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Clinical and Radiological Outcomes of the Eminent Spine Anterior Lumbar Buttress Plate ("Fang Plate®"):

Introduction

Anterior Lumbar Interbody Fusion ("ALIF") is an accepted treatment for reduction of spondylolisthesis, diskogenic back pain, diskitis, trauma, and other conditions. The Eminent Spine ("ES®") Anterior Lumbar Buttress Plate ("Fang Plate®") can be used in conjunction with the ES® ALIF cage ("Cottonmouth®"). The Fang Plate® was developed specifically for the lumbar and lumbosacral spine as a low-profile plating option to address the problems of cage migration, reduce surgical time, and minimize vascular injury.

Fang Plate®
(Buttress Plate)

Purpose

This study evaluates the safety of the Fang Plate® in regards to screw back-out, screw breakage, implant breakage, vascular complications, and protection against migration of the interbody fusion device.

Device Description

The Fang Plate® can be used as an adjunct device to supplement anterior lumbar fixation. The plate consists of titanium and is available in three different footprints (21mm, 24mm, 27mm). The plate is prelordotic at 8°, has smooth contours for vessel protection, a broad wing span for protection against graft expulsion, a large window for clear visualization, and fangs to grip the bone for rotational stability. The Fang Plate® uses self-tapping screws, which are available in two sizes (5.5mm x 20mm, 25mm). The Fang Plate® employs unique TriLobe™ technology to ensure a low profile and prevent the screw from backing out.

Demographic (193 patients)	Diagnosis	Comorbidity
Males **46** Females **44** Age **26-64 (51)** Weight **98-265 lbs (178 lbs)**	Degenerative Spondylolisthesis **92** Degenerative Disk Disease and Post-Laminectomy **16** Degenerative Disk Disease and Diskogenic Pain **16** Degenerative Disk Disease and HNP **20** Degenerative Disk Disease and Stenosis **18**	Smoker **15** HTN **15** Diabetes **6** Previous Abdominoplasty **2** Previous C Section **2**

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Methods

This study examines 90 patients, from June 2009 to present, who were candidates for ALIF and supplemental Fang Plate® fixation. All patients were consecutive. Diagnoses include degenerative spondylolisthesis and degenerative disk disease with post-laminectomy syndrome, diskogenic pain, HNP, and stenosis.
All devices were inserted using an anterior retroperitoneal approach. All patients received an ES® Anterior Lumbar Interbody Fusion Device Cottonmouth® implant. Radiographical assessment includes plain x-rays at 2 and 6 weeks and at 3 and 6 months. All patients had supplemental posterior fixation.

Technique

(*Surgeon must review technique manual prior to insertion)

A standard left-side retroperitoneal approach was used to expose the anterior lumbar spine. After disk space material was removed, Cottonmouth device was inserted between
the vertebral bodies. Then, the correct size Fang Plate® was chosen.
Fang Plate tail should overhang 50-80% of the disk space. The awl was then used to create a pilot hole and the 5.5mm self-tapping screw was inserted. The awl was designed to decrease operative time. Reference the Fang Plate® technique manual on the ES® website.

Results

Of the 90 patients included in the study, each patient completed a 2 and 6 week and a 3 and 6 month follow up based on date of surgery. The mean operative time for the ALIF and Fang Plate® was 40-155 minutes (70 minutes). Estimated blood loss was 50-350cc (120cc). No patient needed re-operation and there was no plate breakage. No screws backed out of the Fang Plate®. There was no migration of the Cottonmouth®.

Discussion

This study has shown that the Eminent Spine Anterior Lumbar Buttress Plate "Fang Plate®" is a device that can be safely implanted. The TriLobe® locking technology is an effective and safe mechanism to lock the screw into the plate. There was no screw back-out. No Cottonmouth® devices migrated anteriorly. Therefore, this study has shown that the Fang Plate® is a safe and effective product. Clinical studies are currently being performed to further evaluate the product.

