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# Clinical and Radiographic Assessment of Lumbar Spine Total Disc Replacement in Athletes with Two Year Follow Up

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**CLINICAL AND RADIOGRAPHIC ASSESSMENT OF LUMBAR SPINE  
TOTAL DISC REPLACEMENT IN ATHLETES WITH TWO YEAR  
FOLLOW UP**

A Thesis Submitted to the  
Yale University School of Medicine  
In Partial Fulfillment of the Requirements for the  
Degree of Doctor of Medicine

**By**

**Mark H. McRae**

**2008**

## ABSTRACT

The purpose of the study was to evaluate the consequences of athletic activity on the clinical and radiographic outcomes of lumbar spine total disc replacement (TDR) patients.

The data for this study is drawn secondarily from a prospective randomized study evaluating the Prodisc prosthesis at Yale New Haven Hospital. Athletic activities prior to the onset of spinal injury, after the onset of spinal injury, and post lumbar spine total disc replacement (TDR) surgery were assessed. Athletic activity was classified into three groups. These were contact/vigorous, moderate, and light, based on effect on the involved spinal segments. Outcomes were assessed both clinically and radiographically.

Out of 195 patients enrolled in the Prodisc study at Yale, 82 qualified for inclusion and fulfilled all follow-up criteria. In these 82 patients 120 disc replacements were performed. The average reduction from pre-operative visual analog pain scale was 44 (std dev 30.1) at a minimum of 2 years follow up. The average reduction in Oswestry disability index was 38% (std dev 23). 74/82 patients returned to athletic activity following TDR. 19 (23%) patients returned to pre-injury athletic activity levels, 47 (57%) returned to athletic activity but not to pre-injury levels, 14 (17%) patients reported activity levels that were unchanged since surgery, and 2 (3%) had activity levels become more impaired since surgery. Of those that returned to athletic activity, 4/74 complained of radiculopathy symptoms during athletic participation. Overall, 14 of 82 patients reported persistent back pain and 8 of

these patients reported radiculopathy symptoms. Segmental flexion and extension at the levels of the implant, and the levels adjacent, revealed that the goal of physiologic motion was not reached at either the level of the implant, nor at the superior or inferior adjacent segments. Three L5/S1 subluxations occurred in heavy weight lifters and were the only radiographic complications.

Athletic activities of varying degrees appear to be well-tolerated following lumbar TDR surgery in single and multi-level cases. Contact-vigorous athletic activities do not appear to result in high levels of clinical or radiographic complications in the lumbar TDR patients except for heavy weight lifting activities in patients who have undergone L5/S1 Prodisc surgery in which we experienced 3 implant subluxations. Further biomechanical and clinical studies are necessary before general recommendations can be made.

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## INTRODUCTION

### Low Back Pain

Low back pain is a common problem, with a lifetime prevalence of 60% to 80% in the general public(1). It is estimated that two out of every three adults will have at least 7 days of debilitating low back pain, that causes them to miss work, school, and athletic activities(2). The most common cause of low back pain is lumbar strain thought to be caused by ligamentous or muscle strain(3). The vast majority of back pain is self-limited and resolves within 6 weeks with non-invasive means such as pharmacology or physiotherapy(3). About 5% to 10% of patients will develop chronic back pain(1). For those that continue to have chronic or debilitating pain, surgical intervention is considered.

In the lumbar spine, each spinal segment consists of three joints, two facet joints, and the intervertebral disc. These result in the range of motion of the spine. The intervertebral disc has four components. The first layer is the annulus fibrosis. This is composed of dense collagen fibrils oriented at 45 degrees and gives tensile strength to the disc. The fibrocartilagenous inner annulus fibrosus is the second layer. The third layer is the transition zone. The central portion of the disc is the nucleus pulposus. The nucleus pulposus provides stiffness and resistance to compression in the spine.

The outer one third of the annulus is innervated by the ventral rami and gray rami communicans anteriorly, and by the sinuvertebral nerve posteriorly.

Low back pain originating in the spine can come from the intervertebral disc, facets or pars interarticularis (portion of lamina that connects inferior and superior facets)(3). Defects in the pars interarticularis are referred to as spondylolysis.

Spondylolisthesis is a condition where one vertebra translates forward on the other and this is a common cause of low back pain. Spinal stenosis is narrowing of the spinal canal leading to compression of the spinal cord and nerve roots. Back pain may be generated if the disc tears and herniates causing impingement of local neural structures such as the spinal cord and nerve roots.

The etiology of pain generated by the intervertebral disc has not been clearly elucidated. As people age fibrous tissue replaces the elastic collagen fibers of the young disc and degenerates(4). There are many people that have degenerative discs, who do not present clinically with pain. Because disc degeneration per se is not the basis for discogenic pain, contributing factors must be at play. It is theorized that a combination of focal damage to the annulus fibrosus, inflammation, neoinnervation, and nociceptor sensitization is necessary to induce discogenic pain(4).

### **Athletics and low back pain**

Low back pain is one of the most common reasons for missed playing time by professional athletes(5).

Granhed et al looked at the lifetime incidence and prevalence of low back pain among 32 retired wrestlers and heavyweight lifters(6). They were compared clinically and radiographically to a control population of 716 men. The lifetime prevalence of back pain was significantly higher in wrestlers than in the control group (61% vs. 31%). Heavy weight lifters did not show significant variation from the control group, although a significant decrease in disc height was found in the lifters.



In a study of 98 adolescents comparing athletes and non-athletes for clinical signs of low back pain and MRI changes, Kujala et al concluded that excessive loading that involves a risk for acute low-back injuries during the growth spurt is harmful to the lower back(7). Kujala et al conclude that the low physiologic maximum of lower segment lumbar extension mobility may cause overloading of specific anatomic structures of the low back among athletes involved in sports including frequent maximal lumbar extension and found that it predicts future low back pain in these subjects.

Bahr et al compared the prevalence of symptoms of low back pain between endurance sports with different loading characteristics on the lumbar region at the national elite level. It was a cross sectional study looking at cross-country skiing, rowing, and orienteering, as well as a non-athletic control group. The prevalence among cross-country skiers of reported low back pain ever (65.4%) and low back pain during the previous 12 months (63.0%) was higher than nonathletic controls (51% and 47% respectively) (OR [95% CI]: 1.94 [1.29 –2.92]). Rowers (25.6%) reported missing training because of low back pain more frequently than orienteers did (13.7%, OR: 2.16 [1.25–3.74]). The authors conclude that low back pain appears to be somewhat more common in endurance sports that specifically load the low back during training and competition.

Studies have shown that very large forces can develop in the lumbar spine during athletic activity. Cholewicki et al documented the compressive loads on L4-L5 of national level powerlifters. Average compressive loads on L4/L5 were estimated up to 17,192N (8). Gatt et al determined the impact force to the lumbar

spine when football players hit a blocking sled (9). They looked at the loads at the L4-5 motion segment throughout the blocking sequence of five Division I-A college football linemen. Three plane forces were then calculated from these data. The average impact force measured at the blocking sled was 3013 +/- 598 N. The average peak compression force at the L4-5 motion segment was 8679 +/- 1965 N. The average peak anteroposterior shear force was 3304 +/- 1116 N, and the average peak lateral shear force was 1709 +/- 411 N. The authors concluded that the magnitude of the loads on the L4-5 motion segment during football blocking exceed those determined during fatigue studies to cause pathologic changes in both the lumbar disk and the pars interarticularis. The mechanics of repetitive blocking may be responsible for the increased incidence of lumbar spine injury incurred by football linemen.

