

Stephen P. Courtney, MD

Plano Orthopedic Sports Medicine and Spine Center, Plano, TX

Clinical Based Evidence of the Eminent Spine Anterior Cervical Plate ("King Cobra®") and the Eminent Spine PEEK Cervical Cage ("Copperhead®") in Cervical Fusions

Introduction

Anterior Cervical Interbody Fusion is an accepted treatment for cervical disk herniation and stenosis, diskogenic neck pain, trauma, and other conditions. The Eminent Spine ("ES®") Anterior Cervical Plate ("King Cobra®") can be used in conjunction with the ES® Cervical Interbody Fusion Device ("Copperhead®"). The King Cobra® was developed specifically for the cervical spine as a low-profile plating option to address the problems of cage migration, reduce surgical time, and minimize vascular injury. The Copperhead® PEEK cervical cage system was developed to provide an alternative to bone grafts, either autologous or allograft.



Copperhead®
(Peek Cage)



King Cobra®
(Cervical Plate)

Demographic (244 patients)	Diagnosis	Comorbidity
Males 114 Females 130 Age 20-81 (55) Weight 120-280 lbs (183 lbs)	Cervical HNP 104 Cervical Stenosis 140 Trauma, infection 0	Smoker 33 Diabetic 15 Previous Levels Fused (3)C4-5 (8)C5-6 (6)C4-7 (8)C5-7 (1)C6-7 (1)C3-7 Pseudarthrosis 1 (C4-5) HIV 3 HTN 41

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Purpose

The purpose of this study is to demonstrate the results of the King Cobra® in regard to screw back-out, screw breakage, plate breakage, any problems with the Twister, and prevention of migration of the cervical cage. The Copperhead® PEEK cervical cage system was analyzed to evaluate cervical fusion, graft collapse, pseudarthrosis, and the need for re-operation. The cost of revision spine surgery is a known factor that greatly increases the cost of the medical system. This study evaluated the need for revision surgery.

Device Description

The King Cobra® can be used as an adjunct device to supplement anterior cervical fixation. The plate consists of titanium, is available in 1, 2, 3, and 4 levels, and has a thickness of 2.2mm. The King Cobra® screws have 14 degrees of conical rotation and are available in 12mm, 14mm, and 16mm lengths with 4.0mm or 4.25mm diameters. Fixed screws are also provided in the set. The Copperhead® PEEK cage system consists of multiple footprints to provide the surgeon options that will fit the individual patient’s anatomy. The “teeth pattern” is propriety to ES and are not diamond pattern. The diamond pattern is too smooth of a surface for bony growth. There is a large “chamber” to allow packing of the cage with bone product. The “rasp” of the instrumentation prep set is vital to prepare the bone of the cervical body. It is .5mm less than the actual implanted cage and compress the bony surface, and helps prevent subsidence of the cage. This unique design of the rasp allows the cage for a “press fit.”

Methods

This study examines 244 patients, with 255 plates, from 3/17/11 to present, who were candidates for Anterior Cervical Interbody Fusion. All patients were consecutive. Diagnoses include cervical disk herniation and cervical stenosis. All devices were inserted using a left anterior approach. All patients received an ES® Anterior Cervical Interbody Fusion Device Copperhead® implant. Bone graft material utilized was DBM and allograft bone chips. Thirty-one patients in 2012 had a left iliac crest bone marrow aspirate utilizing the Arteriocyte machine but was discontinued because of insurance denial. Radiographic assessment includes plain x-rays at 2 and 6 weeks and at 3 and 6 months.

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Size	Small (14x12mm)	Medium (15x13mm)	Large (17x14mm)	X-Large (19x16mm)
5mm		1		
6mm		3		
7mm		5		
8mm	4	61	3	
9mm	57	106	47	
10mm	109	81	142	
11mm	41	35	112	
12mm	25			6
TOTAL	236	292	304	6

Total	838
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Plate Level	
1 Level	(10)C3-4 (8)C5-6 (15)C6-7 (10)C7-T1 (2)T1-T2
2 Level	(15)C3-5 (18)C4-6 (72)C5-7 (3)C6-T1 (1)C7-T2
3 Level	(13)C3-6 (63)C4-7 (2)C6-T1 (2)C4-T1
4 Level	(15)C3-7 (6)C4-T1
Total	255

Screw Size	
4.0 x 12mm	126
4.0 x 14mm	694
4.0 x 16mm	75
4.25 x 12mm	56
4.25 x 14mm	781
4.25 x 15mm	51
Total	1,783

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Technique

(*Surgeon must review technique manual prior to insertion.)

Begin by exposing the anterior cervical spine and perform a discectomy or corpectomy at the correct level. Rasp the disk space which are available in 7-12mm. The rasps are .5mm less than the true implant. This allows for a "press fit" of the final Copperhead® implant. Choose the correct implant. Three different footprints are available. Pack the chamber of the cage with bone graft. Insert the cage and the implant will have a tendency to self distract the disk space. Obtain AP & lateral x-rays to verify implant position.

Remove the anterior osteophytes to allow the plate to lie flush on the "true" anterior cortex of the vertebral body. The plate should be positioned centered on the midline and should not overlie adjacent non-fused disk segments. Use a standard operating room burr or the "awl" to penetrate the anterior cortex of the vertebral body. Start with the cephalad hole of the plate. The tip of the drill guide should be seated into the cervical plate hole. Advance the drill into the bone.

Choose the appropriate length screw. Screws are available in 12, 14, and 16mm lengths and 4.0 and 4.25mm in diameter. Variable or Fixed screws are available. Tighten the screws so that the plate is seated evenly and flush to the anterior cortex of the cervical spine. The screws should be contained in the vertebral body and not penetrate into the spinal canal or adjacent disk space. Place the locking cap driver on the "Twister." Rotate the "Twister" so the edges cover the head of the cervical screws. Obtain AP and lateral radiographs for final plate and screw position. Reference the King Cobra® and Copperhead® technique manual on the ES® website.

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Results

Of the 244 patients included in the study, each patient completed a 2 and 6 week and 3 and 6 month follow-up based on date of surgery.

Lateral and AP x-rays were taken at that time. The OR time for the King Cobra® was 45-230 minutes (115 minutes). Estimated blood loss was 12-400cc (89cc).

No patient needed re-operation and there was no screw back-out, screw breakage, twister malrotation, twister pop-off, or plate breakage.

There was no migration of the Copperhead®. There were no cage subsidence, migrations, cage fracture, or cage collapse.

No patient experienced infection or iliac crest morbidity.

There were no pseudarthrosis and not one patient required a revision. One patient did require a second operation 3 years later at a different disk space.

Complications Plate & Cage	
Screw back-out	0
Screw breakage	0
Twister malrotation	0
Twister pop-off	0
Plate broke	0
Cage subsidence	0
Cage migration	0
Cage fracture	0
Infection	0
Iliac crest morbidity	0
Pseudarthrosis	0
Revisions	0

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Discussion

This study proves that the King Cobra® cervical plate and the Copperhead® PEEK cage system is effective in obtaining cervical fusions. This study demonstrates the Eminent Spine PEEK cervical cages are medically necessary for obtaining cervical fusions.

The success of the King Cobra® Cervical plate and the Copperhead® PEEK cervical cage system had several variables that were consistent throughout.

(a) The variety and different type of footprints that Eminent Spine made available to the surgeon. One size does not fit all, and Eminent Spine's design team provides a complete range of footprints. This is important in order to obtain a "good fit."

(b) The "teeth" pattern on the surface of the implants allows for very good interdigitation with the bone immediately during surgery. The teeth pattern are not smooth nor a diamond type of pattern. A plasma titanium coating spray on the surface was not needed. Titanium coating would increase the cost of the implant and is simply not needed in this day of cost containment of spinal implants. As we move fast forward in a cost conscious era, it is important to identify implants that are effective and minimize complications, especially in regard to revision spine surgery. Eminent Spine's system decrease the cost of implants, not increase them. This is attributed to Eminent Spine's unique proprietary "teeth pattern." Titanium spray coating is not needed if the surface of the cage is designed correctly in the first place. Eminent Spine's engineer design team, has developed the correct surface on PEEK cages, and this Study clearly validates that statement.

