

Out of view of patients, docs, Clinic shop allows for tool rehab, new idea development

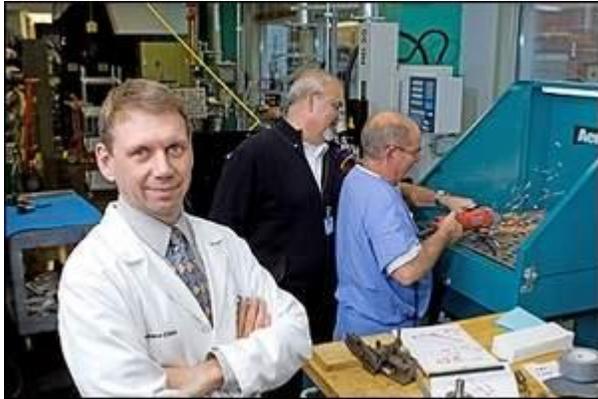


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Karl West, director of the Cleveland Clinic's Medical Device Solutions unit, runs the hospital system's mechanical prototype shop.

By DAN SHINGLER
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Surgeons and other doctors who perform miracles get most of the limelight at the Cleveland Clinic, but in the basement of its main campus, a crew of machinists, fabricators, engineers and researchers does impressive work, too — though mostly on steel and plastic, as well as the occasional human body part.

Unknown to most, the world-renowned hospital and research institution has a full machine shop and other manufacturing-related rooms housed below its medical buildings near University Circle. The shop gives the Clinic the ability not only to make, modify and repair tools for its own doctors,

but also to take doctors' ideas and turn them into new medical devices.

"We are a design group that integrates and works with the physicians to develop their ideas — and not just physicians, but anyone within the Clinic," said Karl West, director of the Clinic's Medical Device Solutions unit.

For example, a Clinic surgeon recently came up with an idea for a new stent that could be used in heart surgery. Taking the technical equivalent of a cocktail-napkin design, Mr. West and his staff turned it into three-dimensional drawings and, eventually, a stent that the Clinic can use internally and possibly can market to other hospitals and surgeons, Mr. West said.

Over in the machine shop, machinists such as Anthony Shawan work on prototypes for new devices, though they also do more mundane work that is just as critical to patient outcomes, if not more so.

"Sometimes, things break during surgery," Mr. Shawan said. On more than one occasion, Mr. Shawan said, he has repaired or altered a surgeon's tool while an operation was under way — a task that requires a faster turnaround than even the most efficient automakers demand of their suppliers.

"We've done stuff in less than half an hour, including machining and sterilization. We're literally running," Mr. Shawan said.



Mr. West holds an aortic valve with calcification created by the shop's Connex 3D printer.

A model of efficiency

All told, 32 people work in Mr. West's unit. They're a mix of seasoned machine shop veterans and tech-savvy, fresh-faced college graduates, and they perform an equally diverse set of tasks.

In one room, subjects with reflective markers at strategic points on their bodies provide data for a "gait lab," where computers take the information and technicians track and model a patient's movements. Using computer modeling, the lab works with patients suffering from neurological conditions or with amputees. It not only helps to research conditions such as multiple sclerosis but also to design better prosthetic devices. The

modeling system even conducts analyses on the throwing motion of baseball pitchers and golfers' swings.

In another lab, researchers and engineers work with a special metal called Nitinol, a relatively new alloy that has amazing abilities when it comes to elasticity and shape memory. The metal is non-reactive with body tissues and extremely flexible, but it's also "springy," Clinic researchers say, and that quality makes it perfect for devices such as cardiovascular stents, in which it's used to make a flexible frame to hold open blood vessels.

Next door, a computer bio- modeling lab would look familiar to anyone who has used a computer-aided design (CAD) system, except the Clinic uses its system to work with more than just metal and plastic.

For instance, technicians can work up a three-dimensional model of a human heart, complete with the plaque that's found in the blood vessels via medical imaging technology. Mr. West said they then can print out their model using a 3-D printer. The result is a life-size model of a patient's heart, with the plaque a surgeon needs to remove highlighted in a different color than the healthy tissue.

"They know it, because they see it in 3-D before they even go in (for surgery)," Mr. West said.

Parts put to work

In another section of the unit, researchers test artificial joints, spinal implants and other mechanical devices that go into the human body. Those devices must be tested the same way auto parts are tested, which means they must be put through wear and tear as close as possible to what they would be subjected to in the real world.

In the realm of prosthetics and implants, such work is messy.

Technicians spend a good deal of their time preparing real human feet, shoulders and other cadaver parts so they can have the devices attached to them and then be driven by robots to mimic the stresses a live human body would impart. While an auto supplier might have a robot compressing a shock absorber hundreds of thousands of times to test its performance, the Clinic's robot flexes an artificial joint over and over again for the same reason.

And, of course, there's the machine shop, where Mr. Shawan and his crew of eight work on a little bit of everything, from producing tools and fixtures for the Clinic's use on its own patients to manufacturing the bits and parts that allow the other parts of the Medical Device Solutions unit to function.

The payoff for the Clinic takes many forms. Immediate access to repair and fabrication work for medical tools and devices is a benefit that's tough to value in dollars; other efforts within the unit provide the Clinic with more direct financial and strategic benefits, such as new patents and research grants. For instance, some of the Clinic's work on Nitinol is financed by a \$3 million grant from Ohio's Third Frontier program.

Setting the pace

The existence of a hospital-based operation with all the research, design, testing and fabrication capabilities that a medical device manufacturer might have is a smart strategy for the Clinic, said Mark Coticchia, founder of Red Wind Innovations, a Cleveland firm that advises universities, hospitals and others on economic development opportunities centered around medical technologies.

As the former vice president of research for Case Western Reserve University, Mr. Coticchia administered federal grants from the National Institutes of Health, including some that went to the Clinic, and he's familiar with the scope of activities in which the Clinic engages.

"The Clinic is really pushing the envelope as far as folding in prototype development and product development activities into their commercialization effort," Mr. Coticchia said. "I'm not aware of any other hospital entity that's taken it as far as the Clinic has."