Interspinous Process Distraction Compared to Non-Operative Care for Moderate Lumbar Degenerative Disc Disease

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Introduction:

Interspinous Process Distraction devices (IPD) aim to alleviate back and leg pain by limiting lumbar extension and unloading the disc. IPDs may offer a treatment option for symptomatic degenerative disc disease (DDD).

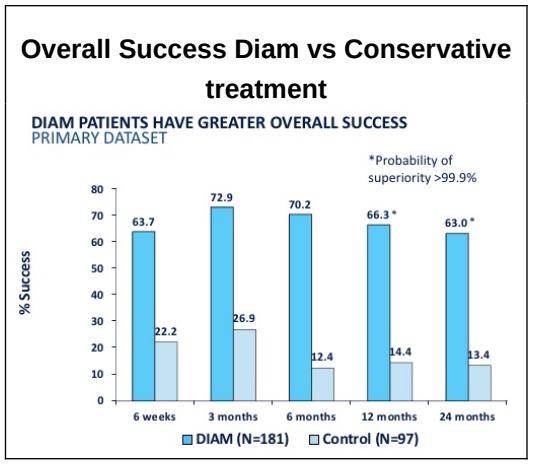
Patients:

Variable	DIAM (n=181)	Control (n=97)
Age, mean (range)	42.5 (18-69)	44.7 (23-70)
Male, number (%)	77 (42.5)	50 (51.5)
BMI, mean (range)	28.3 (18.5-41.1)	28.4 (17.4-39.7)
Caucasian, number (%)	166 (91.7)	88 (90.7)
Tobacco Use, number (%)	46 (25.4)	33 (34.4)
Working, number (%)	121 (67.2)	65 (69.1)
Litigation, number (%)	25 (13.8)	11 (11.3)
Diabetes, number (%)	11 (6.1)	5 (5.2)
Pre-op ODI Score, mean (SD)	50.3 (13.9)	49.9 (13.1)
Pre-op Back Pain, mean (SD)	16.8 (2.3)	16.1 (2.9)
Pre-op Leg Pain, mean (SD)	10.3 (6.2)	9.1 (6.4)

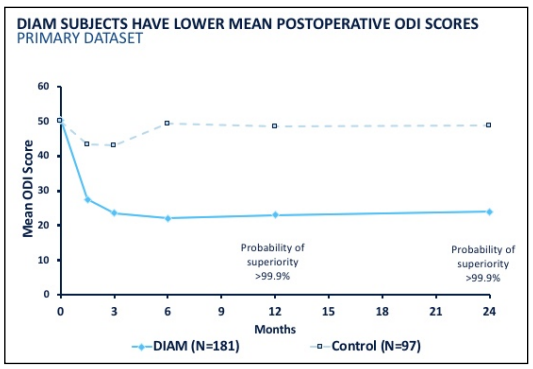
Methods:

Randomized, controlled clinical trial was conducted at 23 US centers, comparing the safety and effectiveness of IPD and non-operative care at 2 years follow-up for treatment of moderate low back pain with or without leg pain secondary to DDD. 278 patients were randomized and treated as follows: Investigational group (n=181) received IPD implantation and Control group (n=97) received a combination of patient education, medication, physical therapy, and/or steroidal injections (with crossover option after 6 months).

Results:

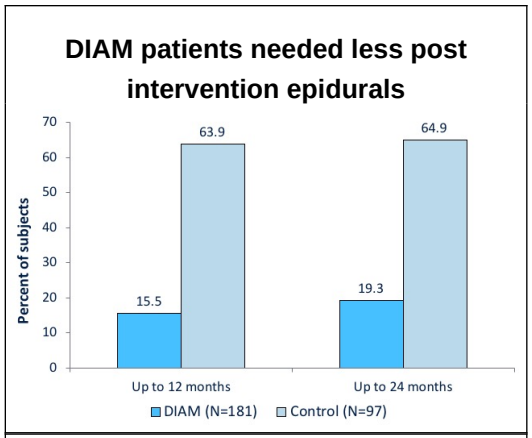


The 12-month primary endpoint was Overall Success, a composite variable including: 1) Oswestry Disability Index (ODI) improvement of =15 points; and 2) no serious adverse event (AE) related to treatment; and 3) no secondary surgery.



The improvement in outcomes at 24 m for IPD was statistically superior to control (pps >99.9%) for ODI (26.4 vs. 1.0), back pain (8.4 vs. 1.2), leg pain (4.9 vs. -1.1 pain increase in control group).

Secondary Interventions and Adverse Events:



Adverse Events

Type of Event	Number of Events		Number of Subjects Number (%)	
	DIAM®	Control	DIAM® (N=181)	Control (N=97)
Any Event	1009	262	170 (93.9)	73 (75.3)
Study Treatment Related Event	42	75	23 (12.7)	39 (40.2)
Serious Event	798	199	159 (87.8)	65 (67.0)
Serious, Study Treatment Related Event	33	69	15 (8.3)	34 (35.1)

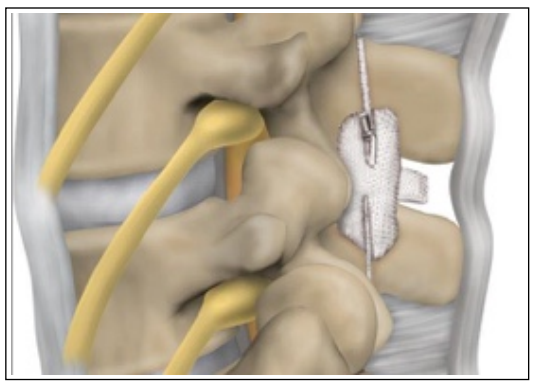
By 24 months, twenty (11.0%) IPD and 67 (69.1%) control patients had secondary surgery at the index level (of which 57 (58.8%) crossed over to IPD).

Conclusions:

- Substantial clinical evidence in support of DIAM superiority over conservative care, up to 24 months, as a treatment for subjects with moderate back pain, with or without leg pain, secondary to DDD
- Risk are minimal and manageable
-Limitations include cross-over design; FDA thought the population was too broad and had concerns regarding the control treatment
-Treatment effect is significant and consistent despite limitations

Learning Objectives

1. Understand the biomechanical properties of the IPD and how it unloads the three joint lumbar motion segment.
2. Understand the design and results of this randomized control multicenter trial comparing the IPD to a control of conservative management.
3. Form a conclusion based on the presented data on the superiority and safety of IPD in management of back pain due to moderate DDD.



DIAM Interspinous Process Device