

Mitral Valve Interventions

Reality and Future Perspectives in 5 years

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Heart Valve Innovation
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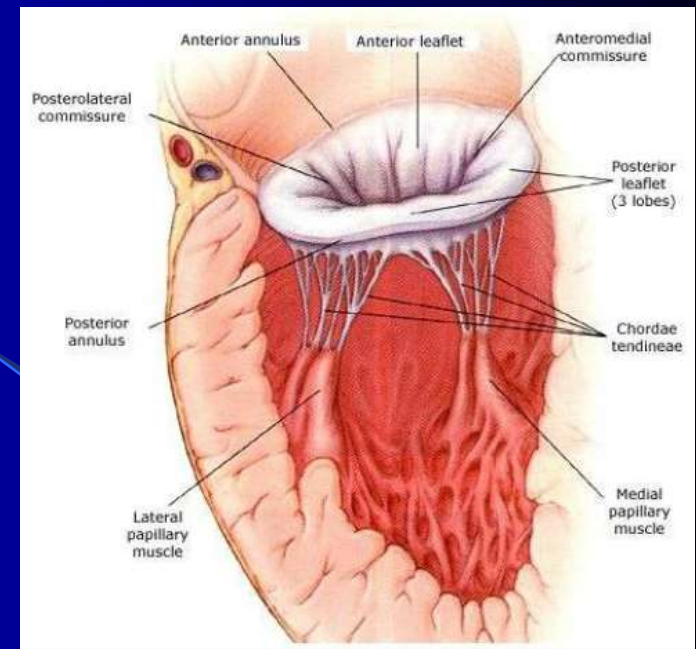
HEART CENTRE
AT ST. PAUL'S HOSPITAL

Disclosure

Consultant:

**Edwards Lifesciences
JC Medical Inc.**

Etiology of MR



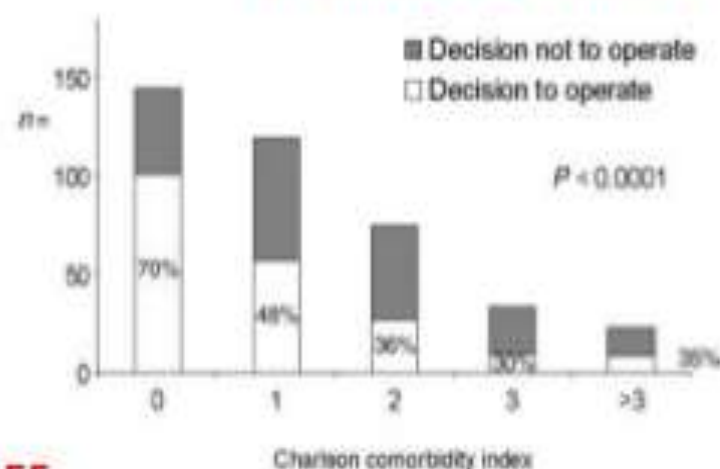
Acute	Chronic Primary	Chronic Secondary
Chordal rupture	Myxomatous	Ischemic
Endocarditis	Endocarditis	Dilated cardiomyopathy
Papillary muscle rupture	Mitral annular/leaflet calcification	
Trauma	Congenital (claft)	
Acute MI	Rheumatic	
	Radiation	
	Collagen vascular disease	

Severe, symptomatic MR: Half of patients do not undergo surgery?

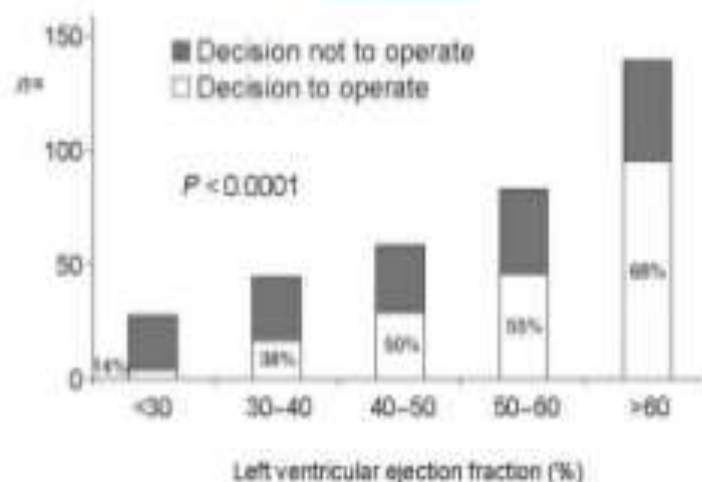
Older age



Comorbid conditions



Lower EF



Transcatheter MV Repair

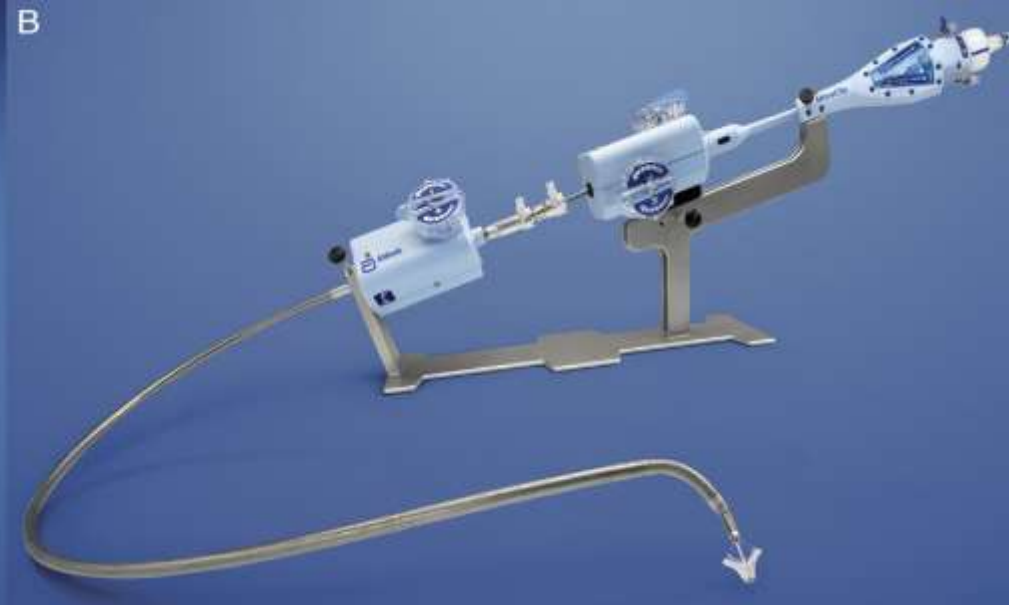
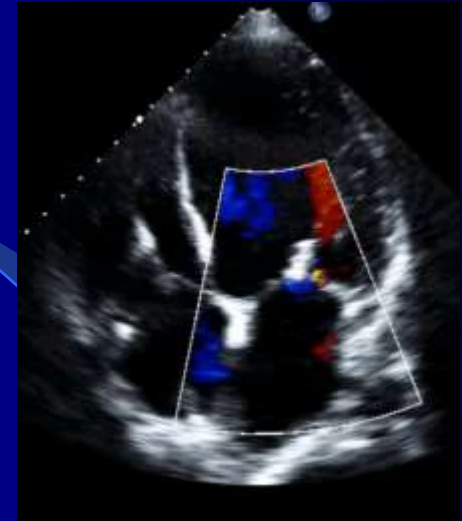
Devices used in humans

