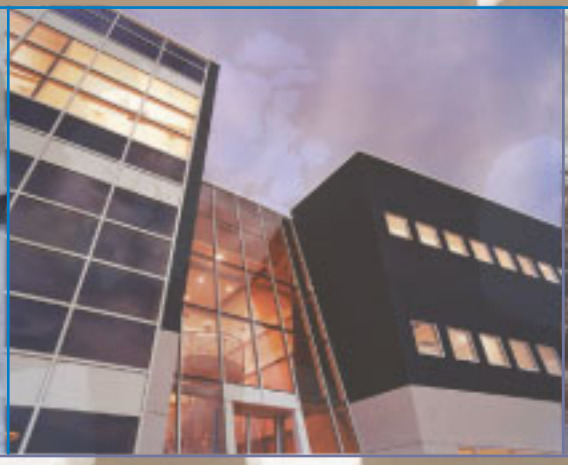
BUILDING BETTER BONE



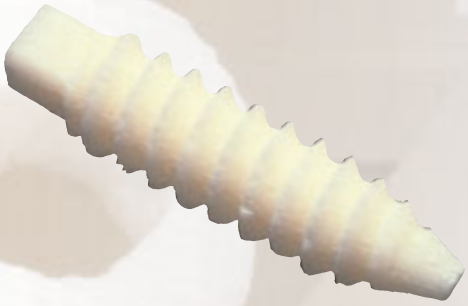
Regeneration Technologies Inc. has grown to become an industry leader in the development of precision-shaped bone implants and other products

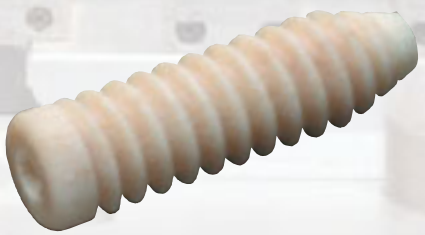
Until the early 1990s, if an orthopedic surgeon wanted to repair a damaged vertebra or some other bone using natural tissue, he or she had to whittle a replacement piece right in the operating room.

"Doctors did their best carpentry work on the operating room back table," says Jamie Grooms, the former president of Regeneration Technologies Inc. "The better carpenters had a better success rate."

Often that tissue came from the patient's own body, known as autograft. Usually it was a piece of the hip, acquired through a separate surgery and necessitating a longer, more painful recovery. Occasionally, it would be bone obtained from a deceased person, known as allograft. Either way, preparing the implant was an often lengthy and imprecise process.

By Joseph Kays





RTI machines allograft into precision-shaped implants using automated equipment, left. The company was the first to introduce precision-shaped biological implants to the medical community.

RTI technicians place tissue into the BioCleanse chamber, right, after the tissue is in its final implant form. The sterilization process is fully automated and monitored by computer.

"If you needed bone, usually you'd use the patient's bone. The morbidity involved in taking the iliac crest (hip bone) was real and permanent," says Dr. Peter Gearen, chair of the UF Department of Orthopaedics and Rehabilitation. "It was a tough surgical situation. The opportunity to take a graft right off the table was a great improvement."

Grooms had worked in all phases of the tissue banking industry by the time he was hired in 1992 to direct a small tissue bank in the Department of Orthopaedics and Rehabilitation that had only six employees and was recovering tissue from fewer than 50 donors a year.

During his eight years in the business, Grooms had become convinced that bone could be machined into very small, precisely sized screws and dowels, complete with threads, notches and slots that would accommodate operating room instruments.

"I believed these new allografts could take the place of metal pins, screws and dowels," Grooms says. "So patients would be able to regenerate their own natural tissue, instead of having metal in their bodies the rest of their lives."

But almost nobody else believed with him.

"I proved the principle that you could thread bone and it would hold the thread," Grooms says. "I presented it to numerous companies, and they all thought it was a bad idea. It was one kid's belief. I had no data."

So Grooms hired Kevin Carter, whom he calls "the ultimate machinist," and they started machining bone themselves at the UF Tissue Bank.

"I would bring Kevin metal implants and say 'Let's make this in bone,' and he would," Grooms says.

Finally, Grooms convinced the medical device company Sofamor Danek to apply its marketing and distribution capabilities to his concept and in 1996 the first precision-shaped allograft, a threaded cortical dowel, hit the market.

Backed by Sofamor Danek's marketing, demand for the dowels took off, and in 1998 the UF Tissue Bank spun off its allograft technology to a new company, Regeneration Technologies Inc., or RTI.

Current RTI Chairman and CEO Brian Hutchison says that first dowel changed orthopedic surgery forever.

