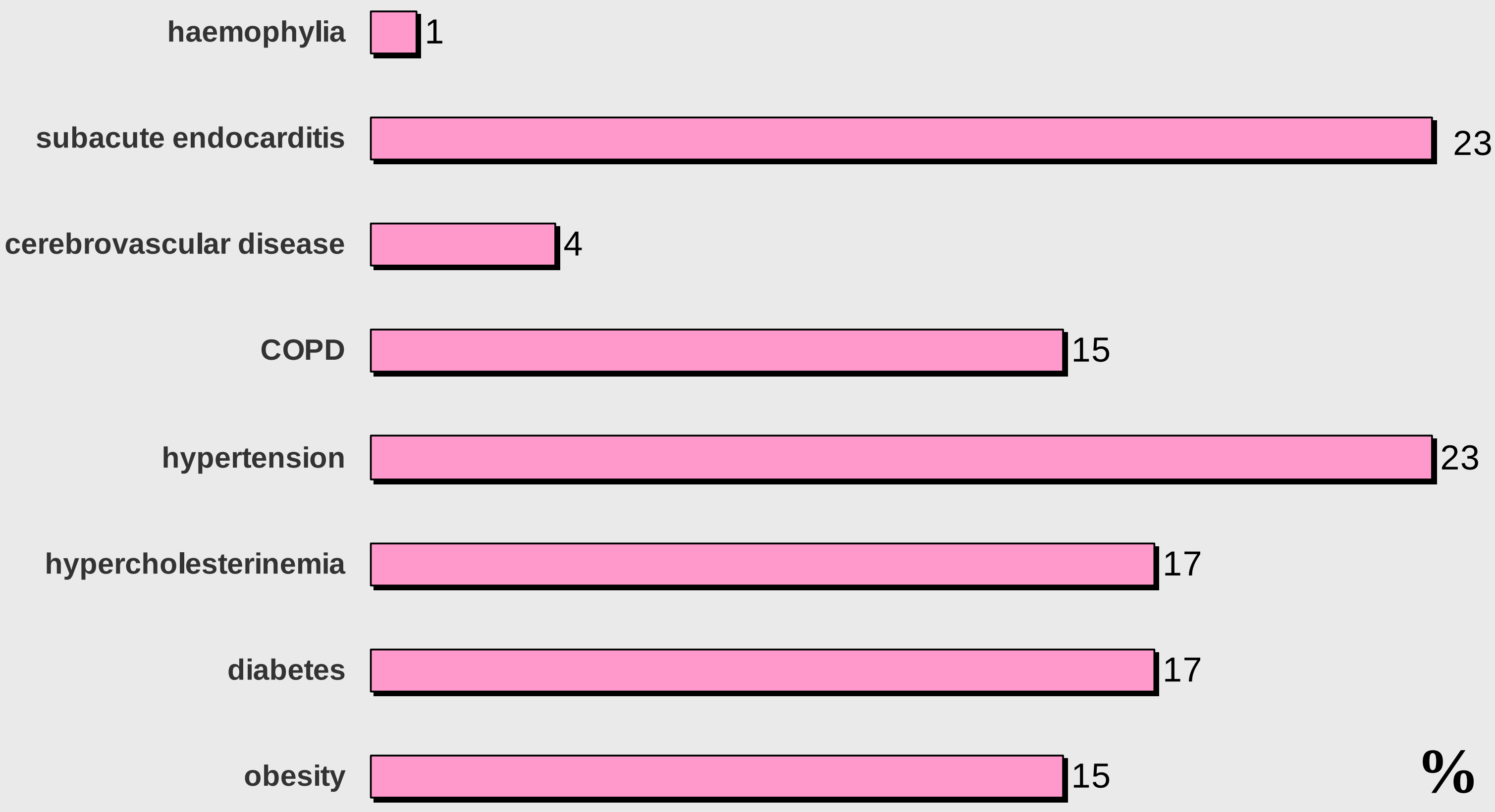
Severe aortic valve stenosis, with aortic root not bigger than 3,5cm

