

CLINICAL OUTCOMES AFTER THE USE OF SPINEJACK® INTRAVERTEBRAL IMPLANTS FOR VERTEBRAL COMPRESSION FRACTURE TREATMENT. 1-YEAR RESULTS FROM A PROSPECTIVE MULTICENTRIC OBSERVATIONAL STUDY

Introduction

This prospective international multicentric observational study was set up and conducted at seven centers throughout Europe. The aim was to confirm the safety and clinical performance of the SpineJack® System in combination with Cohesion® Bone Cement for the treatment of vertebral compression fractures (VCF) due to trauma and/or osteoporosis.

Geographical distribution of study centres



A total of 32 patients were enrolled, with a mean age of 71, 3 years. There were 25 osteoporotic and 7 traumatic fractures.

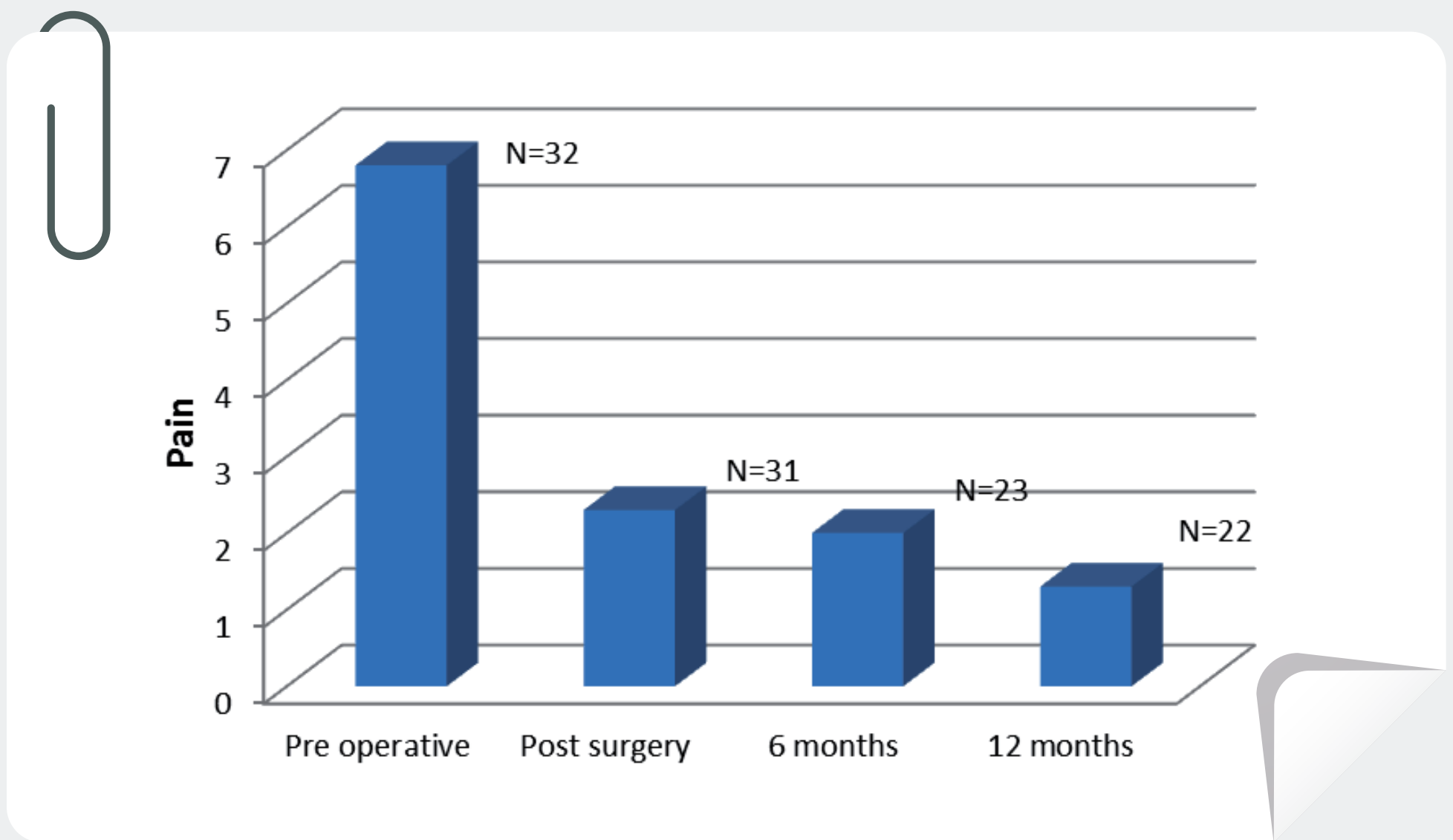
As clinical outcomes we measured; Pain (VAS), the patient's functional capacity (Oswestry Global score, ODI), and patient's quality of life (EQ-5D.) The intake of analgesics was reported.