Device	Target	Regurgitation
MitraClip	Leaflet	Functional/Degenerative
PASCAL	Leaflet	Functional /Degenerative
Cardioband	Annulus	Dilated annulus/Functional
Mitralign	Annulus	Dilated annulus/Functional
Millipede System	Annulus	Dilated annulus/Functional
Spacer	Leaflet coaptation	Dilated annulus/Functional
NeoChord	Chordae	Degenerative
Harpoon TSD-5	Chordae	Degenerative
Amend annuloplasty ring	Annulus	Functional/Degenerative

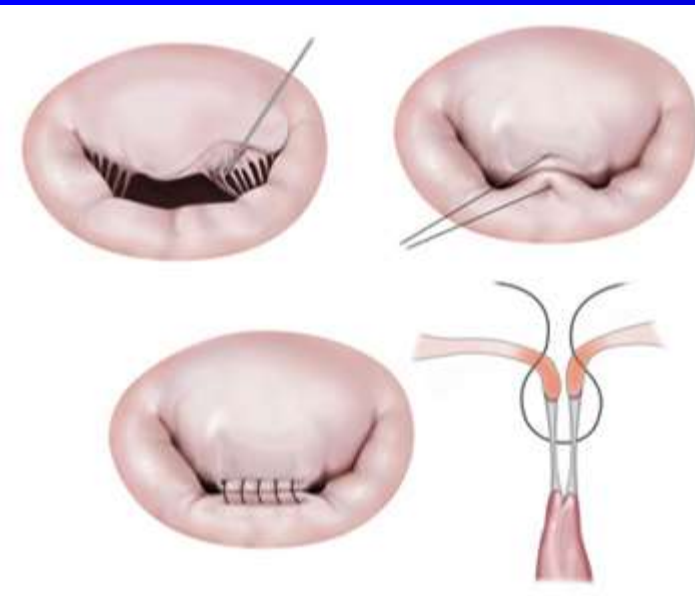
Edge-to-Edge Procedure

MitraClip

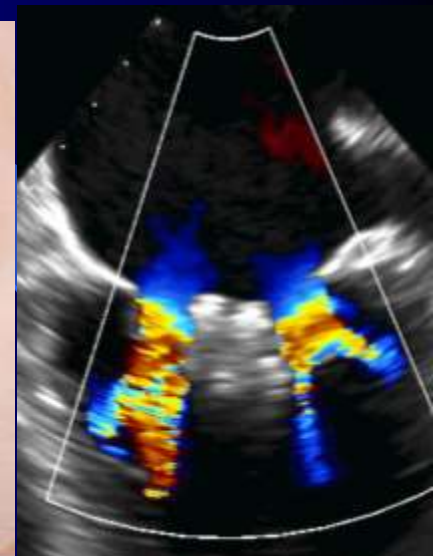
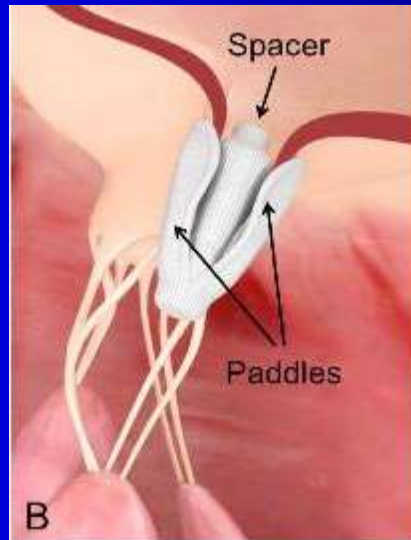
- FDA approval for degenerative MR in high-risk patients
- Ongoing clinical trial on the treatment of functional MR



