A Multi-center Retrospective Evaluation of a Cervical Integrated Interbody System

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Background and goals: Cervical disc/fusion surgery has become one of the most common spinal procedures performed worldwide. Stand-alone devices (those without the requirement of a cervical plate) have recently emerged as a potential alternative to the standard cage/plate/screw constructs currently utilized. This retrospective review is meant to assess the safety and success of cervical fusion using the STALIF C™ cervical interbody fusion device.

Methods: The above surgeons performed a retrospective review of patients undergoing cervical fusion surgery with the STALIF C™ device over the previous 30 month time-period. Sixty patients underwent an anterior cervical discectomy and fusion, and were evaluated with standard spine outcomes parameters (VAS, NDI) and clinical examination. The patients were comprised of both single-level virgin cervical fusions (n=52) and multi-level fusions (n=8).

Results: The primary outcome measures in the study were pain relief as determined by VAS, and functional recovery as determined by NDI. Other measures reviewed were adverse events, the need for revision surgery, mean operative time and presence of any peri-operative complications. 60 patients (39% male, 61% female) with an average age of 50 (range 30-65) were evaluated. Mean follow-up time was 12 months, with 75% of patients implanted during this interval able to be reviewed for the study. Pre-operative VAS and NDI scores were 75 and 55, respectively. Post-operative VAS and NDI scores were 11.45 and 21.6, respectively. Patients underwent post-operative x-rays with flexion/extension to assess for fusion rates, construct stability, or any post-operative issues. No patients required revision surgery related to the STALIF C™ device, and no patients developed adjacent level disease requiring another operation. Mean operative time was 90 minutes (range 35-175 minutes). One patient experienced dysphagia that resolved by the 3-month timepoint.

Conclusion: Although the follow-up period is short, it is our conclusion that the STALIF C™ integrated interbody system is a safe, effective, and reproducible device for fusion in the cervical spine. The overall patient success rates were notable in not only the adjacent level disease patients, for whom the device was initially targeted, but also the many virgin, stand-alone cases for which the device was used. The clear benefits over the standard plate/screw systems are less overall hardware, no risk for disruption of adjacent levels with hardware (i.e., cervical plate), and shorter operative times (as compared to patients with adjacent level disease and needing removal of hardware, etc.).