

# How High is Up? The 2022 ISSLS Spinal Treatment Outcomes Survey and Recommendations for the Future

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Many thanks go out to the 91 members of the International Society for the Study of the Lumbar Spine (ISSLS) who responded virtually to the 2022 ISSLS Spinal Treatment Outcomes Survey, and to the 17 members and guests who discussed the survey's results in an in-person focus group at the annual meeting of the ISSLS in Boston on May 9, 2022. Perhaps even deeper gratitude is owed to the over 3000 patients disabled by chronic back pain who engaged in discussion groups while participating in functional restoration programs at the University of Vermont (1986–2000) and Dartmouth-Hitchcock Medical Center in New Hampshire (2002–2018.) These discussions, as chronicled in *Talking Back: How to Overcome Chronic Back Pain and Rebuild Your Life*,<sup>1</sup> inspired the survey and the formula which it was based on by exposing the chasm between these patients' needs and the meager results produced by the last several decades of related research.

**How We Got Here.** In his 1993 presidential address, John W. Frymoyer acknowledged ISSLS's primary goal to "...improve the quality of life of our patients by relieving pain and improving function."<sup>2</sup> He identified the increasing numbers of people disabled by low back disorders as the single major factor driving the alarming divergence between rising health care costs and both access and quality. He specifically applied formulas of quality and value, developed by general health care policy makers, to treatment outcomes for disorders of the lumbar spine.

The 2022 ISSLS Treatment Outcomes Survey. To create a framework for discussing the current status of outcomes research and for recommending future improvements and priorities, I combined the elements in Frymoyer's formulas

with the concerns and requests repeatedly voiced over the years by patients in the Vermont and Dartmouth discussion groups. Here is the resulting formula:

$$\text{QUALITY} = \frac{\text{Medical Outcomes} + \text{Patient Satisfaction}}{\text{Cost} + \text{Risk}}$$

Medical outcomes include subjective (patient-reported) and objective (observer-reported) assessments. The survey was emailed to all ISSLS members, asking each one to anonymously self-identify as a surgeon, nonoperative practitioner or basic scientist (nonclinical) and to vote PRO or CON for, and to comment upon, each of nine debate-provoking propositions drawn from elements in the formula. The propositions, the voting results (%PRO), and summaries of the comments collected and analyzed by Qualtrics,<sup>3</sup> are presented here.

Respondents identified themselves as surgeons (63%), nonoperative practitioners (23%), and basic scientists (14%), roughly reflecting the ISSLS membership, recognizing that many members belong to more than 1 group. Here are the 9 propositions, percentage PRO and CON responses, and summaries of the comments from the survey integrated with commentary from the focus group:

1. Medical outcomes are more reliable and more important than patient satisfaction. PRO (49%) Medical outcomes are more objective, measurable, validated, standardized, and normalized indicators of treatment success, and they may more accurately predict long-term outcomes. Patient satisfaction is too dependent on variables unrelated to treatment, and it is too qualitative and difficult to measure. We have only defaulted to measuring secondary outcomes such as patient satisfaction and mood, because in clinical trials, treatment effects on medical outcomes have been very small. (Efforts to magnify treatment effects, such as minimum clinically important difference and percentage of patients improved, have proven unproductive.) CON (51%) Patients' self-assessments and priorities often differ from those of health care providers, policy makers and society.

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Patients may not agree with or appreciate what a good medical outcome means to authorities. Patient satisfaction better reflects an individual patient's expectations, needs, desires, and overall perspective. Imaging-based outcomes often do not match the patient's self-assessment. Objective measures requiring patient cooperation and performance are ultimately subjective, as they depend on psychosocial components of participation. Patients may exaggerate symptoms and degrees of impairment in order to plea for more intensive interventions. Conversely, they may overrate treatment outcomes to please the provider. Clinic encounters are better than questionnaires for assessing patient outcomes. Measures of pain and disability neglect the patient's personal goals of positive health and wellness, which are better reflected in patient satisfaction.