Edge-to-Edge Edwards PASCAL Repair System

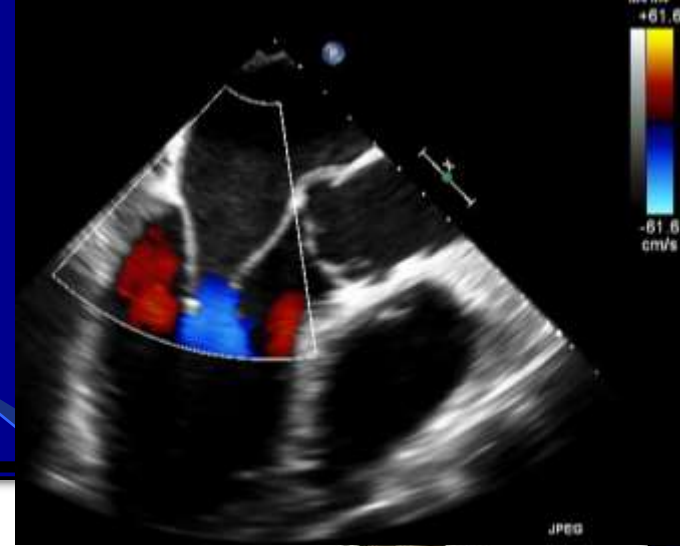


Alfieri stitch



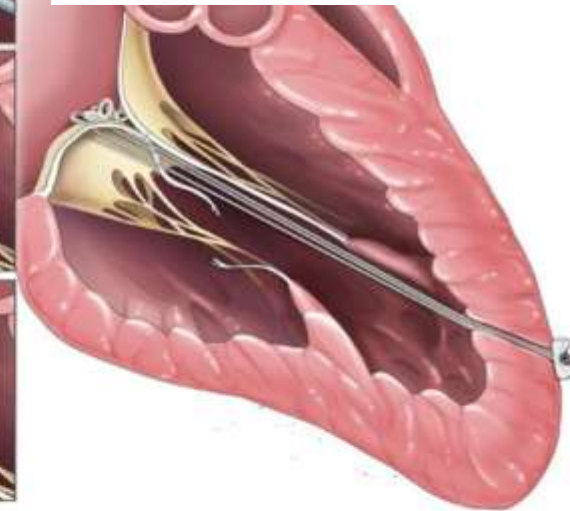
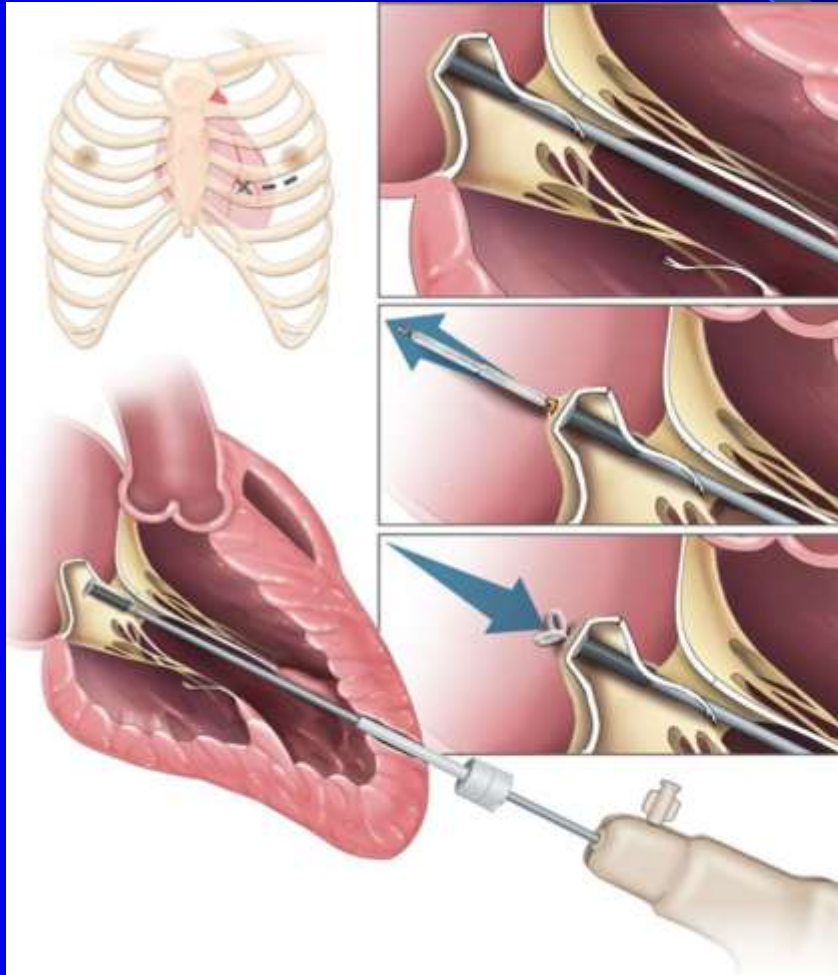
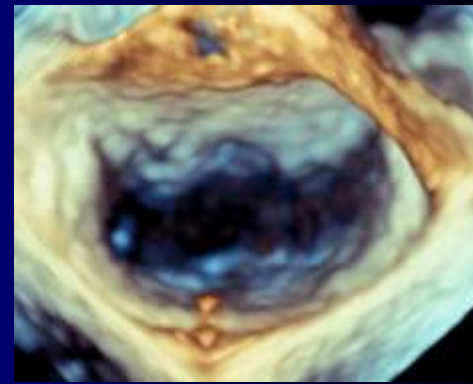
- Spacer is clasped between both Mitral Valve leaflets
- Independent leaflet claspings
- Simple "Commander-like" delivery system
- Conventional transfemoral/transseptal approach

Chordal Replacement NeoChord DS1000 Device



**Surgical
chordal
replacement**

Chordal Replacement Harpoon TSD-5



**Surgical
chordal
replacement**

Harpoon Medical

Effect of Recurrent Mitral Regurgitation Following Degenerative Mitral Valve Repair

