Creating History

The First Minimally Invasive Therapy

When asked to provide a few words about Thomas Fogarty, MD, for the occasion of his being honored as the 2004 New Cardiovascular Horizons Achievement Award recipient, a number of prominent endovascular specialists remarked on the way in which he could look at a complex problem in an elemental way, and then devise a simple solution to it. Dr. Fogarty's first invention was a clutch system for his scooter when he was a young man. This invention evolved to become a motorcycle clutch that is still in use today. Not long after he took a job as a scrub technician to help support his family, Dr. Fogarty began to see what he considered obvious flaws in a widely used surgical procedure, and true to his nature, he devised a simple solution. Most if not all of Dr. Fogarty's myriad inventions bear this characteristic, and an impressive number of them have come to be seen as revolutionary in their respective applications. His invention of the balloon embolectomy catheter did just that, essentially marking the birth of minimally invasive endovascular therapy.

Endovascular Today: Your work conceiving and designing the balloon embolectomy catheter was a revolution in vascular care. What was your early experience with the previous standard of care, and what did you observe in it that pushed you to go so far in another direction?

Thomas Fogarty, MD: I became a scrub technician at Good Samaritan Hospital in Ohio at the age of 15. The real motivator and mentor that I had was an individual by the name of Jack Cranley. He was one of the first men in the United States who dedicated his practice truly and totally to vascular procedures.

The previous standard was open surgery, and it was very, very invasive. There was no pervious standard instrument designed to extract the thrombus. When a patient came in with an arterial occlusion, it was treated with a long operation under general anesthesia, and usually the patient came back for a second operation to reintervene, and then a third operation, which was an amputation. It really takes no advanced thought to observe that this procedure wasn't working. It was that simple.

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EVT: We understand the materials and methods you used to design the device were as unconventional as the concept itself.

Dr. Fogarty: I took the baby finger of a #5 glove, cut it off, and tied it onto the end of a urethral catheter. That was basically the entire design and development process. I did everything at home in my attic. I got a hold of some long test tubes and took old, out-of-date blood and formed makeshift clots within the tubes. I tested the device on those clots, and it seemed to work pretty well. We used the device in a cadaver once, and then treated the first patient. From the time I first thought of it to the first use in a patient took about 2 months. There was no FDA regulation at the time. We made one, and we used it. We did bench testing, and we did cadaver testing to validate its safety, and the first patient who came up, we used it.

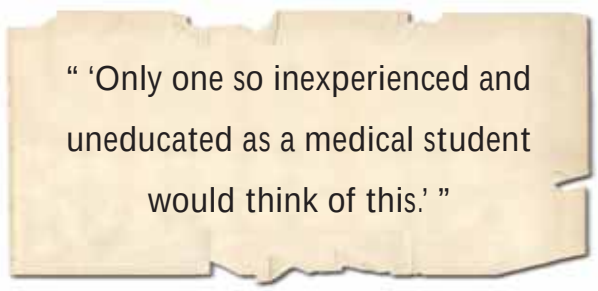
EVT: What was that day like for you, the day when the first procedure was performed?

Dr. Fogarty: The inspiration of the thought of it was exciting, but the implementation, actually seeing it work, was the most exciting part. It was a severe bilateral iliac occlusion, and the clot broke up at the bifurcations. The other fascinating part was that we were able to use local anesthesia. I was a scrub technician, and when I saw it work, my response was "Holy cow!" Drs. Cranley and Krause, who were at the operation, had the same response of "Wow, this really works." I did not at the time appreciate the future implications of its success. I appreciated the fact that I helped an individual patient. From my perspective looking back now, however, it was the start of minimally invasive surgery and of procedures using a dedicated instrument to be used endovascularly.

Now, a lot of people get confused about the distinction between "endovascular" and "minimally invasive," and essentially it's broader than the terminology itself. You can perform "minimally invasive" procedures with very small incisions or big puncture holes. "Minimally invasive" really means that there's no trauma to the patient, less general anesthesia, if you choose, and that the recovery time is a lot quicker.

EVT: How did the device compare to some of the other research that was going on at the time?

Dr. Fogarty: Well, it changed some of the future directions significantly. It was the first catheter to emanate therapy, and it really made people start thinking. Charlie Dotter already knew it, but he didn't implement it. He said that a catheter can be more than a diagnostic tool, but he never really implemented it effectively. He had the concept of coaxial dilatation, which was really quite traumatic. It was very bloody and he had a high failure rate, even though it worked sometimes. And it wasn't Gruentzig that came up with the concept of using the balloon for dilatation, it was actually Charlie Dotter. He actually did the first peripheral procedure with a catheter that I made specifically for him. At the time, he was Chief and Director of Radiology at the University of Oregon. I was an intern there and stayed on for my residency, so he knew of me and had me make catheters for him. It was interesting that iliac dilatation was open 10 years later.



EVT: When did you first have the support of a manufacturer?

Dr. Fogarty: I could get nobody to make this; it took about 3 years to get any kind of support. It was frustrating. But a company by the name of Edwards Lifesciences was the only one that had the vision. Part of the reason was that the traditional academics, the teaching at that time, was that if you manipulated the inside of an artery, it would clot. Well, it didn't. But that was the traditional thinking, and it was almost insurmountable. You did not ever touch the inside of an artery; you kept the forceps off of the artery, and scraping the inside of an artery was considered malpractice. I remember at the University of Cincinnati, where I was a student, Jack Cranley, who did the first procedure and the next ten, presented a grand rounds, and the Chairman of the Department of Surgery and also the President of American College of Surgeons gave a critique. Dr. Cranley credited me with making the instrument, and they said, "Only one so inexperienced and uneducated as a medical student would think of this."

EVT: What would you say are the most exciting developments that are based on this technology that have come since?

Dr. Fogarty: What I'm most pleased with is that it led to, from my perspective, the development of endovascular technology, and it led to additional applications and other cardiac approaches. We didn't do coronaries,

but that balloon led to the concept of doing standard angioplasty. The only difference was that we had a variable volume balloon. The fixed-volume materials just weren't advanced or available. I made some by twisting the tip of the balloon down. Charlie Dotter used some of those, but the technology moves quite quickly, and someone soon came up with a low-profile, fixed-volume balloon. That was the Gruentzig balloon in 1970.

EVT: You have invented a number of devices since the embolectomy catheter. What's next?

Dr. Fogarty: Well, one of my greatest passions now is my vineyard and my wine. I actually believe that the FDA should reconsider classification of wine—it should be classified as a health food. You can abuse any medicine, or any liquid for that matter. You can kill yourself by drinking too much water. You can get in trouble by eating or drinking too much of anything. Moderation is the key.

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EVT: So what do you prescribe?

Dr. Fogarty: Two or three glasses of Fogarty Pinot Noir. My wine is one of my passions, but there's another one that nobody's seen yet that we at Fogarty Engineering have come up with. It will change the whole way we do resuscitation, a major paradigm shift. Essentially, we have developed an automated resuscitator. It weighs 18 pounds, and it comes in about a 20-inch case. Compared to manual chest compression, it provides 60% more cardiac output. That's big. Most people don't recognize that you can't defibrillate a deoxygenated myocardium. You also can't defibrillate a myocardium that is filled with high levels of potassium and low pH, and this device changes all that. We get almost normal coronary perfusion with this device. That's big. Part of the problem with resuscitation is if the heart's not moving, you give adrenaline, but it doesn't get to the heart. This gets the bad stuff out of the heart and allows a proper drug treatment. It's just been introduced in the last year, but we're going to save more lives. It's amazing. It's simple. Once again, simple things are good. ■