Trans-aortic middle pressure gradient >65mmHg

Performed investigations

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

Preoperative co-morbidity N=115pts



Real stentless aortic valve new type of aortic root reconstructive surgery

Accepted as a patent in USA 09.12.2008

The United States of America

The Director of the United States Patent and Trademark Office

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

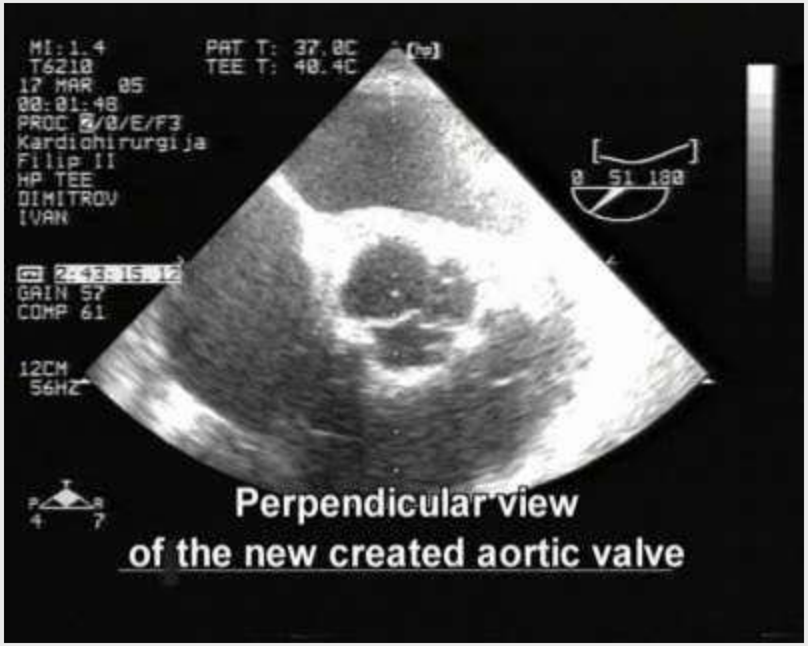
If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the U.S. filing date, subject to any statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121 or 365(c), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory extensions.

(12) **United States Patent**
Mitrev

(10) **Patent No.:** US 7,462,156 B2
(45) **Date of Patent:** Dec. 9, 2008

OTHER PUBLICATIONS

ABSTRACT



Post-operative echo

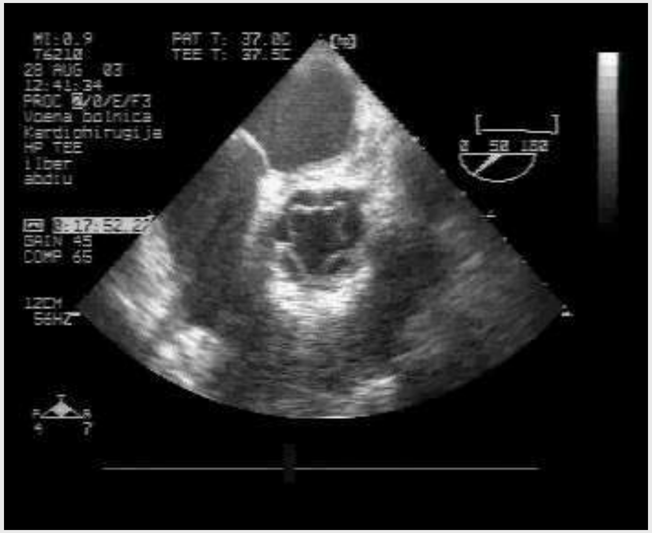
Cardiosurgery – Skopje

Real stentless aortic valve ultrasound evaluation bicuspid valve

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

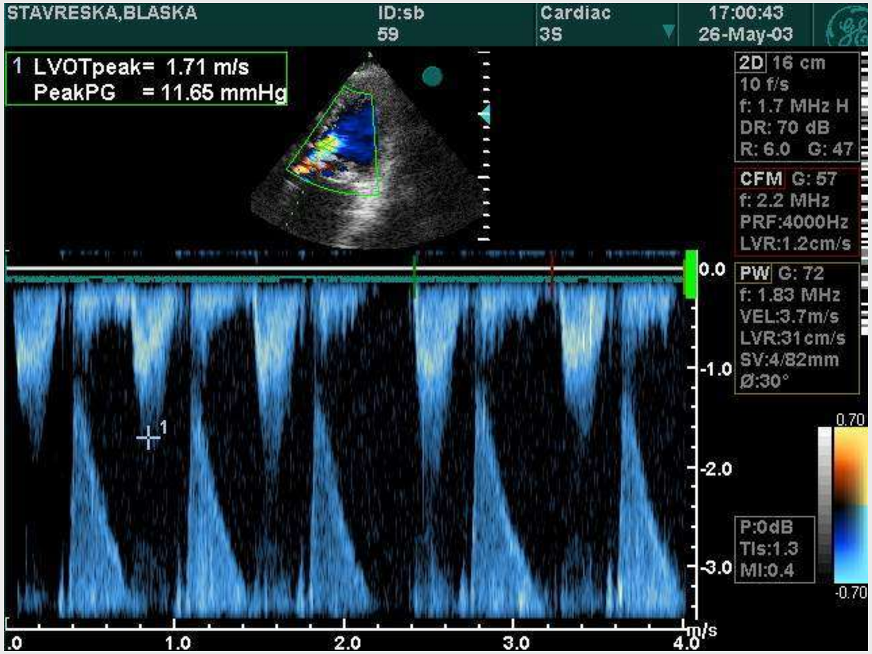
- ▶ Dp/dt = 0.07 0,015; SS= 22±3.2
- ▶ EAO cm2=3.6±0,8; CO = 6,5±2.9l
- ▶ Average systolic valve gradient 14±6.8mmHg
- ▶ Average mean valve gradient 7±5.6mmHg

