Innovative back microsurgery

Press release

Preliminary results of an international clinical study on 103 patients confirm the excellent performance of SpineJack® in treating vertebral fractures

This study shows significant anatomical restoration associated with a major improvement in patient pain and quality of life.

Toulouse, November 5, 2013 - VEXIM (FR0011072602 - ALVXM), a medical device company specializing in the minimally-invasive treatment of vertebral fractures, announces today that the preliminary results of a study on 103 patients confirm the excellent performance of SpineJack® in treating vertebral fractures.

This international prospective observational and consecutive study involved 14 clinical investigating sites located in France, Germany, Switzerland, Spain, Italy and Austria. 103 patients were recruited in this study with a high rate of complex fractures (59%).

The aim of this study was to measure the anatomical restoration, the rate of adjacent fractures and also to evaluate patient pain and quality of life.

A statistically significant height restoration and endplates reconstruction with the SpineJack® were demonstrated immediately postoperative and at 3 months, even with a high percentage of very complex fractures. In the severe fractures group, the mean of maximum height restoration is 7.62 mm (scanner imaging measurements).

The reported rate of adjacent fractures is 2.9% compared with 11% to 21% for vertebroplasty and kyphoplasty techniques[1], thus suggesting a direct link between optimal endplate restoration by SpineJack® and a significant reduction of the risk of further fractures.

Vertebral pain was assessed using a Visual Analog Scale (VAS), and showed a significant post op decrease of 79%. A recent publication[2] in the Spine Journal showed a 68% decrease for balloon kyphoplasty and 67% for the KIVA device.

In addition, the decrease in pain allowed a strong reduction in the consumption of analgesics. 3 months after the operation, 98% of patients were using mild analgesics or no medication at all.

Functional capacity was measured using the Oswestry Disability Index (ODI). Results showed a significant improvement of 81% at 3 months. A recent publication[2] in the Spine Journal

[1] - 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

[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 Volume 38, Number 4, pp 292–299

reported a score of 58% for balloon kyphoplasty and 50% for the KIVA device respectively at 1 year.

In terms of overall satisfaction, 99% of the surgeons assessed that the SpineJack®'s technical performance and safety were very good or good.

Dr. Gianluca MAESTRETTI, Deputy Head Doctor of the orthopedic surgery department at the Fribourg Cantonal Hospital (Switzerland) and one of the study investigators, concludes: "*This study provides further clinical proof of the anatomical restoration by SpineJack® and confirms its efficiency in treating all vertebral compression fractures, even the most complex of A*[3] *traumatic type in young patients. These results also highlight a real and rapid benefit for these patients in terms of functional recovery and quality of life.*"

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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 Turkey, Argentina, India, Taiwan 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

[3] According to MAGERL classification
[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.