

LUMBAR SPINAL STENOSIS – OBSERVATIONS, EVIDENCE, AND TRENDS
FULLING THE UNMET CLINICAL NEED
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Overview of Lumbar Spinal Stenosis

Spine stabilization, which has equated to fusion historically, does help preoperative back pain after open surgical decompression; however, at what cost? Evidence is now showing simple decompression alone may not be enough for high levels of patient reported (VAS) back pain noted before spinal decompressive surgery for lumbar spinal stenosis. A recent new PMA approval suggests an alternative to spinal fusion for spinal stenosis that stabilizes facets, improves postoperative back pain, and requires less recovery after surgical decompression.

Our Past and Recent Trends

The goals for surgery for intermittent non-vascular neurogenic claudication are to provide more room for obstructed and compressed neurologic structures, regardless of where the pathology is located. Every surgical decision and plan has risks, pros, cons, and benefits of intervention. There is cost of incisional morbidity, worsening mechanical back pain, and the risk of revision surgery should decompression on progressively degenerative and arthritic facets worsen in the postoperative period.

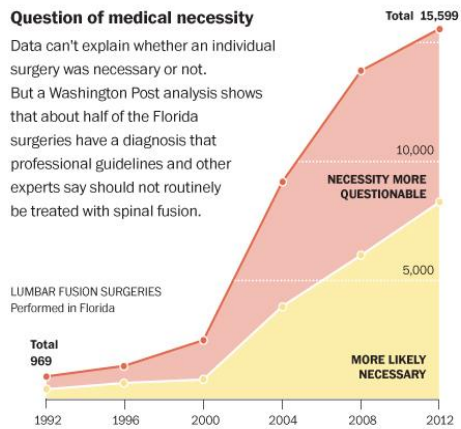
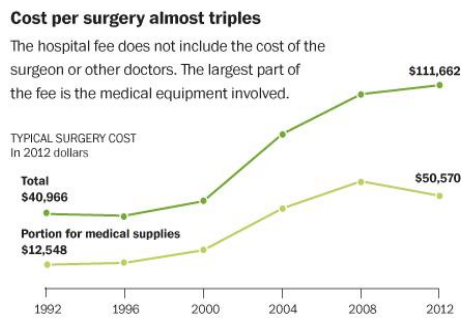
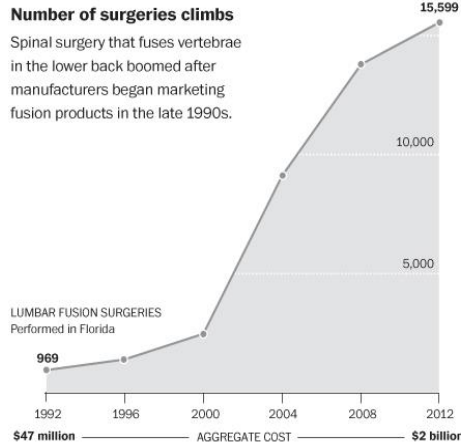
Several innovative diagnostic tools have helped clinicians localize direct neurogenic compression and specific pain generators. Improved imaging from the 1970s including CAT scanning combined with myelography, along with MRI in the late 80s, has improved diagnostic accuracy to support specific neurologic compromise that was found to equate with specific clinical and physical examination findings. Additionally, diagnostic pain procedures helped to localize discogenic and facetogenic sources of pathology to help improve accuracy of intervention. Improved minimally invasive techniques have also lessened the morbidity of the approach, which result was quite often much worse than the disease being treated. The combination of technology and technique has led to focused, precise surgery to decompress intermittent neurogenic claudication. Spine stabilization involving fusion was further enhanced in the early 2000's with approval of rh-BMP2, ceramics, and other bone graft extenders that supported spinal fusion for progressive degenerative disease.

