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Outcome Measures in Spine Surgery: How Far Can we Go Building Evidence?

Relvas H*, Fernandes O and Oliveira R

[1]Portuguese Red Cross School of Health, Lisbon, Portugal

[2]Science & Technology School, Évora University, Portugal

[3]Human Kinetics Faculty, Lisbon University, Portugal

Review Article

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***Corresponding author:** Henrique Relvas, Portuguese Red Cross School of Health, Lisbon, Portugal, Av. Ceuta 1 Ed. Urbiceuta 1300-125 Lisboa - Portugal Email: hrelvas@esscvp.eu

Abstract

There is an imperative need to alleviate the actual and predictably harder burden of spine disorders and particularly the share due to chronic nonspecific low back pain, both at the individual and community-based viewpoint. Studies on global health trends charge a relevant part of the onus to the proposed invasive procedures, raising concern over its inappropriately high and growing use, counteracting clinical guidelines recommendation of a prudent selection of patients, based on clear-cut indications.

Part of this gap between evidence and practice stands from questionable assumptions regarding the usefulness of surgery. Uncertainty on relative benefits and harms in the face of increased risk of adverse events, or the higher costs and health care resources involved, results in controversial decision-making to plan the intervention.

Improvement of knowledge about these questions can be provided by the inclusion in the research agenda of comprehensive and standardized evaluation of outcomes after spine surgery. Such a protocol procedure would enable future systematic reviews to perform a consistent meta-analysis of data from trials, mandatory for high-quality evidence gathering. Outcome evaluation requires both subjective and objective assessments.

This review aims to clarify the role of outcome measures in support of the need to build reliable information on the effectiveness of surgical treatment of spinal disorders.

Keywords: Spine surgery; Spinal disorders; Outcome measures; Evidence-based practice

Introduction

Despite the increasing body of evidence on the management of spinal disorders, studies on global health trends reveal a concerning spread of disability due to low back pain, with a considerable burden both to individuals and community.

This review starts to point out updated information on the global impact of back pain and how clinical guidelines

implementation fails to promote best practice to quality care.

Controversial issues on the use of spinal disorders surgery are discussed regarding benefits and harms.

The role of outcome measures is clarified supporting the need to provide stronger evidence on the effectiveness of surgical treatment of these conditions.

The Global Burden of Spinal Disorders

According to the 2016 Global Burden of Disease study, the prevalence, incidence, and impact associated with low back and neck pain rose up to 50% more since it was first measured in 1990, with low back pain remaining the single leading cause of years lived with disability, and neck pain the fourth [1]. About one billion people worldwide suffer from these conditions throughout a period greater than three months duration [2]. Such an impact is predicted to rise, as mortality rates decline, life expectancy increases and global population ages, associated with the growing prevalence of risk factors for overall musculoskeletal conditions [3].

A substantial burden on society also derives after estimation of the total economic costs associated with the consequences and management of spinal conditions. Studies from many countries attempted to provide useful data, but methodological heterogeneity made it difficult to retrieve a clear global picture from them [4]. Particularly critical is the limited quality of the scarce studies carried out in less-developed rural communities, medically underserved areas and low- and middle-income countries, precluding a more comprehensive knowledge of the subject [5] (Figure 1).

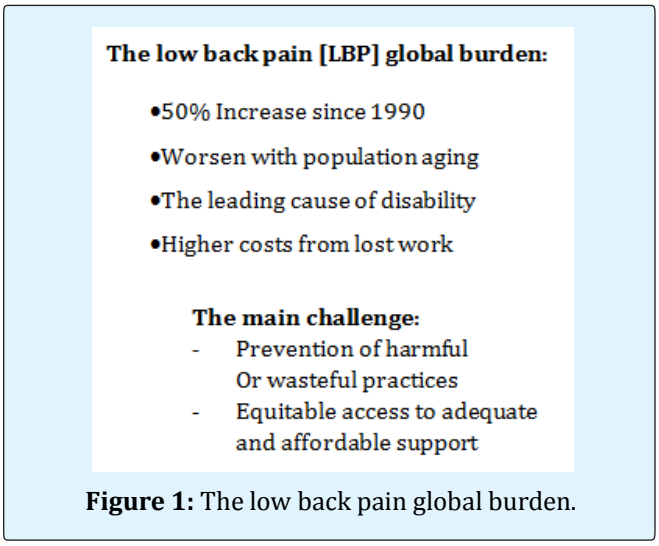

Figure 1: The low back pain global burden.

