Innovative back microsurgery

Press release

A retrospective study of 77 patients with more than 5 years follow-up confirms the excellent long term results of SpineJack® for treating vertebral compression fractures

This study found immediate and long-lasting benefits in terms of pain reduction, recovery of the patient's functional capacities, and maintenance of the anatomical restoration of the vertebra

Toulouse, November 12, 2013 - VEXIM (FR0011072602 - ALVXM), a medical device company specializing in the minimally-invasive treatment of vertebral fractures, announces today that the results of a retrospective study of 77 patients confirm the effectiveness of SpineJack® for treating vertebral compression fractures.

This single-center, retrospective, observational, consecutive study was conducted by Dr. Christian Renaud, an orthopedic surgeon at the Toulouse Lautrec Clinic in Albi (France). The study included 77 patients suffering from vertebral fractures due to trauma or osteoporosis who were followed for up to 5 years after SpineJack®[1] implantation. The objective was to assess the risk/benefit ratio for the patient in terms of pain reduction, recovery of functional capacities, and maintenance of vertebral restoration.

In this study, 100% of patients experienced a significant reduction in vertebral pain immediately after surgery and one year later. Vertebral pain was assessed using a Visual Analog Scale (VAS) and showed a statistically significant decrease of 86% at one year. A recent publication[2] in *Spine* showed a 68% decrease for balloon kyphoplasty and 67% for the KIVA device.

Functional capacity was measured using the Oswestry Disability Index (ODI). Results showed a significant improvement of 81% at one year. A recent publication[2] in *Spine* reported an improvement of 58% for balloon kyphoplasty and 50% for the KIVA device at one year.

The restoration of the spinal balance, obtained through the anatomical reduction of the fracture by the SpineJack®, and the maintenance of this restoration over time are decisive factors in the very low rate of adjacent vertebral fractures observed (2.6%). This excellent result suggests a reduction in morbidity in vertebral fractures treated with the SpineJack®. The rate of adjacent fractures published in literature[3] on vertebroplasty and kyphoplasty is between 11% and 21%.

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[1] 1st and 2nd generation SpineJack®

[2] Korovessis P et al. Balloon Kyphoplasty Versus KIVA Vertebral Augmentation—Comparison of 2 Techniques for Osteoporotic Vertebral Body Fractures - A Prospective Randomized Study, Spine 2013; 38(4):292-9

[3] - Lindsay R, Silverman SL, Cooper C et al. (2001) Risk of new vertebral fracture in the year following a fracture. JAMA 285(3):320-323.
- Fribourg D, Tang C, Sra P, Delamarter R, Bae H. Incidence of subsequent vertebral fracture after kyphoplasty. Spine. 2004;29:2270–6

A second retrospective study of 179 patients with 5 years of follow-up carried out in another international research center, should confirm the excellent results of the study reported here and the previously disclosed international clinical study of 103 patients with vertebral fractures due to trauma. The results of this second retrospective study are currently being analyzed and are expected to be published before year end.

Dr. Christian Renaud comments: *"With more than 5 years of follow-up, this study evaluates the long term benefits of SpineJack® in various types of vertebral compression fractures. The results confirm that this product provides long-lasting restoration of vertebral anatomy in traumatic and osteoporotic fractures. It also produces immediate and long-lasting pain relief, with a real improvement in the patient's quality of life associated with the restoration of the spine's physiological and natural balance."*

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About VEXIM, the innovative back microsurgery specialist

Based in Balma, near Toulouse (France), VEXIM is a medical device company created in February 2006. The Company has specialized in the creation and marketing of mini-invasive solutions for treating traumatic spinal pathologies. Benefitting from the financial support of its longstanding shareholders, Truffle Capital[4] and Banexi Venture, and from OSEO public subsidies, VEXIM has designed and developed the SpineJack®, a unique implant capable of repairing a fractured vertebra and restoring the balance of the spinal column. The Company currently has 50 staff. It has its own sales teams in France, Germany, Italy, Spain, Switzerland and the United Kingdom, as well as distributors notably in Argentina, India, Taiwan, Belgium, South Africa and in the following countries where the product is currently being registered: Mexico, Brazil, Colombia, Venezuela, Chile, Ecuador and Peru. VEXIM has been listed on NYSE Alternext Paris since May 3rd 2012.
For further information, please go to www.vexim.com

SpineJack®[5], a revolutionary implant for treating Vertebral Compression Fractures

The revolutionary aspect of the SpineJack® lies in its ability to restore a fractured vertebra to its original shape, restore the spinal column's optimal anatomy and thus remove pain and enable the patient to recover their functional capabilities. Thanks to a specialized range of instruments, inserting the implants into the vertebra is carried out by mini-invasive surgery, guided by X-ray, in approximately 30 minutes, enabling the patient to be discharged shortly after surgery. The SpineJack® range consists of 3 titanium implants with 3 different diameters, thus covering 95% of vertebral compression fractures and all patient morphologies.
SpineJack® technology benefits from the support of international scientific experts in the field of spine surgery and worldwide patent protection until 2029.

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- **Name:** VEXIM
- **ISIN code:** FR0011072602
- **Ticker:** ALVXM

[4] Founded in 2001 in Paris, Truffle Capital is a leading independent European private equity firm. It is dedicated to investing in and building technology leaders in the IT, life sciences and energy sectors. Truffle Capital manages €550m via FCPRs and FCPIs, the latter offering tax rebates (funds are blocked during 7 to 10 years). For further information, please visit www.truffle.fr and www.fcpi.fr.
[5] This medical device is a regulated health product that, with regard to these regulations, bears the CE mark.
Please refer to the Instructions for Use.