Results II N= 115 pts

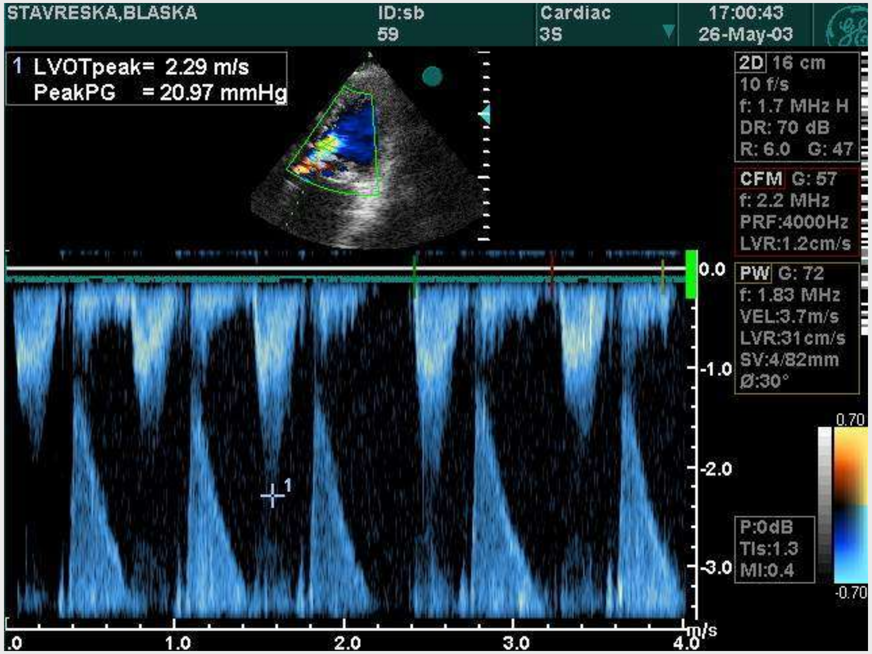
- Early survival (30 days) 94.8% (8pts)
- Other main complication:
- Bleeding 5 pat (3 surg.ethyology)
- Ventilation time 6.8h±2.2
- Stroke 2 (1 with left side hemiparesis)
- 3pts (with preoperative terminal renal failure) with CVVHD (Prismaflex Gambro) 5 days
- Length of ICU stay 8.6d ±2.1
- Hospital 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



