

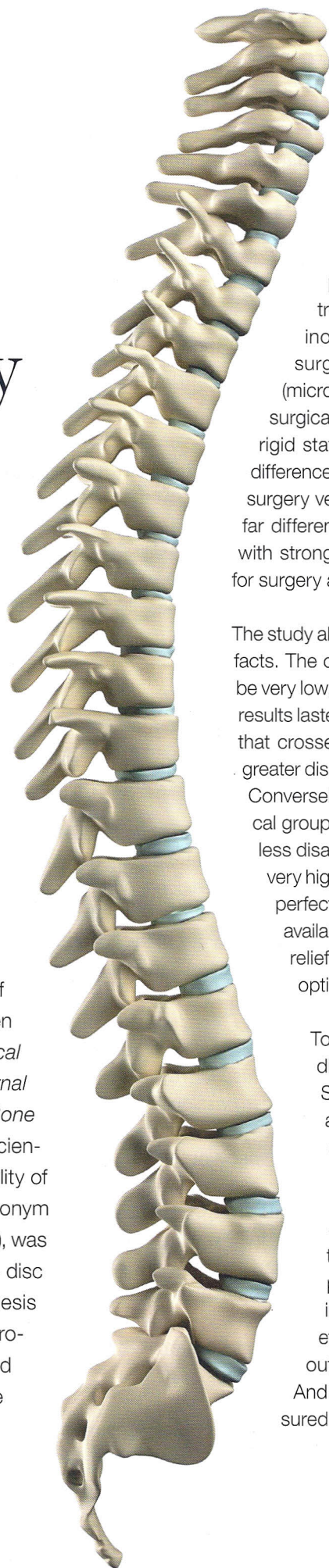
Randomized Controlled Trials in Spine Surgery

The Latest Research



by Paul Kraemer, MD

Randomized controlled trials are quite common in medicine, but in surgical specialties, they are just getting off the ground. In the past, research in spine surgery boiled down to, “Here’s what I did, and it seemed to turn out OK.” But in the last four years, three separate but closely related trials, all funded by the National Institutes of Health and conducted at 13 centers throughout the United States, have brought the quality of evidence we rely on up to par with some of the best studies done in all of medicine. In fact, two of these studies have been published in the *Journal of the American Medical Association (JAMA)* and *The New England Journal of Medicine*, and the third in the *Journal of Bone and Joint Surgery*. This is a testament to the scientific rigor the studies adhered to and the reliability of the results. Each study, all under the catchy acronym SPORT (Spine Patient Outcomes Research Trial), was focused on a common lumbar spine disorder — disc herniations, spinal stenosis and spondylolisthesis — and compared standard common surgical procedures with non-operative treatments. Armed with this information, surgical evaluations are now less opinion and more fact.



What did these studies conclude? The first of these trials was published in *JAMA* in 2006, “Surgical vs. Non-Operative Treatment for Lumbar Disc Herniation.” This study may also be the most controversial, due to the crossover rate — that is, the percentage of patients who did not ultimately undertake the treatment that they were randomized to was inordinately high. Only 50 percent of the surgical group actually underwent surgery (microdiscectomy), and 43 percent of the non-surgical group had surgery. Not surprisingly, the rigid statistical intent-to-treat analysis showed no difference, but if you looked at those who actually had surgery versus those who did not, this data “yielded far different results than the intent to treat analysis, with strong, statistically significant advantages seen for surgery at all follow-up times through two years.”

The study also concluded a number of other interesting facts. The complication rate of surgery was shown to be very low, the satisfaction rate was very high, and the results lasted throughout the study period. The people that crossed over to surgery had worse symptoms, greater disability and rated their pain as getting worse. Conversely, those who crossed over out of the surgical group felt they were getting better, and they had less disability and higher function. Both groups had very high satisfaction rates. Though the study is not perfect, it is widely agreed that this is the best data available and confirms that surgery provides good relief, but non-operative treatments are viable options as well.

To address the crossover issues with the disc herniation trial, the second published SPORT trial, “Surgical vs. Nonsurgical Therapy for Lumbar Spinal Stenosis,” had both an investigational trial arm and a purely observational arm. Again, a high percentage of the nonsurgical patients had surgery, 43 percent (overwhelmingly open laminectomy), and 67 percent of the surgical trial patients had surgery. Here, even the rigid intent to treat analysis showed a clear benefit for surgery (on SF-36 Bodily Pain index), outpaced again by the as-treated analysis. And again, the improvement in outcomes (measured by the ODI and SF-36, standard outcomes

tools) were maintained and significant throughout the study period. Complication rates were low, with nearly 90 percent having no complications (average age, mid-60s, and a number of comorbidities). Complications were generally mild, with no deaths in either group. The authors concluded that surgical treatment was safe and effective and that a wide variety of non-surgical methods (mainly epidural steroid injections) could be well tolerated and lead to successful symptom management as well.

The last trial in 2009 dealt with a common disorder of spinal instability and neurologic compression affecting predominately L4-L5. This study, "Surgical Compared with Nonoperative Treatment for Lumbar Degenerative Spondylolisthesis," had a four-year follow-up period. Again, the crossover rate was large — only 66 percent of surgical randomized patients had surgery (a decompression and instrumented fusion in the majority of cases), and 54 percent of non-surgical patients also had surgery. And, again, ODI, SF-36, and satisfaction scores were in favor of surgery up to four years. Complications were low, although there was a higher reoperation rate. Interestingly, the mortality rate was lower than the age-expected rates from actuarial data.

So how is this data used? As a spine surgeon, I use scientific research to apply fact to surgical evaluations. We know that surgical intervention for nerve compression, common to all of the above trials, is safe and effective, and it lasts. We also know that non-operative means are a viable treatment option — and that those who crossover to surgery fared no worse in the final analysis. Facts, rather than opinion, help patients make the decision that is right for them.

References

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About the Author

Paul Kraemer, MD, is a spine surgeon with Indiana Spine Group, located in Indianapolis. Additionally, he is an assistant professor of orthopaedic surgery at Indiana University Medical Center. Actively involved in research, a few studies he is currently participating in involve surgical procedures of the lumbar spine, as well as a study involving treatment comparisons of cervical spinal trauma. His medical interests include the prevention and treatment of adjacent segment disease; adult spinal deformity; and orthopaedic spinal trauma, including infections, tumors and injuries.