Mitral Regurgitation: Transcatheter Repair

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Valvular Heart Disease
Factors Contributing to Changing Etiology

Rheumatic fever
Syphilis
Life expectancy
Prosthetic valves
Cardiomyopathy
Hemodialysis
Transplantation
Technology
New diseases

Time

Mitral Regurgitation
Most Common Etiologies

**Functional Mitral Regurgitation**
- Dilated Cardiomyopathy
  - ischemic cardiomyopathy
  - non-ischemic cardiomyopathy

**Organic (Degenerative) Mitral Regurgitation**
- floppy mitral valve/mitral valve prolapse

### Mechanisms of Functional Mitral Regurgitation in Dilated Cardiomyopathy

<table>
<thead>
<tr>
<th>Normal left ventricle, left atrium and mitral valve</th>
<th>Cardiomyopathy: left ventricular and left atrial enlargement with mitral regurgitation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Papillary muscle function, orientation</td>
</tr>
<tr>
<td></td>
<td>• Changes in LV geometry</td>
</tr>
<tr>
<td></td>
<td>• Annular dilation?</td>
</tr>
</tbody>
</table>

Functional Mitral Regurgitation (FMR) Natural History - Survival


Mitral Regurgitation Due To Floppy Mitral Valve/Mitral Valve Prolapse (FMV/MVP)

<table>
<thead>
<tr>
<th>Normal Mitral Valve</th>
<th>FMV/MVP</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Normal Mitral Valve Image" /></td>
<td><img src="image2" alt="FMV/MVP Image" /></td>
</tr>
</tbody>
</table>

**Floppy Mitral Valve/ Mitral Valve Prolapse (FMV/MVP)**

- Prevalence is 2-3%.
- At least 2 forms of inheritance:
  - autosomal dominant with variable degree of penetration (most common)
  - chromosome X
- Collagen dissolution and pars fibrosa disruption of mitral valve leaflets.
- Leaflets replaced with loose myxomatous connective tissue.
- Similar histologic abnormalities may be seen in chordae tendineae.

**Organic (Degenerative) Mitral Regurgitation**

Survival Based on New York Heart Association Class

![Survival Graph](image)

Ling LJ, et al. NEJM.1996;335:1417-23
Organic (Degenerative) Mitral Regurgitation Survival Based on Left Ventricular Ejection Fraction (EF)

Survival (%)

Years After Diagnosis

EF > 60%
P = 0.034

EF < 60%


TRANSCATHERETER DEVICES FOR MITRAL REGURGITATION

<table>
<thead>
<tr>
<th>Anatomic Target</th>
<th>Device Name</th>
<th>Manufacturer</th>
<th>Development Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leaflets</td>
<td>MitralClip</td>
<td>Abbott</td>
<td>CE Mark/FDA Approved</td>
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<td></td>
<td>Mitra-Spacer</td>
<td>Cardiovascular Inc</td>
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<td>Middle Peak Medical</td>
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<tr>
<td>Annulus</td>
<td>Direct</td>
<td>Mitralign Inc</td>
<td>Clinical Trial</td>
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<td>Guided Delivery Systems</td>
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<td></td>
<td>Millipede System</td>
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<td></td>
<td>Bus RF Catheter</td>
<td>QuannonCor Inc</td>
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<td>TARA</td>
<td>Mitralign Inc</td>
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<tr>
<td>Indirect</td>
<td>Carilign</td>
<td>Cardio Dimensions Inc</td>
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<td>Kardian MIN</td>
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<td>LV Remodeling</td>
<td>Mitral Loop Circles</td>
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<td>Myocor Inc</td>
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<td>CardAQ</td>
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<td>Trim</td>
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<tr>
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<td>Clinical Trial</td>
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<tr>
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Mitral Regurgitation
Mitral Leaflet Repair - MitraClip

Chest radiograph showing two mitraclips projecting over the heart.

Author: Hellerhoff (CC BY-SA 3.0)
**MitraClip Versus Surgery for Functional or Organic Mitral Regurgitation**

**EVEREST II Randomized Trial**

- Multicenter study that randomized patients with moderate-to-severe (3+) or severe (4+) mitral regurgitation to transcatheter MitraClip versus surgical repair/replacement of the mitral valve.

