

Percutaneous Mitral Repair for MR: *We are ready for device therapy!*

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Evanston Hospital

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Ted Feldman MD, FACC, FESC, FSCAI

Disclosure Information

The following relationships exist:

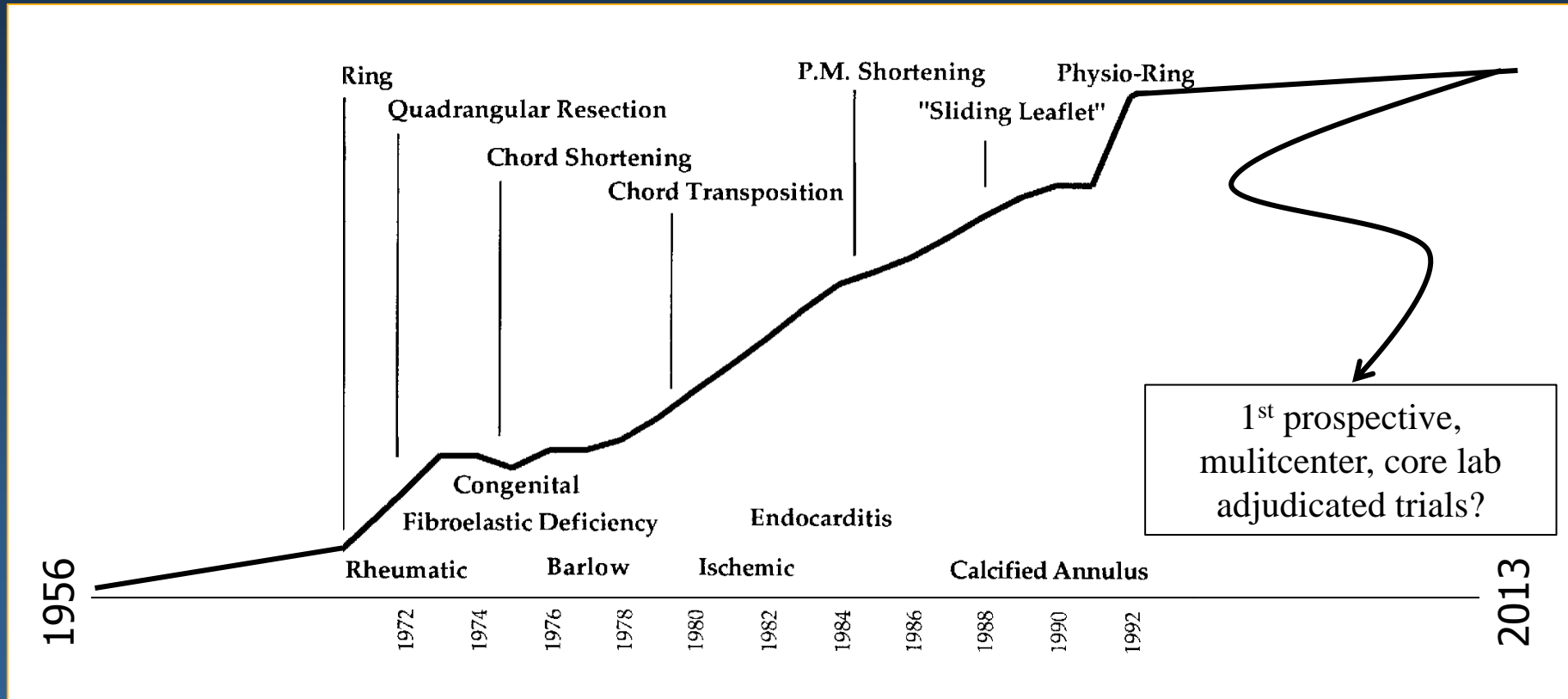
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Consultant: Abbott, BSC, Coherex, Edwards, Intervale,
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Speaker: Boston Scientific

