The Miracle Business
Dr. Ken Gregory spins his futuristic research into business reality
By Alaina Buller

It's probably a safe bet that nothing makes Dr. Kenton Gregory as giddy as a new discovery at the Oregon Medical Laser Center (OMLC). His eyes flash with excitement while his ever-present grin stretches even further across his face.

His enthusiasm is quite infectious, really. What looks like a simple image of soap bubbles floating across a computer screen suddenly seems thrilling.

And then comes the stream of superlatives: "I'm very impressed! I think this is superb…this is out of the box…it's nifty…it's just unbelievable."

This is the future of medical technology in the making. And it's all happening right here in Oregon thanks to Gregory and his staff.

"Things are hopping around here," Gregory says. "Who's coming on tour today? Hopefully someone with lots of money."

As the founder and director of OMLC at Providence St. Vincent Medical Center since 1991, Gregory has had no shortages of exciting moments, beginning with treating the first heart attack patient in medical history using a laser.

Gregory, a native Oregonian born in Salem, made the move to St. Vincent from Harvard's Massachusetts General Hospital with his colleague Peter Block, who headed Harvard Medical School's cardiology department. Gregory brought with him the technology of laser thrombolysis, a procedure used to instantly vaporize clots that cause heart attacks and strokes.

As soon as the technology was approved for a Food and Drug Administration (FDA) clinical trial, the two cardiologists only needed to wait for the right patient.

"I can remember watching with Peter out the window because we had notification that there was a patient in the full throws of a heart attack being flown in from the coast on a helicopter," Gregory says. "I can remember Peter and I staring out the window watching this helicopter coming in and thinking, 'Gosh, we're going to light off a very high-powered laser in somebody's heart.'"

It had never been done before, and after years of lab testing and animal testing it was the moment of truth.

“We see this helicopter come in. It’s really dramatic. You go in and you’re so busy paying attention to every little thing that you don’t have time to get worried. You just do your job. And it worked. It was neat,” he says. “Thank God it worked.”

In the FDA Phase I trial, 20 patients were successfully treated, and 15 years later, the technology is in routine use in most major hospitals.

Ralph Shaw, a member of the Council of Trustees at St. Vincent Medical Center, remembers the buzz Gregory created when he first started using his technologies to treat patients in the early 90s. He was eager to assist Gregory, so he helped create a second council, a board of trustees of sorts, for the OMLC. Shaw was careful to include a variety of sources on the board, including experts in business, politics, grant writing, and health insurance.

“I went to the administration at St. Vincent and said, ‘I think if Ken Gregory is as brilliant as I believe he is, we have to support him in more than just giving him some support for his laser laboratory.’ Everybody was very enthusiastic,” Shaw says.

“This community, I find, responds very spontaneously and with great enthusiasm if only people would ask them to help. In this case, what we asked them to do was to create an environment which could become a much bigger research and development organization — with an emphasis on development.”

The organization has grown into a team of about 30 experts and is now a world leader in medical laser and biomaterials research. The center is home to a confocal microscope — the most advanced microscope of its kind and one of only a few in the United States — that allows scientists to examine stem cells as living, growing objects in three dimensions. The center is also the only one in the state to house a tissue engineering and cell therapy center, or clean room. The clean room provides a pristine environment that aids in the process of transferring new technologies from the academic laboratory to production for clinical use.

With these advanced technologies and facilities, OMLC has stepped closer to realizing the completion of several of their research studies — one of which is laser tissue fusion. After almost 15 years of OMLC research, and decades of research by others in the field, this laser technology that seals and heals wounds in internal organs, instead of using needle and thread, is ready to be tested on actual patients. Once again, Gregory is waiting for the ideal patient.

“People have been trying to do that for 40 years. Even on Star Trek with Captain Kirk they were always doing welding with lasers. Now it looks so corny and unsophisticated,” Gregory says. “Anybody who’s anybody in the laser business has tried their hand at it. We’re just more persistent.”

And they’ve got the process down to a science — no pun intended. The incision is coated with albumin, one of the dominant proteins found in blood, and a sophisticated laser

emitting a soft blue light is guided over the wound. It takes less than a minute to seal a serious incision that might otherwise have been fatal.

“We wanted to keep it as simple as possible so anyone can do it,” Research Assistant Ted Moffitt says. “I’ve taught congressmen and the former Miss America. If I can teach them how to do it, any surgeon can do it.”

