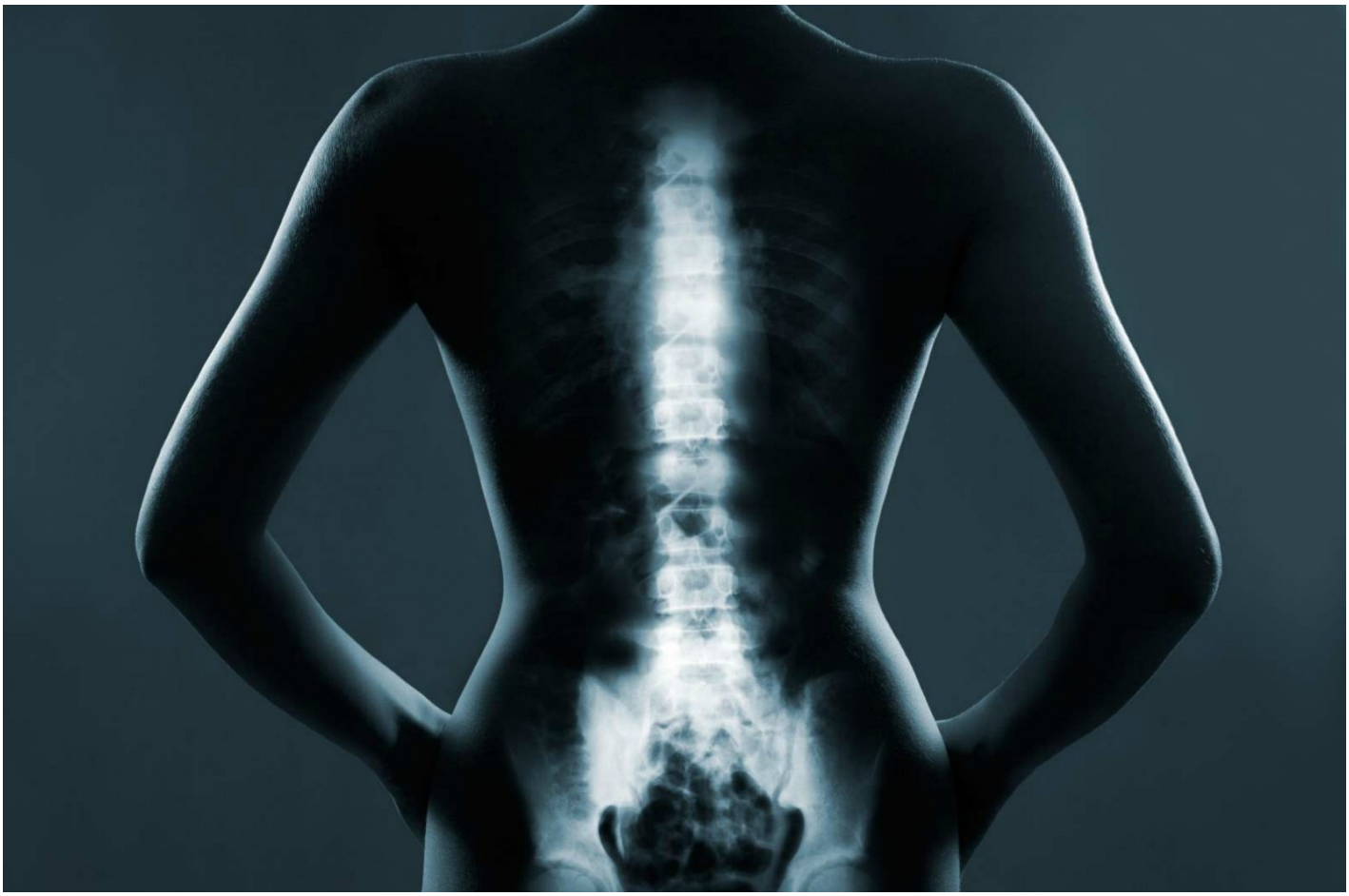
Groundbreaking Cell-Binding Technology Helps Patients Grow New Bone

University of California, San Francisco (UCSF)



CeraPedics, LLC, a Lakewood, Colo., company is developing and commercializing bone graft products based on milestone technology developed at the University of California, San Francisco.

It's been the dream of medical researchers for decades: to step beyond Mother Nature's limitations and grow new bone.

Now, the prospect of growing new bone at the site of spine fusions, trauma and joint reconstruction has become a reality. CeraPedics, based in Lakewood, Colo., is developing and commercializing products that are expected to treat a large and growing segment of the population requiring bone replacement surgery.

The Holy Grail in bone grafting has long been autogenous bone — one's own bone. Now through the development of a bone-growing technology called P-15, CeraPedics' bone growth products can imitate autogenous bone. This is proving to be a safe and effective alternative to the current method of performing surgeries involving the removal of bone from a hip to repair or replace bone lost to disease or trauma. P-15 originally was developed by Professor Emeritus Rajendra

Bhatnagar at the University of California, San Francisco (UCSF), whose research was funded by grants from the National Institutes of Health.