Spine fusion has proliferated over the last 25 years because of improved implants and surgical technique. Recent reports have indicated spinal fusion has increased over 600% over the last 10 years¹ and has become one of the most expensive procedures to our healthcare system. The medical reason for the proliferation of fusion and the default rationale of choosing this type of stabilization revolves around the concern for leaving badly arthritic facets behind after decompression for

¹ Washington Post Business, October 28, 2013.

patients with moderate to severe stenosis. Do Kerrisons and curettes cure badly arthritic facets? Consensus is that the mechanism of action with this technique is to provide more room for compressed neurologic structures to allow for healing of the nerves and, hopefully, improved lower extremity function. Since spinal fusion has been the only approved form of stabilization for the lumbar spine post open surgical decompression, the proliferation of indications and actual number of cases is hardly surprising.

Credit Washington Post Business
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Progressively degenerative lumbar spinal disease is a known fact of an aging population. Spinal stenosis is the product of an active population with a desire to stay active well into their 80s and 90s. Imaging and diagnostic pain procedures have proven facetogenic contribution to back pain and have led to the concept of facet stabilization after lumbar decompressive surgery that may not require spinal fusion to lessen the risk of revision surgery in the older population. More badly arthritic facets may require more decompression to adequately expose the compressed neurologic pathology and may lead to postoperative translational, subarticular, and foraminal recurrence of pathology, as well as instability that may add to the risk of revision surgery. In addition, there is concern that many patients and physicians have not articulated the presence and contribution of preoperative back pain prior to lumbar decompressive surgery, which has led to the observation of continued post-op pain after surgery.

Hence, surgeons have trended toward utilizing lumbar spinal fusion after decompression for spinal stenosis as their preferred and only approved method for spinal segment stabilization. This increasing utilization pattern, along with increasing costs of implants per episode of care, has led to payer pushback, increased utilization pre-certification requirements, and a crisis of evidence. Since technology advanced quickly with new product launches, new biologics, and constantly evolving techniques, little evidence emerged to convincingly prove risk benefit at increasing costs. This crisis of evidence has also led to payer pushback such as the Aetna decision to not cover any PEEK interbody fusion cages for cervical spine arthrodesis because of the lack of evidence and increased costs of care compared to autograft and allograft. This all points to a trend toward evidence-based medicine for lumbar stabilization to support facet and spinal segment degeneration for advancing degenerative disease.

➤ **Hospital Costs At An All Time High**

- Top 3 surgical procedures by cost*:
 - ✓ # 1 - Spinal Fusion (\$11.3B)
 - ✓ # 2 - Balloon Angioplasty (\$11.0B)
 - ✓ # 3 - Total Knee Replacement (\$10.4B)

➤ **Payers Are Pushing Back On Fusion!**

- Payers routinely require pre-authorizations for fusion
- Surgeon increasingly engaged in “justification” of procedure
 - ✓ Burden of evidence needed to support rationale for surgery

➤ **Fusion Procedure Outcomes Under Close Scrutiny**

- The readmission rate for spine fusion is 24.3% at 2 yrs.*

* U.S. Centers for Disease Control and Prevention (CDC) 2011 data.

Evidence

Kleinstück, *SPINE* 2009, using the Spine Society of Europe Spine Tango system observational study, evaluated 211 patients with lumbar degenerative spinal stenosis without previous surgery and up to 3 affected levels with decompression as the only procedure². They conclude that greater back pain relative to leg pain at baseline was associated with a significantly worse outcome after surgical decompression. This suggests there is a strong correlation between increased preoperative back pain prior to lumbar decompressive surgery, and the retention of this back pain symptomatology after decompression for lumbar stenosis. This is intuitive, because facet joint decompression and subarticular decompression does not address facet joint arthritis and the causes of facetogenic low back pain. In fact, facet contact surfaces are reduced after decompression and the joint reactive forces that caused the facet degeneration do not improve with all accepted decompression techniques. Simple decompression alone does not restabilize facet joints, and in fact, may reduce surface-area contact as well as increase instability and foraminal subsidence over time, all of which may actually increase facet pain.