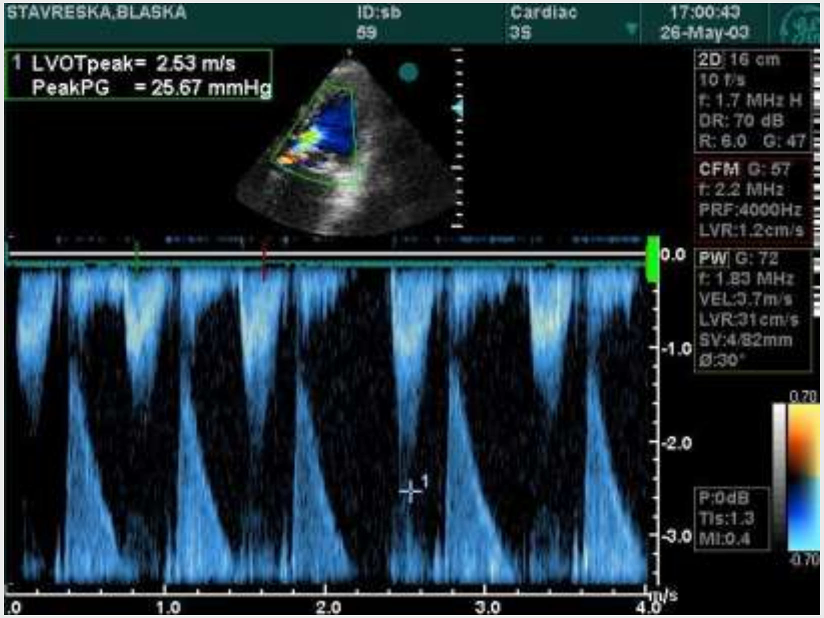
0-stadium



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

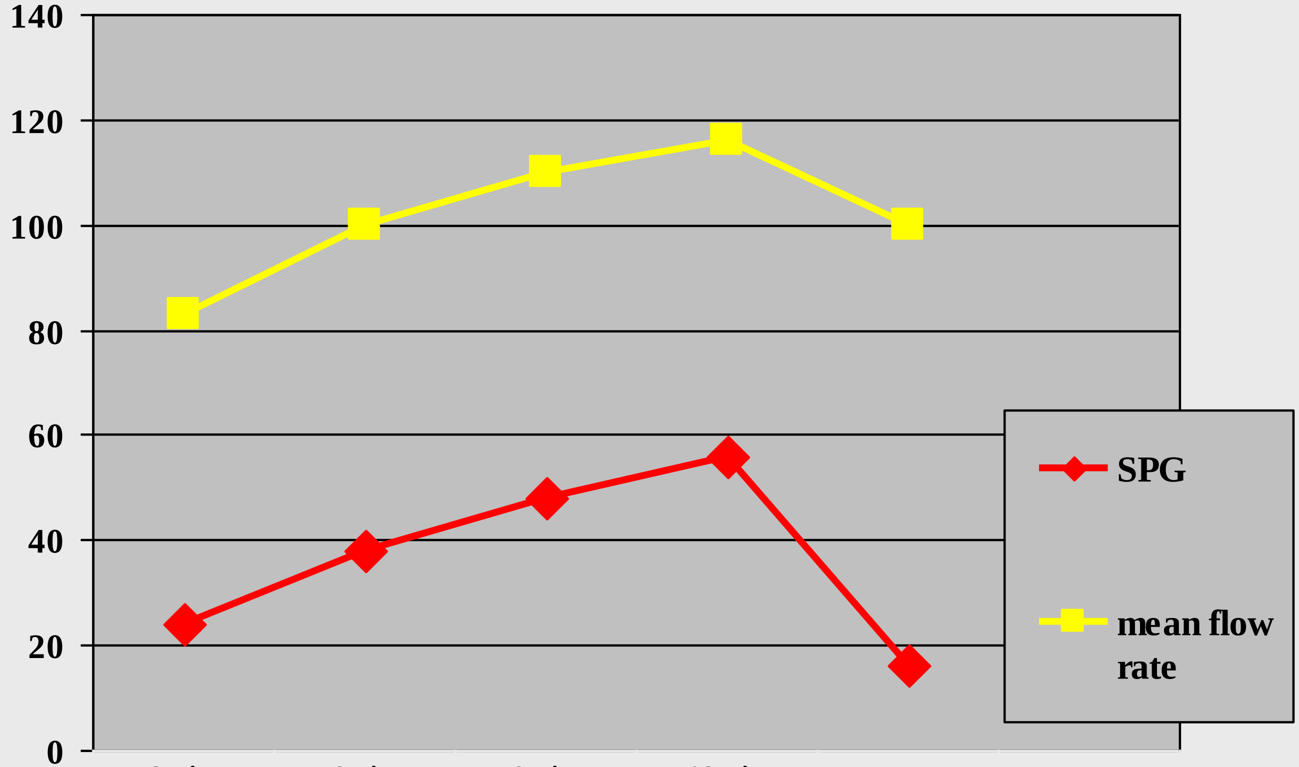
Remarkable: in all pts *CO* increased in a linear module with a pressure gradient . 56mmHg, was the highest measured systolic pressure gradient in the IVth stadium, with a *CO* 7-9l/min,and *dp/dt* as in normal valve, with a good *SS*

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

Basic parameters

SPG=14 ± 3.5

mean flow rate=64 ± 9.5



	3min	6min	9min	12min	recovery
SPG	24	38	48	56	16
mean flow rate	83	100	110	116	100

