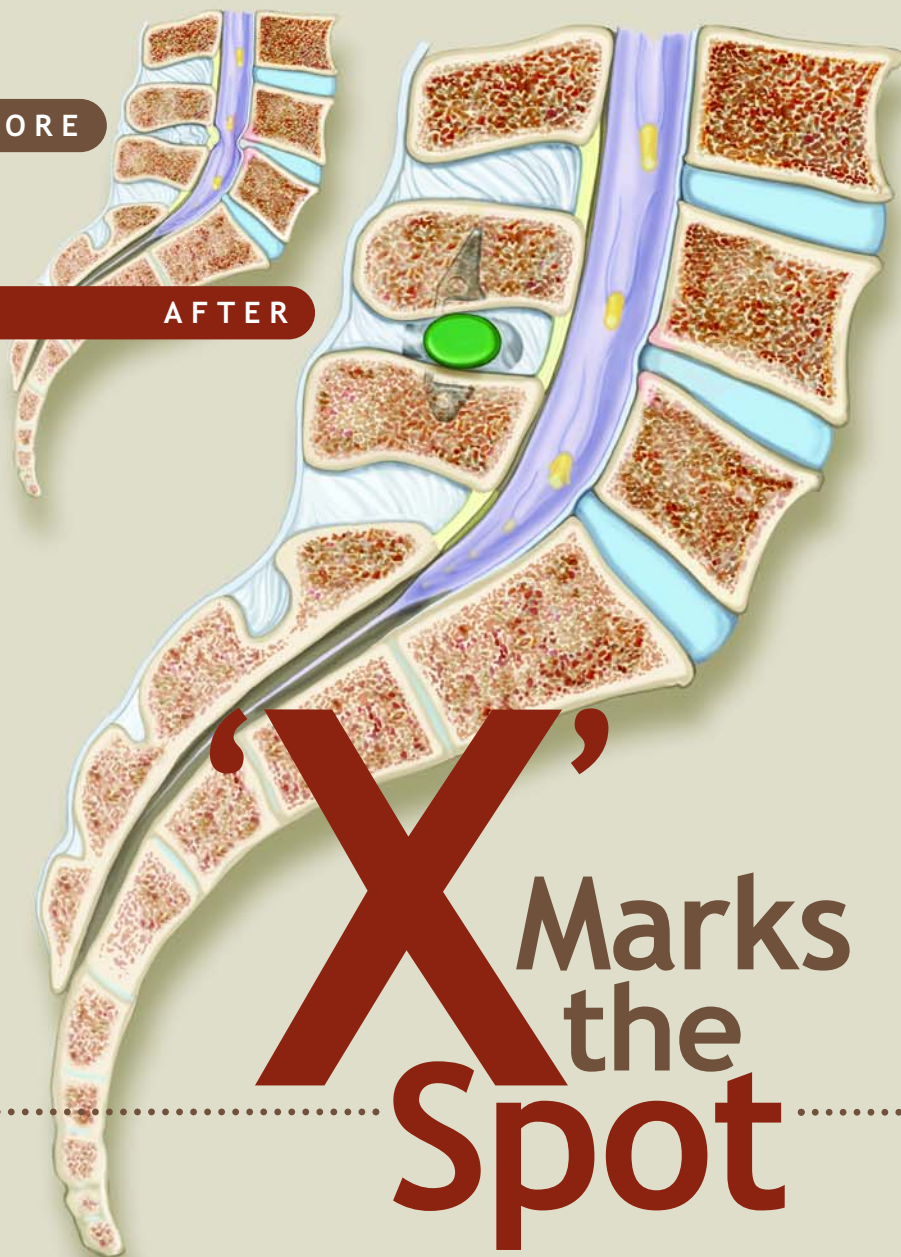


BEFORE

AFTER



“X” Marks the Spot

FDA-Approved Vertebral Spacer Helps Lower Spinal Pain

It doesn't attach to actual bone or ligaments but sits between the spinous processes (bony protrusions) of the lower spine. Yet despite its small size and lack of permanent attachment, the X-Stop® spacer is becoming a popular device for the treatment of symptomatic lumbar spinal stenosis.

