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IMITATING REAL LIFE

Christopher Sakezles hopes his small company will have a large impact on the medical community. Page 6

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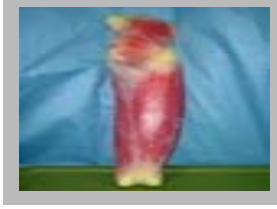



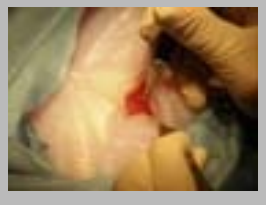


Dr. Christopher Sakezles, President and Chief Technology Officer of SynDaver Labs, shows a synthetic human thigh made by his company to replace live animals in medical device development tests.

MAKING BODY PARTS

SynDaver Labs of Tampa Bay creates novel materials that mimic muscles, tendons, veins and arteries

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God made Adam from a handful of dust, and Eve from a rib, the Book of Genesis says.

Dr. Christopher Sakezles is making a decent imitation from water, fibers, and salt.

One recent morning in his company's lab, he reached into a big plastic tank and pulled out a large, glistening, dripping hunk of something.

Gut reaction? It looks like one of those slabs of meat that Rocky pummeled for practice in the first movie.

It is a thigh of sorts, a convincing replica of a human upper leg. What's more, the beauty is more than skin deep.

Beneath that pink and marbled outer layer of simulated muscle, fat and tendon are simulated veins and arteries, right where the anatomy books show them, Sakezles says. Beneath that is simulated bone and cartilidge.

Touch it and it feels sickeningly real. The weight seems about right, as far as you would know if you could hold a thigh.

After seeing it in person you realize this is no Halloween gag or Hollywood prop, but what you get when a guy with a doctorate in polymer science and engineering gets interested in anatomy: maybe, the next big thing in the medical world.

All about dollars and cents, not animal rights

Dr. Sakezles' company is called SynDaver Labs, at least for now.

Tell him the name would play well with People for the Ethical Treatment of Animals and he seems more than a little disinterested.

Because while his concept might drastically reduce animal testing, he came to it from a perspective of cost rather than animal rights.

Sakezles was working in Princeton, N.J., as a consulting engineer, helping companies design medical devices like heart catheters. But he realized that what was truly innovative was not so much the devices as the anatomical mock-ups he created to test them.

He mentioned the medical mannequins made by another Sarasota company, Medical Education Technologies (METI), and gestured toward a plastic, German-made muscular model.

"The products are good for what they're used for," he said. "But what we're doing is a little bit different."

The German models are about the size and shape of actual human parts. METI's mannequins feature circuitry that mimics a person breathing and having a heart attack.

But neither plastic models nor mannequins respond like human tissue when you stick them with a needle, catheter, scalpel or stent.

Sakezles' creations will, according to multiple patents issued and under review by the U.S. Patent Office.

The company also received an “Excellence in Innovation” award from the U.S. Department of Commerce, one of only a few such awards given since the program's inception.

But Sakezles modestly downplays his products’ complexity.

"Conceptually, what we do is pretty simple," he said. "We're basically just copying human anatomy."

In practice, it is not so simple.

It starts by running a series of tests on live animal tissue, measuring physical properties like resistance to abrasion, compression and puncture, tensile strength, dynamic friction and other more esoteric properties known only to mechanical engineers — one of Sakezles' other college degrees.

Armed with that test data, he formulates a series of candidate materials, and through a combination of designed experiment and trial and error arrives at the closest match to the tissue in question.

"Water, salts and fibers" are how he describes the components, though again, the details are less simple.

One of his many patent applications spells it out in a bit more detail: "interpenetrating polymer networks, fibers, thermosetting polymers, thermoplastic elastomers, methacrylic monomers, etc."

These esoteric materials are then formed into various anatomical components using a combination of manufacturing techniques familiar in the aerospace industry — hand assembly, liquid injection, and insert molding. Like the precise nature of the fibers, these methods are also trade secrets, he said.

"What we do is basic material science," he said. "My expertise is in creating the materials that mimic living tissue. I source living materials and then copy them.”

"As far as generating the anatomy goes — I'm just copying God's work. It’s all laid out in anatomy books."

For something like the Rocky-esque thigh, generating anatomy means developing a number of synthetic tissues: "Cartilage, muscle, tendon, several different kinds of fascia, a couple different kinds of fat, skin, and then you've got the vein and artery components, which themselves are complex constructions," he said.

The result is something that is already saving millions for the world’s leading medical device companies.

"It's basically a way to save money, reduce risk and get new devices to market faster," he said.

"I know that firsthand, because as a former medical device designer, I used to be the guy who was responsible for accomplishing all of that."

Low bar to jump

Sakezles jokes that one reason his company has been successful is that he has such a low bar to hurdle.

"Even if our technology was crap, it would be better than what's out there right now," he said.

He has seen one model for testing catheters, using twisted rubber tubing to simulate arteries, and another that was made from glass.

