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3D Printed Anterior Cervical Stand-Alone Combined Cage-Plate— 300 Consecutive Implants

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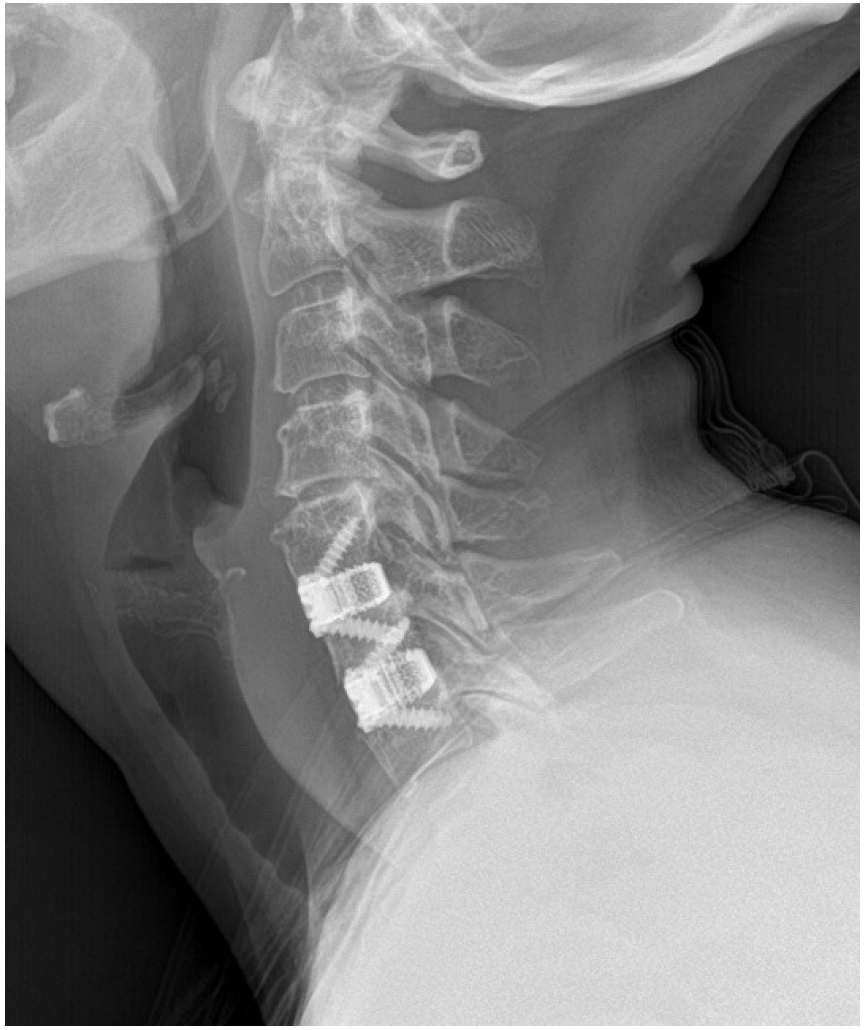
300 Operative levels – 157 Consecutive patients

33.8% single level

42.7% two levels

21.6% three levels

1.9% four levels



AVG Age= 59.7 years
(Range 31 to 85)

49 Males, 51 Females

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Challenging Nature of Cases

16.6% Adjacent Levels (26/157 Patients.