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Clinical and Radiological Outcomes of the Eminent Spine Anterior Lumbar Buttress Plate ("Fang Plate®"):

Complications	
Any type of screw back-out	0
Screw breakage	0
Implant breakage	0
Migration of IBFD	0
Puncture of Iliac vein	0
Pulmonary embolism	0
Urinary tract infection	0
Peritoneal tear	0

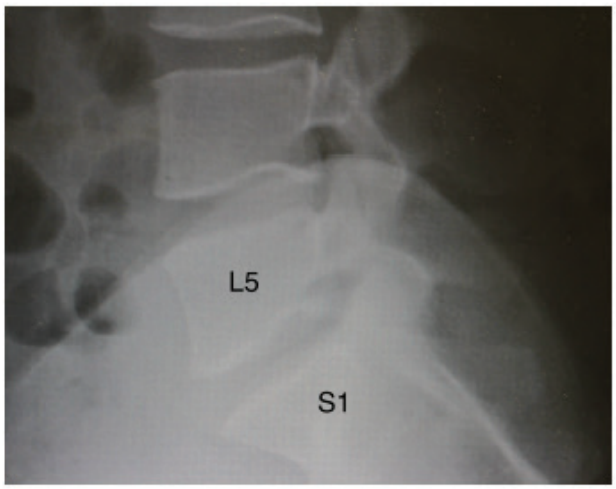
Screw Size	
5.5 x 20mm	29
5.5 x 25mm	104
Total	133

Plate Level	
L2/3	3
L3/4	13
L4/5	57
L5/S1	60

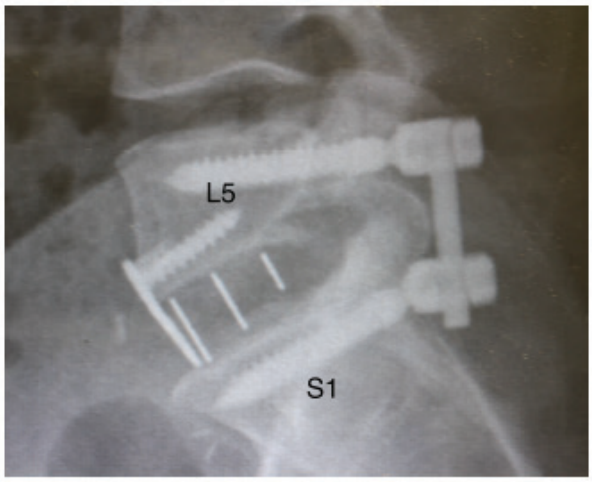
Plate Size	
21mm	2
24mm	30
27mm	101
Total	133

1 Level: L5-S1
Fang Plate®,Cottonmouth®(ALIF) Cage & Diamondback® Pedicle Screw System

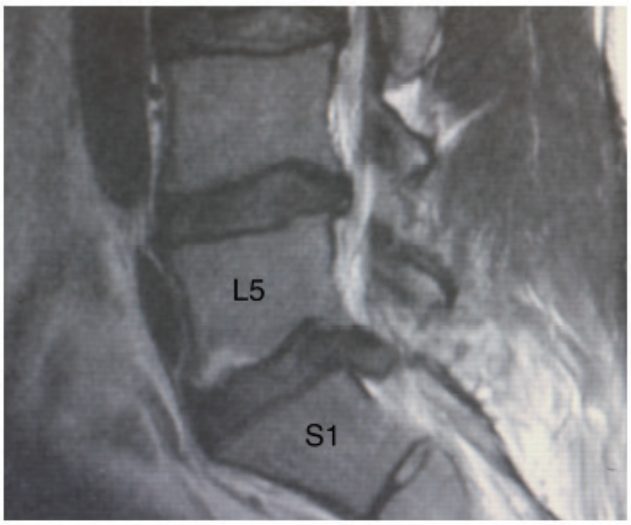
40 y/o WF with DDD and Recurrent Disk Herniation