Morris et al looked at peak compressive and shear force in the lumbar spine of female rowers and found them to be 2,694 +/- 609 (N) and 660 +/- 117 (N), respectively. Peak compressive force at the lumbar spine relative to body weight was 4.6 times body weight (10). It possible that those involved in heavy load bearing exercises would be at increased risk of degenerative spine changes.

Not all studies in the literature support the conclusion that back pain is more prevalent in the athletic population. Videman et al, based on a historical cohort, reported that although athletes were found to have greater degeneration throughout the lumbar spine, back pain was less common among athletes than control subjects and there were no significant differences in hospitalizations or pensions (11). No benefits were shown for vigorous exercise compared with lighter exercise with respect to back findings.

In his review entitled, “low back pain in athletes”, Christopher Bono makes the following comments:

“The prevalence of radiographic evidence of disc degeneration is higher in athletes than it is in nonathletes; however, it remains unclear whether this correlates with a higher rate of back pain. Although there is little peer reviewed clinical information on the subject, it is possible that chronic pain from degenerative disc disease that is recalcitrant after intensive and continuous non-operative care can be successfully treated with interbody fusion in selected athletes.”(12)

Based on the review of the literature, it is plausible that athletes may have an increased predisposition to low back pain. Studies have demonstrated increased loads and levels of degeneration; however, this has not been decisively proven to lead to increased levels of low back pain. Athletes with lumbar back pain pose a significant challenge for physicians based on their baseline level of function, and the demand for effective treatment to provide a pain free and functional outcome.

### **The history of spine surgery**

Low back pain has traditionally been addressed surgically with spinal fusion. Fusion, otherwise known as arthrodesis, can be performed with and without instrumentation. Spinal fusion allows the surgeon to remove any pathologic process, eliminate painful motion, and decompress neural elements while adding stability to the spine segment. Immobilization of the painful segments and sometimes removal of the degenerative disc are thought to be very important for the success of spinal fusion.

Hadra performed the first operative case using spinal instrumentation in 1889. He utilized wires to stabilize the spines of those afflicted with Pott's disease (spinal tuberculosis) (13). Later, significant contributions were made by Fred Albee and Russell Hibbs(14). They used bone grafts harvested from the patient and lay them on the lamina of the spine. This resulted in fusion of the segment and was initially also used in patients with kyphosis from Pott's disease. Later they refined their method to put bone graft on the side of the vertebra. This became known as the postero-lateral fusion, a technique that continues to be used today. They then expanded the indications of spinal fusion to include patients with scoliosis.

Anterior spinal fusion was first proposed by Capener(15), Burns(16), and Mercer(17) in the 1930's. Their approach was more involved but this became another important method of spinal fusion.

In the 1960's, Dr. Harrington began placing hooks under the lamina and connecting them together with rods to facilitate fusion with the use of bone grafts (18). Tourmy(19) first proposed the use of bone screws through the facet joint and decorticated laminae, and the screws were connected to rods. This instrumentation continues to be used today.

There are several techniques used for fusion of the spine included posterolateral fusion, the anterior lumbar interbody fusion (ALIF), and the posterior lumbar interbody fusion (PLIF). Posterolateral fusion involves a posterior midline incision, and the laying of bone graft onto the posterolateral segments of the vertebrae. Bone graft is usually harvested from the pelvis.

The PLIF procedure is approached dorsally and includes removing the disc

between two vertebrae and inserting bone into the space created between the two vertebral bodies. PLIF achieves spinal fusion in the lumbar spine by inserting a bone graft directly into the disc space. When the surgical approach is from the front it is called an anterior lumbar interbody fusion (ALIF). Each of these fusion techniques can be used in addition to the posterolateral fusion.

Spondylolisthesis, disc arthrosis, and segmental instability are the principal indications for spinal fusion. In the low back, lumbar decompression with posterolateral fusion has been shown in prospective randomized studies to be the superior form of surgical management for patients with degenerative spondylolisthesis (20).

Fritzell et al reported a randomized controlled multi-centre study of 294 patients referred for chronic low back pain with radiologic evidence of degenerative disc disease comparing lumbar fusion with commonly used non-surgical treatment. 222 subjects were treated with surgical fusion and 72 were treated non-surgically conservatively. Back pain was reduced in the surgical group by 33% compared with 7% in the non-surgical group. Disability according to Oswestry was also reduced by 25% in the surgical group compared with 6% among the non-surgical group. In the surgical group 63% considered themselves much better or better, compared to 29% in the non-surgical group. They concluded that lumbar fusion in patients with severe and chronic low back pain in highly selected patients can decrease back pain and disability more efficiently than non-surgical treatment (21).

Fritzell et al's report was one of the benchmark studies that established fusion as superior to non-operative management in a select group of patients with chronic

low back pain. As a result, studies have focused on comparing total disc arthroplasty to fusion. Of note, there have been no studies comparing total disc arthroplasty to non-operative treatment.

### **Limitations of spinal fusion surgery**

The utilization of fusion as a surgical intervention increased significantly throughout the 1980's and 1990's (22). Despite this increase in usage, the limitations of fusion in terms of clinical success have been readily apparent.

Blumenthal et al in 1988 reported a series of 34 patients undergoing anterior lumbar interbody fusion for discogenic back pain. The rate of fusion was 73%. The clinical success rate, meaning that patients resumed normal activities and required no medications with the exception of an anti-inflammatory drug, was 74%.

Dawson et al reported on the use of fusion for discogenic pain in 1981 (23). His fusion rate was fusion rate 92%, and his clinical success rate was between 70 – 80%. Fusion does not result in pain relief in all cases.

The long-term success rates of fusion have been documented. Lehmann et al, reported on a series of 62 patients that he treated with lumbar fusion after 33 years mean follow-up (24). At this time 44% were experiencing back pain, 57% had back pain in the last year, 53% were using medications 15% had repeat lumbar surgery, and 45% had segmental instability above the fusion.

The mounting costs of spine surgery must be considered as a negative consequence of spine fusion. Fritzell et al, looked at the cost-effectiveness of lumbar fusion and non-surgical treatment for chronic low back pain in the Swedish Lumbar

Spine Study in 2004 (25). Using incremental cost effectiveness ratios they came to the conclusion that although treatment effects were in favor of surgery, “for both the society and the health care sectors, the 2-year costs for lumbar fusion was significantly higher compared with nonsurgical treatment...”

