

The Technical Aspect

Surgery better than Clipping?

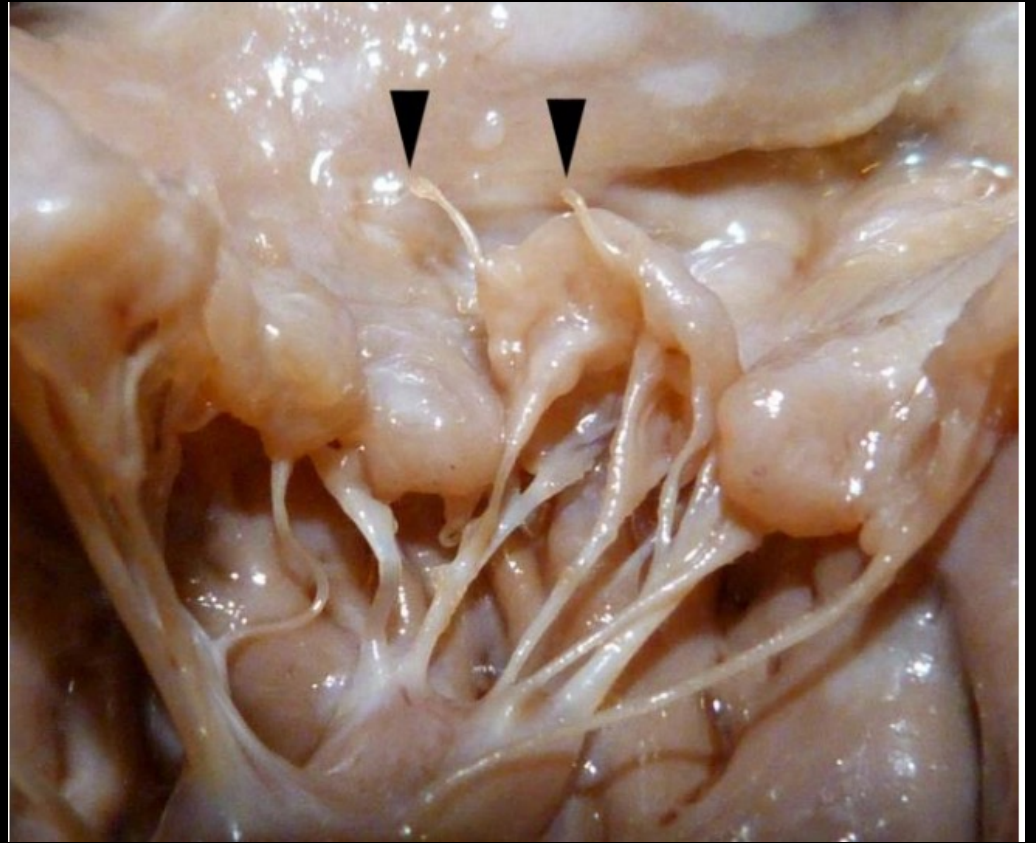
Tom C. Nguyen, MD
Chief Medical Executive | Miami Cardiac and Vascular Institute
Director of Minimally Invasive Valve Surgery
Barry Katzen Endowed Chair of Surgery