(c) Preparing the intervertebral disk space is vital for a good fusion. Eminent Spine's rasp prep set are instrumental in preparing the bone. These rasps are .5mm less than the actual implanted spine cage. These cages are "press fit" into the disk space. Similar to the total joint world of "press fitting" the hip and knee implants. These are machine instruments and they are designed to prepare the bone surfaces to interdigitate with the "teeth" of the cage. The surface of these rasps and the "teeth" pattern of Eminent Spine's cages are vital in order to achieve an excellent environment for fusion to take place. They simply make the Surgeon's craftsmanship (carpentry) better. This study clearly validates how vital it is to have good prep instrumentation sets that compliment the implant. Eminent Spine has mastered that part of the equation.

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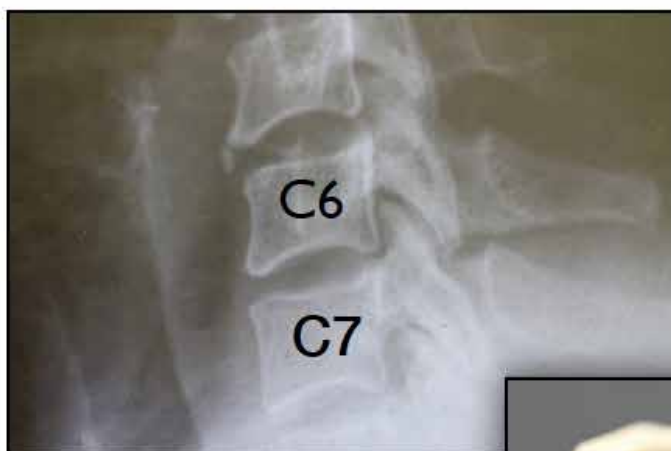
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This Clinical based evidence study regarding cervical PEEK cages clearly proves without a doubt that spinal cages are NOT experimental and investigational per certain Insurance guidelines. The patients in this study were multi-level, large spinal cages were inserted, partial corpectomy, smokers, diabetics, previous pseudarthrosis and HIV patients. Spinal Surgeons have enormous amount of medical and surgical training, and Spinal Surgeons should be the ones to determine what a patient requires in terms of implants and surgical techniques. Insurance company are now practicing medicine and determining what implants get approved. Insurance companies are practicing medicine WITHOUT a medical license. I firmly believe that is wrong and unethical. This Clinical based evidence paper utilizing Eminent Spine's technique and implants provides overwhelming proof and evidence that PEEK cervical cages are NOT experimental and investigational. I would encourage other Spine Surgeons and groups to share their Clinical base information to validate the efficacy and safety of implants that we chose to use. If we do not, no one will and Spine Surgeons will be forced to practice guideline medicine.

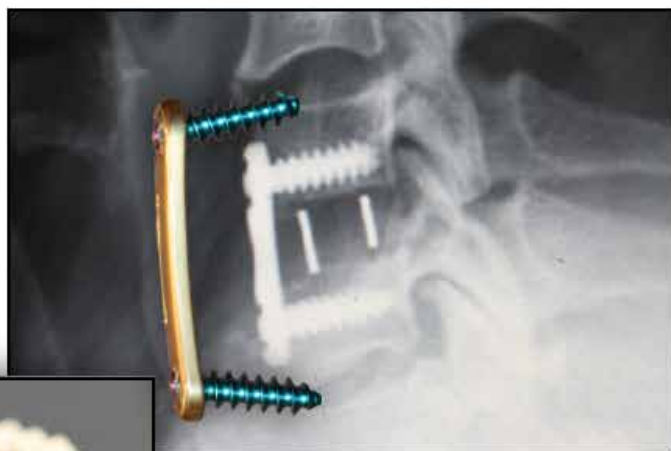
1 Level: C6/7

King Cobra® & Copperhead® Cage

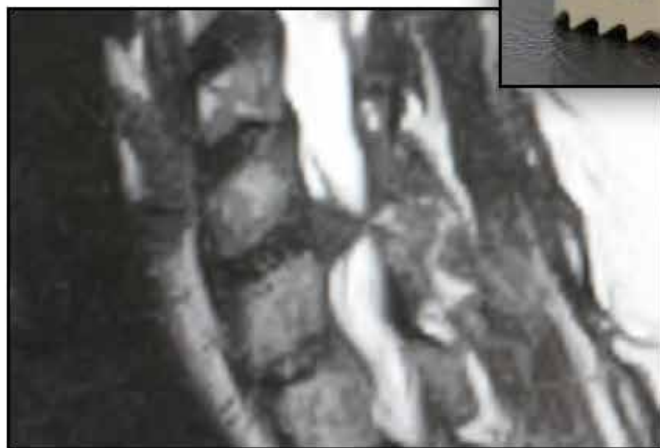
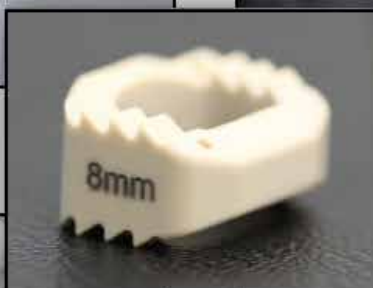
49 y/o WF with Radiculopathy & Triceps Weakness



Pre-Op



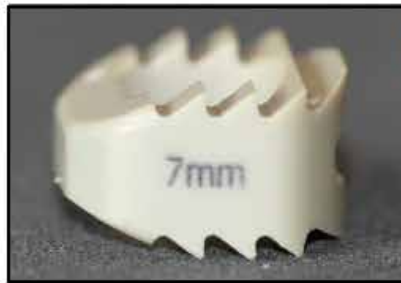
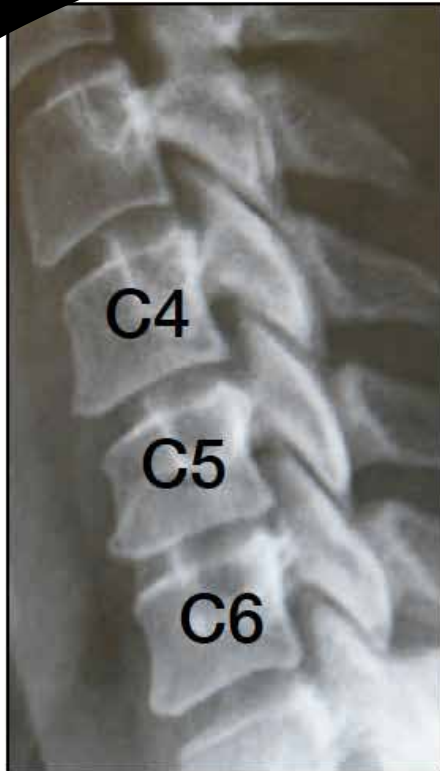
Post-Op



2 Level: C4/5 & C5/6

King Cobra® & Copperhead® Cage

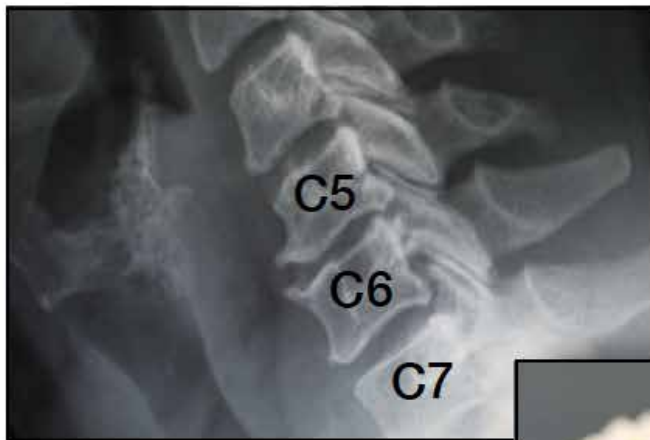
43 y/o WF with Disk Herniation & Biceps Weakness



