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Editorial

# The role of surgery for treatment of low back pain: insights from the randomized controlled Spine Patient Outcomes Research Trials

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## Abstract

Low back pain (LBP) is a common medical problem with high morbidity and healthcare costs. The optimal management strategy, including the role of surgical intervention, remains controversial. The Spine Patient Outcomes Research Trials were randomized controlled studies conducted to assess the effectiveness of surgery for three of the most common conditions implicated in LBP: Intervertebral disc herniation, degenerative spondylolisthesis, and spinal stenosis. Despite challenges in data interpretation related to patient cross over, these studies support the efficacy of surgery as treatment for these three common conditions.

**Key Words:** Low back pain, lumbar disc herniation, spondylolisthesis, stenosis

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## BACKGROUND

Based on the US Center for Disease Control and Census Bureau data analyses from the Survey of Income and Program Participation, back and spine problems are the second most common cause of disability in the United States.[2] Many patients incapacitated by spine disorders seek out medical or surgical care.[5,6] Alarmingly, health care expenditures related to surgical care of spinal disorders have escalated in recent years.[4] Increasingly, there is media, public, and government scrutiny of the rapid rise in the volume of spinal procedures performed.[3,11] In this context, the Spine Patient Outcomes Research Trial (SPORT) was launched to examine the efficacy of spinal surgery for three of the most common forms of degenerative spinal disorders, including intervertebral disc herniation, degenerative spondylolisthesis (DS), and spinal stenosis. These landmark studies adopted modern methodologies established for randomized clinical trials (RCTs) in their design and execution.[12,13,17] This article will review the key findings of the SPORT studies and discuss the limitations of RCT methodologies as they relate to the assessment of efficacy in surgery.

## SPINE PATIENT OUTCOMES RESEARCH TRIAL I, II, III (STUDY DESIGN)

In total, the SPORT studies included approximately 2500 patients, with over 1000 randomized, from 13 sites



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across the country to investigate the clinical efficacy of surgery as treatment for the three common causes of lower back pain and neurogenic claudication, including lumbar disc herniation, DS, and spinal stenosis. An independent RCT was carried out for each of these three disorders. Eligibility criteria were based on evidence-based management algorithms developed by the Agency for Health Care Policy and Research and others. In brief, progression or persistence of incapacitating back pain or neurogenic claudication after a 6–12 week period of nonoperative care was required prior to trial enrollment. Preenrollment nonoperative care included counseling, physical therapy, epidural injections, chiropractic therapy, and opioid analgesics.[12,13,17] Exclusion criteria included prior surgery, cauda equina syndrome, segmental instability (more than 4 mm or 10° of angular motion between flexion and extension), and spine fractures, infections, tumors, or inflammatory spondyloarthropathy. Eligible patients were randomly assigned to surgical treatment or continued nonoperative treatment at the time of enrollment. Patients who met eligibility criteria but declined to be randomized were invited to participate in a separate observational cohort. Primary endpoints were changes from baseline for the Medical Outcomes Study 36-item short-form (SF-36) health survey bodily pain and physical function scales (SF-36) and the modified Oswestry Disability Index (ODI), whereas secondary outcomes were patients' self-reported improvement, work status, satisfaction with symptoms and care, and the sciatica bothersomeness index (SBI). Outcomes were measured at 6 weeks, 3 months, 6 months, and 1 and 2 years from enrollment for initial reports, with subsequent follow-up studies reporting 4 and/or 8-year data. The investigators calculated the treatment effects by measuring these endpoints at baseline and after treatment, and comparing the difference in the mean changes from baseline between surgical and nonoperative groups.[1] The studies were designed to determine the effect of surgical treatment as assigned (intent-to-treat analysis) for the primary analysis. Effect of surgical treatment as received (as treated analysis) was also analyzed.

## SPINE PATIENT OUTCOMES RESEARCH TRIAL I: LUMBAR DISC HERNIATION

This RCT randomized 501 surgical candidates (245 assigned to surgery, 256 assigned to nonoperative management) with imaging-confirmed lumbar intervertebral disc herniation and persistent signs and symptoms of radiculopathy for at least 6 weeks. Patients were randomized to standard open discectomy or nonoperative care as described in the above study design section. Despite the randomized-control study design, adherence to assigned treatment was poor. Within 3 months of enrollment, only 50% of patients assigned to receive surgery underwent surgery, whereas 30% of those assigned to receive nonoperative treatment underwent surgery. The intention-to-treat analysis showed that both treatment groups improved substantially in all primary and secondary outcomes. Between-group differences in primary outcomes favored surgery for all time points up to 2 years, but were statistically insignificant. Some secondary outcomes, such as SBI (at all-time points) and self-reported progress since enrollment (at 1 year only), showed statistically significant improvements with surgery in the intention-to-treat analysis (SBI: −1.6 [95% confidence interval (CI), −2.9 to − 0.4] at 2 years; self-reported progress: 9.0 [95% CI, 0.3–17.6] at 1 year).