"It's senseless doing testing in glass and plastic models," he said. "I mean, tissue's not made of glass. You can stick the device in and see it, but it doesn't tell you anything useful."

Most medical devices are tested on animals, which themselves are cheap. But testing gets expensive, because companies have to comply with the Animal Welfare Act and other international protocols. That means hiring surgeons, anesthesiologists and veterinarians, and contracting outside facilities.

"A $500 pig can easily turn into a $15,000 study," he said.

Using live animals also makes it nearly impossible to get consistent, reproducible results, because of variations from animal to animal and test to test, he said. Animal anatomy also differs from human anatomy.

Cadavers are more anatomically accurate. But death and chemical preservation change the physical characteristics of the tissue and make it respond less accurately.

Simulated tissue solves most of these problems, eliminates biohazard exposure, cuts costs and speeds up the overall process, he said.

"An engineer can sit down on a bench top with one of our models and just generate reams of data, whereas with an animal study or cadaver you get one data point," he said.

"Our products allow engineers to get good data, at the beginning of the development cycle, and perform one animal study at the end instead of wasting their time with a hundred," Sakezles said. "That ultimately saves a whole bunch of time and money."

Running those studies using simulated tissue costs less than one-tenth of the cost of doing the same work in animals, he said. "Once you run the numbers you can't justify not using the technology."

More than a few companies, including divisions of Johnson & Johnson, St. Jude Medical and Cook Group are already buying. The thigh and arteries are from a project for testing a device for closing femoral artery punctures. Another company wanted a mock-up of an aorta, complete with aneurysm. A third, Cook Urological, wanted a functioning penis for sales and marketing demonstrations.

But Sakezles has aspirations beyond device testing. One new market involves realistic products for surgeons to practice techniques — "we envision a synthetic version of what will be rolling into their ERs," he said.

The doctor would cut through the mock tissue, performing the required procedure, and then repair it with suture or surgical glue, or replace it completely.

Alternatives to this process now are cadavers, which are relatively difficult to source, and virtual reality, which is very expensive and difficult to master. He sees his simulations as offering an advantage to both.

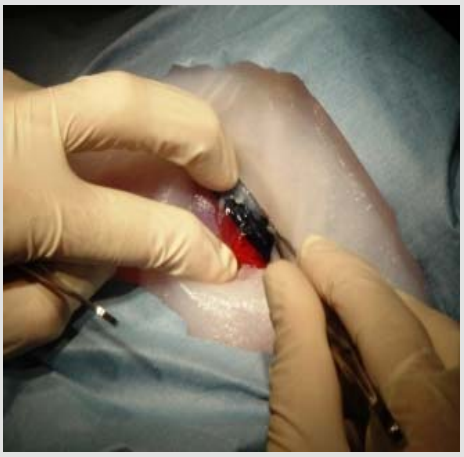
"Surgeons training on our products will just be practicing on synthetic anatomy what they will be doing on real anatomy. There's no computer interface to learn."

To those ends, Sakezles has slated two major new projects. He plans to build an entire synthetic human body, head to toe. Then he wants to open surgical simulation labs, the first located in the Tampa Bay area, with many more to follow.

Surgeons would lease time to practice on his models, and be able to record and repeat their performance.

"Our products will allow a doctor to practice using a laser scalpel, perform a total hip replacement or install a coronary stent," he said.

Of course, all that will take money, and that explains why the little company, which has stayed under the radar for years, is now touting its achievements.



To the investors

So far, investments from Sakezles, his family and friends, plus continuing sales of product, have kept SynDaver Labs in business.

He spent 2005 just filing patents, to protect his ideas when they went public — first appearing at a trade show in early 2006.

The company is planning it's first outside stock offering, in which it will seek to raise up to $1 million from private investors.

Drawing on advice from board members, including some medical device industry executives, Sakezles is keeping the amount small.

"The early rounds are always more expensive to the company," he said. "You have to give away more of the company to get X amount of dollars. It makes the most sense to raise the smallest amount of money you need to get things going."

The small target also means he expects individual investors rather than banks and venture capitalists. "Those guys want you to raise $5 million, $10 million, $20 million. We don't need that much — not just yet."

The funding should also allow the company to expand from its current home in the bay area, but Sakezles said he plans on staying in the area.

He was born in Tampa and received his bachelor's degree from the University of South Florida and his advanced degrees from the University of Florida -- Gator ball caps and other memorabilia are scattered around the office.

"This is home for me," he said. "The company really is wherever I decide to put it, but I like it here."

Besides, another potentially big customer is just up the road. USF is planning on building a state of the are surgical simulation center, and he is in discussions with them about possibly putting his products there.

From there, he sees even more lucrative applications: training battlefield medics, developing advanced armor and weapons systems, and crash testing.

One of his patent applications, for something he dubs his "R&D project," is for a model that incorporates living cells — possibly a way to test drugs and cosmetics, then maybe someday grow live tissue on an artificial scaffold.

"We're a small company right now because we just got started," he said, "but we plan on being really big in the very near future."