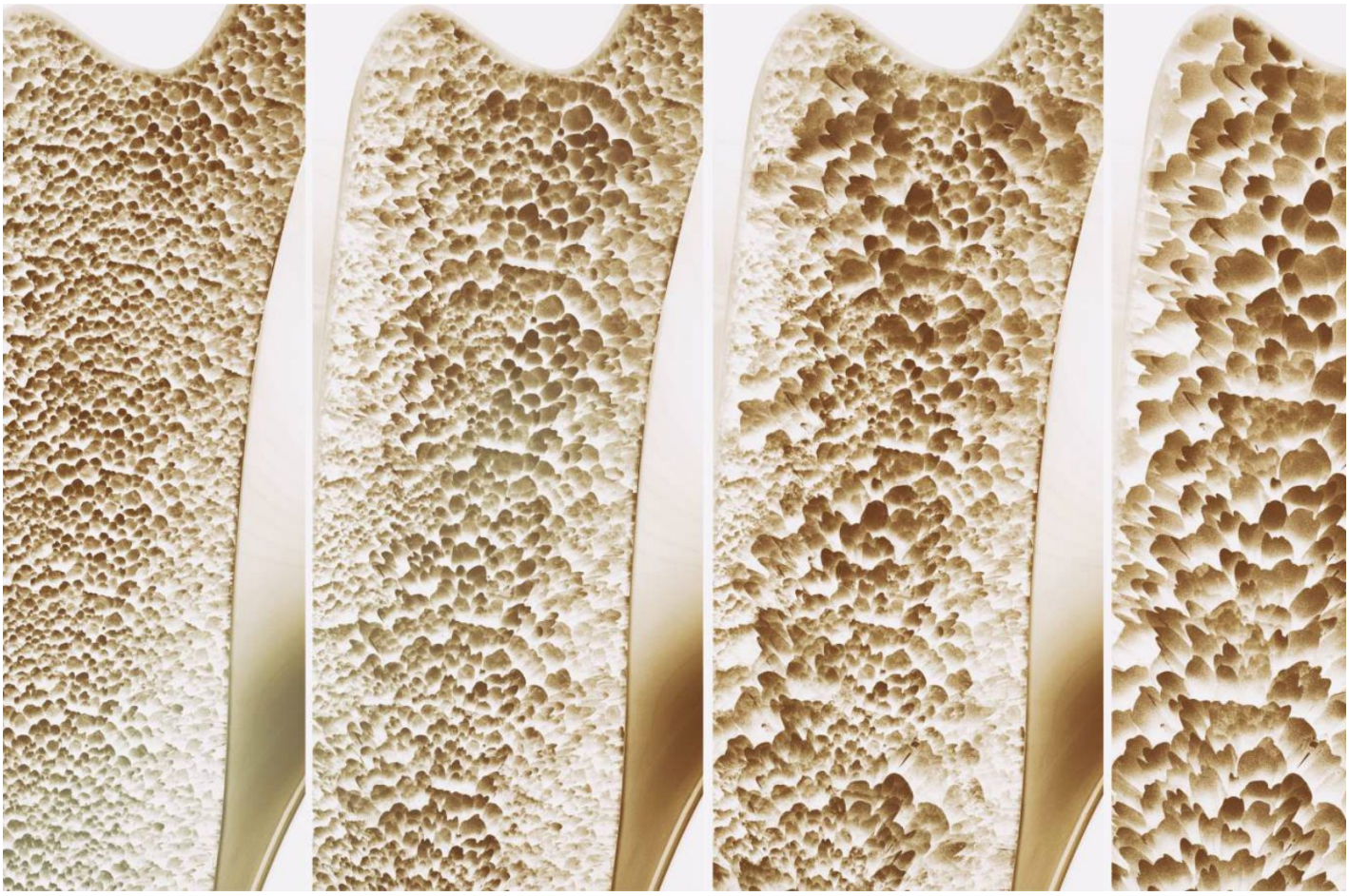
Early Detection And Improved Protection Against Osteoporosis

University of Washington



Early research of collagen, a major component of bone, led to the discovery that discrete fragments of bone that were expelled from the body could indicate bone breakdown, the hallmark of osteoporosis. The technology has had a major impact on the ever-growing arena of osteoporosis detection and treatment.

Osteoporosis has garnered much attention in the past few decades as important research breakthroughs have led to more effective treatments for this highly prevalent and often silent disease. The condition, which affects more than 10 million people in the U.S. alone, is characterized by a gradual softening and breakdown of bones.

> *In the high risk population of peri- and postmenopausal women whose estrogen levels can quickly decline, the rate of bone loss can be especially fast.*

Some women can lose as much as 10 percent of their bone mass in a single year, and in the long term this deterioration can seriously compromise bone health. Because osteoporosis is a preventable medical condition, efforts to ramp up early detection and screening are now linked with efforts to develop more effective treatments to stop bone

resorption.

