Interspinous Process Fixation with the Minuteman G3

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CASTELLVI SPINE MEETING
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What is the Minuteman G3

The world's first spinous process plating system that is:

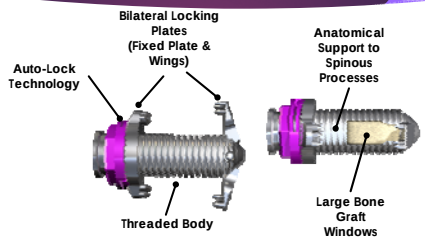
- Minimally Invasive
  - minimal soft tissue dissection and disruption
- Done through a lateral approach
  - guide wire and fluoroscopic guidance
- Minimal blood loss
  - About 5cc per level
- Achieves rigid fixation
- Achieves fusion

How Does it Work?

Actually achieves rigid fixation and FUSION through:

- Bone preparation for fusion via decortication
- Bone is tapped so that threads of the screw fully engage bone
- Threads are Hydroxyapatite (HA) coated
- High volume of bone graft delivery
- Rigid fixation respectful of bone quality

Innovative Device Features

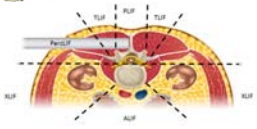


High Volume Bone Graft Delivery

Implant size	Aspen Window Opening	Minuteman G3 Window Opening	Minuteman G3 Bone Graft Volume
8mm	27mm²	89mm²	1.2cc
10mm	40mm²	89mm²	1.45cc
12mm	54mm²	105mm²	1.8cc
14mm	70mm²	109mm²	2.0cc
16mm	87mm²	115mm²	2.5cc

Anterior Cages	Bone Graft Volume
Stryker TLIF Cage	0.34cc – 1.00cc
Biomet TLIF Cage	0.55cc – 1.87cc

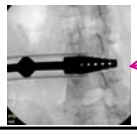
Safe Approach



- Approach is posterior to the facet joints
- Virtually no risk of damaging neurovascular structures, does not require neuromonitoring
- No irreversible damage to pedicles or facet joints
- No need to remove bone or strip any muscle

Preserves Anatomical Support Structures

- Intact Supraspinous Ligament maintains posterior stabilization
  - Most ISP devices require complete removal or sectioning of the Supraspinous Ligament
- Minimal removal of the Interspinous Ligament

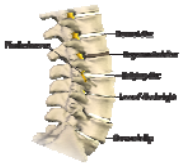


- "Sized to fit" bone tap lightly decorticates, for bleeding bone at the graft location

Indications for use:

Degenerative Disc Disease

- Including the following potential conditions resulting from DDD
  - Lumbar spinal stenosis with neurogenic claudication
  - Synovial cysts
  - Recurrent disc herniation
  - Foraminal Stenosis



Spondylolisthesis

Trauma

Tumor

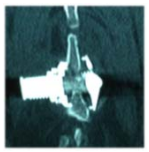
Can be Used with XLIF for Posterior Stabilization

- The Minuteman devices can be used as posterior adjuncts to XLIF procedures by using the same incision without having to change the patient position from the lateral position
- Hospitals have the ability to code for a full 360° fusion and increase reimbursement

Long Term Results

- 800+ cases worldwide
  - No implant failures or reportable events
  - No reported spinous process fractures during surgery

- 90 year old female
- 7 months post-op



- 63 year old male
- 2.5 months post-op

Biomechanical Study

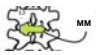
Stability and Decompression Mechanics of Several MIS Lumbar Fixation Technologies: A Biomechanical Study

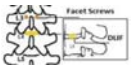
Bruce Cowles, Robin Parrish, William Lassiz, Jerrod Leasure, Jeffrey C Randall, MD

The Taylor Collaboration, San Francisco CA
University of Kansas, Lawrence KS

Minuteman device versus pedicle or facet screws, with lateral cages. Motion planes measured were:

- Flexion-Extension
- Lateral Bending
- Axial Rotation

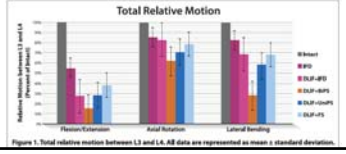


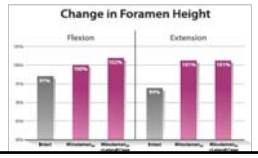


Biomechanical Study

The Minuteman device, when used in conjunction with a lateral cage, provides **no statistical difference in biomechanical stability** compared to bilateral pedicle screws (plus lateral cage).