- 27% functional and 73% organic (degenerative) mitral regurgitation.

---

**Short Term Results**

- 3+ or 4+ mitral regurgitation prior to hospital discharge:
  - 23% in MitraClip group (surgery within 6 months)
  - 0% in Surgical group

- Similar 30-day mortality (~1-2%)

- Small, but statistically significant decrease in LV size (systolic and diastolic) and LV ejection fraction (~2-6%) at 1 year in both groups compared to baseline.
MitraClip Versus Surgery for Functional or Organic Mitral Regurgitation
EVEREST II Randomized Trial

4-Year Follow-up

- Decrease in LV size (systolic and diastolic) sustained at 4 years in both groups.
- Decrease in LV ejection fraction < 5% in both groups.
- Improved NYHA functional class III-IV in both groups:
  - Baseline 46% and at 4 years ~ 6%


**MitraClip Versus Surgery for Functional or Organic Mitral Regurgitation**

**EVEREST II Randomized Trial**

4-Year Follow-up

<table>
<thead>
<tr>
<th>Subgroups</th>
<th>Difference between percutaneous and surgery (%)</th>
<th>P value</th>
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<tbody>
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<td>MR</td>
<td></td>
<td>0.023</td>
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<tr>
<td>Degenerative/Organic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functional</td>
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- 95% successful implantation
- Average hospital length-of-stay 2.9 days
- ~ 90% discharged to home
- No intra-procedural deaths
  - 30-day mortality 6.3% (STS predicted peri-operative mortality 13%)


---

**MitraClip for Organic (Degenerative) Mitral Regurgitation in High Risk Patients**

**EVEREST II High Risk and REALISM Registries**

Procedural Results

- 95% successful implantation
- Average hospital length-of-stay 2.9 days
- ~ 90% discharged to home
- No intra-procedural deaths
  - 30-day mortality 6.3% (STS predicted peri-operative mortality 13%)

MitraClip for Organic (Degenerative) Mitral Regurgitation in High Risk Patients
EVEREST II High Risk and REALISM Registries

1 Year Follow-up

- Mortality 23.6%
- ~85% maintained ≤ 2+ mitral regurgitation
- Small, but statistically significant decrease LV size
- Improved NYHA functional class:
  - Baseline: 86% NYHA class III-IV
  - 1 year: 86% NYHA class I-II
- Significant reduction (73%) in hospitalizations (12 months pre- versus 12 months post-procedure)
- Improved quality-of-life


MitraClip for Organic (Degenerative) Mitral Regurgitation in High Risk Patients
EVEREST II High Risk and REALISM Registries

- 1 year survival based on post-procedure residual mitral regurgitation:
  - 80% for ≤ 1+
  - 83% for 2+
  - 52% for 3-4+

- Patients with severe mitral regurgitation at discharge had no reduction in rate of hospitalizations related to heart failure.

Survival in High Risk Patients with Mitral Regurgitation
EVEREST II High Risk Prospective Study

1 Year Follow-up

%  
\[ \begin{array}{cc}
\text{MitraClip} & 75.4 \\
\text{No MitraClip} & 55.3 \\
\end{array} \]

\[ p<0.05 \]

\[ n=14 \]
59% functional
41% organic

Data from EVEREST II High Risk Study. J Am Coll Cardiol. 2012;59:130-9 used to construct slide.

FDA Approved MitraClip for Organic (Degenerative) Mitral Regurgitation

- Transcatheter reduction of significant symptomatic mitral regurgitation (≥ 3+) due to organic (degenerative) mitral regurgitation in patients determined to be at prohibitive risk for mitral valve surgery.
- Prohibitive risk includes ≥ 1 of the following:
  - STS ≥ 8% for mitral valve replacement or ≥ 6% for mitral valve repair
  - Porcelain aorta
  - Frailty
  - Hostile chest
  - Severe liver disease
  - Severe pulmonary hypertension
  - Other
MitraClip for Functional Mitral Regurgitation
Non-Randomized Studies