2 Level: C5/6 & C6/7

King Cobra® & Copperhead® Cage

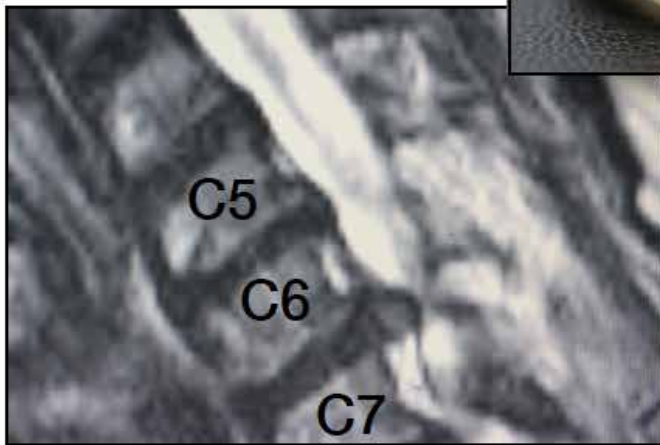
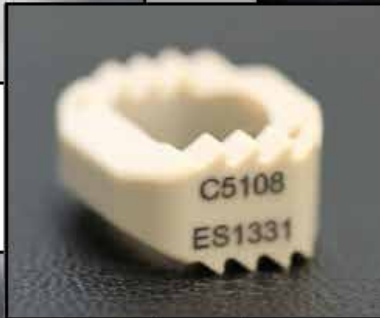
50 y/o WF with Severe Left Arm Radiculopathy & Triceps Weakness



Pre-Op



Post-Op



2 Level: C5/6 & C6/7

King Cobra® & Copperhead® Cage

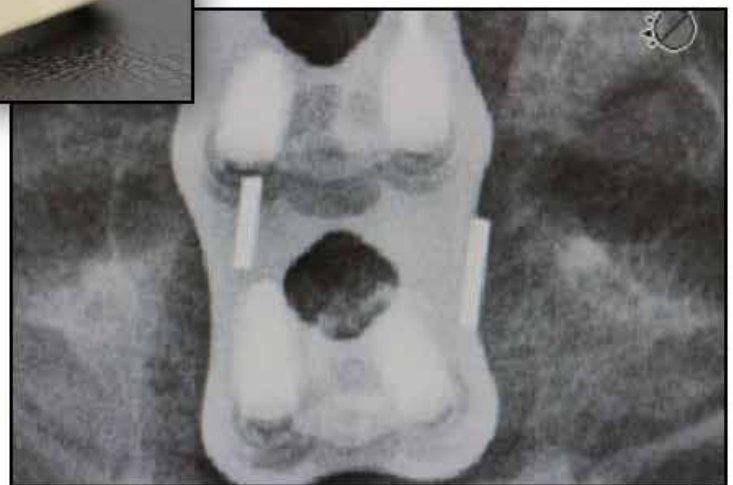
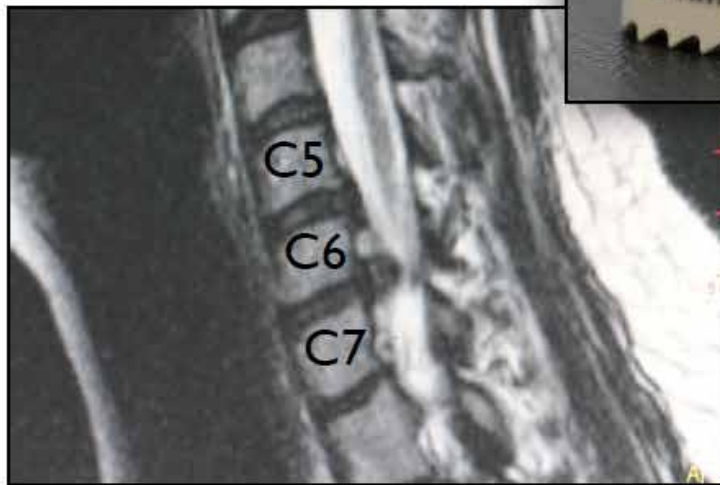
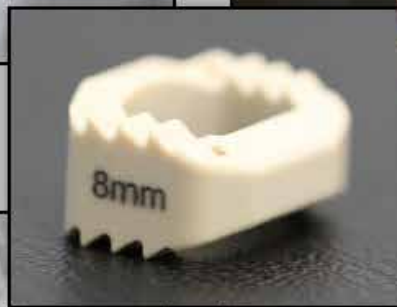
45 y/o WF with Severe Left Arm Radiculopathy & Triceps Weakness



