Editorial

Fixed Center-of-Rotation Disc Prosthesis: What We Know at Ten Years

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Disclosures: Dr. Balderston is a consultant for Synthes Spine.

Section I: Introduction

Degenerative disc disease (DDD) is a problem affecting millions of individuals worldwide, leading to alterations in motion, low back pain, and ultimately loss of normal function of the spine. Treatment options for this problem are multiple, but the mainstay of treatment at present has been fusion of the vertebral bodies. Fusion should eliminate the problematic motion segment from the spine and, ideally, eliminate pain. The spine functions best, however, when it can provide both motion and stability[1].

Problems with fusion stem from the loss and alteration of motion about the fused segments and primarily comprise adjacent segment degeneration and its inherent problems[2,3]. In an effort to eliminate some of these difficulties, motion-sparing surgeries, including disc arthroplasty, have been a promising alternative.

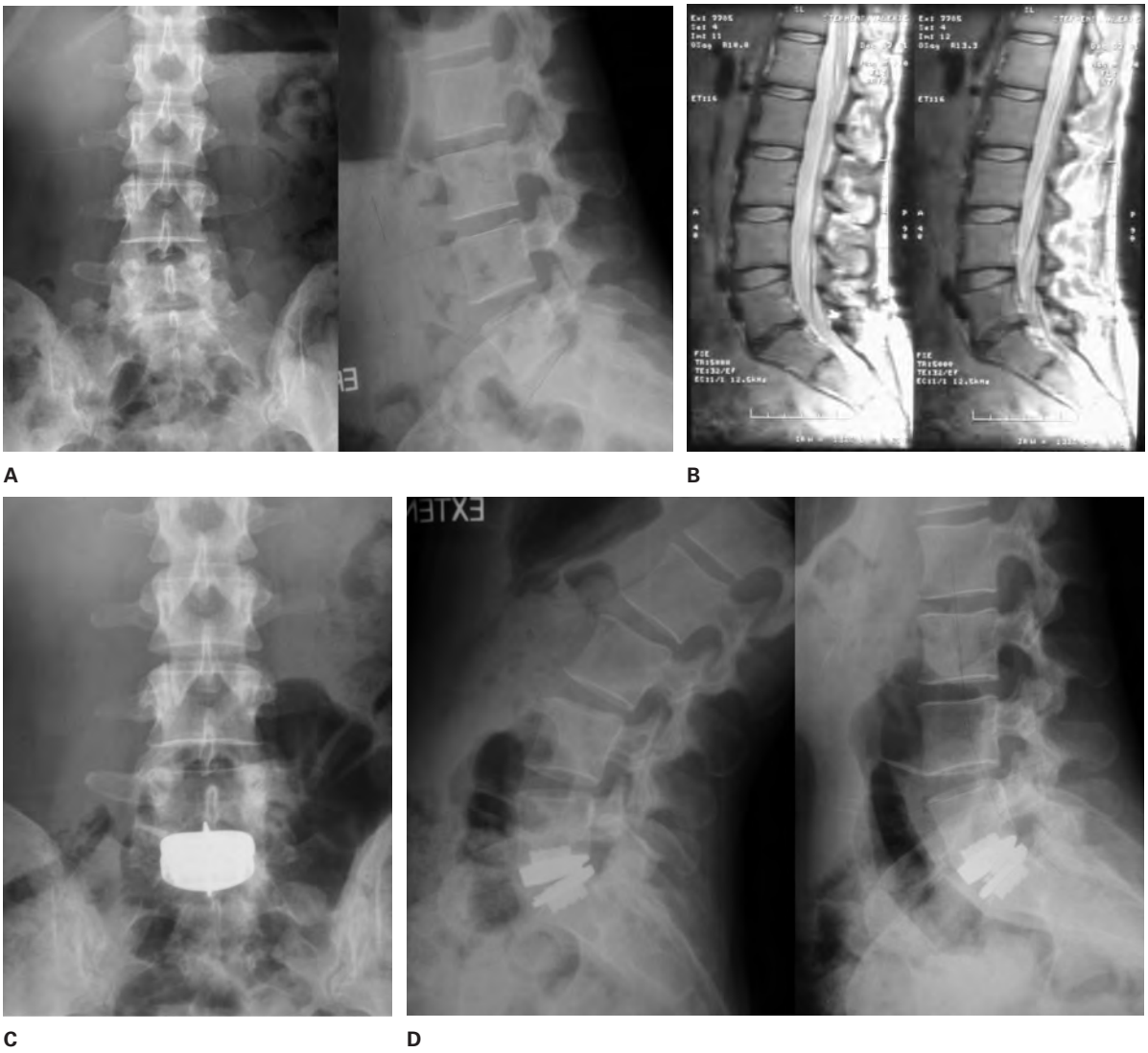
The goals of disc intervention, especially disc arthroplasty, are multiple. While the surgery seeks to eliminate the underlying pain generator, it's equally important that the prosthesis prevent instability. As such, with load transfer from the superior to inferior vertebrae, there is assurance that the neural elements are protected, that the patient does not have pain and there is no pathologic motion. Ideally, the prosthesis should allow compressibility and elasticity that dampens loading peaks with compression and shear. In short, the prosthesis should restore segment mobility, stability, and painlessness, and should function for the lifetime of the patient without breakdown[1].