The large bi-directional crossover in this study nonetheless led the authors to conclude that the intention-to-treat analysis was unable to assess the superiority or equivalence of the treatments.[13] The as-treated analyses demonstrated statistically significant improvement of all primary end points in patients who underwent surgery relative to nonsurgical patients for all time points up through 2 years. The demographics and symptomatology of the two groups in the as-treated analysis differed significantly across multiple variables, with statistical adjustments made for factors affecting treatment crossover in the as-treated analysis. At 1-year follow-up, the differences between the surgical and nonsurgical patients (in favor of surgical patients) for the three primary end points were SF-36 bodily pain index 15.0 [95% CI, 10.9–19.2]; SF-36 physical function: 17.5 [95% CI, 13.6–21.5]; ODI: −15.0 [95% CI, −18.3 to −11.7].[13] The differences between the surgical and nonsurgical patients for the SF-36 bodily pain index, SF-36 physical function index, and the ODI persisted at the 4- and 8-year follow-up,[8,14] with 63% of original enrollees supplying data at the 8-year follow-up.

## SPINE PATIENT OUTCOMES RESEARCH TRIAL II: DEGENERATIVE SPONDYLOLISTHESIS

This multicenter RCT investigated the efficacy of surgery as treatment for spondylolisthesis with spinal stenosis.[12] Surgical candidates with at least 12 weeks of symptoms (back pain, neurogenic claudication, or radicular leg pain with associated neurologic pain) and image-confirmed DS were enrolled in a randomized cohort (304 patients; 159 surgical, 145 nonsurgical) or an observational cohort (303 patients; 173 surgical, 130 nonsurgical).[12] Treatment consisted of standard decompressive laminectomy (with or without fusion) or nonoperative care as described in the above study design section. As was observed with SPORT I, the 1-year crossover rates were high in the randomized cohort (approximately 40% in each direction). The intention-to-treat analysis for this randomized cohort showed no statistically significant difference for the primary outcomes at any time point (treatment effects

at 2 years: SF-36 bodily pain = 1.5, [95% CI, −4.2–7.3], SF-36 physical function = 1.9, [95% CI, −3.7–7.5], ODI = 2.2, [95% CI, −2.3–6.8]).[12] However, as-treated analyses for the combined randomized cohort and the observational cohort showed a statistically significant advantage for surgery for all primary and secondary outcomes at all time points up to 2 years. Differences in demographics and symptomatology of the two groups in the as-treated analysis were included as covariates in longitudinal regression models to adjust for potential confounding effects in the as-treated analysis. For the 2-year follow-up, the differences between the surgical and nonsurgical patients (in favor of surgical patients) for the three primary end points were SF-36 bodily pain: 18.1 (95% CI, 14.5–21.7); SF-36 physical function: 18.3 (95% CI, 14.6–21.9); ODI: −16.7 (95% CI, −19.5 to −13.9).[12] These differences between the surgical and nonsurgical patients for the SF-36 bodily pain index, SF-36 physical function index, and the ODI persisted at the 4-year follow-up, with 70% of initially enrolled patients providing data though this time point.[15]