  @tomcnguyen



Disclosures

- Edwards Lifesciences
- Abbott
- LivaNova
- Medtronic

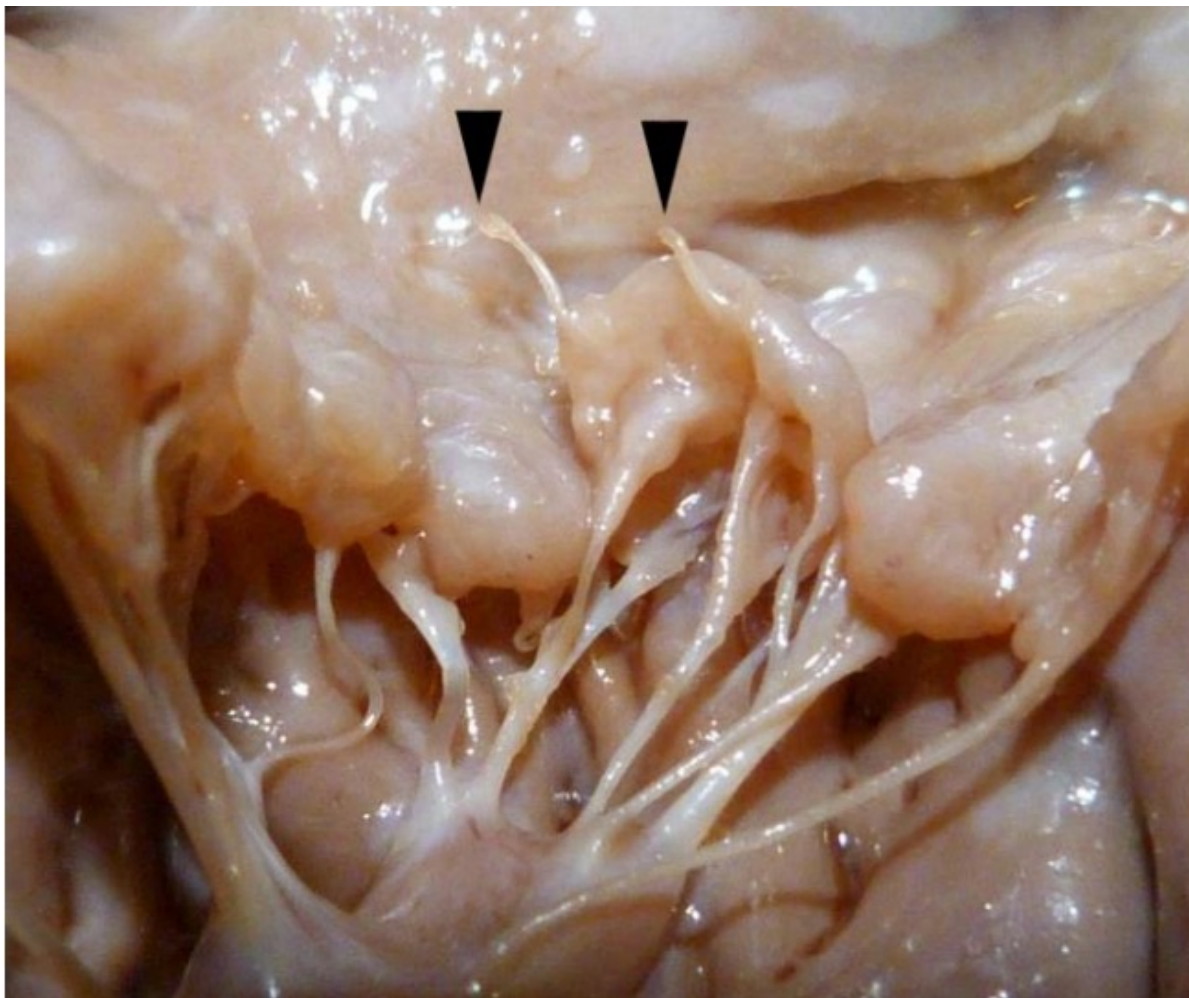




**Comparative
history of the**

**Mitral Valve
&
MitraClip**

QUIZ:



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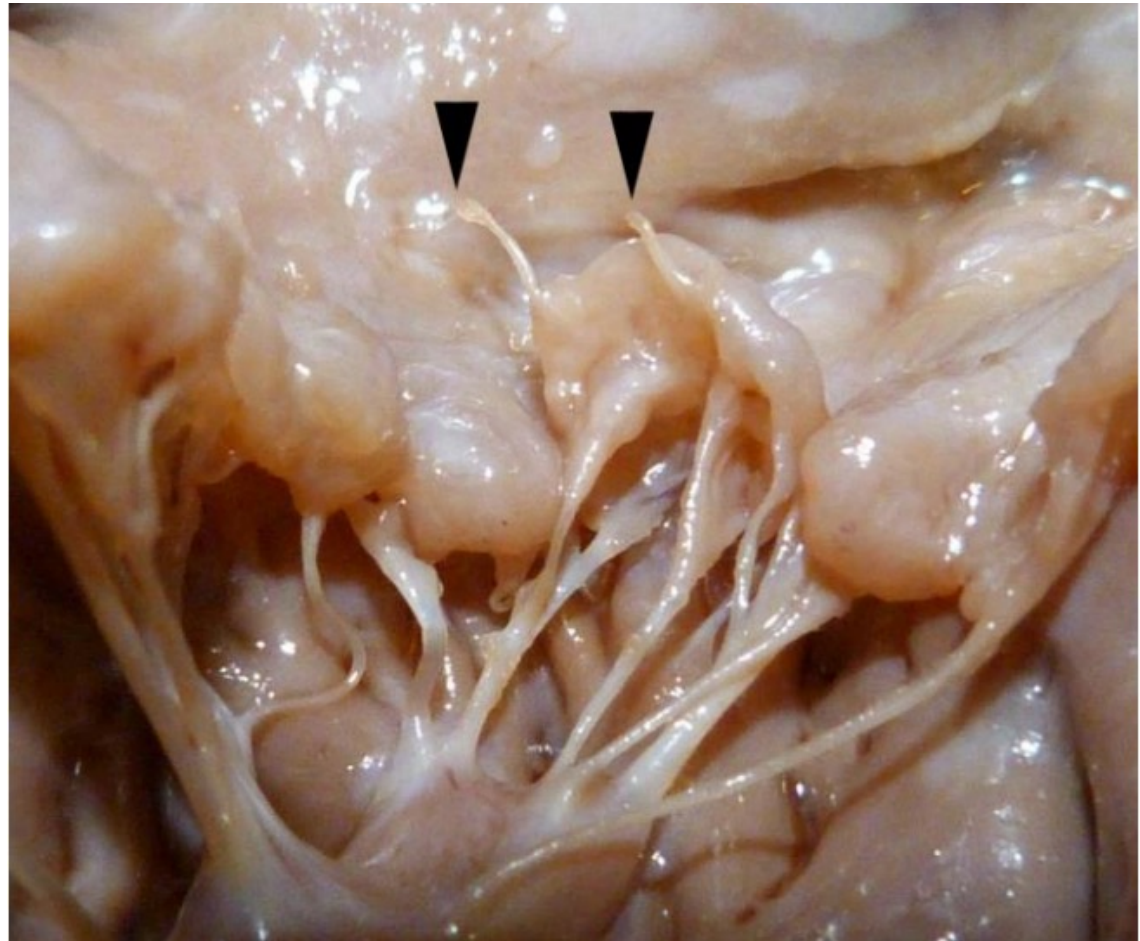
A) Human

