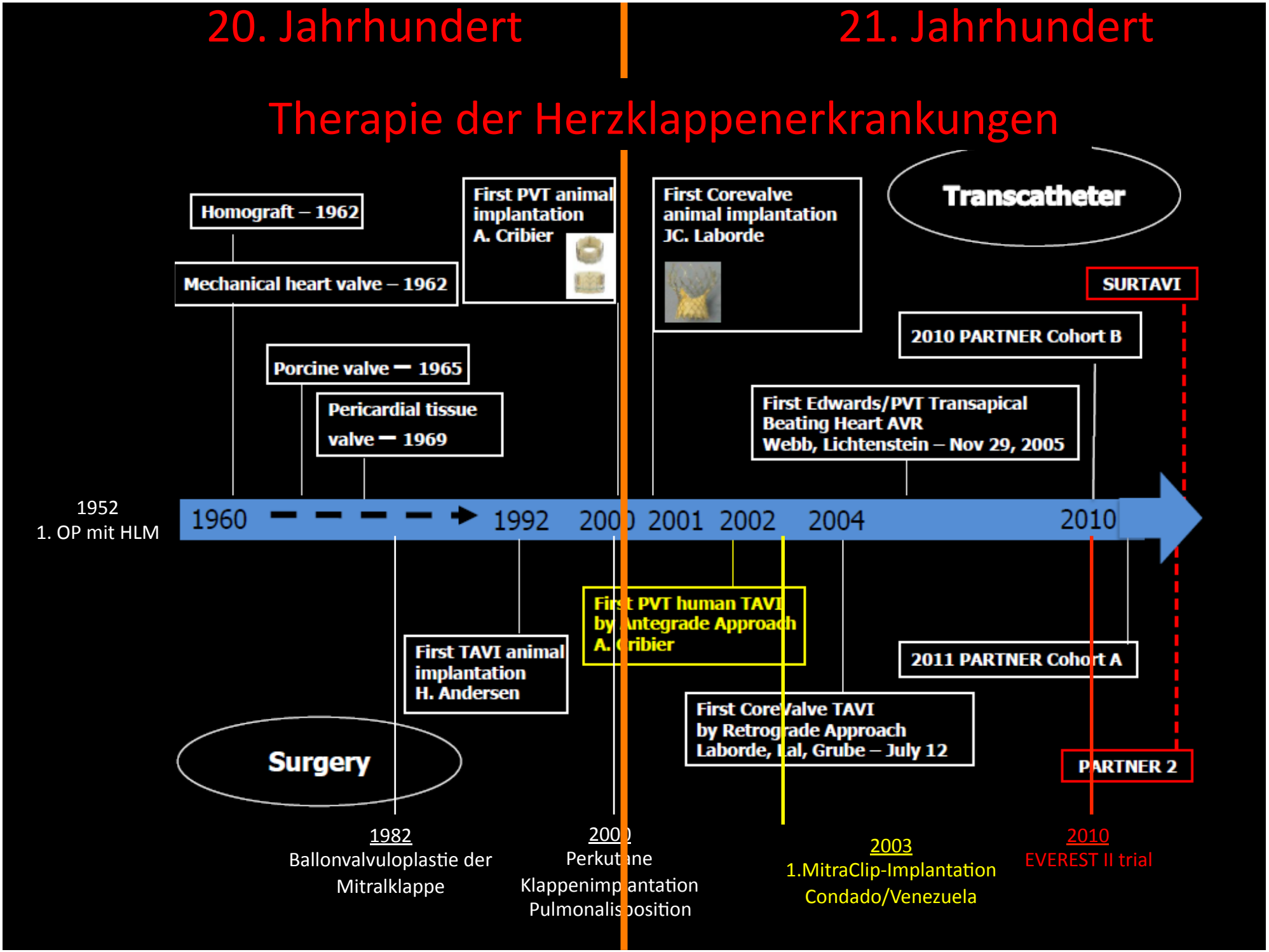
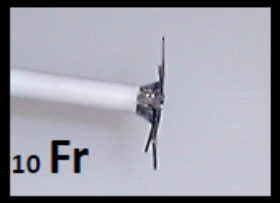
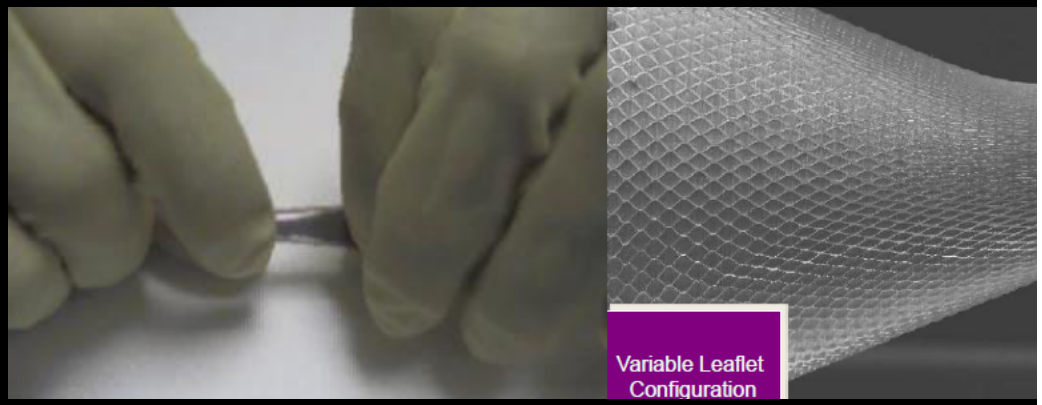
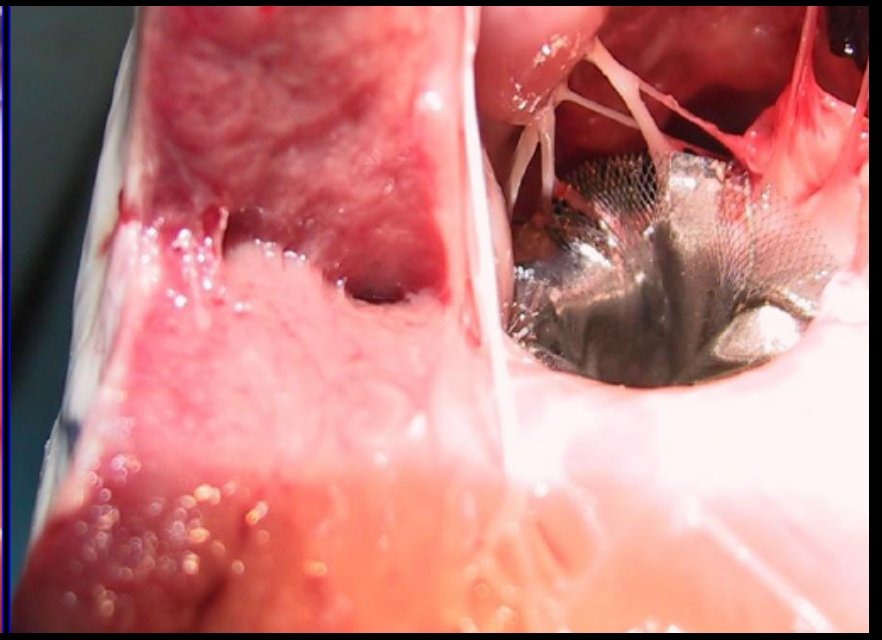
Die Zukunft ist JETZT!


20. Jahrhundert
21. Jahrhundert
Therapie der Herzklappenerkrankungen
Transcatheter
Surgery
Homograft – 1962
Mechanical heart valve – 1962
Porcine valve – 1965
Pericardial tissue valve – 1969
First PVT animal implantation A. Cribier
First Corevalve animal implantation JC. Laborde
First Edwards/PVT Transapical Beating Heart AVR Webb, Lichtenstein – Nov 29, 2005
2010 PARTNER Cohort B
SURTAVI
2011 PARTNER Cohort A
PARTNER 2
First TAVI animal implantation H. Andersen
First PVT human TAVI by Antegrade Approach A. Cribier
First CoreValve TAVI by Retrograde Approach Laborde, Lal, Grube – July 12
1952
1. OP mit HLM
1960
1992
2000
2001
2002
2004
2010
1982
Ballonvalvuloplastie der Mitralklappe
2000
Perkutane Klappenimplantation Pulmonalisposition
2003
1.MitraClip-Implantation Condado/Venezuela
2010
EVEREST II trial



ABPS NiTi eNitinol Membranen



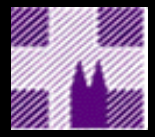


Meine Prognose 2013:

„ In 5 Jahren wird die Mehrheit aller Klappeninterventionen rein perkutan durchgeführt und in 10 Jahren < 10% offen herzchirurgisch „