J Am Coll Cardiol 2016;67:488-98

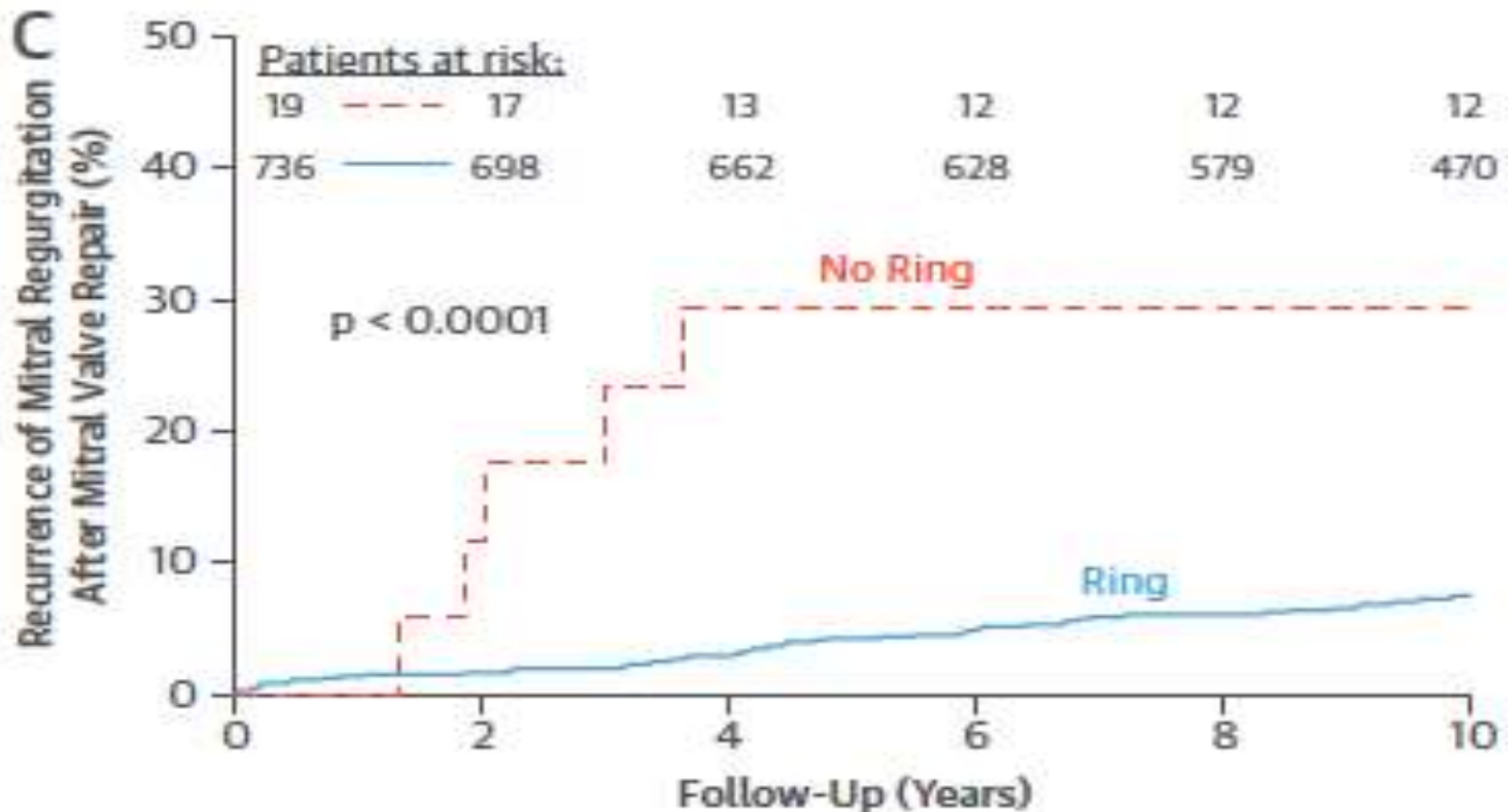
CrossMark



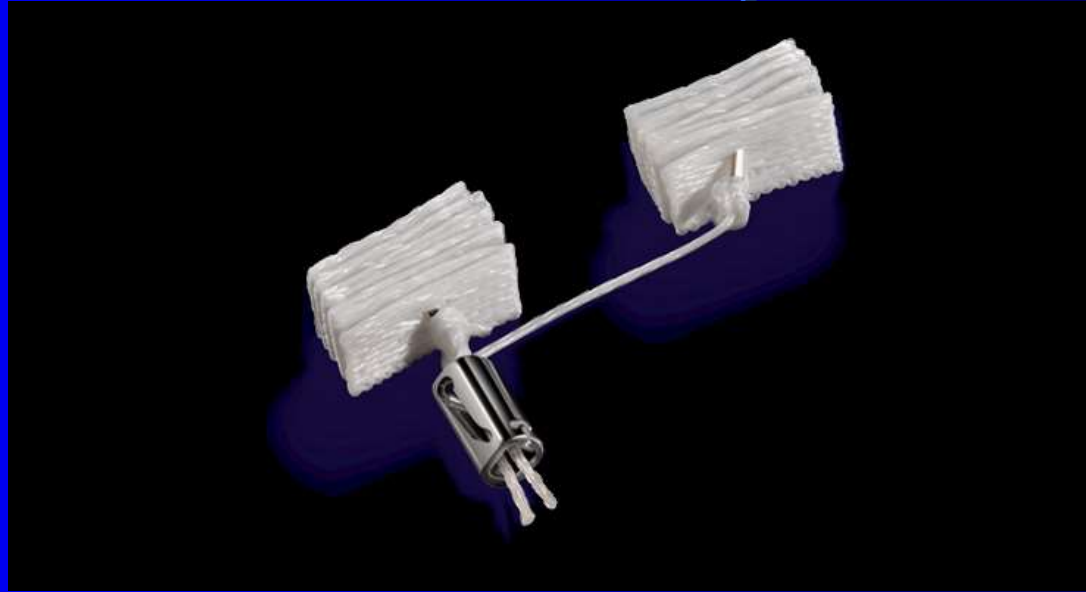
Long-Term Analysis of Competing Outcomes

Rakesh M. Suri, MD, DPHIL,^a Marie-Annick Clavel, DVM, PhD,^{b,c} Hartzell V. Schaff, MD,^a Hector I. Michelena, MD,^b Marianne Huebner, PhD,^d Rick A. Nishimura, MD,^b Maurice Enriquez-Sarano, MD^b

