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Analysis of Change in Scores in Commonly Used Outcome Measures: What Can We Legitimately Assume about the Stability of Individual Patient Scores Based on Group Mean Scores?

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Introduction: It has been reported that in lumbar implant trials, there is little change in outcome scores after 6-month follow-up (Ohnmeiss, SAS J, 2009). However, not addressed in that study was whether stability in group scores is more appropriately attributable to each patient's scores remaining stable or if there is compensatory improvement and worsening between patients producing stable group scores. The purpose of this study was to determine the stability of individual patient scores during 24-month follow-up.

Methods: From a database of total disc replacement (TDR) patients and fusion patients, a group of 195 patients with follow-up data collected at all pre-defined time points through 24 months were identified. To determine if there was a significant change (improvement or worsening) in a patient's scores between follow-up periods, the MCID (minimal clinically important difference) value of 15% was applied to Oswestry scores and 1.8 to visual analog scale (VAS) pain scores. These values were also applied to the change between 6 and 24-month scores.

Results: Between 6, 12, and 24 month visits, the mean Oswestry and VAS scores were stable, not varying more than 0.5 between any two of these periods (Table 1). Six-month Oswestry scores were correlated to 12- and 24-month values (all $r > 0.70$). Similarly, six-month VAS scores were also correlated with later follow-up values (all $r > 0.60$). However, when applying MCID values to individual patient scores between time periods, some patients had stable scores and the percentages of patients with improved or worsened scores were very similar. This was noted for Oswestry as well as VAS scores.

Oswestry	% stable	% improved	% worsened	Mean change
6 to 12 mo	80.5%	9.7%	9.7%	0.3
12 to 24 mo	76.4%	12.3%	11.3%	0.5
6 to 12 to 24 mo	60.0%	23.1%	16.9%	0.2
VAS				
6 to 12 mo	69.2%	16.4%	14.4%	0.1
12 to 24 mo	68.2%	17.9%	13.8%	0.2
6 to 12 to 24 mo	49.7%	29.2%	21.0%	0.1

[Table 1. Changes in VAS and Oswestry scores.]

Discussion: The change in the mean Oswestry and VAS scores for the group of patients was near zero, indicating a high degree of stability in the mean values as has been reported in earlier studies. However, when applying MCID values to individual patient scores, 40% of patients had significant fluctuations in Oswestry scores and 50% had significant changes in VAS scores. Although mean group scores remain very stable during post-operative follow-up, it may not be legitimate to assume each individual patient's scores remain stable and therefore 6-month scores may not have a high predictive value of 24-month scores.