

Orthopedics • This Week

The Right Trial – Coflex®

By Robin Young

Since 2008 the FDA has received 18,000 510(k) submissions and 193 PMA (premarket approval) 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.

If it *were* a rare bird, the ortho PMA would be nearly invisible (1% of all birds) but when sighted, would look like a feathered bull dog and exhibit unfathomably expensive eating habits. The PMA bird literally gobbles up thousand dollar bills.

But in the past 30 days the industry has been graced with sightings of two PMAs—Globus' SECURE-C Cervical Artificial Disc and Paradigm Spine's Coflex.

Of the two, Paradigm's Coflex may well be the most unique because, in many ways, it was the most ambitious and could well influence the broader payer and provider formularies going forward.

No surprise, the architects of the Coflex PMA are none other than the Viscogliosi brothers (Marc, John and Anthony). These three gentlemen have been at the forefront of orthopedic trends for the better part of the past quarter century. They are probably most famous for having defined the motion preservation future of spine care and for also putting the first dollars behind this now stan-



Paradigm Spine's Coflex

dard technology. Before JNJ, Synthes, Stryker, Medtronic. Before everyone.

Could the Coflex trial have the same impact on spine care that the VB's initiatives in motion preservation? We think so.

Consider that:

1. It is 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. It achieved a 95% follow up through two years—the HIGHEST for any PMA approved device in spine.
3. It used lumbar pedicle screw fu-

sion following surgical decompression—the bread and butter of the spine industry—as the control.

4. It included a significant number of Medicare-aged patients.

Then, the outcomes were this good:

1. Coflex saved an average of \$5,000 -\$8,700 per case when compared to pedicle screw fusion for spinal stenosis.
2. Coflex patients spent 40% less time in the hospital compared to fusion patients (1.90 days vs. 3.19 days)
3. Coflex surgeries were 36% faster than fusion (98 minutes vs. 153 minutes).

4. 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.
5. Coflex patients maintained normal adjacent level motion. Fusion patients did not. The fusion patients experienced a 52% INCREASE in adjacent segment range of motion.
6. And Coflex patients reported better outcomes to fusion at every time period.

Coflex

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



Paradigm's Coflex

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.

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

It's a simple product.

But Not a Simple Study

The first patient was treated in October 2006 and 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. There were 21 investigational sites.

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.

The control group 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, and 24 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.

In all, there were **589 data points collected for each patient.**

At the end of the study, the VBs had amassed:

- 55,000 patient completed case report form pages
- 375,000 clinical and radiographic data points
- 12,000 patient X-rays.

And, of course, economic data for lumbar pedicle screw fusion and Coflex.

The Conclusions

“At every assessment time period, the percentage of Coflex patients achieving composite success was greater than fusion, with the largest differences occurring at week six and month three. Sensitivity analyses show that the Coflex device's non-inferiority to fusion is

Table 17: Posterior Probabilities of Success at 24 Months in Coflex Clinical Trial

	Number and Percentage Achieving Month 24 CCS*						Posterior Probability of Non-Inferiority
	Coflex			Fusion Control			
	N	n	%	N	n	%	
Month 24	204	135	66.2%	104	60	57.7%	0.999

Source: FDA SSED Report

* Composite Clinical Success

not sensitive to missing data. In addition, all components of overall success of the Coflex group are comparable to or better than the control group. At 24 months, 85.8% of Coflex patients compared with 76.7% of fusion patients experienced at least a 15 point reduction in ODI.” – from the FDA’s report.

The average operating time in the fusion patients was 55.2 minutes greater than the Coflex patients. Average blood loss in fusion patients was 238.9 cc greater in the fusion patients than in Coflex patients. The average hospital length of stay was 1.29 days longer in the fusion patients.

Non-inferiority of the Coflex group compared to the control group was demonstrated for the Composite Clinical Success (CCS) at 24 months. The CCS at 24 months is determined by the ODI improvement compared to baseline, absence of secondary surgeries or epidural pain management and neurologic success. Patients in the Coflex group demonstrated an 81.9% CCS at 6 weeks which increased to 82.6% at 3 months and gradually fell to 66.2% at 24 months. Patients in the control group

demonstrated 65.7% CCS at 6 weeks which rose gradually from 6 Weeks to 6 Months to 77.1%. CCS fell to 57.7% at 24 months. At every assessment time period, the percentage of Coflex patients achieving CCS was greater than fusion, with the largest differences occurring at week 6 and month 3, demonstrating statistical significance at those time points. The final CCS at 24 months demonstrates numerical success that is 8.5% higher in the Coflex group when compared to the fusion control.

And...Economic Data

The Coflex study was the first Level-1 study to quantify the cost differential based on prospective data comparing the current standard of care (posterolateral fusion) to the new treatment. On average, Coflex saved \$8,700 per case when compared to a fusion. Upon examination of the data, five aspects of the Coflex treatment created these cost differentials: shorter operating room time, faster patient recoveries, less blood loss, less narcotic usage and shorter hospital stays—while also producing faster and more sustained clinical success.

Said Marc Viscogliosi, Chairman and CEO of Paradigm Spine: “This study provides the evidence that insurance companies, surgeons and patients have been demanding. Insurance companies, surgeons and patients finally have an alternative to fusion which, based on independent study data, has demonstrated that Coflex produces better outcomes, faster recover, preserves motion and may be performed on an outpatient basis. For patients, the ability to walk without back pain and the progressive symptoms of stenosis is one of the most cherished functions of the aging population.”

“Better and Lower Cost”

Finally, Reginald Davis, M.D., the study’s principal investigator said, “This is the first time a new spinal technology is proven to be better and more effective than the historical gold standard and is still actually lower cost. I am excited to be able to provide Coflex to my patients without the need for fusion through a simple, motion preserving, and minimally invasive bone saving surgical technique.” ♦



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