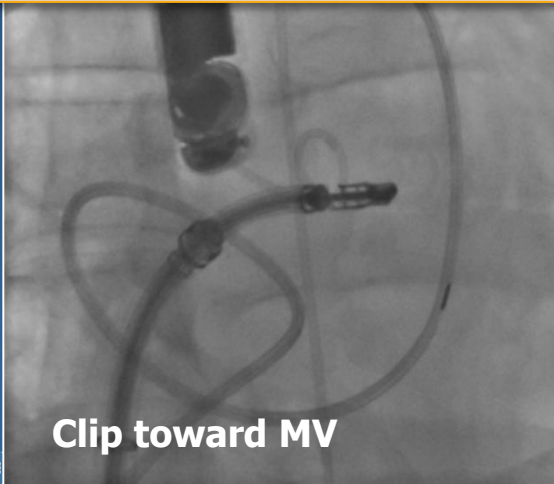
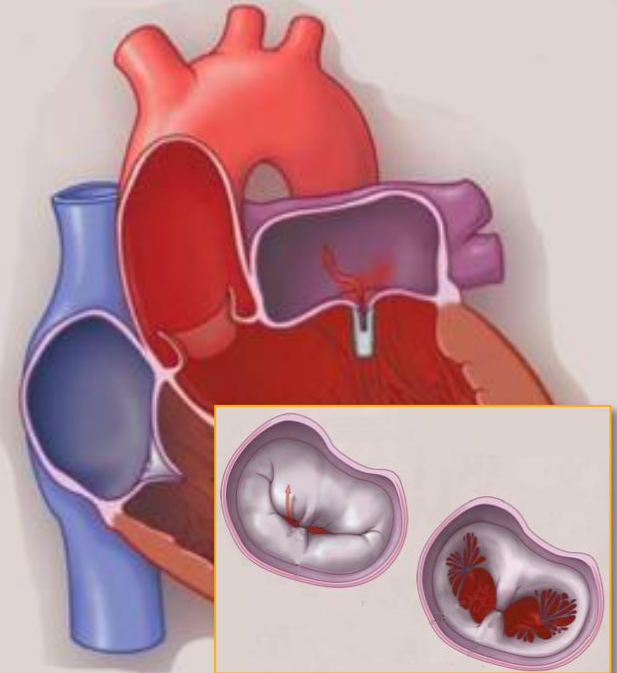
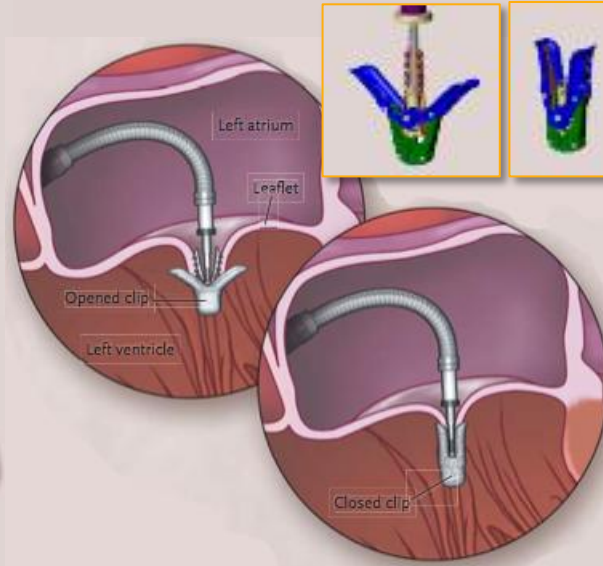
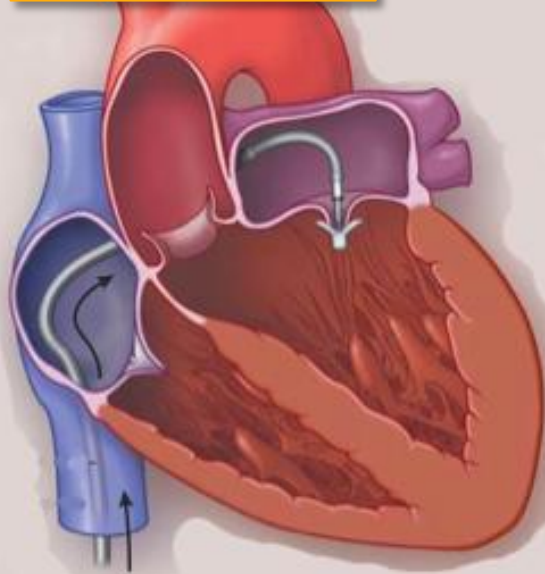
*Off label use of products and investigational devices
will be discussed in this presentation*

History of Surgical Mitral Valve Repair

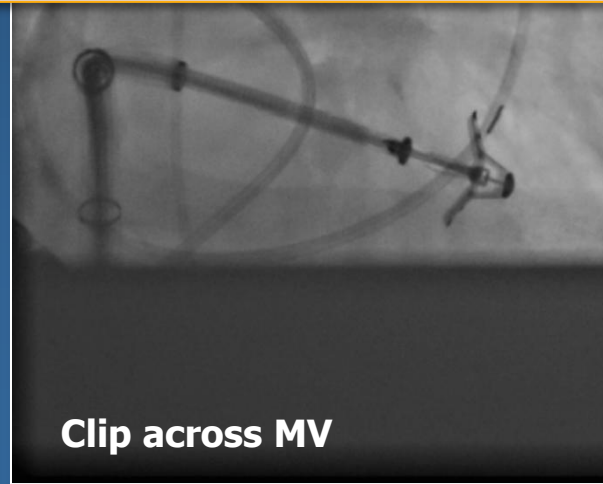


Catheter-Based Mitral Valve Repair

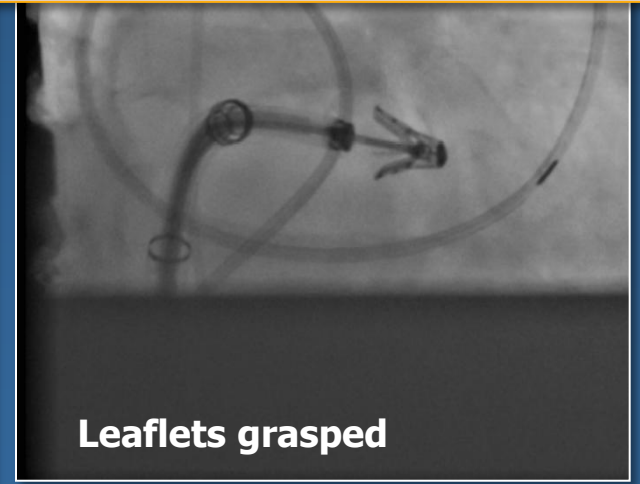
MitraClip System



Clip toward MV



Clip across MV



Leaflets grasped



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Percutaneous Repair or Surgery for Mitral Regurgitation

Ted Feldman, M.D., Elyse Foster, M.D., Donald G. Glower, M.D., Saibal Kar, M.D., Michael J. Rinaldi, M.D., Peter S. Fail, M.D., Richard W. Smalling, M.D., Ph.D., Robert Siegel, M.D., Geoffrey A. Rose, M.D., Eric Engeron, M.D., Catalin Loghin, M.D., Alfredo Trento, M.D., Eric R. Skipper, M.D., Tommy Fudge, M.D., George V. Letsou, M.D., Joseph M. Massaro, Ph.D., and Laura Mauri, M.D., for the EVEREST II Investigators*

BACKGROUND

Mitral-valve repair can be accomplished with an investigational procedure that involves the percutaneous implantation of a clip that grasps and approximates the edges of the mitral leaflets at the origin of the regurgitant jet.