Summary of Results

This summary includes the results from the 22 patients who came to the 1 year follow up visit.

Pain (VAS)

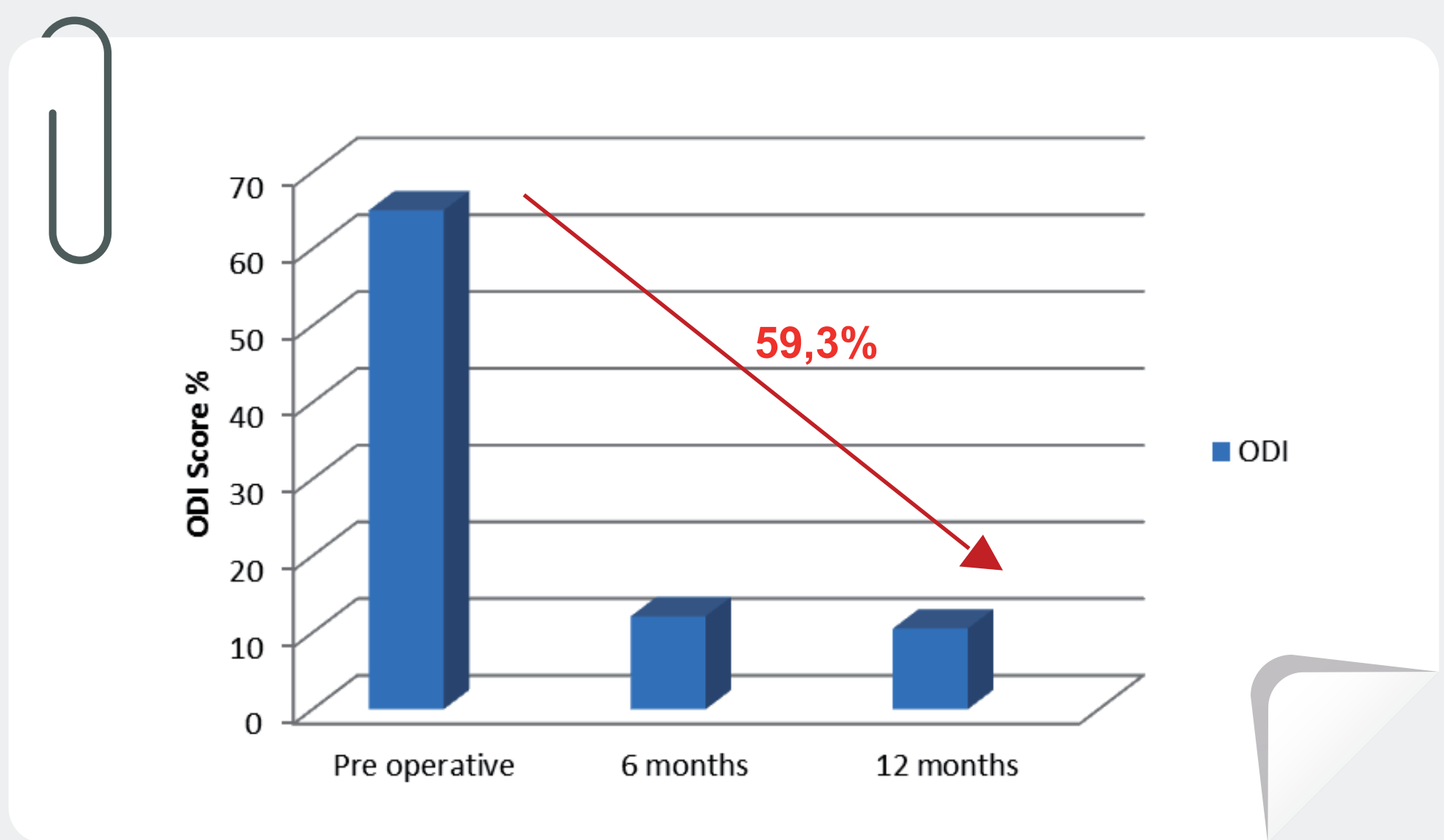
The vertebral pain was assessed using a visual analogue scale (VAS) where 0 is no pain and 10 worst imaginable pain. There was statistically significant, immediate and long lasting reduction in pain as a result of the procedure. The results are illustrated in the figure below.



