FREE Study clinical data summary

Key clinical outcomes at 12 and 24 months.

Our priority has always been to raise awareness of available therapies and of the clinical data supporting the treatment of vertebral compression fractures (VCF).

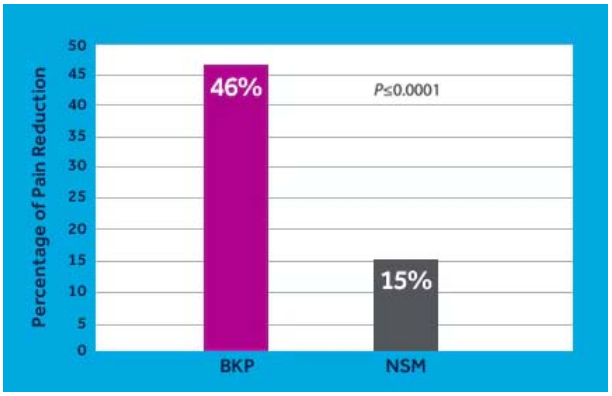
In the largest randomized controlled trial comparing balloon kyphoplasty (BKP) to non-surgical management (NSM) in patients with osteoporosis, balloon kyphoplasty was shown to be more effective than non-surgical management for the treatment of acute vertebral compression fractures (VCFs) at 12 months[1] and 24 months[2].

Rapid and sustained pain relief[2]

BKP patients experienced 3 times greater pain reduction at 1 week compared to NSM patients.

Significantly better pain relief results were seen at 1 month and maintained for up to 2 years versus NSM.

Pain relief was associated with fewer BKP patients using pain medications through 12 months and opioids through 6 months than NSM patients.

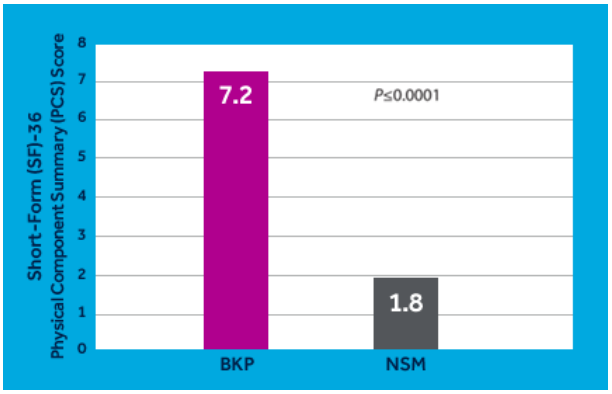


Better quality of life[2]

BKP patients experienced 4 times greater improvement in quality of life at 1 month compared to NSM patients.

Significantly improved quality of life when averaged across two years vs non-surgical management.

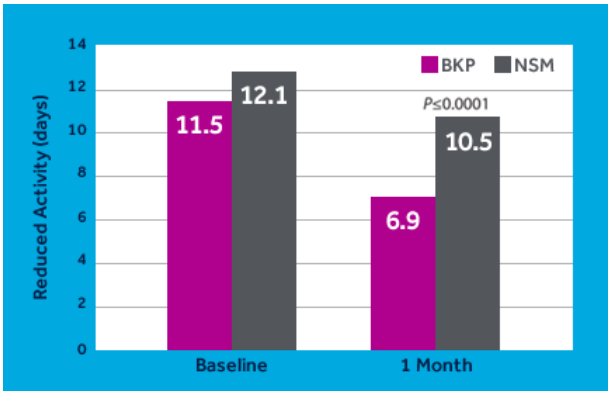
BKP was superior to non-surgical management when measured by SF-36 PCS at one month.



On average through 24 months, BKP patients experienced significantly better quality of life than patients treated non-surgical as measured by EQ-5D and SF-36 PCS.

Quicker return of mobility[1,2]

BKP patients experienced 5 fewer days of restricted activity at1month compared to baseline.



Rapid return to daily activities maintained up to 2 years vs. NSM.

BKP patients has an estimated 136 more days of activity over the 24-month period than those receiving non-surgical management.

BKP patients had significantly better back function than non-surgical management patients on average through 24-month as measure by Roland-Morris Score.

Greater patient satisfaction[1,2]

BKP patients were significantly more satisfied than those treated non-surgically at all time points through 24 months.