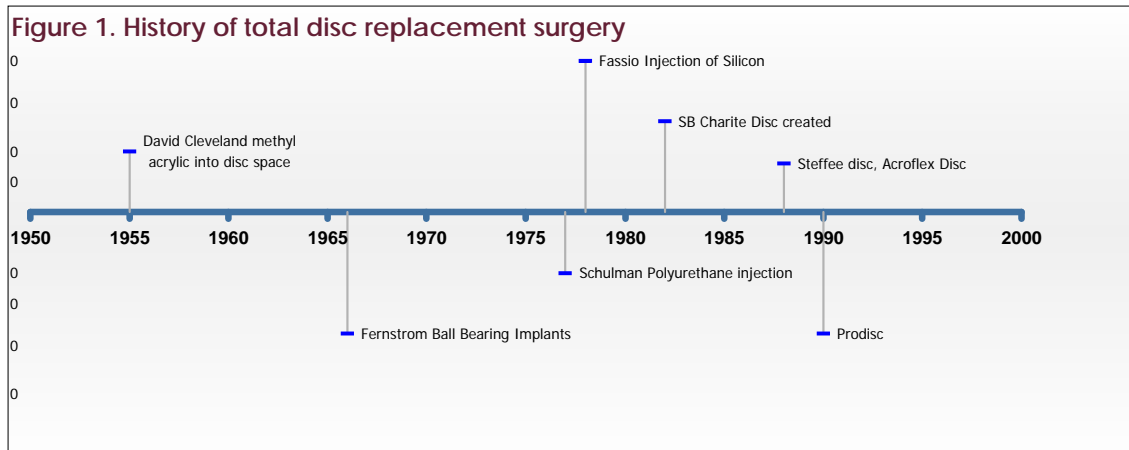
Mirza et al conducted a systematic review of randomized trials comparing lumbar fusion surgery to non-operative care for the treatment of chronic back pain (26). They cited major methodological shortcomings of each of the five randomized clinical trials that were conducted. Fritzell et al’s control group of non-surgical therapy was an unstructured, heterogenous group. As a result, what can be concluded is that compared to unstructured, heterogeneous, nonoperative care, lumbar fusion surgery is more efficacious for the treatment of chronic back pain.

As fusion is being utilized with increasing frequency, sometimes in very young patients such as those with scoliosis, the long term affects of the altered biomechanical environment must be considered as to the affect on the non-fused segments of the spine. There is mounting concern that this contributes to spinal degeneration at the levels adjacent to the fused levels, requiring repeat surgical intervention.

### **Total disc replacement as an alternative to fusion**

In the historical treatment of severe joint disorders of the hip and knee, the pain caused by the degenerative joint was initially thought to be related to its mobility. Fusion was the surgery of choice in these patients until good arthroplasty techniques emerged (27). There are great hopes that the same benefits may be

attained in the spine. This technology has been under investigation for many years (figure 1).



**Figure 1. Timeline of historical events in the development of total disc replacement in the spine**

The Pro-Disc is an articulating disc with polyethylene core created by Thierry Marnay in France in the mid 1980's. The metal endplates are plasma sprayed with titanium and have two vertical fins for fixation in the endplates (Figure 2 and 3).





**Figure 2. The Prodisc Prosthesis<sup>1</sup> implanted in a cadaveric spine as it would sit in the lumbar spine of the total disc replacement patient.**



**Figure 3. The goal of the total disc replacement is to restore physiologic motion to the affected spinal segment**

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<sup>1</sup> © 2006 Synthes Spine, West Chester, PA 19380 USA

### **How total disc replacement works**

The theory behind total disc replacement is that low back pain in a select group of patients can be effectively treated by removal of the disease process, and re-establishment of physiologic motion at the affected spinal segment. The re-establishment of physiologic motion could theoretically decrease the progression of adjacent segment degeneration in patients that have indications for spine surgery. Total disc replacement potentially limits some of the complications related to fusion. There are no drawbacks related to autologous bone graft harvest. Operative times are shorter, and there is potentially earlier return to function.

The current indications for lumbar total disc replacement are different from the indications for cervical spine total disc replacement. In the cervical spine the main indications are radiculopathy or myelopathy caused by either one or two levels of anterior cervical compression. Radicular pain is an indication for total disc replacement in the cervical spine, but has traditionally been seen as a relative contraindication in the lumbar spine (28). In the lumbar spine the main indications are single or double intervertebral level degenerative disc disease at L3–L4, L4–L5 or L5–S1.

Re-operation in the lumbar spine with an anterior approach is a much more difficult operation and is associated with significantly more risk than re-operation in the cervical spine. This must be a consideration in the early studies evaluating this technology.

What percentage of the current patient population is currently considered a candidate for total disc replacement surgery in the lumbar spine? Huang et al conducted a retrospective review of 100 lumbar spine surgical patients evaluating for the presence of contraindications to total disc replacement (29). They found that only 5% of patients that underwent lumbar spinal surgery had no contraindications to total disc replacement surgery such as central or lateral recess stenosis, facet arthrosis, spondylolysis or spondylolisthesis, herniated nucleus pulposus with radiculopathy, scoliosis, osteoporosis, and postsurgical pseudarthrosis or deficiency of posterior elements. The authors conclude that growth in total disc replacement implantation will result from expanding indications of patients for surgery who would not be indicated today or from the elimination of current contraindications.

The expansion of indications, and abandonment of contra-indications is likely as the technology is being evaluated.

### **Risks of total disc replacement surgery**

In addition to the risks of anaesthesia encountered with any surgical procedure, there are several risks associated with total disc replacement surgery in the lumbar spine. These include:

Great vessel injuries, thrombo-embolism, ileus, retrograde ejaculation, haematoma (subcutaneous, epidural, and retroperitoneal), and ureter injuries, device subsidence, device extrusion, and device failure.

### **Biomechanical considerations and adjacent segment degeneration**

The biomechanics of the lumbar spine consists of a rigid lever arm of the sacrum and pelvis, and the mobile lumbar spinal segments. There is a natural lordosis present that can be altered by fusion of these segments.

The presence of adjacent segment degeneration has been a concern for spine surgeons particularly as it relates to fusion. Is this the natural history of disease? Does the new biomechanical environment create disease adjacent to the fused segment? Biomechanical studies suggest that fusion does indeed create extra motion at adjacent segments and contribute to adjacent segment degeneration.

Weinhoffer et al, in a simulated biomechanical model of lumbosacral fusion, found that there are increased intra-discal pressures at the adjacent levels, and that these pressures increase with the number of levels that have been fused (30). Lee et al showed that fusion at one level increases the motion at adjacent levels. The motion also increases with number of levels fused (31).

Ghiselli et al studied adjacent level affects of fusion of the lumbar spine (32). They found that 16.5% of patients that underwent fusion required re-operation at 5yrs, and that 36.1% of fusion patients at 10 yrs warranted decompression or fusion at adjacent spine segments.

Chosa et al found a significant increase in the change of stress on the vertebral endplate and on the annulus fibrosus through flexion and extension in the lumbar spine when the posterior lumbar interbody fusion is applied adjacent to it (33).

