Clinical: Prosthesis
424
Clinical Performance of an Elastomeric Lumbar Disc Replacement 24 Months Following Surgery
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Aim: Elastomeric lumbar disc replacements have been developed as a means to restore the normal shock absorption properties and physiologic center of rotation of the involved level. The Physio-L® is an elastomeric lumbar disc prosthesis which uses compliant polycarbonate polyurethane as the core material and has been designed to have enhanced endurance properties. A multi-center clinical trial is underway to determine the safety of the device in-vivo and the present study reports the 24 month clinical results.

Methods: Eighteen patients presenting with degenerative disc disease were treated by one of two surgeons at two clinical sites. Thirteen patients received treatment at a single level (L5-S1) while five patients received treatment at two levels (L3-L4/L5-S1, or L4-L5/L5-S1). All patients were assessed pre-operatively, and at 6 weeks, 3, 6, 12 and 24 months. Clinical outcome measurements included patient self assessment scores for VAS and ODI. Adverse events were monitored intra-operatively and at all follow up evaluations.

Results: Of the 18 patients, 14 were male and 4 were female. The patients had an average age of 39.2 years (range 25-55) and an average BMI of 25.4 (range 19.4-31.6).

Clinical outcomes: At the 24 month follow up evaluation, the VAS back pain score improved 65% and ODI scores improved 68% when compared to baseline. At the 24 month follow up evaluation, the VAS back pain score improved 80% and ODI scores improved 78% when compared to baseline. Statistically significant differences were observed at all follow-up intervals when compared to the preoperative scores.

Radiographic outcomes: There were no failures or migration of the implanted devices and all of the prostheses are mobile in flexion/extension. One patient has experienced caudal subsidence greater than 2mm.

Adverse events: During the surgical procedure, two patients lost greater than 1500ccs of blood requiring transfusion and one patient experienced vascular damage at L4-L5 that required further surgery to repair. These events were resolved without further incident and did not result in any adverse clinical effect post-operatively. At the six month follow up evaluation, one patient experienced retrograde ejaculation which was resolved at 12 months.

Conclusions: This study is the first to report 24 month clinical results on the next generation of total disc prostheses. While a longer term follow up of these patients is necessary, the initial two-year clinical data for the Physio-L lumbar disc suggests that elastomeric discs may provide a superior approach to treating degenerative disc disease.