Anterior Cervical Discectomy and Fusion Survivorship using a Combined 3D Printed Interbody Spacer, Plate, and Integral Screws: 338 Consecutive Patients.

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INTRODUCTION:
The current study was undertaken to investigate the perioperative and radiographic outcomes of a 3D printed combined interbody spacer with integral screws for anterior cervical discectomy and fusion (ACDF). The primary objectives in this prospective study were to compare the survivorship of 1) a novel Integrated 3D printed interbody spacer, plate, and screws with 2) a PEEK integrated spacer and 3) a traditional allograft spacer and an anterior cervical plate (FDA Control Group).

METHODS:
A consecutive series of 338 patients presenting with cervical radiculopathy, myelopathy, or spondylosis underwent ACDF with the integrated plate, PEEK spacer, and screw system – 228 with PEEK and 100 3D printed porous titanium. The operative levels were distributed as—36% single level, 36.6% two level, 16.1% three level, and 6.85% four level ACDF procedures reconstructed using a stand alone PEEK interbody spacer with integral screws. For all cases, the 3D printed porous titanium and the PEEK cages were packed with local autogenous graft. Radiographic criterion for fusion was defined as 2 degrees or less of segmental motion based on flexion-extension plain films.
RESULTS:
In groups 1 and 2 the mean patient age, EBL, operative duration, and demographics were similar to the FDA Control Group. As expected in the Treatment Group the length of stay (days) was dependent on the number of operative levels: single level (1.8±0.5), two level (2.0±1.0), three level (2.5±2.6), and four level (2.8±3.2) ($p<0.05$). There were 2 patients out of 100 in the 3D Spacer Group that required posterior supplemental instrumentation (2%). There were eight levels in the PEEK group that required reoperation — secondary surgery rate of reoperation 8 of 228 (3.5%) compared to 61 of 912 levels in the 5 FDA Control Groups (6.69%) Chi squared 3 X 2 Contingency Table, These results were statistically significant, $\chi 2(2) = 17.194$, $p < 0.001$. The effect size for this finding, Cramer's V, was small to medium, 0.109.
DISCUSSION AND CONCLUSION:
Anterior cervical fusion using a novel 3D printed titanium spacer with integral screws for ACDF demonstrated more favorable two year results than allograft and plate FDA Control Groups with radiographic evidence of fusion observed in 98.0% of patients treated — representing 98/100 operative levels. The 3D printed group also demonstrated less subsidence and fewer reoperations than the PEEK spacer group which had eight levels requiring secondary surgery. The non-device related AE were similar between all three groups. The current study serves as the first clinical investigation of 3D printed porous titanium stand-alone interbody fusion device, which provides an alternative to the use of conventional anterior cervical plates for ACDF procedures.