METHODS

We randomly assigned 279 patients with moderately severe or severe (grade 3+ or 4+) mitral regurgitation in a 2:1 ratio to undergo either percutaneous repair or conven-

CONCLUSIONS

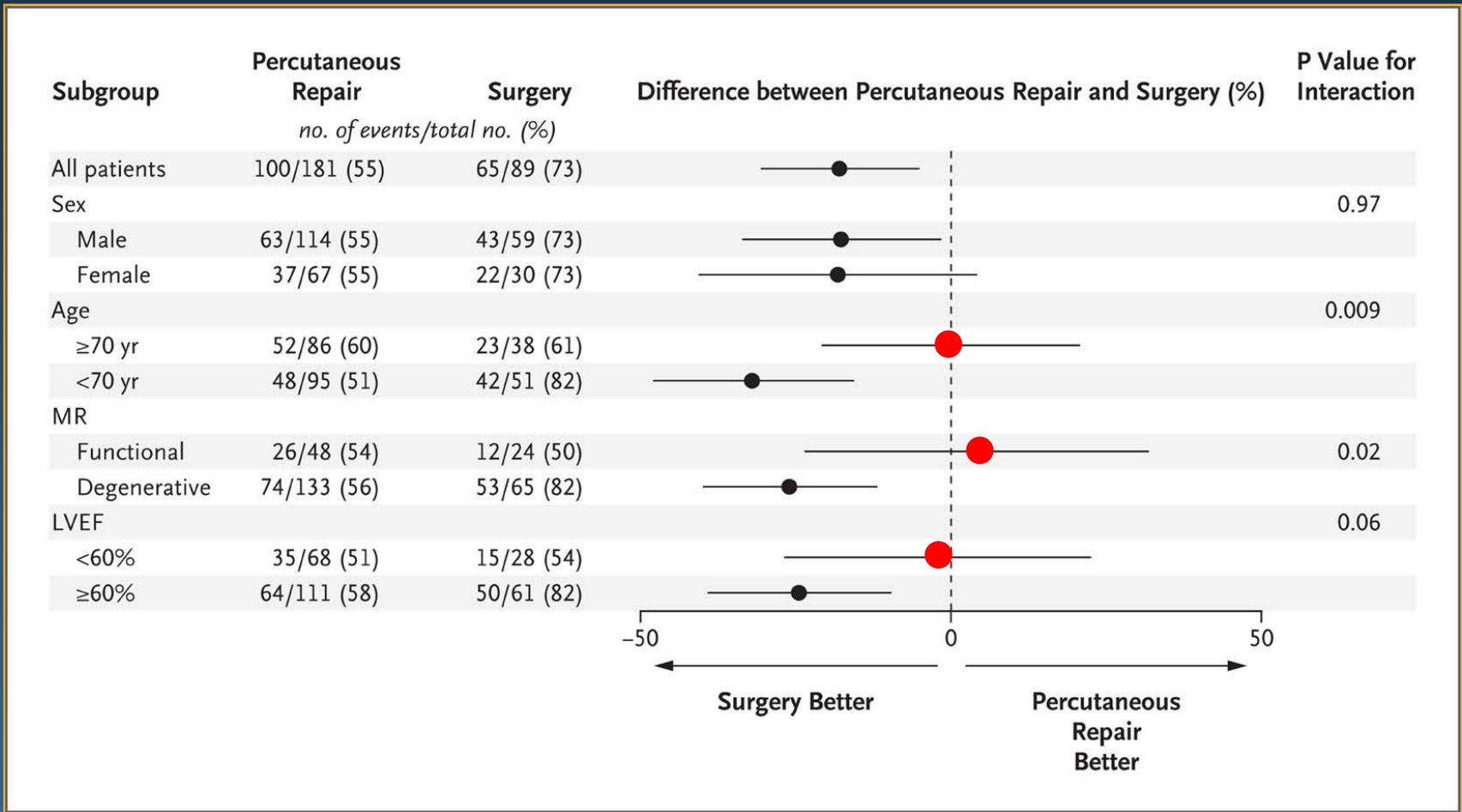
Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes.

the percutaneous repair group and 48% of patients in the surgery group at 30 days ($P < 0.001$). At 12 months, both groups had improved left ventricular size, New York Heart Association functional class, and quality-of-life measures, as compared with baseline.

CONCLUSIONS

Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes. (Funded by Abbott Vascular; EVEREST II ClinicalTrials.gov number, NCT00209274.)

