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Orthopedics This Week

5-Year Data Favors Coflex® Over Fusion for Back Pain

BY ROBIN YOUNG

In a head to head, prospective, Level 1 clinical study, Coflex® beat fusion for patients with moderate to severe lumbar stenosis (up to grade 1 spondylolisthesis) at 21 clinical study sites around the U.S. at the 3 month, 6 month, 12 month, 24 month and, now, 60 month period.

Just let that sink in for a minute.

Better than fusion. At the five year mark.

Data like this will reverberate at payers, hospitals and corporate board rooms throughout this $10 billion industry.

One final point. This was a really well designed and executed FDA supervised, PMA (premarket approval) clinical study.

Game Changer

Consider that low back pain is the single leading cause of disability worldwide. That back pain is one of the most common reasons for missed work and the second most common reason for visits to the doctor's office, outnumbered only by upper respiratory infections. One-half of all working Americans admit to having back pain symptoms each year.

Treating low back pain—in all its forms—is roughly a $50 billion a year industry. The surgical piece of that is about $10 billion.

Coflex/Courtesy of Paradigm Spine, LLC and photo creation by RRY Publications, LLC

And the foundation of the surgical segment is spine fusion surgery.

But, based on this study, Coflex is a better alternative to spine fusion surgery for patients with moderate to severe lumbar stenosis than the current standard—pedicle screw based fixation.

One Surgeon's Experience

Scott Leary, M.D., one of the lead investigators in the study and a San Diego-based neurosurgeon, said this about using Coflex on his patients with moderate to severe lumbar stenosis:

"A Coflex surgery is very different from a fusion surgery. It typically takes an hour and a half or less and the patients stay in the hospital only 1 or 2 nights. I make an incision that is just slightly larger than for a micro-discectomy, so there is hardly any exposure performed. This greatly limits the amount of muscle trauma, unlike a fusion procedure, and therefore the post-operative recovery is much easier on the patient.

"It's a very straightforward implant to place that doesn't take long to master so there's not a difficult learning curve to deal with. Because only a few fluoro images are needed, another hidden benefit is that I never need to wear lead so it's easier on me as well."

"Before placing Coflex you first perform an interlaminar decompression under direct vision. This ensures that you are addressing their primary issue: stenosis. Coflex results in off-loading of the facet joints (reducing their back pain) and it maintains the decompression you just spent all that time doing."

"The study has also proven that it maintains normal motion at the index

level without transferring increased rotational or translational forces to the adjacent levels. We all know that fusing spinal segments can lead to an accelerated breakdown of the levels above and below the fused segment because it does shift loading forces to those adjacent levels. That doesn't happen with Coflex and we've proven it with this landmark study."

"Let me tell you about one of my patients. He was 92 years old. He had severe, painful stenosis at L4-L5. I was very nervous about his expectations because of his age. When we first met I asked him; 'what are your goals for this surgery?' He said to me; 'Doc, I just want to feel like I'm 91 years old again". Literally the day after his Coflex surgery, he was up and walking with complete resolution of his claudication symptoms. And I asked him 'how are you feeling now'. He said; "Doc, I feel like I'm 80!"

"The other thing I love about this surgery is that no bridges are burned. It is easy to convert to a TLIF or an ALIF if that turns out to be needed later on. With Coflex, we're not fusing patients that don't need to be fused."

Incidence Rates for Lumbar Stenosis

Of all the causes of lower back pain, spinal stenosis with up to Grade 1 spondy, is one of the most common diagnosis leading to spine fusion surgery. It is also a diagnosis which increases sharply with age. Here's the data:

- A Swedish study found that the incidence rate for spinal stenosis as defined as a canal of 11mm or less was 5 per 100,000 inhabitants.
- A National Low Back Pain Study recorded that out of 2,374 patients with low back pain, 35% had bone related spinal nerve compression.
- Data from the National Ambulatory Medical Care (NAMCS) survey found that 13-14% of patients with low back pain may have spinal stenosis.
- The NAMCS data shows the incidence in the U.S. population to be 3.9% of 29,964,894 visits for mechanical back problems.
- The Longitudinal Framingham Heart Study found 1% of men and 1.5% of women had vertebral slippage at mean age of 54. Over the next 25 years, 11% of men and 25% of women developed degenerative vertebral slippage.
- 250,000-500,000 U.S. residents have symptoms of spinal stenosis

Background

Coflex had been implanted in more than 10,000 European patients before coming to the U.S. in 2006.