"It demonstrated something everyone in orthopedics thought was possible but had never proved," Hutchison says. "We finally had a biological solution that fit physiologically, immunologically and clinically."

Today, RTI offers hundreds of different machined bone products, plus bone paste and soft tissue like ligaments. Last year RTI processed more than 165,000 implants.

Hutchison says other companies have now followed RTI's lead, but that RTI has worked hard to stay ahead of the pack through innovations like its BioCleanse Tissue Sterilization Process.

RTI spent several years developing the BioCleanse process, which eliminates bacteria, fungi and spores, as well as viruses such as HIV and hepatitis, without compromising the tissue's strength and biocompatibility. Since March 2003 RTI has been labeling its bone implants "sterile," meaning they meet the same sterility assurance level as metal and synthetic implants.

"This label gives surgeons assurance that the tissue they implant is as free from bacteria, viruses, fungi and spores as metal or synthetic implants and other medical products," Hutchison says. "In addition we believe BioCleanse tissue heals faster and better because the process cleans the bone without destroying its structure. At the end of the healing process, we don't want the patient to feel as if they ever had surgery."

Perhaps the greatest challenge in the human tissue industry is maintaining a positive public perception about tissue donation so there will be a sufficient supply of tissue to meet the demand for implants.

"The source of all allograft is tissue that has been donated by people upon their death, with the consent of their family or loved ones," Hutchison says. "RTI honors the gift of tissue donation by treating the tissue with respect, by finding

new ways to use the tissue to help patients and by helping as many patients as possible from each donation."

Hutchison admits RTI has had detractors, mostly non-profit tissue banks who decry the company's for-profit approach. He says he has worked hard to foster more professionalism and cooperation in the industry.

"There has been too much fighting within the industry," Hutchison says. "I have spent a lot of time building relationships. The potential for this industry is huge. None of us has to fail for the rest of us to be successful."

Today, the fruits of the university's relationship with RTI can be seen all over the Gainesville campus.

During the company's early, lean years, the University of Florida Research Foundation, or UFRF, took licensing fees for the bone-shaping technology in hundreds of thousands of shares of then practically worthless stock, leaving the company cash to spend on operating expenses.

"We took a gamble," says UF Vice President for Research Win Phillips. "If the company succeeded, our investment would pay off; if it didn't, our shares would be worthless."

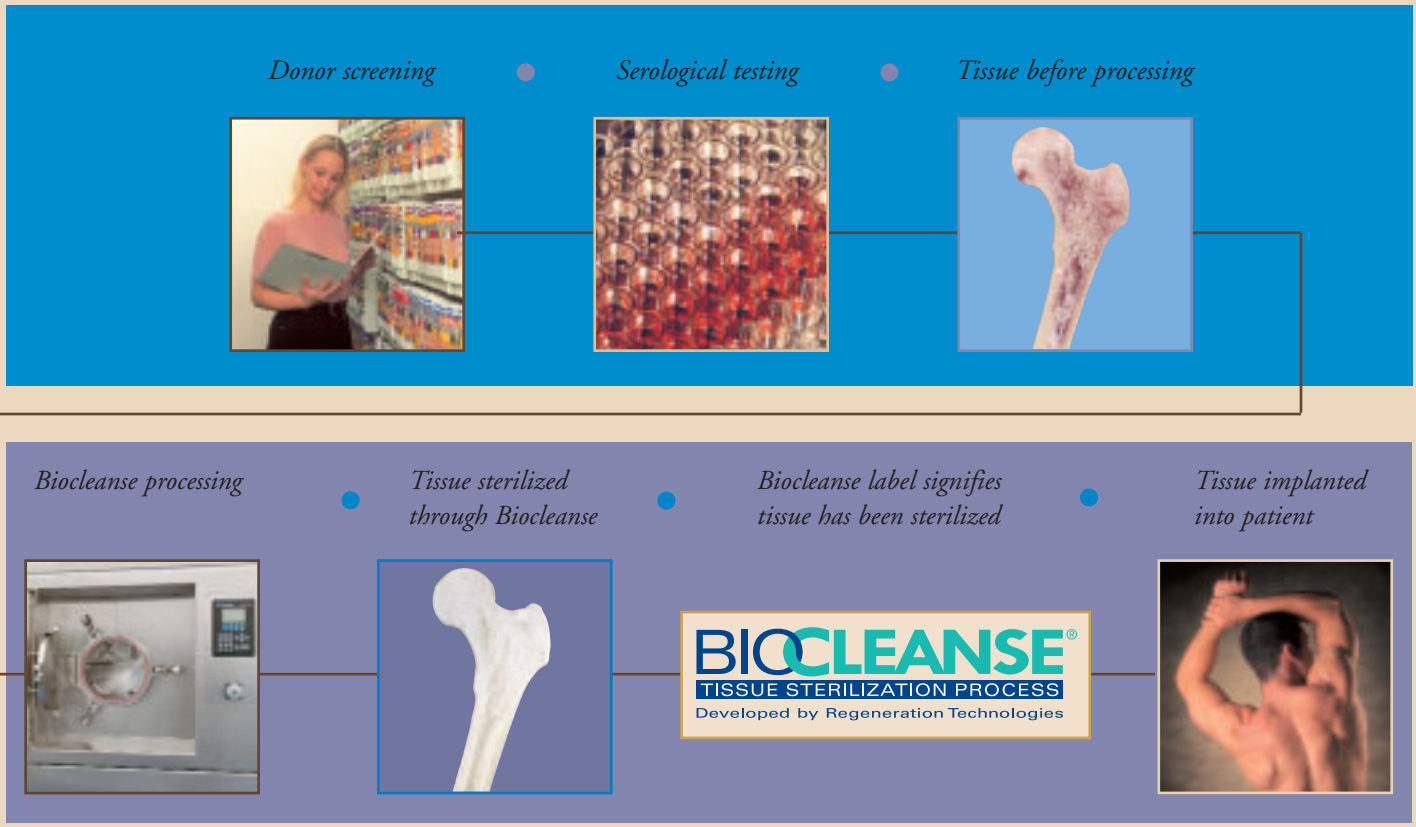
The company did succeed and after RTI went public in August 2000, UFRF was able to sell its stock for more than $60 million, half going to the Department of Orthopaedics and Rehabilitation and half to the College of Medicine. The university is using much of that money to help pay for the construction of two buildings on campus — the Genetics and Cancer Research Building and the Orthopaedic Surgery and Sports Medicine Institute.

