

What to Expect In the Clinical Trial

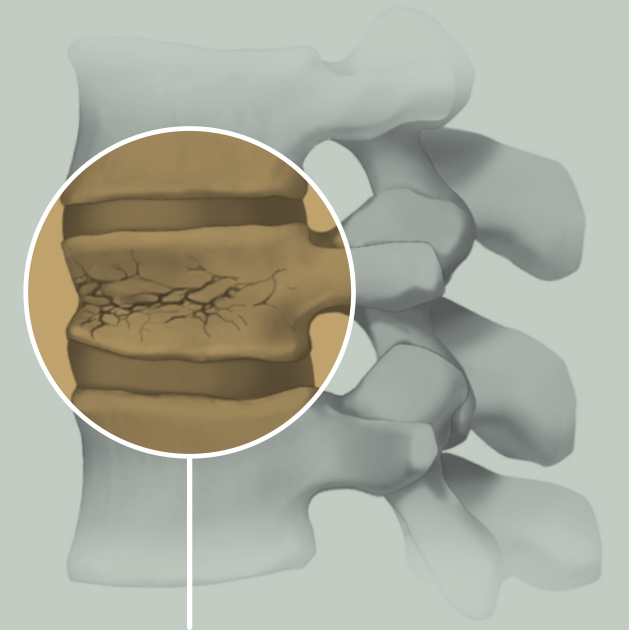
Your doctor has determined that you are a candidate to participate in a clinical trial for the Crosstrees System for Percutaneous Vertebral Augmentation (PVA). If you choose to participate in the clinical trial, you will be asked to make a follow-up visit to the hospital or ambulatory surgery center 24 hours after your procedure; in most cases, this visit will take place before you are discharged. You will also need to be seen for follow-up at two weeks, one month, three months, six months, and one year after your procedure.

At each visit, your physician will review your medical history, ask you questions about any areas of pain and discuss your overall satisfaction with the surgery. In addition, x-ray images of the surgical site in your spine will be taken.

Introducing a **NEW** treatment for vertebral compression fractures

About Your Condition

A vertebral compression fracture (VCF) occurs when osteoporosis, trauma, or some other medical condition causes the bone inside the vertebral body to weaken and collapse, causing severe pain. Vertebral compression fractures usually occur in the middle and lower sections of the spine. These fractures can lead to loss of height, postural deformity and pulmonary complications. ¹



Vertebral Compression Fracture (VCF)



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REFERENCES

1. National Osteoporosis Foundation.

Treatment Options for VCF

The standard surgical treatments for vertebral compression fractures are vertebroplasty and kyphoplasty. Vertebroplasty involves the injection of bone cement into the fractured vertebral body. Kyphoplasty is a similar procedure but uses a balloon to create a cavity in the vertebral body before the cement is injected.

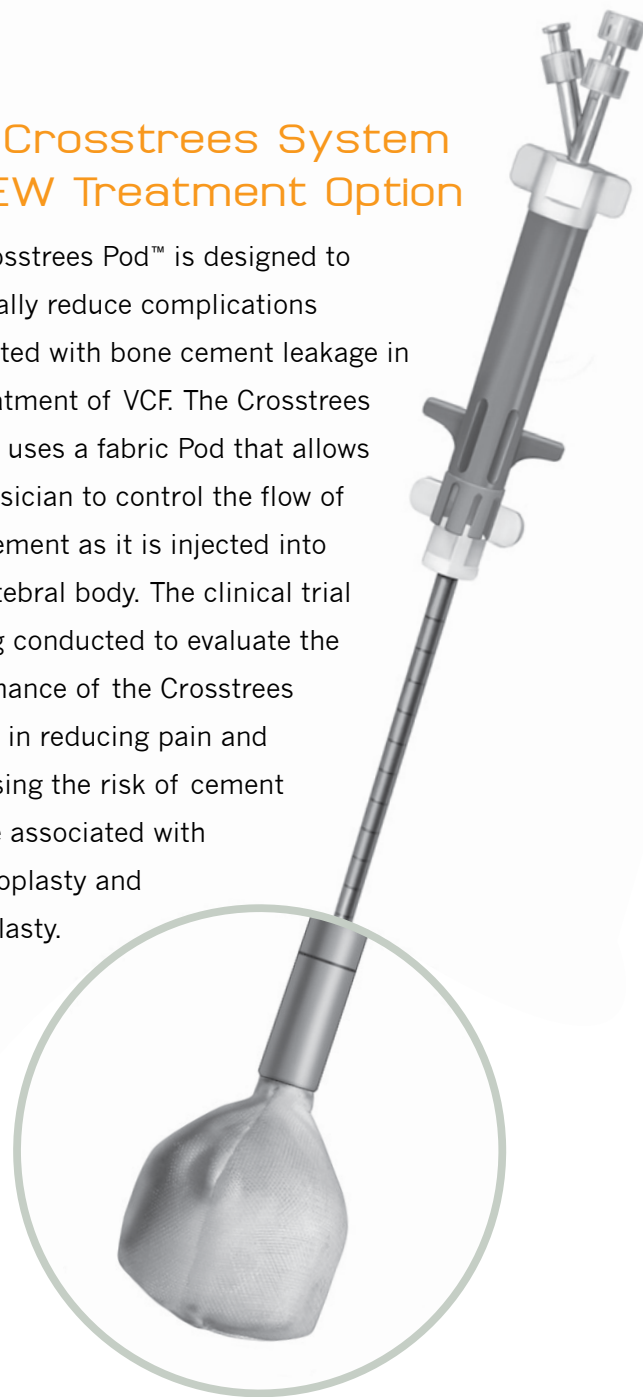
In both procedures, the bone cement then hardens, providing stabilization and pain relief. Because the bone cement is injected directly into the vertebral body, both treatments report a risk of significant bone cement leakage from the vertebral body before it hardens. In a small percentage of patients, cement leaks can result in neurological complications, emboli (blockages of blood vessels), or death.¹⁻⁶

