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Case study reports that orthopedic trauma surgeon injects adult stem cells derived from the patient's own marrow into her broken legs, which had not healed by seven months post-injury—instead of open surgery

"Percutaneous injection of a high dose of adult stem cells prepared at the patient's bedside may offer orthopedic surgeons and patients a new option for treating troublesome nonunions or delayed-healing fractures."

Rafael Neiman, MD, Orthopedic Trauma Surgeons of Northern California

PLYMOUTH, Mass., Feb. 8, 2007—Harvest Technologies Corp. (www.harvesttech.com) announced today that Rafael Neiman, M.D., of Orthopedic Trauma Surgeons of Northern California, injected a 49-year-old female patient's own bone marrow stem cells into the fracture and nonunion sites of both her legs that had not healed since injured in a skiing accident seven months earlier. Dr. Neiman reports that complete fracture closure and union was achieved in both legs. This case is noteworthy because Dr. Neiman treated his patient without open surgery by collecting, processing, and returning the patient's own bone marrow stem cells at the patient's bedside in the same procedure.

It has been widely reported in the scientific literature that percutaneous delivery of a high concentration of adult stem cells can enhance the rate and amount of bone formation. Several studies have documented the effects of injected bone marrow cell concentrates in cardiovascular and orthopedic disease. <u>Until now, it has been difficult to process and concentrate adult stem cells from a patient's own bone marrow at the point of care.</u>

The emerging technology that enables bone marrow stem cells to be concentrated in 15 minutes at the point of care is provided by Harvest Technologies' *BMAC*TM (Bone Marrow Autologous Concentrate) System.

"I believe that Harvest's BMAC technology could be a very significant step forward for orthopedic medicine. In this particular case, I was able to offer my patient the least invasive intervention to treat her seven-month-old leg fractures by producing a highly concentrated bone marrow preparation at her bedside. Union and fracture closure subsequently was seen within eight weeks," said Dr. Neiman.

"It is well-known among orthopedic, vascular and cardiovascular physicians that autologous adult stem cells derived from bone marrow offer *profound* potential as new therapies. Unfortunately, they have been extremely difficult to process outside of the human body—until now," said Gary Tureski, President of Harvest Technologies. "Our breakthrough BMAC technology is making it possible to harvest and concentrate autologous mononuclear cells from bone marrow easily and rapidly at the point of care, in about 15 minutes. The Harvest BMAC System has transferred the ability to process bone marrow, previously found only in specialized laboratories, to the typical clinical setting for use *today* by physicians like Dr. Neiman."

Harvest's *BMAC* System is the world's <u>first</u> and <u>only</u> device that produces highly concentrated stem and precursor cells from a small volume of aspirated marrow in just 15 minutes. In the U.S., the *BMAC* System is currently marketed for use in the clinical laboratory or intraoperatively to process bone marrow aspirate to produce a mononuclear cell concentrate. Since the safety and effectiveness of the device for in vivo indications for use has not been established, Harvest is now actively in discussions with the FDA to commence a multicenter clinical investigation of the *BMAC* System to induce the growth of new blood vessels in patients with untreatable *Critical Limb Ischemia* (CLI).

Harvest Technologies is a privately held company based in Plymouth, Mass.

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