## SPINE PATIENT OUTCOMES RESEARCH TRIALS III: SPINAL STENOSIS

This multicenter RCT investigated the efficacy of surgery as treatment for spinal stenosis.[17] Surgical candidates with at least 12 weeks of symptoms (back pain, neurogenic claudication, or radicular leg pain with associated neurologic pain) and imaging findings of spinal stenosis without spondylolisthesis were enrolled in a randomized cohort (289 patients; 138 surgical, 151 nonsurgical) or an observational cohort (365 patients; 219 surgical, 146 nonsurgical). Treatment consisted of standard decompressive laminectomy or nonoperative care as described in the above study design section. As was observed with SPORT I and II, the 1-year crossover rates were high in the randomized cohort (at 1 year, only 63% of patients assigned to the surgical group had undergone surgery whereas 42% assigned to the nonsurgical group underwent surgery). The intention-to-treat analysis showed a significant treatment effect favoring surgery on the SF-36 bodily pain scale, with differences between the surgical and nonsurgical patients of 7.8 (95% CI, 1.5–14.1). However, no significant differences between the surgical and nonsurgical patients were found on SF-36 physical function (0.1 [95% CI, −6.4–6.5]) or ODI (−3.5 [95% CI, −8.7–1.7]).[17] The as-treated analyses for the combined randomized cohort and the observational cohort showed a statistically significant advantage for surgery for all primary and secondary outcomes at all time points up to 2 years. Baseline differences in demographics and symptomatology between the as-treated groups were included as covariates in longitudinal regression models to adjust for potential confounding effects in the as-treated analysis. For the 2-year follow-up, the differences between the surgical and nonsurgical patients (in favor of surgical patients) for the three primary end points were SF-36 bodily pain 13.6 (95% CI, 10.0–17.2); SF-36 physical function 11.1 (95% CI, 7.6–14.7); ODI −11.2 (95% CI, –14.1.7 to −8.3).[17] These differences between the surgical and nonsurgical patients for the SF-36 bodily pain index, SF-36 physical function index, and the ODI persisted at the 4-year follow-up, with 67% of initially enrolled patients providing data though this time point.[16]

## EXPERT COMMENTS

### "There is a substantial bias in the general medical literature against surgeons even when they are performing appropriate and effective surgery." Daniel K. Resnick, University of Wisconsin, Madison

The importance of the SPORT studies to the neurosurgical and spine community cannot be overstated. Several critically important lessons were learned. First of all, it was realized that performing randomized trials to evaluate established treatments without viable alternative treatments is essentially impossible. Offering previously noneffective treatments to patients in pain resulted in substantial crossover, which destroyed the randomized trial design. Second, it became apparent that there is a substantial bias in the general medical literature against surgeons even when they are performing appropriate and effective surgery. The published conclusions of the initial SPORT reports indicated that surgery was not an effective treatment for lumbar disc herniation even though the data clearly showed improvements in the surgical group in every outcome measure and at every time point. The SPORT authors, to their credit, corrected this misrepresentation of the data in subsequent publications. Third, the studies demonstrated the effectiveness of appropriate surgical intervention for patients with lumbar disc herniation, neurogenic claudication due to lumbar stenosis, or stenosis associated with spondylolisthesis. The differences in outcome were statistically and clinically significant and durable. Therefore, in patients with radiculopathy or neurogenic claudication and appropriate clinical and radiographic findings, surgical intervention is recommended if the patient's symptoms are severe enough (according to the patient) to warrant surgery.

The SPORT studies have gone a long way toward answering fundamental questions regarding the value of spine surgery and have been extremely instructive in terms of planning future research into comparative effectiveness and cost-effectiveness of competing treatment strategies. Performing further randomized studies in the setting of established treatment paradigms and the absence of physician and patient equipoise is not likely going to be productive. Using "big data" and registry projects,

the efficacy of commonly employed treatment strategies for patients with similar disorders can be established and compared. This approach may be used both to answer some questions (do injections with steroids work any better than injections without steroids?) as well as to raise new ones (why do patients in the Northeast derive greater benefit from micro discectomy than those in the Northwest?). Continued analysis and honest appraisal of the results of such analyses should help to improve the efficacy, efficiency, and cost-effectiveness of spine care going forward. Perhaps, the most important lesson learned from the SPORT studies is that we should not fear honest examination of our work. If we are performing appropriate procedures on appropriate patients, they should derive benefit and this benefit will be demonstrable. If our patients do not derive benefit, then it is our job to change what we are doing or whom we are doing it to create benefit.

**"These studies revealed compelling benefits of surgical intervention in patients with neurologic deficits or functional limitations attributable to radiographic findings." Joseph Ciacci, University of California, San Diego**

The SPORT studies elucidate several significant issues in the care of spine patients. These patients are complex, and the difficulties with randomization are significant. Patients with progressive neurological deficits and debilitating pain will often cross over to the surgical group. These studies revealed compelling benefits of surgical intervention in patients with neurologic deficits or functional limitations attributable to radiographic findings. These studies should remind clinicians of the clear indications for spinal surgery in patients with severe neurologic impingement who are progressing through conservative management.