Katheterinterventionelle Behandlung der Aorten- und Mitralklappe

Patientenselektion und OP-Risiko aus Sicht des Kardiologen



Torsten Schwalm

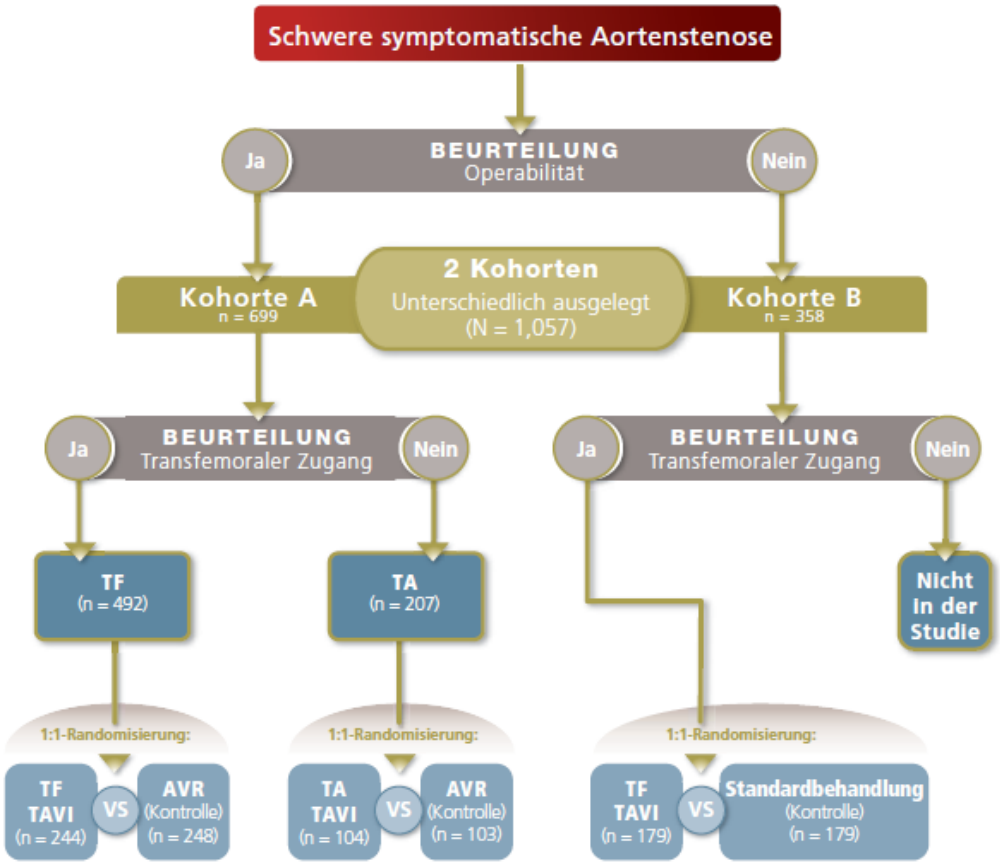
Vergangenheit - Pionierarbeit

1. Etablierte Indikationen:

Was wir wissen

Wissenschaftlicher background: TAVI

2007 – 2010/2011 FDA clinical trial zur Zulassung der Edwards Sapien Klappenprothese: PARTNER-trial *



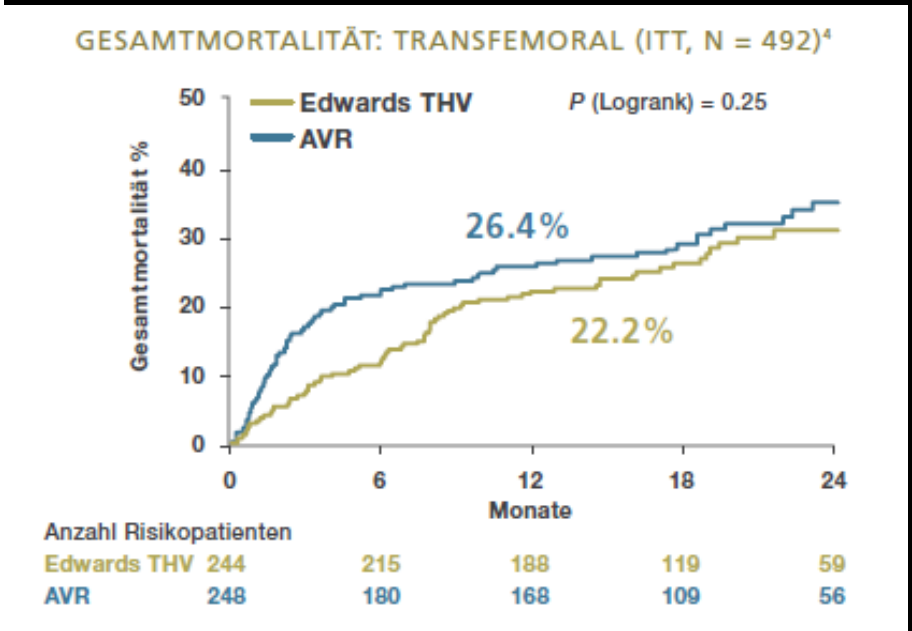
KOHORTE A – EINSCHLUSSKRITERIEN[4-6]		KOHORTE B – EINSCHLUSSKRITERIEN[5]	
STS-Wert und/oder Erwartete Operationsmortalität	≥ 10 ≥ 15%	STS-Wert Erwartete Operationsmortalität	11.6* > 50%†
NYHA-Klasse	≥ II	NYHA-Klasse	> II
AVA oder Mittlerer AVG oder Aortenflussgeschwindigkeit	< 0.8 cm² > 40 mm Hg > 4.0 m/s	AVA oder Mittlerer AVG oder Aortenflussgeschwindigkeit	< 0.8 cm² > 40 mm Hg > 4.0 m/s

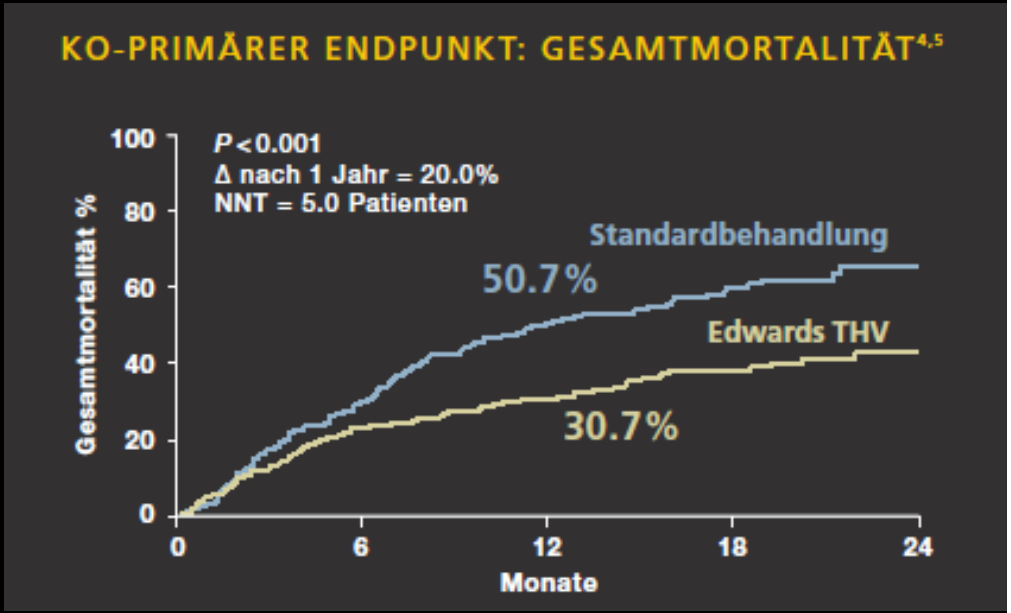
* Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med. 2010;363;1597-1607.