“Lumbar spinal stenosis is very common, especially in a growing geriatric population,” says Kyle Colle, DO, a neurosurgeon with the Brain and NeuroSpine Clinic of Missouri and a member of the Medical Staff at Southeast Missouri Hospital who completed a spinal fellowship at the prestigious Barrow Neurological Institute in Arizona. “Some easy questions that we ask our patients who may be suffering from this condition are: if they go to the grocery store, do they lean on the grocery cart so they can walk without pain, or do they lean over the tractor or lawn mower while working on the farm or outside their home? A positive answer tells us that what they're trying to do on their own is take pressure off of their nerve roots to alleviate pain.”

Lumbar spinal stenosis is a narrowing of the spinal canal. The normal aging process causes the ligaments and bone surrounding the spinal canal to thicken or bulge, sometimes pinching or compressing nerve roots. Pain and tingling in the back and legs often result. The degenerative process usually becomes apparent after age 50 when the normal “wear and tear” of aging catches up and impacts a person's daily activities.

Dr. Colle begins any patient evaluation with a detailed medical history and physical examination, checking for abnormal reflexes, balance issues, muscle weakness and pain locations. Imaging tests follow, including x-rays, MRI and CT scans.



Kyle Colle, DO

Historically, treatment for lumbar stenosis starts conservatively — medications or anti-inflammatory injections to relieve pain, physical therapy to improve flexibility as well as muscle strength, and, sometimes, cautioning patients not to engage in certain physical activities.

“That doesn't always work for the person who has been physically active their entire life,” says Dr. Colle who has treated a number of farmers in the Cape Girardeau region who suffered from debilitating back and leg pain but didn't want to — or couldn't — change their way of life.

Surgical treatment, then, may be the next step. The traditional surgical option is called a decompressive laminectomy. It involves the removal of the lamina, which forms what sometimes is called the “roof” of the spinal canal, and then opening up of the foramen where the nerve roots exit. The procedure widens the area where the nerve roots were compressed, alleviating pressure that causes pain. Oftentimes, surgeons combine a laminectomy with spinal fusion to further stabilize the spine, if needed.

“The drawbacks of a laminectomy with fusion are twofold,” says Dr. Colle. “Although it's quite effective, it requires several months of recovery. Due to invasiveness of the procedure, significant complications can occasionally occur. Also, I believe that fusion changes the overall biomechanics of the spine, limiting mobility and increasing stress on the vertebrae of the spine above and below the place we are stabilizing.”

Enter the X-Stop spacer. Approved by the FDA in 2005 for the treatment of lumbar spinal stenosis, the X-Stop is a titanium implant that sits between the spinous processes in the back of the spine. Available in several sizes, the spacer slides into place during a surgical procedure that lasts an average of 17 minutes and holds the space in the flexed position thereby opening the foramen of the spine and taking pressure off the nerves.

The advantage for the patient is that surgically nothing is taken away. No bone is removed, and the spinal canal is not exposed.

“The objective is the same as a laminectomy in that we take the pressure off the nerve root to alleviate pain,” explains Dr. Colle. “The advantage for the patient is that surgically nothing is taken away. We don't remove any bone or expose the spinal canal at all. It's safer for the patient, requires much less recovery, and is a viable intermediary option for the treatment of lumbar spinal stenosis.”

CONTINUED ON PAGE 20

When Spinal Stenosis Is Suspected

Dull, aching back pain radiating to legs

Numbness or tingling in calves, legs, or buttocks

Weakness or loss of balance

Fatigue or lack of endurance when performing manual labor or physical activity

Pain relief when leaning forward or raising feet while sitting

Patients undergoing the procedure are positioned facedown or on their side so that surgeons can flex the spine into proper position. A special device is used to measure the space where the X-Stop will be inserted. If the spinous processes are broken or overly fragile, the X-Stop can't be used because it can't be held in place. It also cannot be used if a previous laminectomy has been performed at the treatment level. Fluoroscopy allows surgeons the ability to obtain real-time x-ray images during the procedure to ensure accurate placement of the spacer.



Risks after implantation include the possibility that the device may become dislodged or that the spinous processes fracture, or simply that the device fails to relieve severe pain. If a problem occurs, the device easily can be removed and a decompression laminectomy performed to provide definitive treatment of the spinal stenosis.