There have been many studies that have documented the need of further operations following fusion in adjacent segments of the spine. Gilet et al looked at the

fate of patients operated on during a 14-year period for degenerative conditions of the lumbar spine resistant to conservative treatment (34). In those patients with five year follow up, 41% of the patients developed transitional segment alterations, and 20% needed a secondary operation for extension of the fusion. They identified postoperative delay, length of fusion, and spine imbalance as risk factors.

There is no doubt that fusion changes the biomechanical environment of neighboring spinal segments. What continues to be up for debate is the question of whether or not this has a clinical impact.

Kumar et al followed up 28 patients that had undergone surgery for degenerative disc disease with mid-line fusion after more than 30 years and compared with age and gender matched patients that had surgery without fusion over the same time period (35). The incidence of significant radiographic differences was twice as high in the fusion group. Despite the radiographic differences, there was no statistically significant difference in terms of clinical outcomes based on validated clinical instruments, or subjective assessment of back pain.

Penta et al followed 52 patients that underwent lumbar fusion and compared them at 10-year follow-up with a group treated without surgery. They found no difference in the rate of adjacent segment degeneration. About a third of patients in both groups developed degenerative changes at the level above the spinal fusion. Furthermore they found that increasing length of the fusion did not appear to increase the extent of degeneration at the adjacent levels (36).

Lehmann et al. reviewed 32 patients with more than 30 years of follow-up after lumbar fusion. Although almost half developed instability at the segment above

and a third became stenotic at the level above, these adjacent segment degenerative changes did not correlate with clinical symptoms.

Although there are studies that have documented adjacent segment degeneration in relation to fusion, the literature has not yet reached a consensus on the issue of the precise relationship between fusion and adjacent segment degeneration in the lumbar spine. As of today there is no data in publication that has been able to evaluate whether arthroplasty will limit or eliminate adjacent level degeneration in the spine.

### **Randomized controlled trials comparing total disc replacement to fusion**

The scientific literature evaluating total disc replacement in the lumbar spine continues to expand. There have been only two randomized controlled trials to date that have evaluated this new technology (37). What follows is a listing of the main findings of these studies.

The Food and Drug Administration investigational device exemption multi-centre trial of the Charite artificial disc is the first of these randomized controlled studies (38).

The study enrolled 304 patients in 14 centers across the United States and prospectively randomized in a 2:1 ratio to treatment with Charite™ artificial disc (Depuy Spine, Raynham, MA), with anterior lumbar interbody fusion. The inclusion criteria were as follows:

- single-level symptomatic degenerative disc disease either at L4-5 or at L5-S1
- Age between 18 and 60 years
- Oswestry Disability Index on entry of greater or equal than 30

- Visual Analogue Scale for low back pain greater or equal to 40 points/100.
- Failure of conservative measures and chronic low back pain for at least 6 months

A clinical comparison was made between the Charite total disc replacement group and fusion group. In the Charité group, by Oswestry Disability Index (ODI), the mean post-operative ODI score was statistically better than fusion until 12 and 24 months, when there was no longer a difference between groups. The clinical outcomes based on ODI and VAS scores were reported to be equivalent or better than fusion at 24 months. Major neurological events were equal in incidence between groups.

Blumenthal et al also reported on the Charite cohort of patients (39). The criteria for success in this study were fourfold. Criteria number 1 was greater than 25% improvement in Oswestry Disability Index at 24 months. Criteria number 2 was lack of device failure. Criteria number 3 was no major complications. Criteria number 4 was no sign of neurological deterioration.

Patients in the Charite™ artificial disc replacement group had lower levels of disability at every time interval from 6 weeks to 24 months, compared with the control group. They had statistically lower pain and disability scores at all but the 24 months follow-up period. At the 24-month follow-up period, a significantly greater percentage of patients in the Charite™ artificial disc replacement group expressed satisfaction with their treatment and would have the same treatment again (73.7%), compared with the fusion group (53.1%). The hospital stay was significantly shorter in the Charite™ artificial disc replacement group. The complication rate was similar between groups. As a result of this study they report that clinical success of total disc arthroplasty in the lumbar spine, in highly selected patients, is equivalent to fusion.

Although they report equivalence to fusion in this study, Freeman et al notes that overall when looking at all four criteria of success, only 57% of patients with disc replacement and 46% of those with interbody fusion meet all four criteria for success(37). McAfee also published based on this cohort, however it was early data based only on one institution (40, 41).

The second prospective randomized control study of total disc arthroplasty is comparing the Pro-Disc II with 360 degree fusion. Yale is one of the centers involved in this study. This study includes single and double level study arms. The results have not yet been published. Several centers have published preliminary data based on their individual site.

The inclusion criteria for this study were as follows:

- Age 18-60
- At least 6 months of failed non-operative therapy
- Degenerative disc disease at one *or two* adjacent vertebral levels between L3 and S1 where a diagnosis of DDD requires:
  - a) Primarily back or radicular pain
  - b) Radiographic confirmation of DDD
- Oswestry low back pain disability questionnaire score of at least 20/50 (40/100)
- Psychologically and physically able to comply with protocol

The exclusion criteria notably included the following:

- Greater than 2 levels of involvement
- Prior lumbar fusion
- Post traumatic vertebra deformity
- Facet joint degeneration



- Systemic disease, osteoporosis, malignancy etc.

Delamarter et al. 2005, as part of the FDA exemption study, reported the results of 78 patients, with 56 undergoing disc replacement with the Prodisc-II™ prosthesis, and 22 undergoing fusion (42, 43). After treatment, the total disc replacement patients had significantly better results at 6 weeks (VAS) and 3 months (VAS, ODI) compared with fusion patients. Although both treatment groups showed significant improvement compared with preoperative values, there was no longer a significant difference between the two groups by 6 months follow up. The disc replacement group showed significantly decreased pain at 3 months, and quicker increase in functional ability compared to those that underwent fusion. 93% reported that they were satisfied or entirely satisfied with the procedure (43). Follow up was two years. Zigler published the most recent report presenting data on 78 patients with at least 6-month follow-up, with 54 of these patients also having 1-year follow-up comparing Pro-Disc II and 360 degree lumbar fusion (44, 45). Hospital stays were shorter (ProDisc, 2.24 days, vs fusion, 3.26 days [ $p < .01$ ]) for ProDisc patients. There was a reduction for both groups in VAS scores from before to after surgery. They saw a trend in the data for increased satisfaction in the Pro-Disc patients at 6 months and at 1 year that was not statistically significant  $P = 0.08$ . Flexion and lateral bend range of motion was significantly improved in ProDisc patients compared with the fusion group ( $p = .02$ ). Operative time is significantly decreased in the total disc patients compared to fusion (90 minutes v. 232 minutes,  $p < 0.01$ ). Ambulatory status as well as recreational activity improved faster in the ProDisc group.

The most significant limitation of these studies is the absence of long-term follow up. It appears that immediately post-operatively, recovery is consistently shorter in the total disc replacement groups. However, clinical outcome measures tend to equilibrate at around 2 years post-operatively.

### **Expansion of indications, market impact, and responsible use of technology**

Deyo et al speaks to the philosophical disconnect between an increasing number of lumbar spine surgeries being performed despite no major changes in indications over the same time period.