Andrew Tofe, Ph.D., a nuclear scientist, licensed the technology from UCSF in 2001, and founded CeraPedics. Interestingly, the proving ground for CeraPedics was in the dental market. Tofe's former company, CeraMed Dental, used the technology to develop P-15 dental products which helped fill in defects in the bone of the oral cavity. CeraMed Dental was sold to DENTSPLY International Inc. in 2001. According to Tofe, CeraPedics was founded on a simple concept.

"We had success growing bone in the oral cavity, which is a cesspool of bacteria and other contaminants," he explains. "Imagine what you can do in orthopedics, where you have a mostly cellular, sterile environment."

Championing the Future

Transforming human cells into new tissues such as bone more than 40 years of research by Bhatnagar who led UCSF's bioengineering group. The breakthrough, first commercialized in 1999, was extraordinary for another reason. Bhatnagar's discovery focused on using fibroblasts found in the central layers of human skin to transform the cells into bone.

The creative spirit at UCSF was alive and well when Bhatnagar reasoned that since skin is the largest organ of the human body, and therefore easily accessible, it would be possible to take fibroblasts from living skin and gum cells to grow bone cells for filling in space between broken bones. His discovery led to the development of technology such as P-15, which facilitates the successful promotion of new bone growth.

"Dr. Bhatnagar's discovery was phenomenal," says Don Freeman, CeraPedics' director of clinical research and marketing.

While bone grafts aren't new, P-15 is changing the way bone substitutes are being used.

"The beauty of P-15," says Freeman, "is that it accelerates the body's natural rejuvenation process, and at the same time, the technology is safe, cost-effective, and less painful for patients."

While autogenous bone or bone taken from another region in your body is considered the "gold standard" of bone grafts, Freeman says, "It involves a second surgical procedure, usually from the hip, and usually involves a significant amount of postoperative pain as well as the increased cost of operating room and surgeon's time to harvest the graft."

The small peptide combined with the calcium phosphate uses a "cell attachment mechanism" that makes human bone cells grow new bone cells.

"Peptide is defined as a chain of amino acids — building blocks of protein," says Freeman. "In the case of P-15, it is a peptide that is 15 amino acids in length, which is a relatively small peptide."

In describing the role of calcium phosphate, Freeman points out this is the inorganic or mineral portion of the bone which provides the hard structure needed to support the body.

The organic part of bone is mainly type 1 collagen, a primary protein of connective tissue, which the bone cells attach to, beginning the process of bone formation.

"Think of a key fitting in a lock," Freeman explains. "When a bone cell attaches to the calcium phosphate matrix via P-15, it changes the environment. This 'attachment' factor then starts the process of new bone formation in the body."

The P-15 technology offers an affordable alternative to current growth factor technology and is expected to be kept within typical insurance reimbursement coverage.

"P-15 is a synthetic peptide, which means it can be produced at a significantly Pre-filled syringe of P-15 Bone Graft Substitute is carefully placed in a pouch prior to sterilization and final packaging. lower cost than other technologies such as growth factors," explains Tofe.

A Growing Need for Bone Graft Products

The market for bone graft substitutes is moving forward at record speed. In 2005,

"U.S. Markets for Spinal Fusion Products," published by Windhover Information/Medtech Insight reported that the U.S. market for such bone growth factors was expected to grow from $303 million in 2005 to $1.4 billion in 2009. The reasons are many, including an aging baby boomer population and the body's natural deterioration of the muscular and skeletal system, as well as the increased cost of new bone growth factor technologies.

> *One of the fastest growing segments of this market is in spinal fusion procedures, where bone graft substitutes such as P-15 are used.*

The number of procedures in spinal surgery is expected to grow from approximately 581,000 in 2004 to about 763,000 in 2009. CeraPedics anticipates having a large share of this growing market with a product that will be more affordable than current growth factor products. The company began clinical trials in spinal fusion surgery in the second half of 2006.

Reports from the Field

Michael Janssen, D.O., orthopedic spine surgeon and chairman of the Spine Education and Research Institute, a medical educational and research facility in Thornton, Colo., says, "Because of the attachment factor of P-15, which positively changes the environment, we anticipate that it will have enormous impact in advancing surgical techniques and patient outcomes."

Janssen, also is the principal investigator in the current U.S. Food and Drug Administration investigational studies of P-15.

"We're very excited about the possibilities it offers toward promoting the health and welfare of patients," he says.

When Professor Bhatnagar successfully developed the technology that facilitates the formation of new bone, he expressed hope that someday the research would help people with degenerative diseases and injuries.

That time has come. CeraPedics' bone graft products not only are expected to help millions of people with ongoing pain, they are also positioned to alleviate the cost and inconvenience of numerous surgeries.

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