Studies providing data on estimates of total costs associated with back or neck pain reveals that the most significant share is related to indirect costs resulting from lost work productivity [4]. As an example, in the USA, 25.5 million adults lost an average of 11.4 days of work due to back or neck pain in 2012, adding up to 290.8 million lost workdays in that year alone. The same report estimates 284 billion dollars of annual direct costs treating these conditions in the year before, a quarter of this amount being spent on hospitalizations, with discharge to long-term care nearly twice as those for any other health condition [6].

Such a significant impact on people's lives, health-care systems, and community resources, demands a call for action [7], being the global challenge the prevention of harmful or wasteful practices while providing equitable access to adequate and affordable support to whom may need it. In fact, many international initiatives already address back pain as a significant problemfor the public health in overall setting [8].

Clinical Practice Guidelines to Improve Care

There is a widespread agreement on the need to alleviate the consequences of the actual and predictable future burden by increasing high-quality research on risk factors assessment and prevention, and identifying patient-centered, evidence-based, cost-effective and context-specific strategies for the management of spinal conditions. Many recommendations arising from clinical practice guidelines [CPGs] were therefore made available around the world to inform all the protagonists involved [9].

However, in a recent review, the overall quality of CPGs for musculoskeletal pain conditionswas identified as generallypoor, with only eight out of 34 rated as high quality [10], two of which for low back pain [11,12] and one for neck pain [13]. The authors also mentioned how other spinal conditions are under-addressed:only four CPGs addressed neck pain (even being the fourth leading cause of disability as reported above), and no CPGs for thoracic spine pain (although a point prevalence of 72% in young females and one month prevalence estimates of 15.8% to 34.8% [14]).

Spinal Disorders Treatment and The Gap Between Evidence and Practice

While these efforts take place, a profound contrast exists between recommendations from best practice

guidelines, in line with the evidence for the cost-effectiveness of strategies proposed to prevent and treat spinal disorders, and what happens in the real practice, whatever the income setting [9].

The most habitual obstacles are pointed out both to health professionals and population in general, as lack of awareness or an uneven distribution of available guidelines and existing knowledge [10,15]. On the other hand, adherence to known guidelines seems to be a broad issue among clinicians, with substantial average delays as 17 years being reported for the adoption of evidence from randomized control trials into clinical practice [16], representing a consistent resistance to change (Figure 2).

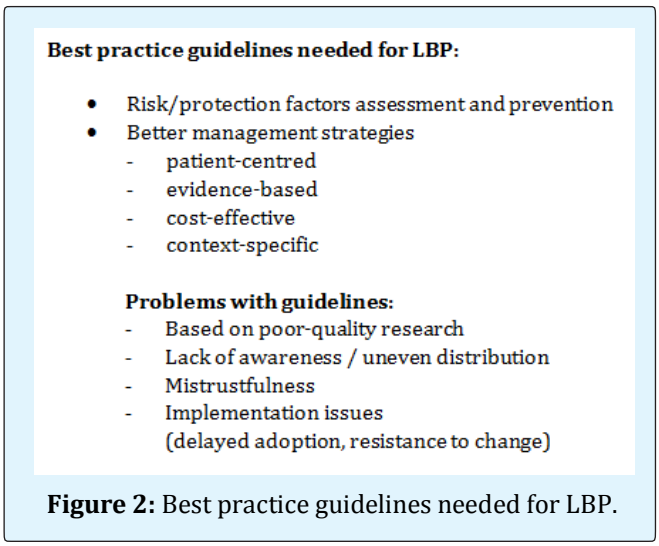

Figure 2: Best practice guidelines needed for LBP.

Common examples of cost-ineffective, health staff over workload and non-evidence based practices are presentations toemergency services and liberal use of diagnostic imaging, opioid prescription, and invasive treatment like spinal injections or surgery, without an improvement in patient outcomes due to patient selection mismatches at primary care level [9,15,17,18]. CPGs should reflect these discrepancies and highlight the crucial role of primary care assistance to promote optimal management pathways of spinal disorders at the baseline, and coherent follow-up at referral levels.

