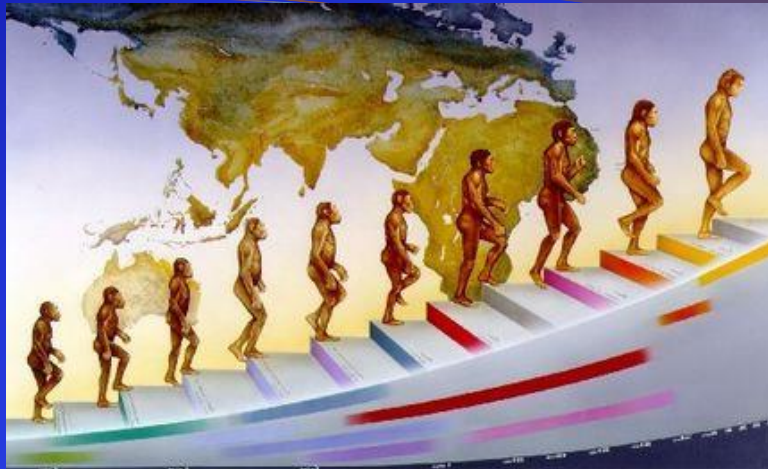


LA SOSTITUZIONE VALVOLARE AORTICA TRA TECNICHE TRADIZIONALI, MINITORACOTOMIA E CHIRURGIA CHE GUARDA A FUTURE PROCEDURE.