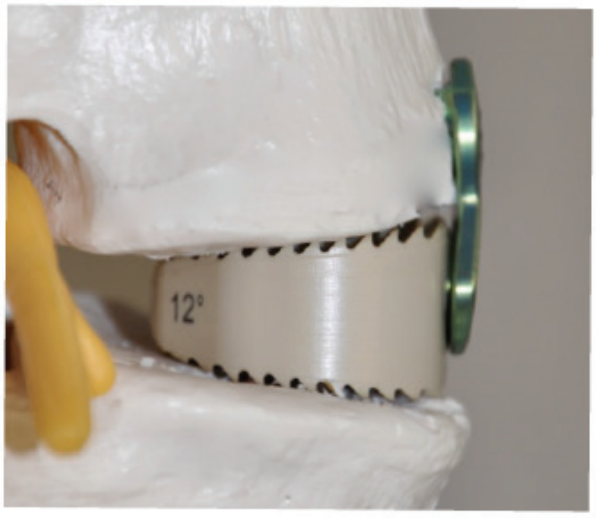
Pre-Op



3-month Post-Op X-ray



Pre-Op MRI

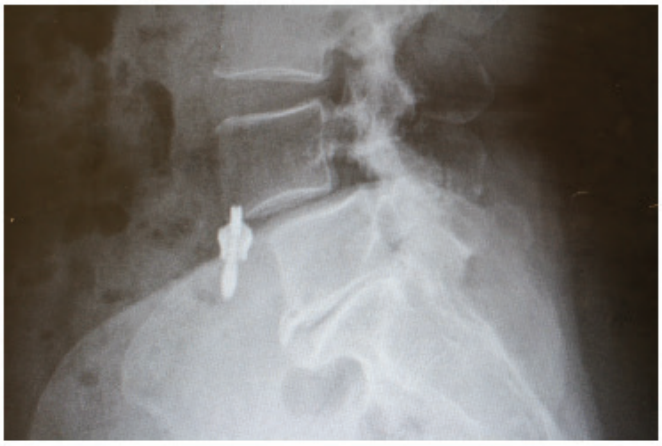


Model side view showing Fang Plate® and Cottonmouth® (ALIF)

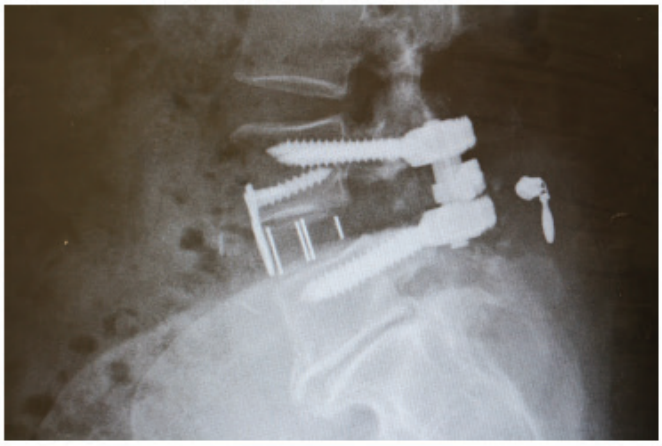
1 Level: L4-L5

Fang Plate®,Cottonmouth®(ALIF) Cage & Diamondback® Pedicle Screw System and Boa Constrictor® Cross Link

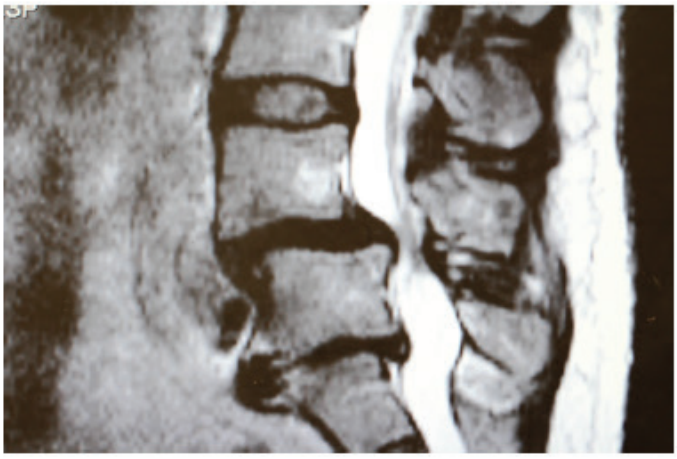
54 y/o WF with Degenerative Spondylolisthesis