Ergebnisse aus Partner B 2010, Partner A 2011

Kohorte A
TAVI vs. SVAR

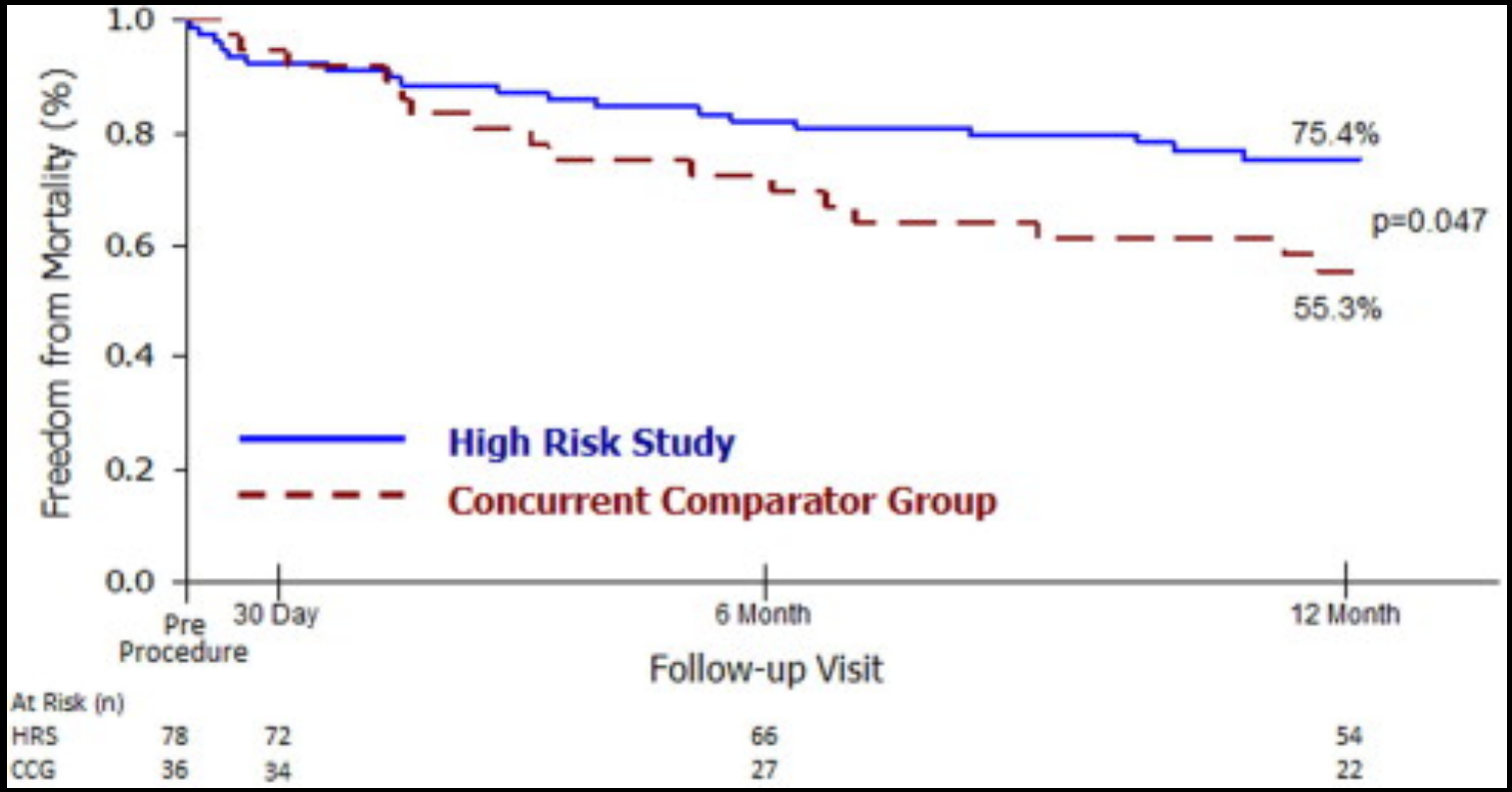
Kohorte B
TAVI vs. Medikamentös





Wissenschaftlicher background: MitraClip

2010/2011 Resultate des 1. RCT zur MitraClip-Therapie: EVEREST II high-risk trial *



* Whitlow PL, Feldmann T et al. Acute and 12-Month Results With Catheter-Based Mitral Valve Leaflet Repair: The EVEREST II (Endovascular Valve Edge-to-Edge Repair) High Risk Study J Am Coll Cardiol. 2012;59(2):130-139

Zusammenfassung 1: **Etablierte** Indikationen

TAVI

MitraClip

Technisch inoperabler Patient
Porzellanaorta, „hostile-chest“, u.a.
Hochrisikopatient, STS > 10% (TAVI), > 12% (MitraClip)

Signifikant besser als die konservative Therapie

Vergleichbare Resultate gegenüber SAVR
Mortalität

Zugangsprobleme
Stroke
Postprozedurale Aorteninsuffizienz
Schrittmacherpflichtigkeit

Vor- und Nachteile gegenüber SMVR
Mortalität
Bessere QOL und 6-minute walk
Identische lv Parameter und NYHA-Klasse
20% im Verlauf dennoch offene Chirurgie
25% MR ≥ 3
schlechteres funktionelles Resultat

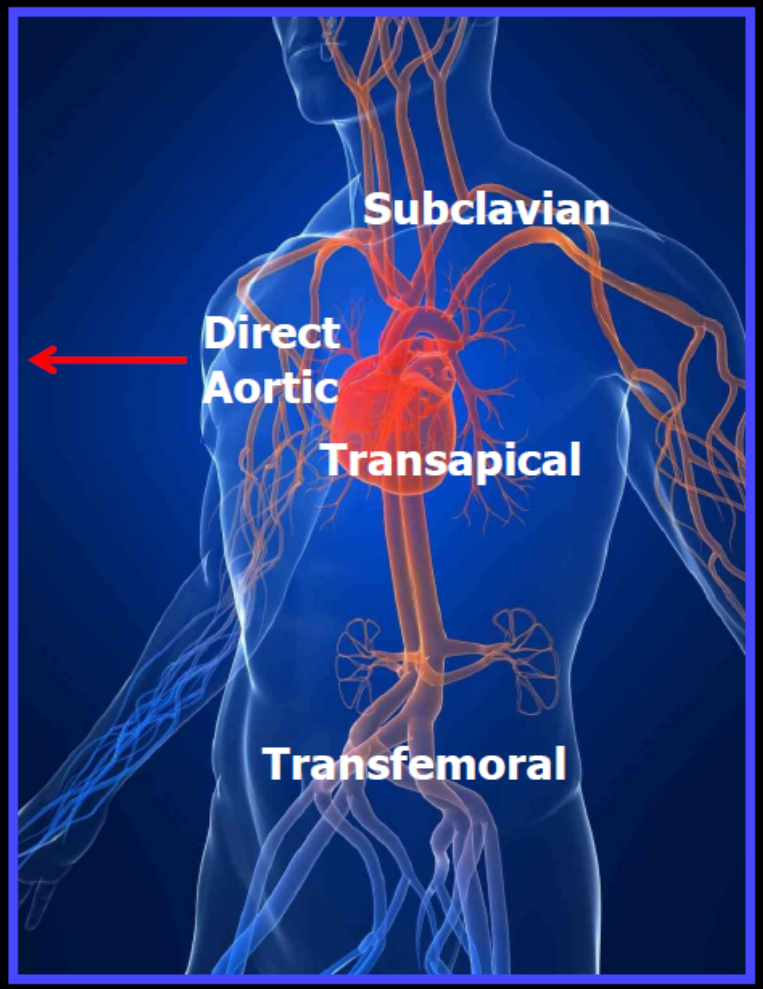
Gegenwart – Technik und Wissenschaft

1. Erweiterung der Indikationen:
   Was glauben wir zu wissen

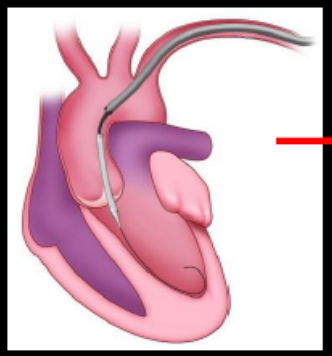
State of the art 2013

Verbesserte, kleinere devices: 16 – 18 – 19 F, geringere Komplikationsraten, alternative

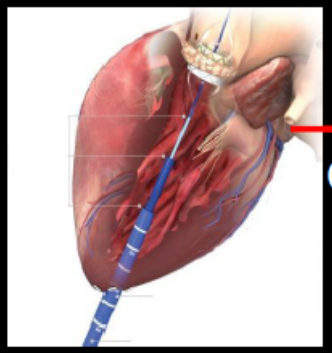
TAVI – access routes



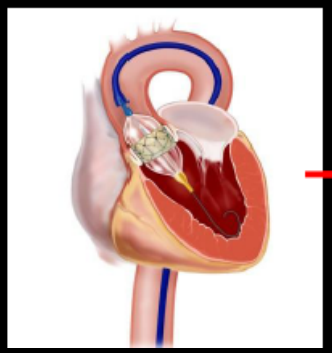
Latsios et al
Cathet Cardiovasc Interv 2010



