

X360

Procedural Overview

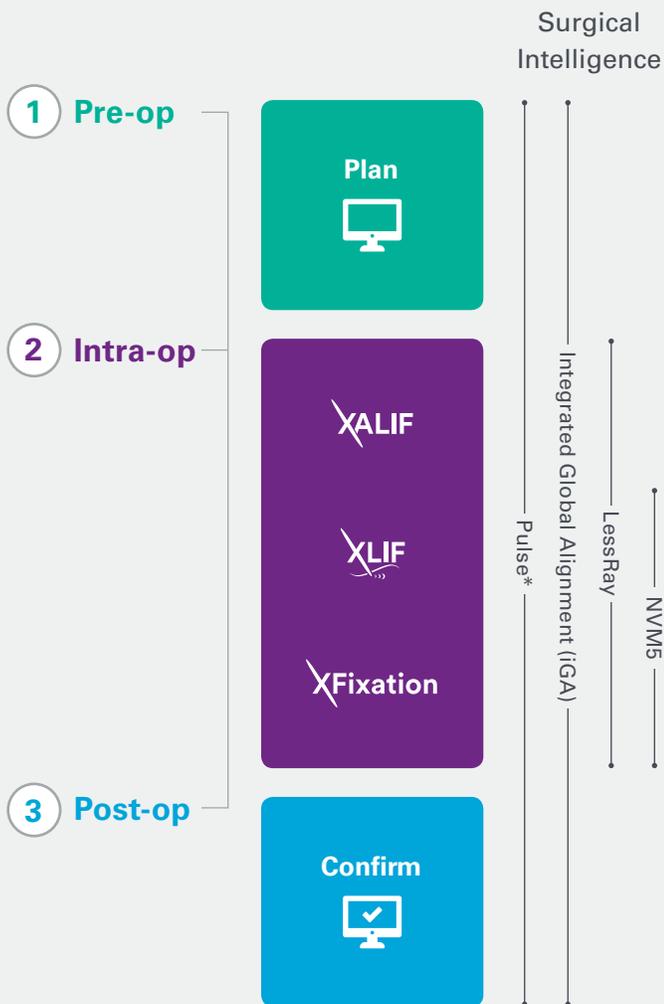




A comprehensive approach to lateral single-position surgery

X360 Powered by Surgical Intelligence

X360 provides significant OR time savings³ by keeping the patient in lateral decubitus throughout the entire surgery. Further OR efficiencies can be achieved by multitasking during procedures.



*Not all modalities available at this time

Key Benefits



Patient

Designed to reduce patient time under anesthesia and lower intraoperative risks^{1,2}



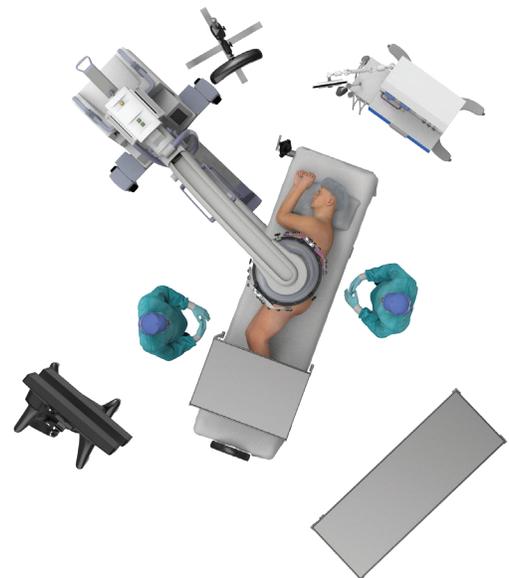
Surgeon

Improve OR efficiency and workflow
Increase the number of operative levels for lateral surgery



Hospital

Reduce mean OR time by up to 60 minutes³, resulting in nearly \$5,000 per patient in hospital cost savings^{4,5}
Shorter hospital stays due to reduced intraoperative risks from less time under anesthesia⁶⁻⁸