Spine surgery for back pain is one of the most controversial issues, regarding uncertainty on relative profits and risk of adverse events [19], in the face of the much higher amount of costs and health care resources involved. Instead, a broader consensus is achieved whenever the referral is based on the presence of severe or progressive neurological impairments [20], or conservative treatment has failed, and there is a clear association of symptoms with imaging findings of structural trouble/pathology, like herniated discs or spinal stenosis [12].

Although limited evidence exists to support this treatment option, the widespread and growing use of invasive procedures in the management of low back pain, especially in high-income countries [9] is adding some concern over these trends. In contrast with conservative approaches, the higher costs and the probability of immediate or late complications, which are inseparably tied to any surgery, request straightforward and explicit indications to the right treatment pathway, driven by updated and high-quality recommendations from CPGs. In fact, indicationsforsurgeryare advocated following unambiguous criteria.

The most usual surgical techniques proposed for back pain show conflicting evidence about their outcomes:

- Discectomy for a herniated disk with radiculopathy results in a faster relief than conservative treatment, but the benefits diminish after a year [20].
- Laminectomy for symptomatic spinal stenosis tends to have some benefits, but improvement results with or without surgery [21].
- Spinal fusion for non-radicular low back pain associated with degenerated discsimaging has benefits similar to those achieved by intensive multidisciplinary rehabilitation and modestly higher than standard non-surgical management [19].
- Spinal fusion after decompressive surgery for symptomatic spinal stenosis, with or without degenerative spondylolisthesis, does not increase outcomes [22-24].
- Disc replacement instead of spinal fusion demonstrated no clinical difference for pain or function in both the short and long-termand showed higher numbers of adverse events below four months [12].
- Interspinous process device decompression instead of conventional decompressive surgery is not supported by sufficient evidence about any advantageous beneficial effect [25].

These procedures have an insufficient evidence in cases of acute low back pain (less than six weeks), and only represent a second-line or adjunctive treatment option in cases of persistent low back pain (more than 12 weeks), where spinal fusion have an uncertain role [17,26] and only offered to patients if part of a randomized controlled trial [12]. Disc replacement should not be offered at all [12] (Figure 3).

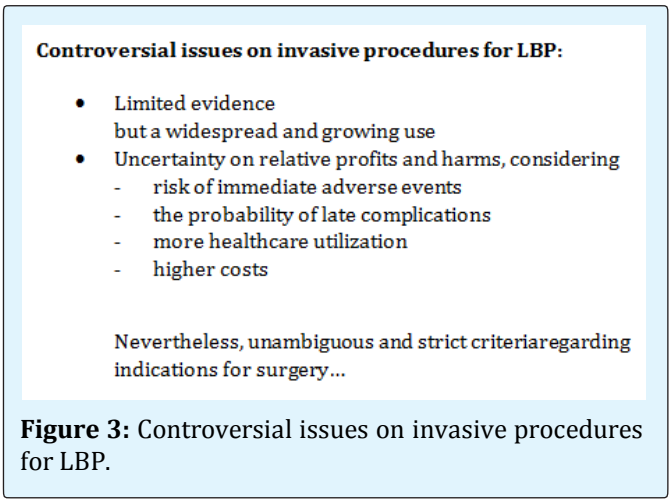

Figure 3: Controversial issues on invasive procedures for LBP.

Clinical research on this subject seems to be biased by a marked tendency to analyze variations in surgical technique instead of looking to clarify what are the indications, if any, for surgery of spinal disorders. In this way, addressing the wrong question by missing the focus on the key problems is pointed out as having a little impact on patient outcomes and lesser evidence to help them regarding surgical intervention [27]. As a result, a paradigm shift about the role of back pain surgery is being delayed.

Current recommendations propose a shared decision-making process between clinicians and patients, to clarify the best choice considering benefits and harms, costs and effectiveness, different surgical techniques, and treatment alternatives. Although toughly implanted in modern approaches driven by patient-centered healthcare and argued as a way to facilitate clinicians use and patient adoption of CPGs with results in outcome improvement, no studies to date support or reject its use in the musculoskeletal pain field [28].