*Quale spazio per la cardiocirurgia
tradizionale rimane al cardiocirurgo?*

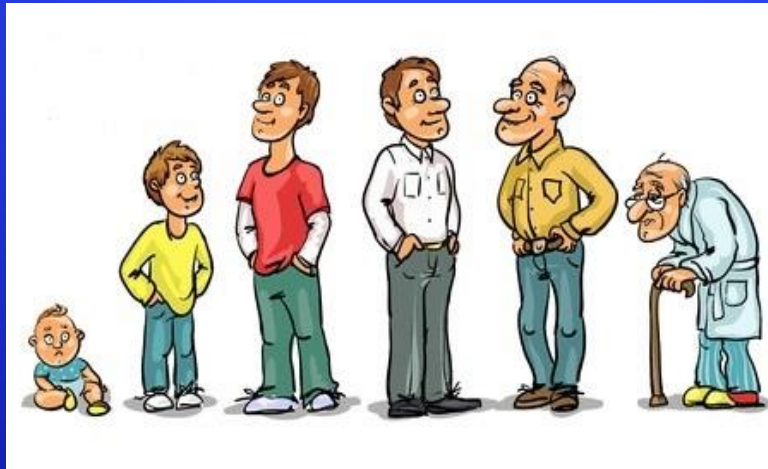
Dott. Maurizio Roberto MD, PhD



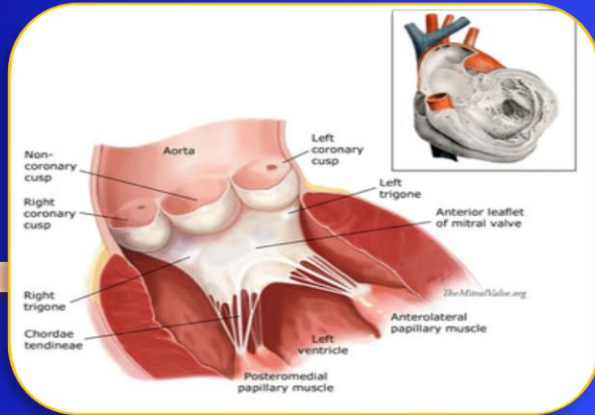


Knowledge evolution

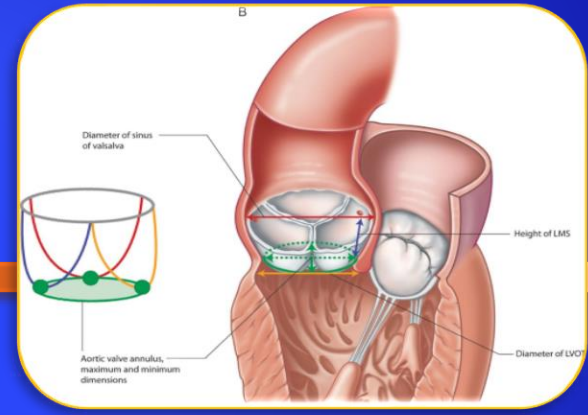
Patient's evolution



AORTIC VALVE



AORTIC ROOT

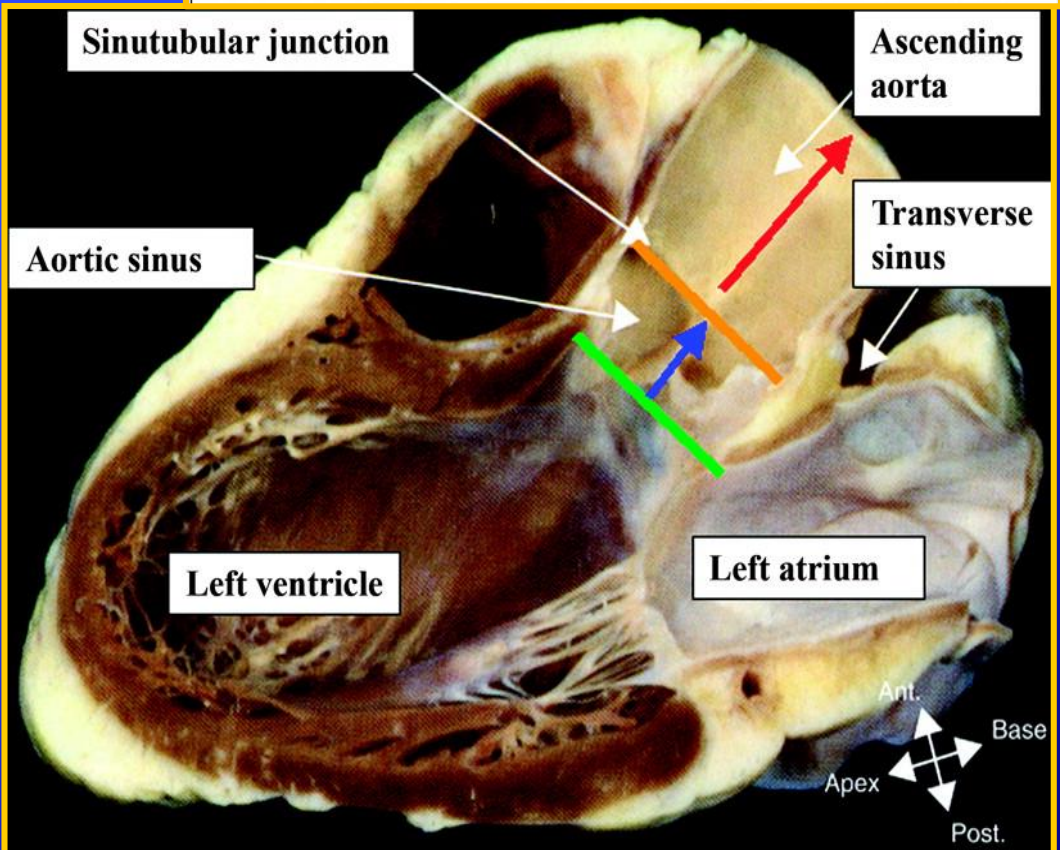
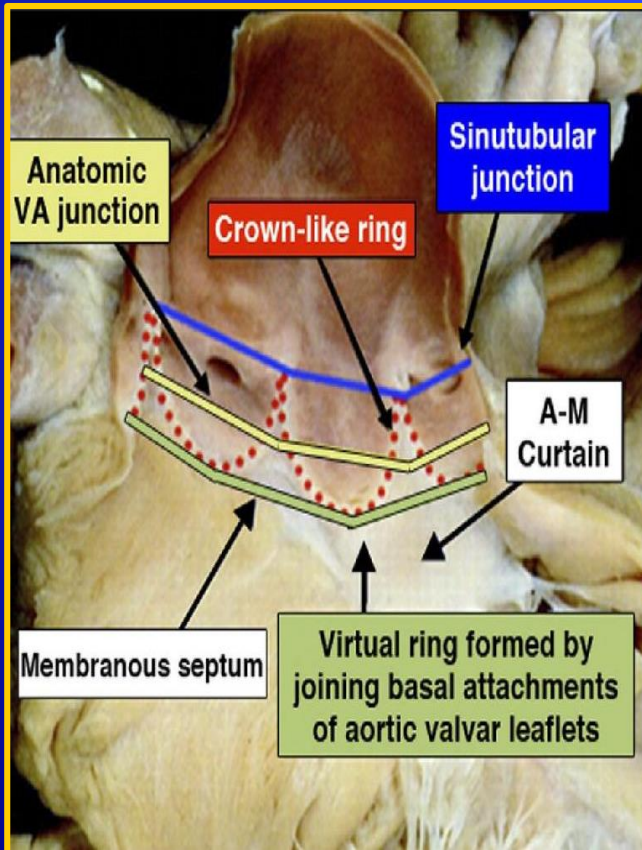
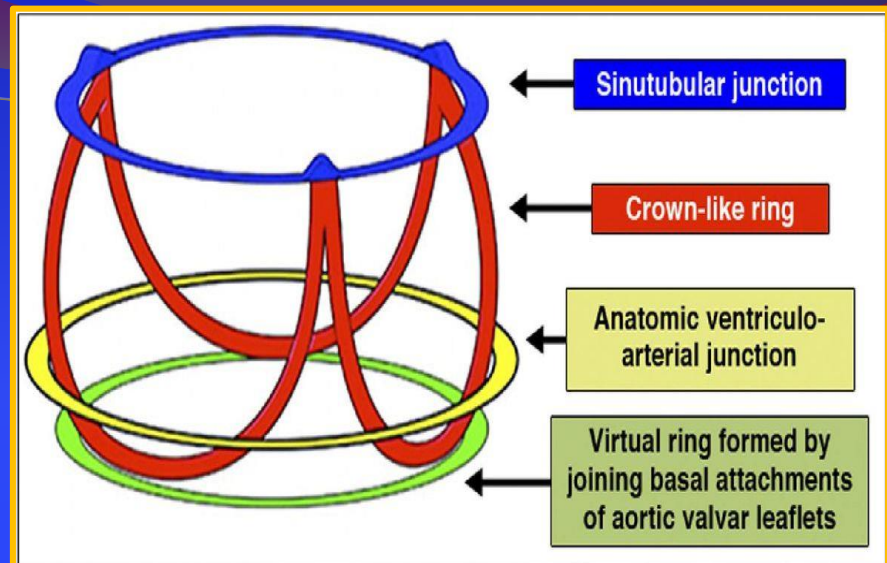


AORTIC ROOT

A MORPHO-FUNCTIONAL UNIT



NOT ONLY THEORY BUT ALSO
SURGICAL PRACTICE



WHERE WERE WE?

10 years of bioprosthesis valve durability



WHERE ARE WE TODAY?

19 years of bioprosthesis valve durability

**Very Long-Term Outcomes of the
Carpentier-Edwards Perimount Valve in
Aortic Position**

Ann Thorac Surg
2015;99:831-7

WHERE ARE WE TODAY?