The architects behind the American launch of Coflex are the Viscogliosi brothers (Marc, John and Anthony). These three gentlemen have been at the forefront of orthopedic trends for the better part of a quarter century. They are probably most famous for having defined the motion preservation sector of spine care and for putting the first dollars behind this now standard technology. Before JNJ, Synthes, Stryker, Medtronic. Before everyone.

In their hands, Coflex began as a very ambitious PMA clinical study.

Remember, since 2008 the FDA has received more than 20,000 510(k) submissions but barely 220 PMA submissions—for all medical devices. It is such an article of faith that orthopedics is based on 510(k) submissions that the rare PMA is greeted with wonderment often reserved for obscure bird species.

In 2013, when the full scope of this study was revealed, the spinal implant community was treated to:

1. The first prospective, Level 1 PMA spine study which collected healthcare economic data in addition to clinical, radiographic and safety data for spinal stenosis.
2. A 95% follow-up rate through two years—the highest ever for a PMA spinal implant (91% follow-up at 5-years!).
3. A head to head comparison with lumbar pedicle screw fusion following surgical decompression—the bread and butter of the spine industry.
4. Inclusion of Medicare-aged patients in the study. CMS reimbursement.

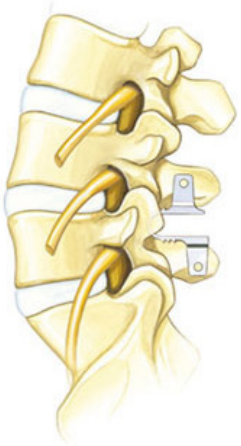
The 2013 follow-up results (2016 results later in this article):

5. Coflex saved an average of $5,000 – $8,700 per case when compared to pedicle screw fusion for spinal stenosis.
6. Coflex patients spent 40% less time in the hospital compared to fusion patients (1.90 days vs. 3.19 days).
7. Coflex surgeries were 36% faster than fusion (98 minutes vs. 153 minutes).
8. Motion was preserved. At two years follow-up, Coflex patients retained their pre-op range of motion and translation at the treated level. Fusion patients did not. By contrast, the fusion patients reported a 62% motion reduction at the treated level.
9. Coflex patients maintained normal adjacent level motion. Fusion patients did not. The fusion patients experienced a 52% INCREASE in adjacent segment range of motion.
10. And Coflex patients reported better pain and function outcomes vs. fusion at 3 months, 6 months, 12

months and 24 months and, now, 60 month follow-up.

Simple Device

Coflex is a simple design—a single, U-shaped piece of metal (medical grade titanium alloy) which is placed (see the illustration) between the spinous processes. The "U" portion fits up against the anterior part of the spine and the two wings extend outward along both the superior and inferior spinous processes. In that position, Coflex decompresses the segment while allowing for motion both at the treated segment and at the adjacent levels.



Paradigm Spine, LLC

It comes in five sizes: 8, 10, 12, 14 and 16mm. Stenosis patients in about 40 countries outside the U.S. (Europe, Middle East, Asia, Central and South America) have had Coflex available for them since 2005.

But Not a Simple Study

The first patient was treated in October 2006. Enrollment continued until March 2010. Three hundred and eighty-four patients were enrolled consisting of up to 40 non-randomized "roll-in" patients and 344 randomized patients.

Excluding 22 protocol violators, 215 randomized Coflex patients and 107 randomized control patients were enrolled.

This study was a prospective, randomized, multi-center, concurrently controlled clinical study.

The surgeons were blinded prior to patient randomization.

The patients were blinded until after surgery.

Control was posterolateral fusion with autograft bone and pedicle screw fixation, following surgical decompression. The products used in the control were the Expedium (Johnson and Johnson, Inc.) and the CD Horizon Legacy (Medtronic, Inc.).

An independent Data Safety Monitoring Board (DSMB) evaluated all safety events on a quarterly basis during the course of the study to ensure patient safety was not compromised. All adverse events were independently reviewed and adjudicated by a Clinical Events Committee (CEC), with their decision binding on the study sponsor. All radiographs were analyzed by an independent core lab (Medical Metrics, Inc.).

All patients were re-examined at 6 weeks, 3 months, 6 months, 12 months, 18 months, 24 months and, now, 60 months postoperatively.

Patients were evaluated for Oswestry Disability Index (ODI), Zurich Claudication Questionnaire (ZCQ), SF-12, back and leg pain (via visual analog scale (VAS)), and neurological assessment at preoperative visit and at all postoperative visits. Radiographic evaluation was performed at all time points. Adverse events and complications were recorded at all visits.