Building Evidence upon the Right Outcome Measures

There is a general agreement that trustworthy CPGs are based on high-quality systematic reviews of evidence [29]. In turn, quality of systematic reviews depend on the methodology used to assemble, appraise and summarize all relevant studies that address a specific clinical question, in a way that limit bias, which in the end mirrors the value of the research methods used by the individual studies, ideally in the form of a randomized controlled trial [30].

Trial selection in clinical research results after the application of inclusion and exclusion criteria. At that stage, a choice is made about the reported outcomes to be extracted and reviewed and those to be excluded, if any [30], from the whole set of measures that the trial team decided to report to quantify changes related to the subject under research. At both levels of decision, erratic or missing outcome data can lead to significant reporting bias, affecting the quality of evidence within a systematic review [31].

Outcome selection should be relevant to patients, clinicians, policy-makers, and stakeholders if systematic reviews of clinical research trials intend to influence practice, future research, and funding. Meta-analyses of clinical trials are unable to include data from all the relevant studies if outcome measures have not been consistently chosen. Outcome measures heterogeneity is a problem across back pain trials, affecting the consistency of reporting and completeness of the description, rendering difficult to accomplish a systematic review, hampering comparisons between studies [32].

The COMET (Core Outcome Measures in Effectiveness Trials) Initiative [http://www.comet-initiative.org/] developed a standardized approach to reporting, to be agreed and pursued among researchers in the form of a core outcome set [COS] that would benefit the systematic review process by increasing the amount of disposable information for use in a meta-analysis [33]. The agreement ensures that important outcomes are consistently assessed but does not preclude the choice of primary or secondary outcomes out of the COS. Only a small number of trials distinguish primary and secondary outcomes or fail to indicate a single primary outcome, which presents a major issue of reporting bias. Recommendations for interventiontrial protocols already include the need to identify primary and secondary outcomes [34].

The lack of an outcome classification system resulting in inconsistency and ambiguity across different studies, and inefficiency in searching published literature, was solved by a proposed new workable outcome taxonomy, the robustness of which has been demonstrated in reliable databases [35].

The initiative joined an international multidisciplinary panel to develop a COS applicable to clinical trials in patients with non-specific low back pain [nsLBP], having reached a consensus on four core outcome domains [36]:

- Physical functioning;
- Pain intensity;
- Health-related quality of life [HRQoL];
- Mortality.

More recently, a new study was conducted to build preliminary updating recommendations specifying a set of outcome measurement instruments for the first three core domains above mentioned, to be used in every clinical trial in patients with nsLBP, both acute and chronic, and updated as further evidence becomes available. An initial set of 25 potential patient-reported outcome measures [PROMs] were selectedregarding their measurement properties, feasibility, frequent use and approval in clinical trials from the nsLBP literature [33]. After a Delphi process to build consensus, only five achieved a place in the recommendations:

- The Oswestry Disability Index version 2.1a (ODI 2.1a [37,38]) or the 24-item Roland Morris Disability Questionnaire for physical functioning;
- The Numeric Rating Scale with a 1-week recall period for pain intensity;
- The Short Form Health Survey 12(SF12 [39]) or the 10-item PROMIS Global Health (PROMIS-GH-10 [13]) for HRQoL.

Standardization and uniformity in outcome data collection brought to spine surgery research the same advantages, with cross-study comparisons more feasible and interpretable, building a stronger evidence-base for spine treatments. Twenty year after the first major initiative proposed by Deyo and colleagues [40], PROMs are increasingly requireddue to their stronger clinical significance as metrics for testing and approval of approaches and devices [41-46].

SPINE TANGO, an international spine registry system [https://www.eurospine.org /spine-tango.htm], with a large web-based spine surgery database, proposes an adaptation of previous core sets, focused specifically to back and neck surgical patients, with translated tools for the different languages of the participating countries [47,48]. Determination of the "minimal clinically important difference" for improvement and deterioration after spine surgery, on the patient's viewpoint is particularly stressed [49], as the standard for determining the effectiveness of a given treatment and describing patient satisfaction in response to that treatment.