B) Swine

C) Dog



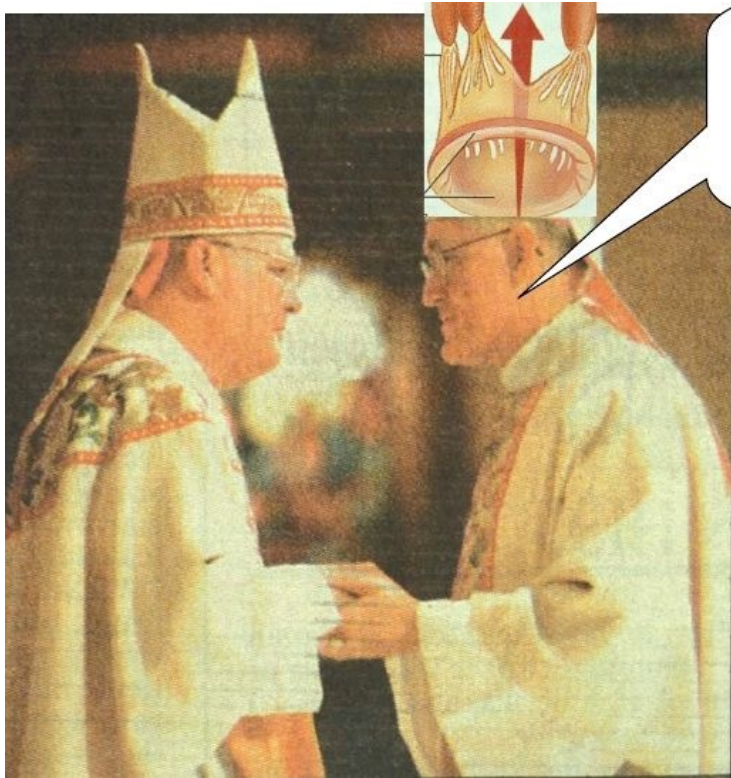
D) Monkey



GOALS

1. The mitral valve is incredibly complex and unique (compared to other valves)
2. Deep Dive Known and Unknowns: Mitral surgery vs. Clip

The Known



Did you hear?
They named a
heart valve after
our mitres!

1. Namesake: Bishop's miter



The Known

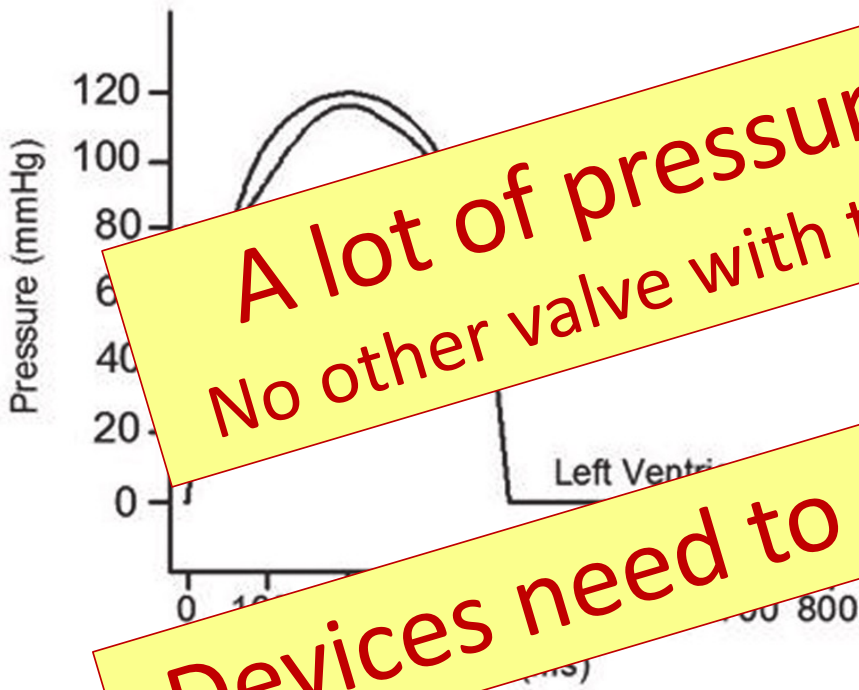
1. Namesake: Bishop's miter

2. Opens/Closes 3 billion times



The Known

1. Namesake: Ptolemy's miter



A lot of pressure for one valve...
No other valve with this level of responsibility

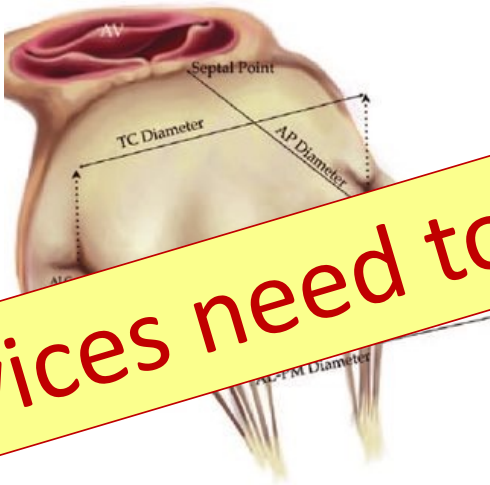
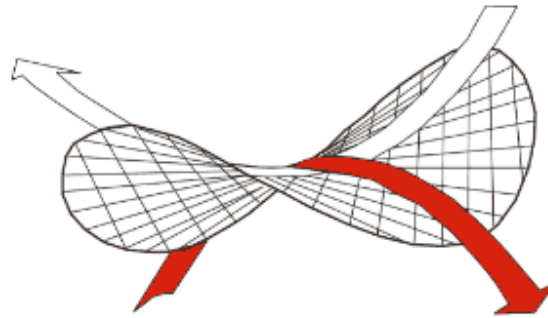
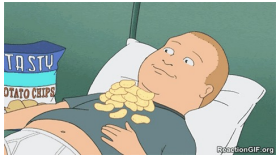
2. Pressure rises 3 billion times

3. Pressure (115 mmHg. (115 mmHg. 3 billion times/life)

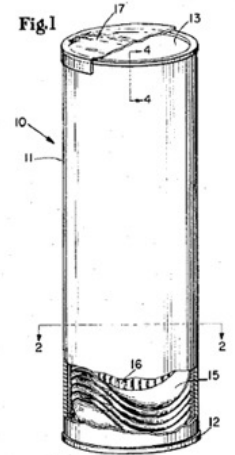
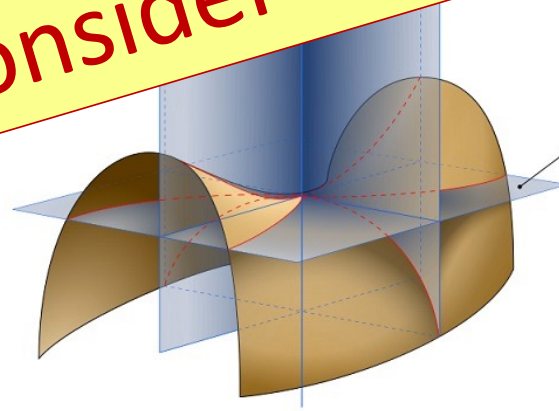
Devices need to consider this complexity...

