

**Minimally Invasive Outpatient Lumbar Fusion
and
Multi-Level Outpatient Cervical Disk Replacement**



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Paradigm Shift

- More and more surgical procedures are being adapted for the outpatient setting
- Less risk of patient infections
- Better control of costs; far less costly than those performed in hospitals

**Factors that have kept these procedures in
the hospital setting:**

- Comorbidities
- Airway Issues
- Patient time under anesthesia
- Blood Loss
- Post-Op Pain Control- IV Medication

Are these procedures safe in the ASC setting?

- **Comorbidities continue to be primary concern**
 - Appropriate patient selection- ASA PS 1-3
 - Appropriate clearance by medical doctor
- **Time Under Anesthesia**
 - Focused hypotensive anesthesia
- **Maintain Low Blood Loss**
 - Surgeon skill
 - Minimal tissue dissection and bony work
 - Well trained and prepared staff
- **Post-Op Pain**
 - Controlled with oral medications

ASA Classifications

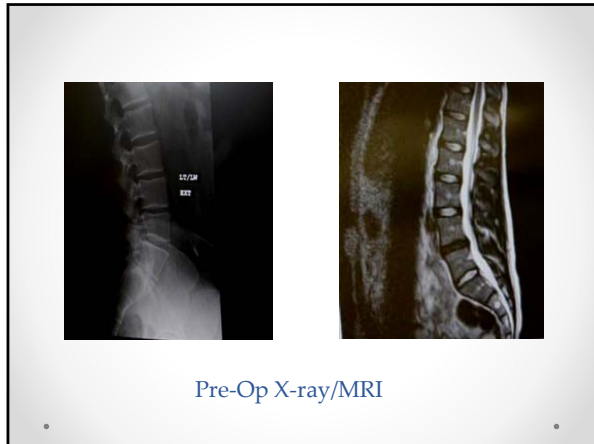
ASA PS Category	Preoperative Health Status	Comments, Examples
ASA PS 1	Normal Healthy Patient	No organic, physiologic, or psychiatric disturbance; excludes the very young and very old; healthy with good exercise tolerance.
ASA PS 2	Patient with mild systemic disease	No functional limitations; has a well-controlled disease of one body system; controlled hypertension or diabetes without systemic effects, cigarette smoking without chronic obstructive pulmonary disease (COPD); mild obesity; pregnancy
ASA PS 3	Patient with severe systemic disease	Some functional limitation; has a controlled disease of more than one body system or one major system; no immediate danger of death; controlled congestive heart failure (CHF), stable angina, old heart attack, poorly controlled hypertension, morbid obesity, chronic renal failure; bronchospastic disease with intermittent symptoms

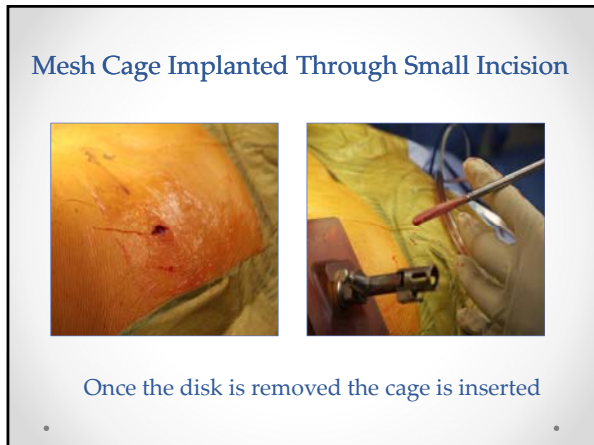
FLIF

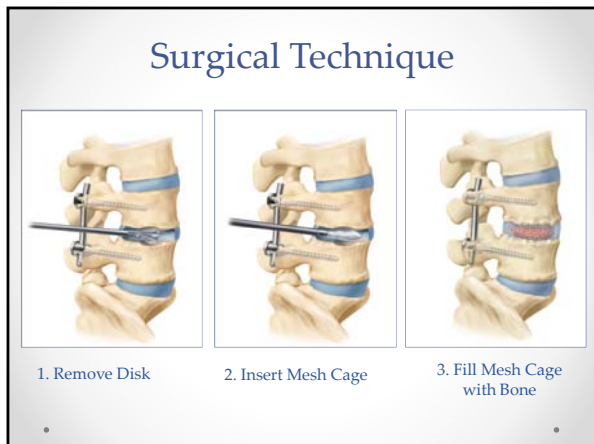
(Far Lateral Interbody Fusion)

