Introduction

Transcatheter edge-to-edge repair (TEER) treatment of mitral regurgitation (MR) was first conceived in the late 1990s based on a novel edge-to-edge surgical repair technique pioneered by Professor Ottavio Alfieri. In 1998, interventional cardiologist Fred St. Goar, after learning of Prof. Alfieri's unique surgical approach, proposed the concept of catheter-delivered mitral valve (MV) repair to the Silicon Valley med-tech incubator, The Foundry. After some basic proof-of-concept work and intellectual property diligence, they founded a startup, Evalve, Inc., in the fall of 1999. Although initial TEER device concepts were focused on installing sutures into opposing valve leaflets[1] or stapling the leaflets together using a catheter,[2] Evalve's early prototyping and testing efforts led to the insight that an implantable Clip (without the need to puncture through leaflets) would be a safer and more effective approach. Working with innovative physician collaborators, Evalve's engineering team built and tested a variety of early device concepts, finally arriving at the first Clip-based TEER technology, known today as the MitraClip™ system (Abbott). Evalve continued the early development of the MitraClip platform through its first-in-human implantation in 2003 and subsequently achieved CE Mark approval in Europe in 2008.[3,4] Evalve was acquired by Abbott Laboratories in 2009.[5] Abbott continued to develop and mature the MitraClip TEER technology and therapy, supporting the approval of the MitraClip system by the United States FDA in 2013.[6]

A REVOLUTION IN TRANSCATHETER MV REPAIR

With a 20-year history, the MitraClip device has defined TEER therapy for treating regurgitant MVs and was the first and only transcatheter valve repair option available for its first 10 years. The MitraClip therapy has been studied extensively with the largest body of clinical data across any transcatheter MV repair therapy, spanning more than 20 trials evaluating more than 80,000 patients with over 3,200 articles published.[7]

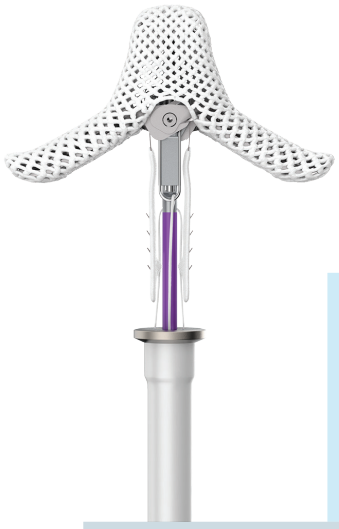
"When we first proposed the concept of catheter-based mitral valve repair 25 years ago, we were cautiously optimistic that it would have significant clinical value. After we performed the initial clinical TEER case in 2003 and witnessed the remarkable reduction in mitral regurgitation, our confidence grew, but we had no idea that it would be such an extraordinary game changer."

–Frederick St. Goar, MD

In real-world use, MitraClip therapy has now been used to treat more than 200,000 patients across the world in more than 75 countries with an excellent safety profile and favorable outcomes in terms of reduction in MR, improved heart failure prognosis, and improved patient quality of life.[8] As will be described in this supplement, steadily improving outcomes have been made possible through the addition of key design features in each MitraClip device generation, along with a continual partnership with highly skilled imagers and implanters who use MitraClip devices to improve the lives of patients in the clinical setting (Figure 1). ■