Normal motion of the lumbar spine entails a mobile center of rotation that varies according to the angular value of flexion, lateral bending and axial rotation as well as the disc-loading characteristics. As yet, no prosthesis mimics a mobile center of rotation that correlates with the normal condition between two vertebrae. One definition of pathologic motion is motion that causes pain or neurologic deficit. We may then define non-pathologic motion as motion that results in neither of the above. Several treatment options are available to provide non-pathologic motion (Table 1). Within this subset are variable-axis and fixed-axis prostheses, of which Pro-Disc is the latter.

Disc arthroplasty is contraindicated in cases where there is infection, tumor or fracture, or where there is inherent axial instability in compression due to loss of bone. Spondylolisthesis, scoliosis and other translational instabilities are more promising and have been the subject

TABLE 1

Treatment Type	Sub-type		Examples
Posterior Dynamic Stabilization			
	Mobile Screw Parts		Cosmic Posterior Dynamic System (Ulrich Gm bH)
	Mobile Connectors		Dynesys (Zimmer Spine)
Nucleus Replacement			
	Injectable		NuCore (SpineWave)
	Pre-formed		NeoDisc (NuVasive)
Total Disc Replacement		Axis type	
	Three-component	Variable	CHARITE (DePuy Spine)
	Two-component	Fixed	Pro-disc (Synthes)
	Single-component	Fixed	Freedom Lumbar Disc (AxioMed Spine)
Facet Joint Replacement			Total Posterior Arthroplasty "TOPS" (Impliant Spine)



A B C D

Figure 1A–D.

of compassionate use FDA-allowed cases early in the Pro-Disc trials ,although they are currently relative contraindications to disc replacement.

There are two general types of artificial disc replacements: fixed-axis (constrained) and variable axis (unconstrained) prostheses. Restoring natural motion, including a near-normal center of rotation, is the primary advantage of an unconstrained prosthesis. Eliminating the shear that accompanies this near-natural motion is the primary advantage of a constrained prosthesis.

Section II: History of the Pro-Disc Prosthesis

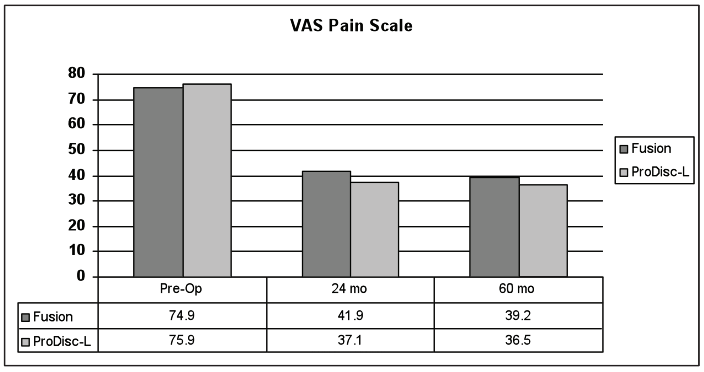
After several years of development in the late 1980s, Pro-Disc was first implanted in Montpellier, France in 1990, by Thierry Marnay and his colleagues. Ninety-three prostheses were implanted from 1990 to 1993 and follow-up from seven to ten years was available for 58 patients. Patients had single, double and triple level surgeries and at follow-up all implants were intact. Migration and subsidence was minimal and range of motion was maintained. Ninety-two percent stated they were satisfied and would have the surgery again. Also, no osteolysis was noted at follow-up.