But as simple as this process may be, Gregory certainly realizes the risk involved as he prepares to test any new technology on patients.

“My brother is a psychologist and he said, ‘Let’s see, you’re doing something on a very high-risk patient that’s never been done before, and it’s ultra high risk. Could you have a more stressful job?’”

Gregory said the only job he thinks could be more stressful is to conduct these procedures while someone is shooting at him. He knows people in the military who have taken this daunting job, and he’s even been offered a position in that field. But he happily replies, “My anthrax vaccinations are not up to date fortunately.”

And of course these high-risk situations are preceded by heavy regulation from the FDA. Gregory admits they’ve got a difficult job, and he says he would not relish the thought of, like the FDA, being in charge of tens of thousands of different drugs and devices.

Andrew Barofsky, one of the principle inventors of the elastin technology, understands the need for rigorous investigations. “Whenever you’re dealing with biological systems like the human body, it’s very complicated. Stuff that works in the labs or in animals works very differently than when you put them in the human body.”

The rigid testing process is divided up over time into several phases once the initial lab and animal testing has proven positive. Sometimes it can take 20 years for a device or drug to make it onto the market.

“I always say if I thought about how long it was going to take me, I probably wouldn’t even start it,” Gregory says.

But Gregory has defied the odds yet again with his world-famous HemCon chitosan bandage. Using chitosan, a compound found in shrimp shells, the bandage is extremely effective at stopping severe external hemorrhaging. Excessive blood loss is the leading cause of death of soldiers killed in action, and this bandage was clearly a way to combat that problem. The medical product was rushed through the FDA testing process and received the second fastest approval in the FDA’s history.

OMLC discovered the positive effects of chitosan in March 2001, and he presented the data for the first time at a military meeting held in Florida on Sept. 11, 2001. In his original presentation, Gregory said he thought he could get the bandage through the FDA in two to four years with about $4 million. The meeting attendees were skeptical and told

him it would take closer to five years and $50 million. The military liked the idea though and asked him to come back with a reasonable proposal.

Shortly after Gregory's presentation that morning, they watched the planes fly into the twin towers, and the tone changed.

"That's when they said, we're going to war with somebody, we don't know who, but it's going to happen this year, and [the bandage] needs to get out. They weren't concerned with the niceties of the FDA. That wasn't a good excuse," Gregory says. "They said they need this, and they wanted to deploy with it. Afterward they said we need this in one year, and we've got about $4-500,000."

It's a good thing the military recognized the capability of Gregory and his staff because the chitosan bandage wasn't always a popular experiment around the lab.

"The staff was always saying this is the loser project. Why are we doing this?" Gregory says.

OMLC was not the first to work on the hemorrhage control problem. Gregory says people have been attempting to stop significant bleeding for thousands of years. At another military meeting held at Fort Dietrich, Gregory even attempted to convince the military to let others work on the bleeding problem, while he continued his work on different projects.

"I was saying, 'Well, that's a really hard problem. The Red Cross is working on that. They've been working on that since World War II. They've got a whole building. They've got tens of millions of dollars and a lot of smart people,'" he says. "Then I realized 90 percent of my funding comes from the Army. When your major patron wants you to do something you think, 'How can I say yes faster?'"

So he returned to his lab and asked Simon McCarthy, a chemist and principle inventor of the bandage, to continue work on the chitosan project. The other experiment McCarthy was hired for wasn't ready yet, so Gregory assigned him to the "loser bandage project" for the time being. Once a successful bandage was developed, Gregory asked McCarthy if he realized that his product was going to save thousands and thousands of lives. McCarthy couldn't comprehend the importance. Now McCarthy is the executive vice president of research and development at HemCon Inc., a company created by Gregory to manufacture the bandages.

"When you see a stroke patient who can't move half their body come in and then walk out of the hospital, or when you watch a blood clot disappear in a couple minutes and the arteries open, or when you see the people who come in with their stories of how they were bleeding out on the battlefield and the bleeding stopped, it doesn't get much better than that. It makes you want to work harder," Gregory says.

Every year Gregory invites military staff to a voluntary meeting to critically look at the projects OMLC is undertaking. Two years ago at this meeting he remembers hearing a young Marine captain tell his story about how the HemCon bandage saved his life. At the time the captain was a tank commander in Iraq. He stuck his head out of the tank for a moment and was hit in the chin with a sniper bullet that blew his jaw bone and neck away. It just so happened that someone had one of the bandages and slapped it on his neck. The bleeding stopped and the captain was able to hold off the Iraqis with a 9 mm.