Pre-Op



Post-Op



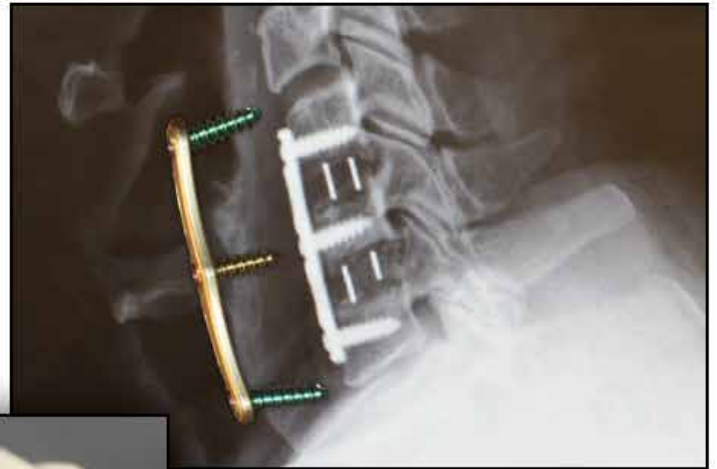
Texas Twister

2 Level: C5/6 & C6/7 King Cobra® & Copperhead® Cage

64 y/o WM with CDD & Right Arm Radiculopathy



Pre-Op



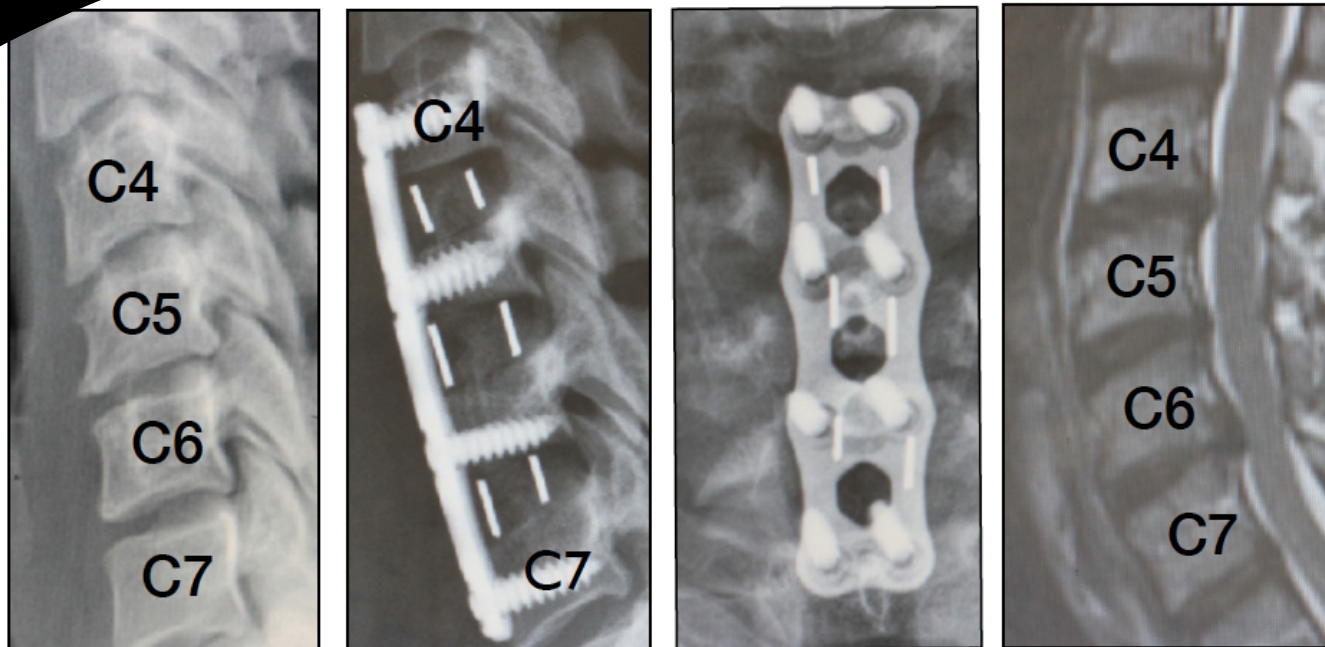
Post-Op



3 Level: C4/5, C5/6 & C6/7

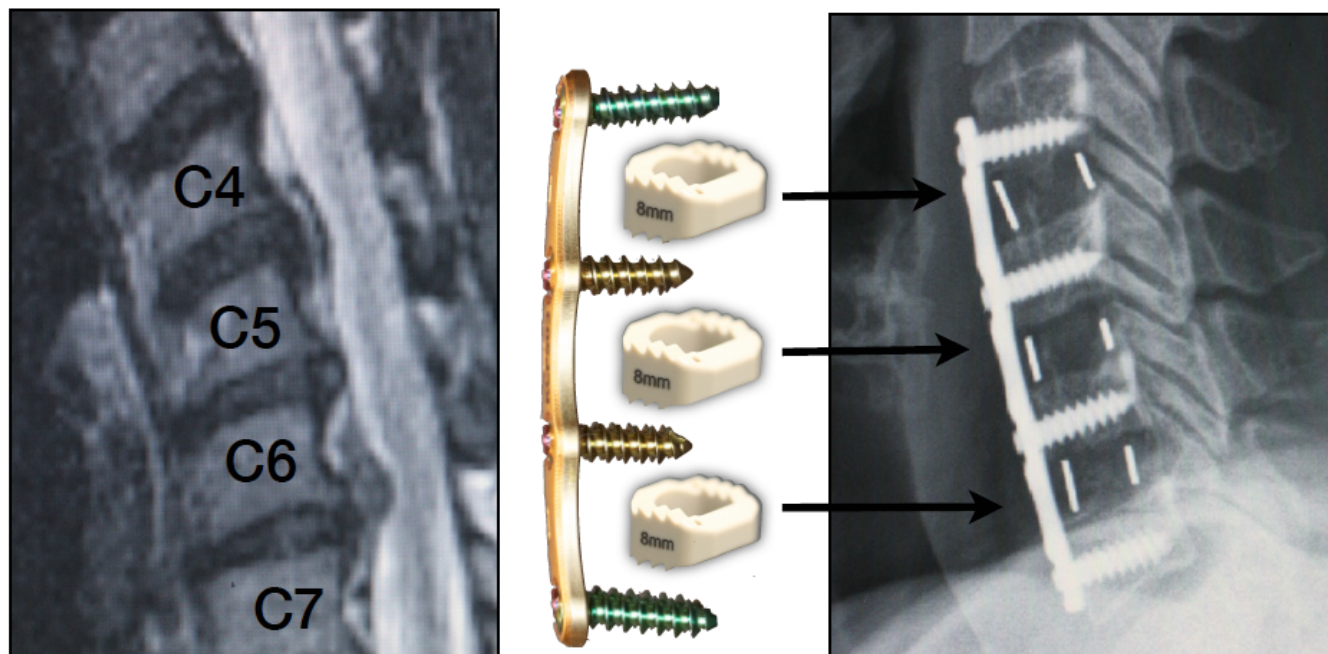
King Cobra® & Copperhead® Cage

