

There may be no better way to get a broad, deep view of what's happening in medical electronics than to sit down over coffee with Mir Imran. An inventor with more than 200 patents to his credit, Imran describes himself as a "parallel entrepreneur," working on several projects at once and spinning out one new startup a year, on average. He is best known as one of the developers of the automatic implantable defibrillator, but his work spans imaging, wireless and artificial organs as well as three successful startups in security.

Today Imran is the chairman of at least eight companies he seeded with his own inventions. He is an active angel investor and handles life sciences investments for a division of Draper Fisher Jurvetson. "He is a truly amazing polymath — a tremendous inventor who is interested in everything," said Steve Jurvetson, a managing director of that Silicon Valley venture firm. Rick Merritt of EE Times spoke with Imran at the small, simple office in Menlo Park, Calif., that is home to his incubator, In-Cube Inc.

EE Times: What are you working on these days?

Mir Imran: Lots of my work in the last few years has been in tissue engineering, to create hybrid devices in which a portion of them are living cells from the patient that integrate with traditionally engineered systems.

For example, we are working on an implantable dialysis system that incorporates the patient's own cells but also has polymers and electronics. The dialysis is performed by the patient's own cells inside the device.

This creates a very delicate balance of keeping cell-based components alive and working inside the man-made materials. It's fascinating work for me. We are working on a number of artificial organs from this perspective.

EET: Such as?

Imran: We are looking at an artificial pancreas, liver and lung. There's an artificial colon, too.

EET: What are the most promising?

Imran: They are all such difficult projects that I would be ecstatic if just one was successful. It's hard to predict. If it were purely an electronic device I could predict how it will work. But when you are dealing with an intimate interaction with the body and blood, and incorporating cells from your system to do some of the heavy lifting — we still understand biology very poorly.

The dialysis unit is an artificial kidney. It's a complex project, and I am not even sure it will ever be successful. We are doing bench testing now, and I hope by next year we can get into animal testing. I don't know when it might get to humans. It doesn't cost much to dream big, but it costs a lot to turn those dreams into realities.

EET: What other areas interest you?

Imran: Right now there is a huge wave of interest from a variety of companies in central nervous system disorders and treating them with electrical stimulation. I was doing research in implantable systems, telemetry and neural stimulation in the mid 1970s. Now, just in the last five to 10 years, there's a big wave of work going on in neural stimulation. There are probably half a dozen companies, including one of mine, working in this area.

The other area where electronics has played an amazing role is in diagnostics, like MRI and ultrasound. I started a company five years ago that is developing the next generation of ultrasound.

EET: Tell us about the devices that can be swallowed, that your startup Entrack is pursuing.

Imran: I think swallowable devices are fascinating. There are a couple other companies in this space.

The small intestine is still a black box for physicians. The 10 to 15 feet of the small intestine isn't touched by colonoscopies and endoscopies. CT scans and other imaging techniques give some information, but you don't learn much about the chemistry and motility of the gut, which is still not well-understood.

So, swallowable devices are new platforms for diagnostic tests and therapeutic procedures. Our IP [intellectual property] includes wireless communications with the device as it passes through the gut, so you can send commands and enable treatments. For instance, you may be able to detect Crohn's disease and treat it with drugs days before someone might otherwise be hospitalized with acute pain.

EET: Will we look back some day and see the current era of nerve-stimulating devices as crude?

Imran: I do think some of the neural-stimulation techniques we use today are gross therapies and will be supplanted by personalized molecular medicine and specialized proteins. Medical electronics will always continue in areas such as imaging and defibrillation. That's not going away. But other therapies, such as stimulating the vagus nerve to treat depression, may not endure.

EET: How did you get involved in medical electronics?

Imran: [It] was accidental. While I was a senior in electrical engineering at Rutgers, I had a summer job developing communication devices for children with cerebral palsy. It was such a powerful experience that when the little institute [that ran the program] offered to pay me what we had agreed to, I declined. I was completely broke, but had so much pleasure — it was such a wonderful experience — that I didn't want any money.

I went on to get a degree in bioengineering, and from there I went to medical school for three years. My third year into medical school, I ran into some physicians from Johns Hopkins and we ended up developing the first implantable automatic defibrillator.

EET: How did that device come about?