The most recent UK guidelines on invasive treatments (including surgery) of low back pain and sciatica [12] agree with the previously mentioned core outcome set but consider psychological distress outcome measures equally critical for decision making. Responder criteria for pain and function, adverse events, revision rate, failure rate and healthcare utilizationwere also considered as important.

Other initiatives like the International Consortium for Health Outcomes Measurement [ICHOM/http://www.ichom.org/] have conducted a survey to define a core set of standardized outcomes, having agreed with the basic three domains, but adding attention to work status, treatment complications, and medication requirements [43]. Psychosocial factors were excluded as they are probably reflected in the quality of life domain [50] (Figure 4).

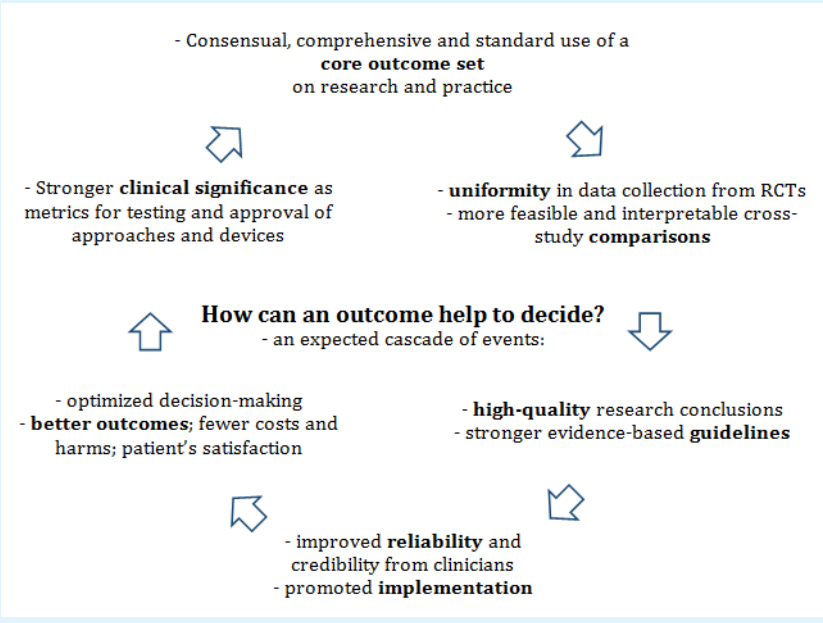

Figure 4: Cascade of events following a systematic use of a core outcome set.

Pitfalls of Patient-Reported Outcomes

There is an implicit commitment from all the health community to focus on patient-centered care, assuming that is crucial to understand how each considers and assesses his health and quality of life [51]. In this sense, outcome measures based on the patient's reportsare increasingly relevant to validate the effectiveness of therapeutic interventions. The confounding subjectivity of its nature ends up being its most powerful argument. Following the ICHOM statement: "… [patient-reported] outcomes are the ultimate measure of success in health care". Economic costs and reporting of outcomes from providers with the participation of patients is driving some focus on the concept of "value-based healthcare" defined as the outcomes of care divided by the cost, with interesting effects on the quality of care [52,53]. With evolving reimbursement systems, it may be conceivable that payment levels adjust based on outcomes [43].

Nevertheless, Schwartz and colleagues [45] account for pervasive paradoxical and counterintuitive findings when such evaluative rating scales are used, raising questions about what they assess and how scores should be interpreted. A good cited example is the "disability paradox", where persons with significant disabilities report good to excellent quality of life. By integrating psychological factors along with patient attitudes and beliefs, PROMs have the potential to cause bias in outcome evaluations [54].

Inconsistent findings are also found in spine surgery in the form of discrepancies between clinical measures and self-reported ratings, affecting comparisons among individuals and within-persons over time [55]. Changes in the appraisal of well-being, symptoms, and functional health may reflect one's values and conceptualization of quality of life induced by experience. In spinal surgery, this "response shift" phenomenon can cause the patient to use the same functional outcome report measure differently pre- and post-treatment [55]. These differences on estimates of treatment benefit may influence the conclusions of clinical trials and cost-effectiveness studies.