37 y/o BF with Multi-Level Stenosis & Right Arm Radiculopathy



Pre-Op

*49y/o WF with Multi-Level Stenosis

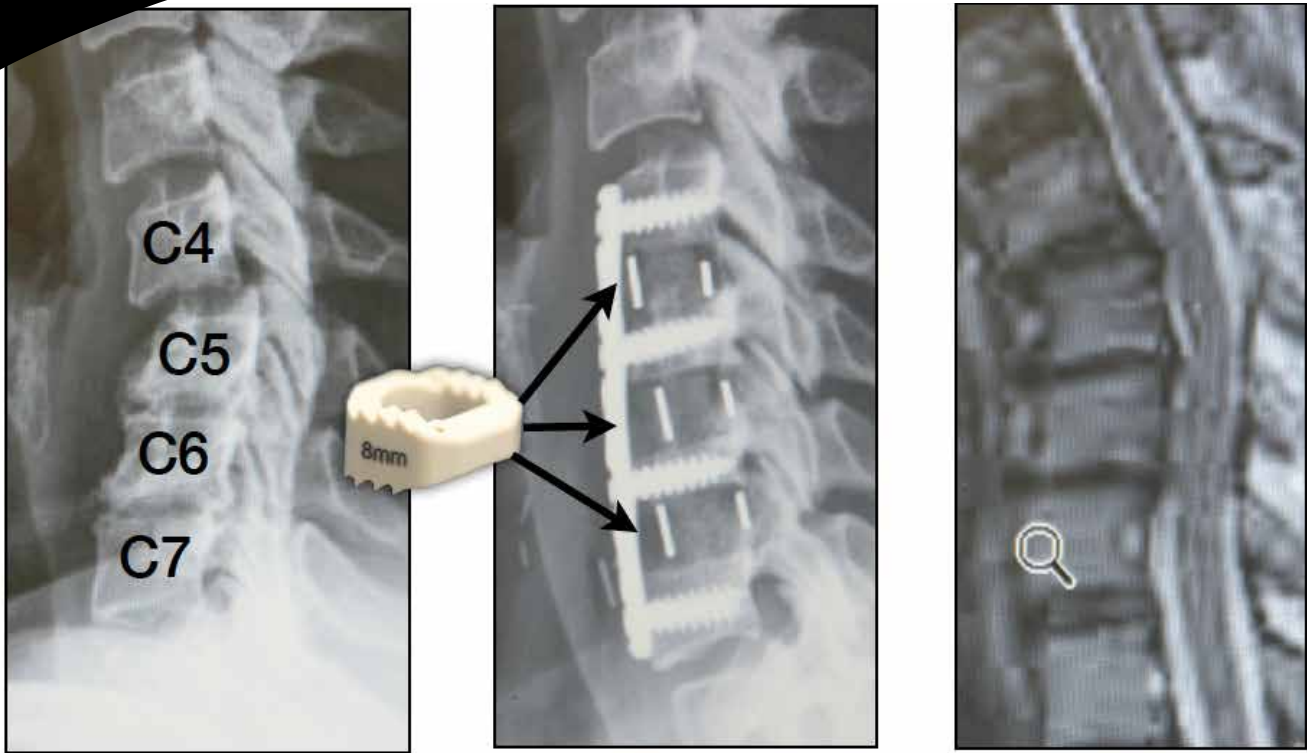


Pre-Op

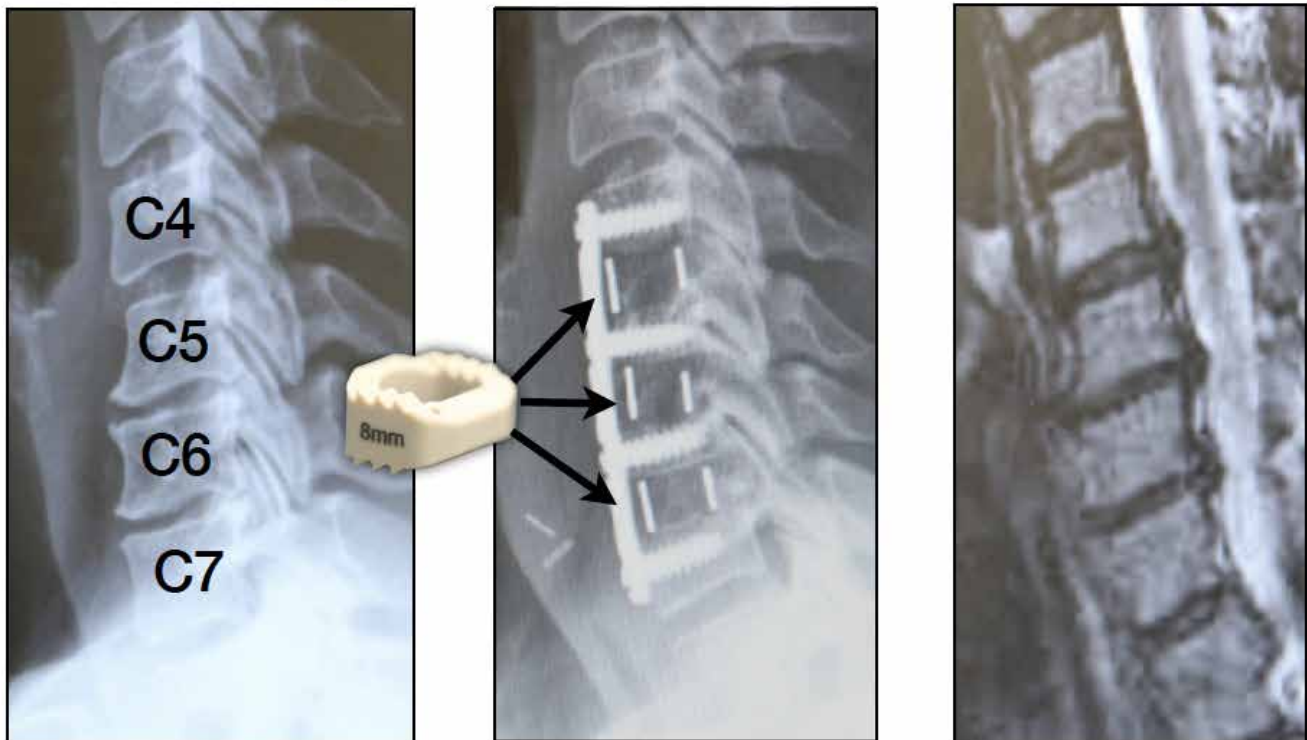
Post-Op

3 Level: C4/5, C5/6 & C6/7 King Cobra® & Copperhead® Cage

61 y/o Multi-Level Stenosis C4-7

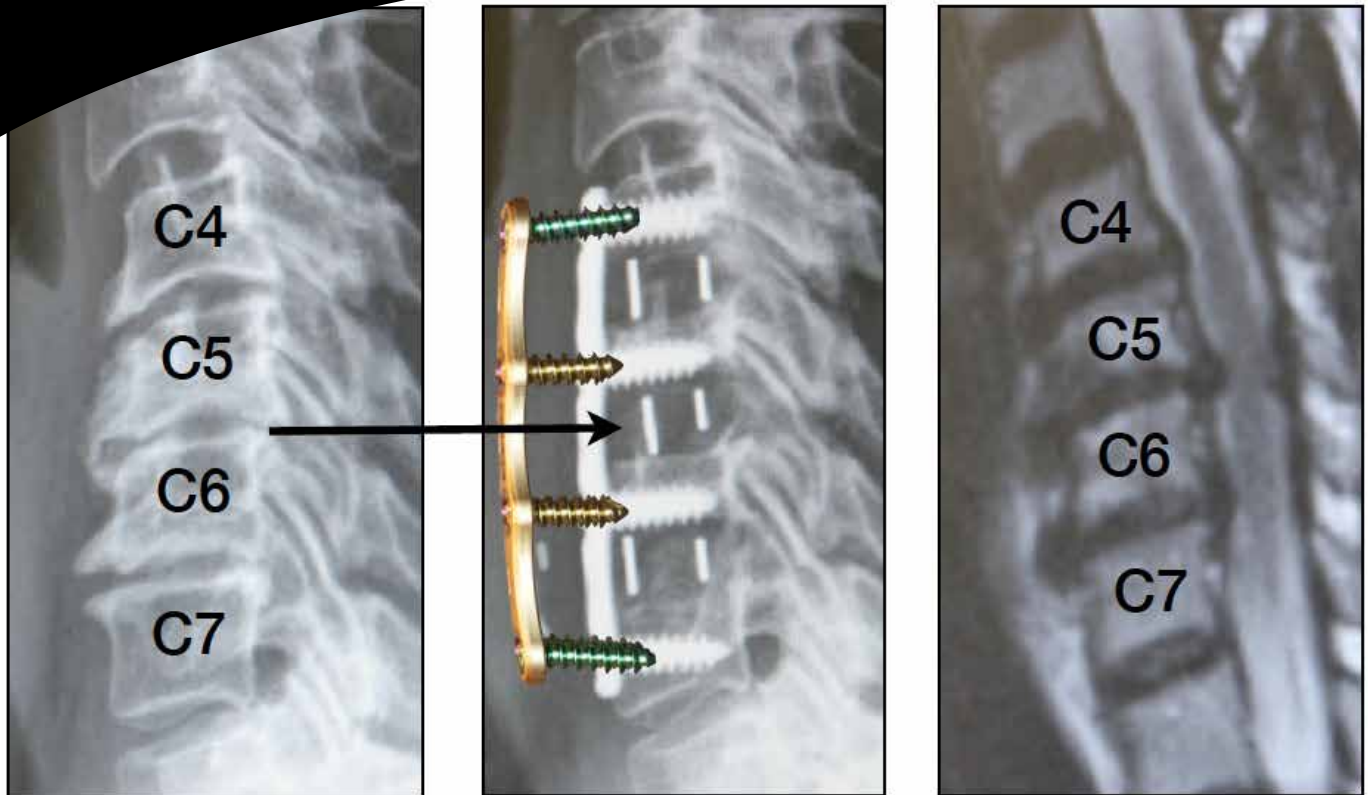


*59y/o Multi-level Stenosis C4-7