- Inoperable or high-risk surgical patients with symptomatic heart failure and 3+ or 4+ functional mitral regurgitation.
- Mean LV ejection fraction ~ 30%.
- Follow-up 6 to 12 months post-MitraClip:
  - significant decrease mitral regurgitation
  - significant reduction LV size
  - significant increase LV ejection fraction
  - significant improvement NYHA functional class
  - 30 day mortality 1-6%


Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation
(The COAPT Trial)

- Randomized, multicenter study of the MitraClip device for the treatment of moderate/severe or severe functional mitral regurgitation in symptomatic heart failure patients not appropriate for mitral valve surgery.
- Randomized to MitraClip device or no device
- Primary end-point: safety and recurrent heart failure hospitalizations
- Secondary end-points: death, stroke, myocardial infarction, mitral regurgitation, LV size, symptoms.
Factors Predicting Decrease Survival after MitraClip Implantation

- End-stage heart failure with significant increase in NT-proBNP (≥ 5000 pg/ml)
- Severe renal impairment (GFR <30 ml/min)
- Chronic obstructive pulmonary disease
- Tricuspid regurgitation ≥ 3+
- Residual mitral regurgitation > 2+

TRAMI Registry. EuroIntervention. 2015.

CASE

- 86 year old female with symptomatic NYHA class III heart failure.
- History of CABG.
- LVEF 30% and moderate-to-severe mitral regurgitation.
- Optimal medical therapy for heart failure (carvedilol, lisinopril, spironolactone, furosemide).
- QRS 94 ms on ECG.
- Coronary and bypass angiogram performed (did not require additional revascularization).
- Systolic pulmonary artery pressure (right heart catheterization) 55 mmHg.
- Assessed by Structural Heart Team for COAPT trial.
Baseline Transesophageal Echocardiogram
Moderate to Severe Mitral Regurgitation

MitraClip and Delivery Device
Fluoroscopy
MitraClip Positioning
Transesophageal Echocardiogram

MitraClip Deployment
Fluoroscopy
Post-Procedure Transesophageal Echocardiogram

Left Atrial Pressure

v-wave 27 mmHg  v-wave 18 mmHg
Hemodynamics Changes Associated with MitraClip

- Pressure changes:
  - decrease left atrial pressure (v-wave by \( \sim 9 \) mmHg; mean by \( \sim 4 \) mmHg)
  - decrease PCWP (mean \( \sim 5 \) mmHg)
  - decrease pulmonary arterial pressure (systolic by \( \sim 9 \) mmHg; mean by \( \sim 5 \) mmHg)

- Increase cardiac output by 0.5 to 1.5 L/min


MitraClip for Significant Organic (Degenerative) Mitral Regurgitation (MR)

Summary

- MitraClip is effective and can be used in patients at high risk for mitral valve surgery:
  - safe and effective in reducing severity of MR in majority of patients
  - improves symptoms
  - decreases hospitalizations
  - may have beneficial effect on survival if residual MR post-procedure was not severe
  - Mitraclip is FDA approved for use in patients with organic MR who are high surgical risk

- Low and intermediate risk patients do better with mitral valve surgery.
MitraClip for Significant Functional Mitral Regurgitation (MR)

Summary

- MitraClip is safe and effective in reducing severity of MR in the majority of patients.
- Improves symptoms.
- May decrease LV size and improve LV function.
- May increase survival?
- These important questions will be further addressed in ongoing prospective, randomized studies (COAPT, other).