12% Performed as Revision procedures requiring Instrumentation Removal

6% Myelomalacia present pre-operatively

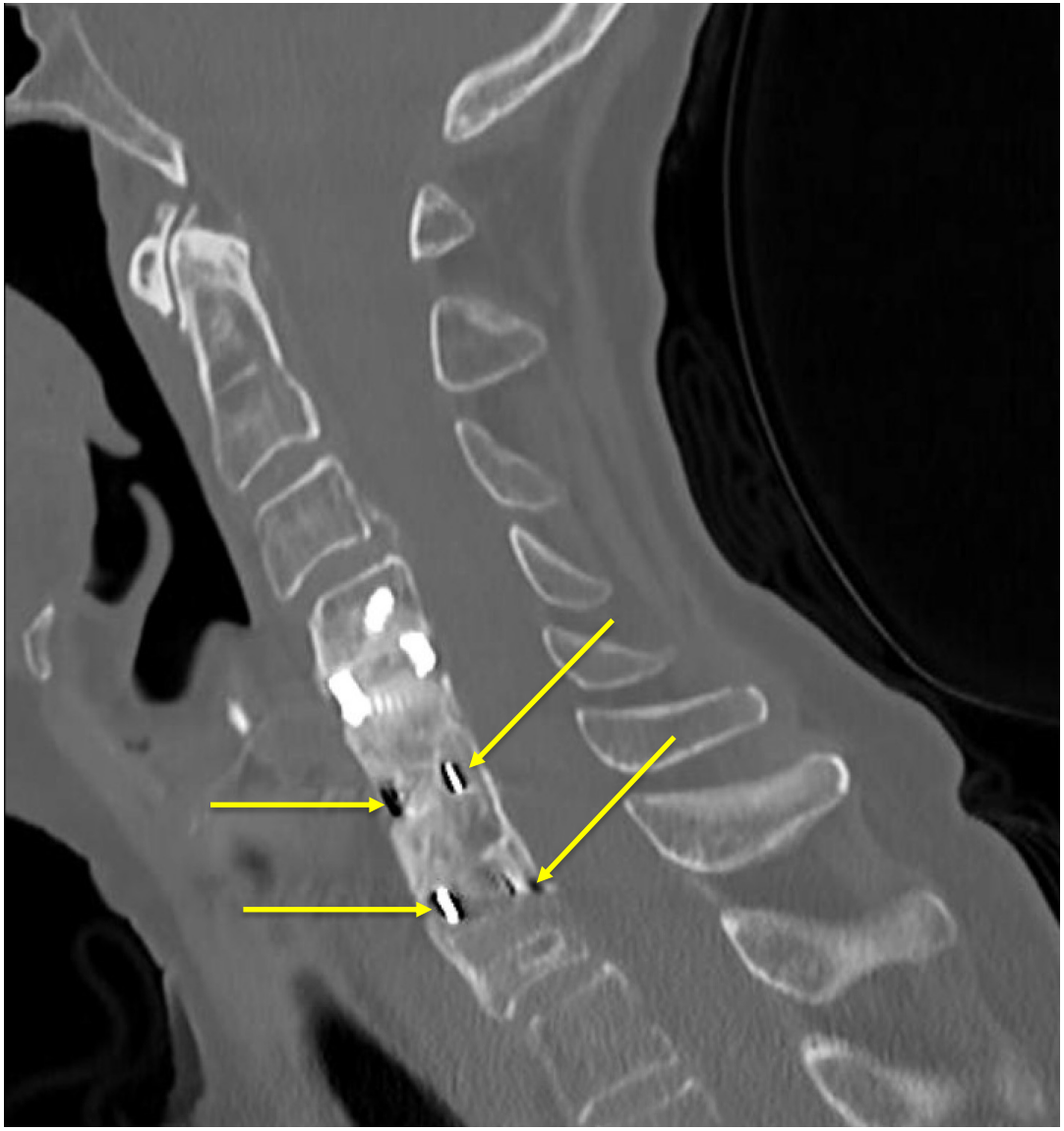
Please note– Any of these three conditions would have excluded the patient from participating in FDA cervical disk replacement prospective studies

16.6% of the 3D Printed Spacers were performed as Adjacent Segment Dz

Unexpected comparative analysis of 3D printed ingrowth at C4-5 after 6 months was superior to

Ingrowth around PEEK spacers at C5-6 and C6-7.

Notice the radiolucent holes in the bone around the PEEK spacers after 3 years. This is confirmed on many multiplanar images. This is not artifact from the tantalum markers.