Mechanical
prosthesis

Biological
prosthesis

Increase in b
events

e rate of
tion

NOT
DIFFERENCE IN
LATE SURVIVAL

Late outcomes comparison of nonelderly patients with stented bioprosthetic and mechanical valves in the aortic position: A propensity-matched analysis The Journal of Thoracic and Cardiovascular Surgery

TRADITIONAL SURGERY IS STILL THE GOLD STANDARD



2017 ESC/EACTS Guidelines for the management of valvular heart disease

The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

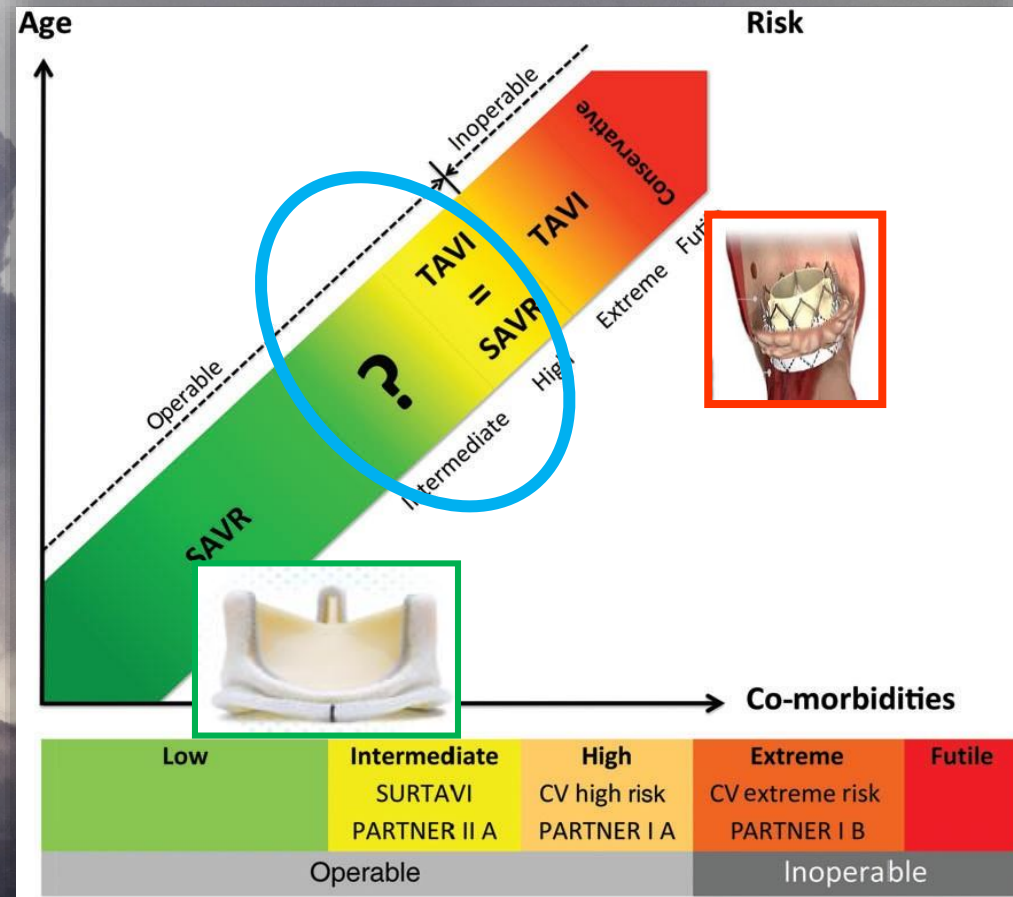
	Favours TAVI	Favours SAVR		Favours TAVI	Favours SAVR		Favours TAVI	Favours SAVR
Clinical characteristics			Anatomical and technical aspects			Cardiac conditions in addition to aortic stenosis that require consideration for concomitant intervention		
STS/EuroSCORE II <4% (logistic EuroSCORE I <10%) ^a		+	Favourable access for transfemoral TAVI	+		Severe CAD requiring revascularization by CABG		+
STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%) ^a	+		Unfavourable access (any) for TAVI		+	Severe primary mitral valve disease, which could be treated surgically		+
Presence of severe comorbidity (not adequately reflected by scores)	+		Sequelae of chest radiation	+		Severe tricuspid valve disease		+
Age <75 years		+	Porcelain aorta	+		Aneurysm of the ascending aorta		+
Age ≥75 years	+		Presence of intact coronary bypass grafts at risk when sternotomy is performed	+		Septal hypertrophy requiring myectomy		+
Previous cardiac surgery	+		Expected patient–prosthesis mismatch	+				
Frailty ^b	+		Severe chest deformation or scoliosis	+				
Restricted mobility and conditions that may affect the rehabilitation process after the procedure	+		Short distance between coronary ostia and aortic valve annulus		+			
Suspicion of endocarditis		+	Size of aortic valve annulus out of range for TAVI		+			
			Aortic root morphology unfavourable for TAVI		+			
			Valve morphology (bicuspid, degree of calcification, calcification pattern) unfavourable for TAVI		+			
			Presence of thrombi in aorta or LV		+			

