

Frederick St. Goar, MD

The interventional cardiologist who founded Evalve, Inc., the company that developed the MitraClip device, shares his thoughts on the latest mitral regurgitation data and his hands-on approach to the development of novel interventional cardiology devices.

What do you think was the most important finding from the EVEREST II trial's 2-year data?

During the course of the EVEREST II trial, I have been impressed with both the acute safety and the predictable and reasonable durability of the MitraClip system (Abbott Vascular, Santa Clara, CA). This is in spite of the fact that EVEREST was the initial trial for a "first-in-class" device. We have learned that if you achieve a good acute result, which in the trial was in the 76% range and now in routine clinical practice in Europe is pushing 90%, that the result will be good durability.

We also learned that the clip was not as effective in achieving 1+ or less mitral regurgitation as the surgical approach, but that clip patients did equally as well if not better both subjectively (New York Heart Association status) as well as objectively (echo volumes and dimensions).

Hearts respond well to the clip, and most importantly from an inventor's perspective, there is no harm or damage from the device. In well-selected cases, there is no downside in attempting to repair mitral regurgitation with the clip. If it works, all the better, and if not, it does not negatively affect surgical options. This is the clear benefit of a less-invasive, safe therapy and will be an attractive alternative for a significant number of patients, many of whom at this point have no other options.

What outcomes do you expect to see in the next round of follow-up data?

I suspect that as we continue to improve the technology of the MitraClip device, as well as the techniques for performing the procedure, results will only get better, and the appropriate patient population for whom it is an effective, valuable therapy will expand. We are only at the very beginning of discov-

ering the exciting treatment options in complex percutaneous valve intervention.

Are there any other techniques or devices on the horizon for treating mitral valve dysfunction?

We continue to see a variety of interesting annulus reduction therapies in development. We clearly need annular therapies, because although direct leaflet apposition intervention (MitraClip therapy [ie, annular cinching]) is applicable to a broader clinical population than we originally anticipated, there is still a significant number of patients who will require direct annular intervention. Several therapies are close to initiating pivotal trials in the United States, and these need to be supported as much as possible, both clinically and fiscally. That said, EVEREST II has set a high bar for these therapies to equal.

Do you think that intravascular ultrasound and fractional flow reserve (FFR) are effective methods for screening high-risk patients for coronary artery disease? What needs to happen for this practice to be widely adopted in the United States?

There is a mandate within the coronary interventional community to screen and evaluate patients and interventions on a more objective level. Intravascular ultrasound (and possibly optical coherence tomography), from an anatomical standpoint, and FFR, from a functional standpoint, both have a growing body of supportive evidence of their clinical value. Based on compelling outcome data, they need to be applied on a more regular basis, and in fact, this may be required by payers in the near future.



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Can you tell us about some of the devices you are currently working to develop?

Two areas that could benefit from innovation energy and focus are the creation of simplified therapies that have the potential for a global impact both from an outcomes perspective and from a cost and efficiency standpoint and, secondly, developing more direct personalized diagnostic and therapeutic interventions. In regard to the former, I am working closely with a company called Nanostim, Inc. (Milpitas, CA), which has developed an elegant leadless pacemaker device that is the size of a large pencil eraser and is implanted in the right ventricular apex with a simple catheter system (my contribution to the project). Theoretically, the device could be implanted using visualization with a small handheld portable ultrasound system. This technology, once perfected, could have a dramatic implication on the global penetration of pacemaker therapy.

Another company that I am working closely with is HeartFlow, Inc. (Redwood City, CA). They are developing technology for an objective, personalized evaluation of coronary artery disease. By applying computational fluid dynamic analysis from data obtained from routinely acquired computed tomographic angiograms, they create a pressure-flow map of the coronary arteries, thus providing noninvasively acquired FFR for any point in the coronary tree. If this technology can be adequately validated compared to invasively acquired FFR (as shown in the recently published DISCOVERFLOW trial), it will add significant objectivity and be a very important tool for the noninvasive evaluation of coronary artery disease. As a testament to the potential impact of this technology, it was recently awarded this year's Innovation Award at the EuroPCR meeting in Paris.

Tell us about your experience with the Fogarty Institute for Innovation. How has this institution provided an opportunity for mentorship/education within the field and for developing new techniques and technologies to improve patient care?

Four years ago, in response to the increasing challenges that innovators face in the early phases of medical device initiation and development, Dr. Thomas Fogarty set up a nonprofit innovation institute. Based at a community hospital (El Camino Hospital, Mountain View, CA) that is staffed with physicians with successful experience in device development and starting companies (Dr. Jim Joye and myself as directors), the institute provides physical space and mentorship from Dr. Fogarty and his wealth of intimate connections within the engineering, business, legal, and regulatory community. The first company to exit the Fogarty Institute, HeartFlow, Inc. demonstrates Dr. Fogarty's commitment to patients' well-being and to

developing and supporting companies with the potential to have a significant impact on global health care.

Are any further studies on percutaneous transmyocardial laser revascularization being performed? Do you think robotic techniques could improve the outcomes of this procedure?

Yes and yes, but it is a long road. At this juncture, it is my understanding that percutaneous transmyocardial laser revascularization (pure mechanical myocardial stimulation) is not being evaluated as a stand-alone procedure but is being used in conjunction with some bone marrow-derived stem cell studies. These therapies are being evaluated in both the angina/chronic ischemic population, as well as in congestive heart failure patients. The trials are extremely challenging to perform, especially if robotic therapy is included, and it will be a good while before outcome and cost-effectiveness studies are likely to show significant indications for routine clinical care.

What areas of interventional cardiology would you like to see an increased awareness of and/or focus on? Are there any critical issues that you believe warrant immediate attention from the medical community?

I am biased, but at this point, looking at underserved disease prevalence and data-derived outcome studies, we need to be more aggressive in treating our valvular heart disease patients and more objective, and perhaps interventionally less aggressive, in treating our coronary artery disease patients. Catheter-based interventions for treating valvular heart disease is in its raw infancy, and it is sure to receive a dramatic increase in awareness and focus.

In regard to coronary disease, if we incorporate even a small portion of the messages from the COURAGE and FAME trials, the attention of the medical community (including payers) will be directed toward treating less of our coronary artery disease patients with interventional therapy, and in those that we do treat, therapies will be applied in a much more objective fashion. ■

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