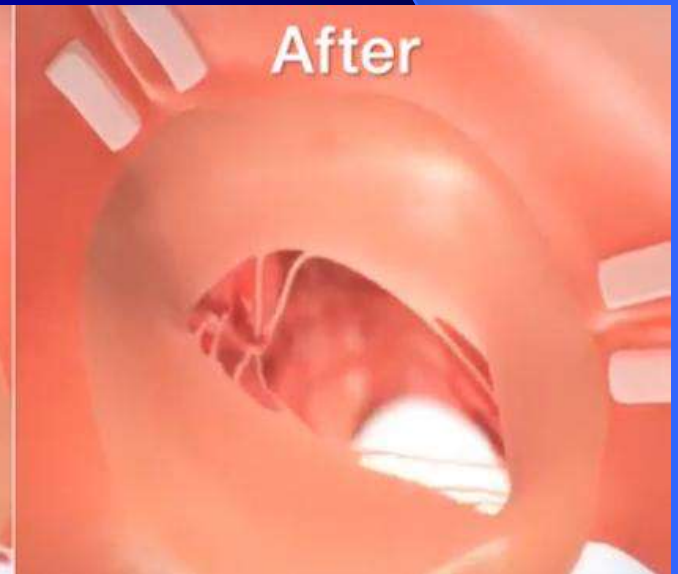
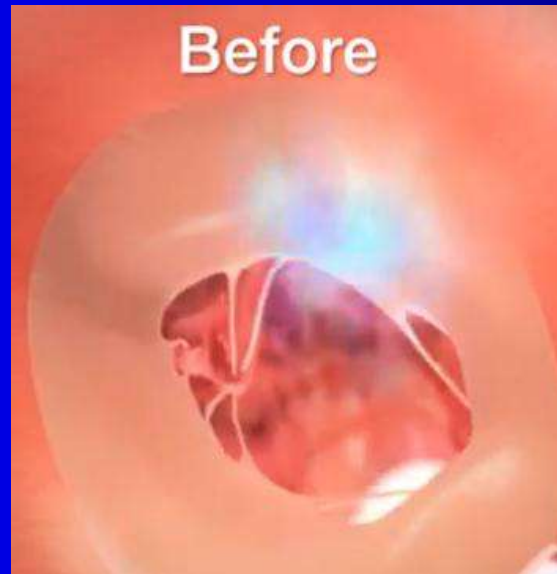
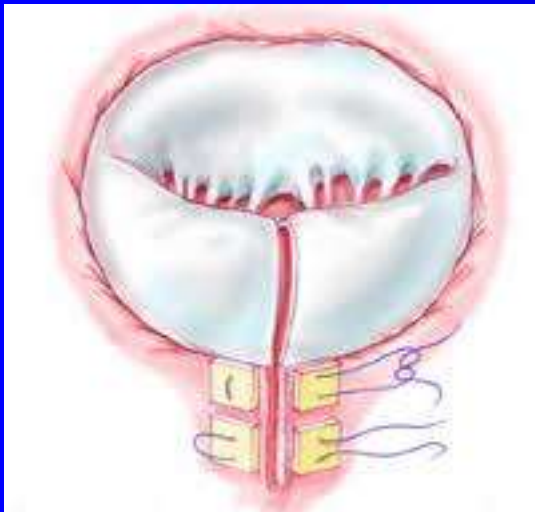
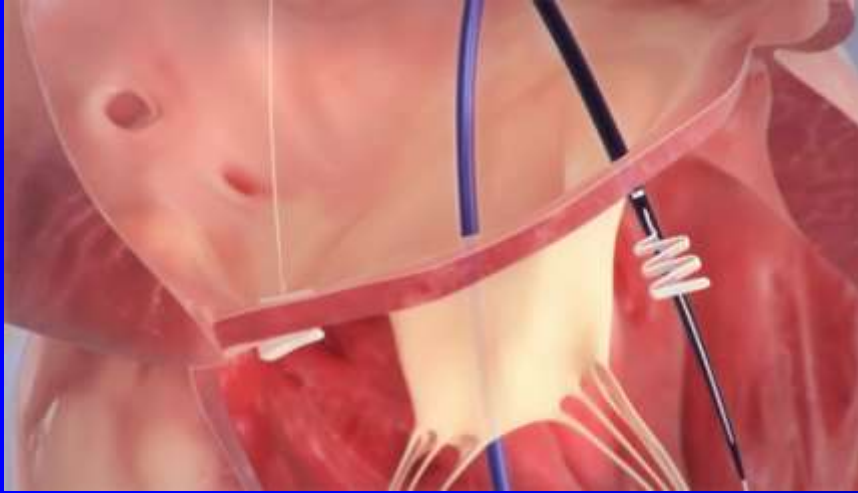
High recurrent rate of MR without mitral ring



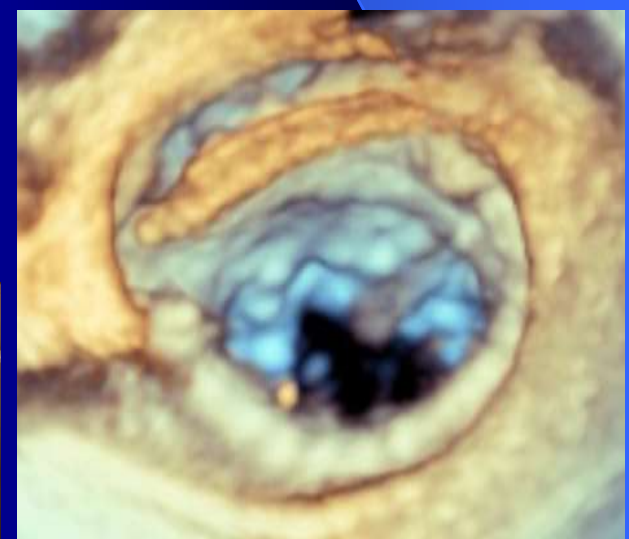
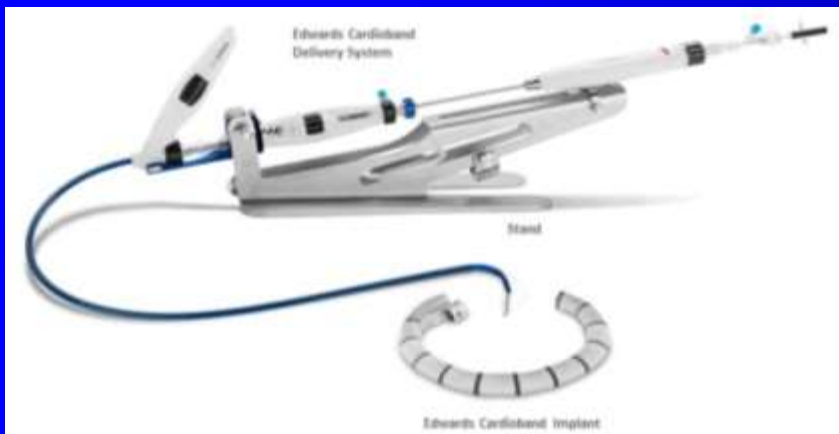
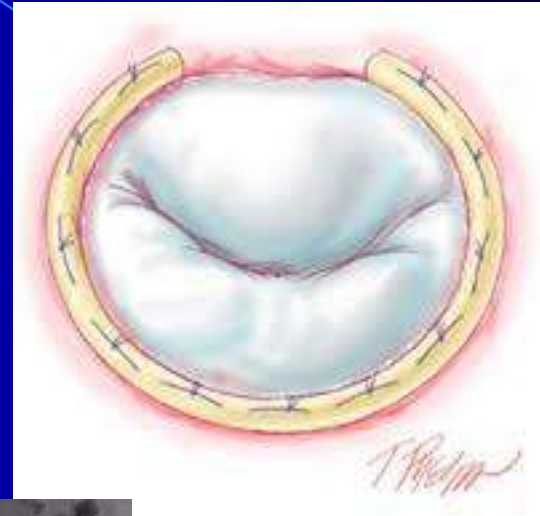
Plication of Annulus Mitralign System