Now, the 5-Year Follow-Up Data

Two tables at the end of this section will provide more details and the study itself is available here http://www.paradigmspine.com/content/abstract-archive.

For all patient derived parameters, the researchers found a statistically significant improvement for patients treated with Coflex through the five-year follow-up period. At five years, more Coflex treated patients reported pain improvement of at least 20mm in VAS leg pain than fusion patients and over 80% at least 15 point improvement in ODI.

By all patient derived parameters, the two treatments (Coflex and fusion) produced similar results—but with most measures at most time points, Coflex patients did better than fusion patients.

At five years:

- More Coflex patients at all follow-up time points achieved at least a 15 point improvement in ODI (80% vs 76%) and at least a 20mm VAS leg pain (80.0% vs 77%) and VAS back pain improvement (83.9% vs 75.5%) as compared to the fusion group.
- 50% of the Coflex patients and 44% of the fusion patients met the FDA's clinical success composite endpoint.
- The FDA required that the Coflex investigators use a Bayesian statistical comparison between the Coflex and fusion groups. Here's what they found: The probability that Coflex is not clinically worse that fusion exceeds 99.9%! The Bayesian posterior probability that Coflex is superior to fusion is 90%.

The two tables on page 4 summarize both the key findings of the study and the narcotics experience with both groups.

Importantly, narcotics use over the five years was also less among the Coflex patients.

To read the study for yourself, follow this link: http://www.paradigmspine.com/content/abstract-archive.

Five Takeaways

1. The five-year data shows that Coflex is durable. Coflex is NOT a precursor to fusion
2. Coflex surgery is simpler and less traumatic than the traditional pedicle screw spine fusion surgery.
3. Coflex lowered the risk of postoperative adjacent level degeneration as compared to spine fusion surgery (we expect to see, by the way, data on the ability of Coflex to reduce adjacent level degeneration presented at the upcoming ISASS meeting).
4. The risk/reward profile of Coflex is compelling for payers and hospitals. Safer than spine fusion. Cheaper. Faster. More efficient use of resources, more surgeries per fixed cost unit. Fewer re-hospitalizations.
5. No bridges burned. If the patient eventually needs a spine fusion surgery, that's always available.

With five-year data like this plus strong payer support, we would expect spinal implant companies to begin to add interlaminar stabilization implants to their product portfolios. ♦

Month 60 Overall Efficacy of Subjects Achieving Clinical Success Defined by the Individual Components of Success

	Coflex® (Decompression + Interlaminar Stabilization)			Spine Fusion (Decompression + Pedicle Screw Fixation)		
Status Pre-Op Compared With Month 60	**N Assessed**	**N Meeting Criteria**	**%**	**N Assessed**	**N Meeting Criteria**	**%**
Improvement of > 15 points in ODI at Month 60 compared to baseline	124	100	80.6	55	41	74.5
No reoperation or epidtural steroid injection	215	148	68.8	107	71	66.4
No reoperations, revisions, removals, or supplemental fixation	215	179	83.3	107	89	83.2
No epidural injection at any lumbar level	215	173	80.5	107	82	76.6
No persistent new or increasing sensory or motor deficit	88	83	94.3	40	40	100
No persistent new or increasing sensory deficit	148	143	96.6	66	66	100
No persistent new or increasing motor deficit	146	144	98.6	74	72	97.3
No major device related complications	215	212	98.6	107	102	95.3
Composite Clinical Success (month 60 CCS-FDA)	191	96	50.3	91	40	44.0

Narcotics Usage

	Coflex® (Decompression + Interlaminar Stabilization)	Spine Fusion (Decompression + Pedicle Screw Fixation)	p-value (Fisher's Exact)
Pre-op	**52.6%**	**53.3%**	**>0.90**
Week 6	**46.0**	**54.2**	**>0.10**
Month 3	**34.4**	**44.9**	**>0.08**
Month 6	**29.8**	**34.6**	**>0.40**
Month 12	**28.0**	**38.2**	**>0.40**
Month 18	**22.3**	**29.0**	**>0.20**
Month 24	**23.3**	**33.6**	**>0.06**
Month 36	**23.3**	**22.4**	**>0.90**
Month 48	**23.7**	**20.6**	**>0.50**
Month 60	**23.7**	**24.3**	**>0.90**

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