Endovascular Valve Edge-to-Edge REpair Study



Subgroup Analyses for the Primary End Point at 12 Months

Acute and 12-Month Results With Catheter-Based Mitral Valve Leaflet Repair

The EVEREST II (Endovascular Valve Edge-to-Edge Repair) High Risk Study

Patrick L. Whitlow, MD,* Ted Feldman, MD,† Wes R. Pedersen, MD,‡ D. Scott Lim, MD,§

Robert Kipp

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Murat Tuzcu

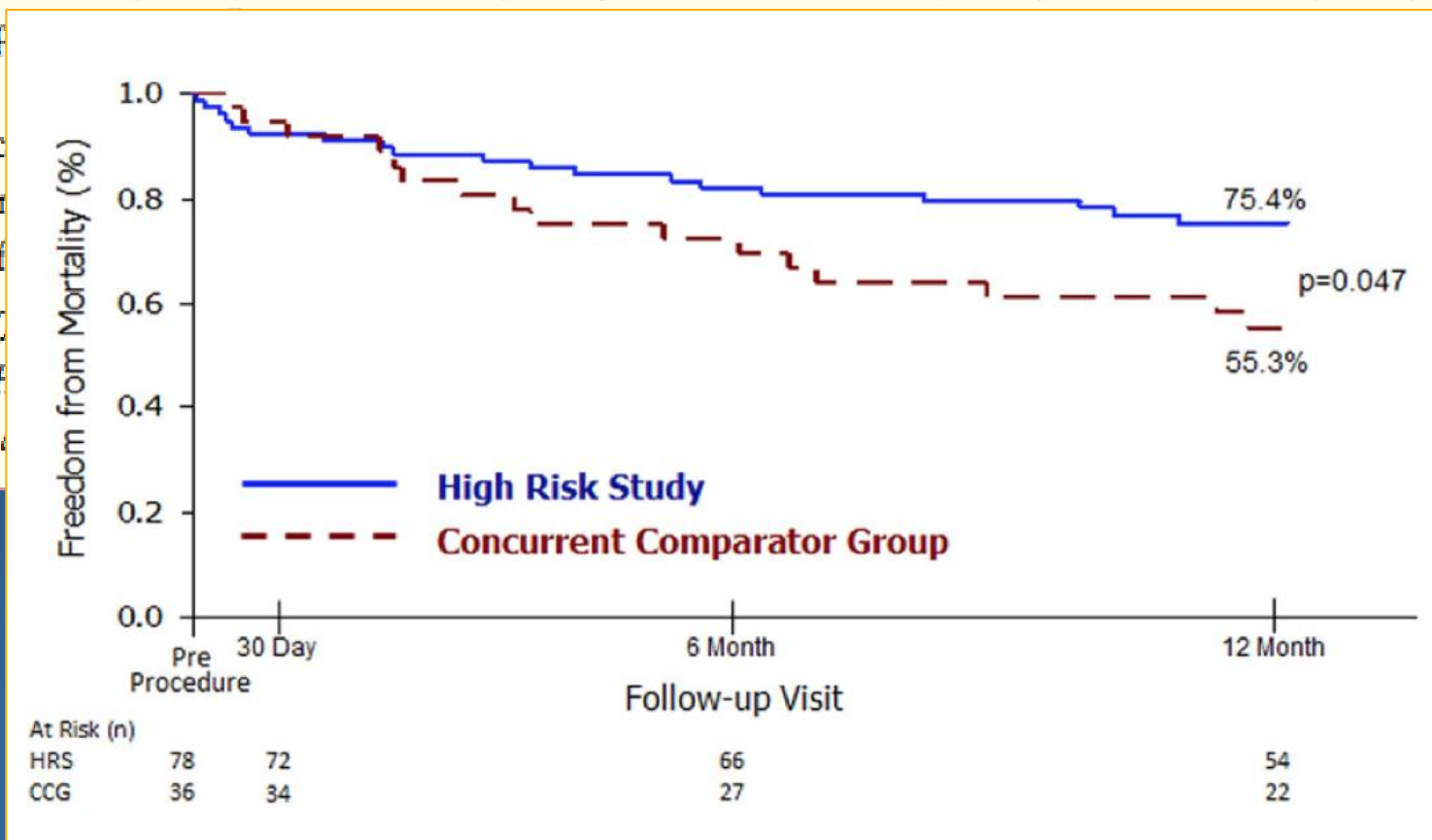
Elyse Foster

on behalf of

Cleveland, C

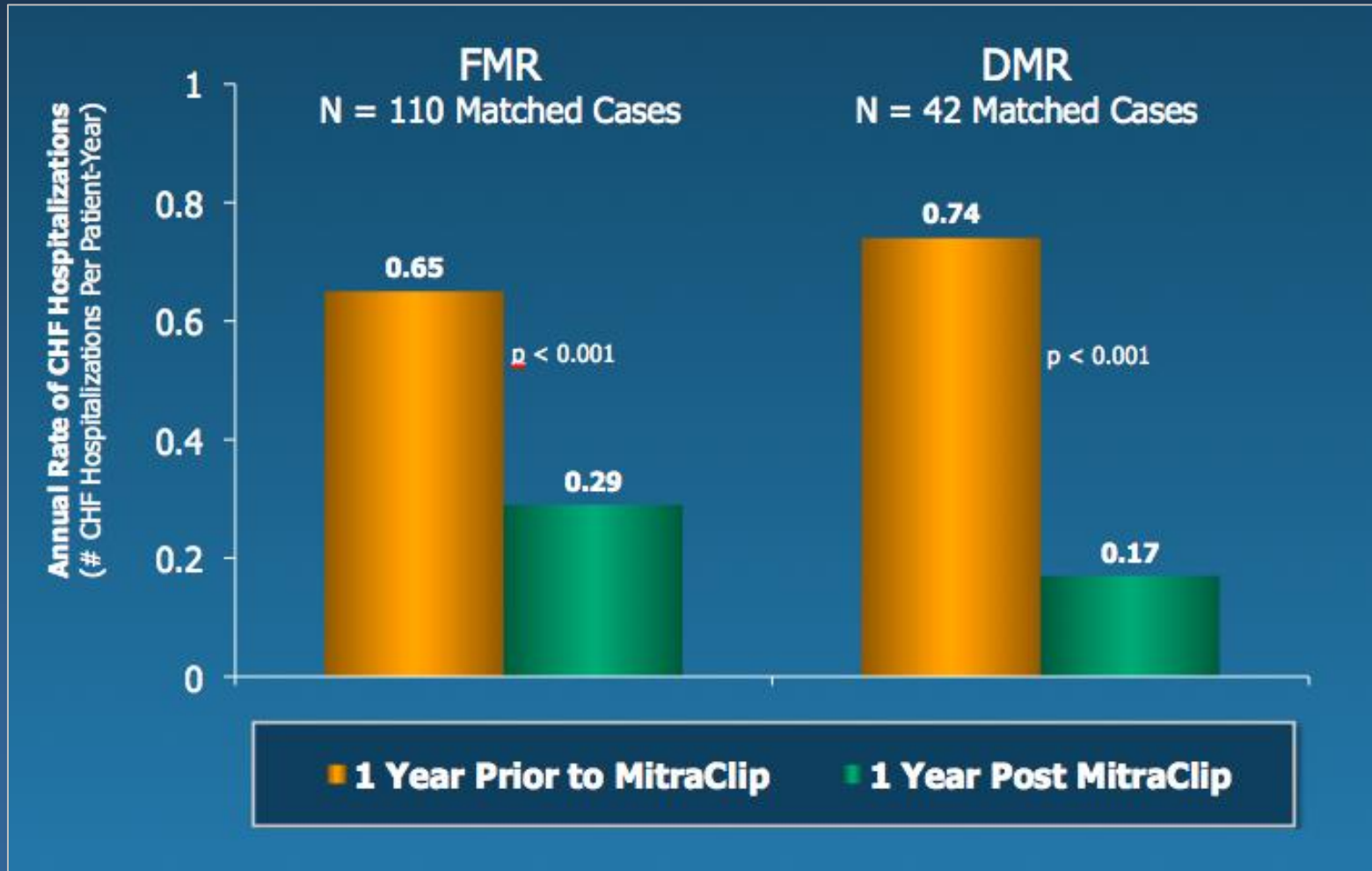
Oklahoma; E

Los Angeles



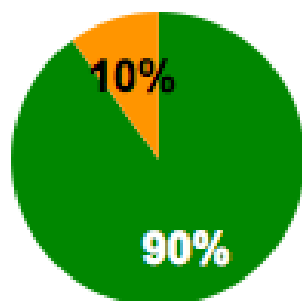
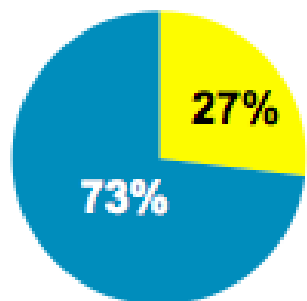
Hospitalizations for CHF

