

THE REST OF YOUR LIFE

A Few Beats Ahead: Medical Device Pioneers

Dr. Thomas J. Fogarty was a 4th-year student at the University of Cincinnati in 1960 when he invented the balloon embolectomy catheter, a device that would eventually transform vascular surgery.

But initial acceptance was slow. Three major medical journals refused to publish a paper he assembled about the device because "it was contrary to all accepted concepts about vascular surgery," Dr. Fogarty recalled in an interview. "It was taught that if you touched the inside of the vessel, even with a forceps, it would immediately thrombose. I was scraping the inside of an artery with a balloon."

He also suspects that part of the initial lukewarm reception had to do with the fact that, at the time, he was in his mid-20s. When he arrived at medical meetings as an invited guest to speak about the balloon embolectomy catheter "I'd show up and they wouldn't believe that I was the individual that was responsible for it," he said. "They would ask, 'Are you sure you're Dr. Fogarty?'"

Dr. Fogarty credits his early success to Dr. Jack Cranley, one of the first surgeons in the country to devote his practice to vascular surgery. The two met when Dr. Fogarty was a high school student working as an orderly at Good Samaritan Hospital in Cincinnati. "My father died when I was very young," Dr. Fogarty said. Dr. Cranley "became my father figure and encouraged me. I worked for him doing various jobs, from mowing his lawn to painting stripes in the [hospital] parking lot."

He eventually became Dr. Cranley's scrub technician in the OR, where the two realized that the surgical technique and instrumentation used to remove a blood clot from occluded arteries in the extremities was inadequate. Dr. Cranley turned to Dr. Fogarty and said, "Tom, you can fix this."

Under Dr. Cranley's mentorship during medical school, Dr. Fogarty designed a balloon catheter and performed experiments in animals and cadavers to perfect the device.

At that time, "there weren't many materials that were medical grade," he said. "The ones that existed [were part of] conventional systems, like a ureteral catheter. I took materials that were available and made the catheter system."

Today, he holds more than 63 patents for surgical instruments, including the AneuRx stent graft, and runs his own engineering company that develops medical devices. He also owns a winery in Woodside, Calif., and teaches surgery at Stanford (Calif.) University, where he served as medical staff president from 1970 to 1979.

A married father of four grown children, Dr. Fogarty said that balancing family with clinical work and the development of medical inventions early in his career was difficult. "If you take on that kind of challenge, you have to spend a lot of time," he said. "Retrospectively, I regret the fact that I didn't spend more time with the family. When you're so dedicated and focused on what you're doing and you love to do it, sometimes you put the family in second place. I am regretful



Dr. Robert A. Levine (left) and Dr. Stephen C. Wardlaw have received more than 400 patents for medical diagnostic devices.

that I did that, but things turned out fine. My kids are doing well."

Inspired by Mentors

Dr. Robert A. Levine found inspiration to pursue work in medical inventions from a pair of mentors. One was Dr. Solomon Berson, an internist who in 1968 became the chair of medicine at Mount Sinai Hospital in New York. The other was Rosalyn S. Yalow, Ph.D., a physicist with whom Dr. Berson developed the radioimmunoassay. Dr. Yalow was awarded the Nobel Prize in physiology/medicine for this achievement after Dr. Berson's death.

"Dr. Berson inspired me to practice both medicine and science," said Dr. Levine, an endocrinologist and clinical professor of laboratory medicine at Yale University, New Haven, Conn. "Dr. Yalow inspired me with her determination, intellect, and professionalism."

In the mid-1970s, Dr. Levine had a busy internal medicine practice 15 miles from New Haven but was frustrated by the time it took to get results from his patients' simple blood tests. "These were patients who came in without appointments [for] a bad cough, possible pneumonia, a stiff neck to rule out meningitis, or a little bit of blood in their stool," Dr. Levine recalled. "I didn't want to wait 24 hours to get the results back from the laboratory."

He and Dr. Stephen C. Wardlaw, also a clinical professor of laboratory medicine at Yale, developed an in-office instrument that performs a complete blood count in

about 5 minutes. They patented the device and licensed it to Becton Dickinson and Co. when they were in their early 30s. The device, currently known as the QBC Star Centrifugal Hematology System, marked the beginning of an invention partnership that has spanned nearly 3 decades.