**Risk stratification
guide therapeutic
approach**

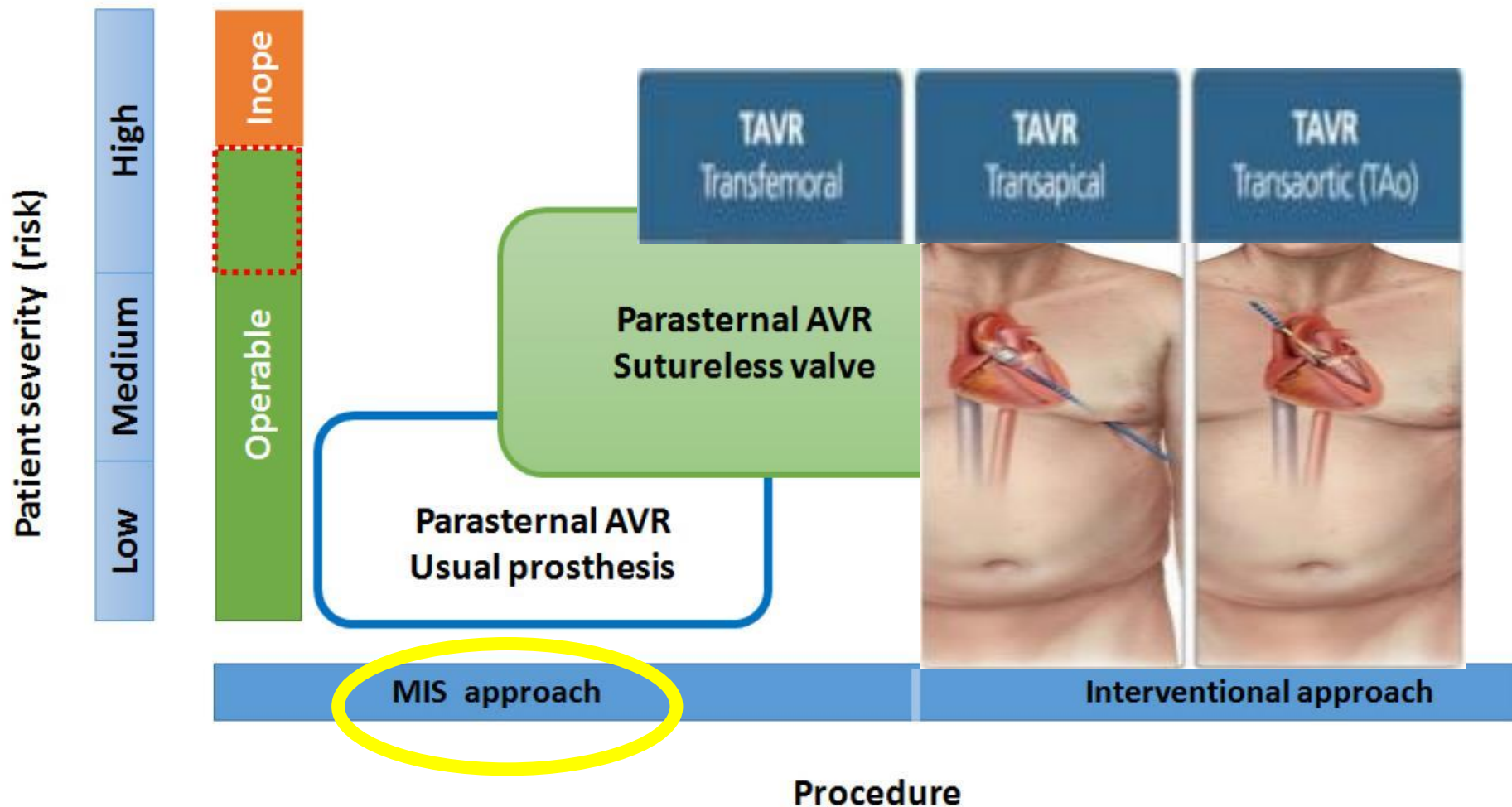


The Grey zone

- AVR is the gold standard in AS
 - TAVI borned as “compassionate procedure” for high risk/inoperable patients
- ↓
- increase of indications



WHAT WE CAN DO IN GREY ZONE?



Transcatheter or surgical aortic valve replacement for patients with severe, symptomatic, aortic stenosis at low to intermediate surgical risk: a clinical practice guideline

Modified parasternal approach is a good alternative for aortic valve surgery

The last frontier..