EVEREST II High Surgical Risk Cohort



EVEREST II

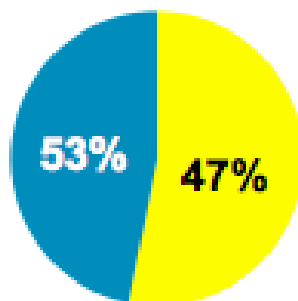
(Randomized Controlled Trial)



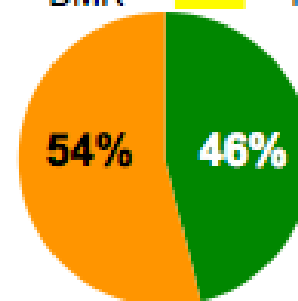
- 178 patients
- Implant rate – 89%

REALISM

(Continued Access Registry)



■ = DMR¹ ■ = FMR¹

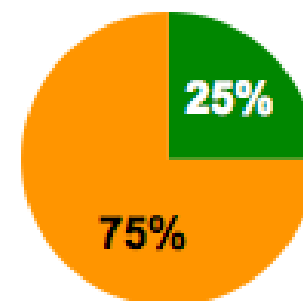
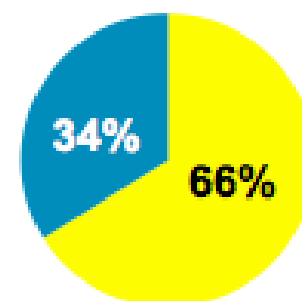


■ = Standard Risk² ■ = High Risk²

- 571 patients
- Implant rate – 94%

Commercial

(Europe, Canada, Asia, Australia)



- 2,472 patients
- Implant rate – 95%

~420 patients enrolled at up to 75 US sites

Significant FMR $\geq 3+$ core lab
High risk for mitral valve surgery
Specific valve anatomic criteria