Procedure Highlights

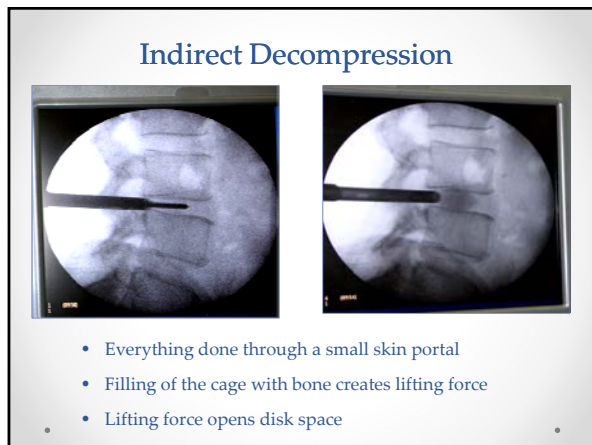
- Outpatient
- General Anesthesia
- Small Incisions
- Biplanar C-arm Fluoroscopy
- Neurospinal Monitoring / Pedicle Screw Monitoring
- 1-3 Circumferential levels possible
- 2-4 Hour Procedure Time
- 2-3 Hour Recovery Time
- Ambulatory and able to void prior to discharge

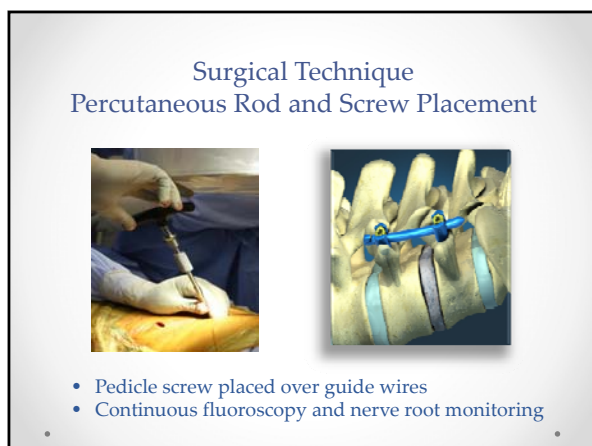








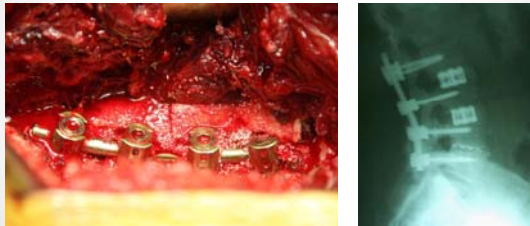






Post-Op X-ray of Outpatient FLIF

Conventional Open Fusion Procedure



FLIF – Clinical Results

Clinical Results	
Average OR Time	129 minutes
Surgeon Time	118 minutes
Recovery Time	180 minutes
Blood Loss	141 cc

Total = 33 patients: 22 (1 Level); 9 (2 Level); 2 (3 Level)

Advantages of FLIF over Conventional Open Instrumented

- Less Blood Loss
- Less Tissue Dissection
- Minimal Epidural Scarring
- Less Post-Op Pain
- More Rapid Recovery

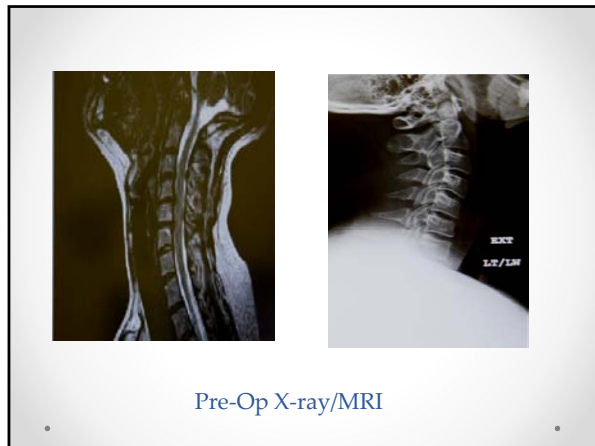
FLIF in ASC

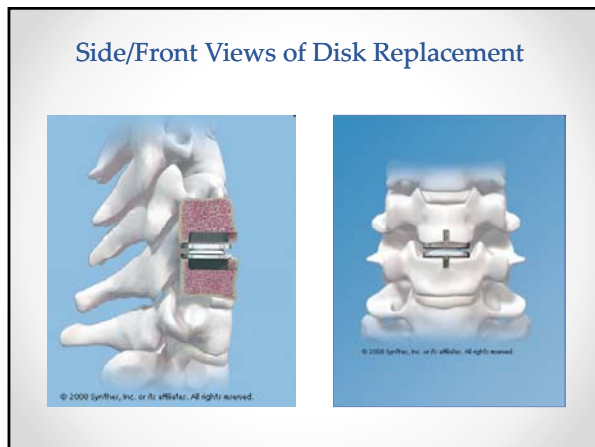
- **Appropriate patient selection**
 - Pre-Op evaluation – ASA status
 - Surgeon/Anesthesiologist dependent
- **Time under anesthesia**
 - Focused hypotensive anesthesia
 - Time under anesthesia < 4 hours
- **Minimal blood loss**
 - Surgeon skill
 - Minimal muscle tissue dissection
 - Intra-Op paraspinal muscle “cocktail”
- **Post-Op pain**
 - Controlled with oral medications
- **IV Antibiotics**
 - One Pre-Op/One Post-Op
- **Hemovac drain removed in 24 hours**