Plication of Annulus Mitralign System



Annuloplasty Band Edwards Cardioband System



Annuloplasty Ring Millipede System

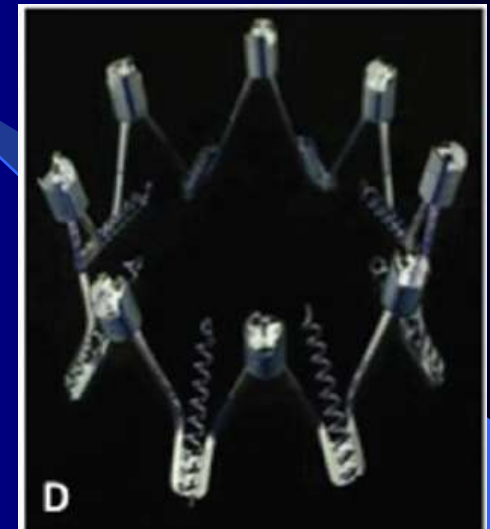
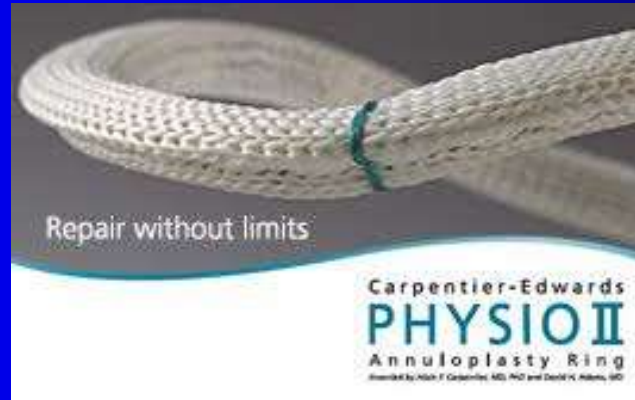
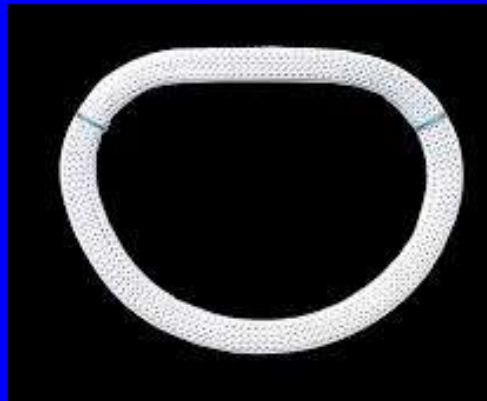


TABLE 1. MITRAL REPAIR TECHNOLOGIES AND REGULATORY STATUS*

Device	Manufacturer	Investigational?	CE Mark Approved?	FDA Approved?
AccuCinch	Ancora Heart, Inc.	Yes	No	No
Amend mitral valve repair annuloplasty ring	Valcare Medical	Yes	No	No
Arto system	MVRx, Inc.	Yes	No	No
Cardioband	Edwards Lifesciences	—	Yes	No
Carillon mitral contour system	Cardiac Dimensions, Inc.	—	Yes	No
Iris complete annuloplasty ring	Millipede, Inc.	Yes	No	No
MitraClip	Abbott Vascular	—	Yes	Yes
Mitralign	Mitralign, Inc.	—	Yes	No
NeoChord DS1000	NeoChord, Inc.	—	Yes	No
PASCAL mitral valve repair system	Edwards Lifesciences	Yes	No	No
TSD-5 device	Harpoon Medical, Inc.	Yes	No	No
VenTouch system	Mardil Medical	Yes	No	No

*As of July 2017.

Abbreviation: FDA, US Food and Drug Administration.

Ongoing Clinical Trials – MV Repair

Study	Device	Type of MR	N. of patient	Country	Year of completion
COAPT	MitraClip	Functional MR	610		2024
Randomized trial	NeoChord (vs surgical repair)	Degenerative MR	585	US	2023
MITRACHORD	NeoChord	Degenerative MR	194	EU	2019
SCOUT	Mitralign system	Functional MR			
ALIGN	Mitralign	50	30	EU	2017
REPAIR	Cardioband system	Functional MR	50	EU	2019
ACTIVE (Randomized)	Edwards Cardioband (vs medical Tx)	Functional MR	375	US	2023
Safety study	Amend annuloplasty ring	MR	40	EU	2018
Safety study	Millipede IRIS	MR	10	EU	2017
CLASP	Edwards PACAL	MR	130	Multi-	2021

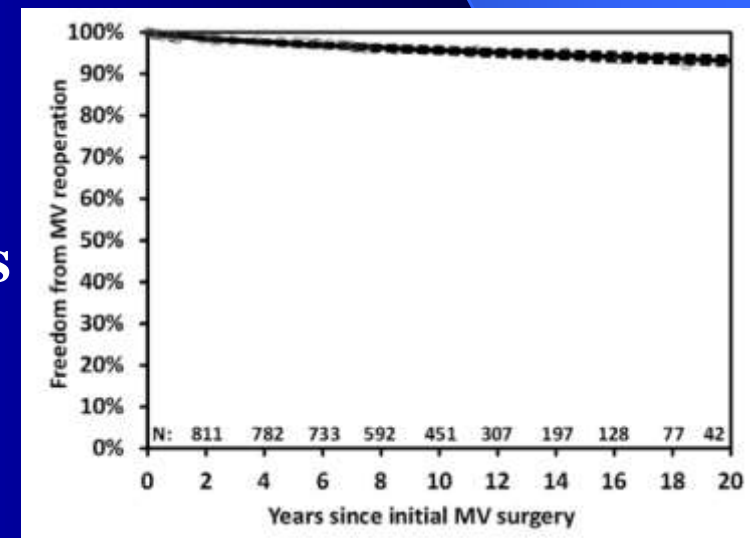
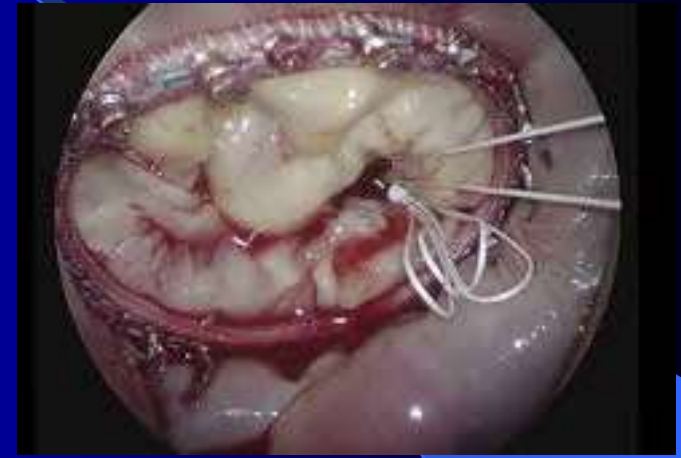
Future Perspective in 5 Years