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Pre-surgical Preparation

Equipment Requirements

OR Items

- Radiolucent surgical table
- Fluoroscopy
- 3-inch tape
- Foam padding
- Wide or block drapes and other draping items
- Light source
- C-arm

Instrumentation

- Neuromonitoring system (Pulse or NVM5)
- XALIF Access System (LATALIFACCESS)
- XLIF Access System (ACCES4)
- Articulating table attachment arms:
 - M4AARM
 - LATALIFARM
- Disc-prep instrumentation:
 - XLIFINS1 and XLIFINS2
 - ALIFDISCPREP1 and ALIFDISCPREP2
- Desired implants:
 - ALIF PEEK: Brigade Lateral
 - ALIF Titanium: BASE
 - XLIF PEEK: CoRoent XL Family, Cohere XLIF
 - XLIF Titanium: Modulus XL Family

- Desired fixation:
 - Reline MAS Reduction
 - XLIF Decade Plate
 - Brigade Plate
 - Halo Buttress Plate
- XLIF disposable kit 3240060 (or 3241000 for low-profile shim)
 - Light cable
 - Shims
 - Annulotomy knife
- XLIF dilator kit 2029950
 - Dilators
 - Probe
 - K-Wire
- Vascular instrumentation:
 - Needle driver
 - Knot pusher
 - Clip applier
 - Peanut
 - Sponge stick
 - Long pick-up
 - 4.0/5.0 prolene
 - Scissors

Surgical Considerations and Patient Selection

OR Staffing Considerations

- Access surgeon prepared for surgical workflow
- Anesthesiologist prepared for surgical workflow and motor response needs
- OR staff prepared for surgical workflow

Preoperative Imaging Considerations

Interpreting Sagittal and Axial MRI (Fig. 1)

- Psoas and lumbar plexus
- Vascular anatomy
- Bifurcation and lateralization of great vessels
- Fatty tissue plane between vasculature and disc space
- Foraminal and central stenosis

Interpreting Lateral and AP X-ray Images (Fig. 2)

- Pathology
- Spinopelvic parameters and sagittal alignment
- Coronal alignment
- Osteophytes
- Crest anatomy

Patient Specific Considerations

- Pain history
- Age
- BMI
- Previous spine surgery
- Previous abdominal surgery
- Previous kidney surgery
- Previous vascular surgery
- Previous retroperitoneal radiation
- Co-morbidities