SUTURELESS

Sutureless



Perceval S™



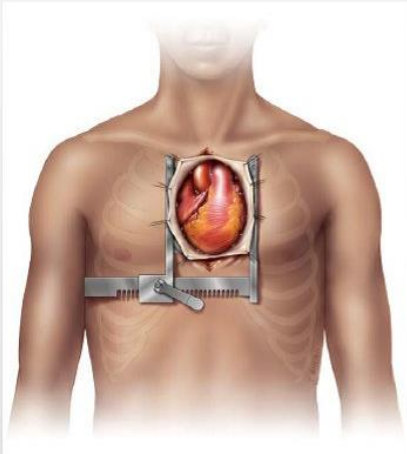
3f Enable valve™



INTUITY Valve System™

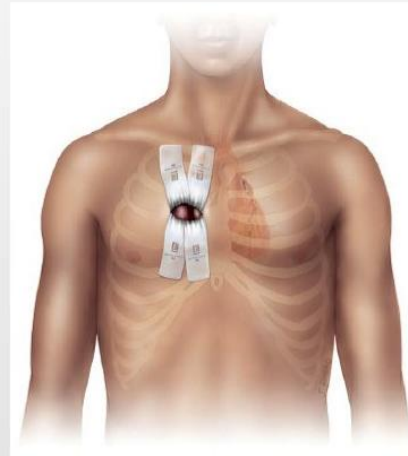
Surgical approach

Conventional

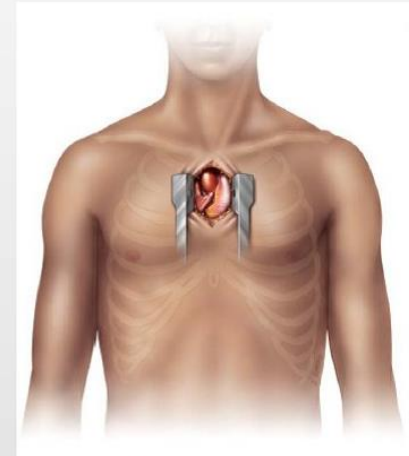


Open-chest or Sternotomy

Minimal Incision



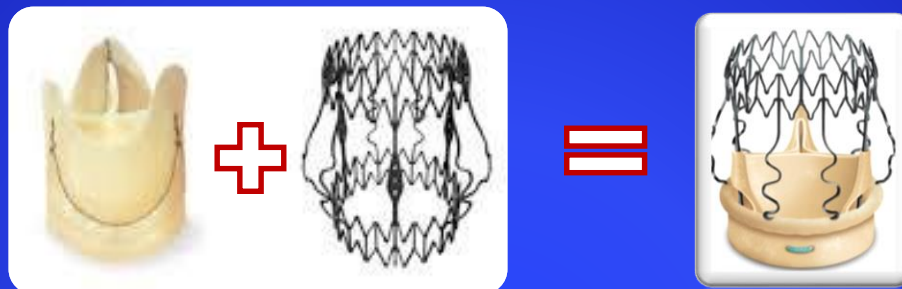
Right Anterior
Thoracotomy



Mini-sternotomy



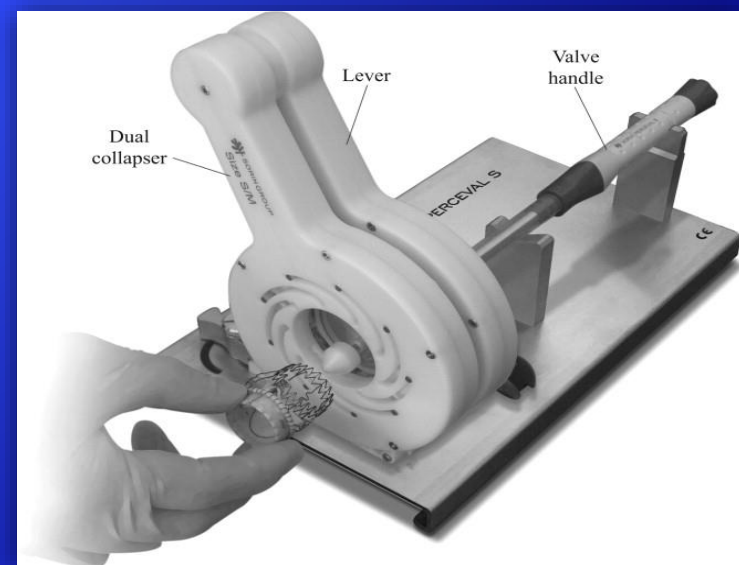
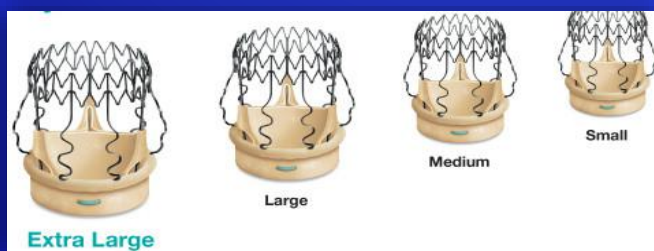
PERCEVAL - self anchoring valve -



