Clinical: Prosthesis
400
Prospective Randomized Series Comparing Maverick™ Lumbar Total Disc Replacement (TDR) with Anterior Lumbar Interbody Fusion (ALIF): Five Year Follow up

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Introduction: The data reported in this abstract is from an IDE clinical trial with a minimum five-year follow-up comparing the Maverick (25 patients) with an ALIF utilizing an LT-CAGE® with INFUSE® Bone Graft (11 patients).

Methods: Patients were blindly randomized 2:1 (Maverick:ALIF). Indications for surgery were similar to lumbar fusion. Inclusion/Exclusion criteria will be discussed. All surgeries were one-level L4-5 (7) or L5-S1 (29). Average patient age was 43 in both groups (range 21-55), with an average BMI of 24 (range 21-27). Surgical technique will be discussed.

Average operating time was 99 minutes (range 68-118) for the Maverick and 60 minutes (range 53-112) for the ALIF. Blood loss averaged 20cc for Maverick and 78cc for ALIF.

Average hospital stay for both groups was 1.6 days (range 1-4).

Time to unrestricted activity averaged six weeks in the Maverick group and six months in the ALIF group.

Results: All 25 Maverick patients had two-year follow-up and 19 patients had five-year follow-up. Ten of the 11 ALIF patients had two-year follow-up and seven patients had five-year follow-up.

Maverick pre-op Oswestry Disability Index (ODI) was 56; One-year ODI was 15; Two-year ODI was 15 for an average improvement of 74% (P< 0.001). The five-year ODI average was 9.6 (P< 0.001). ALIF pre-op ODI mean was 58; One-year ODI was 35; Two-year ODI was 41 for an average improvement of 29% (P< 0.05). The five-year ODI average was 38.3.

Maverick pre-op mean Visual Analog Scale (VAS) was 7; One-year VAS was 3; Two-year VAS was 2 for an average improvement of 71% (P< 0.001). The five-year VAS was 1.5 (P< 0.001). ALIF pre-op VAS was 8; One-year VAS was 5; Two-year VAS was 6 for an average improvement of 25% (P< 0.04). The five-year VAS was 6.

Fourteen of the 19 Maverick patients had an ODI less than 10 and a VAS less than two at five-year follow-up. FDA definition of clinical success was achieved in 84% of the Maverick patients and 55% of the ALIF patients.

One Maverick patient required reoperation for an infection 18 months post op. Three of the 11 patients in the ALIF group required posterior fusion for pseudoarthrosis (27%). One additional patient is awaiting posterior fusion.

Overall patient satisfaction, based on FDA criteria, was 95% for the Maverick TDR and 78% for the ALIF group.

Conclusions: These Maverick TDR results are similar to those reported by six other IDE sites at two-year follow-up. The combined results of 173 Maverick patients from seven IDE sites indicate statistical superior clinical outcomes compared to ALIF at one-year, and two-year follow-up (P< 0.001). This class I data reporting five-year follow-up results indicates no change from the two year results.