The foraminal distraction and motion test results indicate the Minuteman G3 **achieves and maintains distraction of the foraminal space**.





Clinical Trial in the UK

- A prospective randomized trial on the efficacy and quality of life following treatment of lumbar spinal stenosis or degenerative disc disease with the Minuteman implant verses surgical decompression.

Interim Report scope
- Three surgical sites in U.K.
- 32 of 50 patients enrolled
- 5yr monitoring objectives:
  - VAS Leg & Back pain scores
  - Oswestry Disability Index
  - Zurich Claudication Questionnaire
  - Physical function
  - PGIC/CGIC
  - device adverse events
  - Employment status changes

Principal Investigator's assessment to date:
"We have found this new and innovative <Minuteman> device very promising. We have had reasonable experience with inter-spinous distraction devices. This <device> has been very different due to its ability of forming a fusion. So far we haven't had any device taken out for the reason of recurrent stenosis, unlike our past experience with other devices.

Minuteman results compared to Decompression:
- Shorter surgical procedure time
- Minimal post-surgical pain
- Negligible blood loss
- Shorter hospital stays (ready to discharge in few hours)
- Effective leg pain reduction (as good or better in the interim period than the gold standard decompression) with minimal surgical pain
- Effective on stenosis"

Patient #1

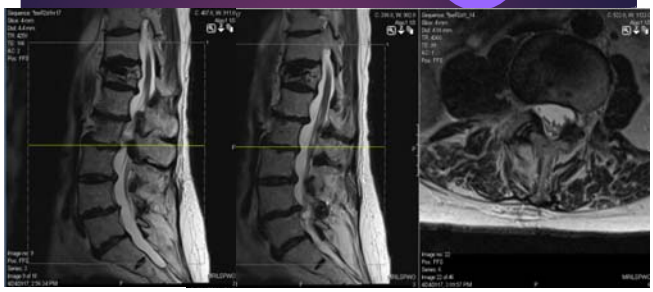
- AR, 90 y/o F with severe right leg pain
- Completely independent, lives alone
- Bedridden for over 1 week, can no longer ambulate
- Difficult to get an exam because of excruciating pain

Preoperative Images

Preoperative Images: T12-L1

Preoperative Images: L1-2

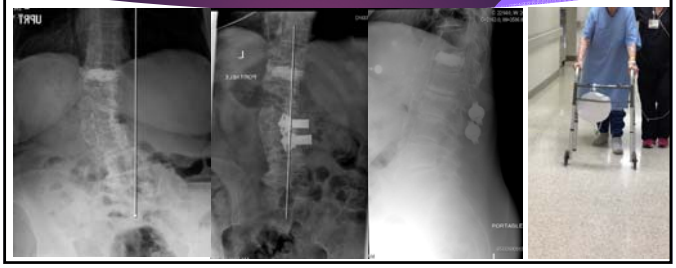
Preoperative Images: L2-3



Preoperative Images: L3-4

Preoperative Images: L4-5

Stage 1: L1-2, L2-3 Decompression and Fusion



Stage 2: T12-L1, L3-4, L4-5 Decompression and Fusion

Stage 2: T12-L1, L3-4, L4-5 Decompression and Fusion- POD 0

Patient #2

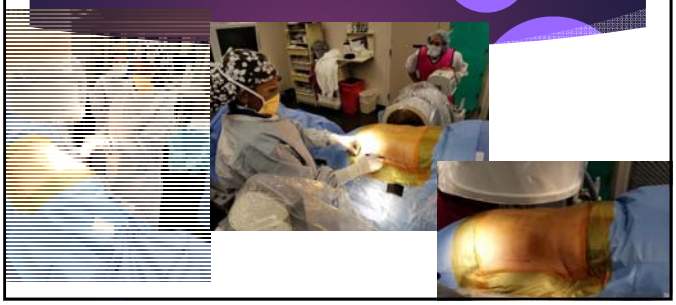
- LD, 83 y/o F
- History of L4-5 interbody cages placed for spondylolisthesis in 2010
- Leg pain did not resolve after surgery
- Presented to me with spinal stenosis with neurogenic claudication
- Cannot walk more than a few yards without weakness and pain