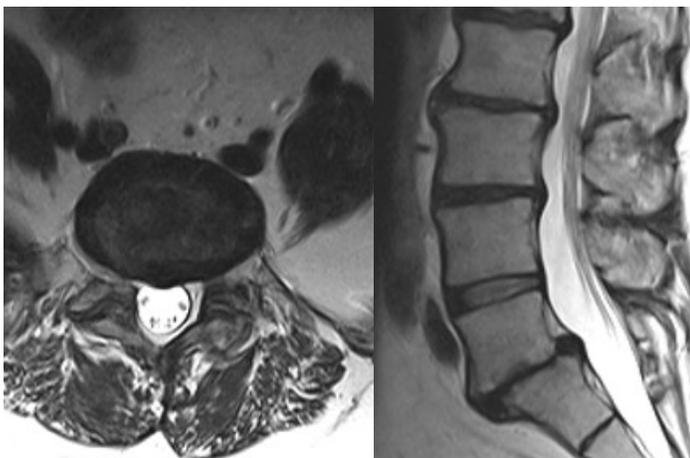


Fig. 1

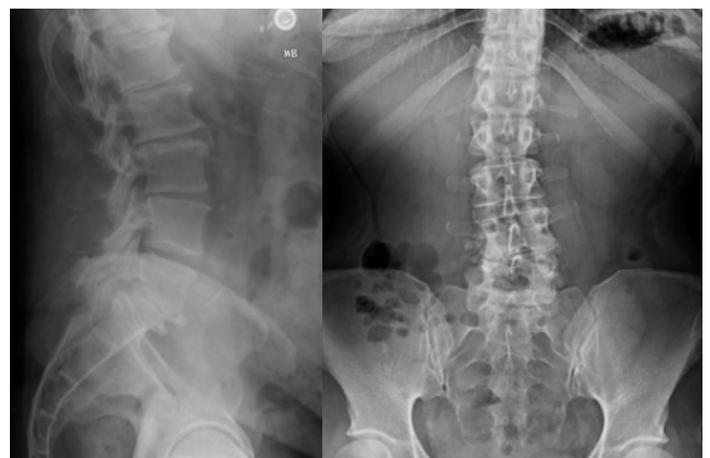
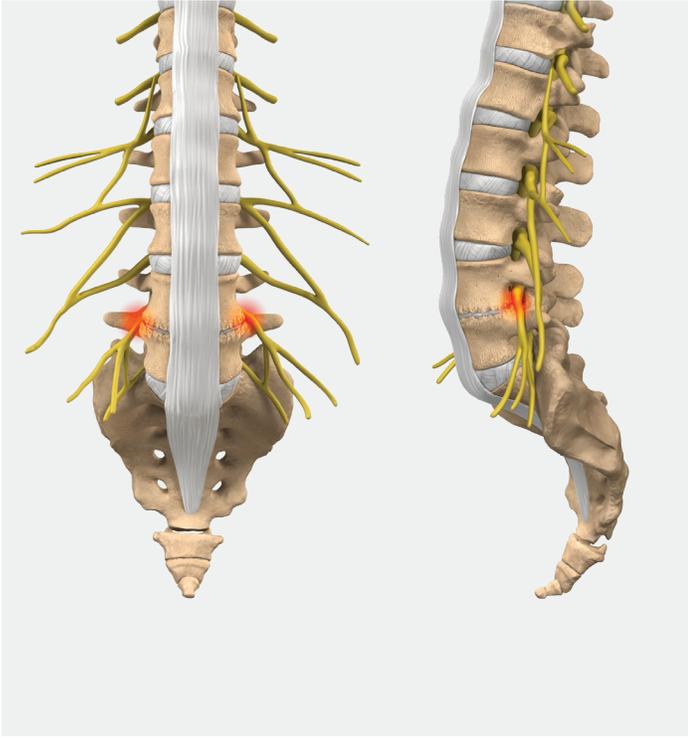