Another possible source of misleading interpretation of patient-reported data in spine surgery trials is the fact that patients could not reasonably be blinded to the intervention. Such a subjective outcome like pain can be modulated under the influence of significant placebo effects associated with the surgical procedure. Particularly in studies comparing surgery versus nonsurgical intervention, bias is likely to happen due to overestimation of benefits, challenging the interpretation of these outcomes [56].

Finally, patients with spine troubles have different clinical and behavioral presentations of their symptoms, according to the neurophysiological mechanisms underlying its origin or stage, experiencing either nociceptive, neuropathic, or central sensitization pain predominantly. This heterogeneityrequires careful interpretation of reported outcomes from ambiguous nature and subgrouping classification of this population to select preferable management strategies in clinical practice [57,58].

The Need for Objective Outcome Measures

Without any detraction to the already praised advantages of patient-reported outcomes, provided that they are used systematically and combined in a consensual core set, it seems reasonable that more objective measures, assessing other issues less prone to uncertainty and bias, could reinforce evidence from trials looking for the effectiveness of spine surgery.

Objective assessment of body structure and functioning is performed for many purposes to quantify impairments or merely to evaluate integrity or measure the exertion of physiological systems. Biophysical factors are identified as importantcontributors to low back pain and disability [8], therefore sensitive to change under the effect of treatment strategies, including surgery, becomingpotential outcome dimensions (Figure 5).

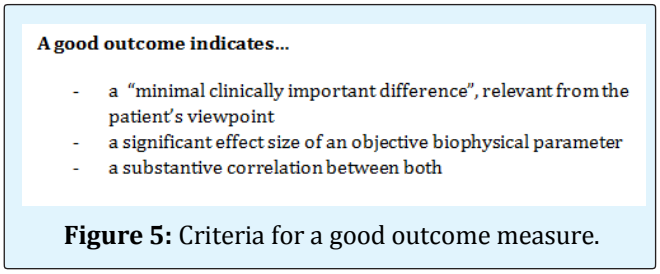

Figure 5: Criteria for a good outcome measure.

If a significant effect size between healthy controls and patients with spinal disorders is found during statistical data processing of a parameter, then it may be eligible as an objective outcome measure to assess the efficacy of surgery to that condition. It could be used to check how much does it improves and how long is it sustained after surgery; what are the baseline differences of that outcome between those who benefit from surgery and those who don't; and finally what are the correlations between the level of a subjective outcome score and the measures of that parameter [59].

Unfortunately, potential pathoanatomical contributions to back pain and many physiological outcomes such as electromyogram activity, spine mobility, or straight leg raising results have a controversial or poor association with pain severity or functional status [41,60,61].

Pathoanatomical Factors

At first instance, back pain surgery aims to repair damaged tissue presumed as possible nociceptive source of pain in the spine, decompress compromised neural tissue, stabilize abnormal intersegmental movement, or correct alignment impairments or deformities. Disc herniations, Modic changes, annular tears, and spondylolisthesis, are examples of imaging findings (e.g.,Rx, TAC, MRI) commonly suggested as contributors to the problem [61]. The term "non-specific" used to classify the most prevalent form of low back pain points out the difficulties in confidently identifying a specific pathoanatomical cause like a vertebral fracture, malignancy, or infection, only present in a small proportion of patients [8,62].

Evidence is missing on whether changes in that kind of imagingfindingsare associated with changes in clinical outcomes, although moderate evidence shows a favorable natural course of herniations and nerve root compression over a relatively shortperiod [61]. Furthermore, lumbar degenerative alterations are prevalent in the asymptomatic population [63], questioning the beliefs that spinal fusion should apply to solve degenerative pathology as a cause of back pain [27].

Postural Alignment

In a study of the general adult population, sagittal standing posture was not reliably related to quality of life in males, but females presenting high pelvic incidence and sacral slope showed increased odds of severe back pain [64]. Those parameters of spinopelvic angulationare determinants of the spine sagittal balance [65,66] and highly correlated with back pain, by the influence of lumbopelvic alignment on vertebral mechanical stress and muscle workload during maintenance of posture [67].