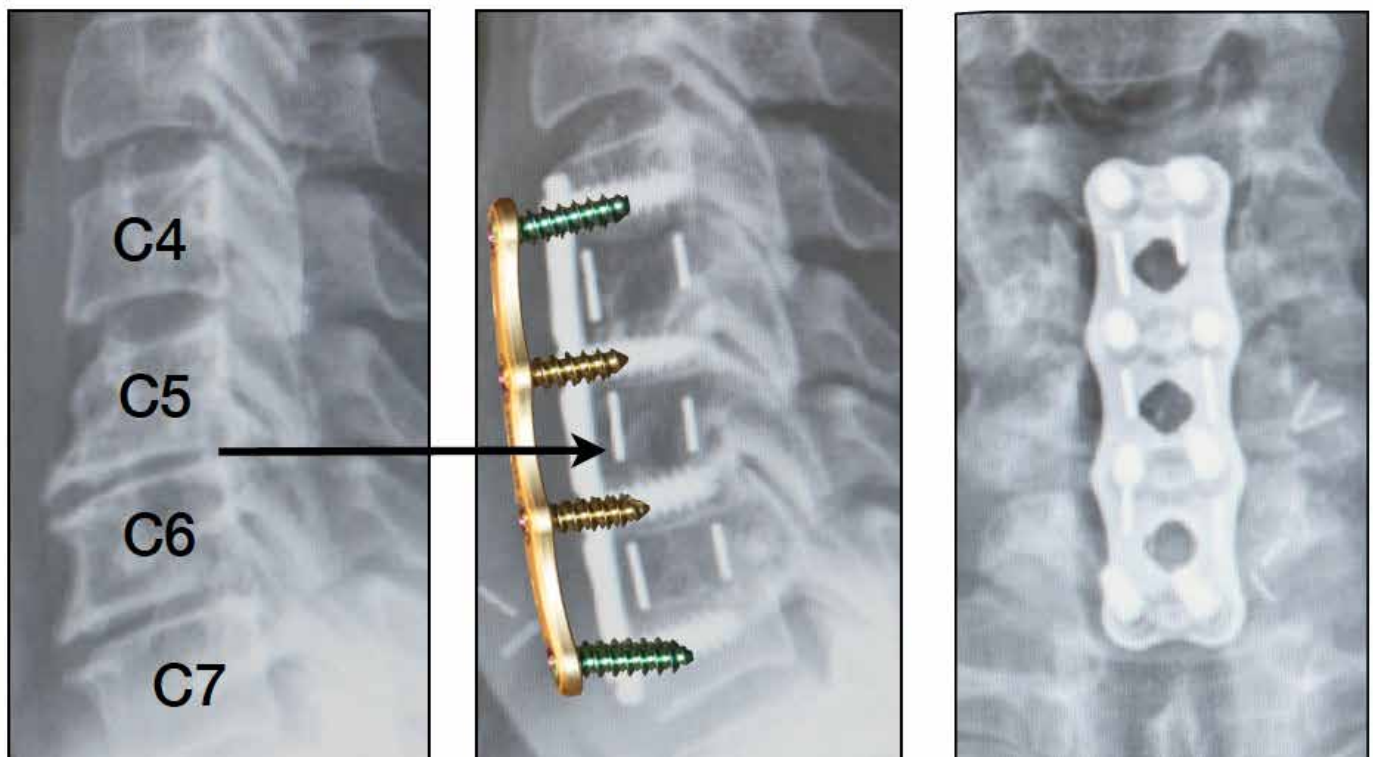


3 Level: C4/5, C5/6 & C6/7 King Cobra® & Copperhead® Cage

66 y/o Multi-Level Stenosis C4-7

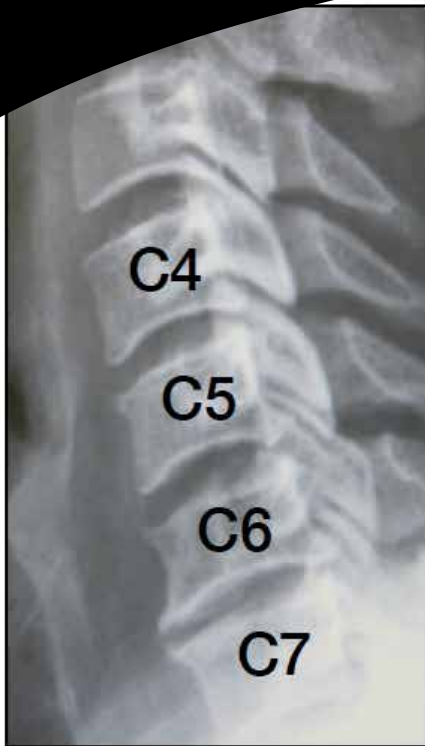


*62y/o Multi-level Stenosis C4-7

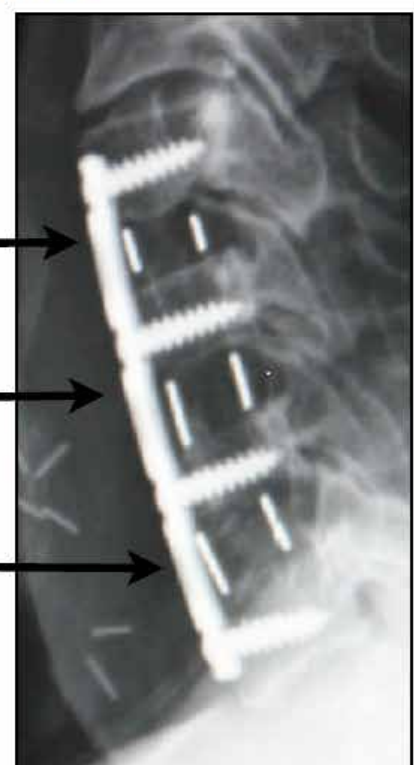
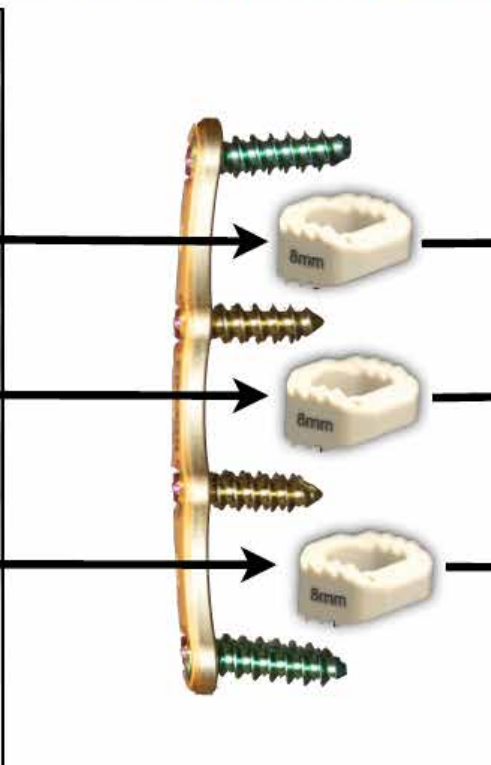
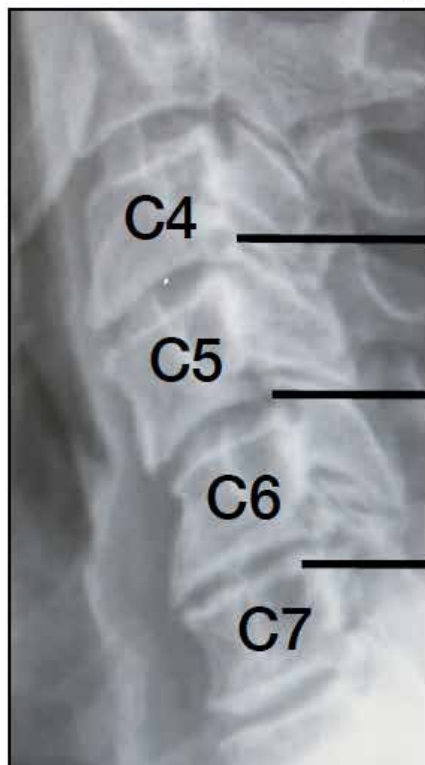