Preoperative Images

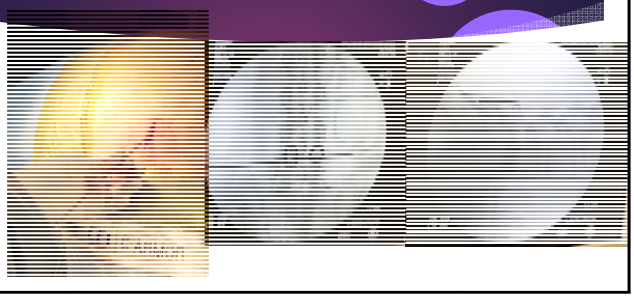
Preoperative Images: L3-4

Preoperative Images: L4-5

Mark Levels On Skin AP and Lateral Planes

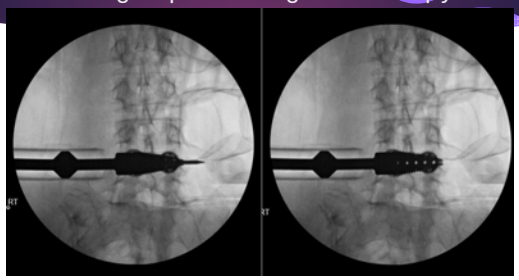


Guidewire Placement in AP and Lateral Planes

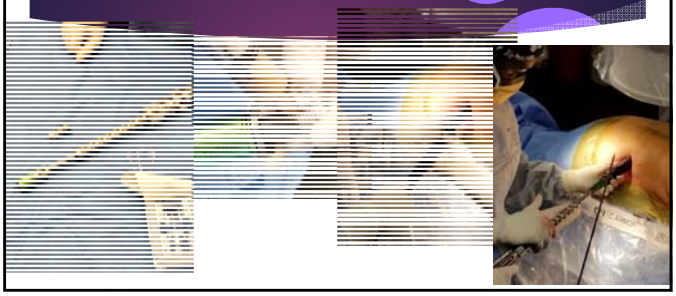


Intraop Video

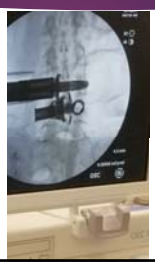
Sizing Implant Using Fluoroscopy



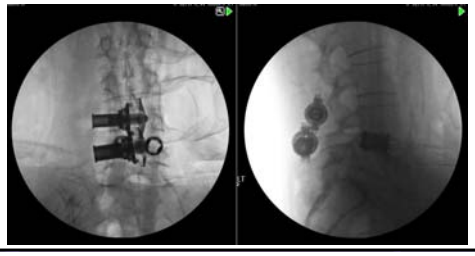
Load Implant, Place Allograft, Insert Implant



Deploy Wings and Compress Plates



Final Images



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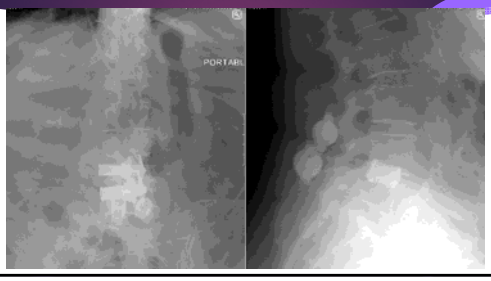

Summary: Clinical Benefits

- **Indirect Decompression** – increases space in the canal and foramina bilaterally
- **Lateral MIS Approach** – Minimal tissue disruption, blood loss or recovery time
- **Immediate, Rigid Stabilization** – No statistical difference between 4 pedicle screws & 2 rods
- **Full Fusion Site Preparation** – The most bone graft volume and the best fusion technique with tapping, decortication and locking plate technology

All Leading To…
A Clinically Proven Solution for Posterior Column Stabilization & Fusion

MINUTEMAN IMPLANT:

INCREASES
- Patient Satisfaction
- Surgeon Efficiency
- Surgeon Reimbursement
- Procedural Profitability

DECREASES
- OR Time
- Hospital Stay
- Blood Loss
- Radiation Exposure
- Reposition the patient
- Infections
- Surgical Complications
- Pain

Thank you!

Questions?