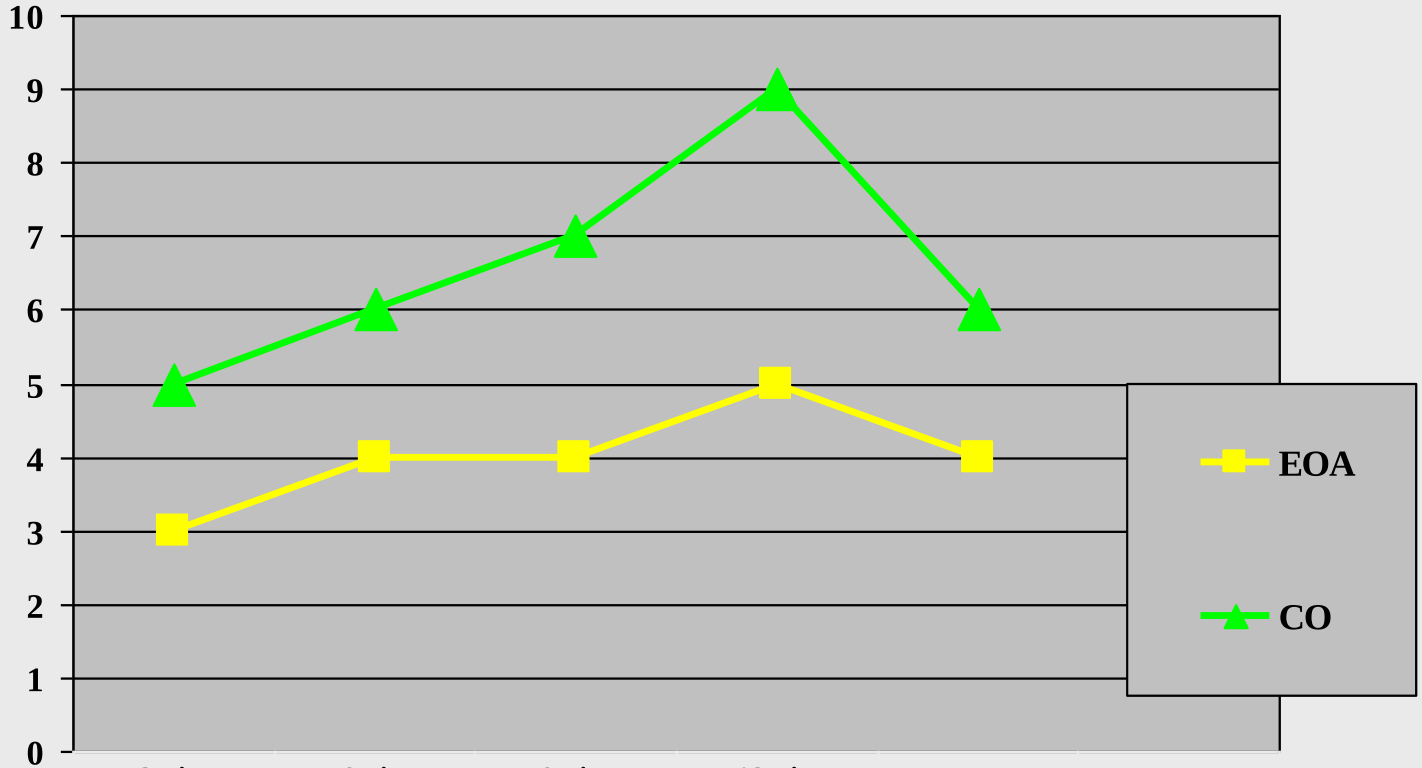
Proportional ratio of EAO and CO during dobutamin stress echo n = 36pts