MitraClip for Significant Mitral Regurgitation (MR)

Concluding Remarks and Future Considerations

- MitraClip is a relatively new method still in evolution for the management of significant MR.
- MitraClip is beneficial in patients with severe organic (degenerative) MR who are at high risk for surgery; MitraClip may be considered in certain critically ill patients with severe organic MR who are high risk for surgery as a bridge to mitral valve surgery.
- MitraClip may be used in certain symptomatic patients due to heart failure with significant functional MR.
- MitraClip or other transcatheter devices may become a common procedure for functional MR in the near future.
Mitral Valve Repair vs. Replacement for Degenerative Mitral Regurgitation

Juan Crestanello, MD
Professor of Surgery
Director, Division of Cardiac Surgery
The Ohio State University Wexner Medical Center

Disclosure

- Research Grants:
  - Medtronic Inc.
  - Abbot Vascular
  - Boston Scientific
Mitral Valve Regurgitation

Degenerative Mitral Regurgitation

Degenerative

Functional

David H. Adams, Raphael Rosenhek, Volkmar Falk

Degenerative Mitral Regurgitation

FED
FED+
Forme fruste
Barlow's

+ ++ +++ ++++

Leaflet tissue

David H. Adams, Raphael Rosenhek, Volkmar Falk
Degenerative Mitral Regurgitation

Thickened Leaflets
Redundant Leaflet Tissue
Elongated-Ruptured Chordae

Leaflet Prolapse
Flail Leaflet

Degenerative Mitral Regurgitation
Natural History – Mortality

Survival (%)

Years after diagnosis

Degenerative Mitral Regurgitation
Natural History – Mortality

NYHA Class

<table>
<thead>
<tr>
<th>NYHA Class</th>
<th>LVEF (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>60±50</td>
</tr>
<tr>
<td>II</td>
<td>50±59</td>
</tr>
<tr>
<td>III-IV</td>
<td>&lt;50</td>
</tr>
</tbody>
</table>

Yearly Rate of Sudden Death: 1.8%/year

J Am Coll Cardiol. 1999;34(7):2078-85
### Degenerative Mitral Regurgitation Repair vs. Replacement

<table>
<thead>
<tr>
<th>Year</th>
<th>Replacement</th>
<th>Repair</th>
</tr>
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<tbody>
<tr>
<td>2015</td>
<td>7027</td>
<td>8764</td>
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</table>

#### STS Adult Cardiac Surgery Database Executive Summary (10 Years through March 2016)

- **Survival**
- **Freedom from Reoperation**
- **Recurrence of Mitral Regurgitation**
- **Functional Status (symptoms)**
- **LV Function**
- **LV Volumes**

Freedom from:
- Bleeding
- Thromboembolism
- Endocarditis
Degenerative Mitral Regurgitation Repair vs. Replacement

STS Adult Cardiac Surgery Database Executive Summary (10 Years through March 2016)

Circulation 91:1022-28, 1995

Expected Repair Replacement
P=0.0004

Overall survival (%)

Years

Repair 195 181 170 125 87 72 49 37 22 12 8
Replacement 214 176 165 152 128 109 85 71 51 40 26

Circulation 91:1022-28, 1995
Degenerative Mitral Regurgitation
Surgical Results

Very Long-Term Survival and Durability of Mitral Valve Repair for Mitral Valve Prolapse
Dania Mohty, MD; Thomas A. Orszulak, MD; Hartzell V. Schaff, MD; Jean-Francois Avierinos, MD;
Jamil A. Tajik, MD; Maurice Enriquez-Sarano, MD

917 patients (MVR in 238, MVRepair in 679)
Follow up: 20 years

Re-Operation Rate: 23% vs 16% p=NS

Degenerative Mitral Regurgitation
Surgical Results

Very Long-Term Survival and Durability of Mitral Valve Repair for Mitral Valve Prolapse
Dania Mohty, MD; Thomas A. Orszulak, MD; Hartzell V. Schaff, MD; Jean-Francois Avierinos, MD;
Jamil A. Tajik, MD; Maurice Enriquez-Sarano, MD

Must do a Good Repair

Re-Operation Rate at 5, 10 and 15 years

No Residual MR: 5%, 9%, 14%
Residual MR: 14%, 18%, 21%
Degenerative Mitral Regurgitation
Surgical Results

Valve repair versus valve replacement for degenerative mitral valve disease

A. Marc Gillinov, MD, Eugene H. Blackstone, MD, Edward R. Nowicki, MD, Worawong Silisatkorn, MD,
Ghassan Al-Dossari, MD, Douglas R. Johnston, MD, Kristopher M. George, MD, Penny L. Houghtaling, MS,
Brian Griffin, MD, Joseph F. Sabik, III, MD, Lars G. Svensson, MD, PhD