Crube et al.
Circulation 2006

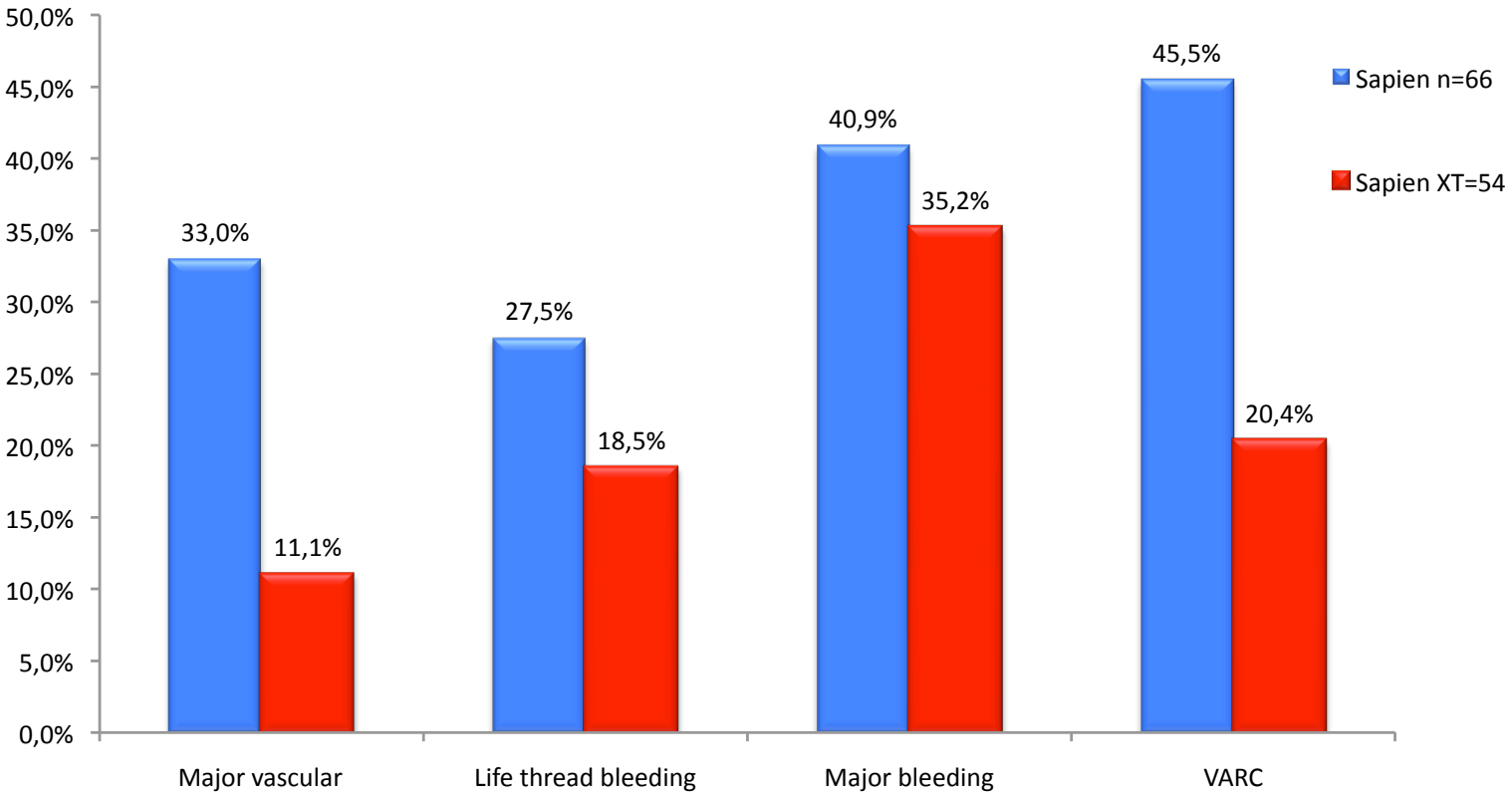


Ye et al. J Thor Cardiovasc Surg 2006



Cribier et al.
Circulation 2002

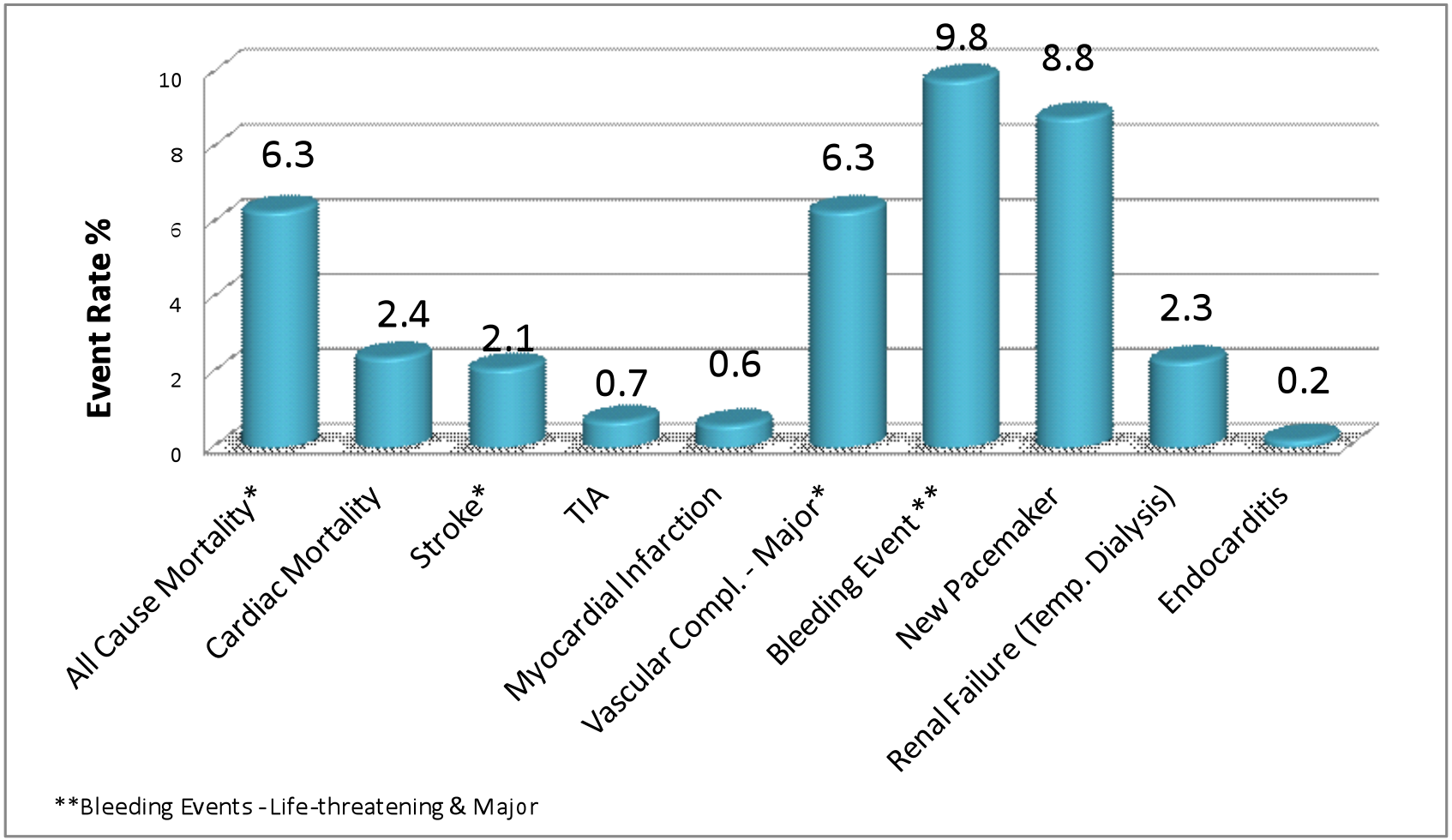
Edwards Sapien vs. Sapien XT Vascular complications