Randomize 1:1

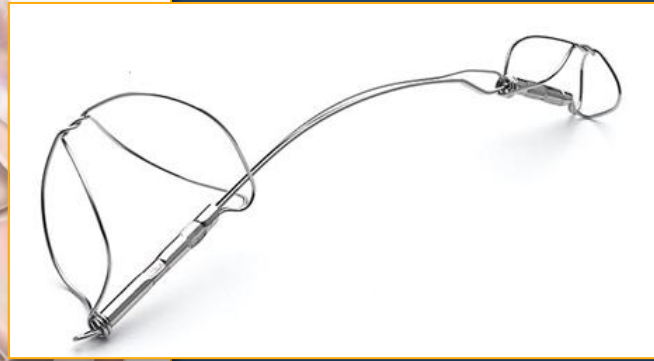
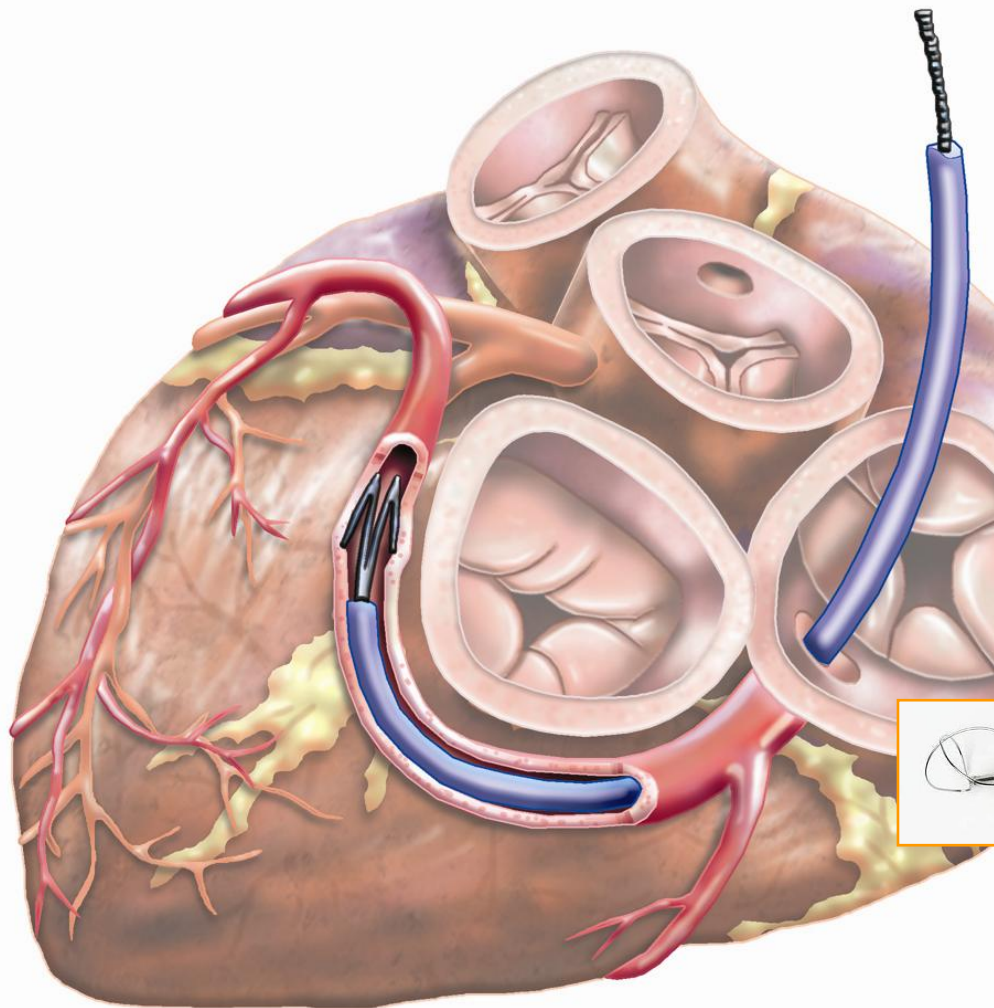
MitraClip

Control group
Standard of care

Safety: Composite death, stroke, worsening renal function, LVAD implant, heart transplant at 12 months