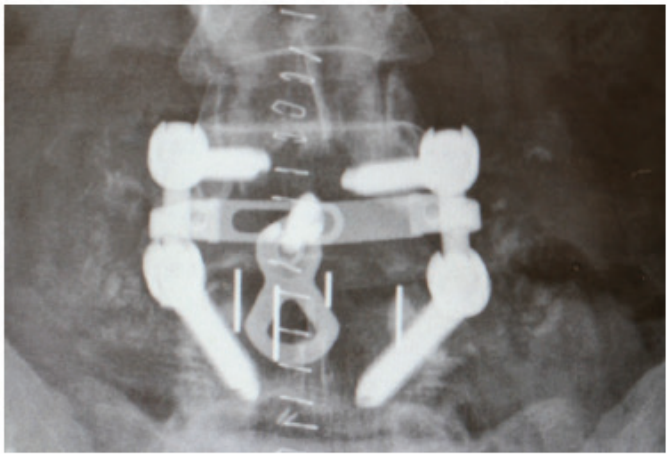
Pre-Op



Post-Op X-ray



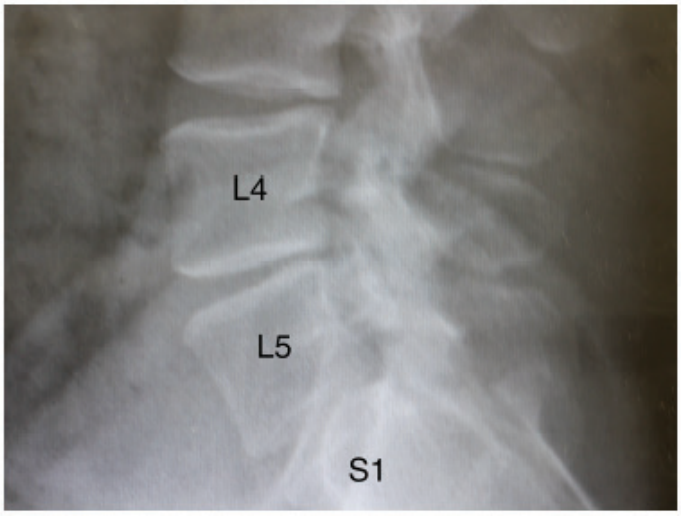
Pre-Op MRI



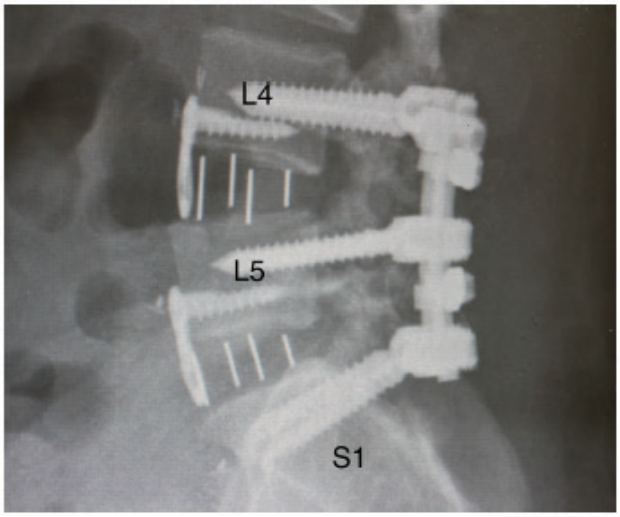
Post-Op X-ray AP

2 Level: L4-L5, L5-S1
Fang Plate®,Cottonmouth®(ALIF) Cage & Diamondback® Pedicle Screw System and Boa Constrictor® Cross Link

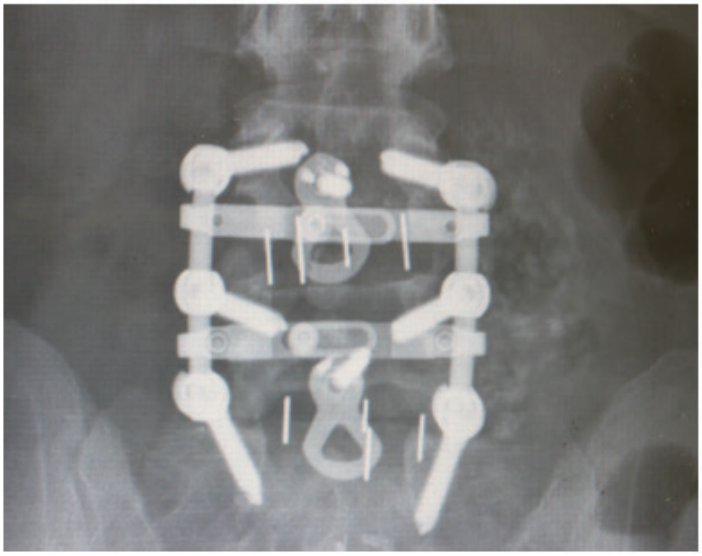
45 y/o WF with Diskogenic Lumbar Pain & Radiculopathy



