Investigating the Potential Effect of “Euphoric Bias” for the New Technology on Results of Randomized Lumbar Total Disc Replacement Trials
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Introduction: The results to date of the lumbar total disc replacement (TDR) vs. fusion trials have shown TDR to produce results similar or superior to fusion. The question has arisen if the results may have been influenced by patients' enthusiasm for getting the new technology, creating what we have termed “euphoric bias”. The purpose of this study was to compare the results of the same TDR device when randomized as the investigational group vs. its results when serving as a control group.

Methods: Charite TDR device was implanted in three different subgroups of patients at a single center: prospective FDA randomized trial (patients randomized to Charite or fusion) as the investigational device (n=48; investigational group), the same protocol under continued access (not randomized; n=12) and as the control device in the Kineflex-L FDA trial (n=28; Control group; patients randomized to one of the TDRs). Only patients with 24-month follow-up were included in the analysis. In all groups, the same version of the Oswestry Disability Index was used. All patients were treated for single-level disc degeneration at L4-5 or L5-1 unresponsive to a minimum of 6 months non-operative care. There were no significant differences between the three groups based on age, gender, body mass index, or level operated. Data were collected pre-operatively, and 6 weeks, 3, 6, 12, and 24 month post-operatively.

Results: There were no significant differences in Oswestry scores with respect to the TDR groups (Figure 1; ANOVA, p>0.05). All groups improved significantly by 6 weeks follow-up and remained improved throughout 24-month follow-up (p< 0.01). There was also no significant difference in the 24-month re-operation rate between the groups: 6.1% in the investigational subgroup, 0.0% in the continued access, and 3.6% in the control subgroup (p>0.05).

Conclusion: There was no difference in results when comparing TDR as the “new” investigational device to which patients were randomized (has been suggested that results were biased due to patients being pleased to get the TDR), patients knowing they would receive the same device as part of a continued access study, or when the same device served as the control, rather than the new investigational device.
This study found that the good results reported for TDR are not likely to be related to a euphoric bias created by being randomized to receive the “newest” technology.