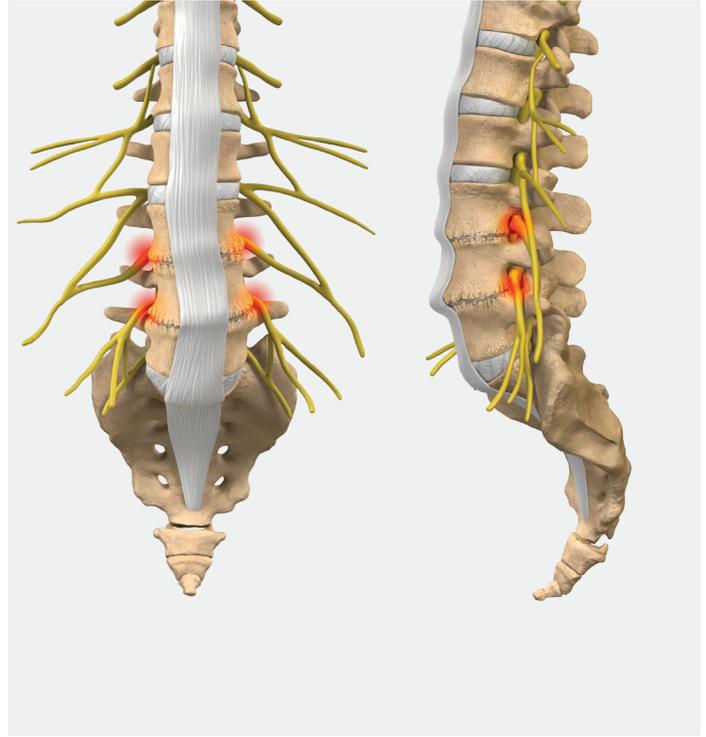
Fig. 2

Indications

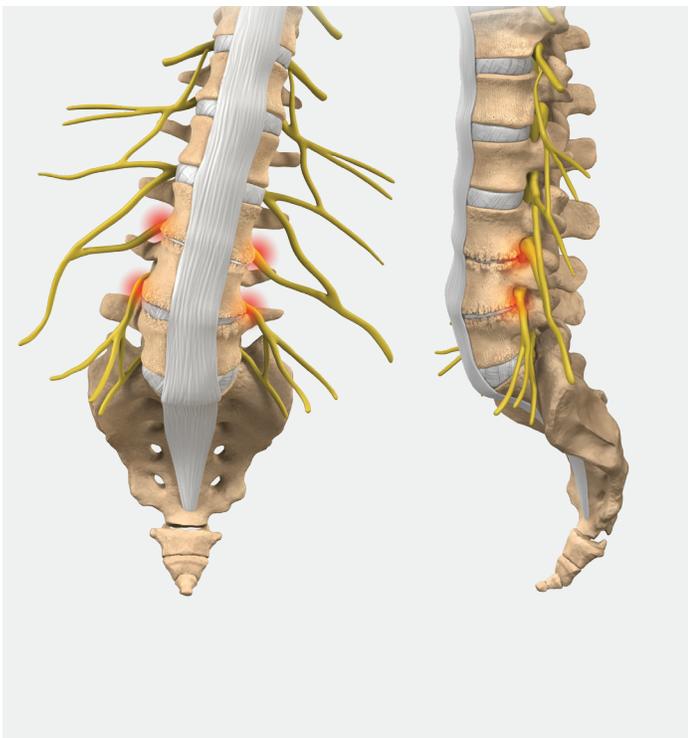
Degenerative Disc Disease (DDD)



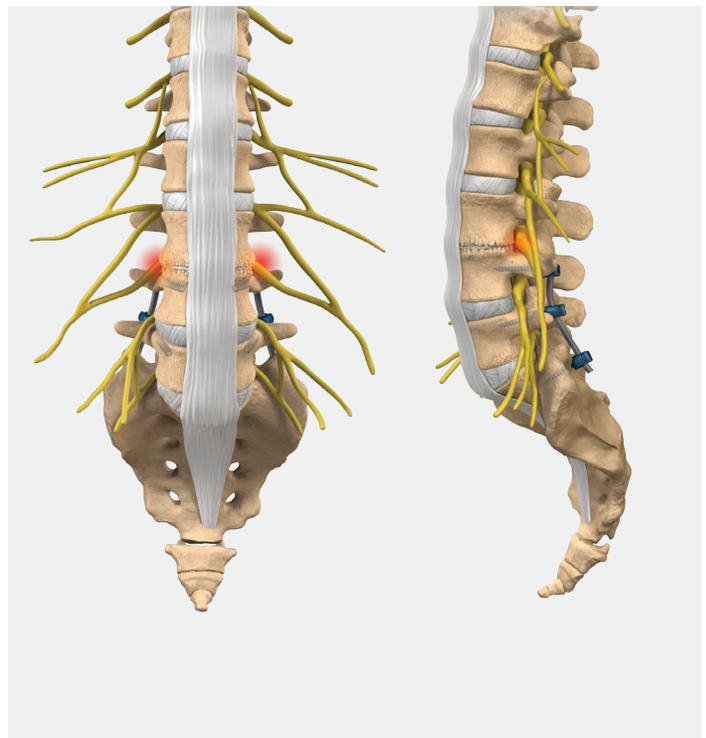
Degenerative Spondylolisthesis



Degenerative Scoliosis



Adjacent Segment Disease Secondary to Advanced DDD



iGA Case Planning

Calculating Alignment

The restoration or preservation of patient alignment begins with calculating spinopelvic parameters and developing a surgical plan.