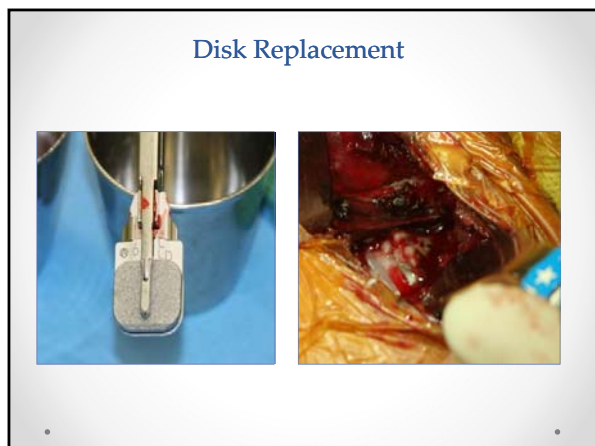
Cervical Disk Replacement

Procedure Highlights

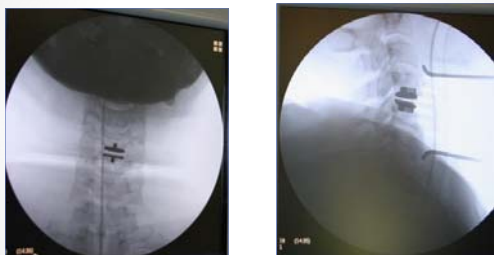
- Outpatient procedure
- Younger Patients with Herniation
- General Anesthesia
- Neurospinal Monitoring
- C-Arm Fluoroscopy
- 5cm incision
- Minimal blood loss
- 1-2 Hour total procedure time
- Motion Preservation/Motion Restoration
- Decreased Risk of Adjacent-Level Degeneration







Anterior /Posterior Lateral X-ray Views



Cervical Disc Replacement

Clinical Results	
OR Time	94.2 minutes
Surgeon Time	77.5 minutes
Recovery Time	140.8 minutes
Blood Loss	95.0 cc
Complications	None

Cervical Disk Replacement in ASC

- **Appropriate patient selection**
 - Pre-Op evaluation – ASA Status
 - Time under anesthesia < 2 hours
 - Surgeon/Anesthesiologist dependent
- **Time under anesthesia**
 - Typically shorter than 1-Level FLIF
 - Focused hypotensive anesthesia
- **Minimal blood loss**
 - Surgeon dependent
 - Minimal bony work
- **IV antibiotics**
 - One Pre-Op/One Post-Op
- **Post-Op pain**
 - Controlled by oral medications
- **Hemovac removal in 24 hours**

Summary

- New Cervical and Lumbar Fusion techniques are far less painful and disabling than those of the past
- Spine Surgery can now be performed safely and effectively, without the hospital stay, by specially trained surgeons in specially equipped surgery centers

This presentation includes off label uses of medical products

- **Physician Directed Applications**
 - Physician directed applications, also known as "off-label"¹ uses, are an integral component of the art and science of medical practice, particularly for specialty physicians. Physicians may choose to use medical products such as prescription drugs, biologics, and devices, for uses not listed in the United States (US) Food and Drug Administration (FDA) approved or cleared labeling.
- **Background**
 - It is not uncommon for some off label uses of medical products to become standard of care in the practice of medicine.² In fact, off label uses of certain medical devices and drugs can be found in standard textbooks for medical subspecialties. In certain patient populations, such as children and cancer patients, off label use of medical products is extensive, when appropriate therapies have not been developed or evaluated for the populations or a clinical trial is not feasible (such as in the case of rare diseases). In these circumstances, physician directed applications provide treatments that may not otherwise be available for some of the nation's youngest and most critically ill patients.

The Alliance of Specialty Medicine has approved this statement.

¹ "Off label" use for prescription drugs, biologics, and approved medical devices means any use that is not specified in the labeling approved by the FDA. For cleared medical devices, "off label" means any use that is not included in the cleared "indications for use." Labeling is considered as any written material which accompanies, supplements, or explains the product.

² Refer to relevant medical specialty society for specific examples.

Thank You!