3 Level: C4/5, C5/6 & C6/7 King Cobra® & Copperhead® Cage

48 y/o HNP & Stenosis C4-7

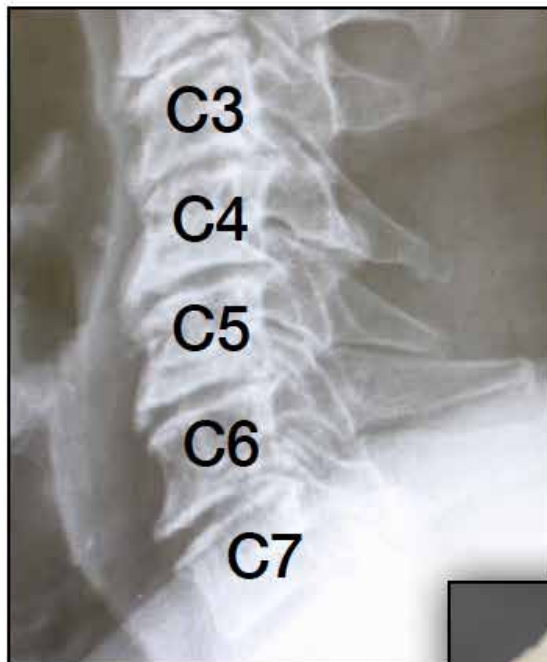


*45y/o HNP & Stenosis C4-7

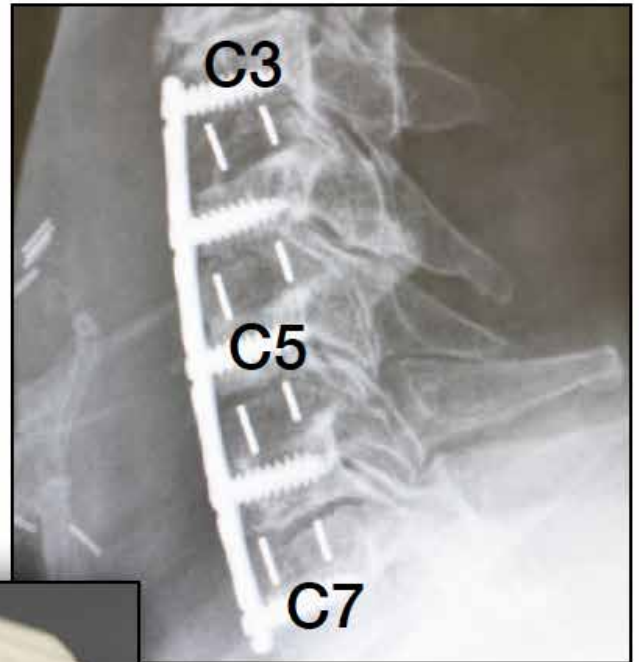


4 Level: C3/4, C4/5, C5/6 & C6/7 King Cobra® & Copperhead® Cage

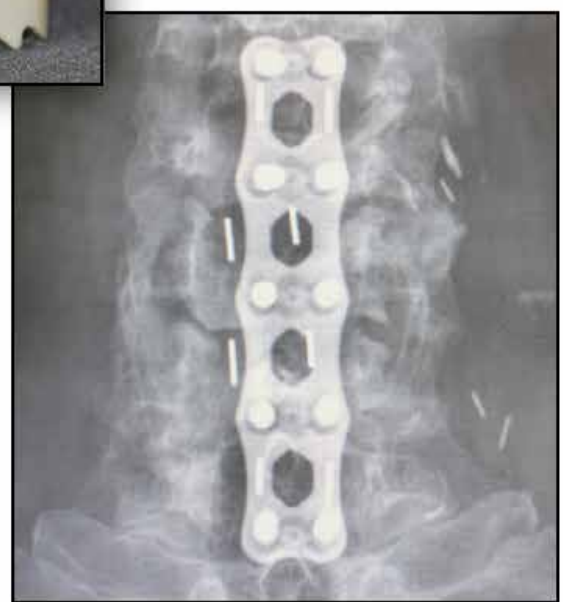
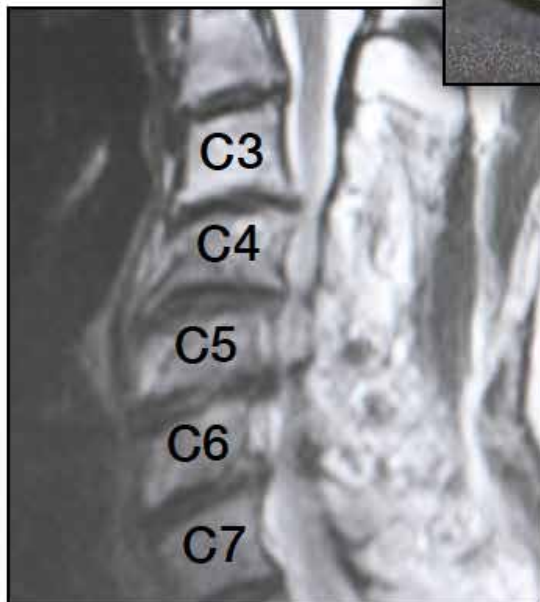
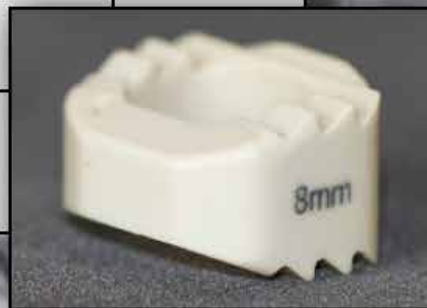
58 y/o WM with DDD & Multi-Level Stenosis