**"Spine Patient Outcomes Research Trial-like trials using minimally invasive spine techniques would likely reveal improved outcomes for surgical treatment of degenerative spine disease in the future." William Taylor, University of California, San Diego**

The SPORT trial remains one of the critical studies in modern history for any medical professional involved with spine care. These studies represent a major step toward removing the public biases against surgical intervention in degenerative spine diseases. The notable efficacy of spinal decompression based on as-treated analyses in these studies should be interpreted in the context of what we consider standard conservative management, including physical therapy, epidural steroid injection, and chiropractic manipulation. These nonsurgical interventions have not stood as the test of RCTs. It is notable that the efficacy of spinal decompression surgery in the SPORT studies compares favorably with many commonly performed and well-accepted orthopedic procedures, such as joint replacement, in cost-utility measures such as quality-adjusted life years and health-related quality of life.[9,10] The efficacy of spinal decompression in appropriately selected patients may be further enhanced through minimally invasive spine (MIS) surgery, since these procedures have been shown to reduce complications, length of stay, and cost, while maintaining equal or superior outcomes.[7] SPORT-like trials using MIS techniques would likely reveal improved outcomes for surgical treatment of degenerative spine disease in the future.

## EDITORIAL COMMENTS

First, it is critical that the findings of the SPORT studies are not misapplied during clinical evaluations of spine patients. Patients with degenerative changes associated with rapidly progressing neurologic deficits, cauda equine syndrome, spinal instability, infection, and spinal tumors were excluded from the SPORT studies. Emergent surgeries in these clinical contexts should not be delayed based on SPORT data because none of the SPORT patients suffered neurologic deterioration during the randomization period or while making the decision to crossover from the nonsurgical arm to the surgical arm.

Second, much of the controversy in the interpretation of the SPORT studies revolves around the issue of "intent-to-treat" analysis versus "as-treated" analysis. It is important to note that intent-to-treat and as-treated analyses are both valid, but they fundamentally differ in terms of the underlying research goal. A major reason that intent-to-treat analysis is preferred by government-funded agencies is that it affords an estimate of treatment effects "as offered." As such, it affords a public health assessment of treatment efficacy in the context of noncompliance, which is a known phenomenon in every medical/surgical intervention. However, if the underlying question is the effect of treatment "as received," then as-treated analysis would be the appropriate. In such analyses, it is critical to statistically account for differences in the pertinent demographic and clinical variables between the cohorts prior to intervention – a task that the SPORTs studies have admirably achieved. As such, findings reported by the SPORT studies represent bonafide support for the efficacy of spinal decompression in patients with degenerative spine/foraminal stenosis when patient selection is firmly grounded in clinical context and filtered through the lens of classic neurologic anatomy.

Finally, the significant crossovers in all three SPORT studies involved not only patients who were assigned to nonoperative treatment, but also to those who were assigned to decompression. The former scenario likely involves symptomatic progress or persistence of incapacitation beyond patient tolerance without a viable

treatment alternative. It is notable that a significant portion of the SPORT patients assigned to surgery ultimately opted not to undergo surgery. Moreover, this proportion of patients was significantly higher than patients who decline medical treatment in RCTs involving medical interventions. This finding suggests that the patient's perception of surgical intervention intrinsically differ from that involved in ingestion of a drug, and that many patients are fundamentally ambivalent about spine surgery. As such, high rates of noncompliance to treatment assignment in future spinal surgery RCTs are likely. In this context, future studies should consider adaptation of study designs grounded in the "as-treated" statistical paradigms.

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# Commentaries

## COMMENTS FROM SURGICAL NEUROLOGY INTERNATIONAL EDITORIAL BOARD MEMBERS

## COMMENTARY #1

The Spine Patient Outcomes Research Trial (SPORT) trial database offered much useful information regarding the efficacy of surgical treatment for lumbar disc herniations, lumbar spinal stenosis, and degenerative spondylolisthesis (DS). 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 to nonsurgical (50%) groups (30%).[3] 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 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 versus without surgery.[4] The follow-up study at 8 years again questioned the value of surgery versus nonoperative intervention.[5] The other SPORT studies dealing with DS appeared to document the benefit of surgical decompression, but could not consistently substantiate the relative value of decompression alone versus noninstrumented versus instrumented fusion.[1,6] The more recent SPORT study in 2015 on spinal stenosis treated with/without surgery, indicated improvement in short-term 4-year outcomes, but that the results of the two arms (surgical vs. nonsurgical) converging at 8 years.[2] Below you will find summaries of six SPORT studies and short commentaries following each study indicating the pros, cons, and short comings of each investigation. Notably, if surgeons better selected patients for surgery, requiring a significant neurological deficit and neuroradiological lesions, and better avoided unnecessary procedures for "black discs alone" or pain alone, the

results of surgical intervention would likely be more clearly confirmed.