The Unknowns

- Why is the mitral annulus saddle shape while other valves more circular?
- Why does the MV have chordae? What are the roles of the chordae? What dictates the location of the chordae?
- How does the MV really close? How does it withstand closing forces over a lifetime? It's a high pressure closure valve, not a high pressure opening valve.
- Why is the AML 2/3 longer than the PML? Why are there 3 cusps?
- Annulus is not rigid but "dynamic" (area changes 20-40% throughout the cardiac cycle)
- It's relatively easy to block the aortic outflow (e.g. long AML, small LV, septal hypertrophy)
- Annulus is much larger than the AV. Why?
- MR is not one disease



planes
of principal
curvatures



Devices need to consider this complexity...

Hyperbolic paraboloid
Double curvature

Prevents lines of stress
Thin yet surprisingly strong

Ability to withstand force
and not crack/break

The Unknowns/Complex MV

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TAVR



*Annulus Size,
Leaflet Calcification*

VS.

TMVR



*Annulus Size, Shape, Excursion,
Leaflet Size, Thickness, Tenting
Sub-valvular Apparatus
Circumflex Coronary Artery
LV Size, Geometry, Function
Risk of SAM
Dynamic environment*

TAVR

VS.

TMVR

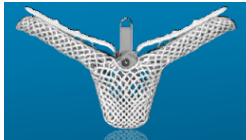


The cockpit of the Endeavour Space Shuttle

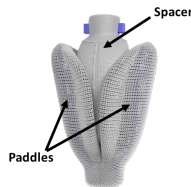
Transcatheter Mitral Landscape - 2019

Repair

Replacement



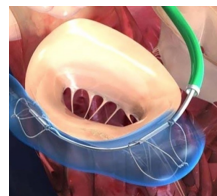
MitraClip



Pascal



Cardioband



Carillon



Millipede



Braile Biomedica



Braile Biomedica



CardiaQ 1st G



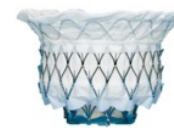
CardiaQ Edwards



Cephea



Direct Flow Medical



Twelve Medtronic



M-Valve



Edwards Fortis



HighLife



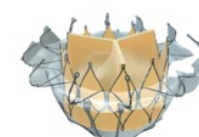
Navigate



Neovasc Tiara



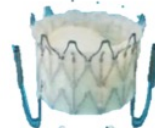
PermaValve MID



Sinomed



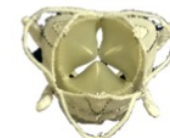
Tendyne Abbott



SATURN TMVR



Mitraltch



Caisson



Sapien M3 Edwards

MitraClip (know the data)



VS



MitraClip (know the data)

1997 – MitraClip Patent Submitted

MitraClip (know the data)

1997 – MitraClip Patent Submitted



Juan Umana (Colombia)



Mehmet Oz (USA)



(19) United States

(12) **Patent Application Publication** (10) **Pub. No.:** US 2004/0199183 A1
Oz et al. (43) **Pub. Date:** Oct. 7, 2004

(54) METHOD AND APPARATUS FOR CIRCULATORY VALVE REPAIR

(76) Inventors: **Mehmet C. Oz**, Cliffside Park, NJ (US); **Gerald M. Lemole**, Huntingdon Valley, PA (US); **Alan Lotvin**, Upper Saddle River, NJ (US); **Juan P. Umana**, New York, NY (US); **William Allen**, Stratford, CT (US); **Howard R. Levin**, Teaneck, NJ (US)

09/747,558, filed on Dec. 23, 2000, which is a continuation of application No. 09/254,111, filed on Feb. 25, 1999, now Pat. No. 6,269,819, filed as 371 of international application No. PCT/US98/13240, filed on Jun. 25, 1998.

(60) Provisional application No. 60/051,078, filed on Jun. 27, 1997.

Publication Classification

(51) **Int. Cl.⁷** A61B 17/128; A61F 2/24
(52) **U.S. Cl.** 606/142; 623/904; 128/898

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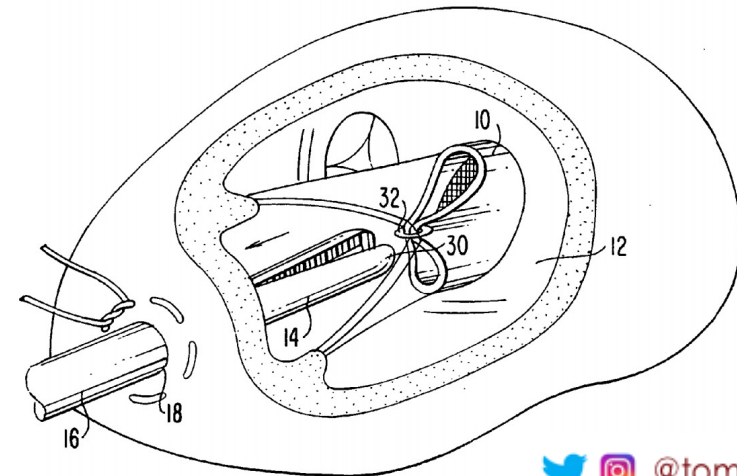
(57) ABSTRACT

(21) Appl. No.: 10/833,659
(22) Filed: Apr. 28, 2004

Related U.S. Application Data

(60) Division of application No. 09/950,163, filed on Oct. 15, 2002, which is a continuation of application No.