NuvaLine (Figs. 3, 4), a simple software application for tablet and mobile devices, is designed specifically for this purpose by intuitively navigating through the calculation measurements. It provides an efficient assessment to determine and evaluate key spinopelvic parameters that are based on anatomical landmarks. Prior to surgery, it is recommended to obtain full 36 inch standing radiographs in both sagittal and coronal planes. If 36 inch standing cannot be obtained, it is critical that the radiograph captures at minimum the following anatomical landmarks:

- Femoral heads
- Sacral endplate
- Superior L1 endplate

NuvaLine is designed to capture three important parameters based on these landmarks in the radiographic image:

- Pelvic Tilt (PT) **(A)**
- Pelvic Incidence (PI) **(B)**
- Lumbar Lordosis (LL) **(C)**

With these, NuvaLine is designed to calculate the proportionality between PI and LL **(D)**, which is a key element in assessing a patient's global sagittal alignment, along with the PT of the patient. Ideally the patient's spinopelvic parameters reflect the primary alignment objectives that are most closely correlated to health-related quality of life (HRQOL) outcomes⁹:

- SVA < 4cm
- PT < 20°
- PI – LL within 10°



Fig. 3

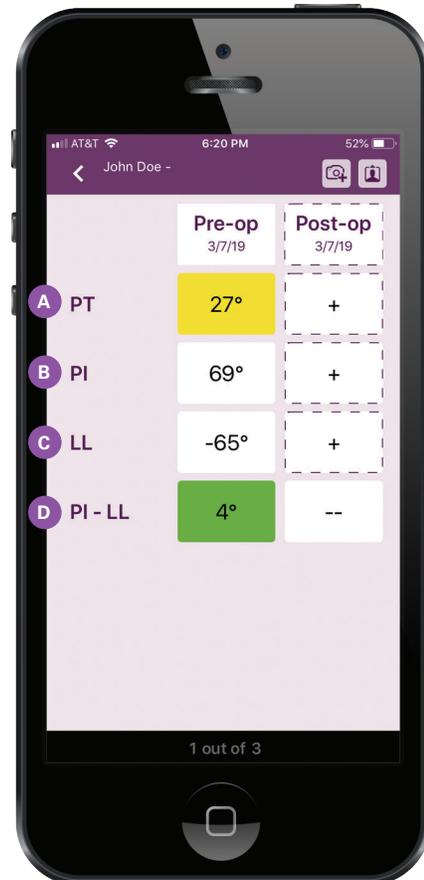


Fig. 4

X360 Procedural Overview

OR Set-up

Room Set-up *(Fig. 5)*

To take advantage of the time benefits associated with X360, it is important to set the operating room up for maximum efficiency prior to the case.

- Radiolucent surgical table centered in the room **(A)**
- C-arm from the anterior side of the patient to prepare for the XLIF and/or XFixation portion of the case **(B)**
- LessRay on the anterior side of the patient **(C)**
- Table array and camera on the anterior and cranial side of the patient **(D)**
- NVM5 neuromonitoring at the foot of the bed **(E)**

