# New implant shows promise for painful osteoporotic spine fractures

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Individuals suffering from spinal fractures—caused by osteoporosis or weakened bones—now have another option to reduce pain, restore function and improve quality of life, according to a study of 300 patients treated with a new type of vertebral augmentation. Results of a randomized, controlled multicenter trial on a new implant treatment for vertebral compression fractures are being reported for the first time at the Society of Interventional Radiology's 39th Annual Scientific Meeting.

Made of medical polymer, the implant is designed to treat painful and debilitating vertebral compression fractures, which cause the bones in the spine to collapse and, left untreated, can lead to pain and a condition called kyphosis (or a curvature of the spine). Recently cleared by the U.S. Food and Drug Administration (FDA), the implant provides a new treatment alternative to vertebroplasty and kyphoplasty, the current standards of care. The implant was shown to meet or exceed the performance of kyphoplasty on every measure studied.

"This the first new method of treating these painful fractures in a decade, which is great news for patients because it not only helps restore quality of life, but it also was shown to outperform our most-used treatment in important ways," said Sean M. Tutton, M.D., FSIR, lead author of the study and professor of radiology, medicine and surgery at Medical College of Wisconsin in Milwaukee. "This Level 1 trial, which provides the highest quality and most reliable data, is one of the largest to date to compare a new treatment for vertebral compression fractures

to standard of care—and the results match or exceed those of the current treatment," said Tutton. "This research also adds to the growing body of evidence supporting the efficacy and safety of these treatments," he added.

"Interventional radiologists are leading the way in providing minimally invasive treatment innovations for the spine, including developing new technologies that show significant patient benefits," said SIR President Scott C. Goodwin, M.D., FSIR. The Society recently published a multisociety position statement on vertebral augmentation, discussing current and future technologies and noting that augmentation is a safe, effective and durable treatment in appropriate patients, added Goodwin, Hasso Brothers' Professor and chair of radiological services at the University of California Irvine (UCI) School of Medicine.

Kiva System as a Vertebral Augmentation Treatment—A Safety and Effectiveness Trial (KAST) was a study conducted with FDA approval in which 153 patients with one or two painful osteoporotic vertebral compression fractures received the new implant and 147 had balloon kyphoplasty. Patients were treated at one of 21 centers in the United States, Canada, Belgium, France and Germany and were followed for one year. Results of the study confirmed that the implant provided essentially the same amount of pain relief and improvement in daily function based on accepted measures for pain and function (visual analogue score, VAS; Oswestry Disability Index, ODI) and safety. Researchers also found patients who had the implant were more likely to benefit from a reduction in the angle of the kyphosis and less likely to have the bone cement leak. Moreover, the study showed a clinically important trend in that the implant patients were less likely to suffer a fracture in adjacent vertebra. This latter finding is despite the fact that the 153 patients who received the implant had higher risk predictors for future fractures.

There are approximately 700,000 osteoporosis-related vertebral compression fractures in the United States every year, which is only expected to continue growing as the population ages, said Tutton. Treatment options include pain medications and bed rest, or now one of three image-guided minimally invasive treatments often performed by an interventional radiologist or interventional neuroradiologist: vertebroplasty, balloon kyphoplasty and the placement of this new implant. The implant is designed to provide structural support to the vertebral body and a reservoir to direct and contain bone cement. "We are moving away from traditional vertebroplasty or balloon-based vertebral augmentation, which relies solely on the administration of bone cement. This new approach allows the treating doctor to deliver a much more predictable supportive structure into the vertebrae," said Tutton.

**More information:** Abstract 238: "KAST Study: The Kiva® System as a Vertebral Augmentation Treatment—A Safety and Effectiveness Trial," S.M. Tutton, M.D., FSIR, Medical College of Wisconsin, Milwaukee; R. Pflugmacher, M.D., Universitätsklinikum Bonn, Germany; M. Davidian, M.D., Radiological Associates of Sacramento, Calif.; D. Beall, M.D., Clinical Radiology of Oklahoma, Edmond; F.R. Facchini, M.D., FSIR, Vascular and Interventional Radiology Associates, Hinsdale, Ill.; C. Nutting Jr. DO, FSIR, Radiology Imaging Associates, Greenwood Village, Col.; J. Hierholzer, M.D., Klinikum Ernst von Bergmann gGmbH, Potsdam, Germany; D. Nguyen, M.D., Radiology, Penn State Hershey Medical Center, Pa.; R. Smith, M.D., radiology, Toronto Western Hospital, Ontario, Canada; F. Schils, Saint Joseph, Liege, Belgium; J. Rappaport, M.D., Sierra Regional Spine Institute, Reno, Nev.; P. Jarzem, M.D., Montreal General Hospital, Quebec, Canada; D.F. Kallmes, M.D., Mayo Clinic, Rochester, Minn.; J.A. Stone, Mayo Clinic Jacksonville, Jacksonville, Fla.; F. Komlos, El Camino Hospital, Mountain View, Calif.; J. Zucherman, M.D., St. Mary's Spine Center, San Francisco, Calif.; E. Kerr, M.D., Spine Institute of Louisiana, Shreveport; M. Alonzo, M.D., North Shore

University Health System, Evanston, Ill.; H. Deramond, M.D., Radiology, CHU Amiens, France; S.R. Garfin, M.D., Orthopedics, UC San Diego. SIR Annual Scientific Meeting, March 22-27. This abstract can be found at www.SIRmeeting.org