Innovative back microsurgery

Press release

Vexim Reports 1-year Results of Comparative Randomized Study of SpineJack® versus Balloon Kyphoplasty

Study demonstrated SpineJack® is highly effective in treating vertebral compression fractures and resulted in:

- *Greater and sustainable restoration of vertebral height compared to Balloon*
- *Greater, faster relief of vertebral pain*
- *Shorter surgery time*

Toulouse, April 17th, 2015 - **VEXIM (FR0011072602 – ALVXM / PEA-PME eligible)**, a medical device company specializing in the minimally invasive treatment of vertebral fractures, confirms today the excellent 1-year results of a pilot feasibility study comparing the safety and performances of SpineJack® to the Medtronic balloon in the treatment of vertebral compression fractures in patients with osteoporosis.

This study was conducted by Prof. David Noriega, of the Hospital Clinico Universitario in Valladolid, Spain, and supported by Vexim after having received approval from the hospital's Ethical Committee to treat 30 patients. Of the 30 patients, 15 were treated with SpineJack® and 15 were treated with the Medtronic balloon. These two devices are composed differently but achieve the same purpose. Patients were monitored post implantation and results were assessed at six months and 12 months post-surgery.

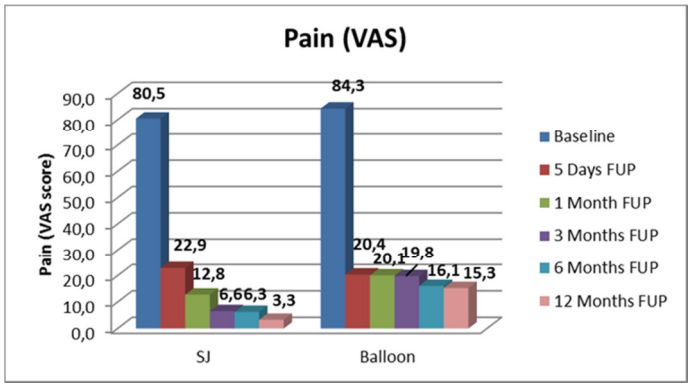
Vertebral fractures were assessed using Genant classification: wedge fractures: 88%, biconcave fractures: 6%, crush fractures: 6% and the severity of the fracture graded from 0 to 3 and distributed as follows: mild grade 1: 25%, moderate grade 2: 41%, severe grade 3: 35%.

The radiological parameters were all assessed using X-rays. X-ray images were treated by FXA™ software, developed by ACES Ing.-GmbH, an independent Core Radiographic Lab (Filderstadt, Germany). All radiological results provided below were calculated by the software and assessed independently from Vexim or the surgeon.

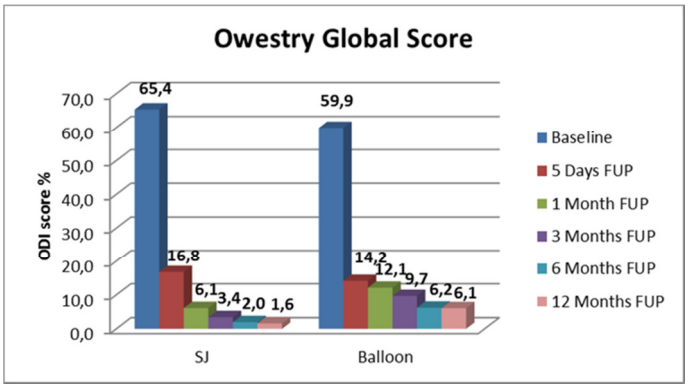
Vexim confirmed excellent outcomes with SpineJack® compared to the Medtronic balloon at 1-year post implantation.

Patient groups treated with SpineJack® achieved:

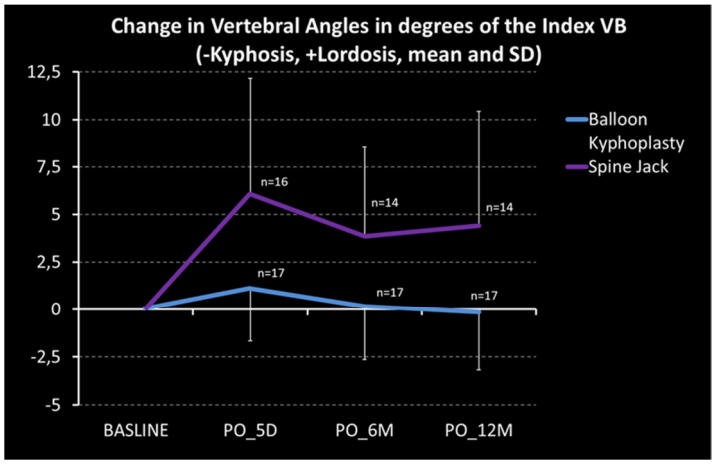
→ A significantly shorter intervention period (23 minutes) compared with the balloon (32 minutes);
→ A strong, rapid and long-lasting decline in pain (96% at 12 months for SpineJack® compared to 82% for the balloon);