## SURGICAL VERSUS NONOPERATIVE TREATMENT FOR LUMBAR DISK HERNIATION: THE SPINE PATIENT OUTCOMES RESEARCH TRIAL: A RANDOMIZED TRIAL

Weinstein *et al*. in 2006 also evaluated surgical versus nonsurgical treatment for lumbar disc herniations utilizing the SPORT database in a randomized fashion.[4]

They identified 501 surgical candidates with neurodiagnostic studies confirming lumbar intervertebral disk herniations in patients with at least 6 weeks of radiculopathy. Patients underwent "standard open diskectomy versus nonoperative treatment," outcomes were again assessed with the 36-item short-form (SF-36) and modified Oswestry Disability Index (ODI) at 6 weeks, 3 months, 6 months, and 1 and 2 years from enrollment. Notably, there were some problems in the study design: "50% of patients assigned to surgery received surgery within 3 months of enrollment, whereas 30% of those assigned to nonoperative treatment received surgery in the same period." They found that "patients in both the surgery and the nonoperative treatment groups improved substantially over a 2-year period," but the large numbers of patients who are crossing over did not lead to a clear conclusion regarding the benefits of either treatment modalities.

**Comments:** This study highlights 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: Those initially choosing surgery opting for conservative care with others initially opting for conservative treatment going for surgery. Therefore, although the numbers were large and the theoretical design was excellent, the authors had to clearly confront their inability to claim superiority of surgery over nonoperative 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 for lumbar disc herniations.

## SURGICAL VERSUS NONOPERATIVE TREATMENT FOR LUMBAR DISK HERNIATION: THE SPINE PATIENT OUTCOMES RESEARCH TRIAL OBSERVATIONAL COHORT

Weinstein *et al*. in 2006 evaluated the relative efficacy of diskectomy versus nonoperative 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).[3] Outcomes were assessed using the SF-36 health survey 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, 40.9vs. nonoperative care, 26.0); physical function (mean change: Surgery, 40.7 vs. nonoperative care, 25.3)." They also showed greater improvement on the ODI: −36.1 versus nonoperative 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 nonrandomized 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 versus nonoperative group (191 patients). However, they 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 NONOPERATIVE TREATMENT FOR LUMBAR DISC HERNIATION: 4-YEAR RESULTS FOR THE SPINE PATIENT OUTCOMES RESEARCH TRIAL

Weinstein *et al*. in 2008 published their concurrent, prospective, randomized, and observational cohort study looking at the 4-year outcomes of surgery versus nonoperative care for lumbar discs.[5] There were 501 prospective, randomized patients and 743 cohort patients in this study utilizing standard open discectomy versus usual nonoperative care. 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 nonoperatively treated patients (except work status)."

**Comments:** This combined 4-year study involving randomized and cohort patient participants showed better outcomes for surgically treated versus 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 or cause inadvertent injury attributed to inadequate exposure.

## SURGICAL VERSUS NONOPERATIVE TREATMENT FOR LUMBAR DEGENERATIVE SPONDYLOLISTHESIS; 4-YEAR RESULTS IN THE SPINE PATIENT OUTCOMES RESEARCH TRIAL

Weinstein *et al*. in the 2009 SPORT trial (13 centers/11 states) evaluated 4-year postoperative results of surgical versus nonoperative treatment of DS.[6] Patients were symptomatic for at least 12 weeks' duration, had studies documenting DS with spinal stenosis (randomized cohort or observational cohort), and were treated with decompressive laminectomies (with or without fusion) versus nonoperative 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 nonoperatively, patients in whom DS and associated spinal stenosis are treated surgically to maintain substantially greater pain relief and improvement in function for 4 years."

**Comments:** In this large SPORT study, patients with DS and spinal stenosis were treated with decompressive laminectomy (with or without fusion) versus nonoperative care.[19] Four years later, they found 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 nonoperative treatment? The answer was "yes," and this was accomplished with substantially greater validity.

## DEGENERATIVE SPONDYLOLISTHESIS: DOES THE FUSION METHOD INFLUENCE OUTCOME?

Abdu *et al*. in 2009 compared outcomes of different fusion methods to treat DS.[1] Data were obtained from 13 centers in 11 states (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 (PLF) (21%: PLF: 80 patients), posterolateral instrumented fusion with pedicle screws (PPS) (56%; PPS: 213 patients), PPS plus interbody fusion (17%: 63 patients: 360°), 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, noninstrumented and instrumented fusions yielded comparable results.