2. The visual analog scale (VAS) is the best measure of pain. PRO (55%): the VAS is simple, easily understood and administered, most established and accepted. CON (45%): it is too simplistic and needs narrative qualification regarding chronicity, psychosocial factors, and functional consequences to the individual. The best measures of pain consider how much the pain affects the patient's ability to do things that are important to the patient and the degree to which the pain bothers the patient. Patients in lower socioeconomic and educational groups may have difficulty with the VAS concept and understanding anchoring words.
3. The Oswestry disability index (ODI) is the best measure of disability. PRO (62%): the ODI is easy to use. It is the most established, accepted, and validated measure, enabling comparison of outcomes from multiple trials and treatments. CON (38%): the ODI is not patient-specific enough in that it does not weight functional limitations according to the individual patient's needs. For instance, it does not contextualize limitations in terms of desired work capacity and recreation. No questionnaire can replicate the treatment outcome assessments that occur during patient-provider visits in the clinic, wherein there are powerful psychosocial interactions. Original ODI terms may take on different meanings in translations.
4. Objective measures of physical capacities (trunk bending, lifting, walking) are more important than subjective reports of pain and disability. PRO (35%): pain complaints and self-reports and measurements of physical function do not correlate strongly. Physical capacities are more measurable, reliable, and reproducible. They may indirectly measure pain in that on a bad day a given patient may be able to do less than what he or she can do when pain-free. CON (65%): physical capacity measurements do not accurately indicate how the patient functions in his or her environment, because they are affected by fear avoidance. Objective measurements must be compared with the patient's needs. Subjective reports reflect the patient's reality, which is what prevents people from doing things. Physical performance is subjective, in that it depends on current and anticipated pain levels and on willingness and effort. Self-reports are more stable and predictive over time than objective measures.
5. There is no reliable way to measure patient satisfaction. PRO (39%): satisfaction is highly subjective, and a patient's level of satisfaction with the same outcome may change over time. Satisfaction depends too much on multifactorial "external" circumstances to be captured with a single measure. The scales require better definition. Measurements must clarify the sources of satisfaction: treatment, outcome, and care received. A patient may be satisfied with his or her pain level, but not with his or her functional capacities, and vice versa. Patients may exaggerate satisfaction to please the provider. Satisfaction is too dependent on the patient's expectations. The overall assessment of treatment value must recognize that 2 patients with the same questionnaire scores can have very different levels of satisfaction due to differing goals and expectations, which should be considered in planning treatment in the first place. CON (61%): some questionnaires are reliable and validated. Personal interview is the best measure. Achievement of the patient's goals, which is measurable, may be the most important component of patient satisfaction. Questionnaires must differentiate satisfaction with the specific treatment outcome from more general assessments of satisfaction with life.
6. Patient satisfaction is too influenced by nonspinal issues to be useful in measuring spinal treatment outcomes. PRO (49%): satisfaction is very important, but it requires multifaceted questionnaires. Goal setting may clarify and account for nonspinal issues, but it may require unavailable clinical skills and may be too time-consuming for some clinical settings. CON (51%): satisfaction depends on pretreatment information and on the patient's beliefs, personality, needs, and desires. Consideration of "nonspinal" issues is critical for treating the whole patient. The reason for satisfaction is irrelevant: what matters is simply whether or not the patient is satisfied.
7. Private or government-provided insurance data is the best source for determining medical costs. PRO (57%): there is no other good source. CON (43%): both patient and payer want to know what the treatment will cost them, not just what costs may be reported in large data sets. Cost can play a major or minor role in patient satisfaction, and pretreatment cost information varies greatly between countries and even between providers in the same area. Insurance systems vary from country-to-country. The quality of insurance data is poor, and it can be influenced by

- reimbursement negotiations. Insurance data omit uncovered, out-of-pocket, indirect and societal costs.
8. There is no good way to measure the cost of disability. PRO (56%): financial costs are difficult to measure, and impact on the quality of life impact is even more so. The cost to the payer is not the same as the cost to the patient. Country-to-country differences are confusing. CON (44%): the concept of quality adjusted life years holds some promise.
  9. There is no reliable way to measure posttreatment worsening of pain or disability. PRO (36%): subjective outcomes are not reliable for a given patient. Group mean differences are not sufficient. Percent improved or worsened could be used instead. Prospective monitoring over time is work intensive and expensive. Pretreatment discussions of risk can affect treatment choice and especially outcomes, depending on resulting expectations. CON (64%): pretreatment and posttreatment differences in pain and disability can be measured and compared.

Lessons learned from the ISSLS survey and the patients in Talking Back. The inescapable and overwhelming take away from these 2 sources is that our traditional measures of treatment outcomes have fallen woefully short of answering the most fundamental question for each person disabled by back pain: “What is the best treatment for me?”

In 1962 Thomas S. Kuhn, published his book, *The Structure of Scientific Revolutions*, and introduced the concept of paradigms.<sup>4</sup> By this term he meant, “...models from which spring particular coherent traditions of scientific research.” Since the 1970’s, the randomized controlled trial (RCT) has dominated the back pain research world as the preeminent paradigm. However, over the decades since their arrival on the research scene, RCTs of treatments for back pain and disability have generally produced limited and often conflicting conclusions. As a result, we are left with RCT-derived treatment guidelines that offer patients and their care-givers lists of qualified suggestions, but no clear “best” answer for the particular patient. Kuhn observed that, “Failure of existing rules is the prelude to a search for new ones.” Now is the time for a new paradigm.

Where to Now? Thinking Outside the Box of RCTs. May I suggest a new approach, if for no reason other than to inspire others to raise their own novel paradigms? Rather than persisting in costly and complicated studies of

how randomly assorted groups of supposedly similar patients with a given medical condition respond to a treatment, think backwards from the goal of prescribing the best treatment for each individual patient. Recalling the Osler-attributed maxim, “it is much more important to know what sort of patient has the disease than it is to know what sort of disease the patient has,” consider searching for what it may be about each patient that one needs to know in order to match him or her with the best treatment. Above and beyond more traditional quantitative demographics and diagnosis, recent reports of personal goal achievement driving patient satisfaction suggest that the most important patient characteristics in the new model may well be narrative and qualitative; relating to beliefs, attitudes, and goals.<sup>5</sup> Future researchers, armed with large patient data bases and registries, both quantitative and qualitative data collection and analysis techniques, machine learning models and artificial intelligence, might consider creating models in which very personal profiles (VPPs) of patients who have had success or failure with treatment could be developed. Continuously improving algorithms derived in this way might then enable a patient to self-identify with a specific virtual VPP and select the best treatment accordingly. That patient, should surgery be indicated, for example, would then not waste time, effort, and resources seeking manual therapy, injections and the myriad other nonoperative options. Another patient, reassured by their VPP link with a high likelihood of spontaneous recovery, might avoid useless therapies all together.

In closing, I would like to repeat my thanks to my ISSLS colleagues and to the patients who contributed to Talking Back for making the 2022 Treatment Outcomes Survey possible, and to convey best wishes and encouragement to the next generation of researchers looking for better answers to the patient’s fundamental question, “What is the best treatment for me?”

## References

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