Gearen says that when Grooms interviewed to become director of the Department of Orthopaedics and Rehabilitation tissue bank in 1992 he laid out a vision that included spinning the department tissue bank off to become a direct support organization of the university, then a for-profit company, then a publicly traded company. Gearen even remembers discussion of a new orthopedics building.

"He knew what he wanted to do," Gearen says, "and everything he outlined came to fruition."

The Department of Orthopaedics and Rehabilitation is using $27 million of its RTI royalties to construct the Orthopaedic Surgery and Sports Medicine Institute, a 120,000-square-foot building that will house all of the orthopaedic clinics and other non-surgical functions of the

The Path from Recovery to Implantation



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department. It is scheduled to open later this year.

"This building will offer us the opportunity to significantly improve the efficiency and quality of patient care," Gearen says, "as well as make it much easier for patients to receive services."

Also included in the institute are radiology and physical therapy facilities, making a visit to the orthopaedic clinic a "one-stop" experience for most patients, Gearen says. The building will also house a state-of-the-art Human Motion Laboratory.

The College of Medicine contributed more than $27 million of its RTI royalties to the construction of the 280,000-square-foot Genetics and Cancer Research Building. The building will house the university's Genetics Institute, Shands Cancer Center, Interdisciplinary Center for Biotechnology Research and C.A. Pound Human Identification Laboratory. The facility will include research laboratories, animal-research facilities, faculty and administrative offices and a rooftop greenhouse. It is expected to be completed in the spring of 2006.

"Think about it," Gov. Jeb Bush marveled at the April groundbreaking for the Genetics and Cancer Research Building. "Money generated by the licensing of UF research is now being rolled back into this research building. This is exactly how we want university technology transfer to occur."

Gearen credits Grooms with "recognizing when his personal ability to run a for-profit company had reached its limits" and recruiting Hutchison from the medical device company Stryker.

"RTI's evolution from a start-up company to a wonderfully run business is a testament to Jamie and Brian," Gearen says. "Jamie's ego did not prevent him from recognizing when he was in over his head on the business end. Usually that doesn't happen."

Grooms is now president and CEO of another Gainesville start-up called Axogen, which is developing technologies for using allograft nerve tissue to repair nerve damage.

RTI maintains close ties to the university, with Gearen serving on the board of directors, and Hutchison says he looks forward to future collaborations with the university.

"If there are opportunities to work with the university, we want to do it," Hutchison says. "A lot of great ideas come out of there and we want to partner on those ideas."

Related Web site:
www.rtix.com

Early in 2003, RTI introduced an additional sterilization step for its packaged biological implants, setting a new standard for allograft safety.