"I tell my patients that the X-Stop is classified as an intermediary device for the treatment of spinal stenosis," notes Dr. Colle. "I've put in hundreds of these devices both here in Cape Girardeau and elsewhere, and I have found that a greater number of patients have not had to undergo any further procedure to alleviate their pain." In other words, many patients may never have to undergo a laminectomy later in life, so the benefit of trying the X-Stop implant is that a patient may never need anything else, and it has less complications and risks than the laminectomy procedure. And instead of having a long recovery process, as with the laminectomy, X-Stop patients can go home within a day and are active almost immediately.

"For patients such as farmers and those who are physically active all the time, the X-Stop is a viable option for symptomatic lumbar spinal stenosis causing neurogenic claudication," Dr. Colle says.

"I've put in hundreds of these devices both here in Cape Girardeau and elsewhere, and I have found that a greater number of patients have not had to undergo any further procedure to alleviate their pain."

Kyle Colle, DO

"A single X-stop spacer can be inserted in an outpatient procedure, but I generally prefer using general anesthesia and keeping a patient overnight for observation," says Dr. Colle. "I am able to insert a maximum of two spacers during a single procedure. Patients who undergo surgery in the morning are typically up and walking that afternoon."

Dr. Colle's associates at the Brain and NeuroSpine Clinic of Missouri, Scott R. Gibbs, MD, Kevin A. Vaught, MD, and Paul J. Tolentino, MD, PhD, also are highly experienced in inserting the X-Stop implant.

Know the Risks

Implanting the X-Stop spacer requires surgical skill and the right patient for the procedure.

Patients who may be candidates include those over the age of 50 who are diagnosed with lumbar spinal stenosis and also:

- Have leg pain relieved with flexing of the spine (i.e. bending forward or sitting)
- Experience leg pain worse than back pain
- Have not benefited from conservative medical treatment
- Have healthy bones



The X-Stop spacer is about the size of a quarter.

Award

Hospital Quality, Patient Safety and Service Nationally Recognized

WINNING

SE Southeast Missouri Hospital is among an elite group of hospitals — the top 5 percent of all hospitals in the United States — recognized with the **2009 Patient Safety Excellence Award™** from HealthGrades®. The award is significant because patient safety incidents are one of the leading causes of death in this country.



"The sad fact is that, many, if not most, of these errors are preventable. Patients shouldn't die or experience unnecessary harm as a result of medical errors in hospitals," says Rick May, MD, senior physician consultant at HealthGrades and co-author of a study examining the prevalence of patient safety events in American hospitals. "The good news is that there are hospitals that are doing an amazing job when it comes to patient safety and we commend them. Patients need to know that they have a substantially lower risk of experiencing a medical error and therefore a lower risk of death or complications when they are admitted to one of these exceptional, top-performing hospitals."



James W. Wenthe, FACHE, CPA

"Patient safety is a top priority at Southeast Missouri Hospital," says James W. Wenthe, Southeast Missouri Hospital President and CEO. "Our goal, as always, is to provide the best possible care for our patients. Our success in that endeavor is the result of the daily efforts of our skilled and compassionate nurses and our talented physicians. This award reflects the strong commitment of our entire staff to provide the best healthcare for our region."

HealthGrades, a leading independent healthcare ratings organization, has analyzed patient safety for the past six years among Medicare patients in almost 5,000 U.S. non-federal hospitals using 15 indicators as developed by the federal

government's Agency for Healthcare Research and Quality (AHRQ). It found that hospitals in the top tier save lives and prevent errors at a higher rate than other U.S. hospitals. Patients treated in these hospitals had, on average, a 43 percent lower chance of experiencing one or more medical errors.

CONTINUED ON PAGE 22



This year, Southeast Hospital was one of only 242 hospitals nationwide that garnered the Patient Safety Excellence Award.

AHRQ Primary Safety Indicators Analyzed by HealthGrades®

- Complications of anesthesia
- Death in low mortality Diagnostic Related Groupings (DRGs)
- Decubitus ulcer (bed sores)
- Death among surgical inpatients with serious treatable complications
- Iatrogenic pneumothorax
- Selected infections due to medical care
- Post-operative hip fracture
- Post-operative hemorrhage or hematoma
- Post-operative physiologic and metabolic derangements
- Post-operative respiratory failure
- Post-operative pulmonary embolism or deep vein thrombosis
- Post-operative sepsis
- Post-operative abdominal wound dehiscence
- Accidental puncture or laceration
- Transfusion reaction