An apparatus for the repair of a cardiovascular valve has leaflets comprising a grasper capable of grabbing and co-opting the leaflets of the valve. In a preferred embodiment the grasper has jaws that grasp and immobilize the leaflets, and then a fastener is inserted to co-opt the leaflets. The apparatus is particularly useful for repairing mitral valves to cure mitral regurgitation.



MitraClip (know the data)

1997 – MitraClip Patent Submitted

2003 – MitraClip First in man

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2005 – EVEREST Phase I Clinical Trial

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- 27 patients
- 18 patients free from surgery at 6 months... 9 pts (33%) required surgery
- Follow-up only 6 months
- 64% of patients discharged had $\leq 2+$ MR... 36% pts w 3-4+ MR

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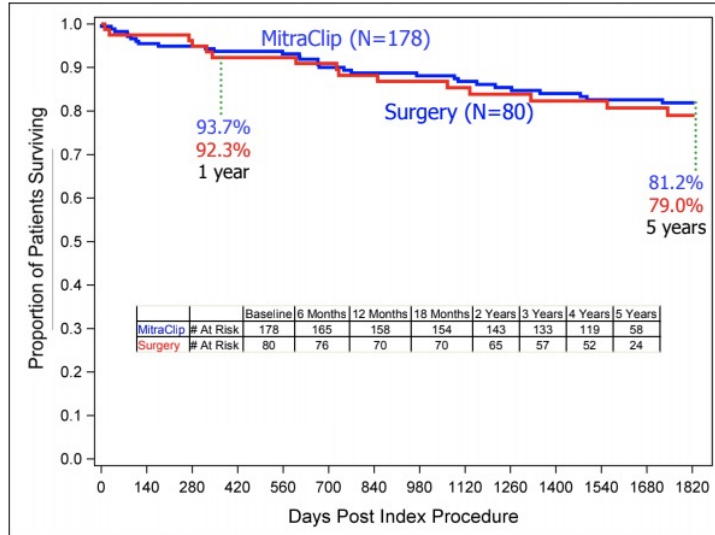
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Kaplan-Meier Freedom From Mortality
EVEREST II RCT



- RCT MitraClip (n=154) v Surgery (n=56)
- 27% prior surgery
- Study included FMR and DMR
- MR 3-4+ at 5y:
MitraClip (12.3%) v Surgery 1.8%
- Mortality: Same 20.8% and 26.6%
- Conclusion: Surgery more effective at reducing MR, but MitraClip comparable to surgery with improvement in remodeling
- Only RCT comparing MitraClip v surgery

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2018 – COAPT

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2018 – COAPT

- Moderate-Severe MR
- **100 sites**, 610 patients
- MitraClip v medical therapy in prohibitive risk patients
- STS > 8%
- Highly selective group: 63% pts excluded
- 61% required more than 1 clip
- Mean EF 31%, LVEDV 101