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98.7 % Survivorship Success

FDA criteria– no failures, no anterior reoperations, no instrumentation removals, no subsidence requiring surgery

4 cases required Return to O.R. = 4/300

Case 7 = C2 to C5 2 months post-op

Case 19 = Occiput to C6 4 days post-op

Case 130 = Osteoporotic Kyphosis. 3 Months

One significant subsidence (Case 118) 6 weeks

At lease one grade improvement in ASIA neurologic impairment score—

99% improve
1% maintain

Neck Disability Index = NDI

Mean Pre-operative NDI = 36.3%

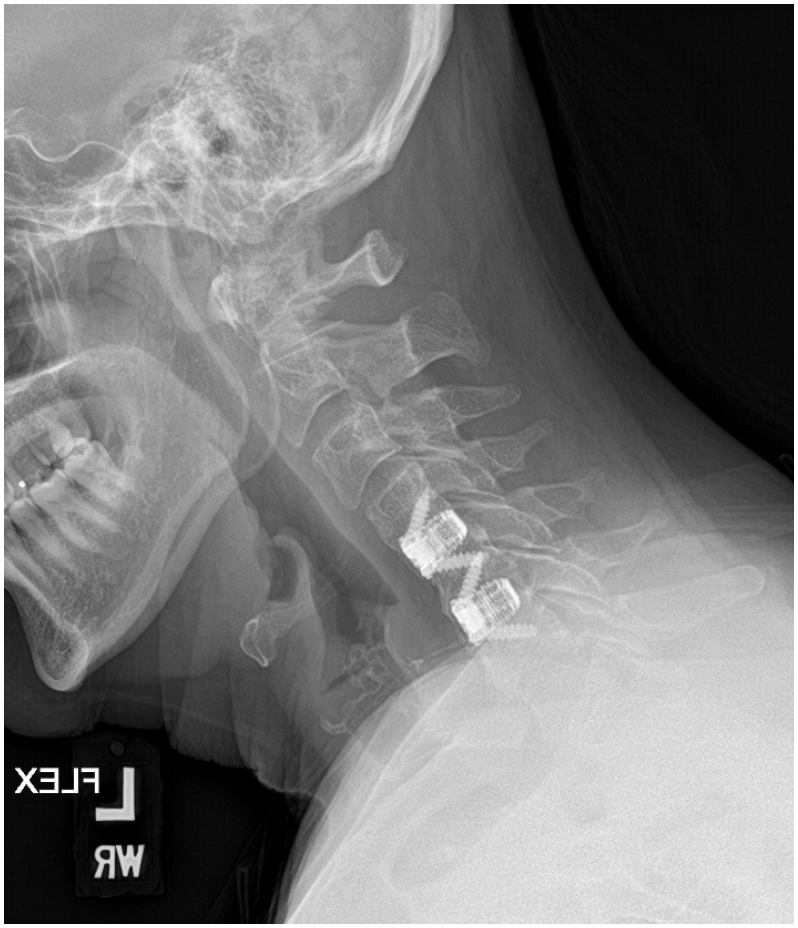
Mean Post-operative NDI = 18.6%

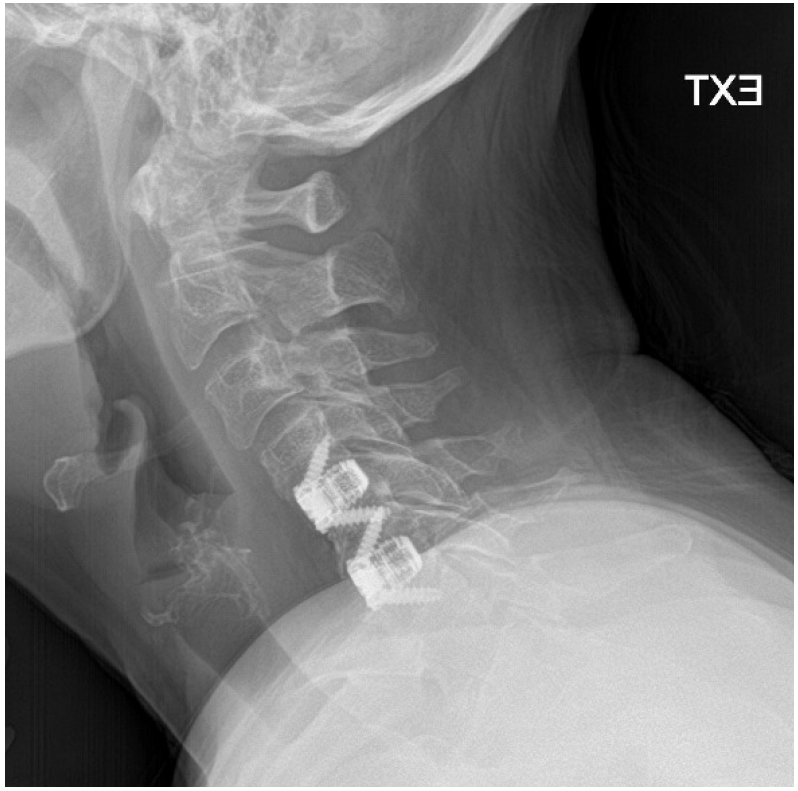
PROM- Patient Reported Outcome Measures

- Neck Disability Index
- Number of cases with NDI improvement by 15% or greater (same as Cervical Arthroplasty Criteria)

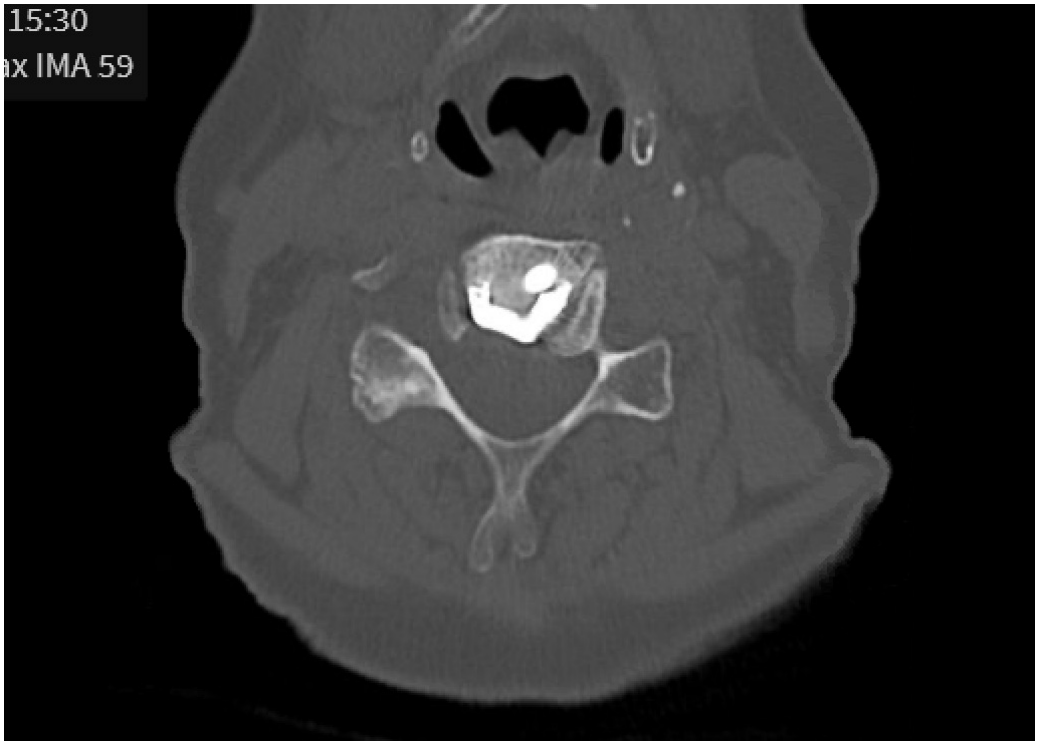
YES	NO
53	15
53 / 68	15 / 68
77.9%	22.1%

