



From the Subjective to the Objective era of outcomes analysis: how the tools we use to measure outcomes must change to be reflective of the pathologies we treat in spinal surgery

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An *outcome measure* is an instrument used to evaluate a patient's clinical status at a point in time. Outcome measures provide an interpretation, a score, or a risk categorization of a patient. In spine surgery, or indeed with any intervention, an outcome measure provides baseline metrics, or a 'measurement of disability'. These results assist to determine a plan of treatment. The same tool/s may be used in successive assessments to establish whether a patient has demonstrated change. Therefore, outcome measures need to be credible and reliable to justify an intervention, especially if invasive or with risk. Outcome measures fall within the spectrum of highly subjective to highly objective tools available for the clinician and researcher. Subjective measurements rely on human judgment, such as "How is your back pain today?", often with great variability in reporting. Objective measurements are quantifiable, impartial, and recorded with a diagnostic instrument, such as an oximeter for blood oxygenation or wearable device to measure step count.

In addition to the highly subjective VAS Pain Scale Score, the Oswestry Disability Index Questionnaire (ODI) is the most used subjective measurement tool used in the assessment of lumbar spine pathology. The ODI reflects important aspects of functional and pain-related disability in activities of daily life. ODI is self-administered, validated and a consistent questionnaire used to evaluate and plan further therapy and treatment options in patients with lower back problems. It remains one of the primary tools used to assess intervention recovery, however it is measured at single timepoints and is highly variable depending on patient psychology, potential secondary gain, or disability at

the moment of data capture. The 'spot check' nature of this scoring method does not provide a continuous picture of recovery, nor the peaks and troughs that may be an insight into the benefits of rehabilitation or the first signs of post intervention complications.

Subjective *vs.* Objective tools are contingent on the concepts of validity, reliability, and bias. *Validity* refers to the quality of the measurement and its capacity to assess the patient outcome or underlying scientific question. *Reliability* means that a measurement will repeatedly capture the same information each time when no change occurs. *Bias* is how accurate/inaccurate the measurement is to reality. In general, objective measurement tools are more valid, reliable, and unbiased, however this may not always be the case. Let's say we use a step counter after fusion surgery to see how well a patient is improving. While the number of steps is technically an objective measurement of movement, and a validated tool to gauge recovery post intervention, it needs reinforcement by patient inputs such as their pain perspective (VAS) and need for assistance (ODI). Many would argue that both measurement tools are necessary to paint the complete picture. It is authors opinion that both tools are of benefit, however the continuous nature of objective data capture with wearable devices paints a unique and immersive portrait of the overall recovery, or the 'kinetics' of recovery, rather than a single 'spot check' assessment.

Lumbar spinal stenosis (LSS) is an excellent example of a pathology that would benefit from a balance between subjective and objective measurement tools. In the article from Betteridge *et al.* (1), the authors have quantified the gait

metrics of patients with LSS as compared with a normative population. These metrics can form a baseline indicator of degree of severity for patients presenting with LSS. This data is in addition to previous reports linking objective and subjective tools for LSS using the validated measure of GPi which incorporates step count, walking speed, step length and body angulation during walking (2). Objective measurement of gait performance using wearable sensors for LSS presents a powerful and non-biased assessment of pre intervention disability and post intervention recovery (3). Subjective tools add flavour to this assessment via patient perception of their global disability with patient reported outcome measures such as the ODI.

In summary, objective outcome assessments overcome the shortcomings of subjective, patient-reported outcome measures, which suffer from poor reliability, recall and reporting bias and a lack of capacity for continuous assessment. The information collected by an individual while living with a spinal condition however is more than just 'objective' or 'subjective'. We need to amalgamate these data streams into a composite score of health. The author recommends that spine care providers maintain a 'minimum data set' of outcome measures including:

Subjective (single time point assessment/"Human" captured):

- (I) VAS Pain Score;
- (II) Oswestry Disability Index;
- (III) General health measure such as the EQ-5D.

Objective (continuous assessment/"Device" captured):

- (I) Daily step count;
- (II) Walking speed.

The future of outcomes assessment will favour objective measures as these can be obtained by smart/wearable devices that constantly detect and record the true kinetics of health, rather than a 'spot check' approach of subjective patient reported outcome measures.

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