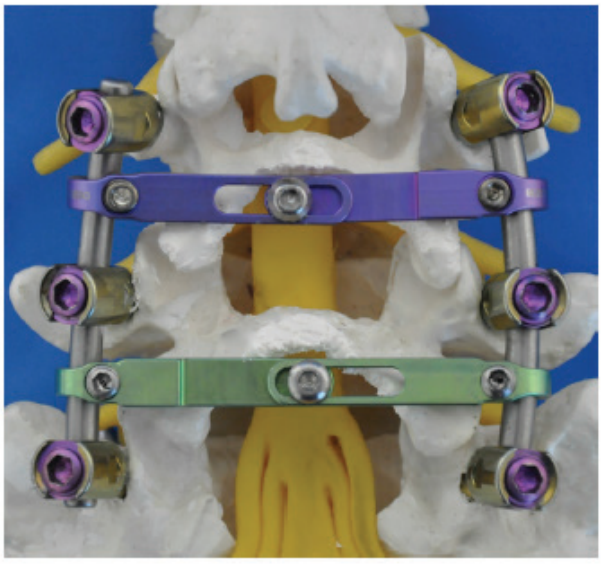
Pre-Op



6-month Post-Op X-ray



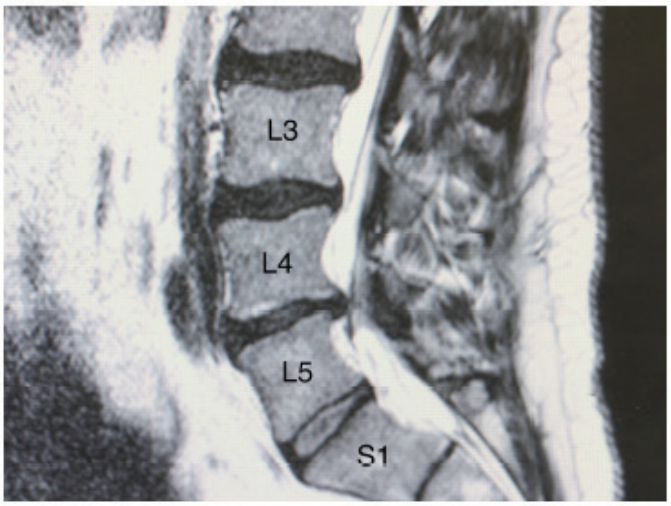
6-month Post-Op X-ray AP



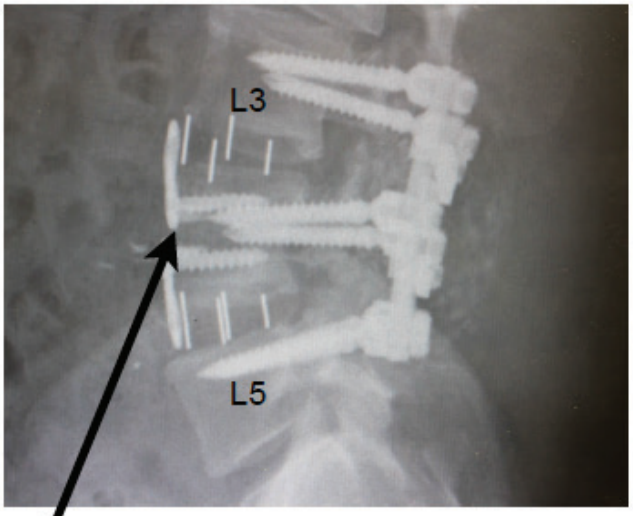
AP model view

2 Level: L3-L4, L4-L5
Fang Plate®,Cottonmouth®(ALIF) Cage & Diamondback® Pedicle Screw System and Boa Constrictor® Cross Link

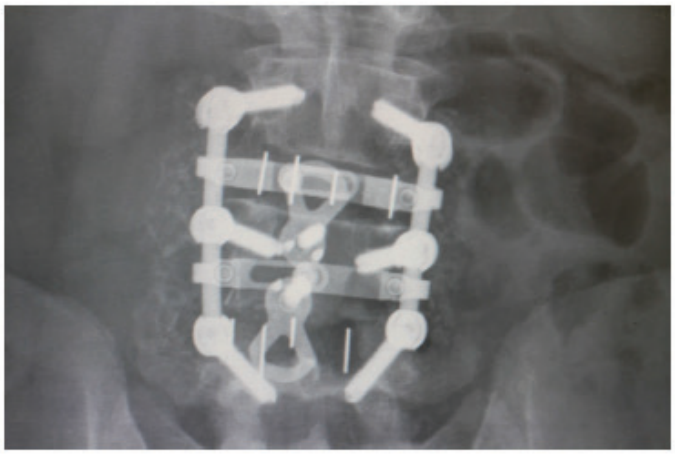
50 y/o WM with DDD and Stenosis



Pre-Op MRI



*Fang Plate® placed per vascular anatomy



6-month Post-Op X-ray AP

Model view of Fang Plate®