<u>Basic parameters</u>

EOA=3.2 ± 1.5

CO=6.2 ± 2.5

EOA=CO/√sist. mean press.gradient



	3min	6min	9min	12min	recovery
EOA	3	4	4	5	4
CO	5	6	7	9	6

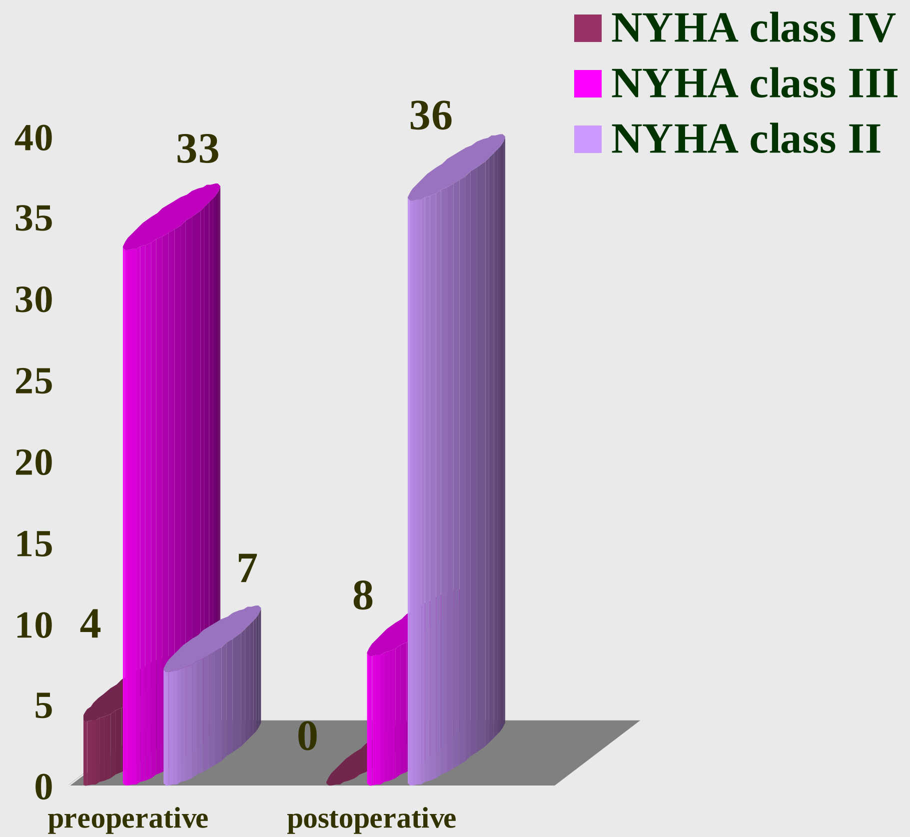
Late complications and NYHA class

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

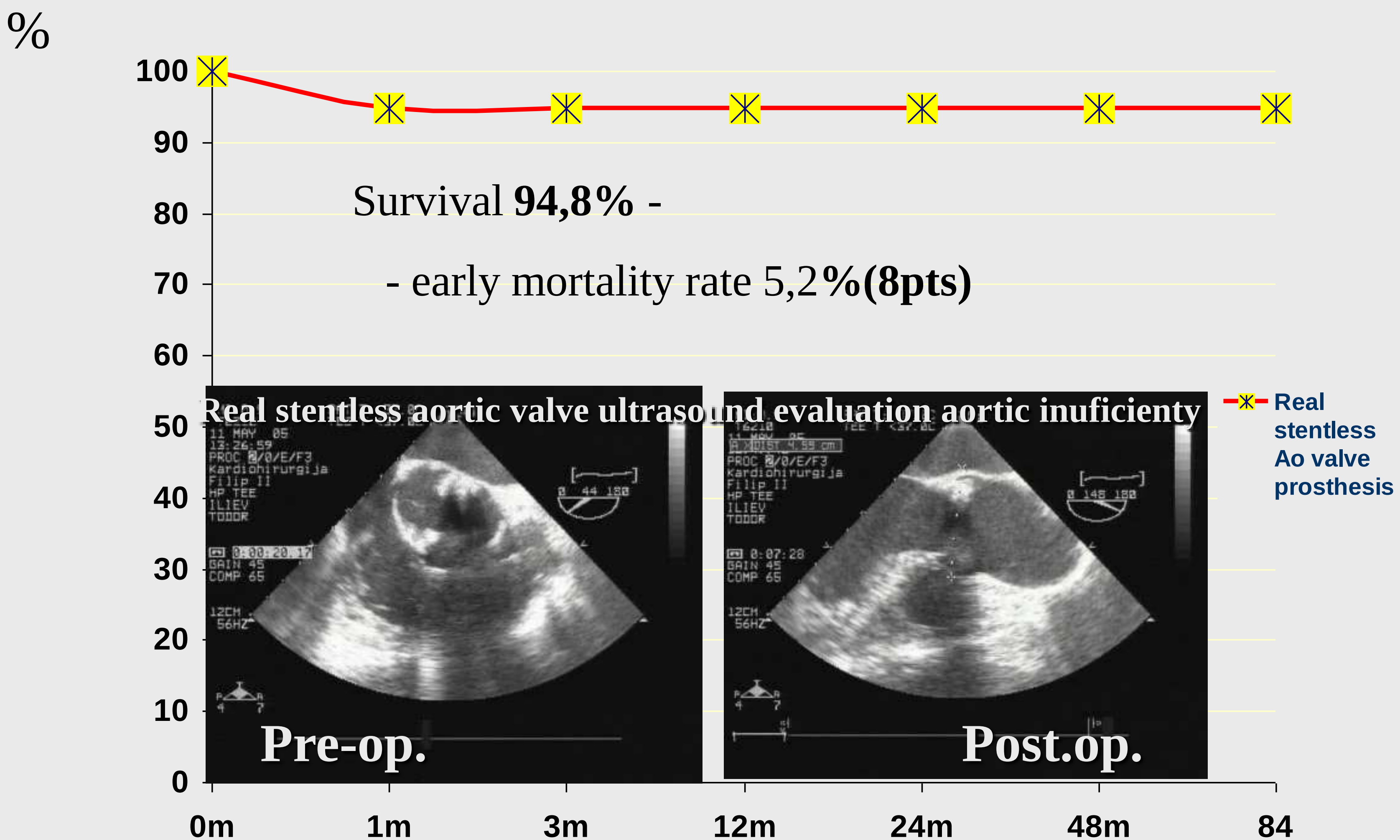
1-due to infective endocarditis



Late mortality 0%.

