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**Direct Comparison of Two Lumbar Total Disc Replacement Devices: Results from a Prospective, Randomized, Multicenter FDA-regulated Trial**

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**Introduction:** Randomized trials have reported total disc replacement (TDR) to produce results similar or superior to lumbar fusion. Reported results for various TDRs appear to be similar, but differences in study design and outcome measures pose challenges in definitively comparing devices. The purpose of this study was to perform a direct comparison of two lumbar TDRs in a prospective, randomized trial.

**Methods:** TDR was performed in 457 patients from 21 sites (261 subjects in the investigational group (Kineflex Disc; metal-on-metal design, 204 randomized and 57 non-randomized training cases), and 196 in the control group (Charité Artificial Disc; metal with polyethylene core; 190 randomized and 6 non-randomized training cases)). All patients were treated for single-level symptomatic disc degeneration of at least 6 months duration. Success was defined to be at least 25% improvements in Oswestry scores, no re-operation, and no major adverse events.

**Results:** There were no significant differences between the groups when comparing operative time, blood loss, or length of hospital stay. Both groups improved significantly on Oswestry and VAS scores ( $p < 0.01$ ; see table) with no differences between the groups.

	Oswestry		VAS	
	Investigational	Control	Investigational	Control
Pre-op	59.5	60.2	79.2	78.9
6 wk	37.0	36.5	37.4	32.3
3 mo	27.4	28.2	31.1	27.0
6 mo	24.6	24.7	28.7	28.4
12 mo	23.9	22.2	28.1	24.5
24 mo	23.0	23.0	26.5	26.7

[Table 1. VAS and Oswestry scores improved.]

Success rates were similar (75.5% investigational vs. 73.5% control). At 24-month follow-up, 94.1% of the investigational group and 91.9% of controls were satisfied with outcome. Re-operation was performed in 5.4% of the investigational group and 6.6% of controls.

**Discussion:** This prospective, randomized, controlled study comparing two TDRs, the first to the authors' knowledge, found the devices produced very similar clinical outcomes. Both groups improved significantly by 6 weeks post-operative and remained improved throughout follow-up with a high patient satisfaction rate.