1. St. Goar FG, I-Lin Fann J, Deem ME, et al, inventors; Evalve, Inc., assignee. Methods and apparatus for cardiac valve repair. US patent 6629534B1. October 7, 2003.
2. Oz M, Lemole G, Lotvin A, et al, inventors; Columbia University of New York, assignee. Method and apparatus for circulatory valve repair. US patent 20010005787A1. June 28, 2001.
3. Condado JA, Acquatella H, Rodriguez L, et al. Percutaneous edge-to-edge mitral valve repair: 2-year follow-up in the first human case. Catheter Cardiovasc Interv. 2006;67:323-325. doi: 10.1002/ccd.20603
4. Evalve, Inc. announces CE Mark approval of the world's first percutaneous valve repair system. News release. BioSpace. March 25, 2008. Accessed August 21, 2023. https://www.biospace.com/article/releases/evalve-inc-announces-ce-mark-approval-of-the-world-s-first-percutaneous-valve-repair-system-/
5. Cardiovascular News. Abbott to acquire Evalve, a leader in mitral valve repair technology. News release. September 14, 2009. Accessed August 21, 2023. https://cardiovascularnews.com/abbott-to-acquire-evalve-a-leader-in-mitral-valve-repair-technology/
6. American College of Cardiology. FDA approves device for treatment of degenerative mitral regurgitation. News release. October 25, 2013. Accessed August 21, 2023. https://www.acc.org/latest-in-cardiology/articles/2013/10/25/11/10/fda-approves-device-for-treatment-of-degenerative-mitral-regurgitation
7. De Backer O, Wong I, Taramasso M, et al. Transcatheter mitral valve repair: an overview of current and future devices. Open Heart. 2021;8:e001564. doi: 10.1136/openhrt-2020-001564
8. Freixa X, Estévez-Loureiro R, Carrasco-Chinchilla F, et al. Percutaneous mitral valve repair: outcome improvement with operator experience and a second-generation device. J Clin Med. 2021;10:734. doi: 10.3390/jcm1004073

ONGOING COMMITMENT TO INNOVATION



GEN 5 AND FUTURE GENERATIONS

FUTURE

Continuous clinical data driven:
- EXPAND G4
- EXPANDed
- RESHAPE
- REPAIR MR
- Other TEER RCTs

GEN 4 (G4)

2023

COAPT 5 YRS OUTCOMES

EXPANDED
EXPAND + EXPAND G4
2205 Patients

2020

EXPAND-G4 STUDY
Observational Study
Core Lab
2020–2022
1164 Patients
Study Ongoing

REPAIR MR
Observational Study
Multi-Center RCT – IDE Trial
Enrollment Ongoing
500 Patients

MITRACLIP RUSSIA
Single-Arm Study
2020
16 Patients

MITRACLIP KOREA PMS
Post-Market Surveillance
Enrollment Ongoing
600 Patients/4 Yrs

MITRACLIP CHINA PMS
Post-Market Surveillance
Enrollment Ongoing
50–100 Patients

MITRACLIP INDIA PMS
Post-Market Surveillance
2020–2022
90 Patients

GEN 3 (NTR/XTR)

MITRACLIP FDA APPROVAL FOR SMR

2019

MITRACLIP PAS
Secondary MR
Commercial Registry
2019–2020
5000 Patients
Study Ongoing

2018

EXPAND STUDY
Observational Study
Core Lab/CEC Adjudication
2018–2019
1041 Patients

MITRACLIP JAPAN PMS
Post-Market Surveillance
2018–2019
500 Patients

GEN 2 (NT)

MITRACLIP JAPAN MINISTRY OF HEALTH, LABOUR, AND WELFARE (MHLW) APPROVAL

2017

COAPT CAS
Continued Access
2017–2019
162 Patients

GEN 1

2015

MATTERHORN*
RCT, SMR
Enrollment Ongoing
210 Patients

MITRACLIP HEALTH CANADA APPROVAL

2014

MITRA-FR*
RCT
2014-2017
304 Patients

RESHAPE-HF2*
RCT, SMR
Enrollment Ongoing
650 Patients

MITRACLIP FDA APPROVAL FOR PMR

2013

COAPT™
RCT
2013–2017
617 Patients

2009

EVEREST II REALISM
Continued Access
2009–2014
965 Patients

MITRACLIP™ PAS
Prohibitive Risk Primary MR Commercial Registry
2013–2016
1998 Patients

MITRACLIP CE MARK APPROVAL

2008

ACCESS EUROPE
Single-Arm Study
2009–2012
567 Patients

2007

MITRACLIP™ FIRST IN HUMAN

EVEREST II HIGH RISK STUDY
Single-Arm Study
2007–2008
78 Patients

2005

EVEREST II
RCT
2005–2008
279 Patients

2003

EVEREST I
Feasibility Study
2003–2006
55 Patients

Note: Asterisk indicates Investigator Sponsored Study. Data on file at Abbott.

Figure 1. The evolution of MitraClip™ technologies and associated clinical studies.