



VCF Treatment System

Clinical Data Summary

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

	Title / Design	Publication	Key Points
Clinical Studies	<p>Title KAST: The Kiva System as a Vertebral Augmentation Treatment – A Safety and Effectiveness Trial</p> <p>Design Prospective, randomized clinical trial to evaluate the safety and effectiveness and support non-inferiority of the Kiva VCF Treatment System versus BKP: 300 patient trial</p>	<p>Tutton, Garfin, et al. Spine, March 2015</p> <p>LEVEL I</p>	<ul style="list-style-type: none"> 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* <p><i>*Posterior probability of superiority was $\geq 90\%$</i></p>
	<p>Title Balloon Kyphoplasty versus Kiva Vertebral Augmentation. Comparison of two Techniques for Osteoporotic Vertebral Body Fractures. A prospective randomized study</p> <p>Design Prospective, randomized study: 168 patients treated</p>	<p>Korovessis et al. Spine, February 2013.</p> <p>LEVEL I</p>	<ul style="list-style-type: none"> Significant restoration of the Gardner angle in patients treated with Kiva whereas BKP did not meet significance Lower extravasation rates with Kiva Lower cement volume with Kiva VAS, ODI, and SF-36 were similar
	<p>Title Comparison of balloon kyphoplasty with the new Kiva VCF System for the treatment of vertebral compression fractures</p> <p>Design Matched pairs study of Kiva vs. balloon kyphoplasty with Medtronic balloons: 52 patients</p>	<p>Otten, Pflugmacher, et al. Pain Physician Journal, October 2013.</p>	<ul style="list-style-type: none"> 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
	<p>Title Economic Analysis of Kiva VCF Treatment System compared to Balloon Kyphoplasty Using Randomized Kiva Safety and Effectiveness Trial (KAST) Data</p> <p>Design Economic analysis of KAST randomized trial, focusing on medical resource use and costs</p>	<p>Beall, Olan, et al. In Press, Pain Physician Journal</p>	<ul style="list-style-type: none"> 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
	<p>Title 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</p> <p>Design A retrospective study of 38 patients</p>	<p>Korovessis et al. European Journal of Orthopaedic Surgery and Traumatology, August 2013.</p>	<ul style="list-style-type: none"> Only the Kiva implant restored significantly the posterior vertebral body height Pain and function improved in both groups
	<p>Title Percutaneous Vertebral Augmentation Assisted by PEEK Implant in Painful Osteolytic Vertebral Metastasis Involving the Vertebral Wall: Clinical Experience on 40 Patients</p> <p>Design Single-arm, prospective, study conducted in 40 consecutive patients, spinal mets, including multiple myeloma, with vertebral wall involvement</p>	<p>Anselmetti et al. Pain Physician Journal, July 2013.</p>	<ul style="list-style-type: none"> 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

Select Bibliography

Additional Publications

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Tutton SM, Facchini F. **Minimally invasive treatments for osteoporotic vertebral compression fracture: current concepts and state-of-the-art technologies.** Techniques in Regional Anesthesia and Pain Management Journal, April 2013.

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Rosales LM, Dipp JM, Flores R, Bajares G, Perez A. **Vertebral augmentation treatment of painful osteoporotic compression fractures with the Kiva VCF Treatment System.** SAS Journal, December 2011.

Korovessis P, Repantis T, Miller LE, Block JE. **Initial clinical experience with a novel vertebral augmentation system for treatment of symptomatic vertebral compression fractures.** BMC Musculoskeletal Disorders, September 2011.

Abstracts and Presentations

Emery J, Connolly R, McGrath T, Lee J, Schaller L. **A Novel, Flexible PEEK Implant for Treatment of Vertebral Compression Fractures: From Concept to Clinic.** 1st International PEEK Meeting , April 2013.

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

Becker S. **Experience with a new bone preserving kyphoplasty procedure.** EuroSpine Annual Meeting, September 2011.

Pflugmacher R, Bornemann R, Kabir K. **Kiva Kyphoplasty a new kyphoplasty system in comparison to (VP) Vertebroplasty: A prospective evaluation.** Spine Arthroplasty Society (SAS) Annual Meeting, May 2011.

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Pflugmacher R, Bornemann R, Otten L. **Kiva Kyphoplasty in Comparison to Balloon Kyphoplasty.** International Society for the Advancement of Spine Surgery (ISASS) Annual Meeting, April 2013.

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Wilson D C, Zhu Q , Kingwell S, Kitchel S, Cripton PA. **Biomechanical Evaluation of an Innovative Vertebral Compression Fracture Treatment System.** Orthopaedic Research Society(ORS) Annual Meeting, February 2009.

Korovessis P, Repantis T . **Balloon Kyphoplasty (BK) versus Kiva Vertebral Augmentation for Osteoporotic and Metastatic Vertebral Fractures.** International Meeting on Advanced Spine Techniques (IMAST) Annual Meeting, July 2012.

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Dipp JM, Flores R, Rosales LM, Bajares G, Perez A. **Vertebral augmentation treatment of painful osteoporotic compression fractures with the Kiva VCF Treatment System.** EuroSpine Annual Meeting, September 2010.

Flores R, Dipp JM, Rosales LM, Bajares G, Perez A. **Vertebral augmentation treatment of painful osteoporotic compression fractures with the Kiva VCF Treatment System.** Society for Minimally Invasive Spine Surgery (SMISS) Annual Meeting, October 2009.

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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 T6-L5. It is intended to be used in combination with the IZI Vertebral Augmentation Cement Kit.

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