Imran: The concept was pioneered by Michel Mirowski at Johns Hopkins. A close friend of his died of cardiac arrest, and the ambulance couldn't come fast enough to resuscitate him. [Mirowski] was heartbroken and started working with the concept of an implant, but he wasn't an engineer, and miniaturizing [an external defibrillator] into [an implantable] package was a challenge. One of my professors at med school was a friend of his or his company, and he said they should talk to me. So I put a small engineering team together.

EET: What were the design challenges?

Imran: We had a lot of challenges figuring out normal heart rhythms — when to shock and when not to shock the heart. Even with external defibrillation, it's not pleasant for the patient. When you discharge 700 volts across the heart, patients describe it as being kicked in the chest by a mule.

There was a whole series of challenges. How do you put high-voltage capacitors in such a small device? What kind of battery do you need? How do you detect a heart attack? How do you put in safety systems, because false positives and negatives are not tolerable?

We borrowed some concepts from pacemakers, but the battery technology had to be developed from scratch. I worked with Honeywell to develop a special lithium chemistry, which is still in use today. I ended up developing several CMOS chips for the first defibrillator and doing a lot of the electronic and mechanical design myself. It was another amazing experience, literally bringing patients back from the brink of death when seconds counted. We ultimately sold the company to Eli Lilly and it was later spun out as Guidant.

EET: How long did it take to develop?

Imran: Probably less than two years for the first product. The reason it didn't take so long was the FDA [U.S. Food and Drug Administration] was in its infancy. The regulatory environment was very different then. The FDA was chartered in 1976. It was only three or four years old when we were doing this. They were much smaller and more nimble, and the approval process was more streamlined then.

Today, in medical implants, product development is a small fraction of the time-to-market. You can develop an implant in a year, but it takes another year to do animal testing and other tests. Then you start human clinical tests that take another two to three years. So it takes six to eight years to develop a product. Clinical testing is where the real costs of development come in these days.

EET: How do you see the regulatory environment today?

Imran: Regulatory agencies tend to react strongly one way or another, such as in the '80s, with the breast implant scare. Many companies couldn't survive the incredibly slow response of the FDA. The agency has evolved in the last 25 years to become more rational and scientific.

Where I see a struggle for the next 20 years in regulatory issues is areas that are new, and are therefore the hardest to regulate, because you don't know where the boundaries should be, such as in stem cell therapies or products that are combinations of drugs and a device. There are separate groups for drugs and devices at the FDA today. They are creating multidisciplinary

teams to deal with these things, but that has the impact of dramatically slowing down the approval process.

EET: Do medical electronics companies need a multidisciplinary approach?

Imran: One of the problems I see in some medical companies is [that] engineers may not have an understanding of another engineering discipline, let alone medicine. Mechanical engineers are generally allergic to electrical engineering. It's almost a mental block. I have heard so many engineers say, "That's not my area of expertise." So what? Why not explore it? It's not that difficult. My advantage is, I have good training in electrical and mechanical engineering, as well as material science, medicine and software. That gives me the toolbox to solve a lot of clinical problems. When you put together teams of mechanical, electrical and chemical engineers and doctors, these people don't speak the same language. So it can take a lot longer to come to a solution than when you have all those disciplines in one person.

I wish more engineers were trying to deepen their understanding of biology and chemistry, because they would be developing a very powerful potential to solve problems that would advance medicine beyond where it is today.

EET: Why aren't they?

Imran: Most of the engineers I grew up with were fascinated by technology. They don't realize their training is to solve problems, leveraging what they know.

I don't care about technology — whether it's an electronic or mechanical solution, whether it uses nanotechnology or MEMS [microelectromechanical systems]. People are creating a lot of unnecessary hype about nanotechnology. It's just like in the mid-1980s, when everybody wanted to solve problems with MEMS. But when you have technology looking for a problem, you wind up force-fitting the technology on a problem that doesn't need it. Not every problem needs MEMS or nanotechnology.

I focus all my energies on problem solving and the clinical problem, the disease process, the existing therapies and how well they work. Once you understand where the problems are, inventing a new therapy can be a simple consequence of that understanding.

EET: How would you characterize the health of the medical electronics sector?

Imran: It's been growing at an amazing rate, and it will continue to do so. We are leveraging everything that is being developed, from DSPs in imaging to RF communications to noninvasively program and interrogate [implantable] devices.

I have seen dozens of people coming into medical technology from other disciplines, but I have never seen them go back, because it is such a satisfying experience. In meaningful ways, you are helping people. The problems we deal with have been there for centuries. Heart disease is not going away, [whereas] a new protocol for wireless communications has a limited life.