Reconstructive fusion surgery of adult spine with degenerative deformities may result in a fixed sagittal imbalance, depending on the locked position of the fused vertebrae. The consequence is loss of lumbar lordosis with forward inclination of the trunk, decreased sacral slope, increased pelvic tilt and decreased thoracic kyphosis. This compensatory mechanisms aggravates previous damage due to physiological aging and may become a significant cause of chronic disability [68]. During lumbosacral arthrodesis, the mainchallenge is how it addresses optimal sacral alignment dealing with the risk of failing to correct or causing excessive retroversion of the sacrum [67].

On follow-ups, specific surgical alterations in this spinopelvic parameters are correlated with postfusion back pain and a higher risk of adjacent segment degeneration, and a predictive factor for degenerativespondylolisthesis. In contrast, restoration of normal lumbar lordosis and anterior pelvic tilt after surgeryis correlated with a good outcome [67,68].

Sagittal alignment also plays an importantrole in outcomes after surgical correction of adolescent idiopathic scoliosis, but most of the significant correlations between spinopelvic parametersand clinical/functional outcomesfound in adult spinal deformity surgery, do not apply here [69]. Therefore, there is aneed for prospective comparative studies that consider pre- andpostoperative measures of radiographic spinopelvic parameters of sagittal balance and compare complicationrate and a standard core set of patient-reported outcomes, to prevent functional disability and provide more robust evidence on the effectivity of adolescent and adult spinal deformity surgery.

Postural Control and Balance

For any given task, several control strategies will ensure a stable spine, protecting against injury and pain, chosen to emphasize performance or reduced metabolic costs [70]. Evidence points out that people with low back pain have different control strategies than healthy individuals, using higher levels of trunk muscle co-activation as a protective coping scheme, exhibiting a rigid postural control with lesser variability in the range of options from their motor behavior repertoire [71,72]. Structural and functional changes of the deep trunk muscles (transversus abdominis and lumbar multifidus) are also reported such as inhibition, delayed onset, atrophy, fatty infiltration and muscle fiber type mutation [73-75].

After spine surgery, studies also show that besides pain interference [76], patients may present some form of sensorimotor impairments compromising their motor performance [77,78]. Proprioceptive deficit is referred as remaining from preoperative neural tissue compression or consecutive to surgical iatrogenicity by afferent denervation and dysfunctional central processing due to changes in spinal curvatures or insertion of rigid segments into a previously mobile linked system [79].

Assessment of postural control by measuring body sway during stance over a force platform is used to evaluate changes in motor performance due to spinal disorders or the outcomes of its management strategies [80,81]. The trajectory of the center of pressure [CoP] of the ground reaction force under the feet is a measure strongly related to the movement of the body's center of mass, and its quantification is applied to interpret balance behavior.

To our knowledge, only one systematic review was conducted on the use of postural control measures in spine disorders surgery. Yen and colleagues [82], analyzed the seven studies that met the full set of criteria, including the use of balance assessment tests pre- and post surgery (four on spinal fusion for scoliosis, two on decompression surgery for disc herniation, and one on spinal fusion for chronic low back pain). The most common parameters used were range/area, traveled distance, and velocity of CoP, assessed on force platform during upright stance.

Data analysis from spinal fusion for scoliosis surgery in adolescents revealed that body sway increased immediately following surgery but gradually reduced approaching the 1-year post spinal fusion assessment, denoting a prolonged period required for the proprioceptive system to adapt to changes in body posture and reach optimal truncal balance. For patients with disc herniation, all sway measures decreased immediately (3–4 days) post surgery. This improvement in postural balance is interpreted as patients having increased the role of hip strategy while standing, previously avoided due to increased back pain as a consequence of the heightened motion of the spine and its muscles [78].

Overall recommendations from this review indicate the need of longer follow-up times, assessed correlation with levels of reported pain, preference on time domain parameters over frequency domain (especially CoP velocity and sway area), and eyes-closed condition as more sensitive for identifying alterations in balance behaviors pre and post spinal surgery [82].

All studies in Yen's review used standard linear measures to quantify the amount of sway read from posturographic data as an index of postural stability, assuming that less sway means better control. However, the magnitude of this variability around an average fails to account for the structured temporal organization of motor behavior, in the form of how a body sways to keep balanced or in the movement patterns during dynamic task performance [83,84]. The concept of nonlinear dynamics suggests that complexity of motor behavior is the best measure of its variability, meaning to say that complexity can be revealed by nonlinear measures of the regularity and variability of motor output over a time series [85]. Combining linear and nonlinear tools (e.g., sample entropy, Lyapunov exponent, autocorrelation) can provide a comprehensive interpretation of the functionality of postural sway, useful to unveil different underlying motor strategies adopted in response to pain and other influences from pathology or treatment approaches [86], and become a significant set of outcome measures to apply in spine disorders/surgery patients.

