# Kiva Clinical Data Summary

Kiva has been demonstrated to meet or exceed the performance of Balloon Kyphoplasty (BKP) in 3 separate comparative studies.

## Clinical Studies

<table>
<thead>
<tr>
<th>Title / Design</th>
<th>Publication</th>
<th>Key Points</th>
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| **KAST:** The Kiva System as a Vertebral Augmentation Treatment – A Safety and Effectiveness Trial | Tutton, Garfin, et al. Spine, March 2015 | • Improvement in pain and function were similar to balloon kyphoplasty  
• Similar safety to balloon kyphoplasty  
• Reduced rate of adjacent level fractures as compared to balloon kyphoplasty - per protocol population*  
• Reduced rate of extravasation as compared to balloon kyphoplasty - as reported by investigators*  
• Significant reduction in cement volume over balloon kyphoplasty*  
*Posterior probability of superiority was ≥ 90% |
• Lower extravasation rates with Kiva  
• Lower cement volume with Kiva  
• VAS, ODI, and SF-36 were similar |
| Comparison of balloon kyphoplasty with the new Kiva VCF System for the treatment of vertebral compression fractures | Otten, Pflugmacher, et al. Pain Physician Journal, October 2013. | • New fractures following treatment with Kiva were significantly lower  
• Cement extravasation was significantly less with Kiva  
• Mean cement used was less than half with Kiva  
• Pain improvement was significantly better with Kiva at 6 months |
| Economic Analysis of Kiva VCF Treatment System compared to Balloon Kyphoplasty Using Randomized Kiva Safety and Effectiveness Trial (KAST) Data | Beall, Olan, et al. In Press, Pain Physician Journal | • Kiva found to produce direct medical cost savings of $1,118 per patient and $280,876 per hospital vs. balloon kyphoplasty  
• Cost savings attributed to reduction in adjacent-level fractures and their associated treatment costs |
| Transpedicular vertebral body augmentation reinforced with pedicle screw fixation in fresh traumatic A2 and A3 lumbar fractures: comparison between two devices and two bone cements | Korovessis et al. European Journal of Orthopaedic Surgery and Traumatology, August 2013. | • Only the Kiva implant restored significantly the posterior vertebral body height  
• Pain and function improved in both groups |
| Percutaneous Vertebral Augmentation Assisted by PEEK Implant in Painful Osteolytic Vertebral Metastasis Involving the Vertebral Wall: Clinical Experience on 40 Patients | Anselmetti et al. Pain Physician Journal, July 2013. | • All patients achieved clinically relevant pain improvement  
• All patients on opiates switched to NSAIDS or no treatment at all  
• All patients experienced functional improvement  
• None of the 37 patients who wore a brace before intervention required one post-procedure |
### Additional Publications


### Abstracts and Presentations


Becker S. **Early experience with a new bone preserving kyphoplasty procedure**. SpineWeek Meeting, May 2012.


### Posters


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The Kiva VCF Treatment System is indicated for use in the reduction and treatment of spinal fractures in the thoracic and/or lumbar spine from T5-L5. It is intended to be used in combination with the IZI Vertebral Augmentation Cement Kit.

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