SPORT, Weinstein, et al *NEJM* 2008 also noticed that in their Low Back Pain Bothersome Index that there was only a 32% improvement in low back pain scores after decompression in their series after simple decompression for spinal stenosis³. This could be essentially a placebo effect of observation after surgery and might not represent a meaningful clinically significant improvement after surgery. This is of concern and also supports the Kleinstück, Spine 2009 article finding that simple decompression alone does not mechanically or neurogenically improve low back pain noted preop lumbar decompressive surgery.

Richter, et al *European Spine Journal* 2010, takes a different viewpoint to patients with intermittent neurogenic claudication⁴. They studied 62 patients operated by two surgeons in two non-randomized cohorts with lumbar decompression for spinal stenosis. Both patient groups received microsurgical decompression with the cohorts being differentiated by the addition of the coflex® device. They conclude improvement in both groups compared to baseline but after two years there was no significant difference between the two groups in all assessed outcomes. This level 2 study contains the bias of determining which patient gets which procedure based on non-validated selection processes. The coflex® device had a significantly higher preop ODI compared to the fusion group and actually had better improvement compared to the decompression control. Also, it is unknown whether this was a consecutive series or only those that could complete the follow-up. The lack of

² The influence of preoperative back pain on the outcome of lumbar decompression surgery. Kleinstück FS, Grob D, Lattig F, Bartanusz V, Porchet F, Jeszenszky D, O'Riordan D, Mannion AF. *Spine* 2009 May 15;34(11):1198-203.

³ Surgical versus nonsurgical therapy for lumbar spinal stenosis. Weinstein JN, Tosteson TD, Lurie JD, Tosteson A, Blood E, Herkowitz H, Cammisa F, Albert T, Boden SD, Hilibrand A, Goldberg H, Berven S, An H. *New England Journal of Medicine* 2008;358:794-810.

⁴ Does an interspinous device (coflex) improve the outcome of decompressive surgery in lumbar spinal stenosis? One-year follow up of a prospective case control study of 60 patients. Richter A, Schütz C, Hauck M, Halm H. *Eur Spine J.* 2010 Feb;19(2):283-9.

randomization, patient selection and inclusion, and the concern about the robustness of the collected data offer concerns about the methodology of the study. Of interest is the fact that evidence from the recent PMA approval October, 2012 for the coflex® Interlaminar Stabilization™ device (Paradigm Spine, LLC New York, New York) showed a marked improvement in visual analog scale (VAS) for low back pain. This level 1 study as a prospective randomized controlled study (RCT) has shown improvement to be 70% for patients who were randomized to the coflex® device, after surgical decompression for moderate to severe lumbar spinal stenosis and up to grade 1 spondylolisthesis. There was a 66% improvement in VAS back pain scores for those patients randomized to lumbar fusion in the coflex® study⁵. These two findings support that facet joint restabilization after lumbar spinal stenosis decompression is a strong component to patient improvement noted after surgical decompression for intermittent neurogenic claudication for lumbar spinal stenosis.

The coflex® Implant – 2 Part Functional Design

Neutral Interlaminar Stabilization

- Unique coflex® design allows for deep insertion post surgical decompression
- Apex of "U" permanently maintains foraminal height and volume
- Offloads facets and posterior annulus



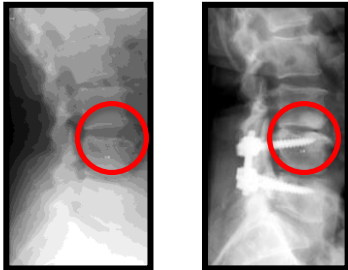
Motion Preservation

- *coflex® is compressible in extension
- *Axial force shock absorption
- *Maintains sagittal balance and lordosis
- *Maintains physiological adjacent segment kinematics