While the first-generation Pro-Disc patients were being followed, Pro-Disc II was being developed in the mid-1990s. Substantive changes included the substitution of one central keel for the two keels in the original design. The central keel allowed for easier midline insertion with roentgenographic control intraoperatively. Also, the articulating surface was changed from a titanium-poly interface to a cobalt chrome-ultrahigh molecular weight polyethylene. In addition, the surgical technique was altered such that en bloc insertion was evolved into a modular assembly that allowed for positioning in the posterior disc space followed by distraction and insertion of the poly.

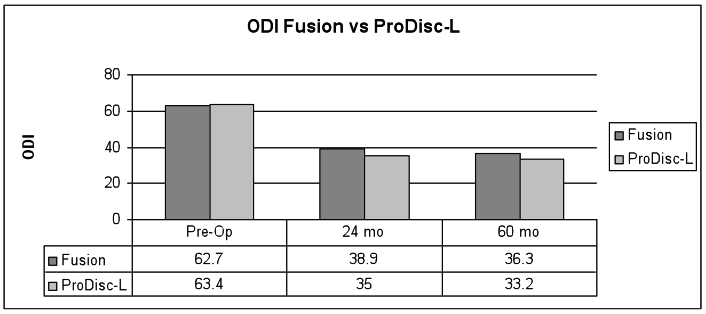
Fixation of the Pro-Disc to the bony endplate involves keel fixation which provides immediate stability in rotation and shear in all planes and a titanium plasma sprayed coating that allows for fixation to be achieved with bony ingrowth within six weeks.

TABLE II.	
Preliminary 5 year follow-up	
VAS Pain	
ProDisc-L:	52% decrease
Fusion:	48% decrease
Oswestry Disability Index (ODI)	
ProDisc-L:	48% decrease
Fusion:	42% decrease

VAS



ODI



* Difference between treatment $p < 0.05$ at 24 months

TABLE III.	
Reoperation Rate	
ProDisc-L:	5.6%
Fusion:	13.3%
ROM within functional range	
ROM @ baseline	7.2°
ROM @ 60 months	6.1°
Patient satisfaction remains high for ProDisc-L	
Would you have the surgery again?	
ProDisc-L	80%
Fusion	63%

3 additional ProDisc-L from 24-60 months
2 fused for ongoing pain (ProDisc-L left intact)
1 spinal cord simulator

The actual flexion-extension motion allowed by the prosthesis is 13 degrees flexion and 7 degrees extension for an overall motion and flexion-extension of 20 degrees which is a theoretical 5 degree improvement on normal motion of the lumbar disc which is 15 degrees.

Section III: U.S. Multicenter FDA IDE Study

The first Pro-Disc was inserted in the U.S. in the autumn of 2001, as part of an FDA clinical trial, comparing disk replacement to fusion. Seventeen centers were utilized and in the initial study there were both one and two-level arms. The randomization to anterior-posterior fusion was 2 to 1 compared to arthroplasty. In the years 2000 and 2001 the FDA recommended an anterior-posterior fusion as this method of lumbar fusion has the highest success rate with respect to fusion being achieved. Fortunately, in 2011, anterior-posterior fusion still has the highest fusion rate. The study design was prospective randomized, with both the patient and the surgeon blinded to which operation would occur on the day

TABLE IV.	
Recreation Status	
Pre-op	
ProDisc-L:	42.2%
Fusion:	49.3%
24 months	
ProDisc-L:	87.4%*
Fusion:	77.3%

*Significantly different from control p=0.0307

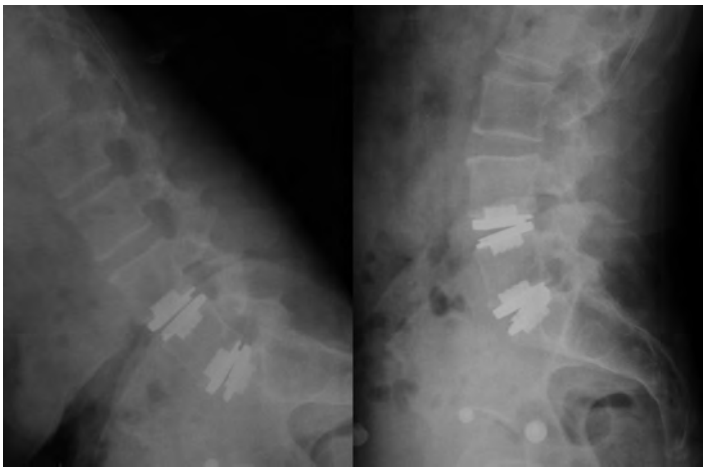


Figure 2.