Effectiveness: Recurrent heart failure hospitalizations

CARILLON Mitral Contour System



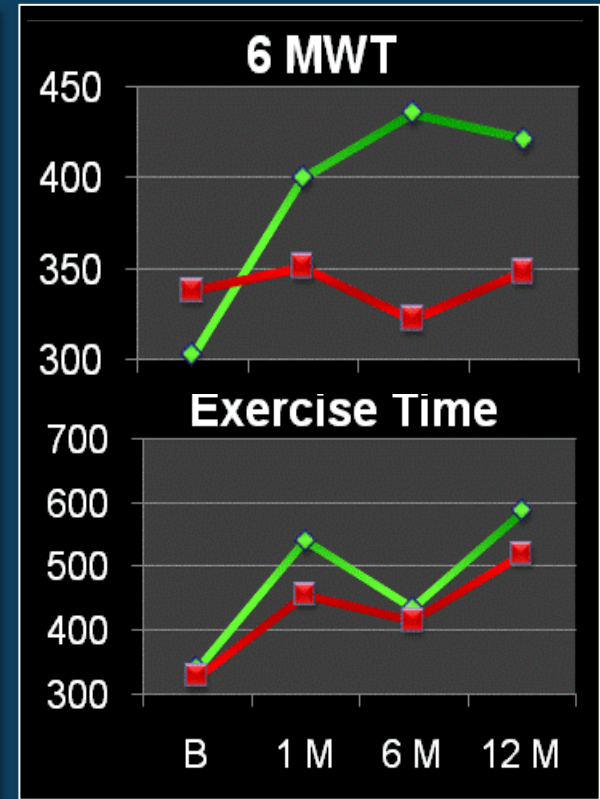
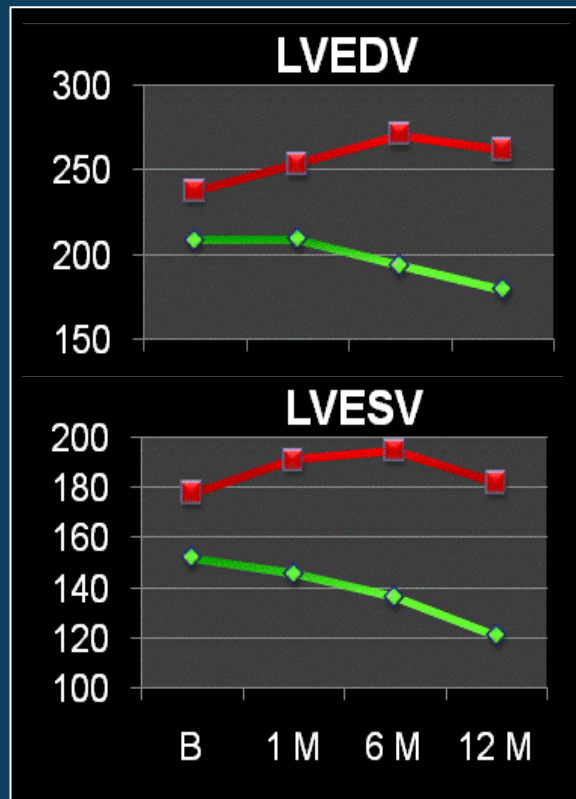
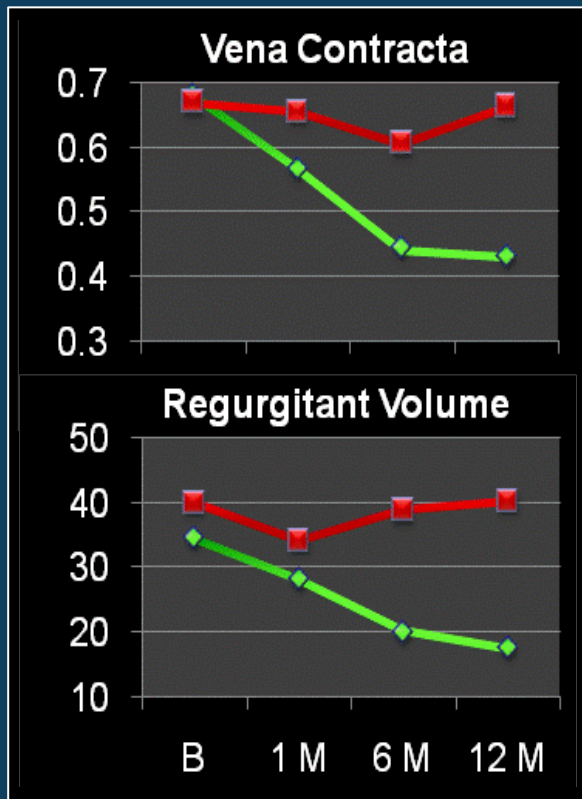
TITAN Trial