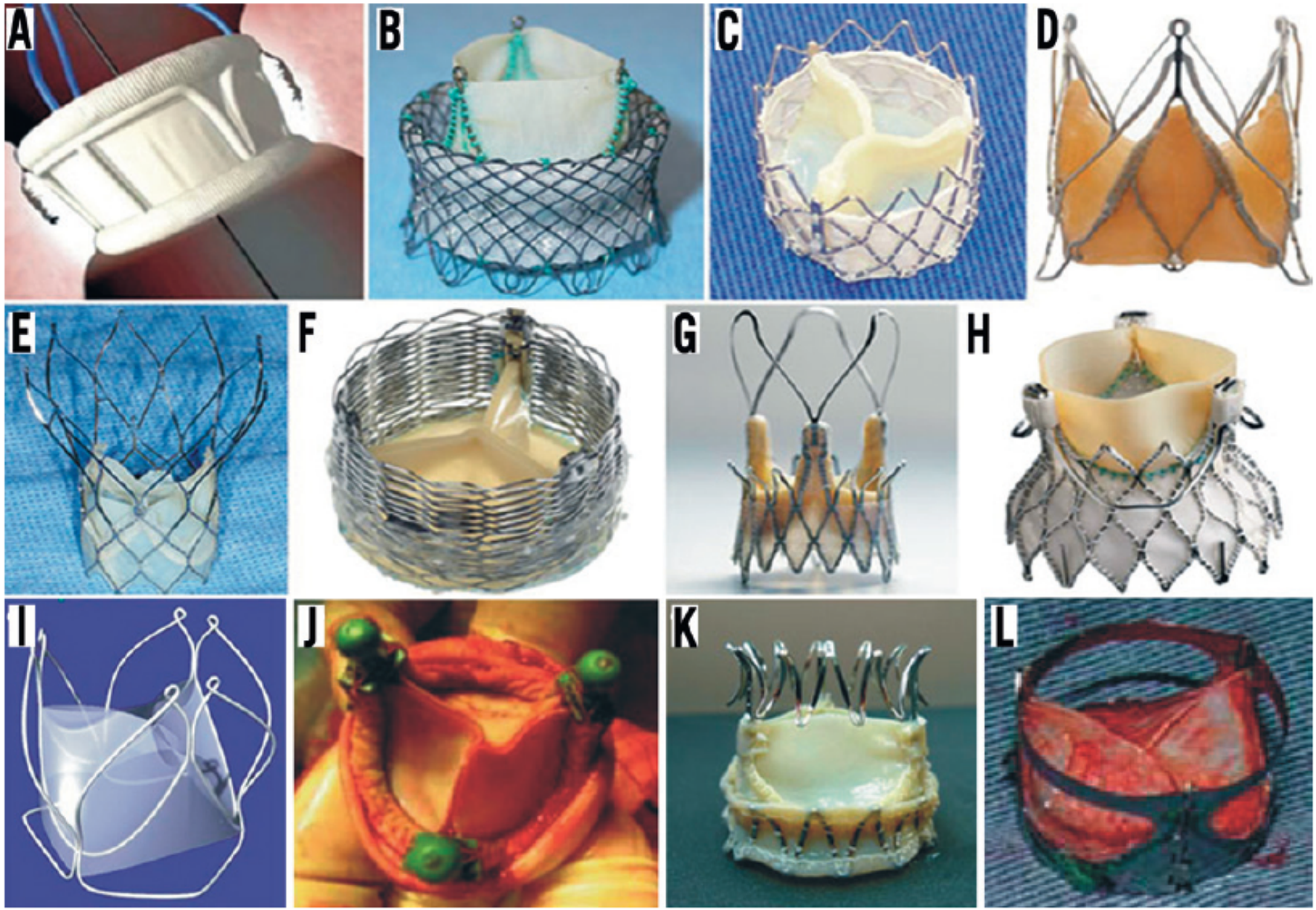
Mussardo et al. Milan, 2011

n = 120, single-center

SOURCE XT-Registers: Events nach 30 Tagen



**Bleeding Events - Life-threatening & Major

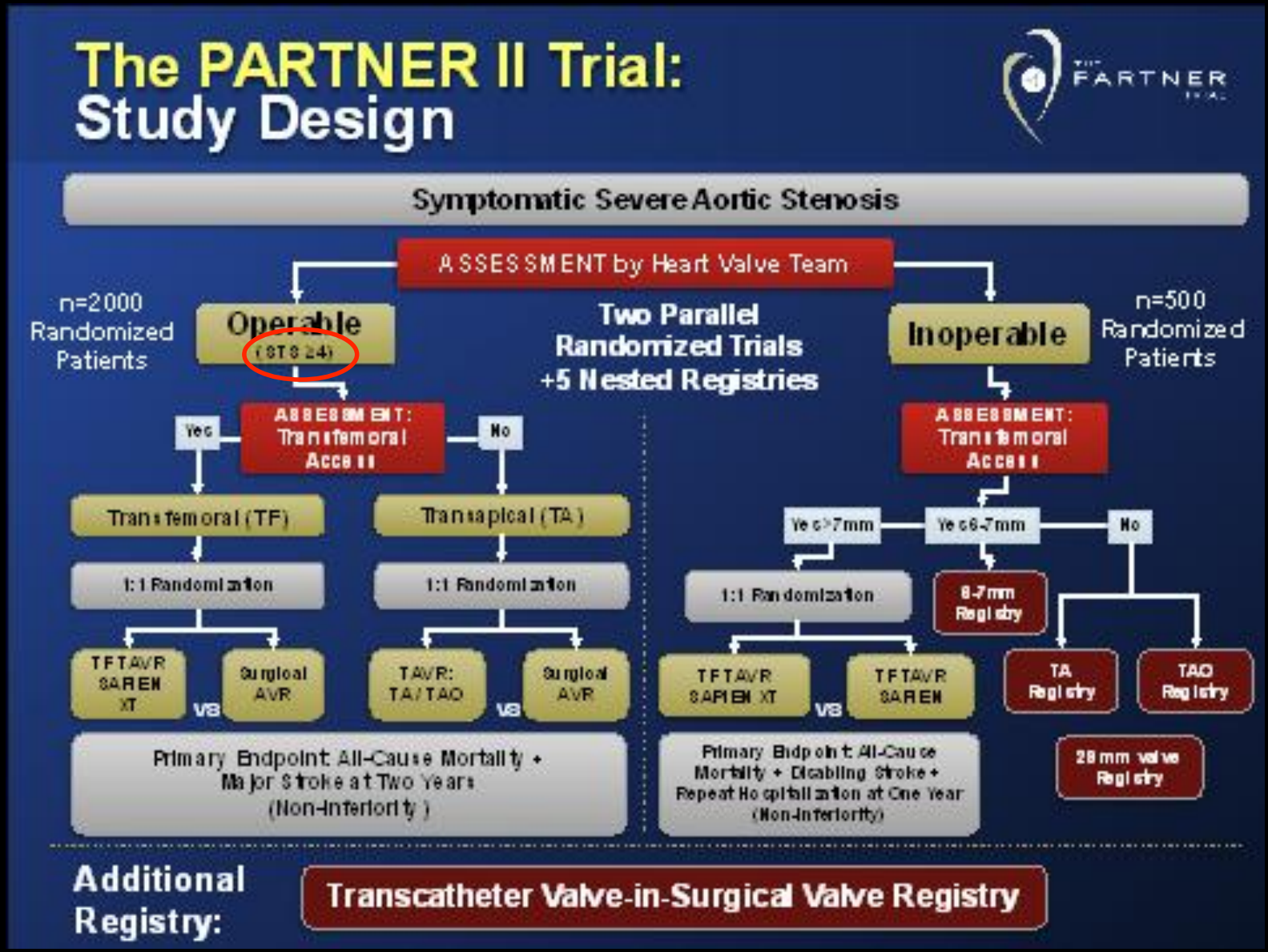

A
B
C
D
E
F
G
H
I
J
K
L

Vergrößerung der Datenbasis und Erweiterung der Indikation

Device	Name	Aim	Design	Number of patients	Follow-up	Primary endpoints	Secondary endpoints
Edwards SAPIEN XT	ARTE	Compare the efficacy of aspirin with the combination aspirin and clopidogrel in patients who had TAVI treatment	Randomised, double blind	200	1 year	1. All-cause mortality, stroke, transient ischaemic attack, MI, life-threatening bleeding	1. All-cause mortality, death, stroke, transient ischaemic attack, bleeding at 30 days 2. MI, stroke at 30 days and 1 year 3. Major or minor bleeding at 30 days and 1 year 4. Cardiovascular death at 30 days and 1 year 5. Cost-effectiveness
CoreValve	SIMPLIFy TAVI	Demonstrate that the avoidance of BAV before TAVI is associated with better outcomes	Randomised, open label	110	1 year	1. All-cause mortality, stroke, MI, kidney injury and PPM implantation at 30 days	1. Cardiovascular and all-cause mortality, stroke, kidney injury and PPM implantation at 6 and 12 months 2. Echocardiographic assessment 3. Hospital admissions for cardiac causes
CoreValve	CoreValve Advance II	Identify the best practice for CoreValve implantation, which would reduce the risk of conduction abnormalities	Prospective, non-randomised	150	6 months	1. Incidence of Class I or II PPM indications based on the 2007 ESC Guidelines	–
Sadra Lotus	Reprise II	Assess the safety and performance of the Lotus valve system in high-risk patients	Prospective, open label	120	1 month	1. Device performance and evaluation of the aortic valve gradient at 30 days 2. All-cause mortality at 30 days	–
Engager		Engager European Pivotal Trial	Prospective, non-randomised	150	5 years	1. All-cause mortality at 30 days	1. All-cause mortality at 6 months 2. MACCE and hospitalisations at 30 days and 6 months 3. Procedural and device success 4. Haemodynamic metrics 5. Changes in NYHA and 6 minutes walk test from baseline to 6 months
Portico	Portico 23 TF EU	Assess the safety and effectiveness of the 23 mm Portico valve	Observational, prospective, non-randomised	50	1 year	1. All-cause mortality at 30 days	1. Procedural success 2. Functional improvement from baseline to 30 days 3. Event rate (MI, stroke, kidney injury, bleeding, cardiovascular death) at 30 days
SHEF	DEFLECT I	Examine the safety and performance of the SHEF system	Prospective, open label	36	30 days	1. Device performance 2. Procedure-related adverse events at 30 days	
CoreValve	CoreValve vs. SAVR-Denmark	Compare TAVI with CoreValve and SAVR in patients >70 years old	Randomised, single blind	280	5 years	1. All-cause mortality, MI and stroke at 1 year	1. Procedural complications and admission length within the 1st month post procedure 2. Death, cardiac, renal, cerebral and pulmonary complications at 1 year 3. NYHA and quality of life at 1 year 4. Echocardiographic findings at 1 year
CoreValve	CoreValve U.S. Pivotal extreme risk cohort	Demonstrate the safety and efficacy of CoreValve in high-risk inoperable patients	Non-randomised	487	5 years	1. All-cause mortality and stroke at 1 year	1. Individual MACCE and MACCE-free survival at 5 years 2. Need for PPM at 5 years 3. Changes in NYHA and quality of life at 5 years 4. Changes in 6 minutes walk test at 12 months 5. Procedure-related complications 6. Echocardiographic findings at 5 years
CoreValve	CoreValve U.S. Pivotal high risk cohort		Non-inferiority, randomised, controlled, open label	790	5 years	1. Freedom from all-cause death at 12 months	1. Individual MACCE and MACCE-free survival at 5 years 2. Need for PPM at 5 years 3. Changes in NYHA and quality of life at 5 years 4. Changes in 6 minutes walk test at 12 months 5. Procedure-related complications 6. Echocardiographic findings at 5 years
Edwards SAPIEN XT	PARTNER II cohort A	Compare TAVI with the Edwards SAPIEN XT and SAVR in moderate risk patients	Non-inferiority, randomised	2,000	2 years	1. All-cause mortality and stroke at 2 years	1. Functional improvement from baseline 2. Freedom from stroke, MI, vascular complications, bleeding, re-operation, valve-related complications, AR, AS, PPM implantation, mitral dysfunction and acute kidney injury at 30 days and 2 years
Edwards SAPIEN XT	PARTNER II cohort B	Compare Edwards SAPIEN THV and Edwards SAPIEN XT in inoperable patients	Non-inferiority, randomised	500	2 years	1. All-cause mortality, stroke and repeat hospitalisation at 2 years	1. Stroke, MI, bleeding, acute renal failure, vascular complications, need for PPM, valve-related complications at 30 days, 6 months and 1year
CoreValve	SURTAVI	Compare TAVI with the CoreValve and SAVR in intermediate risk patients	Non-inferiority, prospective, randomised	1,800	5 years	1. All-cause mortality or stroke at 2 years	1. MACCE, kidney injury, vascular complications, valve dysfunction, bleeding and need for PPM at 30 days, 6, 12, 18 and 24 months and 3, 4 and 5 years 2. Changes in functional capacity at 30 days, 6, 12, 18 and 24 months and 3, 4 and 5 years 3. Echocardiographic assessment of the valve at 30 days, 6, 12, 18 and 24 months and 3, 4 and 5 years

