

# Commentary on: The role of surgery for treatment of low back pain: Insights from the randomized controlled SPORT trials

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## Abstract


**Background:** The SPORT trial database offered much useful information regarding the efficacy of surgical treatment for lumbar disc herniations, lumbar spinal stenosis, and degenerative spondylolisthesis. Data were obtained from 13 sites and included 2500 patients.

**Methods:** The randomized trial for lumbar disc herniations was contaminated by the immense crossover of patients from surgical (50%) to non-surgical (30%) groups. Weinstein *et al.* concluded that they could not claim superiority of one treatment modality over the other. Weinstein’s next SPORT study on lumbar discs, performed utilizing a prospective cohort of patients undergoing lumbar disc surgery (those that would not agree to be randomized), appeared to demonstrate better outcomes with vs. without surgery.

**Results:** The follow-up study 8 years later again questioned the value of surgery vs. non-operative intervention. The other SPORT studies dealing with degenerative spondylolisthesis appeared to document the benefit of surgical decompression, but could not consistently substantiate the relative value of decompression alone vs. non-instrumented vs. instrumented fusion. The more recent SPORT study in 2015 on spinal stenosis treated with/without surgery indicated improvement in short term 4-year outcomes; however, the two arm-results (surgical vs. non-surgical) converged at 8 years.

**Conclusions:** Here, the 6 SPORT studies and short commentaries following each study indicate the pros, cons, and shortcomings of each investigation are presented. Notably, if surgeons better selected patients for surgery and avoided unnecessary procedures for “black discs alone” or pain alone, the results of the surgical intervention would likely be more clearly confirmed.

**Key Words:** Degenerative lumbar disease, lumbar disc, spondylolisthesis, SPORT trial

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## COMMENTARY

The SPORT trial database offered much useful information regarding the efficacy of surgical treatment for lumbar disc herniations, lumbar spinal stenosis, and degenerative spondylolisthesis. Data were obtained from 13 sites and included 2500 patients. The design of these studies allowed for the evaluation of large numbers of patients with reduced bias. It was of interest that the randomized trial for lumbar disc herniations was contaminated by the immense crossover of patients from surgical (50%) to non-surgical (30%) groups.<sup>[3]</sup> Weinstein *et al.* concluded from that study that they could not claim superiority of one treatment modality over the other. Weinstein's next SPORT study utilizing a prospective cohort of patients undergoing lumbar disc surgery (those that would not agree to be randomized), appeared to demonstrate better outcomes with vs. without surgery.<sup>[4]</sup> The follow-up study 8 years later again questioned the value of surgery vs. non-operative intervention.<sup>[5]</sup> The other SPORT studies dealing with degenerative spondylolisthesis appeared to document the benefit of surgical decompression, but could not consistently substantiate the relative value of decompression alone vs. non-instrumented vs. instrumented fusion.<sup>[1,6]</sup> The more recent SPORT study in 2015 on spinal stenosis treated with/without surgery indicated improvement in short term 4-year outcomes, but the results of the two arms (surgical vs. non-surgical) converged at 8 years.<sup>[2]</sup> Below you will find summaries of the 6 SPORT studies and short commentaries following each study indicating the pros, cons, and shortcomings of each investigation. Notably, if surgeons better selected patients for surgery, requiring a significant neurological deficit and neuroradiological lesions, and avoided unnecessary procedures for “black discs alone” or pain alone, the results of surgical intervention would likely be more clearly confirmed.

### **Surgical vs. nonoperative treatment for lumbar disk herniations: The Spine Patient Outcomes Research Trial (SPORT): A randomized trial**

Weinstein *et al.* in 2006 evaluated surgical vs. non-surgical treatment for lumbar disc herniations utilizing the SPORT database in a randomized fashion.<sup>[4]</sup>

They identified 501 surgical candidates with neurodiagnostic studies confirming lumbar intervertebral disc herniations who had exhibited at least 6 weeks of radiculopathy. Patients underwent “standard open discectomy” vs. non-operative treatment. Outcomes were assessed with the Short-Form 36 (SF-36) and modified Oswestry Disability Index (ODI) at 6 weeks, 3 months, 6 months, and 1 and 2 years from the time of enrollment. Notably, there were some problems in the study design: “50% of patients assigned to surgery received surgery within 3 months of enrollment, while 30% of those

assigned to non-operative treatment received surgery in the same period.” They found “Patients in both the surgery and the non-operative treatment groups improved substantially over a 2-year period.” However, the large numbers of patients who crossed over did not lead to a clear conclusion regarding the benefits of either treatment modality.