CARILLON Mitral Contour System for Functional MR

40% reduction in MR

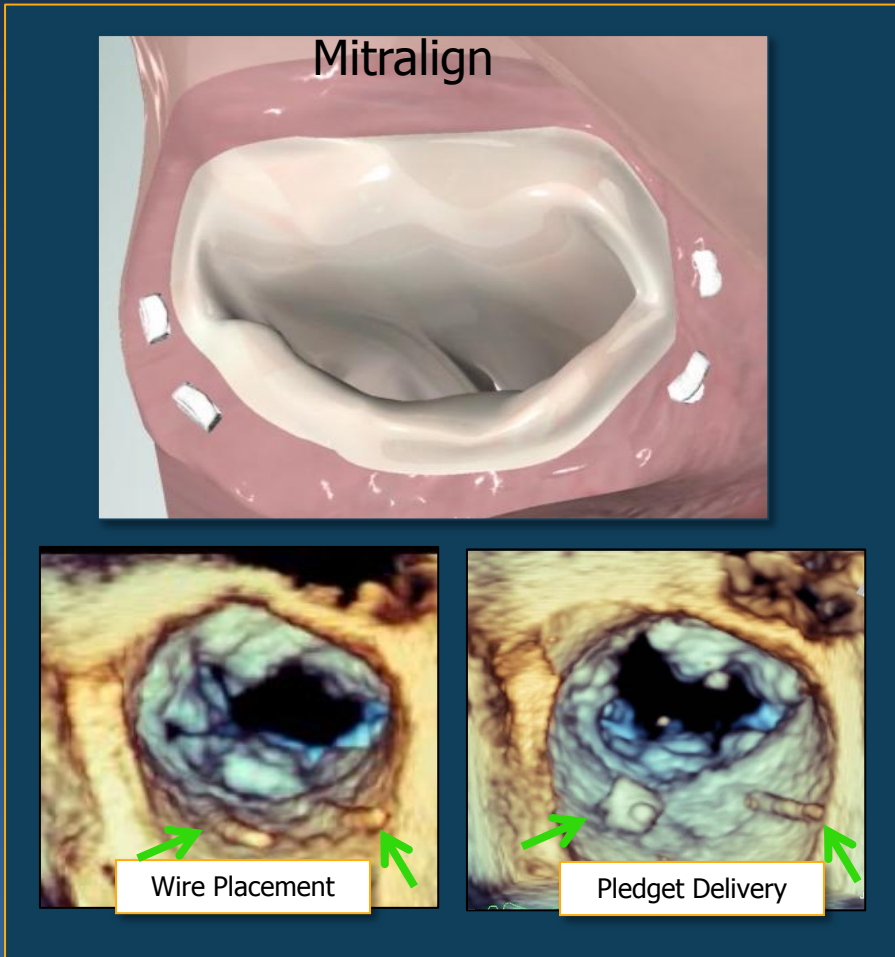
Reverse remodeling

Functional improvement



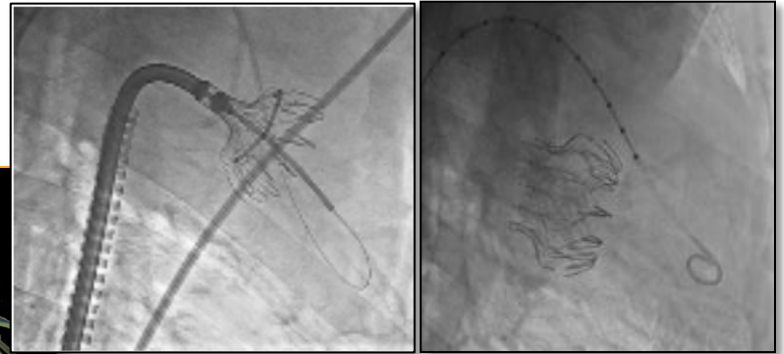
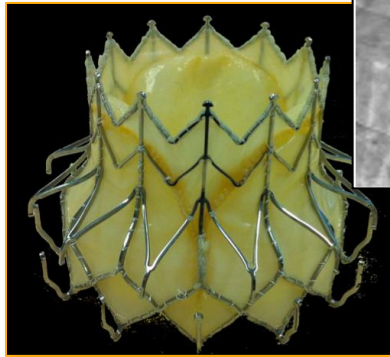
◆ Implanted (n=36) ■ Non-Implanted (n=17)

Direct Annuloplasty



CardiAQ Valve Technologies

Transcatheter Mitral Valve Implantation



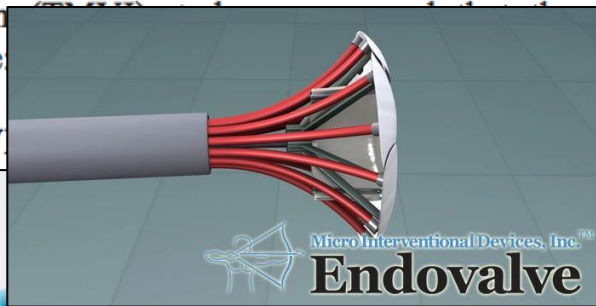
NEWS RELEASE

FOR IMMEDIATE RELEASE

CONTACT: RONALD TRAHAN, APR, RONALD TRAHAN ASSOCIATES, INC., +1 508-359-4005, x108

CardiAQ™ Valve Technologies reports cardiovascular medicine milestone: first-in-human nonsurgical percutaneous implantation of a bioprosthetic mitral heart valve

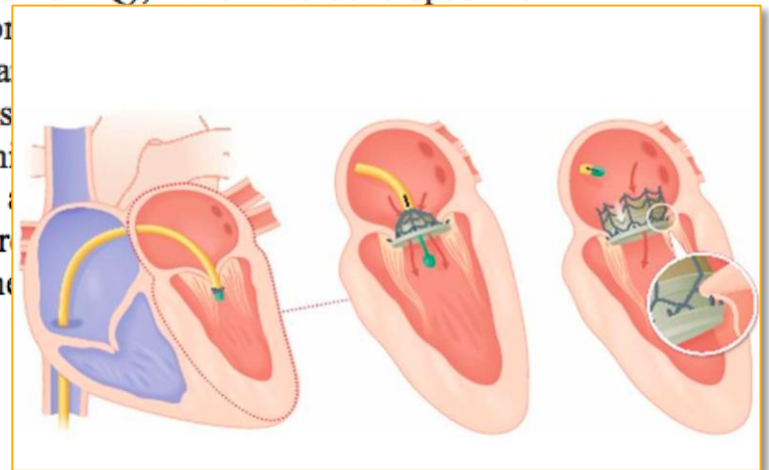
IRVINE, Calif., June 14, 2012—CardiAQ Valve Technologies (CardiAQ), which has developed the world's first self-conforming and self-anchoring technology for Transcatheter Mitral Valve Implantation (TMVI), has achieved a cardiovascular medicine milestone by successfully implanting the first transcatheter mitral valve (TMV) into a patient's heart. This breakthrough TMV



Micro Interventional Devices, Inc.™
Endo Valve



Tiara



History of Percutaneous Mitral Valve Repair

The 1st 56 Years

