

Orthopedics • This Week

September 14, 2005



Robert Tofe
Chief Operating Officer
CeraPedics, L.L.C.

THE PICTURE OF SUCCESS

CeraPedics, L.L.C.

By Elizabeth Hofheinz, M.Ed., M.P.H.

You could say that CeraPedics, LLC has a technology it can really sink its teeth into. In fact, at this orthopedic bone-grafting company in Lakewood, Colorado, dental roots run deep.

Robert Tofe, Chief Operating Officer, explains: "For many years my father was President and CEO of CeraMed Dental. At the age of 15 I joined him at the company and rotated through all the departments. It may sound easy, but there was a lot of pressure to perform more work because I was the owner's son. The summer before I left for college, my dad wanted to ensure that I'd be on the straight and narrow. He lined my desk up perpendicular to that of the CFO. It was a long summer."

It seems he made enough of an impression on dad, however, because on January 1, 2002, he joined his father's new company...CeraPedics, LLC.

Says Tofe, "My father, Andrew Tofe, Ph.D., founded CeraPedics in 2000, but operations commenced in 2001 after CeraMed Dental was sold. He had built and expanded CeraMed and eventually sold it for \$25 million." It sounds like dad has lots to offer the next generation.

And Tofe the Elder knew a good gamble when he saw one. Says Robert, "CeraPedics was founded on a single, extraordinary technology platform—P-15™. Essentially, it's a small peptide that kick starts the bone growth process. Our product affects the early stages of bone growth, whereas other products, namely, growth factors, come later in the cascade of events. There are several strategic advantages to our product: the data shows that it's equally as effective as growth factors, we can manufacture very inexpensively (whereas a bone growth factor can cost \$5,000), there's no question that our products are reimbursable, and, perhaps most importantly, our product has an excellent safety profile. In fact, the previous license holder of P-15 engaged in a three-year study in non-unions. The results were outstanding. In 20 of 22 cases, the P-15 produced healing in the patients...highly successful, to say the least. This study will be submitted for publication in the near future."



P-15 Putty

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Orthopedics This Week is published 40 times a year by Robin Young Publications, a subsidiary of Robin Young Consulting Group.

Address: 116 Ivywood Lane
Wayne, PA 19087
Phone: 917-887-7376

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Robert had much to contribute to this exciting technology journey. With an M.B.A. in Entrepreneurial Studies, Tofe the Younger brings ten years of experience related to the bone substitute market with direct exposure to all facets of the business including manufacturing, development, marketing and strategic planning. Talking about his work habits and style, Tofe says, "Selling runs in the family. By nature, I'm high energy and have a natural curiosity. I always have a lot of questions and find science to be fascinating."

So, what kind of science is going on over at CeraPedics? Again, Robert Tofe: "We are currently developing three products for use in the orthopedics market. The first to market will be P-15 Putty for use in orthopedic procedures. The second will be P-15 Flex, which is a lyophilized version of P-15 Putty. The third product, P-15 Matrix, will be used in inter-transverse process fusions and is currently in the early developmental stage. An IDE was submitted in August and we expect to have PMA approval for the P-15 Putty in 2007, thus making it the first small peptide bone substitute to be approved for use in orthopedics."



P-15 Flex

And how good is this putty? "The technology has been used since 1999 in dentistry," says Robert. "In two multi-center studies focused on getting PMA approval for dental applications, compared to DBM and synthetic bone substitute, P15™ had significantly greater clinical results. To date there have been 250,000 doses

of ABM/P15, the active ingredient in P-15 Putty, in the oral cavity with absolutely no safety problems related to the product. And, it's the only dental bone substitute with FDA-approved claims of superiority."

Regarding milestones, Tofe has this to say: "We have defined our regulatory path. We are establishing an in-house manufacturing facility. CeraPedics has developed an ideal carrier. P-15 is carefully mixed into bio-compatible hydrogel, packaged, and sterilized. In a short time, we have made a great deal of progress."

Says Robert Tofe, it feels good to look to the future. "We expect to have the CE mark for P-15 in six months. After that we'll look at distribution options in Europe. We're basically funding ourselves through the initial money we raised...founder money and two rounds of private placements. We're poised to raise additional capital to bring the P-15 through clinical trials."

Growing a company is about as hard as growing bone. Robert Tofe wants a certain group to receive its due. "The toughest place to grow bone is in the rather inhospitable region of the mouth. There aren't a lot of cells and there's a high risk of infection. Since the 1970's the dentistry field has been using various bone substitutes to regenerate bone and investigating ways to improve implant integration. Orthopedic surgeons are also actively involved in achieving the same results."

And, by pushing this technology into the future...into the orthopedics field, so is CeraPedics.