- **Edge-to-edge repair remains the main technology for percutaneous MV intervention given the low risk procedure. But it will be offered only in high-risk MR patients.**
- **Transcatheter chordal replacement could be an initial therapy in selected patients with degenerative MR.**
- **Percutaneous mitral annulus plication or annuloplasty could be a reasonable choice in the treatment of MR secondary to annulus dilation in high risk patients.**
- **Development of combined procedures, such as Edge-to-edge or chordal replacement + annuloplasty/plication, is expected, which would provide better long-term outcomes.**
- **Randomized clinical trials are needed.**

Catheter-base therapy will not replace surgical repair in 10 years!

Surgical repair techniques

- various types of leaflet resection
- suture leaflet repair
- leaflet enlargement
- decalcification of leaflet or MAC
- chordal replacement
- chordal transfer
- sliding and plication of mitral annulus
- various types of mitral rings/bands



Transcatheter MVR



TMVR First in Human Experience

12 cases
Feasibility Trial
pending



Edwards CardiAQ
June 2012

24 cases
Feasibility Trial
CE Mark Trial



Neovasc Tiara
Jan 2014

38 cases
Pivotal Trial



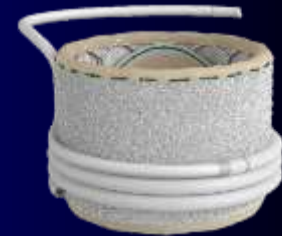
Medtronic Intrepid
Nov 2014

5 cases
Feasibility Trial



Highlife
Feb 2016

>10 cases



Edwards M3
Aug 2017

Abbott Tendyne
Feb 2013



>50 cases
Feasibility Trial
completed
EU CE Mark Trial

Edwards Fortis
Feb 2014



23 cases
Program
Discontinued

NaviGate
Oct 2015



Caisson
June 2016



< 10 cases
Feasibility Trial

Early Clinical Outcomes

TABLE 3 TMVR System Preliminary Clinical, Procedural, and Follow-Up Features

	CardiaQ-Edwards (N = 13)	Intrepid TMVR (N = 27)	Fortis* (N = 13)	Neovasc Tiara (N = 19)	Tendyne† (N = 30)	Caisson (N = 5)	HighLife (N = 6)
Procedural and 30-day data							
Technical success	12/13 (92.3)	24/26 (92.3)‡	10/13 (76.9)	16/19 (84.2)	28/30 (93.3)	4/5 (80.0)	5/6 (83.3)
Valve dislocation/embolization	NA	NA	2/15 (15.4)	3/19 (15.8)	0/30 (0.0)	0/5 (0.0)	0/5 (0.0)
Conversion to open-heart surgery	NA	NA	2/15 (15.4)	3/19 (15.8)	0/30 (0.0)	0/5 (0.0)	1/6 (16.7)
Post-procedural ≥ moderate MR	NA	0/26 (0.0)	0/9 (0.0)	NA	1/30 (3.3)	0/4 (0.0)	0/6 (0.0)
LVOT obstruction	NA	0/26 (0.0)	0/9 (0.0)	0/19 (0.0)	1/30 (3.3)	0/4 (0.0)	0/6 (0.0)
Procedural mortality	2/13 (15.4)	4/27 (14.8)	4/13 (30.8)§	0/19 (0.0)	0/30 (0.0)	0/5 (0.0)	1/6 (16.7)
30-day moderate or severe MR	NA	NA	NA	NA	0/26 (0.0)¶	0/3 (0.0)	0/4 (0.0)
All-cause 30-day mortality	7/13 (53.8)	6/25 (24.0)	5/13 (38.5)	3/19 (15.8)	1/30 (3.3)	1/4 (25.0)	2/6 (33.3)
Follow-up							
Follow-up, months	NA	8.1 (0-20.7)	6 (1-15)	NA	NA¶	3.4 (3-4)	4.1 (3-6)
MR ≥ moderate	NA	0/24 (0.0)	0/8 (0.0)	0/14 (0.0)	0/5 (0.0)	0/4 (0.0)	0/4 (0.0)
NYHA functional class ≥III	NA	2/18 (11.1)	2/8 (25.0)	NA	NA	0/3 (0.0)	0/4 (0.0)
Mortality	7/13 (53.8)	7/27 (25.9)	6/13 (46.2)	3/19 (15.8)	0/5 (0.0)	1/4 (25.0)	2/6 (33.3)

Challenges

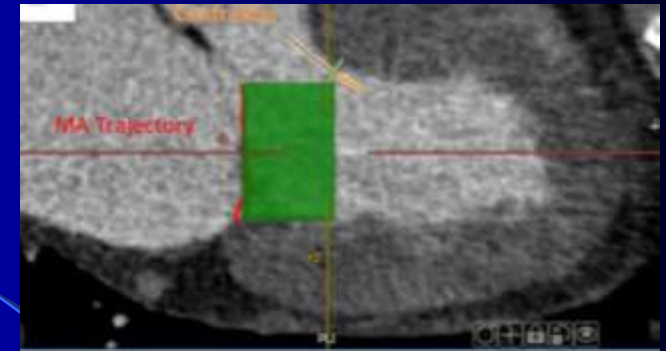
**Targeting different disease
and etiology**

Delivery (transapical, transseptal)

Complexity of implantation

**Anchoring (instability, migration,
embolization)**

Sealing (PVL)



