You might remember *Fantastic Voyage*, the 1966 science-fiction film in which a submarine and its crew are shrunk to nanoparticle size and are injected into the blood stream of a scientist. The goal: to zap a blood clot on the fellow’s brain from the inside.

It was pretty cool stuff at the time. But now? That’s old school. Paul J. Wang, a Stanford University cardiologist and professor of both medicine and bioengineering by courtesy, has a much more up-to-the-minute idea: a tiny, heart-treading “moon rover.”

Wang, funded by a federal Small Business Innovation Research grant, is designing a technique that would allow a little motorized heart cart to attach itself to the heart’s inner surface for coronary troubleshooting.

“It basically attaches and then literally rolls around,” Wang says. “It can sample tissue just like the moon rover samples...
DOCTOR AS DESIGNER

Dr. Alan Greene, practicing pediatrician and chief medical officer of Scanadu, whose handheld Scanadu Scout scanner—when pressed briskly to patients’ foreheads—can collect their full set of vital signs.

Is it true that you are working on a “tricorder” scanner like the one Dr. McCoy of Star Trek used to perform patient diagnoses?

There actually is a $10 million Tricorder X Prize competition going on. We are involved in that—and are considered by many to be the leaders.

You say that because of the Internet doctors no longer are the sole repositories of medical knowledge. And because of emerging technologies, doctors’ diagnostic role is disappearing. Explain that. Medicine is about to change exponentially. We’re going to open up the doors so that people can explore their own bodies, figure out what is happening in them and actually get diagnoses on their own.

So, as you say, doctors must begin thinking of themselves as “designers”?

Yes. Doctors need to jump outside our traditional clinical roles and create the solutions. Often it means working with engineers and technologists, and maybe business people, to make that happen.

Isn’t that an industrial approach to medicine?

It is. But it’s even beyond industrial. The medicine of the future will be located wherever the patient is. It will be with them—maybe even in them. And doctors need to be there, helping to design that.

How long will it be before doctors think of themselves as designers?

I would think that by the time that kids who are in kindergarten now are adults, that transition would have taken place. —K.F.

Q & A
a high-tech heart sock. Results of their work were published online in the journal Nature Communications in February.

"It will have a mechanical system that records how it moves with every heartbeat," Efimov says. "It could even detect if your patient is [experiencing] the beginning of a heart attack."

Such silicon membranes could also be attached to the inner surface of the heart to treat ventricular disorders such as atrial fibrillation. Since they will be wireless and stretchable, the continuous natural motion of the heart—100,000 beats per day—will never wear them out, he says.

Efimov’s fascination with 3-D printing technology doesn’t end there. In recent months, he and WUSTL cardiologist Gautam Singh have collaborated on integrating...

KEEPING THE BEAT
While the future of cardiac devices edges into the realm of science fiction, existing technologies have already taken treatment of certain diseases to new frontiers. Two experts spoke to Sky about how devices have made a difference in treating heart failure, a disorder in which the heart loses the ability to pump effectively.

"VENTRICULAR ASSIST DEVICES ARE PUMPS THAT CAN BE SURGICALLY IMPLANTED TO ASSIST THE FAILING HEART. OVER THE PAST FEW YEARS, OUR TEAM HAS SUCCESSFULLY USED A WIDE VARIETY OF DEVICES TO HELP PATIENTS WITH SEVERE HEART FAILURE GET STRONGER WHILE WAITING FOR A HEART TRANSPLANT OR TO GIVE THEIR OWN HEART A CHANCE TO RECOVER." DR. JAMES TWEDDELL, MEDICAL DIRECTOR OF CARDIOTHORACIC SURGERY AT CHILDREN’S HOSPITAL OF WISCONSIN AND CHIEF OF CARDIOTHORACIC SURGERY AT THE MEDICAL COLLEGE OF WISCONSIN

"WHAT HAS BEEN EXTREMELY EXCITING [IN RECENT YEARS] IS THE USE OF FLUID REMOVAL DEVICES IN THE TREATMENT OF CONGESTIVE HEART FAILURE. ULTRA-FILTRATION, WHICH IS A GENTLE AND PORTABLE WAY OF REMOVING FLUID THROUGH A SMALL CATHETER IN THE VEIN, HAS BEEN SHOWN TO SAFELY AND EFFECTIVELY REMOVE FLUID IN PATIENTS WHO ARE RESISTANT TO CURRENT THERAPIES." DR. JOHN WIGNESWARAN, VICE PRESIDENT OF MARKET DEVELOPMENT AND CLINICAL STRATEGY AT FRESENIUS MEDICAL CARE

Ashequl Islam, MD (left) Interventional Cardiologist
Joseph Flack, MD (right) Cardiac Surgeon

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For a referral, contact Noel Harrington, MSN, heart valve coordinator, at 413-794-2572 or Noel.Harrington@baystatehealth.org
3D printing technology into Singh's pediatric heart practice.

Singh treats infants with heart defects. They often require surgery—on hearts the size of strawberries—very early in their lives. In some cases, surgeons have to open the baby's chest, place him or her on a life-support machine, extract the heart, examine it, quickly determine the problem and correct it.