Drugs like Fosamax®, Evista®, Actonel® and Premarin® are now widely prescribed and contribute to the multi-billion dollar osteoporosis market. Yet with new treatments come new challenges. Osteoporotic drugs may be abundant, but clinicians who prescribe them and patients who take them need to know if these medications are actually doing their job. Is bone breakdown slowing? Are fragile bones gaining back the advantage as bone growth is stimulated?

Innovation Inside and Outside the Lab

One technology transfer success story helps to answer such questions. The story begins in the 1980s in a research laboratory at the University of Washington's Department of Orthopaedics and Sports Medicine. While pursuing studies on collagen, a key component of bone and cartilage, David Eyre, Ph.D., professor and director of research, discovered a group of discrete protein fragments that were reproducibly appearing in urine samples. Chemical analysis revealed that the fragments were type 1 collagen peptides, and they derived from bone degradation.

Eyre and his colleagues then developed monoclonal antibodies that could bind to the peptides and an immunoassay, which could accurately reveal the presence of the peptides in human urine. Further development of the technology led to a prototype test for measuring stable end products of collagen breakdown. Eyre named the test NTx — later commercialized as Osteomark® NTx — for the origin and chemical composition of the peptides (they are cross-linked N-telopeptides of type 1 collagen), and recognized the promise of the technology.

Because levels of NTx in urine correlated with rates of bone degradation, the test might aid in the detection of individuals at risk for developing osteoporosis, as well as help monitor the effectiveness of anti-osteoporotic medications. In an innovative technology transfer arrangement with the University of Washington, Eyre sought the help of Seattle legal and business expert Ray Cairncross to form a startup company and eventually move NTx into the public domain.

The company, called Ostex International Inc., was founded in 1989 and acquired the exclusive license for the technology from the university. As part of the agreement, Eyre chose to continue pursuing his academic research at the university and retain his status on the faculty. In the meantime, Cairncross and his law firm organized a group of local investors and generated enough capital in the first round of financing to move forward with the development of the Osteomark NTx technology.

Though Ostex functioned as a virtual company early in its history, Eyre soon announced that his product was ready to be commercialized and the time had come to create physical space and hire personnel. As chair and chief executive officer of Ostex, Cairncross again succeeded in raising funds in a second round of financing, and the emphasis turned to building the company and optimizing the NTx technology.

Ostex International hit the ground running and went public just six years later, raising more than $30 million in its initial public offering. The first product, designed to test for NTx In urine samples, led to a second modified assay that measures collagen peptide fragments in human blood. Samples are acquired for the test in a clinician's office, then sent to centralized laboratories for results.

Scientists developed several different versions of the original Osteomark technology in quick succession, and they received approval from the U.S. Food and Drug Administration. When Osteomark first went commercial, Eyre remembers feeling that his vision had finally become a reality. “It was very satisfying,” he says, “to know that our basic research had translated directly into a product that could improve human health.”

New Product Delivers Results in Five Minutes

The most current version of the Osteomark technology, the NTx Point-of-Care device, is perhaps the most revolutionary. The device allows clinicians to test patients’ urine for the presence of collagen peptide fragments right in the physician’s office, so a result is available within five minutes. Its ease of use means that patients can be tested every three to six months for a more updated status of their disease and assessment of their response to therapy. Most importantly, the disposable handheld kit allows physicians and patients to confer and make decisions about osteoporosis treatment based on the test results during that same appointment.

The Osteoporosis Education Project in East Syracuse, N.Y., was selected as one of four test sites nationwide to participate in clinical trials designed to evaluate the Osteomark NTx Point-of-Care device for home use. Susan E. Brown, Ph.D., C.C.N., and director of the project, points Out that one of the most critical aspects of evaluating bone degradation in osteoporosis patients is the rate of bone loss.& It's helpful to monitor when changes occur, and how fast they occur, in people undergoing bone breakdown,” Brown says.

“Is a patient currently losing bone? Is the patient continuing to lose bone, or is it something that happened in the past? Now we can distinguish those who are losing bone at a rapid rate, rather than at a more normal, moderate rate.”

Brown’s assessment of the utility and impact of the Osteomark technology complements Eyre’s perception of the changing emphasis in osteoporosis treatment. “The standard for bringing new drugs to market in the pharmaceutical industry has relied on measurement of bone resorption. It used to be that DEXA (dual energy X-ray absorptiometry), which is typically performed only once every one or two years, was the exclusive test,” Eyre says. But he says that mindset is changing as doctors begin to focus on a patient’s bone quality, rather than simply bone density and mass.

Since the development of the NTx point-of-care device, Ostex International was acquired by Inverness Medical Innovations Inc., based in Waltham, Mass. The merger, completed in 2003, provided Inverness Medical Innovations with the intellectual property rights in the field of osteoporosis testing, and the Osteomark technology continues to provide a valuable way to quantify bone degradation in osteoporosis patients.

This story was originally published in 2006.

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