Comments: This large SPORT database study evaluated 380 patients variously treated with decompressive laminectomy with PLF, PPS, PPS plus interbody fusion, or laminectomies alone.[1] 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: 8-YEAR RESULTS OF THE SPINE PATIENT OUTCOMES RESEARCH TRIAL

Lurie *et al*. combined a randomized with a concurrent observational cohort study evaluating over a 4-year period, outcomes of surgery versus conservative treatment for patients with symptomatic lumbar stenosis.[2] Utilizing the SPORT data and criteria, treatment included standard decompressive laminectomy versus typical nonoperative 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 years). The data at 8 years included 55% of those in the randomized group and 52% in the observational group. Of interest, "70% of those randomized to surgery and 52% of those randomized to nonoperative 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 6–8 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 as here again those randomized to the different treatment groups demonstrated substantial crossover: Only 70% randomized to surgery actually had it, whereas 52% in the nonoperative groups had surgery by the 8$^{th}$ year of the investigation. What was of interest was the documented 4-year benefit of surgery, which appeared to dwindle/disappear in the 6$^{th}$ to 8$^{th}$ postoperative year. As many patients were lost to follow-up, the conclusions of the study were further jeopardized.

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## COMMENTARY #2

The utilization of clinical experience in the practice of medicine is time-honored. The documented outcomes of spinal conditions when operative care has been withheld inappropriately are well known (especially if you are my age). Wise and high integrity clinicians, who were our leaders and professors, entered into medicine and surgery to help patients recover from their diseases. Once they found a medicine or operation that was truly helpful that information was passed on and taught to us. We did the same. Nearly, all earlier articles in our medical journals were clinical series/reports, where a treatment was tried and reported, even with complications. As time passed, with the eagerness to publish, more articles provided over-optimistic outcomes, thus, the SPORT trials. It is a very important contribution. Many of our treatments/operations are still not perfect. However, neither are we as surgeons. We "practice" medicine. No two patients are the same. No two surgeons are the same. Judgment and a moral compass need to be our guides. Science alone will not help as much without integrity. Is the patient being treated like we would want to be treated ourselves? My part-time work now is as a reviewer and a guideline approver. I have read/seen some very poor indications for operative care. I am, at age 78, more worried about the morality and conscience of the provider. I agree that some patients have inappropriate expectations/demands/goals. Admittedly, the many ramifications of a clinical presentation can sometimes be difficult to judge! However, our "practice" of medicine cannot be turned into "chemical reaction" science. The SPORT trials add to our judgment and to our clinical experience. The complaint of "back pain" is simply just one of the many factors used in our clinical judgment in recommending operative care.

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## COMMENTARY #3

The SPORT trials are one of the most aggressive attempts to accurately assess surgical outcomes compared to the time-honored nonoperative or conservatively treated common spinal maladies that plague our society. Unlike randomized controlled drug trials, this study points out the problems we have in designing this type of protocol in surgically treated patients where sham techniques would be unethical. Just as the AO North American study on the treatment of cervical myelopathy gives outcomes of surgical intervention in this patient population, the SPORT study gives the surgeon the best set of information available to counsel patients on the surgical options available in the treatment of common lumbar pathological processes. Is it a perfect study? No, but it is the best science we have available at the present time.

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## COMMENTARY #4

This paper is an editorial review of a series of studies attempting to establish the efficacy of surgery in three common degenerative disorders of the spine: Intervertebral disc herniation, DS, and spinal stenosis. The purpose of the studies is not clearly explained, but beyond the usual scientific curiosity that inspires clinical investigations, these studies were without a doubt. Influenced by an increased "…media, public, and government scrutiny of the rapid rise in the volume of spinal procedures performed…" (lines 30–31), an opinion supported by this incredible (and naive) statement: "These studies represent a major step toward removing the public biases against surgical intervention in degenerative disc disease" (lines 191–192).

The methodology chosen for these studies was a variant of the randomized clinical trial (RCT) design. The design was not appropriate for the questions asked and not unexpectedly, compliance with the requirements of the treatment groups into which the patents inserted were graded by the investigators as "poor." Primary and secondary endpoints were heavily weighted with patient

opinion (e.g., self-reported surveys of patient satisfaction conducted by mail or telephone contacts) recorded, for example, by newly designed but largely unproven instruments for quantifying pain. The inclusion/exclusion criteria focused on pain and on "appropriate" imaging data, suggesting the designers of these studies had before them the AANS guidelines on the surgical treatment of low back pain, as they worked.