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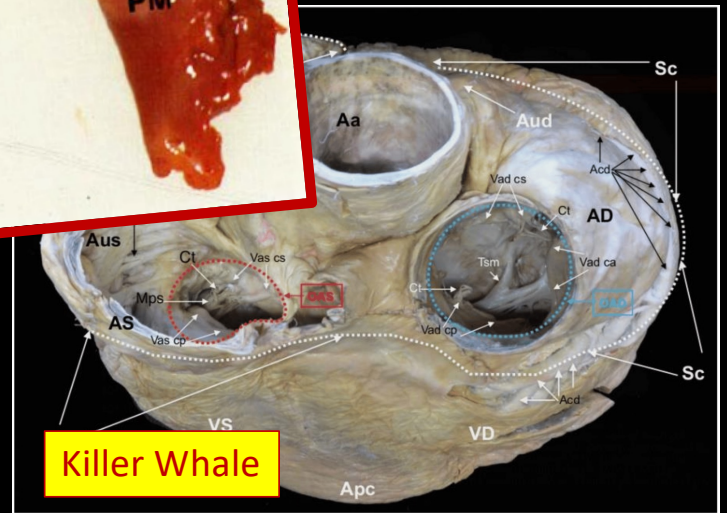
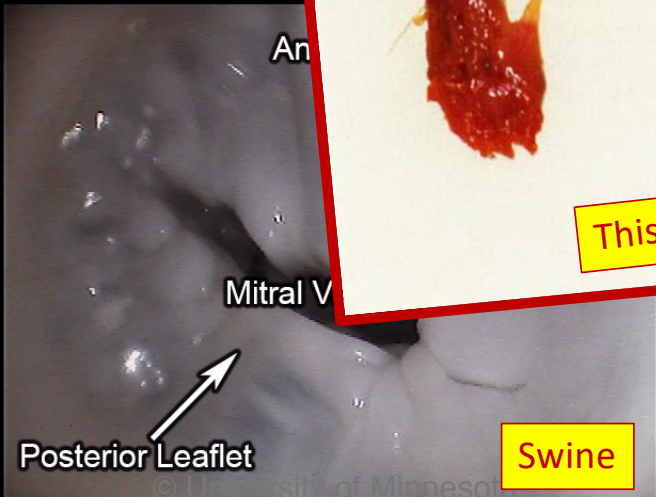
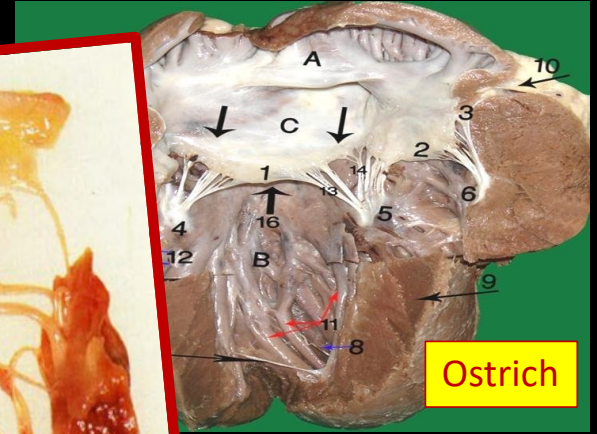
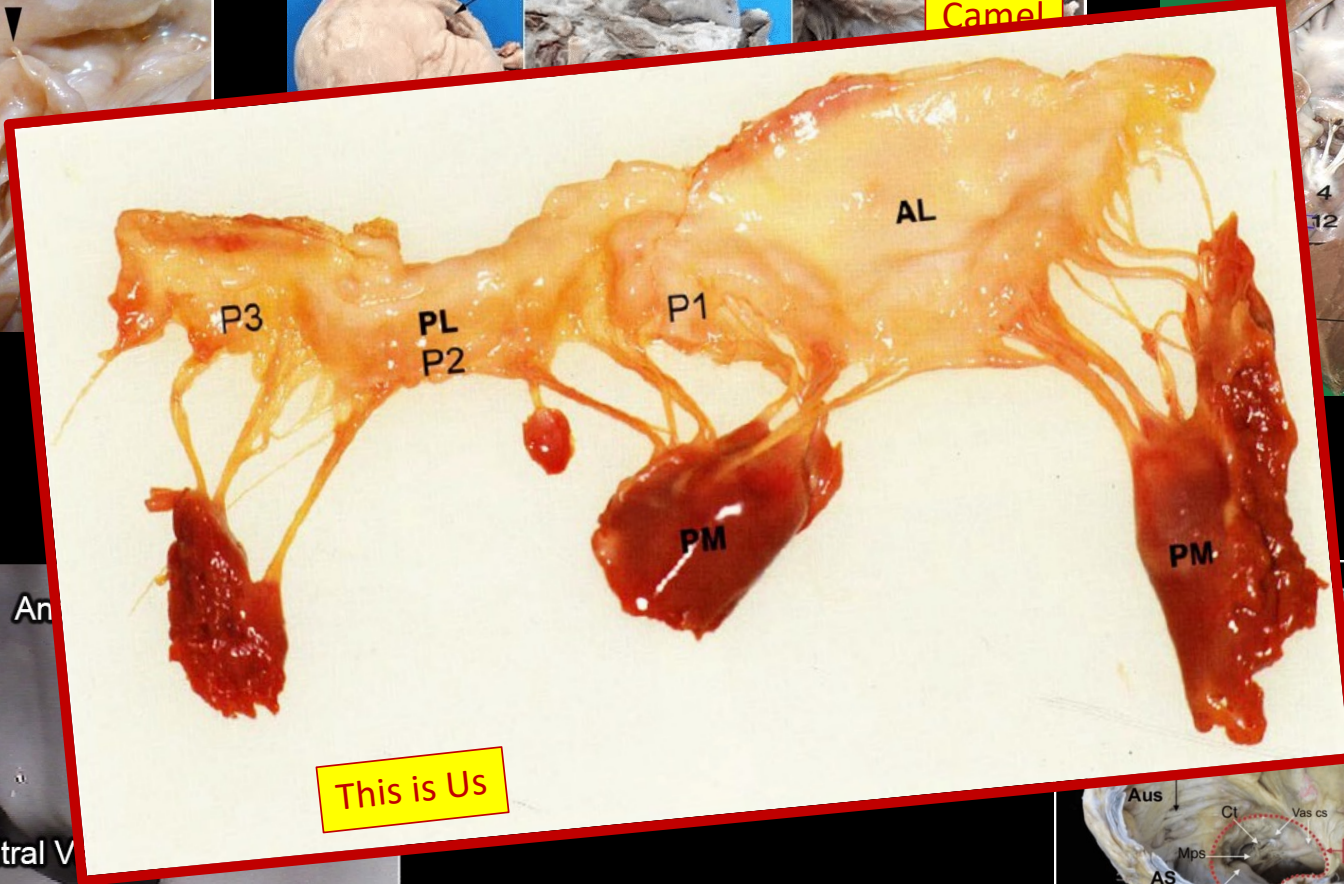
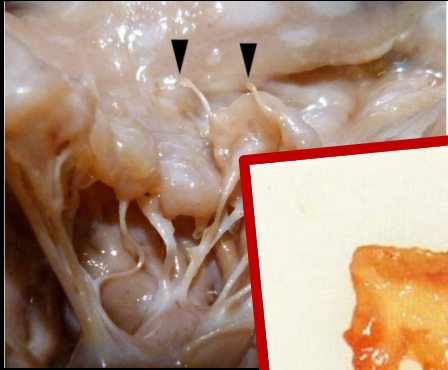
2018 – COAPT