“In 2001, over 122,000 lumbar fusions were performed nationwide for degenerative conditions. This represented a 220% increase from 1990 in fusions per 100,000. The increase accelerated after 1996... From 1996 to 2001, the number of lumbar fusions increased 113%, compared with 13 to 15% for hip replacement and knee arthroplasty... These increases were not associated with reports of clarified indications or improved efficacy”(22).

The potential economic effect of spine arthroplasty in the United States was investigated by Singh et al (46) Conservative figures approximate \$2.18 billion dollars and 47.9% of the market share being captured by motion sparing technology by 2010. Looking at historical trends of spinal surgery, and adaptation of new technology, the market forces will ultimately influence usage, and eventually complications:

“Unfortunately, as demand for new technology increases, so do the indications. A rapid rise in arthroplasty usage will potentially be associated with an increased rate of

complications. If complications reach a significant level, spine surgeons and the FDA will become proactive in regulating its implantation. They conclude that regardless of the clinical outcome of disc arthroplasty, its potential economic impact will be significant.”(46)

Total disc replacement is an emerging technology with the potential for a significant market impact. Surgeons and scientists must proceed methodically and cautiously, with well-designed clinical studies, in order to apply this new technology and allow it to attain its greatest utility for society. This takes on even greater importance as financial incentives will encourage expansion of indications and increased application in patients with low back pain.

## **PURPOSE**

We set out to assess the hypothesis that total disc replacement is a viable and safe surgical procedure in athletes with chronic low back pain associated with one or two levels of degenerative disc disease in the lumbar spine at two-year follow up.

There has only been one study of 39 patients in Europe that looked at the return to athletic activity in total disc replacement patients that was published during the preparation of this manuscript (47). Here we report on the analyses of 82 patients that were identified as athletes, who had undergone lumbar spine total disc replacement surgery at Yale University. The goal is to evaluate the safety and efficacy of total disc replacement in the lumbar spine of athletes at two-year follow up through clinical and radiographic evaluation.

## METHODS

The data for this study is drawn secondarily from a prospective randomized study evaluating the Prodisc prosthesis at Yale New Haven Hospital. Institutional review board approval was attained. Patient data were analyzed for the pre-operative and post-operative athletic activities in lumbar spine total disc replacement (TDR) patients. Athletic activities prior to the onset of spinal injury, after the onset of spinal injury, and post-total disc replacement surgery were assessed.

Yale New Haven Hospital is one of three international centers involved in this study. Yale is the North American site. There is a site in Europe and in Australia that are conducting identical studies. I was involved in the data gathering and analysis only at the North American location, and will not include the data set from the other two institutions. The data presented is from total disc replacement surgeries utilizing the Pro-Disc prosthesis and limited to the lumbar spine. Outcomes were evaluated both clinically as well as radiographically.

Out of 195 lumbar spine total disc replacement patients in the original Prodisc study at Yale, 82 fulfilled inclusion criteria for this study. All patients in this series were operated on between January 2003, and November 2005 and fulfilled the criteria for significant athletic activity in this study.

To be considered a participant in athletics, self-identification as an amateur or professional athlete was necessary. Patients were asked the following question: did you engage in athletic activity greater than once/week prior to your injury? Then they were asked to list the primary athletic activities that they participated in. Athletic

activity levels and complications during athletic activity were recorded based on patient report of pre-injury, post injury, and at last follow up. The data concerning athletic activity level was gathered during clinic appointments and during telephone interviews. Pre-injury levels of athletic activity were assessed at a time point after the injury but prior to surgery. Patients were not randomized based on athletic activity in the original study evaluating the Prodisc prosthesis. As a result there were only five cases of fusion in this cohort of athletes that served as a control group.

Divisions were made into one of three groups based on the effect on the involved spinal segments, as determined by the principal investigator, informed by knowledge of the biomechanical forces that would be produced by that activity on the lumbar spine. The divisions were light, moderate, and contact/vigorous.

To qualify in the contact/vigorous category, the athletic activity must have a high potential for significant forces (compared to baseline physiologic forces on the lumbar spine), and be performed at a level of activity that would expose the patient to these forces frequently during participation. The light group was determined to have levels of athletic activity that do not produce forces on the lumbar spine that is significantly greater than usual daily activities of living. The moderate group was determined to be those subjects that participate in an athletic activity that expose the participant to forces in the lumbar spine greater than those found in usual daily activities (light), but a level of activity that does not consistently expose the patient to large forces in the lumbar spine (contact/vigorous). See **table 1** for a list of the breakdown of where each athletic activity was classified. Based on level of

participation, a given athletic activity can have subjects within it that fit into more than one category.

**Table 1. List of Athletic Activity and Assignment of Activity Level**

Sport	Activity Level*
Football	Contact vigorous
Marshall Arts	Contact vigorous
Ice Hockey	Contact Vigorous or Moderate
Water ski/wake board	Contact vigorous or moderate
Weight lifting	Contact vigorous or moderate
Downhill Ski	Contact vigorous or moderate or light
Basketball	Moderate
Track and Field	Moderate
Soccer	Light or moderate
Tennis	Light or moderate
Field hockey	Light or moderate
Volleyball	Light or moderate
Kayaking	Light
Hiking	Light
Biking	Light
Running/aerobics	Light
Dance	Light
Golf	Light
Baseball	Light
Softball	Light

\*These classifications are not set in stone and there is a degree of interpretation within them. For example a professional catcher in baseball could still qualify as returning to contact/vigorous activity.

### **Major Surgical Inclusion Criteria at Yale:**

Patients enrolled in this study were between the ages of 18-60 years, and had the following indications for surgery:

- The presence of degenerative disc disease in one or two levels from **L3-S1**
- Radiographic confirmation of degenerative disc disease
- The presence of back and/or leg pain
- > 6 mos of conservative therapy

- Oswestry Score > 40 (20/50)

Greater than one of the following criteria must be fulfilled to be considered an athlete:

- Frequency of athletic activity greater than 1/week pre-injury, pre-operatively or post-operatively
- Participation in contact sports
- Self identification as an amateur or professional athlete
- Athletics required for profession (ie gym teacher)

### **Major Surgical Exclusion Criteria at Yale**

- Radiographic confirmation of facet joint disease or degeneration
- Lytic spondylolisthesis or spinal stenosis
- Degenerative spondylolisthesis > Grade 1
- Osteoporosis: DEXA T-score < -2.5
- Presence of degenerative disc disease in greater than 2 levels
- Presence of prior spinal fusion

Patient radiographs were taken of the lumbar spine pre-operatively as well as at 3, 6, 12, and 24 months post-operatively. They were taken in ap- and lateral view as well as dynamic flexion/extension images. Images at last follow up were assessed for proper implant positioning, subsidence, sublaxation, dislocation, or total prosthetic failure. Disc subsidence is defined as minor migration of less than 5 mm into the vertebral body, while the implant is still functional. Subluxation is defined as migration of the implant within the joint space of less than five mm without loss of height in the disc space. Dislocation is migration of more than 5mm, or loss of functionality of the prosthetic disc.