TABLE V.		
Reoperation Rate at Index Level through 24 months for 2 Level Disease		
	Fusion	ProDisc-L
Reoperation Rate	8.2%	2.4%

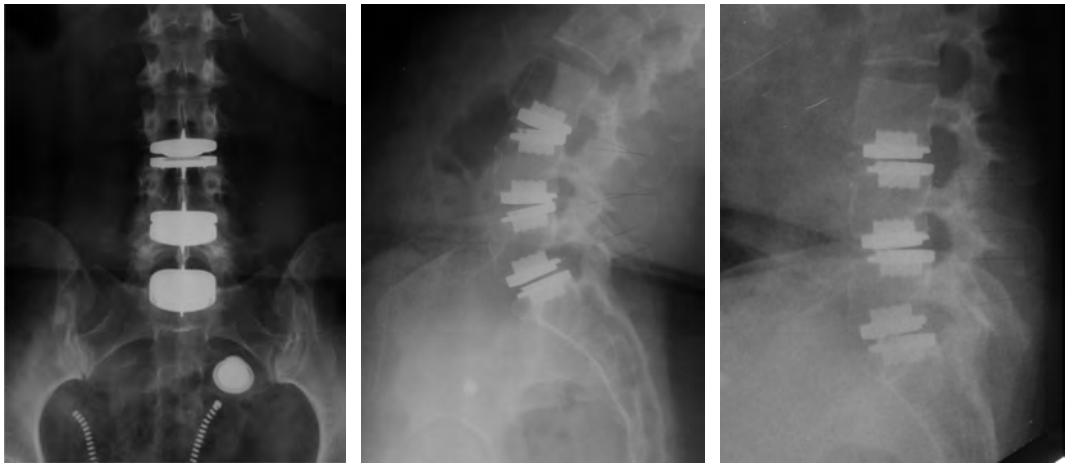


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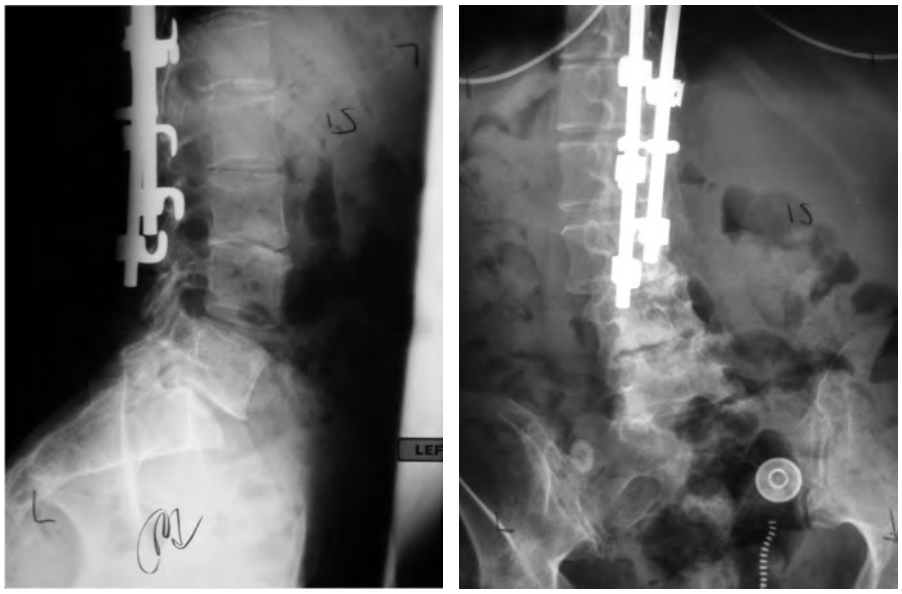
Figure 3A–C.