“After ten operations he came back and told his story to my staff. There wasn’t a dry eye in the place. He told this story about how he saw his life spurting away and he was only going to live a minute longer, and then next thing he’s got his normal life back now. So that had a big impact,” Gregory says. “We had a reception at my house, and he was the guest of honor. He had his medals all over the place, and my mom posed with him.”

Involvement in the military has always been important to Gregory. He says he has a lot of friends in the service and if they are willing to put themselves in harm’s way, he will do anything he can to help them. In 1996, Gregory and the OMLC research staff received a grant from the Army to reconstruct arteries and other tissues using a protein called elastin, a natural tissue protein that gives blood vessels, skin and lungs elasticity.

“If you notice, there are not that many replacement parts for people. That’s because most conventional plastics, glasses and metals don’t really react well with the rest of your body,” Gregory explains. “And so I thought I’ll see how Mother Nature makes her parts and use the same materials. It doesn’t take rocket science.”

The elastin parts are intended to repair or replace an artery, skin, ureter, or esophagus, and they would most often be welded to the affected area using the laser tissue fusion. Gregory has taken the elastins through the necessary pre-clinical trials, and he’s currently looking for an industry partner to take them to the next step.

The next big medical project on Gregory’s plate is a biggie: limb regeneration. Prior to the HemCon bandage, the death from bleeding in the battlefield had not changed since the Civil War. Now, after this most recent conflict, the death rate from bleeding has decreased for the first time in military history. Now that Gregory is partially responsible for bringing soldiers home, he wants to concentrate on giving them a normal life once they’ve returned.

Gregory points out that about 20,000 men and women return with injuries to their extremities. That’s 20,000 people whose lives may be forever changed because their arms or legs are disfigured or dysfunctional. Gregory thinks that’s too many people.

His theory is that before each soldier leaves for battle, he or she would donate their own stem cells. Scientists will increase the number of stem cells from a couple thousand to a hundred million and freeze them. Then if necessary, these stem cells could be injected into the injured soldier and help regrow heart cells, nerve cells or skeletal muscle cells.

OMLC is working closely with hospitals in Germany, the world leaders in stem cell research, to develop this concept. German hospitals have been regenerating hearts in patients for about six years, and they have been more than willing to share their findings.

“If you go to a major German hospital and have a big heart attack or part of your heart dies, before you go home they’ll give you an injection of your own stem cells. Six weeks later your heart is partially regenerated,” he says. “If you have a big heart attack in Portland, that’s not going to happen. All of America is behind the rest of the world because of stem cells. If you say stem cells here, you’re killing babies and stuff like that.”

It certainly helps the process along when the military funds a project, but the research is only half the battle when scientists are left to their own devices to get a product on the market. As Gregory puts it, “Scientists are bad businessmen. I’m living proof of that.”

He remembers trying to get a credit line for HemCon in the early stages of the company. He met with the banker, showed him a video of the bandage in action and really had him interested the company. The banker said, “Well, what’s your ROI?” Gregory responded, “What’s ROI?”

“You should have seen the banker’s face,” he says. “We didn’t get the credit line.”

For this reason, Gregory has created the Oregon Biomedical Engineering Institute (OBEI), a company that specializes in transferring technology from the academic world to the business world. While OBEI will have a laboratory to conduct research, its primary focus will be creating patents, licensing and new companies. Gregory has hired scientists and people from the business world to take on this task.

Gregory’s first choice to help form OBEI was Barofsky, who is now its vice president and general counsel. In addition to his elastin research at OMLC for five years, Barofsky also completed law school and business school and worked at Schwabe, Williamson and Wyatt as a patent attorney.

“For me, it’s a little bit of a dream job. It allows me to use the background that I have in all the different areas and professional directions that I’m headed in. I get to sit in on science meetings, help orchestrate business strategies and take care of some of the legal aspects,” Barofsky says.

Both Gregory and Barofksy site the lack of business experience as the main reason technologies often falter. Gregory compares the process to attempting to span a large crevasse.