A significant reduction in analgesics intake was also observed. The number of patients requiring moderate to strong analgesics decreased from 75.0% at before the surgery to 9% at 1 year.

ODI - Functional Capacity

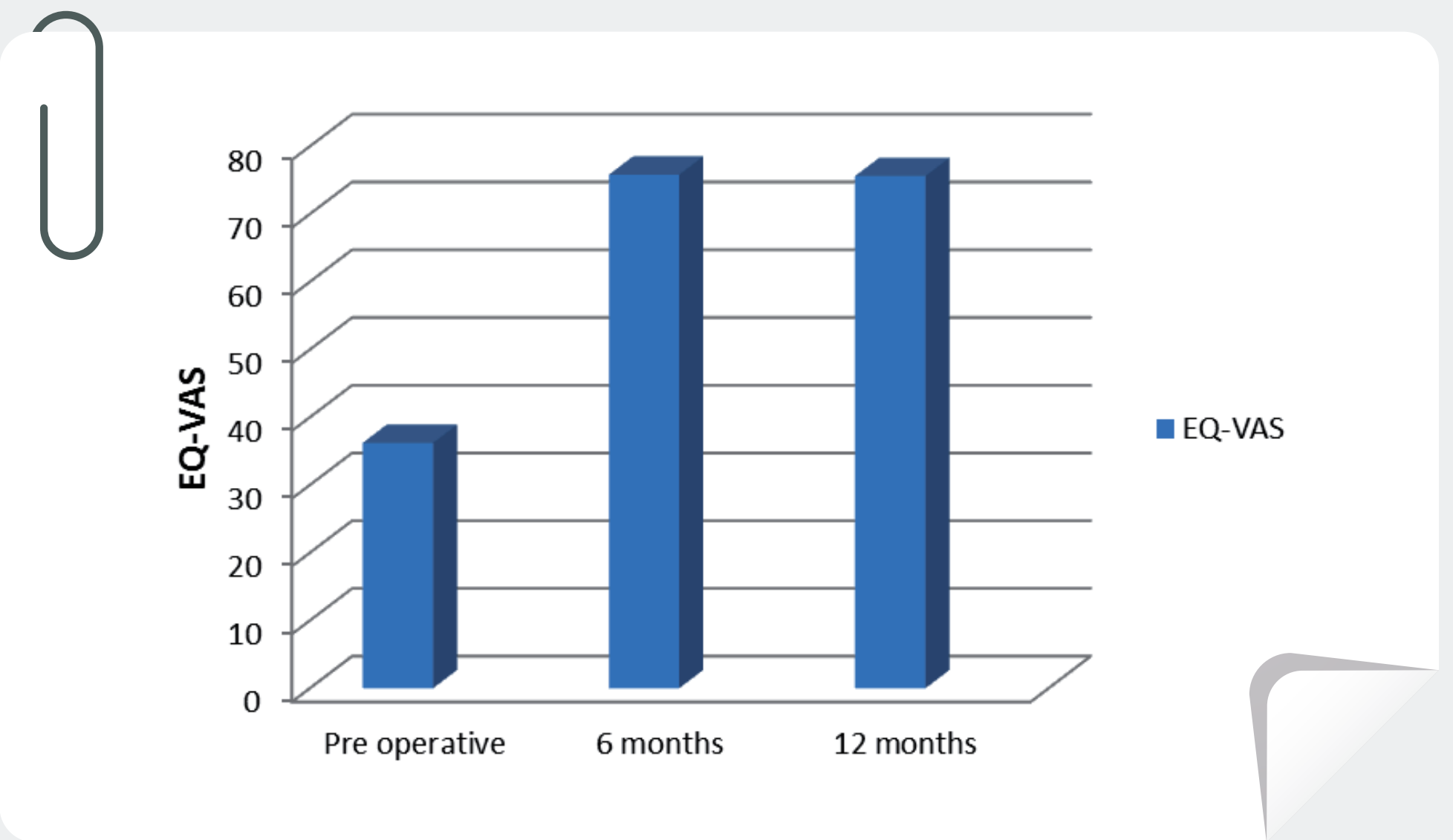
The functional capacity was assessed using the Oswestry Disability Index (ODI) which is a self-rated patient questionnaire giving information on patient ability to manage his/her everyday life including parameters such as: pain intensity, personal care, walking, lifting, sleeping and social life. A low ODI score means that the condition for the patient does not affect the patient's life very much, while a high score means that the pathology affects the patient's life a lot. The results are presented in figure below.



The results of the ODI are very good, showing a significant decrease of patient disability.

