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F.D.A. I.D.E. Prospective Randomized Comparison of Three Lumbar Artificial Disc Replacements (A.D.R.) with Minimum Three-year Follow up

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Purpose: To establish safety and efficacy between the Maverick™ (M), Charité™ (C), and Kineflex™ (K) A.D.R.'s.

Method: Follow up on three ADR's performed by two surgeons, at one I.D.E. site were reviewed. There were 25 Maverick, 31 Charité, and 35 Kineflex patients. The majority of A.D.R.'s were performed at L5-S1 vs. L4-L5 (M) 19 to 6, (C) 19 to 12 and (K) 28 to 7. Inclusion/exclusion criteria will be discussed.

Results: Re-operations included: (M) 1 infection, (C) 3 implant complications (K) 1 implant complication. These cases will be presented.

ODI results for all groups: Pre-op = (M) 57.6, (C) 63.8, and (K) 61.1; One-year post-op = (M) 16.3, (C) 27.3, and (K) 20.4;

Three-year post-op = (M) 14.6 (p< 0.001), (C) 20.5 (p< 0.001), and (K) 19.3 (p< 0.001).

VAS results for all groups: Pre-op = (M) 74.1, (C) 85, (K) 83.9; One year post-op = (M) 27.9, (C) 31.4, and (K) 27.3;

Three-year post-op = (M) 20.5 (p< 0.001), (C) 33.8 (p< 0.001), and (K) 26.9 (p< 0.001)

F.D.A. clinical success was met in (M) 90%, (C) 83.5%, (K) 90.5% of patients. Patients with a VAS less than 2 occurred in (M) 68%, (C) 29%, (K) 47%. Patients with an ODI less than 10 occurred in (M) 67% (C) 33%, (K) 52%.

Patient satisfaction at three-year follow up was (M) 96%, (C) 84%, and (K) 91%.

Conclusions: All three ADR's demonstrated safety with a trend to more device related complications with (C) 3 compared to (M) 1 and (K) 1. They all showed efficacy with a statistically significant improvement in ODI and VAS at three year follow-up (p< 0.001). F.D.A. clinical success was (M) 90%, (C) 83.8%, (K) 90.5%. This is the only class one data comparing three ADR's from one IDE site.