LVOT obstruction

Valve thrombosis

Valve performance

**Stent
fatigue/fracture**

Durability

Future Perspectives in 5-10 Years

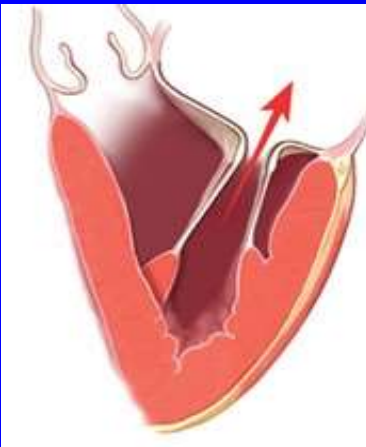
Catheter-based Therapy

Surgery

TMVR

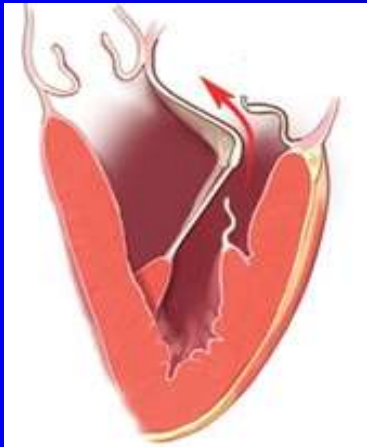
high risk

high risk



Type I
Normal leaflet motion

LEAFLET PERFORATION
ANNULAR DILATION



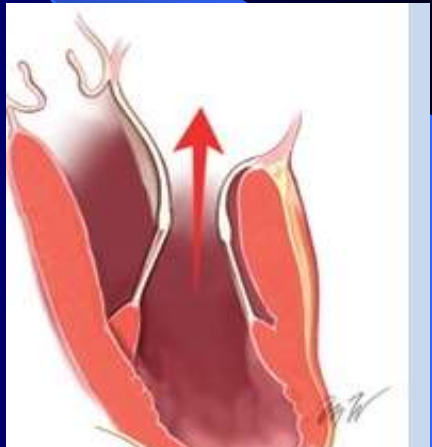
Type II
Increased leaflet motion

CORDAL ELONGATION OR RUPTURE



Type IIIa
Restricted leaflet motion (systole and diastole)

RHEUMATIC DISEASE



Type IIIb
Restricted leaflet motion (systole)

ISCHEMIC OR NONISCHEMIC LV REMODELING

Interdisciplinary Rounds

Decision-making

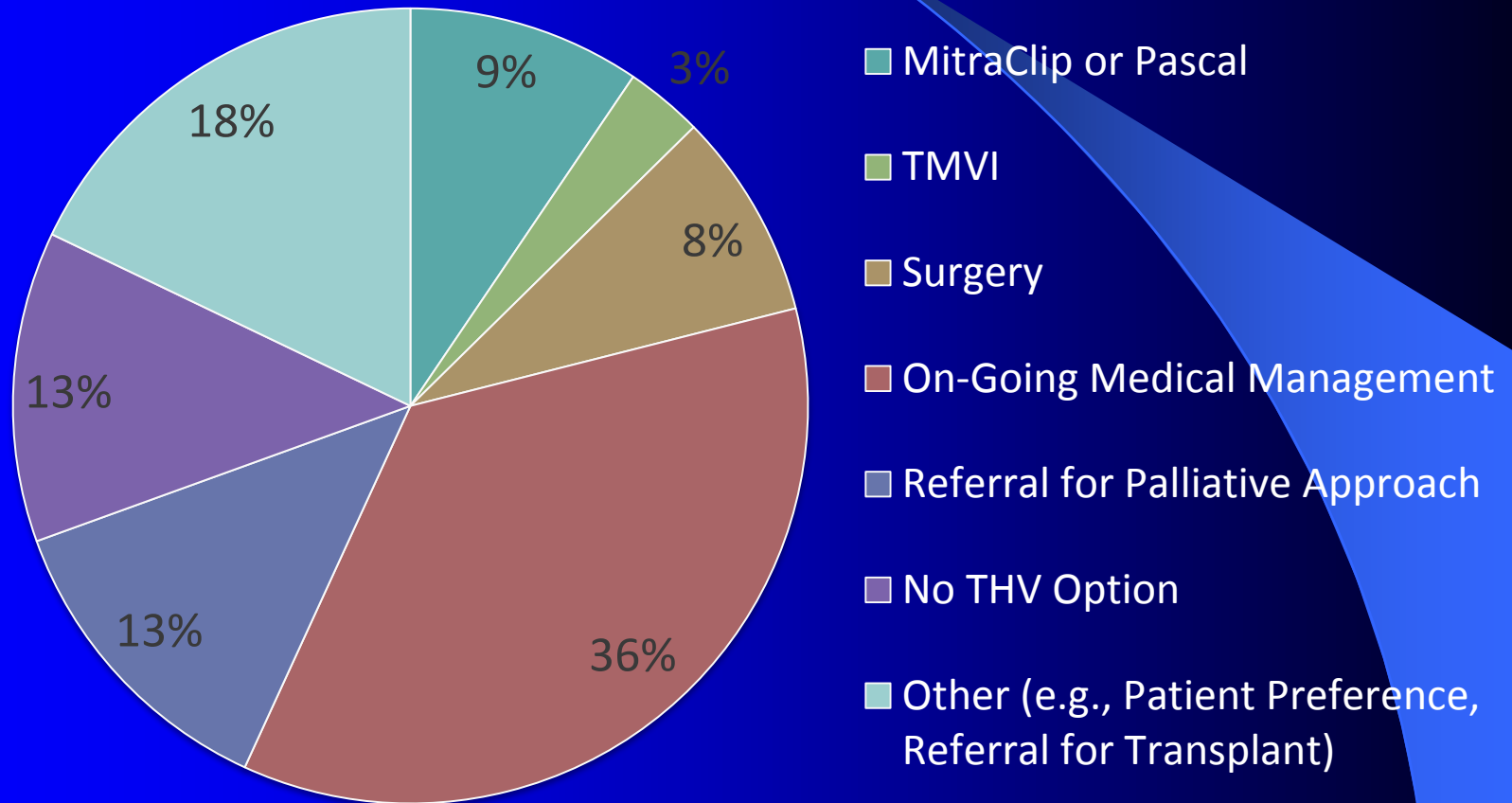
- Interventional cardiologists
- Cardiac surgeons (**Valve repair surgeon**)
- Echocardiologist
- Radiologist
- Anesthetist
- THV nurses
- Other specialists



Centre for
Heart Valve Innovation
St. Paul's Hospital, Vancouver

Treatment Decision (%)

2016 (Jan – Oct, 110 patients)



THANKS!