3265 patients (MVR in 235, MVRepair in 3051)
Follow up: 20 years

Long term survival was better for Repair than MVR
Propensity Matched Survival was the same

Degenerative Mitral Regurgitation
Surgical Results

Mitral valve reconstruction in Barlow disease: Long-term echocardiographic results and implications for surgical management

Jérôme Jouan, MD, Alain Berrebi, MD, Sylvain Chauvand, MD, Philippe Menasché, MD, PhD,
Alain Carpentier, MD, PhD, and Jean-Noël Fabiani, MD, PhD

Objective: Owing to the complexity of the underlying lesions, Barlow disease remains a challenge for surgeons performing mitral valve repair. We aimed to assess whether our most recent results involving several surgeons were comparable with those of a previous experience in which mitral valve repair was performed by a more limited group of surgeons.

200 patients MVRepair
ECHOCARDIOGRAPHIC FOLLOW UP

Freedom from MR>2+ 90% at 8 years
Degenerative Mitral Regurgitation Surgical Results

4-Year Results of a Randomized Controlled Trial of Percutaneous Repair Versus Surgery for Mitral Regurgitation

Laura Mauri, MD,† Elyse Foster, MD,† Donald D. Glover, MD,§ Patricia Agrunese, MS, † Joseph M. Massaro, PhD,†† Howard C. Herrmann, MD,¶ James Hermiller, MD,# William Gray, MD,** Andrew Wang, MD,‡ Wesley R. Pedersen, MD,†† Tanvir Bajwa, MD,†‡ John Lasala, MD, Phippen Reginald Low, MD,¶¶ Paul Grayburn, MD,¶¶ Ted Feldman, MD,## for the EVEREST II Investigators

MVRepair (95 patients) vs. MitraClip (184 patients) 
Rigorous ECHO Follow up

MV Repair: MR 3+ or 4+: 9% at 4 years

Is All Mitral Valve Disease the Same?

Posterior Leaflet

Anterior Leaflet

Bileaflet

David H. Adams, Raphael Rosenhek, Volkmar Falk
### Degenerative Mitral Regurgitation

**Surgical Results**

#### Survival

Repair (1173 patients) or MVR(238 patients) for leaflet Prolapse

**20 year follow-up**

<table>
<thead>
<tr>
<th>Leaflet Type</th>
<th>Survival Comparison</th>
<th>HR</th>
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<tbody>
<tr>
<td>Posterior</td>
<td>Survival better for MV Repair</td>
<td>0.49</td>
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<tr>
<td>Bi</td>
<td>Survival better for MV Repair</td>
<td>0.59</td>
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<tr>
<td>Anterior</td>
<td>Survival MVR=Repair</td>
<td>0.78</td>
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#### Re-Operation Rate

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Comparison</th>
<th>Outcome</th>
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<tbody>
<tr>
<td>MV Repair</td>
<td>equal to MVR with Mechanical Valve</td>
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</tr>
<tr>
<td>MVR</td>
<td>with tissue valve much higher</td>
<td></td>
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</tbody>
</table>
Degenerative Mitral Regurgitation
Surgical Results

Survival Advantage and Improved Durability of Mitral Repair for Leaflet Prolapse Subsets in the Current Era
Rakesh M. Suri, MD, DPhil, Hartzell V. Schaff, MD, Joseph A. Dearani, MD, Thoralf M. Sundt III, MD, Richard C. Daly, MD, Charles I. Mullany, MB, MS, Maury E. Olson, MD

Re-Operation Rate and Risk of Reoperation
Repair (1173 patients) or MVR (238 patients) for leaflet Prolapse
20 year follow-up
- Lowest for Posterior Leaflet Prolapse (0.5%/yr)
- Highest for Anterior Leaflet Prolapse (1.6%/yr)
- Bileaflet Prolapse = MVR with Mechanical valve (0.9%/yr)