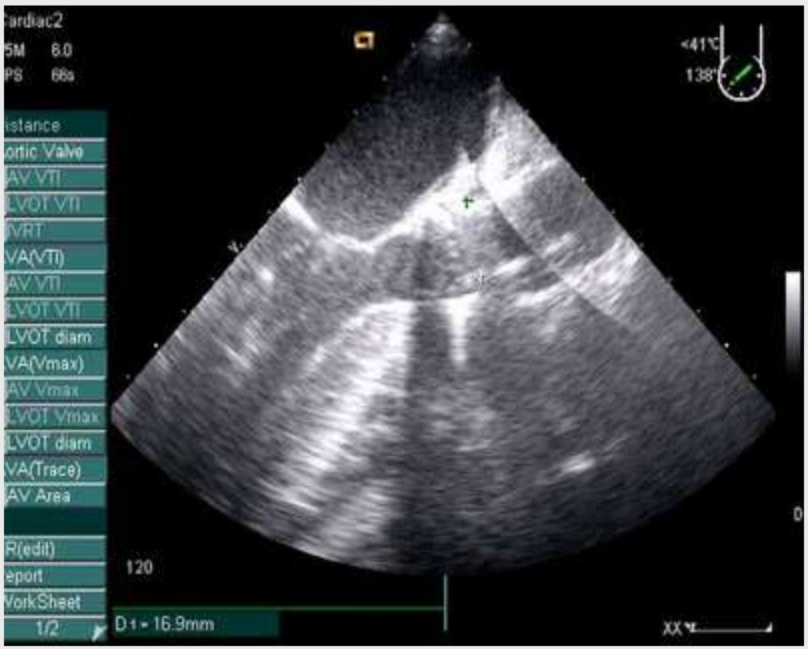
Follow up 4-84 months

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

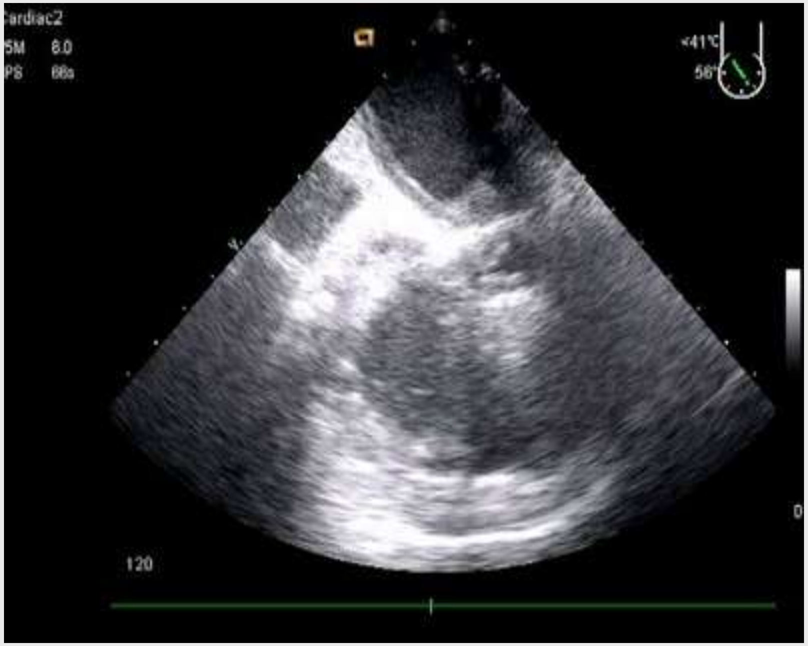
Small aortic root – 16,9mm

Severe calcificated ascending aorta up to aortic arch

Once deleted operation- because of her condition

Small-root case report

operation



6 months follow up