A limited number of studies exist using other objective methods of motor performance assessments applied longitudinally following spinal treatment procedures. Examples include gait analysis [87,59,88] and other kinetic and kinematic analysis of range of motion and movement patterns using 3D video motion analysis [89], electromagnetic tracking systems [90], inertial sensors [91,59], electronic inclinometers [60], EOS imaging system [91,92], 3D CT scans [93,94], digitized dynamic X-rays [95-100] and motion analysis software (Figure 6).

Conclusions

Although implementation issues blur best practice based on already proven evidence, there is still a room for improvement of knowledge about the effectiveness of surgical treatment of spinal disorders, looking to optimize decision-making on those cases without a clear indication for surgery.

The inclusion of comprehensive and standardized evaluation of outcomes after spine surgery in the research agenda will enable future systematic reviews to perform a consistent meta-analysis of data from trials, mandatory for high-quality evidence gathering. Outcome evaluation requires both subjective and objective assessments.

Subjective outcomes should be patient-reported and use consensual measures of pain intensity, functionality, health-related quality of life, defining a primary core set for systematic application. Psychological distress and work status should be considered if not accounted in global quality of life measures. Further effort is still required to develop a universal international set of outcomes, available and validated in many languages to be measured and compared as a part of standard clinical practice.

Mortality, adverse events, revision rate, failure rate and healthcare utilizationshould be consideredrelevant outcomes to include in spine surgery trials.

More studies should be encouraged to apply and develop objective outcome measures, harvesting stronger evidence of the impact of surgery on the patterns of posture and movement. Kinetic and kinematic measuring tools to study biomechanical and neuromuscular functions under the effect of constraints due to surgical procedures or subsequent rehabilitation approaches should have a more widespread diffusion. A better analysis of the correlations between subjective outcome scores and the measures of motor behavior parameters will provide reliable and useful information.

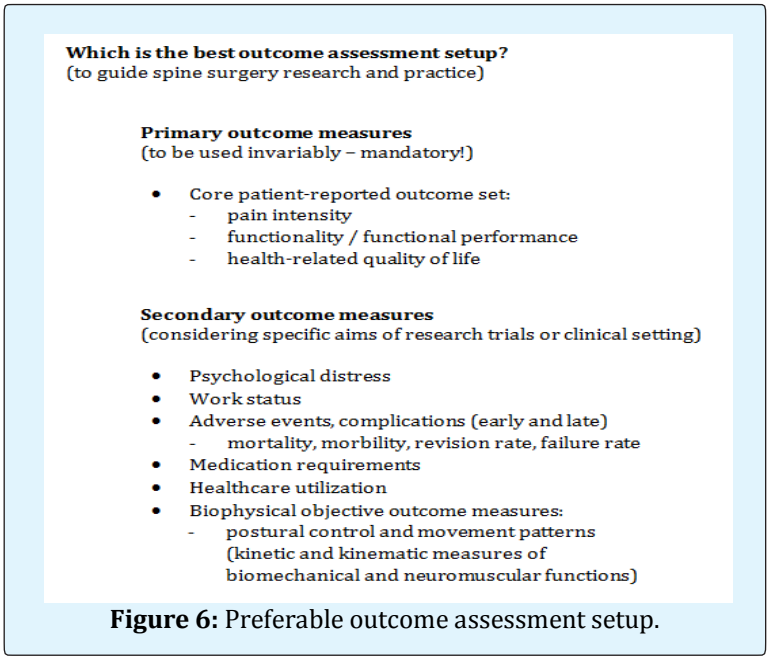

Figure 6: Preferable outcome assessment setup.

Promoting high-quality research on risk factors assessment and prevention and identifying the best patient-centered, evidence-based, cost-effective and context-specific strategies for the management of spinal conditions, we will undoubtedly be at the frontline in this call for action to relieve the burden.

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