Functional flexion/extension images were analyzed for segmental range of motion.

Pre-operative visual analog scale, and pre-operative Oswestry Disability Index were taken. Post-operative visual analog scale and post-operative Oswestry Disability Index were recorded at last follow up. Pre-injury athletic activities, post injury activities, and post total disc replacement activities were recorded along with their frequency per week. Complications during athletic activity following total disc replacement surgery were noted.

Implantation of the disc was performed in the standard fashion, approached with a mini laparotomy, as per manufacturer guidelines (48). Patients are allowed to weight bear at post-operative day one. Patients were instructed that there was to be no lifting over 25 pounds until 6 weeks, and no contact sports until 12 weeks of recovery. After 12 weeks athletic activities were permitted to resume if they could be tolerated without pain with the exception of contact sports. Therapy was begun at 2 weeks post-operatively only if necessary. Contact sports were discouraged.

#### Statistical analysis

All data was recorded using Microsoft Excel 2002 (Microsoft Inc., Redmond, WA). This was then transferred to SPSS 14.0 2005 (LEAD technologies, Inc., Chicago, IL) for statistical analysis.

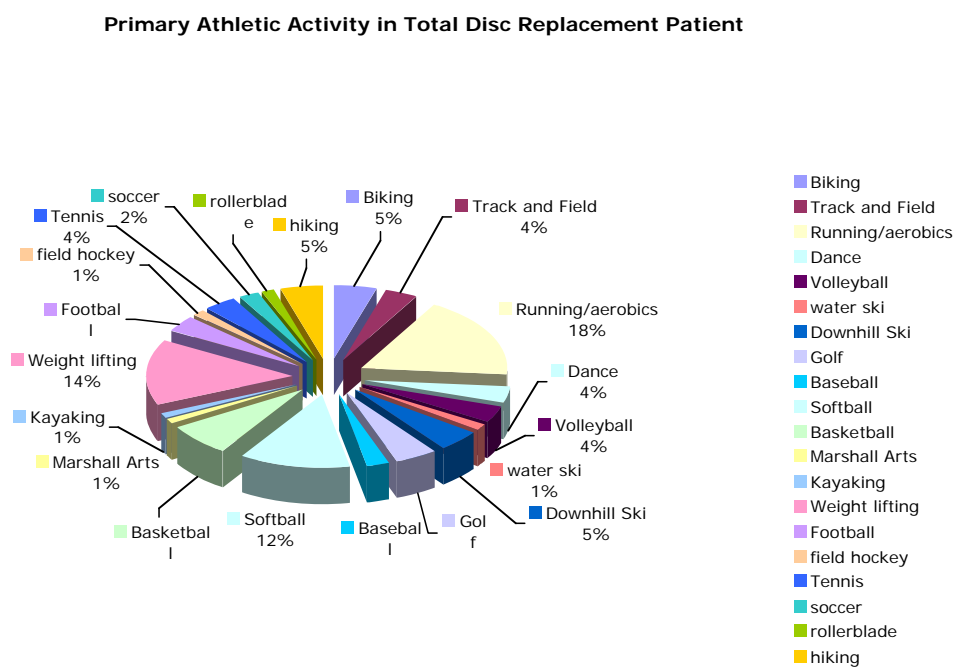
## RESULTS

### Yale Data

#### Demographics

82 patients fulfilled inclusion criteria. There were 52 males and 30 females.

The average age was 38 years old. The primary athletic activity of this patient population is listed in figure 4.



**Figure 4. Frequency and distribution of primary athletic activity in the lumbar spine total disc replacement at Yale University**

No patient had previous fusion or lumbar total disc replacement operations.

One hundred and twenty disc replacements were performed in the 82 patients. Single level (mono-segmental) operations ( $n= 44$ ; 54%) and double level (bi-segmental) ( $n= 38$ ; 46%) operations were performed.

Total number of disc replacements that were performed at L3/L4 ( $n = 7$ ; 6%), L4/L5 ( $n=51$ ; 42%), and L5/S1 ( $n = 62$ ; 52%).

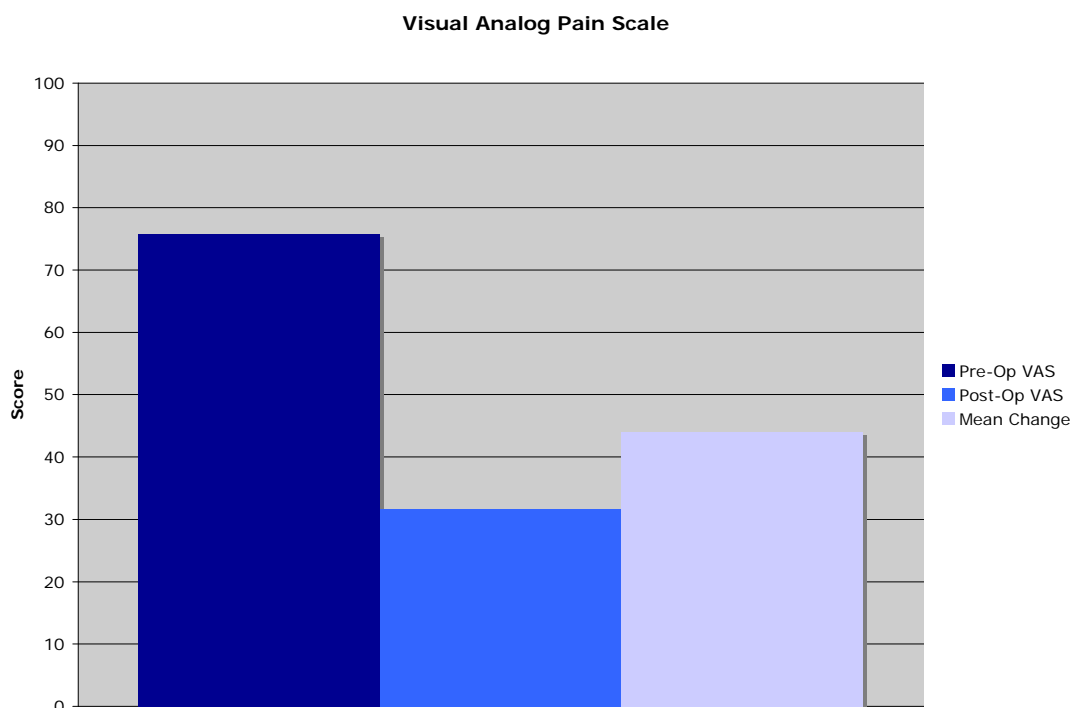
In single level operations the distribution of levels operated on were L3/L4 ( $n = 2$ ; 5%), L4/L5 ( $n = 13$ ; 29%), L5/S1 ( $n = 29$ ; 66%).

Of the forty-one double level patients, thirty-six were performed at L5/S1 and L4/L5, while five were performed at L4/L5, and L3/L4.