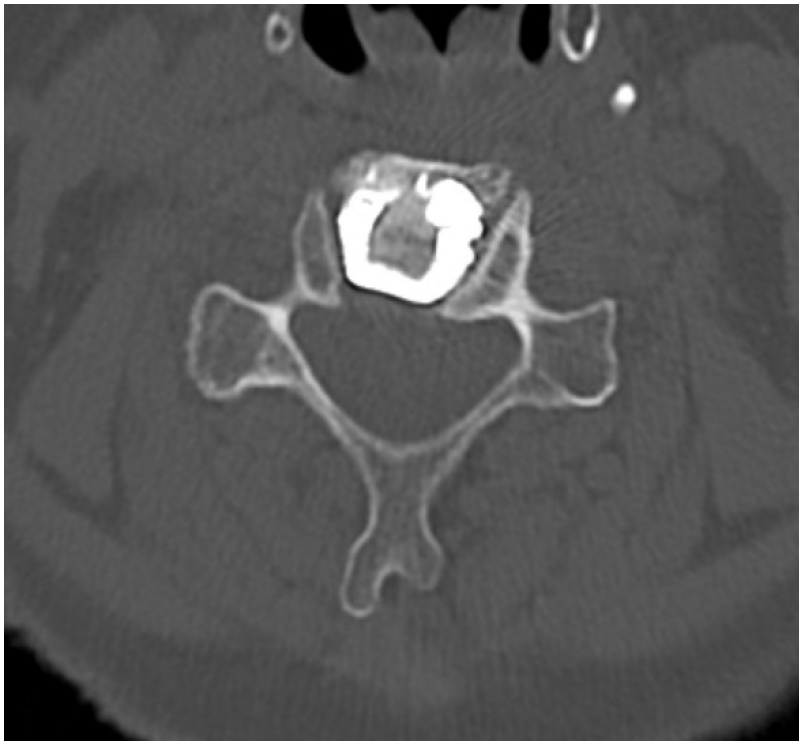
Post-operative Flexion + Extension Radiographs for all 300 Levels at each Follow up Visit.