→ An immediate and long-lasting reduction in functional disability (ODI) (98% at 12 months for SpineJack® compared to 90% for the balloon);

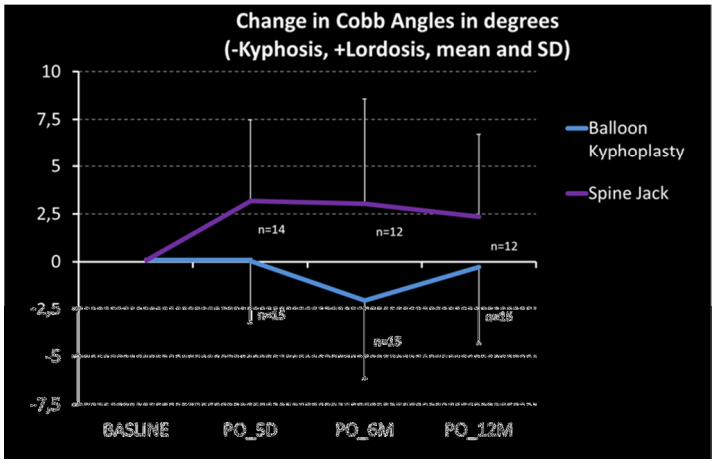


→ Near-perfect restoration of vertebral height : evolution of anterior vertebral angle ratio
  → SpineJack® pre-op/immediate post-op from 65% to 80%, 77% at 6 months, 78% at 12 months
  → Balloon pre-op/immediate post-op from 73% to 78%, 75% at 6 months, 73% at 12 months (no maintenance of height restoration between post op and 12 months);
→ Perfect restoration of the physiological angle of the spine : evolution of the treated vertebral angle :
  - SpineJack® pre-op/post-op -6.1°, -4.4° at 12 months
  - Balloon pre-op/post-op small change of -1.1° which decreased to 0.2° at 12 months. This indicates that the SpineJack® produced a larger restoration of the vertebral body angle which was still evident 12 months after implantation.



→ Maintenance of Cobb angle:

- SpineJack® group: Cobb angle has been improved post-op and maintained with almost no change 12 months after treatment
- In the Balloon Kyphoplasty group, the Cobb angle has not been improved post-op and has approximately no change 12 months after treatment.



→ No serious device-related adverse events reported; it was not necessary to re-operate on any of the treated vertebrae. No device migration reported at 6 and 12 months.

The clinical results confirmed that both techniques are safe and efficient for the treatment of osteoporotic VCF. However, radiological results indicate that the SpineJack® procedure has a higher potential for vertebral body height restoration and maintenance over time in comparison to the balloon procedure.

Professor David Noriega, Principal Investigator, commented: *"This randomized clinical study, which has been conducted over the last several months, has allowed us to confirm the great potential of the SpineJack® implant compared to another well-known technique used for balloon kyphoplasty. The results obtained have allowed us to observe a greater fracture reduction capacity in the treated vertebra, as well as an improved segmental angular correction, providing better clinical benefits for the patients. The results observed from patients with osteoporotic compression fractures confirm those obtained in previous studies on traumatic fractures, increasing the use of this fracture reduction*

technique. It also confirms that the vertebral reduction technique with SpineJack® can be used independently of bone quality."

Vincent Gardès, CEO of VEXIM, concludes: "*We are very pleased with the excellent outcome from this European comparative study. SpineJack® demonstrates its abilities to not only treat osteoporotic fractures with impressive patient outcomes but to restore and maintain the vertebral body height, as well. These results support our confidence in Vexim becoming the new reference and best approach to all vertebral fractures treatment in the near future."*

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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 minimally-invasive solutions for treating traumatic spinal pathologies. Benefitting from the financial support of it longstanding shareholder, Truffle Capital[1] 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 60 members on its staff. It has its own sales teams in France, Germany, Italy, Spain, Switzerland, the United Kingdom and United States, as well as distributors in Turkey, Argentina, Taiwan, Belgium, Estonia, Poland, Portugal, South Africa, Saudi Arabia, Colombia, Panama, Venezuela, Chile, Peru and Ecuador and in the following countries where the product is currently being registered: Mexico, Brazil. Vexim has been listed on NYSE Alternext Paris since May 2012.
For further information, please visit www.vexim.com

SpineJack®, 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 minimally-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 through to 2029.

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

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[1] 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.