2018 – Mitra-FR

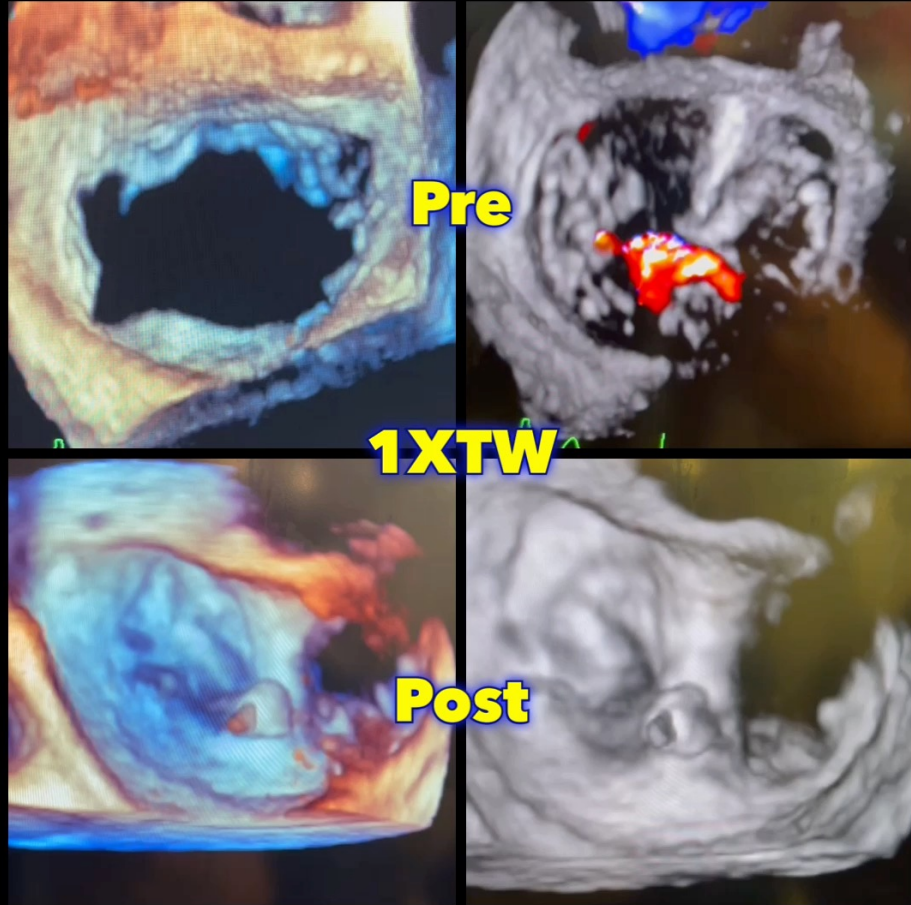
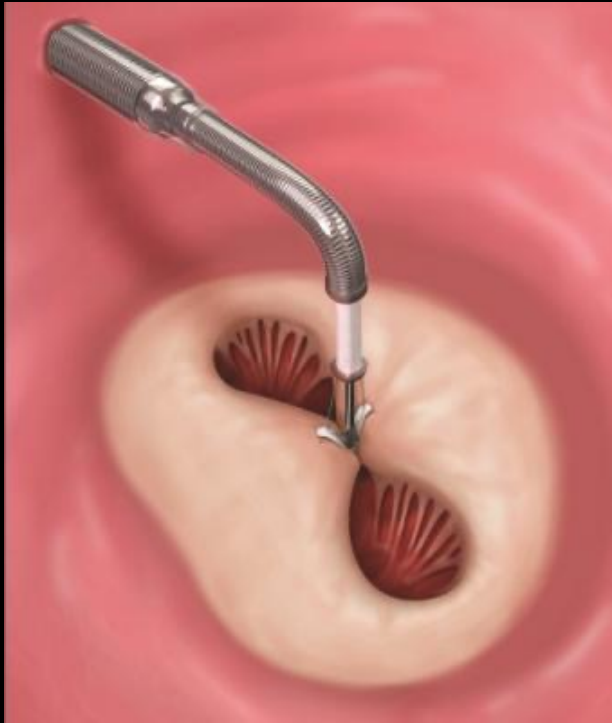
- Severe MR
- 37 sites, 304 patients
- MitraClip v medical therapy in high risk patients
- Funded by French government
- No difference in death/rehosp at 12mo
- 32% patients excluded
- Mean EF 33%, LVEDV 135