Borned as TAVI valve → Better application in SAVR

Collapsing, not crimping

4 sizes: S - M - L - XL





PERCEVAL – *self anchoring valve* –

Proven Pericardial Technology

New Innovations

Bovine pericardium and ThermoFix™ process

Tri-leaflet matched for thickness and elasticity

Polyester sealing cloth

Balloon-expandable stainless steel frame

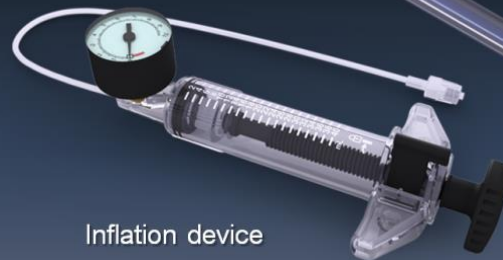
Proprietary balloon delivery system



Un-Deployed



Deployed

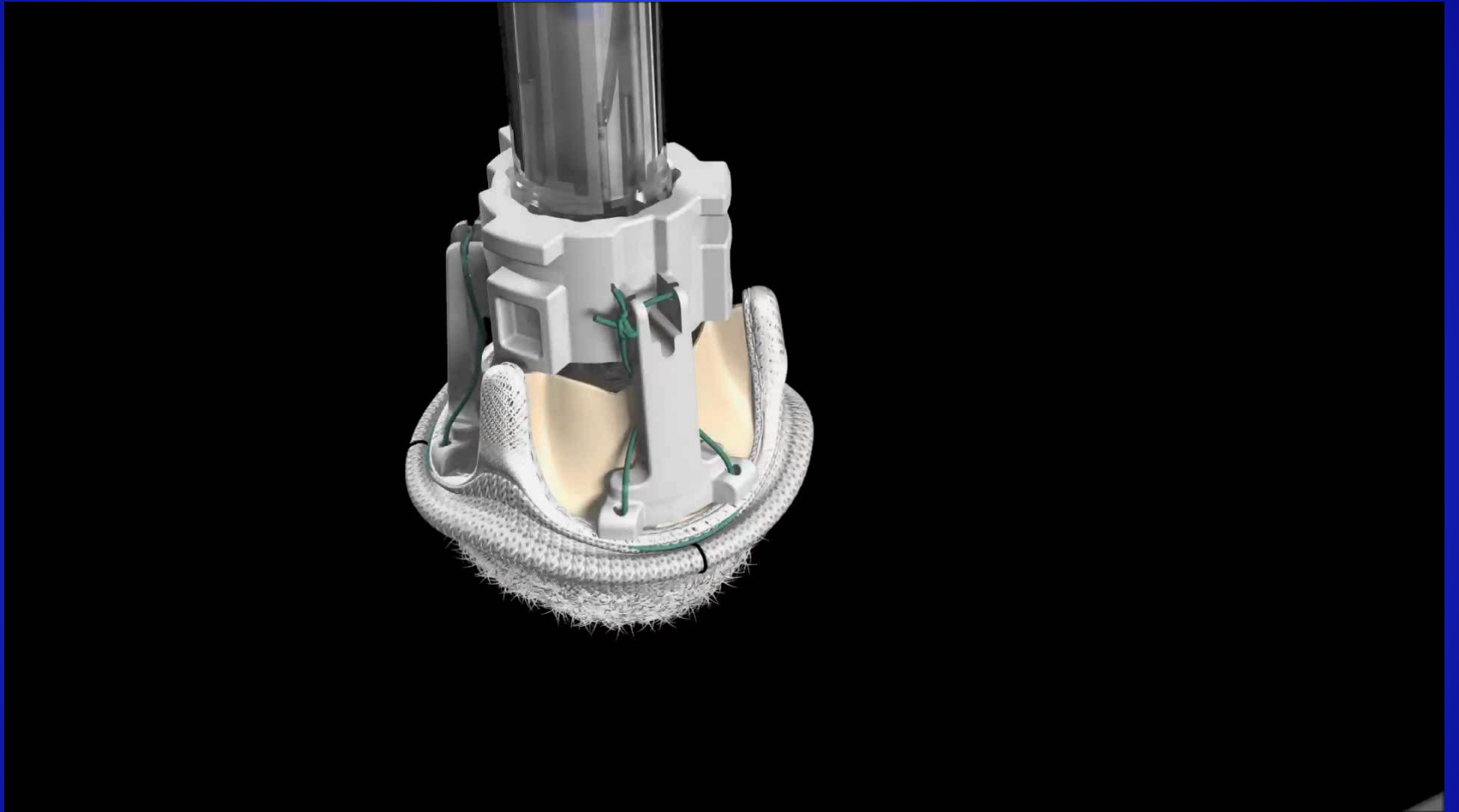


Inflation device

Controlled balloon expansion

Cloth-covered, stainless steel frame

INTUITY ELITE - rapid deployment-



INTUITY ELITE



ADVANTAGES

- Reduced cross-clamp time
- Reduced CPB time
- Reduced myocardial ischemia time
- Complete removal of diseased native valve
- Easy implantation
- Mini-invasive approach

DISADVANTAGES

- Paravalvular leak
- Surgical trauma vs TAVI
- Delayed dislocation
- Height of aortotomy



OUR EXPERIENCE

OUR EXPERIENCE - *Perceval* -

Period: 06/2014 till now
29 pt: 23 women + 6 men
Age: 74±5
NYHA II (24pz) - III(4pz)
ACS: 3

EF: 62 ±16
PΔ: max 78±26 – mean 47±16
Anulus 19,6±16

Sizing S 8 – M 11 – L 7 – XL 3
AVR + CABG: 7 pt
AVR+ atriclip: 1

Post-operative period:
1 revision for emhorrage
2 neurological events
11 AF, 4 LBB,
2 PM implantation



OUR EXPERIENCE - *Intuity* -

Period: 12/2011 till now

156 pt: 51 women + 105 men

Age: 73 ± 8

NYHA II (94 pz) - III(35 pz)

ACS: 12 CAD 32

REDO: 14 (7 AVR)

EF: 60 ± 10

P Δ : max 77 ± 26 - mean 47 ± 15

Sizing: 19 (12) - 21(40) - 23 (53) - 25 (39) - 27 (12)

AVR + CABG: 21 (11= 1 graft)

AVR + MVR: 2

AVR + other: 18

Intra-operative complications: 17 \rightarrow 3 prosthesis replacement

\rightarrow 2 conversion to full sternotomy

\rightarrow other

Post-operative period 3 death

5 PM implantation

10 revision for emorrhage



PATIENT'S SELECTION CRITERIA

- FRAGILE PATIENT
- MINI-INVASIVE APPROACH
- SMALL ANULUS
- COMBINED SURGERY



OUTCOMES



Intuity vs Perceval

Direct Comparison of the Edwards Intuity Elite and Sorin Perceval S Rapid Deployment Aortic Valves

Oliver J. Liakopoulos, MD, Stephen Gerfer, MD, Simone Weider, MS, Parwis Rahmadian, MD, Mohamed Zerrouh, MD, Kaveh Eghbalzadeh, MD, Anton Sabashnikov, MD, Yeong-Hoon Choi, MD, Jens Wippermann, MD, Thorsten Wahlers, MD

Postoperative Outcomes	Intuity (n = 117)	Perceval (n = 39)	p Value
Thirty-day all-cause mortality	2.6 (3)	5.1 (2)	0.599
Isolated AVR	1.7 (1)	4 (1)	0.509
Combined AVR	3.4 (2)	7.1 (1)	0.483
Stroke	0.9 (1)	5.1 (2)	0.154
RDV-related complications	12.0 (14)	20.5 (8)	0.192
Mortality	0.9 (1)	0 (0)	1.000
Nonstructural valve dysfunction	0.9 (1)	0 (0)	1.000
Mild paravalvular leak	1.7 (2)	7.7 (3)	0.525
Moderate or severe paravalvular leak	0 (0)	0 (0)	NA
Pacemaker implantation	8.5 (10)	12.8 (5)	0.530
Second-degree AV block	0.9 (1)	5.1 (2)	0.154
Third-degree AV block	7.7 (9)	7.7 (3)	1.000
Renal failure with dialysis	2.6 (3)	2.6 (1)	1.000
Rethoracotomy for bleeding	3.4 (4)	5.1 (2)	0.640
Length of stay, days			
Intensive care unit	2 (1-41)	2 (1-19)	0.503
Hospital	11 (4-52)	10 (3-30)	0.065

- Early clinical outcomes
- valve related complications
- valve performance



Safety and efficacy
 Comparable good early outcomes
 Low valve related complications
 Excellent performance
 Comparable PM implantation

Sutureless vs traditional AVR



**RASONABLE
ALTERNATIVE
IN SELECTED CASE!**

Do rapid deployment aortic valves improve outcomes compared with surgical aortic valve replacement?