TAVI: transcatheter aortic valve implantation; BAV: balloon aortic valvuloplasty; MI: myocardial infarction; PPM: permanent pacemaker; MACCE: major adverse cardio and cerebrovascular events; ESC: European Society of Cardiology; SAVR: surgical aortic valve replacement; NYHA: New York Heart Association; AR: aortic regurgitation; AS: aortic stenosis

The PARTNER II Trial: Study Design

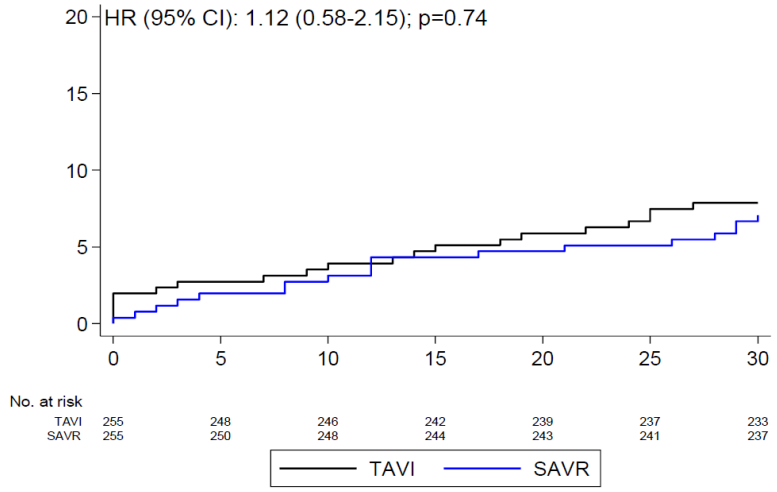


BE(rn)R(n)MU(nich)(Rotter)DA(m)-study

N= 392 pro Arm, TAVI vs. SVAR und STS-score 3-8%

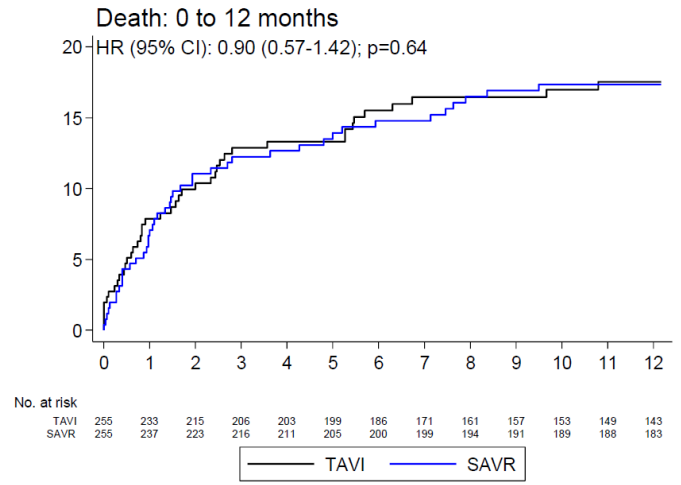
z.B. : 80-jähriger Mann mit AS und Hypertonie, STS 8%
70-jähriger Mann mit AS, STS 5%
60-jähriger Mann mit AS, STS 3,5%

30-days Mortality (STS 3-8%)



Bern-Rotterdam-Munich Study

1-year Mortality (STS 3-8%)



Bern-Rotterdam-Munich Study

Weiterentwicklungen und Ziele:

- Vollständige Retrahier- und Repositionierbarkeit des Systems
- Reduktion der Devicegrösse
- Optimierte Pharmakotherapie
- Neue Verschlusssysteme
- Ballonexpandierbare Schleusen
- Erweiterung der Datenlage
- Haltbarkeitsanalysen
- Anatomisch korrekte Platzierung
- Antimineraloide Beschichtungen (alpha-amino-Ölsäure (AOA))
- Optimierte Bildgebung

Aktuelle Differentialindikation TAVI vs. SAVR

	SAVR	TAVI
Alter	++	+
KHK	+	+
Lungenerkrankung	+++	+
paVk	+	+++
Gebrechlichkeit (frailty)	+++	+
Porzellanaorta	+++	-
hostile chest	+++	-

Zusammenfassung 2: Mögliche Indikationen

TAVI

Operable Patienten mit intermediärem Risiko
(STS 3 -8)

MitraClip

Hochrisikopatienten mit FMR

Mutmaßlich ähnliche Resultate
im Vergleich zu offener Chirurgie

Technische Entwicklungen
Vermeidung und Therapie von Komplikationen

Optimierte Patientenselektion
Mortalität

Zukunft – Expansion der Indikation

1. Alle Patienten:

Was wir hoffen

Edwards Centera

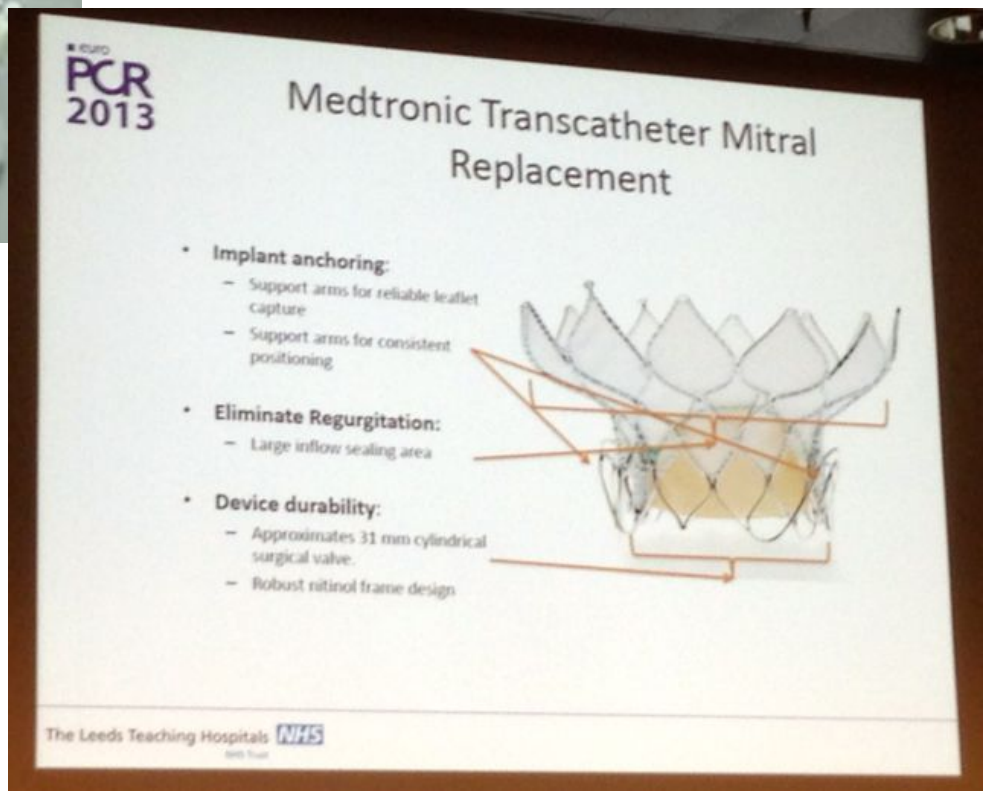
Motorisierte Freisetzung
Selbstexpandierend
14 F
Annulusverankerung
Repositionierbar