“Many of these technologies run full blast, and they go right over like lemmings into a crevasse and never come up. It’s sad. I’ve got some of my technologies down there as we speak,” he says. “It’s a rare one that can get over that crevasse, from transferring it from the academician to the guy in marketing or the guy in business development or the CEO of a company.”

Many supporters believe that Gregory is one of that rare breed. Barofsky says Gregory has the perfect combination of energy and personality, as well as bright ideas in technology and research. Gerry Frank, a member of the Providence Board of Trustees, says he is knowledgeable, down to earth and able to communicate his technology so the average person can understand it.

Gregory says he's just afraid the business guys will take his technology and ruin it if he doesn't keep a close eye.

But perhaps Gregory's innovative spirit is best summed up by Shaw: "Just because things have been done in a certain way doesn't mean that's the only way to do them or the correct way to do them. I think that characterizes the way Ken Gregory looks at things. He has an extraordinarily inquiring mind, he has substantial confidence that solutions can be accomplished, and he's willing to accept the risk of failure to accomplish big things."

One Miracle, One Technology at a Time

Since 1991, the Oregon Medical Laser Center (OMLC) has created revolutionary solutions to medical problems. The center expanded its original focus of laser technology to include biomaterials research and tissue regeneration. Prepare to be amazed by the innovations created by Dr. Kenton Gregory and his staff.

Chitosan Bandage

OMLC is probably best known, nationally and internationally, for the chitosan bandage, a breakthrough in hemorrhage control technology. Chitosan, found in shrimp shells, adheres to red blood cells and quickly forms a clot to stop massive external bleeding. With the military's support, the chitosan bandage received the second fastest approval in FDA history. Developed in early 2001, the bandage was deployed for use in the Iraq war in 2002. It was recently used at Providence St. Vincent Medical Center to treat the first civilian trauma case. Gregory and his colleagues created HemCon Inc. to manufacture the bandage.

Heart and Limb Regeneration

Still in the early stages of research, the heart and limb regeneration program is Gregory's way to help wounded soldiers return to a normal life once they've come home. He hypothesizes that a soldier will donate their own stem cells before being deployed, then scientists will amplify these cells from a few thousand to a hundred million and freeze them for safe keeping. If the soldier returns injured, their own cells will be injected to regenerate muscles. Gregory has spent the past several months campaigning to gain the military's interest and support.

Elastin Replacement Tissue

Most conventional replacement parts are made from materials foreign to the body and, therefore, do not react well when implanted. Gregory created replacement tissues made from a natural material known as elastin, a tissue protein responsible for the elasticity of blood vessels, skin and lungs. OMLC scientists use these tissues to create replacement

arteries and other life-saving parts. OMLC began this project 12 years ago and is currently performing the FDA-required pre-clinical trials.

Laser Tissue Fusion
Laser tissue fusion is used to instantly seal and heal tissue with a laser light (where a needle and thread are not effective) in organs such as the liver, kidney or spleen. Attempting to suture those areas is like attempting to sew through Jello, Gregory says. The wound is coated with albumin, a protein found in human blood, and a laser is used to heat the albumin and seal the injury. After lengthy research — more than 10 years — OMLC plans to treat the first human patient with laser tissue fusion technology in the near future.

Photodynamic Therapy
Photodynamic Therapy (PDT) uses lasers to diagnose and treat cancerous tissue. Patients are given light-activated drugs that are absorbed by the cancer cells. A low-power light is then shined over the area killing the cancerous cells and leaving the adjacent normal cells unharmed, often resulting in a lack of chemotherapy effects. The OMLC was the first to use this treatment in the Pacific Northwest. The FDA has approved the use of PDT on several forms of cancer, and this technology is used routinely in most major hospitals, Gregory says.

Optical Diagnostics
OMLC researchers are developing methods to scan blood or tissue using light to detect disease. This technology could eliminate the need to remove blood and tissue samples for testing. Several groups around the country are developing laser light-based systems to diagnose various conditions. Optical diagnostics for cancer developed by the OMLC are used locally at Providence and OHSU. Gregory says the procedure is completely safe, but they are still working to determine the accuracy.

Laser Thrombolysis
Laser thrombolysis was the first use of laser energy to treat a heart attack patient in medical history. The technology was created to instantly remove blood clots in an artery using laser light, which then restores blood flow without damaging the artery wall. This procedure was first used in heart attack patients in 1991 and in stroke patients several years later. The technology is now in routine clinical practice.