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**Lumbar Disc Arthroplasty versus Anterior Lumbar Interbody Fusion: Five-year Outcomes for Patients in the Maverick® Disc IDE Study**

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**Introduction:** The 2-year FDA IDE clinical trial of the Maverick Disc was reported previously, demonstrating the clinical outcomes superiority of lumbar disc arthroplasty using the MAVERICK® Disc when compared with anterior interbody fusion with the INFUSE® Bone Graft/LT-CAGE® Device. The purpose of this report is to present up to five-year interim outcomes for patients in the continuation of the IDE trial, while follow-up at 5 years is still ongoing.

**Methods:** The Maverick IDE study was a large prospective, randomized (2:1), controlled study at 31 centers, enrolling 405 investigational and 172 control patients with single-level disc disease (L4 to S1). Patient groups were similar in demographics and preoperative clinical measures. Patients were assessed preoperatively and at 1.5, 3, 6, 12, 24, 36 and 60 months post-op, using self-reported measures including Oswestry Disability Index (ODI), SF-36, and back and leg pain questionnaires, physiologic measures including neurological status, and functional measures including work status. Radiographic outcomes included disc height, index and adjacent level angular motion, and fusion success.

**Results:** Mean score improvement for key clinical outcome measures including ODI, SF-36 PCS, back pain and leg pain was statistically significant ( $p < 0.001$ ) versus pre-op for both groups at all follow-up intervals. ODI improvement was noteworthy for both groups at 24 (n=370/138) and 60 (n=261/99) months: (MAVERICK 33.8/34.9 points; Fusion 29.2/29.9 points at 24/60 months respectively), surpassing reported mean ODI improvements for all devices in previous IDE studies for lumbar disc arthroplasty. At each follow-up beyond 3 months, over 80% of investigational patients and over 70% of control patients reported an ODI improvement of at least 15 points, an FDA-defined measure of success. Statistical superiority over fusion was concluded for MAVERICK at all follow-up intervals up to and including 24-months for Oswestry ( $p=0.004$ ), SF-36 PCS ( $p=0.009$ ), back pain scores ( $p=0.022$ ), and patient satisfaction with surgery ( $p=0.003$ ). At 5 years, superiority is concluded for Maverick mean improvements in ODI ( $p=0.009$ ), SF-36 PCS ( $p=0.002$ ) and patient satisfaction ( $p=0.043$ ). Neurological status was statistically equivalent in the two groups. Investigational patients returned to work 21 days sooner than control patients, which was statistically significant. At both 2 and 5 years after surgery, over 70% of patients in each group were working. At 5 years post-op, 87.0% of the investigational patients said that they would have the surgery again, versus 82.7% for the control group ( $p=0.190$ ). Seven second surgeries in 4 additional patients occurred at the index level after 24 months in both the investigational group and in the control group, although more than twice as many investigational patients were followed as the control patients. There was no second surgery after 36 months in the investigational group.

**Conclusions:** Consistent with the 2-year IDE study outcomes, treatment of single-level lumbar degenerative disease with the MAVERICK Disc resulted in outstanding clinical outcomes at 5 years after surgery, including Oswestry and SF-36 PCS, resulting in improved physical function, reduced pain, and greater patient satisfaction.