Edwards Sapien III

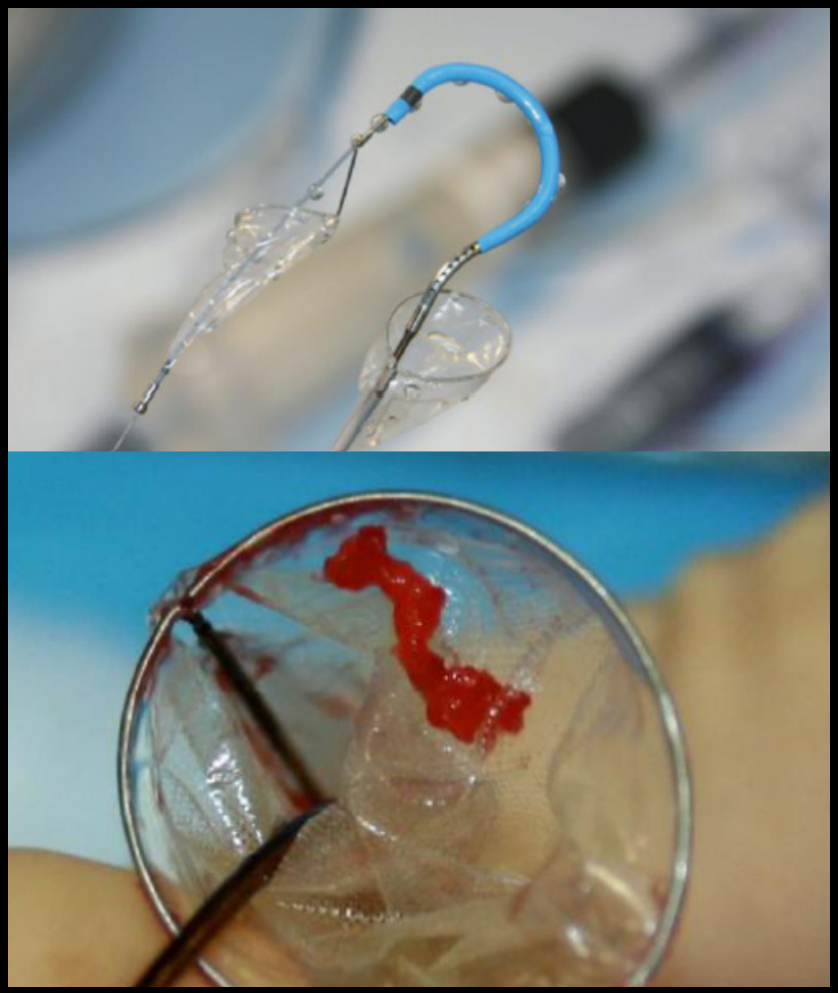
14 F
Retrahierbar
Sealing-cuff

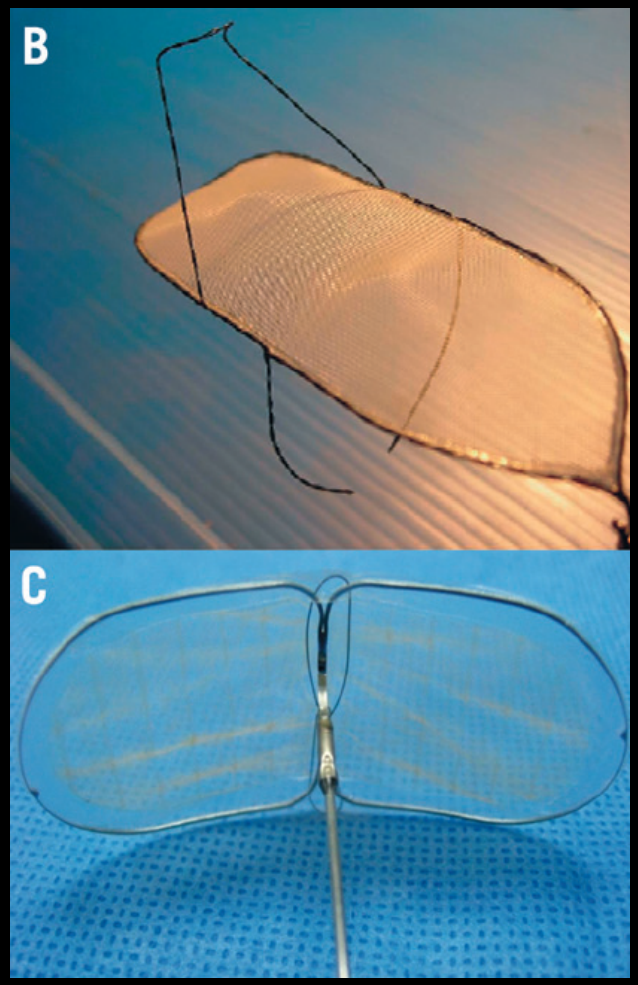
Neue devices !

