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.

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

Pan (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, \( p < 0.001 \), immediate and long lasting reduction in pain as a result of the procedure. The global pain score reduction at 1 year is 80.9% compared to the pre operative situation. The results are illustrated in the figure below.

EQ-VAS – quality of life
The Quality of life was assessed using the EQ-SD 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 of the EQ-VAS show a statistically significant increase of the quality of life, \( p < 0.001 \). The overall improvement was a 52.1% increase of the EQ-VAS at 1 year. The results are illustrated in the figure below.

Cement leakage
The cement leakages rate in this observational study was 30.8%. The leakages were all asymptomatic and had no consequences on clinical outcome or safety for the patients. The majority of leakages were detected on CT scan, a very precise method, and looking into the literature on published studies from competition, higher leakage rates are seen when leakages are reported from studying CT scans. In Dohm et al leakages were identified on CT scans and the cement leakage rate in this observational study was 30.8%.

Conclusion
This clinical investigation confirms promising results regarding safety and efficacy of the SpineJack® procedure when used in combination with high viscosity Cohesion® bone cement, with statistically significant improvement in all clinical outcomes including pain, functional capacity, patient’s quality of life and decrease in analgesic intake without causing any serious complications.