

DIGITAL JOURNAL

Second Independent Study Demonstrates Clinical Advantages of Kiva® Over Balloon Kyphoplasty

Pain Physician Journal Publishes Results that Show Significantly Better Pain Improvement and Fewer New Fractures with Kiva

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SANTA CLARA, Calif., Oct. 29, 2013 /PRNewswire/ -- An independent evaluation of the safety and effectiveness of the Kiva VCF Treatment System, developed by [Benvenue Medical, Inc.](#), compared with balloon kyphoplasty, found that Kiva delivered significant improvements in back pain. The Kiva system also resulted in significantly fewer new fractures and half the mean cement used as compared to balloon kyphoplasty. The peer-reviewed study results were published online and in the September/October edition of *Pain Physician Journal*, the official publication of the American Society of Interventional Pain Physicians. This is the second independent study to be published this year that provides results that favor Kiva.

"Historically, balloon kyphoplasty has offered my osteoporotic VCF patients benefits. We evaluated Kiva as a new treatment option to see if those benefits were improved," said Lucia Otten, University Hospital in Bonn, Germany, and author of the study. "Patients in our study treated with Kiva experienced a pronounced improvement in back pain over balloon kyphoplasty. Additionally, patients treated with Kiva demonstrated a lower incidence of newly occurring fractures and we used less than half the cement."

"This study indicates that using Kiva to treat VCFs offers statistically significant advantages over balloon kyphoplasty in addressing pain, as well as in improving longer-term results by reducing future fractures," said Robert Pflugmacher, MD, Professor of Surgery at the University Hospital in Bonn, Germany.

The study, titled "Comparison of Balloon Kyphoplasty with the New Kiva VCF System for the Treatment of Vertebral Compression Fractures," was conducted on the basis of matched pairs, with 52 patients suffering from 68 osteoporotic fractures and followed for six months. Those treated with balloon kyphoplasty were treated with KyphX-Systems by Medtronic, the current gold standard of care and most common vertebral augmentation treatment in the United States. Outcome measurements were Visual Analog Scale (VAS, a measure of pain), Oswestry Disability Index (ODI, a measure of function), cement usage, cement extravasation, height restoration, and new fractures. The study concluded several statistically significant outcomes in favor of Kiva over balloon kyphoplasty:

- Pain improvement was significantly better with Kiva at 6 months ($p < 0.0001$)
- New fractures following treatment with Kiva were significantly lower, 12%, than after balloon kyphoplasty, 54% ($p < 0.0001$)
- Mean cement used was less than half with Kiva (2.2 – 2.6 mL) vs. balloon kyphoplasty (4.7 – 7.5 mL)

Although not demonstrated in this study to be a statistically significant difference, cement extravasation was less with Kiva (23%) vs. balloon kyphoplasty (31%). Vertebral height restoration and functional improvement were equivalent in both groups.

"This is the first independent study to show that the Kiva system was better at improving pain and reducing subsequent fractures in patients with VCFs than balloon kyphoplasty. But it's the second to show significant clinical advantages of using Kiva over balloon kyphoplasty," said Robert K. Weigle, CEO of Benvenue Medical, Inc., a developer of minimally invasive solutions for spine repair.

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 the subject of a pending 510(k). If cleared, Kiva would be the only new implant in the VCF market supported by published, peer-reviewed outcomes from Level I study comparisons to Medtronic's kyphoplasty devices.

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 System

The 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[®], 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. develops next-generation, minimally invasive expandable implants for the spine. The company is privately held and funded by De Novo Ventures, Domain Associates, Technology Partners and Versant Ventures. 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.

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