To date, the duo has more than 400 patents for medical

diagnostic devices and has generated more than \$1 billion in sales. Other notable inventions include the Quantitative Buffy Coat analysis test for malaria and the HemaWipe test for colon cancer screening. "All the diagnostics and all the inventions that we've made were [developed] because we saw a need that wasn't being met," Dr. Levine said.

He said that, early in his career, he struggled to balance his clinical private practice with his teaching obligations at Yale and the pursuit of inventing medical devices. "In order to be a successful inventor, the inventions have to become an obsession," said Dr. Levine, who is married and has three grown children. "In order to be a successful husband and father, you must never let the inventions become an obsession. You must balance and make sure you spend the appropriate quality time with your children. You have to operate at the interface of those two. Occasionally, I would spend too much time on my invention."

The balancing act was difficult, he added, "because I loved everything I was doing, but there's only a finite amount of time."

He retired from clinical practice in 2004 but still mentors medical students and internal medicine residents at Yale. "I have no unmet goals other than to continue doing what I'm doing," he said. "I love it."

All in the Family

Dr. Dan Osterweil calls himself the idea man behind inventions intended to help fall-prone elderly, but he leaves the tech-

nical work to his brother, Joseph, who is a retired engineer.

"I create the challenge and the problem and bring the clinical background," said Dr. Osterweil, professor of medicine at the University of California, Los Angeles, who also codirects the university's multicampus program in geriatrics and gerontology. His brother "comes up with the electronic solution and then we test it."

Their first project came in 1987 when the brothers created a restraint-free monitoring device that alerts nurses and other caregivers when a patient is leaving a bed, wheelchair, or room. At the time, Dr. Osterweil was medical director of the Los Angeles Jewish Home for the Aging, and he saw the need for a product that would "bridge the gap between inability to provide the right supervision [of patients] and ... the potential for falls."

Today, the device, currently known as the TABS mobility monitor, is widely used in long-term care facilities. Though he holds four other patents, Dr. Osterweil said that he's most proud of the TABS mobility monitor "because it was ahead of its time," he said. "The feeling of pioneering something gives me satisfaction."

He and his brother recently patented a system that assesses the wound healing process. "The methodology uses visual imaging and can provide to even non-trained individuals information on size, depth, color, and characteristics," he said.

Given his busy clinical and teaching schedule and his responsibility as editor in chief of the Journal of the American Medical Directors Association, Dr. Osterweil devotes only about 5% of a given work week to invention-related matters. But he's focused with that short window of time.

"The key is to be organized, to compartmentalize your activities, be a delegator on one hand and a sharer on the other hand," he said. "If somebody's obsessive-compulsive and wants to do everything himself, and doesn't trust people around him, that's the person who will have a miserable life." But, he said, for the person who "feels good about himself and surrounds himself with people who are talented or better than him, and he knows when to delegate, then life is enjoyable." ■

By Doug Brunk, San Diego Bureau

Edison Was Right: Inspiration Is Just the Beginning

So, you think you have a great idea for a medical invention or device? Experts shared the following advice:

- **Find a mentor.** Innovation and invention are "really a mentoring process," said Dr. Fogarty. "It's difficult to teach in a classroom. Find a mentor and spend a fair amount of time with that mentor."
- **Form partnerships.** "Always align or create partnerships with people who have deeper expertise in a component of your invention that you may not have," said Dr. Osterweil. "You may have the great idea but you may not

know how to take it to the next step.

- **Don't give up your medical practice abruptly.** Inventing "is best done with a full stomach, which means you should not give up your medical practice," said Dr. Levine. "All my inventions were funded with my own money. I saved my money, lived modestly, and invested in myself."
- **Find a competent patent attorney.** This is essential. "Just because you're a doctor doesn't mean you're going to be a good lawyer," Dr. Levine said.
- **Prepare to be labeled as an outlier.**

Innovation "by its very nature makes you an outlier because you are violating standards of practice," Dr. Fogarty said. "You're subject to ridicule and criticism. Be prepared for that; it's part of the process."

- **Don't be wed to it.** "When you get to the point where you have a product, let somebody who is skilled in marketing do it for you," Dr. Osterweil advised. "Don't micromanage it."

Those who want more advice can visit www.mdinventions.com, a Web site run by Dr. Levine and Dr. Wardlaw.