Pre-Op

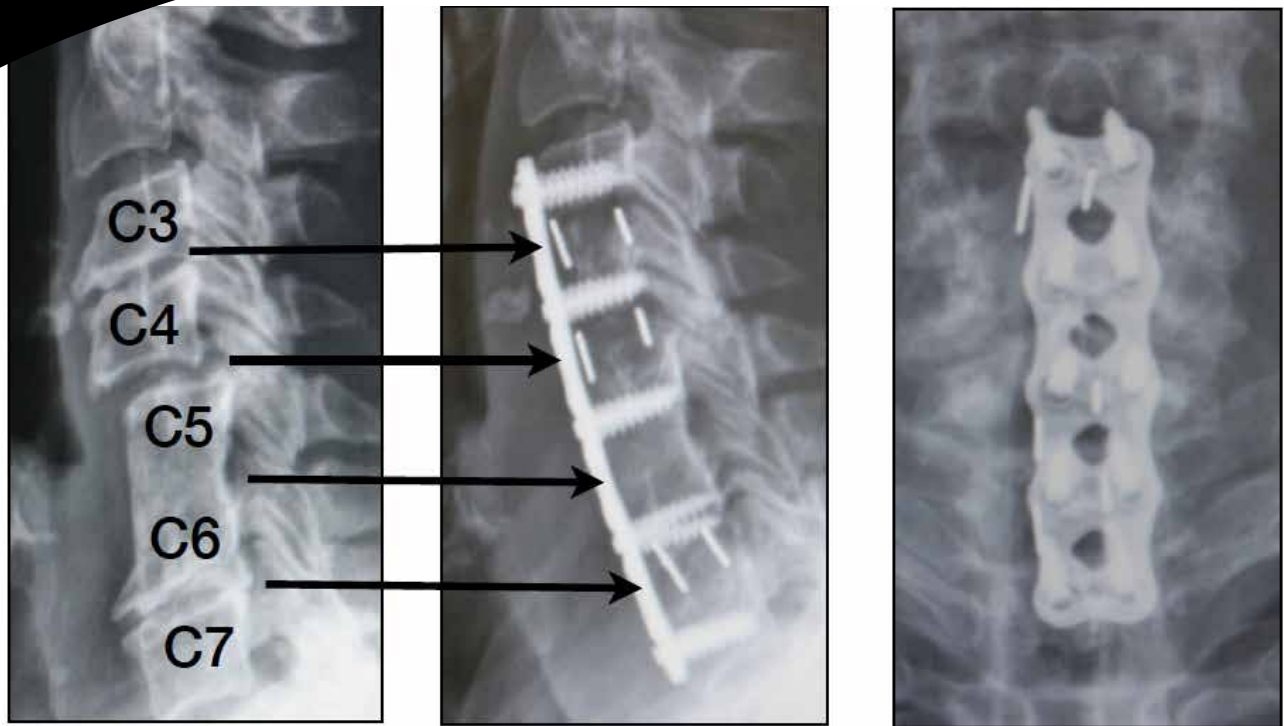


Post-Op

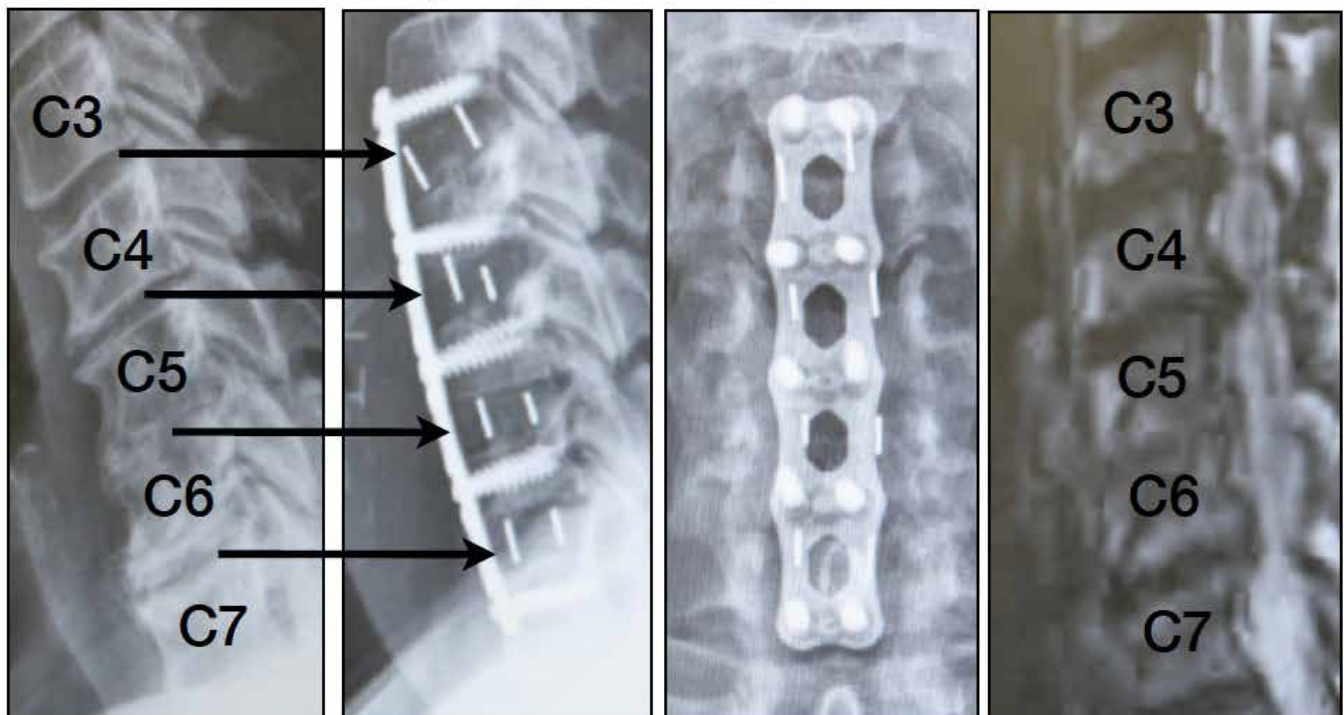


4 Level: C3/4, C4/5, C5/6 & C6/7 King Cobra® & Copperhead® Cage

59 y/o with previous fusion C5/6

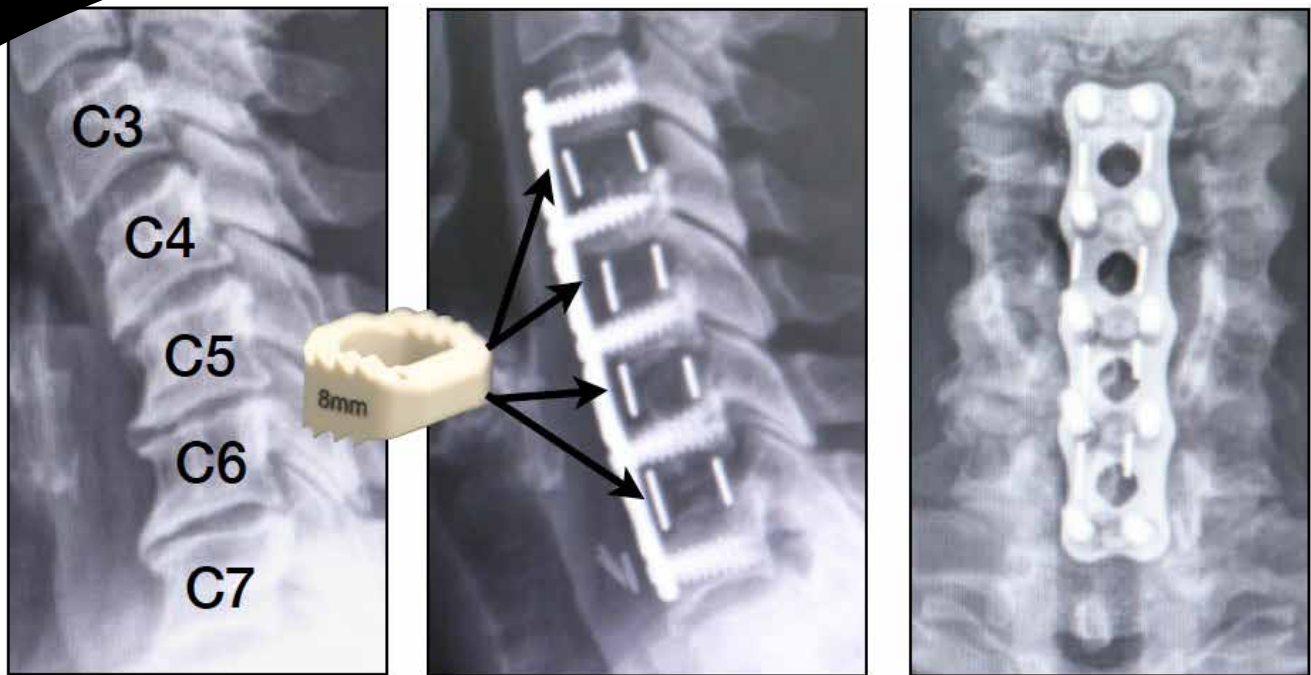


*63y/o Multi-level Stenosis

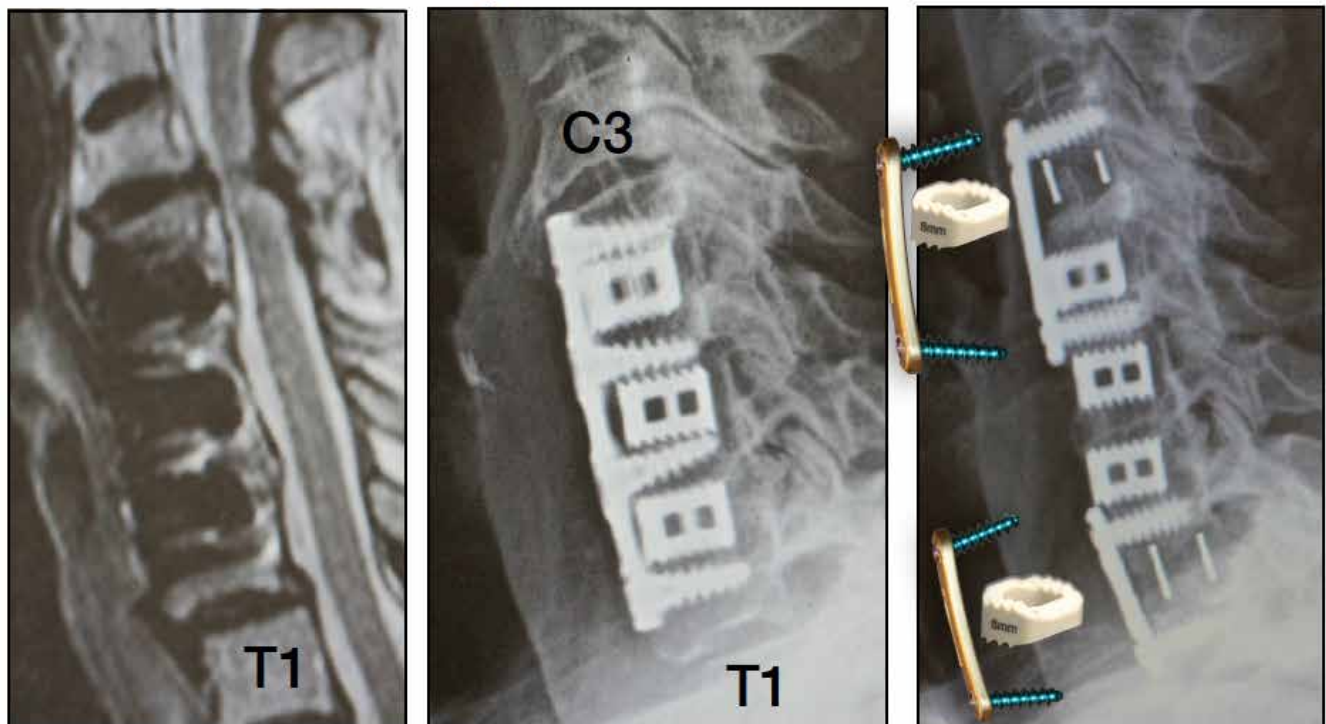


4 Level: C3/4, C4/5, C5/6 & C6/7 King Cobra® & Copperhead® Cage

55 y/o with DDD & Stenosis

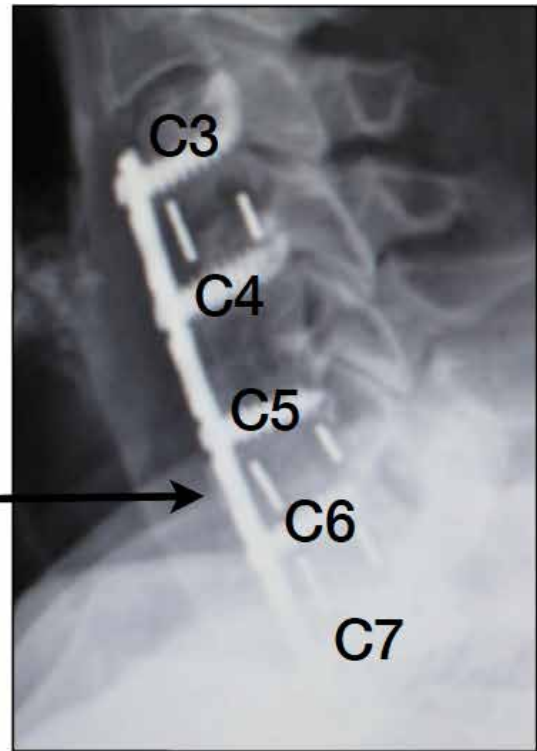
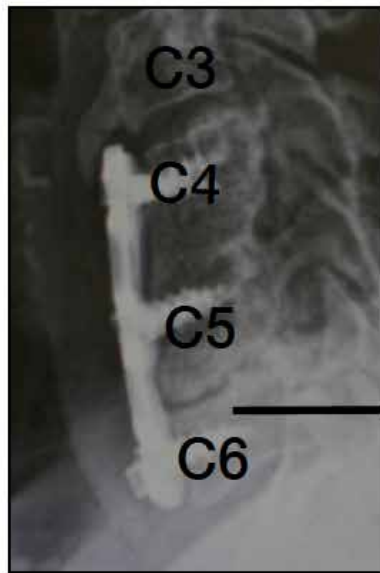


*68y/o C3-T1 Revision



4 Level: Revision King Cobra® & Copperhead® Cage

67 y/o with Pseudarthrosis & Screw backing out



*64y/o with screw backing out C7