Perceval vs traditional AVR



Valve is safe
Minimally invasive surgery
Greater diameter of bioprosthesis
Reduction in BT, AKI, Haemodynamic profile



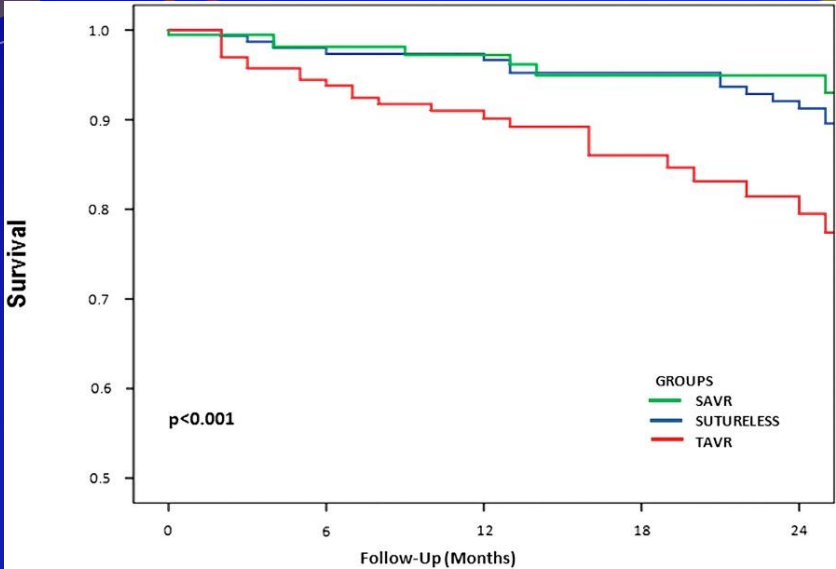
Any mortality benefits
Similar PM implantation



- BETTER POST-OPERATIVE COURSE
- DESERVE CONSIDERATION IN PATIENT AT HIGH SURGICAL RISK

Sutureless Perceval Aortic Valve Versus Conventional Stented Bioprostheses: Meta-Analysis of Postoperative and Midterm Results in Isolated Aortic Valve Replacement

Outcomes in grey zone



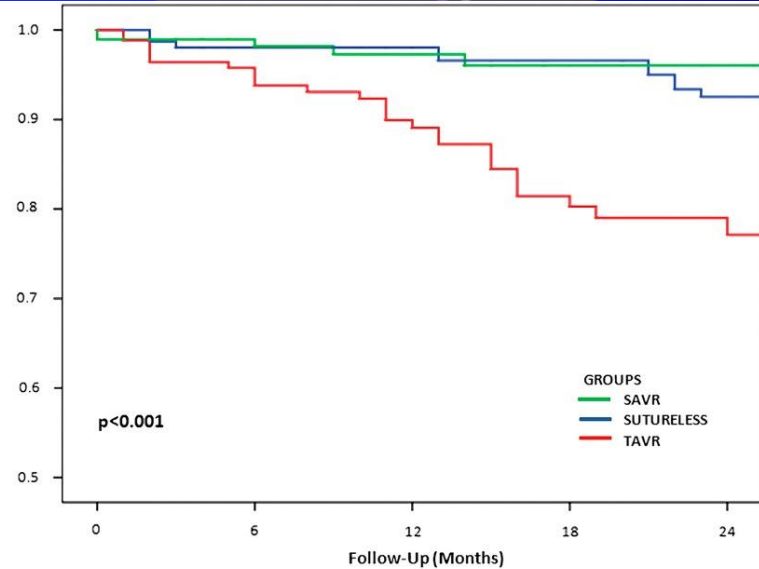
Patients at Risk

AVR	197	169	148	136	111
SUTURELESS	192	147	125	91	49
TAVR	184	141	109	76	41

FOLLOW-UP timepoints	Groups					
	SAVR		Sutureless		TAVR	
6-Months	97.4%	(96.1%-98.7%)	98.1%	(97.0%-99.2%)	93.8%	(92.0%-95.6%)
12-Months	96.7%	(95.2%-98.2%)	97.2%	(95.8%-98.6%)	90.1%	(87.7%-92.5%)
18-Months	95.2%	(93.4%-97.0%)	94.9%	(92.8%-97.0%)	86.0%	(82.9%-89.1%)
24-Months	91.3%	(88.9%-93.7%)	94.9%	(92.8%-97.0%)	79.5%	(75.2%-83.8%)



Overall survival



Patients at Risk

AVR	197	167	146	131	111
SUTURELESS	192	145	122	88	49
TAVR	184	141	108	76	41

FOLLOW-UP timepoints	Groups					
	SAVR		Sutureless		TAVR	
6-Months	100%		98.2%	(97.1%-99.3%)	93.8%	(91.9%-95.7%)
12-Months	96.6%	(95.1%-98.1%)	97.3%	(95.9%-98.7%)	89.9%	(87.4%-92.4%)
18-Months	96.6%	(95.1%-98.1%)	96.0%	(94.2%-97.8%)	80.3%	(76.6%-84%)
24-Months	92.6%	(90.3%-94.9%)	96.0%	(94.2%-97.8%)	77.1%	(72.9%-81.3%)



Survival free from the composite end point of MACCE (cardiac death, AMI, major hemorrhagic events, stroke)

Treating the patients in the 'grey-zone' with aortic valve disease: a comparison among conventional surgery, sutureless valves and transcatheter aortic valve replacement



FUTURE

WHICH SURGICAL TREATMENT OFFERS THE MOST BENEFITS IN THE MANAGEMENT OF PATIENT WITH SEVERE AS?