**Comments:** This study nicely highlighted the difficulty in obtaining significant data regarding the superiority of one treatment modality over another. Here, the randomized design was clearly contaminated by “crossovers” in both directions. That is, those initially choosing surgery opted for conservative care with others initially opting for conservative treatment later undergoing surgery. Therefore, although the numbers were large, and the theoretical design excellent, the authors had to clearly confront their inability to claim superiority of surgery over non-operative care. I congratulate the authors for their honesty and attempts to conduct such a complex study. It is interesting to note that the cohort study performed simultaneously appeared to indicate superiority of surgery vs. non-operative intervention for the treatment of lumbar disc herniations.

### **Surgical vs. non-operative treatment for lumbar disk herniation: The Spine Patient Outcomes Research Trial (SPORT) observational cohort**

Weinstein *et al.* in 2006 evaluated the relative efficacy of discectomy vs. non-operative care for lumbar discs. In this study, they prospectively evaluated “a cohort of potential” surgical candidates with neurodiagnostic confirmation of lumbar disc herniations treated in 13 centers in 11 states (met SPORT criteria but declined randomization).<sup>[3]</sup> Outcomes were assessed using the SF-36 for bodily pain and physical function scales and a modified ODI. There were 528 of 743 patients enrolled who underwent spinal surgery; 191 were treated without surgery. Three months later, patients who opted for surgery demonstrated greater improvement: “bodily pain (mean change: surgery, 40.9 vs. non-operative care, 26.0); physical function (mean change: surgery, 40.7 vs. non-operative care, 25.3). They also showed greater improvement on the ODI: -36.1 vs. non-operative care, -20.9. The authors concluded that although all patients improved, those undergoing surgery demonstrated consistently better results. They also cautioned that these data were culled from a non-randomized group of patients (e.g., unlike the subsequent study).

**Comments:** The study involved a large sample of patients, but was admittedly a prospective cohort study, in which there were many more patients (528 patients) in the operative vs. non-operative groups (191 patients). However, they nicely demonstrated utilizing two major patient-based outcome measures (SF-36 and ODI) that those undergoing operative intervention showed better outcomes than those managed without surgery.

### **Surgical versus non-operative treatment for lumbar disc herniations: four-year results for the Spine Patient Outcomes Research Trial (SPORT)**

Weinstein *et al.* in 2008 published their concurrent, prospective, randomized, and observational cohort study looking at the 4-year outcomes of surgery versus non-operative care for lumbar discs.<sup>[5]</sup> There were 501 prospective, randomized patients and 743 cohort patients in this study. They utilized a standard open discectomy versus usual and customary non-operative. Patients were again assessed with the SF-36 and modified ODI.

Here they concluded that at “4 years, patients who underwent surgery for a lumbar disc herniation achieved greater improvement than those treated non-operatively (except work status).

**Commentary:** This combined 4-year study involving randomized and cohort patient participants showed better outcomes for surgically treated vs. conservatively managed lumbar discs. Note that the operative modality was a “standard open procedure”: This likely accounted for the better surgical outcomes as too many of the minimally invasive techniques leave pathology behind (e.g. residual discs or insufficient disc resection contributing to recurrent discs) or cause inadvertent neural or dural injury due to inadequate exposure.

### **Surgical versus non-operative treatment for lumbar degenerative spondylolisthesis; four-year results in the Spine Patient Outcomes Research Trial (SPORT)**

Weinstein *et al.* in the 2009 SPORT trial (13 centers/11 states) evaluated 4-year postoperative results of surgical versus non-operative treatment of degenerative spondylolisthesis.<sup>[6]</sup> Patients were symptomatic for at least 12 weeks’ duration and had studies documenting degenerative spondylolisthesis with spinal stenosis (randomized cohort or observational cohort), treated with decompressive laminectomies (with or without fusion) versus non-operative care. Outcomes were assessed utilizing the SF-36 and ODI scales starting at 6 weeks and extending up to 4 postoperative years. The authors concluded; “compared with patients who are treated non-operatively, patients in whom degenerative spondylolisthesis and associated spinal stenosis are treated surgically maintain substantially greater pain relief and improvement in function for four years.”