Such operations should be carefully planned and every bit of information about the defect documented in advance, Singh says. With that in mind, he and Elfner are working on a way to combine high-resolution cardiac imaging, off-the-shelf AutoCAD software and 3D printers to print out real-world facsimiles of babies' hearts. These printers can produce exact copies of hearts in a soft plastic material that mimics the feel and pliability of real heart tissue. They match every contour, every vein, valve, chamber and defect, precisely. They can even be proportionally enlarged, allowing the doctor to study the baby's unique defect in detail up close and even cut into them for surgical dry runs. It has long been possible to use magnetic resonance imaging and computerized tomography scans to study heart defects in detail. But as good as those images are, they are two-dimensional—and you can't take a scalpel to a computer screen. For Singh, there is no substitute for an exact, manipulable replica.

**Mission Control**

Medical devices get developed in many number of ways. But doctors are usually a key link in the chain of device and technology innovation.

“Many innovations over the years start with a physician entrepreneur identifying an area where they are frustrated by the lack of treatment options,” says Hill Murray, CEO of the Minneapolis-based Medical Device Innovation Consortium.

Sometimes doctors come up with ideas for new technologies and partner with manufacturers to build them, licensing the resulting intellectual property over to those companies.

In other cases, device makers brainstorm ideas in consultation with advisory committees, which generally are stocked with clinicians. Occasionally, physicians strike out on their own.

E. Martin Kloosterman is director of the Lynn Heart and Vascular Institute at the Boca Raton Regional Hospital. He falls into the latter category.

Three years ago, Kloosterman found a way to use iPads to visualize, in real time, the activity of pacemakers and defibrillators and to help reprogram the devices. Getting such readouts is not new. Modern pacemakers and defibrillators are computerized and can be read and reprogrammed on the fly. Doing that has required that hospitals and clinics keep “programmers” or propriety computers from the device manufacturers ready at hand. If no one on the floor knew how to operate a programmer, a company technician would have to come before a patient shows up for surgery.

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be brought in, which caused delays in treatment. Programmers are still required, but Kloosterman saw a way to minimize the potential for interruption. “I thought we could do a lot better than that,” he says. “My motto on this was, ‘If we can control a robot on Mars, we can certainly control a pacemaker in Boca Raton, Florida.’”

In 2011, Kloosterman developed a system for real-time wireless monitoring and reprogramming of cardiac devices using iPads and iPhones via Wi-Fi. It allows doctors to bypass programmers and get readouts directly to their mobile devices. Doctors could then suggest changes to the device’s settings, which nurses execute using touchscreen laptops.

In reality, it is hard for even the most creative physician to be both a full-time doctor and an inventor. William Peters, chief technology officer at Minnesota-based Sunshine Heart, found a way around that problem. A former cardiac surgeon who helped develop keyhole heart surgery while at Stanford University two decades ago, Peters left surgery to become an entrepreneur (he also currently has an academic appointment in Auckland University’s department of surgery).

Peters had noticed that some heart failure patients were undergoing radical procedures even though their hearts were really not that far gone. He suspected heart failure might even be reversed in such patients if their hearts could be given a little extra boost.

With that in mind, he created the C-Pulse, which works somewhat like a blood pressure cuff for the aorta. A wire attached to the heart picks up electrical signals and triggers the device to inflate and deflate with the patient’s natural heart rhythm.

The C-Pulse has been approved for marketing in the European Union, but things work slower in the United States. A 388-patient American pivotal study has just gone underway—14 years after the device was first developed. Still, Peters is thrilled to be closing in on his goal.

OUT THERE
You can imagine how much potential these technological advancements—and the remarkable innovations that came before them—have in the transformation of cardiac medicine. But if you were Bud Frazier, director of cardiovascular surgery research at the Texas Heart Institute, you wouldn’t have to imagine it. He has personally witnessed the steady parade of progress in the field since shortly after the first...
A pacemaker was implanted in a patient in 1958.

Frazier first began studying under cardiac surgery pioneer Michael DeBakey at Baylor University in 1963. Frazier worked with the team that developed the first artificial heart and as a medical student wrote a research paper on the project. The first artificial heart was implanted in a patient in 1969, buying patient Haskell Karp 64 hours until a transplant heart could be located. Unfortunately, he died shortly after receiving his new natural heart.

Frazier has worked on too many revolutionary cardiac technologies over the years to list briefly. Suffice it to say that it was Frazier who conceived and helped to develop the battery-powered, continuous circulation, ventricular pump device that kept former Vice President Dick Cheney alive—without a heartbeat—for two years until Cheney finally received a natural heart transplant.

At age 74, Frazier is far from finished. He insists that implanting mechanical hearts as a bridge to a transplant is the wrong goal. So he is codeveloping BiVACOR—a permanent, pulseless human heart designed to last as long as the patient, hopefully many years. The device, about half the size of a man’s fist, could fit into an 8-year-old’s chest, yet has plenty of pumping capacity to permanently replace an adult’s human heart. "We are hopeful that it will be ready for implantations in the next four to five years," he says.

Clearly, cardiac medicine has advanced well beyond limits of those 1960s sci-fi moviemakers’ wildest visions. “Take all of the advances in computer science, for example,” Frazier says, adding sardonically: “I don’t even like to think about it.”

Others, including Stanford’s Wang, relish it. More technologies are still to come. And, says Wang, the involvement of doctors and patients will always be critical in designing and developing ever more refined, targeted and, for lack of a better phrase, out there cardiac care technologies.

“What is important is understanding how the design of these technologies best suits what’s needed,” Wang says. “You could say that’s what Steve Jobs did—he understood best what the user interface was.”

“We’re doing the same thing,” Wang adds. “The user interface is the patient-to-physician interface. And the user is both the patient and the physician, together.”

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