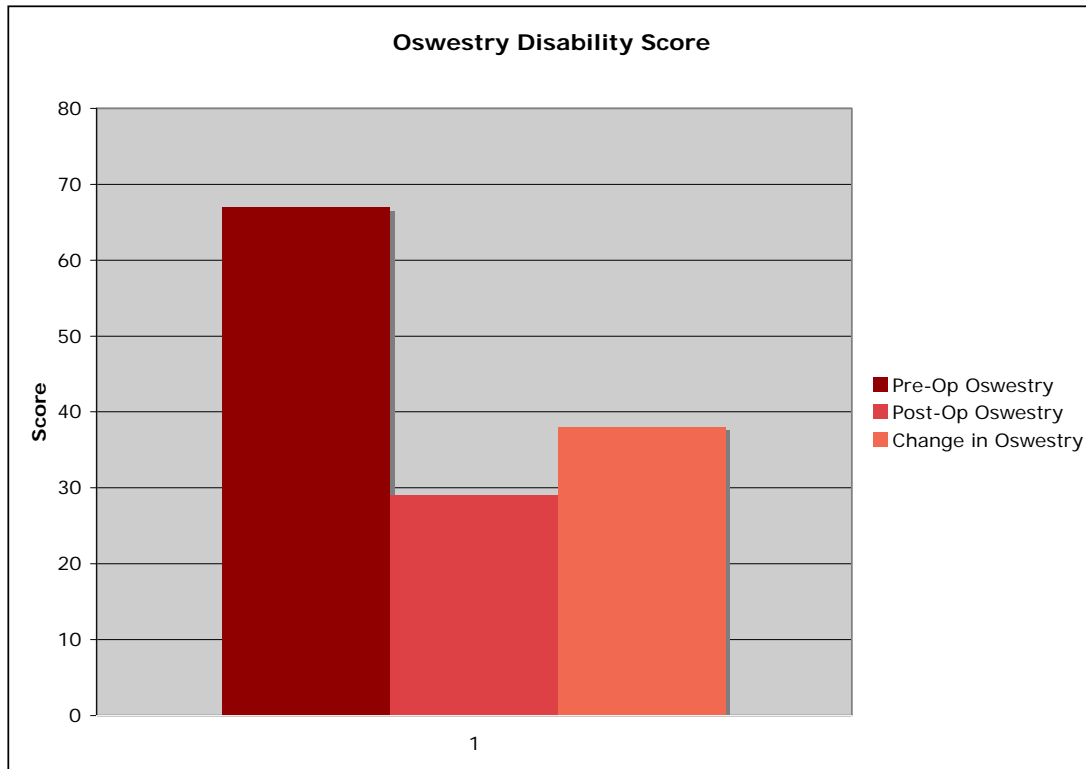
### Clinical Outcome

The mean follow up time was 29 months (standard deviation= 9).

The average reduction from pre-operative visual analog pain scale was 44 at last follow up (standard deviation= 30.1) (**Figure 1**). The average reduction in Oswestry disability index was 38% (standard deviation= 23) (**Figure2**).



**Figure 5. Lumbar spine total disc replacement assessed by visual analog pain scale pre-operative, 2 years post-operative, and the mean change in these values**



**Figure 6. Lumbar spine total disc replacement assessed by Oswestry Disability Index. Mean score pre-operative, 2 years post-operative, and the mean change in these values.**

14 of 82 patients reported persistent back pain and 8 of these patients reported radiculopathy symptoms.

**Table 2. Athletic activity level following total disc replacement at 2 years follow-up**

Reported Activity Level Post TDR	N (%)
Return to pre-injury athletic activity level	19 (23%)
Return to athletic activity but not to pre-injury levels	47 (57%)
Activity level unchanged since surgery	14 (17%)
Activity level decreased since surgery	2 (3%)

**Table 3. Athletic activity level following fusion at 2 years follows up**

<b>Reported Activity Level Post Fusion</b>	<b>N(%)</b>
<b>Return to pre-injury athletic activity level</b>	<b>1 (20%)</b>
<b>Return to athletic activity but not to pre-injury levels</b>	<b>3 (60%)</b>
<b>Activity level unchanged since surgery</b>	<b>1 (20%)</b>
<b>Activity level decreased since surgery</b>	<b>N/A</b>

Outcomes of total disc arthroplasty patients were compared controls that had received fusion over the same time period. The same surgeon performed both the total disc replacement and the fusion control cases.

### **Return to Athletic Activity**

All patients in the North American center were amateur athletes. Before total disc replacement surgery, 6 people reported limited ability to perform athletic activity, and were significantly impaired. All other patients reported no athletic activity prior to surgery. Following total disc replacement, 74/82 patients were able to participate in athletic activities (14 contact/vigorous, 18 moderate, and 42 light) (**table 2**). 4 of 74 patients complained of radiculopathy symptoms during athletic participation.

Of the five athlete lumbar fusion control patients, one of the patients reported light athletic activity prior to surgery. At 6 month and 2 year follow up, 4/5 were able to resume athletic activity (3 moderate, 1 light) (**table 3**).

### **Radiographic Outcome**

Lumbar level physiologic flexion extension range of motion has been determined by Panjabi et al (49).

The following is the mean angular range of motion +/- standard deviation (inches) at all levels of the lumbar spine:

L1-L2	5.0 +/- 1.0
L2-L3	7.0 +/- 1.2
L3-L4	7.3 +/- 1.5
L4-L5	9.1 +/- 2.5
L5-S1	9.0 +/- 2.0

**Table 4. Segmental motion in fusion controls compared to physiologic motion**

Fusion at L3-L4: n=1

	Range of Motion	Physiologic Range of Motion
Superior adjacent segment (L2-L3)	7.8	7.0 +/- 1.2
Fused L3-L4	0.2	7.3 +/- 1.5
Inferior adjacent segment (L4-L5)	3.6	9.0 +/- 2.0

Fusion at L4-L5 and L5-S1: n=4

	Range of Motion	Physiologic Range of Motion
Superior adjacent segment (L3-L4)	8.53	7.0 +/- 1.2
Fused L3-L4	0.35	7.3 +/- 1.5
Inferior adjacent segment (L4-L5)	0.4	9.0 +/- 2.1

**Table 5. Segmental motion in superior segment in total disc arthroplasty patients compared to physiologic motion**

	Range of Motion (std dev)	Normal Physiologic
Superior Adjacent Segment (L2-L3)	5.63 (2.44) Range = 2 to 9.4	7.0 (+/-1.2)
Superior Adjacent Segment (L3-L4)	7.34 (4.78) Range = 0.7 to 17.7	7.3 (+/- 1.5)

**Table 6. Segmental motion in the inferior segment in total disc arthroplasty patients compared to physiologic motion.**

	Range of Motion (std dev)	Normal Physiologic
L5-S1	5.94 (2.52)	9.0 (+/- 2.0)

**Table 7. Segmental motion in the operative segment in total disc arthroplasty patients compared to physiologic motion**

	Range of Motion (std dev)	Normal Physiologic
L3-L4	1.32 (1.28)	7.3 (+/- 1.5)
L4-L5	5.09 (4.48)	9.1 (+/- 2.5)
L5-S1	4.70 (3.64)	9.0 (+/- 2.0)

### **Radiographic complications**

Three L5/S1 implant subluxations occurred on radiographic evaluation. All of these cases presented in patients participating in heavy weight lifting post-operatively.