Outcomes comparison of different surgical strategies for the management of severe aortic valve stenosis: study protocol of a prospective multicentre European registry (E-AVR registry)

Registry (enrollement: 11/2017- 12/2019)

5-10 years follow-up → mid to long term safety and efficacy

17 European Cardiac Surgery Center

Can we wait?



SCIENTIFIC
COMMUNITY

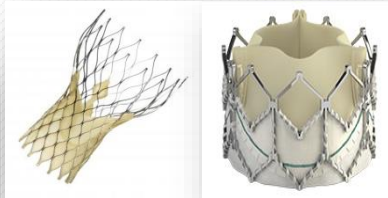


WHAT'S THE CHOICE?

**MEDICAL
TH**



TAVI



AVR



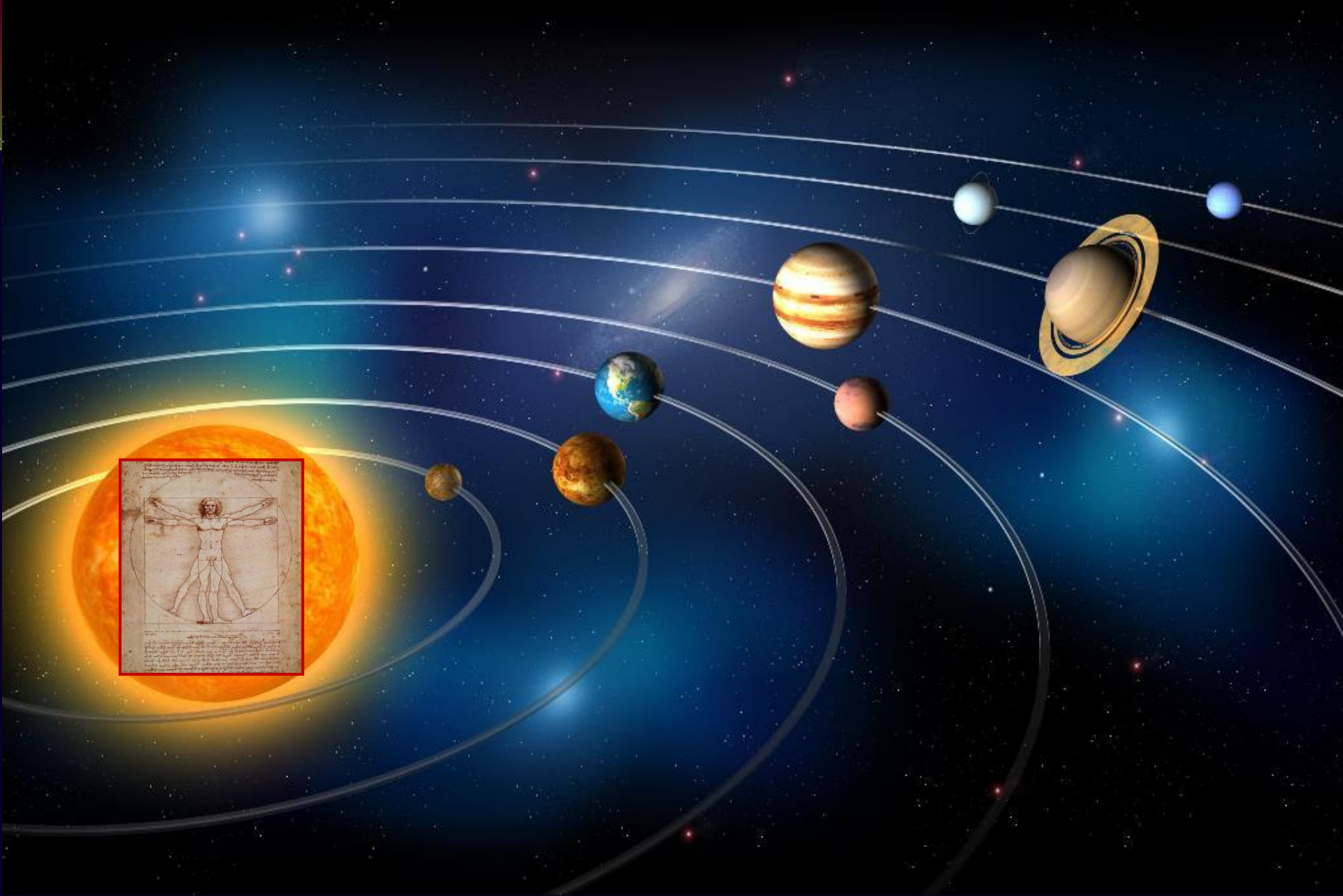
SUAVR



TIMING



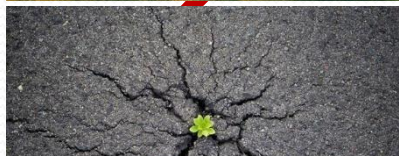
**SEVERE
AS**



“Patient centric” vision



**FRAILTY
PATIENT**



QUALITY OF LIFE



Tailored therapeutic approach



**BIOLOGICAL
VS
ANAGRAPHIC
AGE**



**INSTRUMENTAL
EXAMS**



ABOUT SURGERY



Don't worry..



..be prepared!

Thanks !!!