EQ-VAS – quality of life

The Quality of life was assessed using the EQ-5D questionnaire and especially the EQ-VAS which measures the self-rated health state, where a high score means “the best health you can imagine”, and a low score means “the worst health you can imagine”. The results are illustrated in the following figure.

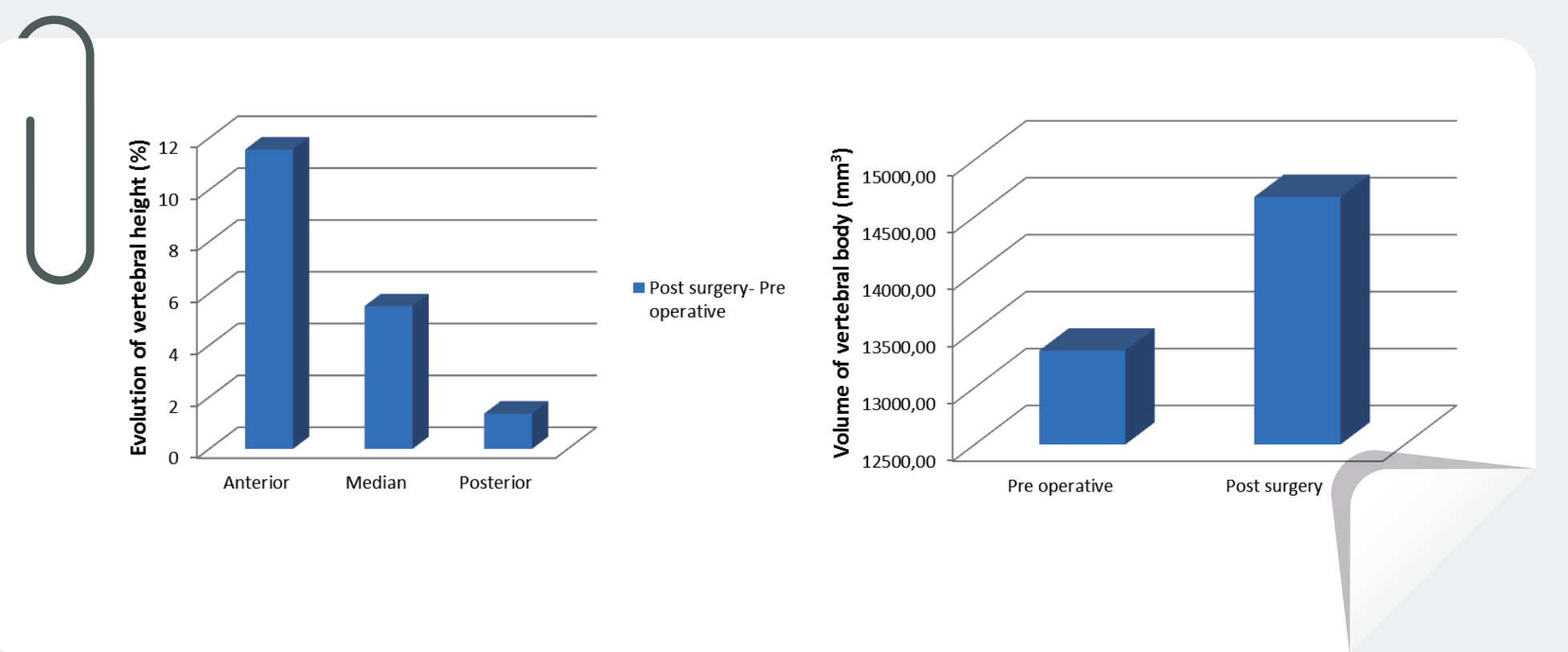


The results of the EQ-VAS are very good, showing a significant increase of patient's quality of life.

Cement leakage

The cement leakages rate observed in this observational study is 30.8%. The leakages had no consequences on clinical outcome and safety for the patients. The majority of leakages were detected on CT scan, a very precise method, and looking into the literature and other published studies from competition, they have reported leakages rates in same range, but assessed in X-rays (Refer. Free Study – Medtronic- 27%). It is suggested by Yeom (2003) that a factor of 1.5 should be considered when comparing leakage rates from X-ray and from CT scan, which means that the 27% leakage rate published for in the Free study should correspond to a leakage rate of about 40% if seen in CT scans.

Vertebral Height and volume of vertebral body



Conclusion The results from this observational study confirm the benefits of using the SpineJack® system. Both clinical and radiological results obtained from this observational study definitely confirm that the SpineJack® procedure is a safe and efficient intervention for the treatment of VCFs in both traumatic and osteoporotic fractures. The cement leakage rate is low, especially while considering it has been documented in CTscans, a very precise method compared to radiographs.

References

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