Degenerative Mitral Regurgitation
Surgical Results

Recovery of left ventricular function after surgical correction of mitral regurgitation caused by leaflet prolapse
Rakesh M. Suri, MD, DPhil, Hartzell V. Schaff, MD, Joseph A. Dearani, MD, Thoralf M. Sundt, MD, Richard C. Daly, MD, Charles I. Mullany, MB, MS, Maurice Enríquez-Sarano, MD, and Thomas A. Orszulak, MD

[Graph showing recovery of LVEF, LVEDD, and LVESD over time]
Degenerative Mitral Regurgitation
Surgical Results

Predictors of Left Ventricular Remodeling After Surgical Repair or Replacement for Pure Severe Mitral Regurgitation Caused by Leaflet Prolapse

Mario Sénéchal, MDᵃ,⁎, Jimmy MacHaflany, MDᵇ, Olivier F. Bertrand, MD, PhDᶜ, Kim O’Connor, MDᵃ, Julie Parenteau, MDᵈ, Isiél-Nicolas Dubois-Sénéchal⁵, Olivier Costerousse, PhD⁴, Michelle Dubois, MSc⁶, and Pierre Voisine, MD⁷

Repair vs. Replacement

Repair (42 patients) or MVR(30 patients) for leaflet Prolapse
2 yr ECHO follow-up

Similar Improvements in LVEF, LV dimensions and Volumes

Degenerative Mitral Regurgitation
Surgical Results

4-Year Results of a Randomized Controlled Trial of Percutaneous Repair Versus Surgery for Mitral Regurgitation

Laura Mauri, MD,⁺ Donald D. Glower, MD,§ Patricia Apruzzese, MS,⁺ Joseph M. Massaro, PnD,‖ Howard C. Herrmann, MD,‡ James Herrmiller, MD,³ William Gray, MD,⁎ Andrew Wang, MD,⁺ Wesley R. Pedersen, MD,‖ Tanvir Bajwa, MD,‖⁺ John Lasala, MD, PnD,§ Reginald Low, MD,‖⁺ Paul Grayburn, MD,‖⁺ Ted Feldman, MD,‖⁺ for the EVEREST II Investigators

MVR repair (95 patients) vs. MitraClip (184 patients)
Rigorous Follow up

MV Repair: 93% NYHA class I or II 4 years
Degenerative Mitral Regurgitation Surgical Results

Freedom From Thromboembolism, Bleeding, Endocarditis

<table>
<thead>
<tr>
<th></th>
<th>1 yr (%)</th>
<th>5 yr (%)</th>
<th>10 yr (%)</th>
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<tbody>
<tr>
<td>Thromboembolism</td>
<td>98.8</td>
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<td>Bleeding</td>
<td>99.7</td>
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<tr>
<td>Endocarditis</td>
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Degenerative Mitral Regurgitation Surgical Results

Outcomes 15 Years After Valve Replacement With a Mechanical Versus a Bioprosthetic Valve: Final Report of the Veterans Affairs Randomized Trial

Freedom From Thromboembolism, Bleeding, Endocarditis

<table>
<thead>
<tr>
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<th>Mechanical(%)</th>
<th>Bioprostheses (%)</th>
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<tbody>
<tr>
<td>Thromboembolism</td>
<td>81</td>
<td>77</td>
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<tr>
<td>Bleeding</td>
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<td>69</td>
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<td>Endocarditis</td>
<td>89</td>
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<tr>
<td>Valve Failure</td>
<td>95</td>
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### Degenerative Mitral Regurgitation
#### Repair vs. Replacement

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<thead>
<tr>
<th></th>
<th>Repair</th>
<th>Replacement</th>
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<tbody>
<tr>
<td>Survival</td>
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<td>✔</td>
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<tr>
<td>Freedom from Reoperation</td>
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<td>✔</td>
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<tr>
<td>Recurrence of Mitral Regurgitation</td>
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<tr>
<td>Functional Status (symptoms)</td>
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<td>LV Function</td>
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<tr>
<td>LV Volumes</td>
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<tr>
<td>Freedom from:</td>
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<tr>
<td>• Bleeding</td>
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<tr>
<td>• Thromboembolism</td>
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<tr>
<td>• Endocarditis</td>
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