**Comparative
history of the**

**Mitral Valve
&
MitraClip**



© University of Minnesota

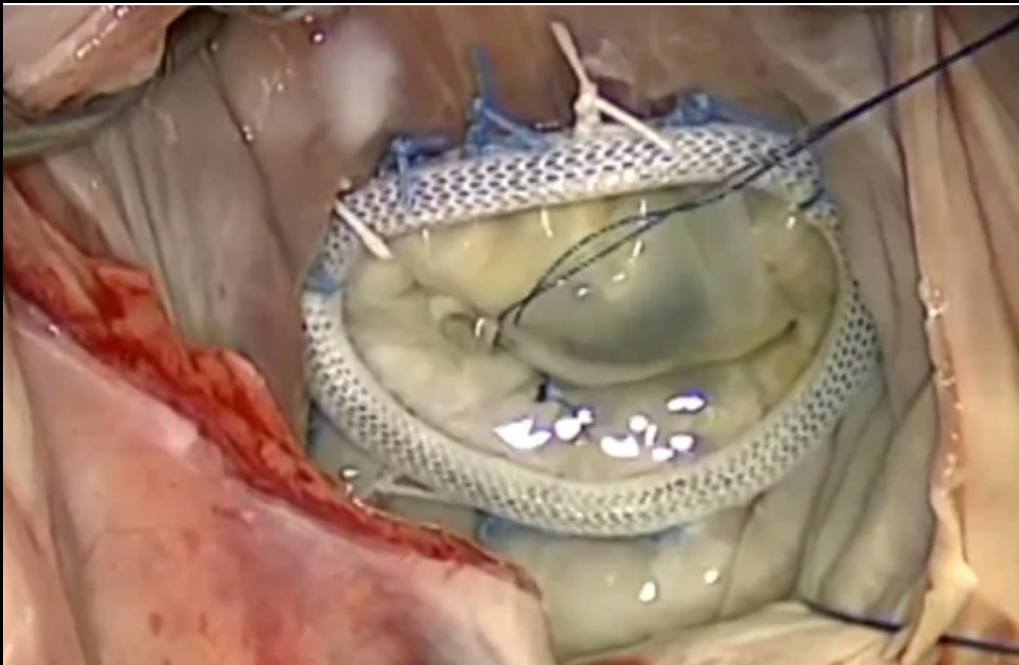


Pre

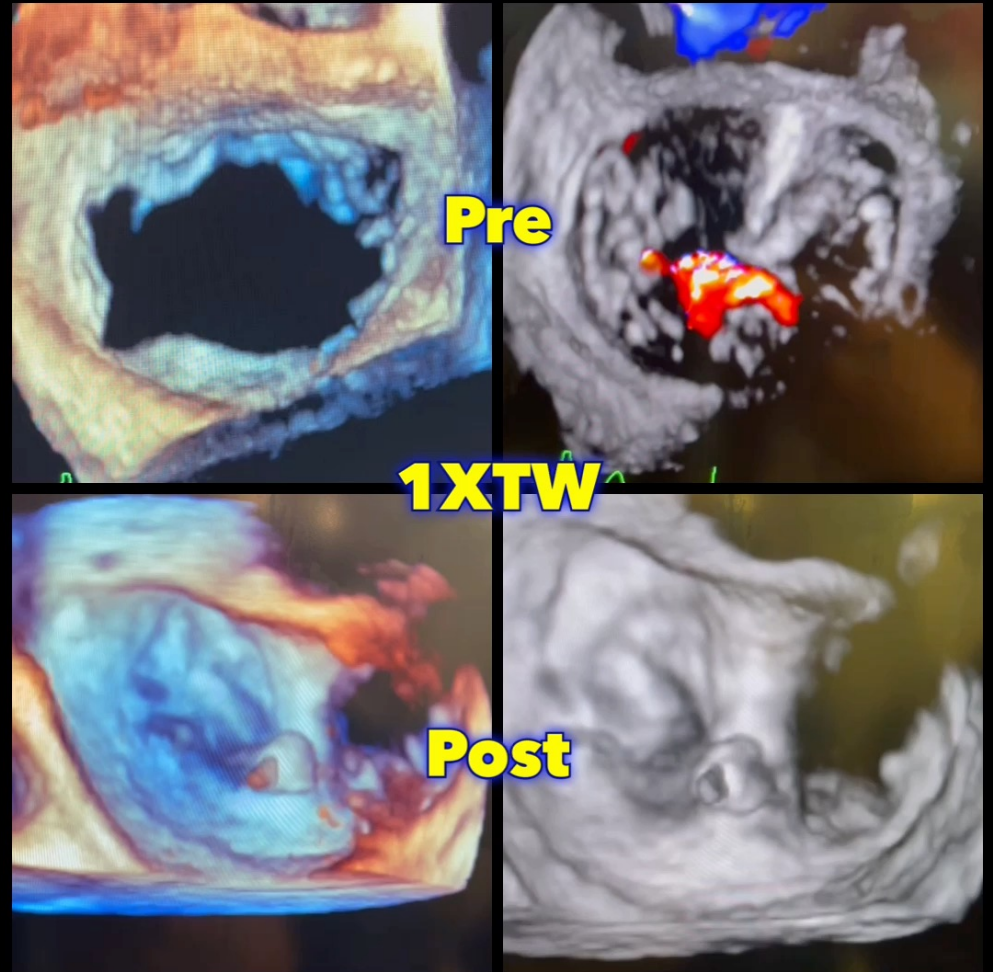
1XTW

Post

Maintain Form and Function



Surgical repair



MitraClip

Conclusion = Questions

1. Is surgery vs. clip better in intermediate risk patients?
2. Is clip better than replacement in low-risk patients at INEXPERIENCED centers?
3. Because of the price of clip (and TAVR), can we ever really ever have a balanced study comparing surgery vs. clip when we have to rely on industry for trials?

Thank you



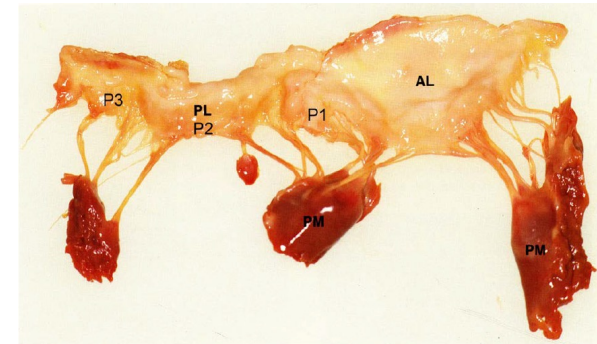
Circa October 2021



September 23, 2022



Circa 5 months ago



Circa 55 million years ago

What % of clips at your center is being performed on low intermediate risk patients?

Know the limitations

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- Only RCT comparing MitraClip v Surgery is EVEREST II in high-risk patients (7+ RCT comparing TAVR v Surgery)
- Despite TAVR and MitraClip starting around the same time (i.e. 1995 and 1997), paucity of RCT for MitraClip
- Longest follow-up from RCT is 5y from EVEREST II
- EVEREST II did not randomize to mitral valve repair. Surgery included both mitral repair and replacement. Two different populations.
- EVEREST II: Mean number of MitraClips per center = 5; Mean number of surgery per center = 2.5. Low-volume mitral surgeon?

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Important as we consider MitraClip in younger patients

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