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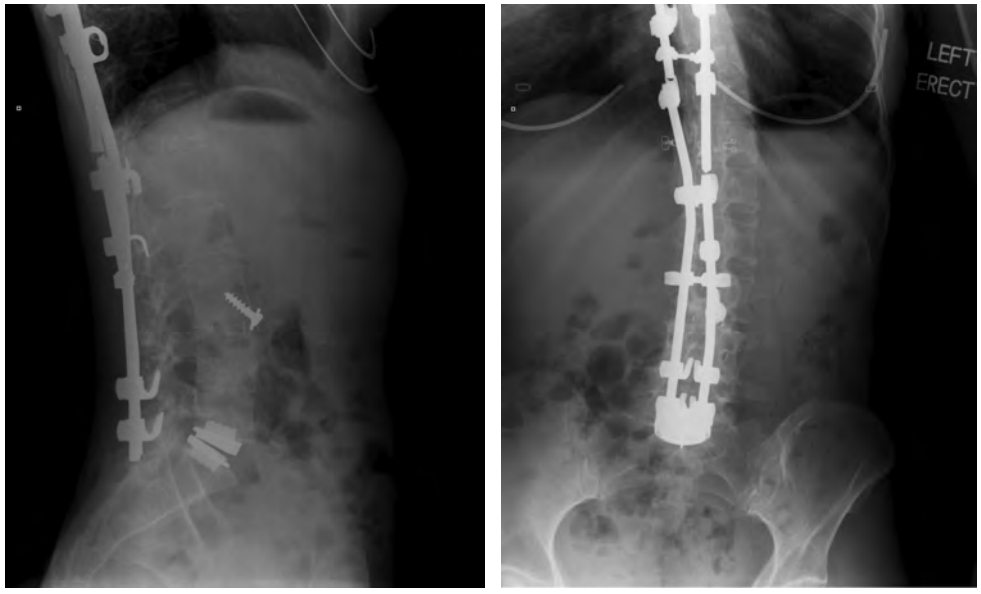

C D

Figure 4A–D.

of surgery. The results of the randomization or the single-level study yielded maximum sets of patients with respect to sex, age and weight. Ultimately, 292 patients were enrolled in the study. The randomized patients included 162 Pro-Discs and 80 fusions; in addition, there were 50 so-called "training cases" which were performed at a rate of three per center to allow surgeons to perform the procedure under the direct supervision of Dr. Marnay. At Pennsylvania Hospital, all patients underwent history and physical evaluation with plain x-rays, MRI scanning and provocative discography. All patients in the single-level study had abnormal studies at the index level with provocative concordant pain at low pressure with all other levels being normal in all roentgenographic studies (Figure 1).

Both two and five-year follow-up studies have been reported. Both experimental and control groups demonstrated significant improvement and patient status with respect to Oswestry Disability Index (ODI) and visual analog scale (VAS) pain scores, with clinically significant separation between the Pro-Disc and fusion at 24 months with the self-administered ODI (Tables 2 & 3).

Among the data produced by the study is the status of patient recreation at 24 months. For Pro-Disc, 87% of patients at two years stated that they had a satisfactory result with respect to their preoperative recreation desires after surgery. The corresponding level for fusion was 77% (Table 4).

Section IV: Results of the Two-Level Study

For the two-level study (Figure 2), the clinically significant separation between Pro-Disc and fusion at two years was greater than in the one-level study. At two years the revision rate with fusion at two levels was 8.2% and with the two-level Pro-Disc, the revision rate was 2.4% (Table 5).

Section V: FDA Compassionate Use Cases

The FDA during the first four years of Pro-Disc implantation in the U.S. did allow special dispensation for patients with clinical problems that did not have a good solution. Two sets of patients that were evaluated and managed with Pro-Disc at Pennsylvania Hospital during this time period were patients with three level degenerative disc disease and patients with scoliosis fusions between 10 to 12 levels who suffered degeneration below their fusions and would be candidates for sacral fusion. They are currently following these patients at Pennsylvania Hospital who five years after their three level Pro-Disc or L5-S1 Pro-Disc with a fusion down to L5 in adulthood or adolescence. As yet the patients have not had deterioration of function nor have any of them required revision surgery (Figures 3 & 4).

Section VI: What We Have Learned

Results in patients with one-level Pro-Disc at greater than five years show continued improvement in VAS and ODI scores. Most patients who have had a good result at one year continued to show good results at greater than five years after surgery. Motion is maintained between two and five years with an average range of motion above six degrees per level with Pro-Disc.[4-6] There are very few centers with any significant experience with revision surgery. Indeed, at Pennsylvania Hospital we have had no prosthesis explants in our first ten years of experience with the Pro-Disc.

It must be remembered at this time that, as with Pro-Disc, there are no other prostheses that produce range of motion with harmonious motion of the facet joints. The long-term result with respect to this situation and facet remodeling or facet pain is unknown. Also, the compressibility and elasticity of the prosthesis is minimal and thus the peak loads in flexion and axial loading are still being handled by the normal discs adjacent to the Pro-Disc. Again, we do not know the long-term results of this situation.

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