**Comments:** In this large SPORT study, patients with degenerative spondylolisthesis and spinal stenosis were treated with decompressive laminectomy (with or without fusion) versus non-operative care.<sup>[6]</sup> Four years later, they found that those managed surgically had better outcomes. Large SPORT trial databases better enable us to answer basic questions like this one; does surgery help patients with stenosis/spondylolisthesis versus non-operative treatment? The answer was “yes,” and this

was accomplished with substantially greater validity due to the large data base utilized in this SPORT study.

### **Degenerative spondylolisthesis: does the fusion method influence outcome?**

Abdu *et al.* in 2009 compared outcomes of different fusion methods to treat degenerative spondylolisthesis.<sup>[1]</sup> Data were obtained from 13 centers in 11 states [Spine Patient Outcomes Research Trial (SPORT)]. The 380 patients selected were symptomatic for at least 12 weeks, and underwent the following surgical procedures; decompressive laminectomy with posterolateral *in situ* fusion (21%; PLF 80 patients), posterolateral instrumented fusion with pedicle screws (56%; Pedicle Screws (PS) 213 patients), pedicle screws plus interbody fusion (17%; 63 patients 360 degree surgery), or laminectomies alone (6%). Outcomes were assessed at 1.5, 3, 6 months, and yearly up to 4 postoperative years utilizing the SF-36 and the modified ODI. At 2 years, 360 fusions showed better outcomes, but “no consistent differences in clinical outcomes were seen among fusion groups over 4 years.” In short, non-instrumented and instrumented fusions yielded comparable results.

**Comments:** This large SPORT database study, evaluated 380 patients variously treated with decompressive laminectomy with posterolateral *in situ* fusion, posterolateral instrumented fusion/pedicle screws, pedicle screws plus interbody fusion (360 degree procedures), or laminectomies alone.<sup>[1]</sup> Outcomes were assessed at 4 postoperative years using major validated questionnaires (SF-36, ODI). They concluded that patients in all groups (e.g., with/without instrumented fusions) demonstrated comparable outcomes.

### **Long-term outcomes of lumbar spinal stenosis: eight-year results of the Spine Patient Outcomes Research Trial (SPORT)**

Lurie *et al.* combined a randomized with a concurrent observational cohort study evaluating, over a 4-year period, outcomes of surgery vs. conservative treatment for patients with symptomatic lumbar stenosis.<sup>[2]</sup> Utilizing the SPORT data and criteria, treatment included standard decompressive laminectomy versus typical non-operative care. Outcomes were again assessed utilizing the SF-36 Bodily Pain and Physical Function scales and the modified ODI (e.g. at 6 weeks, 3 months, 6 months, and yearly up to 8 postoperative years). The data at 8 years included 55% from the randomized group and 52% from the observational group. Of interest, “70% of those randomized to surgery and 52% of those randomized to non-operative (group) had undergone surgery by 8 years.” Furthermore, the “early benefit for surgery out to 4 years converged over time, with no significant treatment effect of surgery seen in years 6 to 8 for any of the primary outcomes.” Alternatively, the observational group showed

a “stable” advantage for surgery at 5 and 8 years. In addition, many patients were lost to follow-up.

**Comments:** Again, the study design is a major challenge because here again those randomized to the different treatment groups demonstrated substantial crossover; only 70% randomized to surgery actually underwent surgery, whereas 52% in the non-operative groups had surgery by the 8<sup>th</sup> year of the investigation. What was of interest was the documented 4-year benefit of surgery, which appeared to dwindle/disappear by the 6<sup>th</sup> to 8<sup>th</sup> postoperative year. Because many patients were lost to follow-up, the conclusions of the study were further jeopardized.

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