Position Statement: Cervical Total Disc Arthroplasty

To: SAS Members and the General Spine and Medical Communities

Purpose: This position statement reflects the opinion of SAS: International Society for the Advancement of Spine Surgery that total disc arthroplasty (TDA) is an acceptable, proven alternative to anterior cervical discectomy and fusion (ACDF) in the treatment of symptomatic cervical disc disease (CDD) for the prescribed indications.

Statement:

Symptomatic cervical disc disease (CDD) refractory to non-surgical care is currently treated with anterior cervical discectomy and fusion (ACDF) with good clinical results reported\(^1\)-\(^3\). Fusion does however eliminate natural motion increasing stresses on adjacent levels, and progressive degeneration at the levels around the fusion has been reported. The rate of symptomatic adjacent segment degeneration (ASD) is estimated to occur at 3% per year and to be present in up to 25% of patients at 10 years\(^4\). The etiology for ASD is likely a combination of the altered biomechanical environment imposed by fusion and the patients’ underlying disc disease or genetic predisposition\(^4\),\(^5\). ASD after a prior cervical fusion is not a benign condition and has been reported to lead to an annual incidence of additional surgery ranging from 0.7% to 3.8%\(^1\),\(^2\),\(^6\)-\(^8\). In response, motion-sparing alternatives such as cervical total disc arthroplasty (TDA) have been developed to mitigate the biomechanical contribution to ASD.

Biomechanical studies have demonstrated that TDA in the cervical spine preserves motion at the treated level and facilitates more physiologic distribution of forces at adjacent levels compared with fusion. In an in vivo study, Sasso and colleagues demonstrated that the levels adjacent to a fusion exhibited significantly greater sagittal plane translation compared with that seen after TDA\(^9\). In a cadaveric spine model, Dmitriev et al found that TDA maintains physiologic motion and adjacent level intradiscal pressures, while fusions produced elevated adjacent level pressures and altered kinematics\(^10\). Similarly, other studies of TDA have demonstrated relative protection of the adjacent levels with maintenance of more physiologic motion\(^11\)-\(^12\).

Recent data from the multi-center, prospective, randomized United States Investigational Device Exemption trials comparing ACDF with TDA support TDA as either equivalent or superior to ACDF, with an acceptably low rate of complications. At 2 years post-operatively, Heller et al recently demonstrated that TDA had significantly greater improvement in Neck Disability Index (NDI) and neck pain with greater overall success compared with ACDF, with a similar rate of implant-related adverse events, and a quicker return to work\(^13\). Murrey et al recently reported excellent clinical outcomes with a significantly lower rate of secondary surgeries with TDA at 2 years (1.9%) compared with ACDF (8.5%), and lower narcotic usage\(^14\). Mummaneni et al
reported similar findings at 2 years with TDA achieving a significantly greater improvement in NDI, neurologic success, and physical component SF-36 scores, while requiring significantly fewer secondary surgeries and re-operation for ASD\textsuperscript{15}. At 2 years post-operatively, it was also reported that TDA patients maintained or improved their range of motion\textsuperscript{13-16}. Although not a controlled study, Robertson et al nonetheless demonstrated that patients who received TDA required significantly fewer medical treatments for symptomatic ASD at 2 years compared with fusion (33.0\% ACDF vs 1.3\% TDA) \textsuperscript{17}. The evidence clearly supports clinical efficacy, and in some instances superiority of TDA over ACDF, with multiple studies reporting less symptomatic ASD and significantly lower re-operation rates at the 2 year time point.

Device-specific complications of TDA that may occur include heterotopic ossification, device subsidence, vertebral body fracture, and implant extrusion, all of which have been reported to occur at acceptably low rates\textsuperscript{13-16}. Though short term results indicate clinical benefit of TDA over ACDF, the spine community collectively awaits longer term results to assess device performance and specifically, the fate of the index level, adjacent levels, and facet joints\textsuperscript{11,18}.

Given the Level I data from multiple studies with over 1000 TDA and 963 ACDF patients enrolled and various implant types with 2 year follow-up, the International Society for the Advancement of Spine Surgery (SAS) concludes that cervical disc arthroplasty is non-experimental, as described for FDA approved devices. TDA is a viable treatment option in patients who meet the patient indications as prescribed in the FDA approvals and is at least equivalent and often superior to ACDF. Even at the relatively early 2 year post-operative time point, several high quality studies have shown significantly lower re-operation rates after TDA when compared to ACDF. Further data will be needed to characterize and expand upon the apparent benefits of TDA. SAS will keep abreast of the reported literature on longer term results with TDA in general, as well as reports from studies with new disc replacement devices.
Reference List