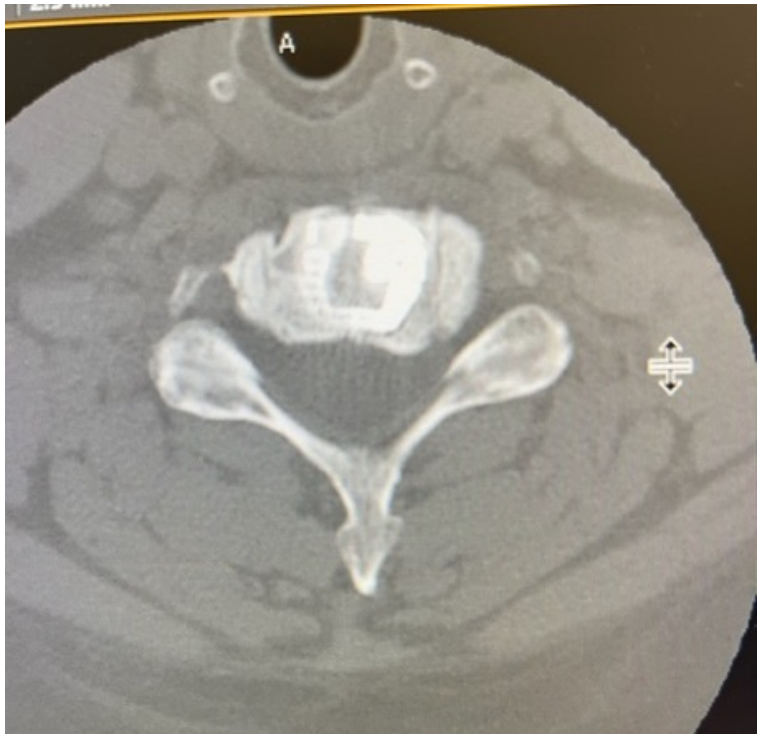


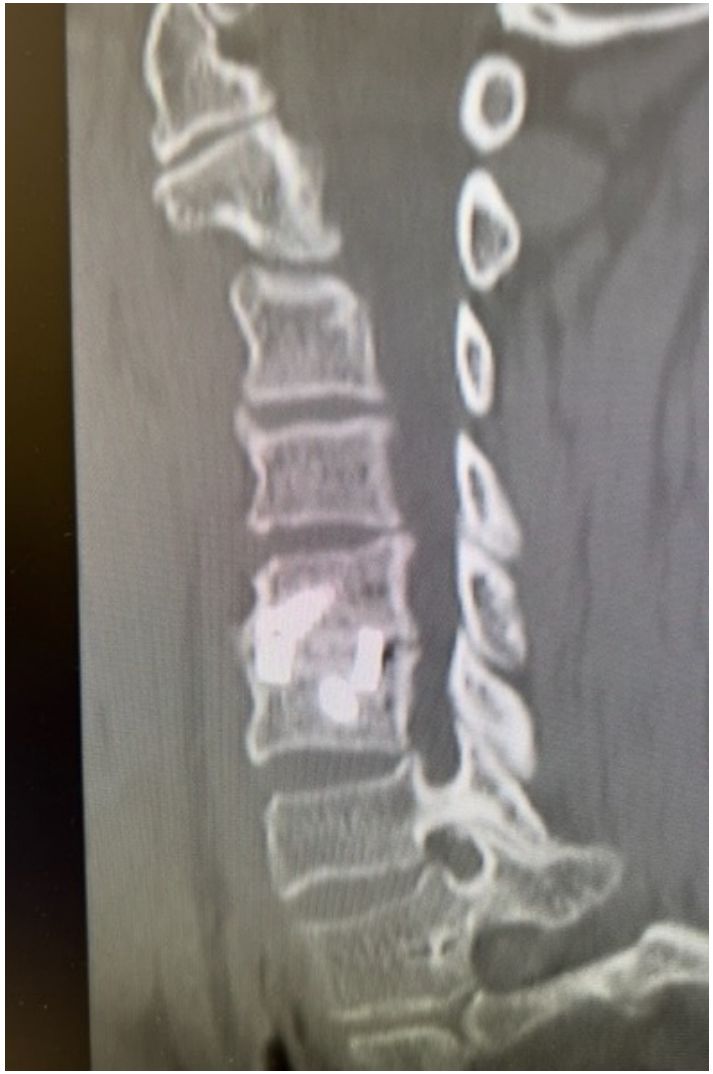
Typical Ingrowth from autograft Reamings at 2 years
Inside 3D Printed Titanium Spacer





Another Typical Case Illustrating Ingrowth with 3D Printed Titanium





Use FDA Prospective RCTs as Control Group for Integrated Spacers

Table I - ACDF SURVIVORSHIP

Study (2 Year FDA Results)	Reoperations	Control Group*
Prodisc C Murray et al, Spine Journal 2009	9	106
Bryan Heller et al, Spine 2009	8	221
Prestige Mummaneni et al, J Neurosurg. 2007	24	268
Secure-C PMA FDA SSE 2012	10	133
PCM Phillips et al, Spine 2013	10	184
Totals	**61**	**912**
Allograft + Plate Survivorship		**851/912 = 93.3%**
Integrated Plate, PEEK Spacer + Integral Screws		**451/460 = 98.0%**

* Totals in Control Group at 24 mos.

3D Printed Titanium Spacer 296 / 300 = 98.7%