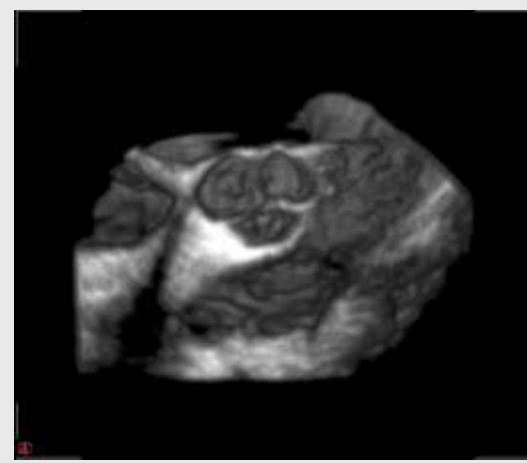
Excellent haemodinamic

Normal quality of life

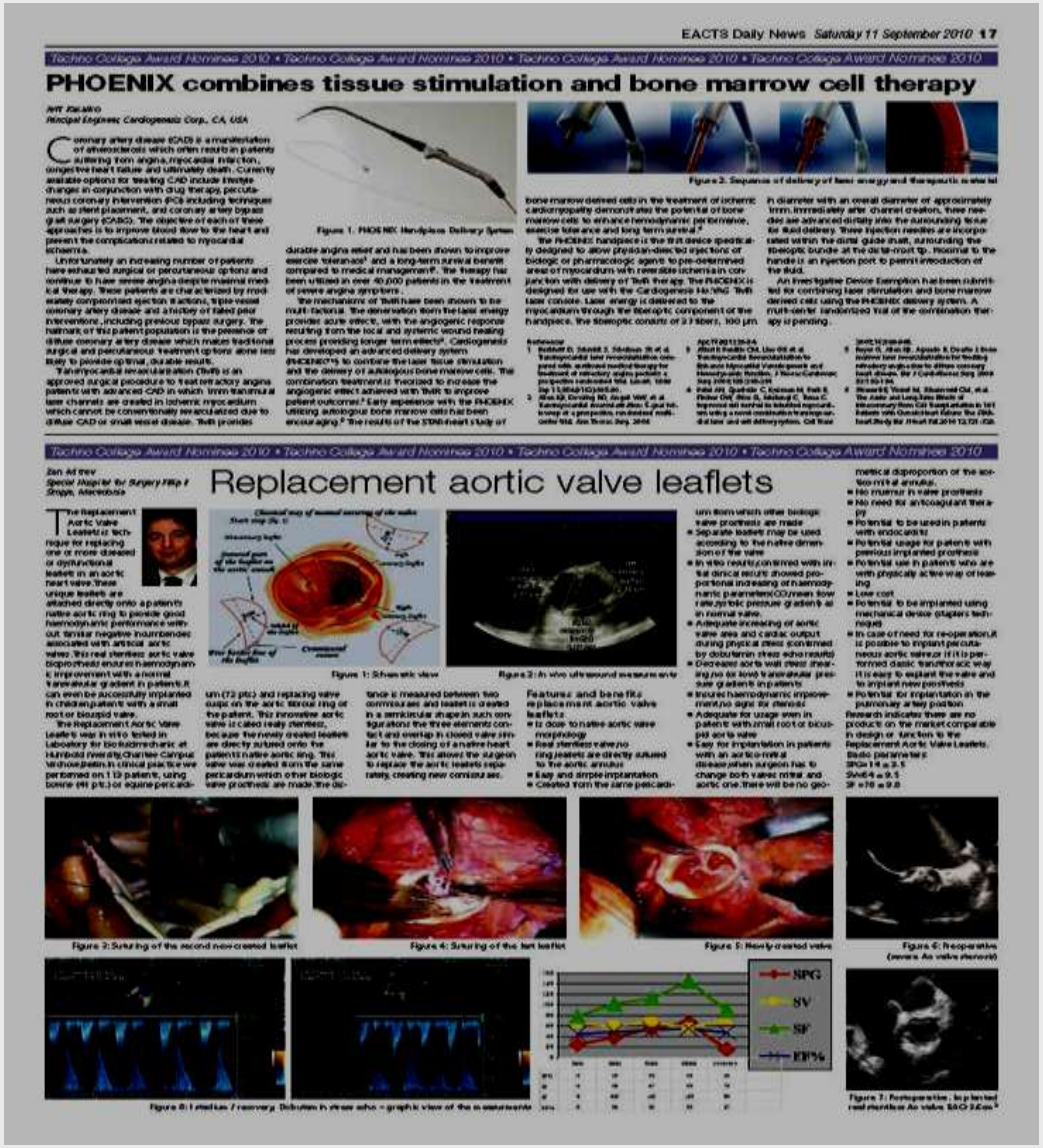
Small-root case report 3D TEE approach

Post operative

Pre operative



normal aortic valve,perpendicular view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Replacement aortic valve leaflets

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