PRESS RELEASE

Feb. 19, 2013, 8:00 a.m. EST

Independent Study Demonstrates Clinical Advantages Of Kiva Over Balloon Kyphoplasty

Spine Publishes Results Showing Kiva Restored Deformity and Reduced Extravasation

PR Newswire
United Business Media

SANTA CLARA, Calif., Feb. 19, 2013 /PRNewswire via COMTEX/ -- An independent, prospective, randomized study of patients with vertebral compression fractures (VCFs) comparing the effectiveness of balloon kyphoplasty with the Kiva VCF Treatment System by Benvenue Medical, Inc. found that only the Kiva system significantly restored vertebral body wedge deformity, Gardner angle. The Kiva system also resulted in significantly lower rates of extravasation and cement volume than balloon kyphoplasty. The peer-reviewed study results were published online and in the Feb. 15 edition of Spine.

BenvenueMEDICAL
Advancing Spine Repair

"This study revealed statistically significant, advantages of Kiva over balloon kyphoplasty," said Panagiotis Korovessis, MD, PhD, Chief of the Department of Orthopaedic Surgery at General Hospital "Agios Andreas" in Patras, Greece, and author of the study. "The study results also indicate that using Kiva to treat painful VCFs may positively influence the medium and long-term results. Patients may experience less back pain and fewer frequent adjacent fractures."

The study, titled "Balloon Kyphoplasty versus Kiva Vertebral Augmentation. Comparison of Two Techniques for Osteoporotic Vertebral Body Fractures," included 168 patients with 255 osteoporotic fractures less than three months old with an average 14-month post-operative follow-up. Outcome measurements were vertebral body height, segmental kyphotic angle, extravasation rates, pain, function, and quality of life. The study concluded several statistically significant outcomes in favor of Kiva over balloon kyphoplasty, the current gold standard of care and most common vertebral augmentation treatment in the United States:

-- Significant restoration of the Gardner angle in patients treated with Kiva ($p= 0.002$) where as balloon kyphoplasty did not meet significance ($p=0.067$)

-- Lower extravasation rates (3% for Kiva and 9.8% for balloon kyphoplasty, $p<0.05$)

-- Lower cement volume (1.8 mL for Kiva and 2.8 mL for balloon kyphoplasty, $p<0.001$)

"This study suggests that the Kiva system may restore vertebral body height, but more significantly, restore normal mechanics and spine alignment in patients with VCFs. This has important implications for body mechanics and future fractures. It would appear that the system allows the use of less cement which translated into less leakage,"

said Sean M. Tutton, MD, FSIR, Professor of Radiology and Surgery at the Medical College of Wisconsin in Milwaukee.

The Kiva VCF Treatment System is commercially available in Europe and is distributed by Zimmer Spine. Kiva is investigational in the United States and is currently the subject of an approved IDE study.

"Publication of these study results in a peer-reviewed journal further validates the benefits the spine community reports with Kiva. We continue to work very closely with the FDA on our IDE study and we're pleased with the significant progress we're making toward bringing this system to the US market," said Robert K. Weigle, CEO of Benvenue Medical, Inc., a developer of minimally invasive solutions for spine repair. The Kiva VCF Treatment System is being evaluated in the KAST (Kiva System as a Vertebral Augmentation Treatment - A Safety and Effectiveness Trial) clinical trial, sponsored by Benvenue Medical. The KAST trial completed enrollment of 300 patients in June 2012, more than 200 of whom have completed their one-year follow-up. KAST is being conducted to support a 510(k) filing for market clearance from the U.S. Food and Drug Administration (FDA), which Benvenue Medical expects to submit in the third quarter of 2013.

The National Osteoporosis Foundation estimates that there are 700,000 osteoporosis-related vertebral compression fractures annually in the U.S. alone, yet only 200,000 kyphoplasty procedures are done globally.

About the Kiva VCF Treatment SystemThe Kiva VCF Treatment System provides a new approach to the treatment of painful VCFs. The Kiva VCF Treatment System features a proprietary flexible implant made from PEEK-OPTIMA&#65533;, a biocompatible polymer that is widely used and well accepted as a spinal implant. The Kiva Implant is designed to function as a mechanical support structure and a reservoir to contain and direct the flow of bone cement.

The Implant is delivered percutaneously in a continuous loop into the vertebral body through a small diameter, single incision. The amount of the Kiva Implant delivered can be physician-customized during the procedure to adjust to various fracture types. Delivered over a removable guidewire, the Implant is designed to provide structural support to the vertebral body and to directionally control and contain bone cement.

The minimally invasive Kiva System is designed to offer the following potential benefits:

-- Reduce polymethyl methacrylate (PMMA) bone cement volume

-- Preserve cancellous (porous and mesh-like, as opposed to dense) bone structure

-- Reduce adjacent level vertebral fractures

-- Reduce extravasation rate (leakage into surrounding tissue)

About Benvenue Medical, Inc.Founded in 2004, Benvenue Medical, Inc. is advancing spine repair through the development of proprietary, minimally invasive surgical and interventional solutions. The company is privately held and funded by Versant Ventures, DeNovo Ventures, Domain Associates and Technology Partners. Its first products are designed for the treatment of vertebral compression fractures and degenerative disc disease, which have combined revenues of $1.6 billion globally. For more information, visit www.benvenuemedical.com.

MEDIA CONTACT:Betsy MerrymanMerryman Communicationsbetsy@merrymancommunications.com310-560-8176

SOURCE Benvenue Medical, Inc.

http://rt.prnewswire.com/rt.gif?NewsItemId=SF61850&Transmission_Id=201302190800PR_NEWS_USPR_____SF61850&DateId=20130219