

Percutaneous Outpatient Treatment of Lumbar Pain in Patients with Degenerative Disc Disease: Advances with New Technology Cleared for Use Outside the U.S.

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Some would argue that surgical fusion today is considered to be the standard treatment of care for lumbar pain in degenerative disc disease (DDD) patients failing non-operative (“conservative”) treatment. However, patients with mild to moderate DDD may decline “major” surgery which irreversibly alters the spine, prolongs recovery time and limits return to work or other important quality of life benchmarks in younger patients. Most back pain patients are, in our opinion, grossly underserved today as chronic back pain left untreated can lead to seriously diminished quality of life, including the socio-economic consequences of work stoppage. The search for new and effective back pain interventions must continue even against the added requirements of cost containment pressures seen in all health-care systems of the world.

In an effort to ameliorate this set of unmet clinical needs, a host of new, nonfusion technologies have been offered to practitioners by a variety of companies since 2000. Christie *et. al.* published their article in *SPINE*, Vol. 30/No. 165/August 2005, “Dynamic Interspinous Process Technology,” a retrospective survey of articles published on a variety of Interspinous Process Devices focused on the pathophysiology, mechanisms of action and types of implants intended to “manage disorders of the spine related to deformity, pain or instability,” absent fusion. The survey concluded that “because of the anatomic considerations of the S1 spinous process, these implants are not favorable, nor currently recommended for use at L5-S1.” This caveat alone precludes treatment of one of the largest segments of the affected patient population.

We became aware of a new nonfusion device designed to relieve pain by supporting the facets without radically altering the spinal anatomy. (Palmer *et. al.*, *Neurosurg Focus*, Volume 22/January 2007, “Biomechanical and radiographic analysis of a novel, minimally invasive, extension limiting device for the lumbar spine.”) The authors concluded that “the dynamic stabilization device (PercuDyn™ System two-piece implant, Interventional Spine, Inc.) significantly maintains posterior disc height and foraminal area during extension by limiting the extension motion of the facet joints.”

We were impressed with this bilateral facet augmentation system, which can be used to treat the L5-S1 level of the lumbar spine. This alone was reason enough for us to want to try the system in practice, as we wanted to be able to offer our back pain patients alternatives to open fusion surgery.

The system design includes a tissue Retractor (Teleport®, Interventional Spine, Inc.) used for percutaneous introduction of the implants under fluoroscopic control. Our observation was that in combination, the implants and the tissue retractor system minimize tissue trauma for patients needing to return to normal life as soon as possible.

We discovered as well that we could maximize the efficiency of our practice with the system when compared to open fusion surgery, as

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one level of bilateral treatment (two-implant) using the system usually takes less than 30 minutes, saving cherished OR time and increasing our caseload potential. Also, the implantation of these devices is performed in our practice as an outpatient procedure, further reducing the cost per patient when compared to open surgery or even other devices with dynamic stabilization claims.

Finally, we feel strongly that the techniques required for proper implant, over-the-wire control of the system components during the percutaneous procedure, are easily within the skill sets of most practitioners presently operating on the lumbar spine. This consideration could have a significant benefit to underserved patients worldwide.

The Summary of Experience in Our First Year

Following is our report on treating lumbar DDD pain by percutaneously implanting novel bilateral facet augmentation devices in outpatient settings via the system.

Patient Selection

Patients with DDD at one to three levels from L1-S1 with persisting pain after three months of non-operative care. Patient Profiles at one year: 34 patients (21 male, 13 female) aged 21 to 67 yrs (mean 37), BMI 20 to 35 (mean 26).

Outcomes Measured

Procedure time, recovery time, anesthesia and medication use were acutely assessed. Treatment effectiveness, pain and functional disability were assessed at follow up by physical exam, x-ray, VAS and ODI.

Methods

Patients with mild to moderate DDD and concordant imaging were treated percutaneously for lumbar pain. In a neutral or slightly flexed prone position, patients were sedated and anesthetized with five to ten cc of Xylocaine with epi bilaterally at each level treated. All patients received 500mg Levaquin intravenously.

Using fluoroscopy, percutaneous over-the-wire techniques and a 15mm posterior incision, a working tract was established to the base of the inferior facet using a proprietary access port (Teleport™, Interventional Spine, Inc.). The two device components were introduced serially and mechanically connected *in vivo*. Procedure times, anesthesia and medications were recorded. Follow up was scheduled at two, six, 12, 26 and 52 weeks.

Results

34 patients were treated at one to three levels from L2-3 to L5-S1. Ninety-six devices were implanted, two per level: one level (21), two

levels (12) and three levels (one). Most implants were at L4/5 (23) and L5/S1 (21), with two each at L2/3 and L3/4. Mean procedure time was 15 minutes per level (12 to 19 minutes). All patients were treated as outpatients, with recovery times based on levels treated and OR scheduling. For patients treated early in the day, recovery was four to six hours for one to two level cases; patients treated late in the day (13) were kept overnight. Thirty-two patients sedated with Propofol did not require a definitive airway; two patients requested general anesthesia. No additional antibiotic or DVT prophylaxis was required. Marked improvement in ODI and VAS scores at two weeks continued in later visits. (See Exhibit 1.)

Exhibit 1: Mean ODI and VAS Scores in Treated Patients

Interval (weeks)	Pre-op	2	6	12	26	52
n	34	32	30	28	24	13
ODI	65	28	14	9	8	1
VAS	9	3	2	1	1	0

There was no anatomic or functional impact on the spine. Five adverse events in five patients were minor, unrelated to the device and resolved with minimal or no treatment: three operative site (muscle herniation, facet pain, steri-strip skin rash) and two systemic events. Following a serious accident, one patient had new onset low back pain and requested device removal.

Our Conclusions to Date

Lumbar back and functional disability due to DDD can be successfully treated in ambulatory patients using percutaneous techniques and devices, resulting in shorter procedure and recovery times, fewer medication requirements and low complication rates. This technique alleviates pain and allows rapid functional recovery while deferring the need for a major, irreversible procedure such as fusion. Our experience also evidenced a very short learning curve required to achieve results reported with percutaneous methods under fluoroscopic control.

Even though our experience reported here with these devices is limited, as of today, to relatively short follow up, we will continue to bring these patients back for evaluation. We will also report in the future on our expanding series of interventions done with this technology and with these techniques.

We expect that others adopting the general use of the system will also evaluate and document their clinical outcomes.

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