The path laid out by the authors of this review, as they analyzed the data, is uncharted without precedence in clinical investigations. To try to connect specific data summaries with conclusions, for the reader, will require a tortuous journey of such expenditure of scholarly energy as to invite fatigue and by default, acceptance. Thus, in this comment, I invite the reader to the sidelines to focus with me not on the data, but on the conclusions of the authors of this review. I take this step because this review clearly was not written to address the scientific soundness of the clinical studies or the value of the data; it is a political document created preemptly to supply answers to the socioeconomic questions sparked by the scrutiny of spine surgery. It is a product of the coupling, arranged by the AANS, of its guidelines for the surgical management of back pain and its substitution of the principles and practices of the business world for those of the medical profession when it adopted the 501(c)(3) tax status a decade ago.

An important conclusion of the authors of the review is that "…these landmark… (SPORT) studies… (utilizing RCT methodology) …have gone a long way towards answering fundamental questions regarding the value of spine surgery…" (lines 160–161). Writing of important lessons learned in a review of these studies, its authors note that "…it became apparent (during the process of their review) that there is a substantial bias in the general medical literature against surgeons even when they are performing appropriate and effective surgery" (lines 148-150) (emphasis added). Then, more specifically, comes the following: "The published conclusions of the initial SPORT reports indicated that surgery was not an effective treatment for lumbar disc herniation even though the data clearly showed improvements in the surgical group in *every outcome measure*, and at *every time point*" (lines 150–152) (emphasis added). But, in the section, SPORT II: Degenerative spondylolisthesis located this observation: "The intention-to-treat analysis for this randomized cohort showed *no statistically significant difference for the primary outcomes at any time point* (treatment effects at 2 years: SF-36 bodily pain = 1.5, [95% CI, −4.2–7.3], SF-36 physical function = 1.9, [95% CI, −3.7–7.5, ODI = 2.2, [95% CI, −2.3–6.8]) (lines 100–103) (emphasis added). Moreover, in the section, SPORT III: Spinal stenosis, it is noted that "…no significant differences between the surgical and nonsurgical patients were found on SF-36 physical function (0.1 [95% CI, −6.4–6.5]) or ODI (−3.5 [95% CI, −8.7–1.7])." Concluding this section is the observation: "The SPORT authors, to their credit, *corrected* this misrepresentation of the data in subsequent publications" (lines 152-153) (emphasis added).

A major problem in the design and execution of these studies was that of patient noncompliance within treatment groups was described as poor. In the spinal stenosis section, it was noted that "…at 1 year, only 63% of patients assigned to the surgical group had undergone surgery, while 42% assigned to the nonsurgical group underwent surgery" (lines 122–124). In the section on lumbar disc herniation "…(w) ithin 3 months of enrollment, only 50% of patients assigned to receive surgery underwent surgery, while 30% of those assigned to receive nonoperative treatment underwent surgery" (lines 70–72). In the studies overall, "…a significant portion of the SPORT patients assigned to surgery ultimately opted not to undergo surgery… a proportion of patients… significantly higher than…(those)…who declined medical treatment in RCTs involving medical interventions" (lines 229–231). However, patients with progressive neurological deficits "often" crossed over. A conclusion was drawn by the authors of the review that "…the patient's perception of surgical intervention intrinsically differs from that involved in ingestion of a drug, and that many patients are fundamentally ambivalent about surgery" (lines 232–233).

In other words, the patients seem to understand that when pain is not associated with neurological deficit, the treatment should be medical, but with deficit, surgery should be considered. This observation was made, initially, in the 1990s during a large nation-wide National Institutes of Health funded study of the history of treated back pain (principal investigator, The Study of Back Pain Group within the Department of Neurosurgery at Johns Hopkins University School of Medicine; contributing investigators were neurosurgeons at the University of Missouri, Case Western Reserve University, University of Tennessee, and the University of Florida, and orthopedic surgeons from the UCLA School of Medicine; for more details of the study and the investigators see Long DM, BenDebba M, Torgerson WS, *et al*. Persistent Back Pain and Sciatica in the United States: Patient Characteristics. J Spinal Dis 1996;9:40-58).

Patients (whose medical condition included back pain, was not the subject of litigation, a term I will use generally to refer to goals some patients carry with them in their search for medical treatment that artificially introduces nonobjective states of bias and sensitivity to placebo) with back pain of acute onset, with noticeable and limiting neurological deficits identified clearly and repeatedly on examination by the primary treating physician, whether or not the acute episode was superimposed upon a

prior history of periodic limiting episodes of back pain, recovered very well with decompressive surgery regardless of the degenerative diagnosis—lumbar intervertebral disc herniation, degenerative lumbar spondylolistheses (usually with a stable slippage of 25% or less), and spinal stenosis. Fusion, rarely entertained, was most often offered to patients with clearly described neurogenic claudication–back pain at rest that increases in intensity, radiating into the legs with activity, especially walking, and at its zenith is associated with an objective limiting neurological deficit, such as a clear and reproducible unilateral foot drop identified by the patient or demonstrated by the surgeon. The number that returned to their previous levels of desired activity—work, play, relaxation, serious involvement in physical sports—approached 90%, with serious long-term life-altering outcomes present in <2%.

