

# A PROSPECTIVE RANDOMIZED COMPARATIVE STUDY OF SPINEJACK® VS. BALLOON KYPHOPLASTY IN OSTEOPOROTIC PATIENTS: 1 YEAR RESULTS

## Introduction

The objective of this study was to compare the safety and effectiveness of the SpineJack® device with the KyphX Xpander® Inflatable Bone Tamp for use in VCF reduction procedures in patients with painful VCFs due to osteoporosis. This monocentric study was conducted by Prof. David Noriega, at the Hospital Clinico Universitario in Valladolid, Spain.

## Materials and Methods

Of the 30 patients included (mean age  $68.1 \pm 5.3$  years), 15 were treated with SpineJack® and 15 were treated with the balloon. Time since symptoms appearance was a mean of 28.2 days prior to the surgery. There were no statistically significant differences between both groups for demographics and pre-operative baseline characteristics.

Vertebral fractures were assessed using Genant classification: wedge fractures: 88%, biconcave fractures: 6%, crush fractures: 6% and the severity of the fractures graded from 0 to 3 and distributed like this: 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). Patients were monitored post op and results were assessed at 6 and 12 months post-surgery.

## Results :

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 min) compared with the balloon (32 min).
- A strong, rapid and long-lasting decline in pain (VAS): 96% at 12 months for SpineJack® compared to 82% for the balloon. Results in Fig.1.
- An immediate and long-lasting reduction in functional disability (ODI): 98% at 12 months for SpineJack® compared to 90% for the balloon. Results in Fig.2.
- Evolution of the treated vertebral angle (Fig. 3):
  - SpineJack®: pre-op/post-op  $-6.1^\circ$ ,  $-4.4^\circ$  at 12 months.
  - Balloon: pre-op/post-op small change of  $-1.1^\circ$  which decreased to  $0.2^\circ$  at 12 months.
- Maintenance of Cobb angle (Fig. 4):
  - SpineJack®: Cobb angle has been improved post-op and maintained with almost no change 12 months after treatment.
  - Balloon: 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.

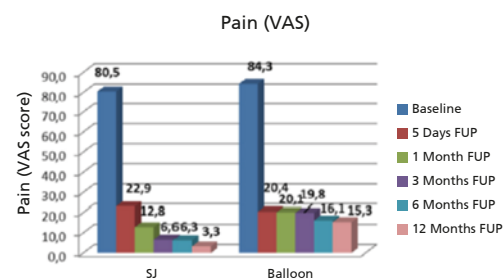


Fig. 1

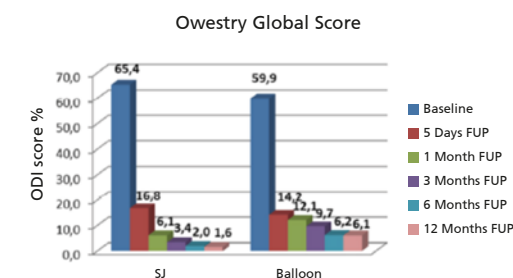


Fig. 2

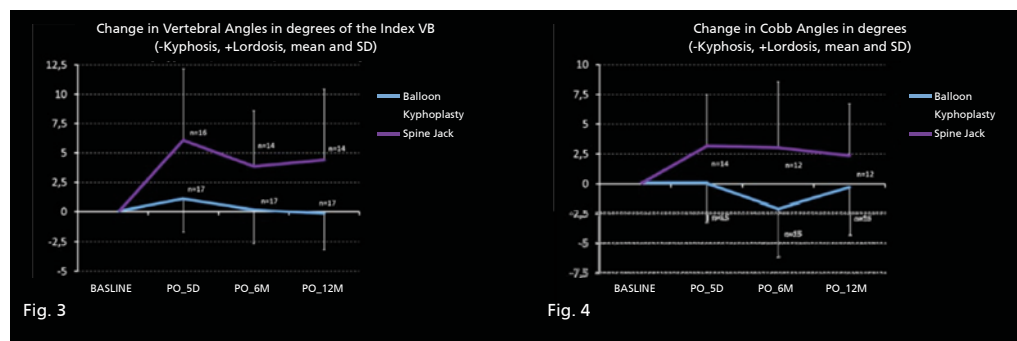


Fig. 3

Fig. 4

**Conclusion\_** The clinical results confirmed that both techniques are safe and efficient for the treatment of osteoporotic VCF. Excellent outcomes with SpineJack® compared to the Medtronic balloon at 1-year post implantation. 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.