## DISCUSSION

There have been few studies that have looked at return to athletic activity as an end-point in evaluating spine surgery alternatives. There has been one study that has reported on the return to athletic activity in total disc replacement patients that was published by Sieppe et al. in the European Spine Journal during the preparation of this manuscript (47). Sieppe et al found that 37/39 (94.6%) patients achieved resumption of sporting activity following total disc replacement surgery. Athletic performance improved significantly in 33/37 (84.6%). These numbers are superior to those found in our study, and this may be due to a more healthy patient population. Pre-operatively, 25/37 (64.1%) of the patients participated in sport but at a reduced level up until the time of surgery. In our patient population only 6/82 patients (7.3%) participated in sports pre-operatively. Average reduction in visual analog pain scale was 57/100 (versus 44 in our study) and Oswestry Disability Index was decreased by 30% (versus 38% in our study).

The rate of return to athletic activity in our study compares favorably among the available literature of spinal surgery alternatives.

Matsunaga et al reported that the rate of successful return to manual labor was 89% after spinal fusion, but no difference was observed between simple disc excision and percutaneous discectomy (50). Return to competitive sports was achieved at rate of 81% after percutaneous discectomy in that study. Debnath et al followed prospectively 22 young athletes who had undergone surgical treatment for lumbar



spondylolysis (51). After spinal fusion and rehabilitation for a mean of seven months (range of 4 to 10) eighteen patients (82%) returned to their previous sporting activity.

In our study ninety percent of patients that underwent total disc replacement were able to return to athletic activity at last follow up. Our patient population was more heterogeneous than the studies cited above, and the indications are not directly comparable.

The instances of subluxation in this study all occurred in weight lifters. This athletic activity places considerable stress on the lumbar spine and subluxation in these cases is concerning. One theory is that both subluxation and subsidence is the result of inappropriate placement of the prosthesis at surgery. This is a question that merits further study. We should continue to follow all athletes closely for signs of subsidence, subluxation, and device failure as long-term data is accumulated. As a result of these findings, patients are now being advised to restrict activities such as squat and leg press following total disc replacement in the lumbar spine.

A major limitation in our study was the number of patients enrolled in the fusion control group. Although this study established a control group of fusion patients, the numbers were very low, and the conclusions that can be made based on this control are limited due to its very low power.

This study indicates that total disc replacement appears to be a viable and safe surgical alternative for athletes that are looking to return to athletic activity, at two years follow up. Long term follow up data is needed before definitive claims can be made.

### **Total disc arthroplasty, the physiologic biomechanical relationship of the spinal segments, and adjacent segment degeneration**

In order to address the question raised in the introduction about the restoration of physiologic range of motion in light of adjacent segment degeneration, we recorded the flexion extension range of motion at the lumbar spine segments adjacent to and at the level of operative intervention.

Table 3 compares the segmental motion of fused segments and adjacent segments in the lumbar spine of our fusion control patients. We were able to confirm that radiographic fusion at the operative level was successful in all five cases. As was expected, the superior adjacent segmental motion did indeed show increased range of motion compared to physiologic motion. The control group is too small to make significant conclusions, however our results are consistent with the corpus of literature presented in the introduction (22-27).

The goal of total disc arthroplasty is to restore both the natural disc height, and the physiologic motion of the spine segment. Table 4 and 5 reveal that the mean range of motion in the superior adjacent segment appears to be well maintained in our patient sample. This mean value however is not able to match the natural physiologic motion at these adjacent levels. It must be noted that there is a large range of values (2 to 9.2 in L2-L3 and 0.7-17.7 in L3-L4). The mean value is encouraging, yet the consistency of the prosthesis in delivering physiologic range of motion at the adjacent segment of the spine should be addressed with further prosthesis development efforts. Table 6 reveals that the goal of physiologic range of motion at each of the operative levels falls short of this goal.

A question that needs to be answered in order to evaluate this data is the following: How much motion is necessary to slow or halt the progression of adjacent segment degeneration in the lumbar spine? Such an answer is not readily available, and warrants further study. Until a response to this question is formulated, the goal of physiologic motion at each segment utilizing total disc replacement should continue to be pursued.

Le Huec et al. was the first group to look at the affect of a single level total disc replacement on the sagittal balance (ie lordosis) of the spine in 35 patients. They concluded that the sagittal balance was maintained from the pre-operative state (52). The prosthesis has enough freedom of motion to allow the patient to maintain the natural sagittal and spinopelvic balance needed to prevent potential undue stress on the muscles and the sacroiliac joint. Of note, they did report a significant decrease in lordosis in the segment above the prosthesis. We did not note a significant decrease in lordosis in our sample, but this should continue to be evaluated as the data from the other centers is analyzed.

Huang et al in a retrospective radiographic study of 42 patients who had placement of 58 first-generation Prodisc prostheses at a mean follow-up of 8.7 years, conducted flexion extension studies of the spine. They noted the following:

“A statistically significant association between the amount of flexion-extension motion present at a prosthetic level and the incidence of junctional disc degeneration at the level above” (53).

The affect of total disc arthroplasty on the biomechanical environment of the lumbar spine is an area of expanding research. In a study by Cakir et al, total disc

replacement increased segmental lordosis significantly while total lumbar lordosis remained unchanged (54). When comparing the lumbar spines physiologic lordosis, to the lordosis present in the spine after monosegmental disc replacement, the authors found that monosegmental total disc replacement increases the segmental lordosis in most of the cases while preserving the total lumbar lordosis that produces a decrease of lordotic angle in the adjacent segment(s). Although short-term clinical results are not affected, the segmental lordosis increase and adjacent segment(s) alteration may influence long-term outcome. We have not yet conducted this analysis in our sample, and should do so in future publication.

Leivseth et al concluded that mobility is limited in total disc replacement compared to normal in the lumbar spine.(55) At L4-L5 and L5-S1 it was only 45%. However, the control group that was treated non-operatively also had this decreased mobility. This suggests that it may be pre-operative soft tissue compensation that fails to allow disc replacement in the lumbar spine to restore normal segmental rotational motion in the sagittal plane. This is a compelling argument for why we also saw limitations in flexion/extension compared to the goal of physiologic motion in each of the spinal segments (**table 6**). This conjecture would suggest that a future study is warranted to assess the affects of soft tissue rehabilitation such as post-operative physical therapy or other modalities to regain physiologic range of motion.

## **Conclusion**

To this point studies have shown equivalence up to a 2 year time period in terms of clinical outcome of total disc replacement compared to fusion. Many questions will need to be answered before this technology should have wide spread application in our low back pain population. Today we do not know how close the prosthesis must come to physiologic motion to be effective in preventing progression of the disease process. We do not have rigorous long-term clinical outcome data in total disc arthroplasty patients, and we do not know how the prosthesis will perform beyond two years. Total disc arthroplasty presents unique challenges for development and tremendous possibilities for improved outcome in athletes with low back pain. This study is one of the first to document short-term outcome results in this group of patients.

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