Surgeon acceptance of restabilization after decompression of arthritic facets has a cost to the patient and to society. One of the observations in the coflex® PMA study (FDA approval October 2012), as well as the recent publication by Davis, et al in August 2013 in *SPINE*, notes increased angulation, translation, and adjacent segment disease at the adjacent level in the patients undergoing lumbar fusion with pedicle screw restabilization after decompression for lumbar spinal stenosis⁴. Longer follow-up data, including 4-year reoperation rates, are greater than 2 times the rate of reoperation for patients with lumbar fusion and pedicle screws for restabilization vs. restabilization with the coflex® Interlaminar Stabilization™ device. Along with these findings, other data suggests that the coflex® device does stabilize facets, maintains index range of motion after decompression, and maintains foraminal height, now considered to be significantly similar to baseline at 4 years after lumbar decompression. The coflex® study also supports the fact that adjacent level kinematics are not altered proximally or distally to lumbar decompression when the coflex® Interlaminar Stabilization™ device is utilized. The combination of reduced operative time, reduced blood loss, reduced PACU time and inpatient hospitalization time, as well as narcotics after surgery suggests that the coflex® device provides adequate stabilization at the level of diseased pathology, and at a reduced cost with less postoperative morbidity after lumbar decompressive surgery with restabilization.

⁵ Decompression and coflex interlaminar stabilization compared with decompression and instrumented spinal fusion for spinal stenosis and low-grade degenerative spondylolisthesis: Two-year results from the prospective, randomized, multicenter, Food and Drug Administration Investigational Device Exemption trial. Davis RJ, Errico TJ, Bae H, Auerbach JD. Spine. 2013 Aug 15;38(18):1529-39.

Adjacent Level Degeneration (Fusion)



Preop

48mo Postop

Maintenance of Foraminal Height (coflex®)



Preop

24mo Postop

The coflex® Implant



Neutral

Extension

Conclusion

The coflex® device provides the opportunity to restabilize facet joints without the need for spinal fusion after open surgical decompression for moderate to severe spinal stenosis. History has shown that no one device alone, without some sort of open visualized surgical decompression, can predictably improve most patient's intermittent neurogenic pseudo-claudication with higher-grade stenosis. The coflex® Interlaminar Stabilization™ device has the PMA approval and 4 year long-term follow up that combines both the decompression techniques of today's microsurgery, with the restabilization of degenerative and unstable facets that protects the intended decompression and maintains foraminal height. With maintenance of index level range of motion, long term foraminal height, and adjacent level kinematics, why would one consider stabilization with rigid fixation as a first alternative, as opposed to motion preserving restabilization considering the recent PMA approval of the coflex® Interlaminar Stabilization™ device? The coflex® implant does provide an alternative to spinal fusion stabilization post decompression for these patients with moderate to severe spinal stenosis. Surgeons and patients are encouraged to discuss the preoperative assessment of back pain prior to decompression for stenosis as the coflex® device may be considered an alternative to spinal fusion to help improve postoperative back pain. The PMA study

and publications by Davis, et al *SPINE* 2013, Davis et al, *Journal of Neurosurgery – Spine*, 2013, as well as other publications suggest that patients will enjoy less morbidity, reduced cost, and have less chance of long-term revision surgery⁶. The coflex® study has provided an alternative to this unmet clinical need.

For more information on the coflex® device, call 1.888.273.9897 or visit our corporate website at www.paradigmspine.com or our patient-focused website at www.coflexsolution.com.

⁶ Can low-grade spondylolisthesis be effectively treated by either coflex interlaminar stabilization or laminectomy and posterior spinal fusion? Two-year clinical and radiographic results from the randomized, prospective, multicenter US investigational device exemption trial: clinical article. Davis R, Auerbach JD, Bae H, Errico TJ. *J Neurosurg Spine*. 2013 Aug;19(2):174-84.