Medtronic News

Two-Year Study Continues to Demonstrate Benefits of Kyphon(R) Balloon Kyphoplasty Compared with Non-Surgical Care in Treating Spinal Fractures

Advantages of Kyphon Balloon Kyphoplasty Include Better Back Pain Relief and Quality of Life, with Higher Patient Satisfaction, Study Shows

MINNEAPOLIS, Feb 17, 2011 (BUSINESS WIRE) --

Medtronic Inc., (NYSE: MDT), announced today thattwo-year data from the largest multicenter randomized controlled study of Kyphon Balloon Kyphoplasty for spine fractures indicated that balloon kyphoplasty relieved back pain, increased patient satisfaction and improved mobility and quality of life more than non-surgical care in the treatment of painful spinal fractures.

The FREE (Fracture Reduction Evaluation) study of 300 patients at 21 centers in eight countries was published online on [add date here] in *The Journal of Bone and Mineral Research.1* The two-year data follows the one-year results published by *The Lancet* in February 2009.2

"Although not all vertebral compression fractures (VCFs) come to clinical attention, they are the most prevalent type of osteoporotic fractures, and may be associated with severe back pain, kyphosis, disability and even an increased risk of death. There is sufficient evidence that VCFs are under-reported and if reported, appropriate intervention is often not initiated. The two-year results of the FREE study confirm that Kyphon Balloon Kyphoplasty is a safe and appropriate intervention to treat painful VCFs," said Professor Steven Boonen, lead author of the study and director of the Leuven University Hospital Center for Metabolic Bone Diseases, Leuven, Belgium.

Patients in the study were randomized to either the balloon kyphoplasty group (n=149) or a non-surgical control group (n=151). At 24 months, data were available for 232 patients (120 kyphoplasty and 112 non-surgical patients); 68 patients were no longer participating in the study. The primary endpoint of the study was the change in quality of life at one month as measured by improvement in physical symptoms (Physical Component Summary or PCS of the SF-36 health survey).

The key findings of the study were as follows:

- Decreased Pain - Those receiving Kyphon Balloon Kyphoplasty had a greater reduction in a 10-point back pain scale than those receiving non-surgical care on average throughout the 24-month study (-1.49 points, $p<0.0001$). This reduction in back pain was rapid, with statistically significant difference in the balloon kyphoplasty group at seven days (-2.2 points, $p<0.0001$) compared with the control group. This statistically significant difference was shown at all subsequent follow-up visits including at 24 months (-0.80, $p=0.009$). Similarly, the balloon kyphoplasty group had greater improvement in bodily pain as measured by the SF-36 subscale on average over 24 months (9.75, $p<0.0001$) and at all time points, including at 24 months (7.1, $p=0.022$).
- Higher Patient Satisfaction - Patients treated with balloon kyphoplasty were significantly more satisfied with their treatment compared with the non-surgical group, as measured by the 20-point Likert scale, when averaged over the two years (treatment effect 3.09 points, $p<0.0001$), and at all time points including 24 months (2.31 points, $p<0.0001$).
- Better Quality of Life - On average over 24 months, patients treated with Kyphon Balloon Kyphoplasty demonstrated a statistically significant improvement in physical symptoms compared with those receiving non-surgical care as measured by the 100-point PCS component of the SF-36 (3.24 points, $p=0.0004$). Also on average over 24 months, those treated with Kyphon Balloon Kyphoplasty showed a statistically significant quality of life improvement as measured by the 1.0-point EuroQol 5-Dimension Questionnaire or EQ5D (treatment effect 0.12 points, $p=0.0002$) compared with the non-surgical group. The statistically significant difference as measured by EQ5D was also shown at 24 months (0.08, $p=0.04$).
- Improved Mobility- Over 24 months, those treated with Kyphon Balloon Kyphoplasty reported more days of activity (estimated 136 more days) than those receiving non-surgical care. The balloon kyphoplasty group also experienced statistically significant improvement in back function compared with the non-surgical group on average over 24 months as measured by the 24-point Roland Morris Disability Questionnaire (-3.01 point difference, $p<0.0001$).
- Safe Procedure - The overall frequency of patients with a medical adverse event was similar between the two groups (134/149 balloon kyphoplasty, 134/151 control). Eleven (7.4%) patients in the balloon kyphoplasty group had new clinical