Comparable safety results

There were similarities in overall frequencies of adverse events and serious adverse events between treatment groups during the 24-month study.[2]

- The kyphoplasty group had 11 patients (7.4%) with new clinical fractures that the investigator considered possibly or probably related to cement.
- There was no statistically significant difference between BKP and NSM in the number of patients with subsequent radiographic fractures or subsequent radiographic adjacent fractures.
- One hematoma SAE at the surgical site was device-related and one exacerbation of a recurrent urinary tract infection SAE (owing to catheterization) occurred within 2 days of surgery and was considered procedure-related.
- There were two serious adverse events related to bone cement that occurred after 1 year. The patient who had the urinary tract infection (above) also developed spondylitis near the cement in the treated vertebral body 376 days after surgery; biopsy indicated that the bacterium causing the urinary infection was the same as that causing the spondylitis. Another patient had a recurrent fracture of an originally treated level with subsequent anterior migration of the cement. These serious adverse events were uncommon and should be monitored.
- One patient from each treatment group terminated the study early owing to an AE during the 24-month follow-up period.

- There were 23 deaths, 12 in the kyphoplasty group and 11 in the nonsurgical group. All deaths were considered unrelated to treatment.

Study design and follow up

Randomized controlled trial

- Patients (300) were randomly assigned by computer-generated sequence to either balloon kyphoplasty (n=149) or non-surgical care† (n=151).
- Investigators referred all participants in both groups for treatment with calcium and vitamin D supplements and antiresorptive or anabolic agents.

Participating centers

- 21 European sites
- 8 countries (Germany, France, Sweden, The United Kingdom, Italy, Austria, The Netherlands and Belgium)

Patient inclusion

- 1-3 vertebral fractures between T5 and L5
- At least 1 fracture with edema on MRI
- At least 1 fracture with ≥ 15% loss of vertebral body height on X-ray
- Fracture(s) caused by osteopenia due to primary or secondary osteoporosis, multiple myeloma, or osteolytic metastatic tumors
- Back pain score ≥ 4 (on a scale of 0=no pain to 10=worst pain imaginable)

Patient exclusion

- Patient age ≤ 21 years
- Fracture age > than 3 months
- Previous vertebroplasty
- Pedicle fracture
- Neurological deficit
- Radicular pain
- Spinal canal narrowing
- Spinal cord compression
- History of back disability unrelated to VCFs
- Dementia

- Non-ambulatory prior to VCFs
- High-energy traumatic fractures

Follow-up

- Follow-up at 1, 3, 6, 12, and 24 months

Study endpoints

Balloon kyphoplasty was shown to be more effective than non-surgical management for the treatment of acute VCFs.

Primary endpoints

- SF-36 PCS (Physical Component Summary) (scaled 0-100)
- The difference in change from baseline at 1 month
- Validated global quality of life measure, weighted on physical abilities
- Normal range for people over the age of 65 is 8-59 points

Secondary endpoints

- Quality of Life
    - SF-36 subscales (scaled 0-100) [20]
    - EQ-5D (EuroQol-5 Domain) health outcome questionnaire (scaled 0-1)
- Back Function & Mobility
    - Roland-Morris back function disability questionnaire (scaled 0-24)
    - Reduced activity days due to back pain during the previous 14 days
- Back Pain
    - Back pain score (scaled 0-10)
    - Narcotic analgesic use (percent of patients taking opioids)
- Adverse Events (device- and procedure-related)
    - All adverse events and serious adverse events, defined per IOS 14155, were reported; investigators assessed whether they were device- or procedure-related.
- Radiographic assessments
- Economic data

[†]Non-surgical group received analgesics, bed rest, back braces, physiotherapy, rehabilitation programs, and walking aids according to standard practices of participating hospitals.

References

1. Wardlaw D, Cummings SR, Van Meirhaeghe J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomized controlled trial. *Lancet*. 2009 Mar 21;373(9668):1016-24.
2. Boonen S, Van Meirhaeghe J, Bastian L, et al. Balloon kyphoplasty for the treatment of acute vertebral compression fractures: 2-year results from randomized trial. *J Bone Miner Res*. 2011;26:1627-1637.

Important safety information

Kyphon™ Balloon Kyphoplasty is a minimally invasive procedure for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor.

The complication rate with Kyphon™ balloon kyphoplasty has been demonstrated to be low. There are risks associated with the procedure (e.g., cement extravasation), including serious complications, and though rare, some of which may be fatal. Risks of acrylic bone cements include cement leakage which may cause tissue damage, nerve or circulatory problems, and other serious adverse events, such as: cardiac arrest, cerebrovascular accident, myocardial infarction, pulmonary embolism, and cardiac embolism.

This procedure is not for everyone. A prescription is required. For complete information regarding indications for use, contraindications, warnings, precautions, adverse events, and methods of use, please reference the devices' Instructions for Use included with the product.