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Effect of Operative Level and Lumbar TDR Design on Disc Height, Settling, and Subsidence: A Prospective Randomized Study Comparing an Unconstrained, Semi-constrained, and Constrained Implant

R. Garcia¹, J. Yue², P. Newman³, N. Wharton³, J. Hipp³
¹Orthopedic Care Center, Aventura, FL, USA, ²Yale University School of Medicine, Orthopedic Surgery, New Haven, CT, USA, ³Medical Metrics, Inc, Houston, TX, USA

Introduction: Appropriate implant sizing is critical to successful lumbar total disc replacement (TDR) outcomes. The goal of lumbar TDR is to recreate normal segmental characteristics such as disc height. Underdistraction of the disc space can be associated with post-operative nerve root irritation and possibly even impaired mobility. Oversizing of the implant can lead to implant migration or subsidence. Implant design may play a significant role in the disc height change achieved at surgery, and any post-operative loss of disc height.

Purpose: The purpose of the current study was to compare the effect of operative level and implant design on post-operative disc height in both the immediate and mid-term follow-up.

Methods: Patients enrolled in 2 centers participating in a prospective, randomized study comparing 3 different lumbar TDR implants were included. The implant designs included an unconstrained implant (Charite), a semi-constrained implant (Activ L), and a constrained implant (Prodisc). All patients had single level surgery at either L4/5 or L5/S1. Patients with either osteopenia or osteoporosis were excluded from the study. All data were collected prospectively. All radiographs were digitized and analyzed by an independent core laboratory (Medical Metrics, Inc.) using validated, computer assisted methods. Implant settling was defined as post-operative loss of disc height, and implant subsidence was defined as implant migration into vertebral bone greater than 3 mm. Follow-up times ranged from 3 to 24 months.

Results: Implantation of a lumbar TDR (n=87) increased disc height by an average of 5.4mm +/- 2.2. The increase in disc height was greater (p=0.036) at L5/S1 (5.8mm) than at L4/5 (4.8mm), and was greater (p=0.05) with the Charite (6.2 +/- 1.9mm) than with the Prodisc (4.1 +/- 1.9mm). The height increase with the Activ L (5.4 +/- 2.2mm) was not different than with the Charite or Prodisc (p>0.18). Relative to the initial post-operative visit, the average change in disc height remained constant from 3 to 24 months (p=0.2). The change in disc height between post-op and latest available time point averaged 0.48 +/- .57mm, with no significant difference between different TDR implants (p=0.27) and no significant difference between L4/5 and L5/S1 implantations (p=0.8). There was no post-operative subsidence (implant penetrating into bone by 3 mm or more) and the maximum loss of disc height was 1.9mm. There was 1 case of settling (1.1%) where the implant was not completely seated when the immediate post-operative x-ray was obtained.

Discussion/conclusions: The data from this scientific study suggests that the immediate increase in disc height associated with lumbar TDR averages 5.4 mm and is significantly greater at L5/S1 than at L4/5. Charite implantation was associated with a significantly larger increase in disc height than Prodisc. Finally, our data suggests that following lumbar TDR, disc height remains constant during the intermediate follow-up regardless of operative level or implant type. Further prospective randomized studies will be needed to determine what, if any, is the clinical significance of our findings.