REFERENCES

1. Chen HL, Wong CS, Ho ST, et al. A lethal pulmonary embolism during percutaneous vertebroplasty. *Anesth Analg* 2002;95:1060-2.
2. Childers JC Jr. Cardiovascular collapse and death during vertebroplasty. *Radiology* 2003;228:902-3.
3. Scoop R, Eskridge J, Britz GW. Paradoxical cerebral arterial embolization of cement during intraoperative vertebroplasty: Case report. *AJNR Am J Neuroradiol* 2002;23:868-70.
4. Stricker K, Orlor R, Yen K, et al. Severe hypercapnia due to pulmonary embolism of polymethylmethacrylate during vertebroplasty. *Anesth Analg* 2004;98:1184-6.
5. Tozzi P, Abdelmoumene Y, Corno AF, et al. Management of pulmonary embolism during acrylic vertebroplasty. *Ann Thorac Surg* 2002;74: 1706-8.
6. Yoo KY, Jeong SW, Yoon W, et al. Acute respiratory distress syndrome associated with pulmonary cement embolism following percutaneous vertebroplasty with polymethylmethacrylate. *Spine* 2004;29: E294-7.

The Crosstrees System A NEW Treatment Option

The Crosstrees Pod™ is designed to potentially reduce complications associated with bone cement leakage in the treatment of VCF. The Crosstrees System uses a fabric Pod that allows the physician to control the flow of bone cement as it is injected into the vertebral body. The clinical trial is being conducted to evaluate the performance of the Crosstrees System in reducing pain and decreasing the risk of cement leakage associated with vertebroplasty and kyphoplasty.

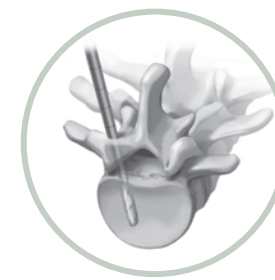


The Crosstrees Pod is designed to control bone cement delivery.

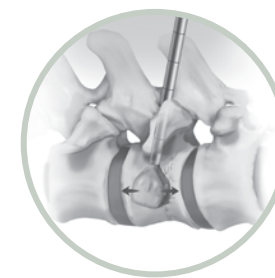
The Crosstrees Procedure

Your physician will insert the Pod into your vertebral body through a very small skin incision. This is the same surgical technique used in standard treatment options. The Pod will be filled with bone cement and then opened and removed so that only the bone cement remains.

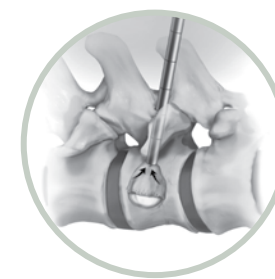
The duration of the Crosstrees procedure is comparable to that of other VCF treatments and can be performed under local or general anesthesia. Your physician will decide whether or not an overnight stay in the hospital is required. Recovery time is brief; most patients are expected to be up and walking within hours.



1. Inserting the Pod.



2. Injecting the cement.



3. Removing the Pod.

Frequently Asked Questions:

Q: What are the risks associated with this procedure?

A: All surgical procedures carry risks. The risks of the Crosstrees procedure are expected to be no greater than the risks associated with vertebroplasty and kyphoplasty treatments for vertebral compression fractures. These include leakage of bone cement out of the vertebral body; fracture of a spine pedicle or the sternum or ribs; injury to vertebral body endplates; injury to veins, arteries, and nerve tissue of the spine; recurrent disk herniation; spinal fluid leak; and re-operation. Unknown risks associated with the Crosstrees System may include the risk of component materials remaining within the body following the procedure.

Q: Why should I participate in the clinical trial?

A: The primary benefit to you is the potential reduction in risk of cement leakage and the side effects associated with it. Participation in the clinical trial is voluntary and based on your informed consent.

Q: Does it cost anything to participate in the clinical trial?

A: The Crosstrees System will be provided to you at no charge. Your insurance company will be billed for the cost of the procedure and visits that are considered to be normal and customary medical care for the treatment of VCF.

Q: Will my information be kept confidential?

A: Your identity will be kept confidential at all times except to a few employees or subcontractors (monitors and auditors) of Crosstrees Medical who need to check study data and to inspectors of national or foreign regulatory authorities. They will see your name and your medical information but will never disclose your name to anyone else. Your name or anything that could identify you will not appear in any report or record of the study.