1. Generation perkutaner kathetergestützter Mitralklappen

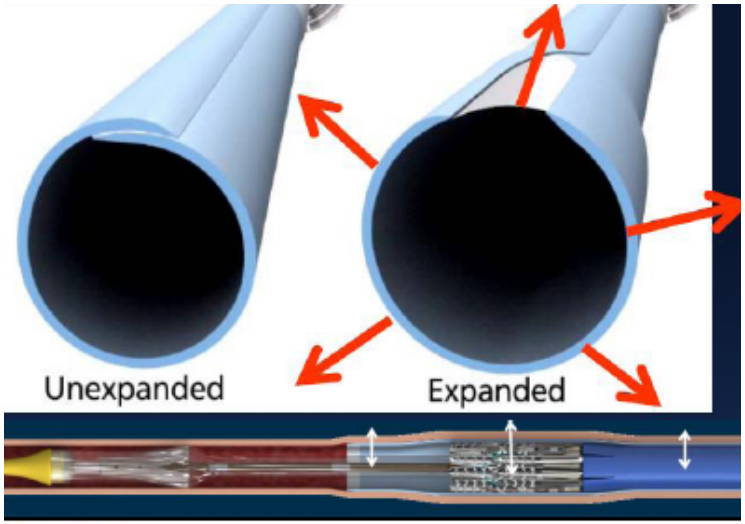


Embolic protection devices





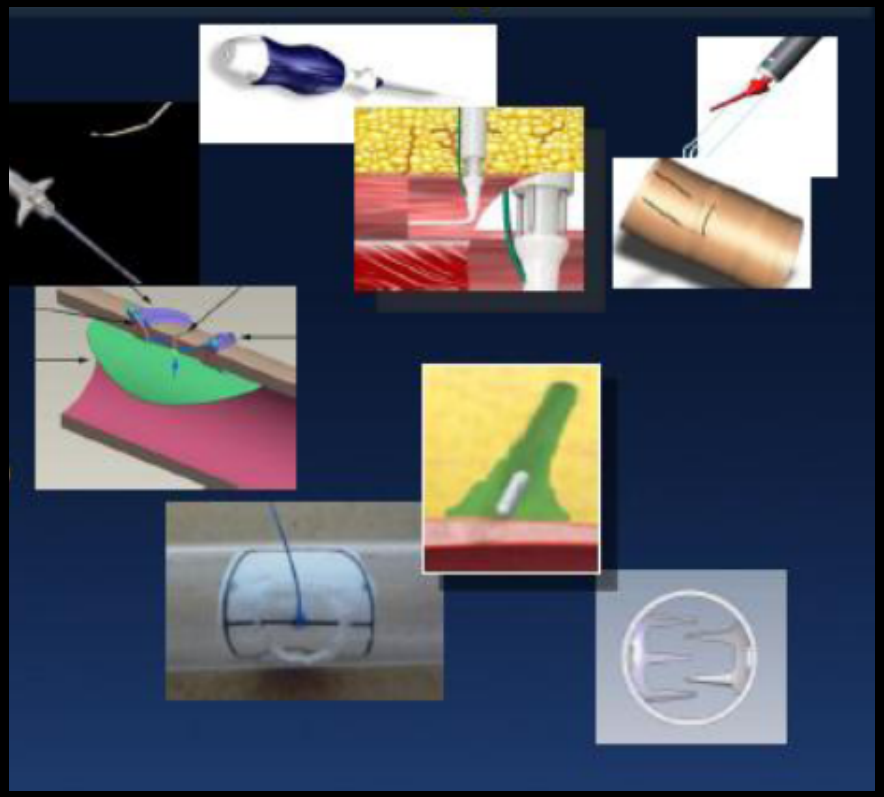
Neue Schleusen



Edwards eSheath

Terumo
Solopath

Neue Verschlusssysteme, neue Pharmaka



Dabigatran

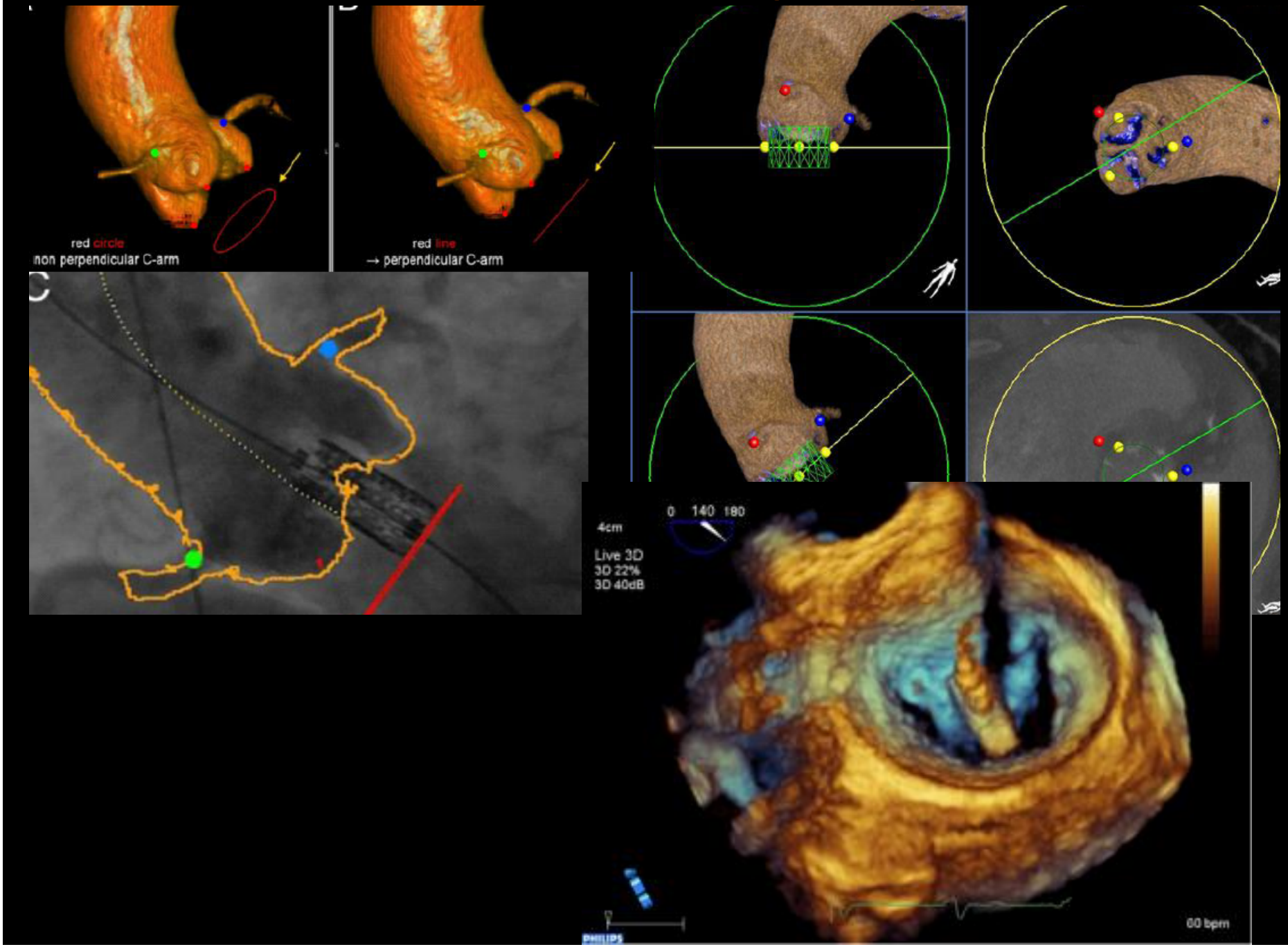
Rivaroxaban

Prasugrel

Ticagrelor

Apixaban

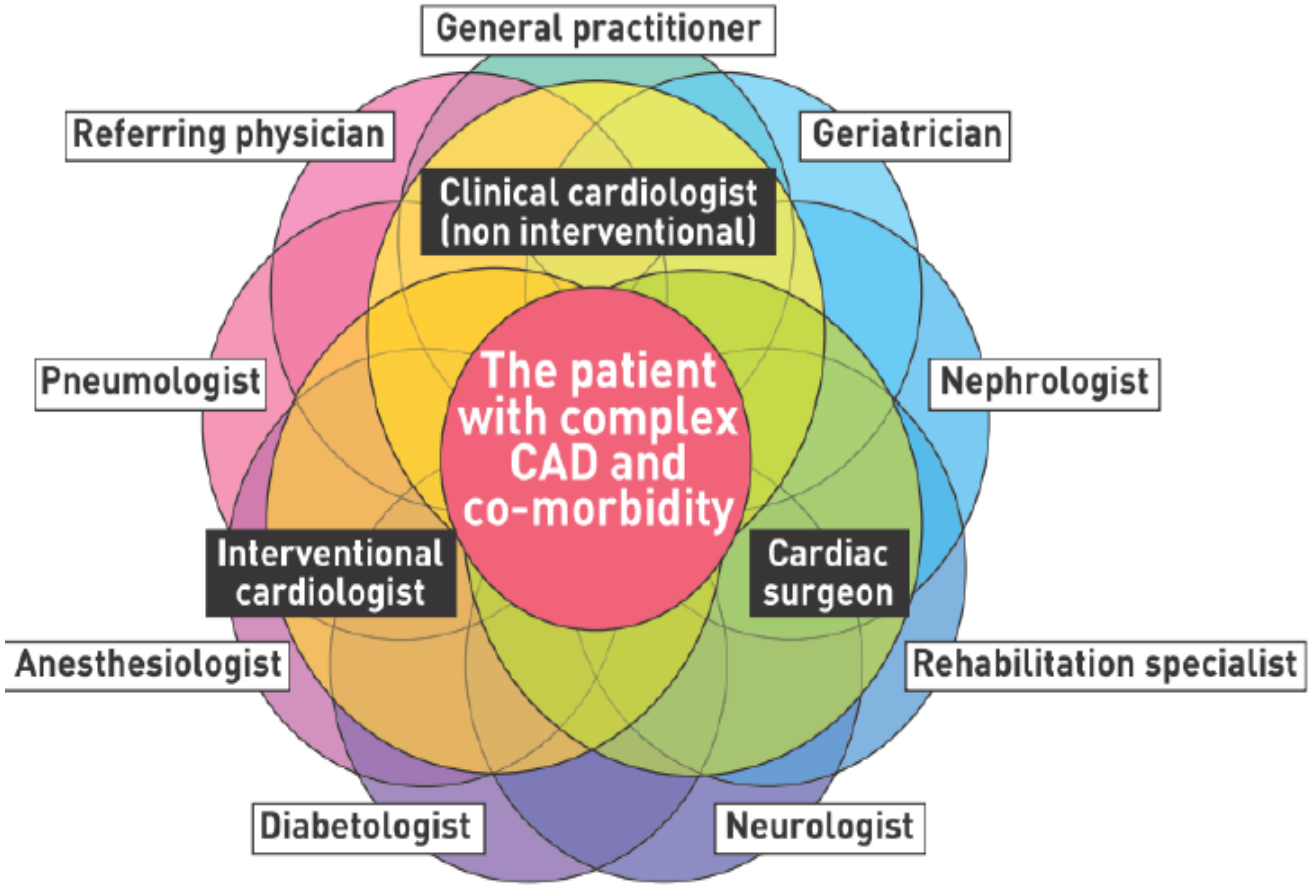
Optimierte Bildgebung



Score-Systeme

- Entwicklung neuer Score-Systeme zur Risikoevaluation und Gegenüberstellung perkutan vs. offen
- Es gibt keinen TAVI/pMVT-score, wir extrapolieren gegenwärtig nur das Risiko hinsichtlich einer offenen Chirurgie
- Wichtige Risikofaktoren werden in den STS-score nicht einbezogen (frailty, Leberkrankungen)

Multidisziplinärer Zugang



Zusammenfassung 3: Zukünftige Indikationen

TAVI

Alle Patienten mit Ausnahme von

simultaner Koronar-/Aortenchirurgie

pMVT

Alle Patienten mit FMR,
50% der DMR mit Ausnahme von

Technische Entwicklungen

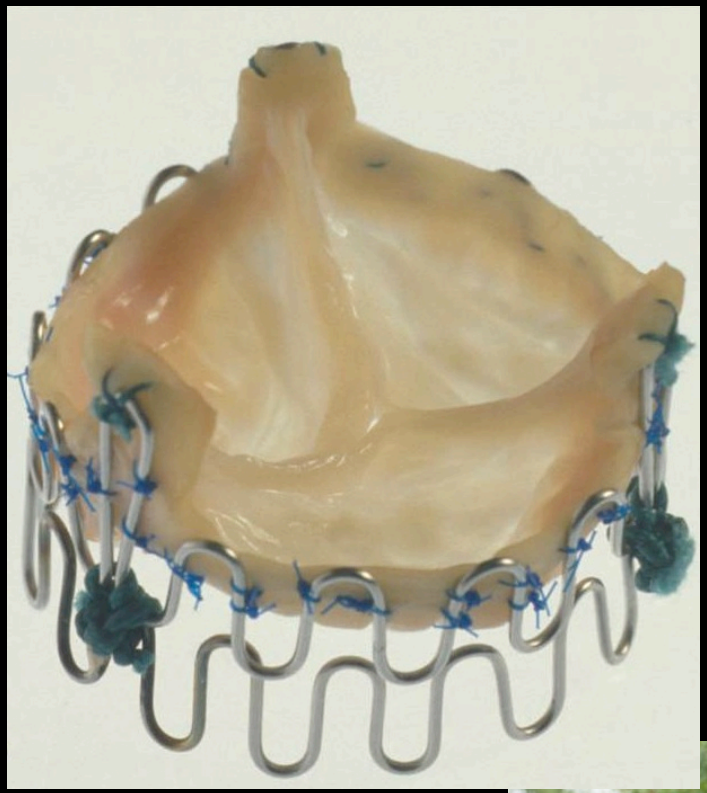
take-home message

Wachsende Evidenz zur Wertigkeit der TAVI und pMVT
Etablierte Verfahren bei inoperablen und Hochrisiko-Patienten
Mit zunehmender Vertrautheit und technischer Entwicklung kann die Indikation (intermediäres Risiko (TAVI), funktionelle Mitralinsuffizienz (pMVT)) erweitert werden

Das gelingt nur durch

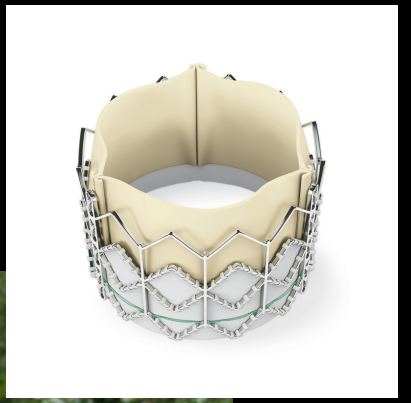
Demonstration der Überlegenheit und Sicherheit im Vergleich zum SVAR an Niedrig-Risikopatienten
Nachweis der Haltbarkeit

1998



Wer hätte das in 1998 gedacht ?

2011



TAVIs „unsung hero“

Henning Rud Andersen
Aarhus, Denmark

Vielen Dank für Ihre Aufmerksamkeit !