spinal fractures that could possibly or probably been related to the cement. As reported in the one-year results, there were two procedure-related serious adverse events (hematoma and urinary tract infection). There were two device-related serious adverse events in the second year at the index vertebrae (spondylitis and anterior cement migration). The study indicated that those treated with Kyphon Balloon Kyphoplasty do not face a greater risk of subsequent spinal fractures compared with those receiving non-surgical care. There was no statistically significant difference in the number of new radiographic fractures between the two groups at 24 months (56/118 balloon, 45/102 control, or 3.4% difference, p=0.68). Also, no statistically significant differences between the two groups were found in the number of patients with subsequent adjacent radiographic fractures (28/118 balloon kyphoplasty, 17/102 control, p=0.24) or clinically recognized fractures (26/149 balloon kyphoplasty, 17/151 control, p=0.125)

The complication rate with Kyphon Balloon Kyphoplasty has been demonstrated to be low. There are risks associated with the procedure (e.g., cement leakage), including serious complications, though rare, some of which may be fatal. This procedure is not for everyone. A prescription is required. Patients should consult their physicians for a complete list of indications, contraindications, benefits, and risks. Only patients and their physicians can determine whether this procedure is right for a particular patient.

"The 24-month data from this landmark study confirm the value of Kyphon Balloon Kyphoplasty, a minimally invasive procedure that has been performed on over 700,000 patients worldwide for the past 10 years," said Dr. Jan Van Meirhaeghe, member of the FREE publication committee and orthopedic spine surgeon at AZ Sint-Jan Brugge-Oostende AV, Brugge, Belgium. "This study showed that patients treated with balloon kyphoplasty experienced much more rapid and sustained pain relief, were more satisfied with the treatment, had fewer days of limited activity and had greater improvements in their quality of life than those receiving non-surgical care on average over 24 months."

The study was sponsored by the Kyphon Products Division at Medtronic, Inc. (NYSE: MDT) and supports the benefits specifically of Kyphon Balloon Kyphoplasty compared with non-surgical care. Devices to perform Kyphon Balloon Kyphoplasty are sold by Medtronic.

For more detailed information on the findings of the study, go towww.compressionfracturestudy.com. For more information on Kyphon Balloon Kyphoplasty, go to www.balloonkyphoplasty.com.

About Kyphon Balloon Kyphoplasty

During the minimally invasive Kyphon Balloon Kyphoplasty procedure, working tubes are used to create small pathways into the fractured bone, generally on both sides of the vertebral body. Orthopedic balloons are inserted and then inflated inside the fractured bone in an attempt to return it to its correct position. Inflation and removal of the balloons create cavities in the vertebral body that are filled with bone cement, forming an "internal cast".

Balloon kyphoplasty differs from other surgical therapies for vertebral compression fractures such as vertebroplasty, which is designed to stabilize the fracture without correcting vertebral body deformity or providing a controlled fill and distribution of bone cement. With balloon kyphoplasty, inflation of the balloons compacts the cancellous bone. The presence of the space also allows a more viscous bone cement to be injected under low manual pressure.

About the Spinal and Biologics Business at Medtronic

The Spinal and Biologics business is based in Memphis, Tenn. It is the global leader in today's spine market and is committed to advancing the treatment of spinal conditions. The Spinal and Biologics business works with world-renowned surgeons, researchers and innovative partners to offer state-of-the-art products and technologies for neurological, orthopedic, dental and spinal conditions. Medtronic is committed to developing affordable, minimally invasive procedures that provide lifestyle-friendly surgical therapies. More information about the company and its treatment therapies can be found at www.medtronic.com and its patient-education Web sites, www.back.com, www.iscoliosis.com, www.maturespine.com and www.necksurgery.com.

ABOUT MEDTRONIC

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

Kyphon Balloon Kyphoplasty incorporates technology developed by Gary K. Michelson, M.D.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

1 Boonen S, et al. Balloon Kyphoplasty for the Treatment of Acute Vertebral Compression Fractures: 2-year Results from a Randomized Trial. J Bone Miner Res. Published online on Feb XX, 2011.

2 Wardlaw W, Cummings SR, Van Meirhaeghe J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. Lancet. Mar 21;373(9668):1016-24. Published on www.thelancet.com on February 24, 2009.

SOURCE: Medtronic, Inc.

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