The patents seen because of an acute episode of back pain, without neurological deficit, whether or not there was a prior history of periodic limiting episodes of back pain, with or without radiographic suggestions of (often wide spread) osteoarthritis, and were provided detailed and accurate instruction, appropriate to their educational level, by committed, knowledgeable, and experienced allied health professionals (e.g., physical therapists (PT), occupational therapists (OT), nurses) in the anatomical, physiological, and metabolic determinates of spine health, along with specific recommendations regarding diet and general physical behavior at work and at play when healthy, personalized for the patient, with modifications of these principles and practices when limited by back pain, interestingly, but not surprisingly, did very well. Their favorable outcomes exceeded those who had undergone surgery, as detailed above, when examined at 12 months and at 18 months. Return to desired physical activity in this group exceeded 93%, with life-altering complications negligible, limited to missed diagnosis—abscess, tumor. A minority of these patients developed their pain in more gradual, less acute, scenarios, but they were distinguished from the group of patients discussed below by receiving the attention those of this group regarding their spine health.

As follow-up approached 2 years, the difference between the two groups began to narrow to insignificance. This finding is easily understood when the life cycle of a degenerative osteoarthritic spine is examined. That life cycle will continue after any temporary intervention for local disease, whether trauma, disc herniation, or nonsteroidal anti-inflammatory medication. This is the reason it makes no sense to look for long-term results–>2 years, up to 8 years in the review—when evaluating treatment protocols for acute disorders, which periodically complicate chronic disease.

The other, more heterogeneous, group of patients in the study (again, when the elements of distracting litigation are excluded as factors that must be addressed during treatment) had outcomes less favorable than the other two groups, depending on the degree to which they had interventions, diagnostic and therapeutic, repeated and progressively more complex than necessary, often long after any soft tissue injured at the time of the acute episode had healed. These patients often became enmeshed in a tragic web of emotional judgmental dependency on the tools of their providers, a condition I refer to as iatrogenesis, a condition of helplessness, hopelessness, and dependency, similar to that seemingly more common today, in the morally unconscionable and professionally embarrassing era of "pain management."

The SPORT studies, submitted as investigative proof of the value of surgery, must be considered a colossal failure, an embarrassment to the profession similar to realized with the disclosures of the unethical reporting of the studies involving the use of BMP in the lumbar spine. Attempts by the authors of this review to convince their readers of the scientific value of the studies are negated by emotional charges of bias attributed to others of charges of interference in the practice of spine surgeons by public scrutiny and of poor compliance by the patients within the RCT model, which reveal the nonscientific purpose of the review.

But, the paper has value. The observations of the noncompliant patients are extremely revealing. The patients recognized the difference between the back pain related to their osteoarthritis, and that associated with neurological deficits. Those with generalized osteoarthritic degenerative disease are monitored and treated by their primary care physicians over time along with their other medical conditions, during which they gain trust in their physician. They generally learn self-management. The patients who present with acute localized back pain, experience neurological deficits, and see their condition unique in their medical experience, realize they have a different disease than the patient with chronic disease. They are more incapacitated, the neurological deficits are much more localizing of the pathology than the chronic conditions, they are submitted to tests of more technological sophistication, they see surgeons they do not know; trusts is replaced by snippets of reputation. The complications of treatment they face are different. They know they have a different disease. The two groups require different treatment plans. The patient without localizing neurological deficit knows he/she does not belong with others who have deficits. Moreover, they are correct. Attempts to pull the patient with steady chronic back pain that periodically worsens into the group with clearly localizing pain and neurological deficits will end as these studies. Without neurological deficits, otherwise stable patients do not have a surgical disease.

This point is clear to the patients; why it is not clear to spine surgeons, is unclear to me.

However, a final conclusion of the authors of the review on which I wish to comment is revealing: "The importance of the SPORT studies to the neurosurgical and spine community cannot be overstated" (line 144). As I pondered this opinion, I recalled three aphorisms, popular in medical school that collectively offer additional wisdom to the debate of the role of surgery, whether decompression or fusion, in the management of the patient, otherwise stable, with chronic back pain.

The offer: To cut is to cure

The standard: First do no harm

The caution: Buyer, or customer (or patient) beware.

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