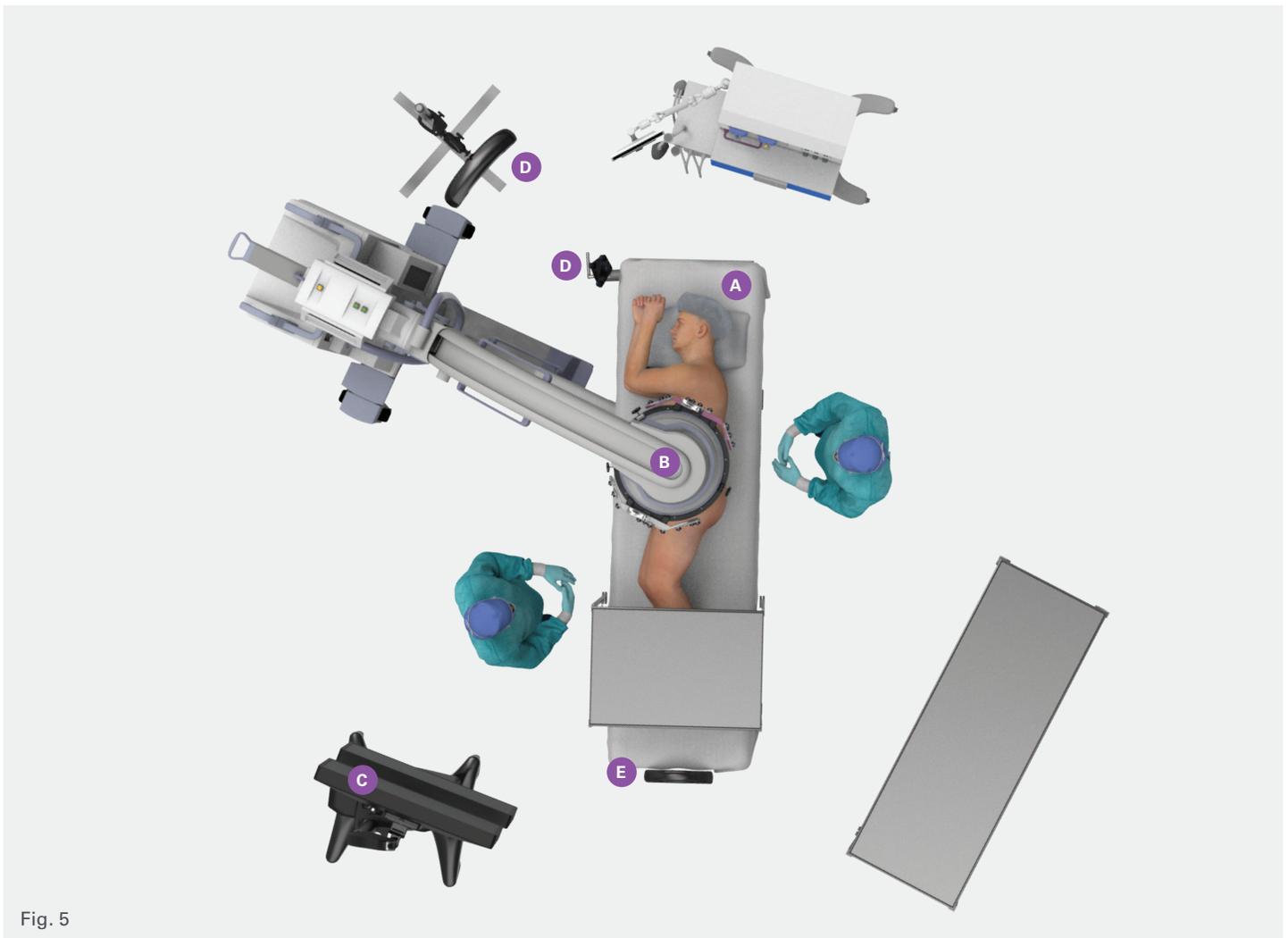


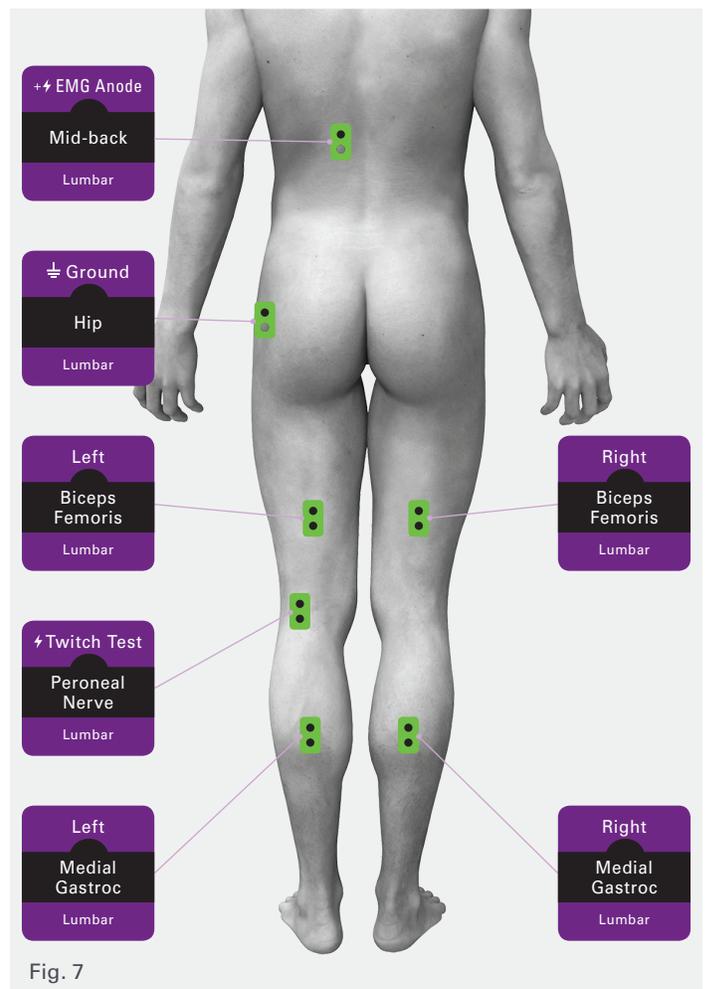
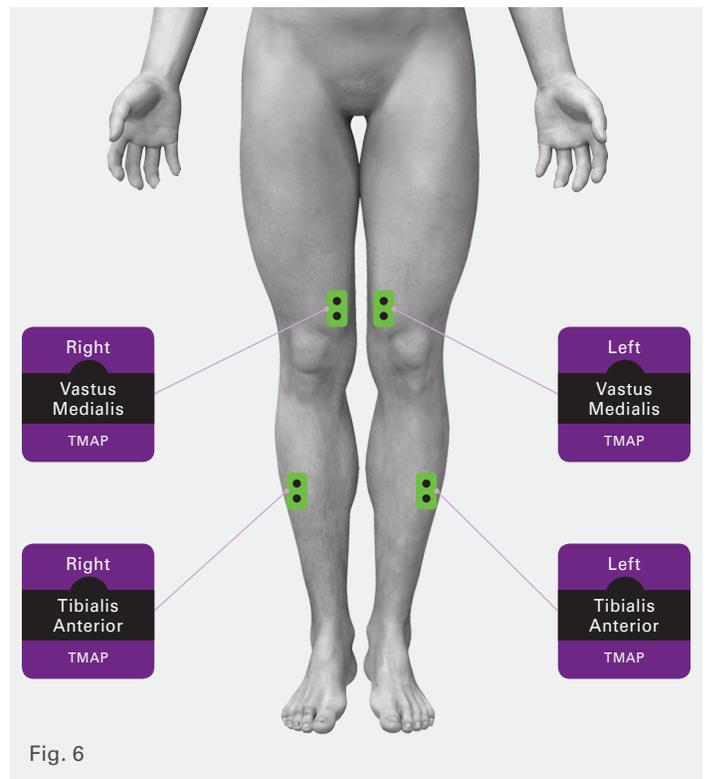
Fig. 5

Patient Positioning and Taping

Step 1

Apply the Necessary Neuromonitoring Leads (Figs. 6, 7)

- **Mark** the electrode sites (see image for reference)
- **Clean** the electrode sites with skin prep pad
- **Place** the surface electrodes
- **Confirm** acceptable impedance after all surface electrodes are placed



Patient Positioning and Taping (cont.)

Step 2

Flip to the Lateral Position (Fig. 8)

- Confirm the patient's hips are 2-4 inches from the posterior edge of the bed to prepare for XFixation (A)
- Confirm the top of the patient's iliac crest is positioned over the break of the bed for XLIF if any table break is necessary (B)
- Bend the patient's hips and knees to reduce the tension on the psoas muscle and allow for greater mobilization

Note: Consult with the access surgeon to confirm the hip bend will not interfere with the XALIF exposure.

- Place an axial roll under the armpit of the patient to support a natural position
- Secure the patient's head
- Secure the patient's arms anterior and cranial to prevent interference with the C-arm
- Confirm there is padding between the patient's knees, ankles, and arms
- Place a bed clamp on the anterior side of the bed at the knee of the patient (C)
- Place a bed clamp on the posterior side of the bed at the shoulder blade of the patient (D)
- Under fluoroscopic guidance, confirm the patient is in the true lateral position

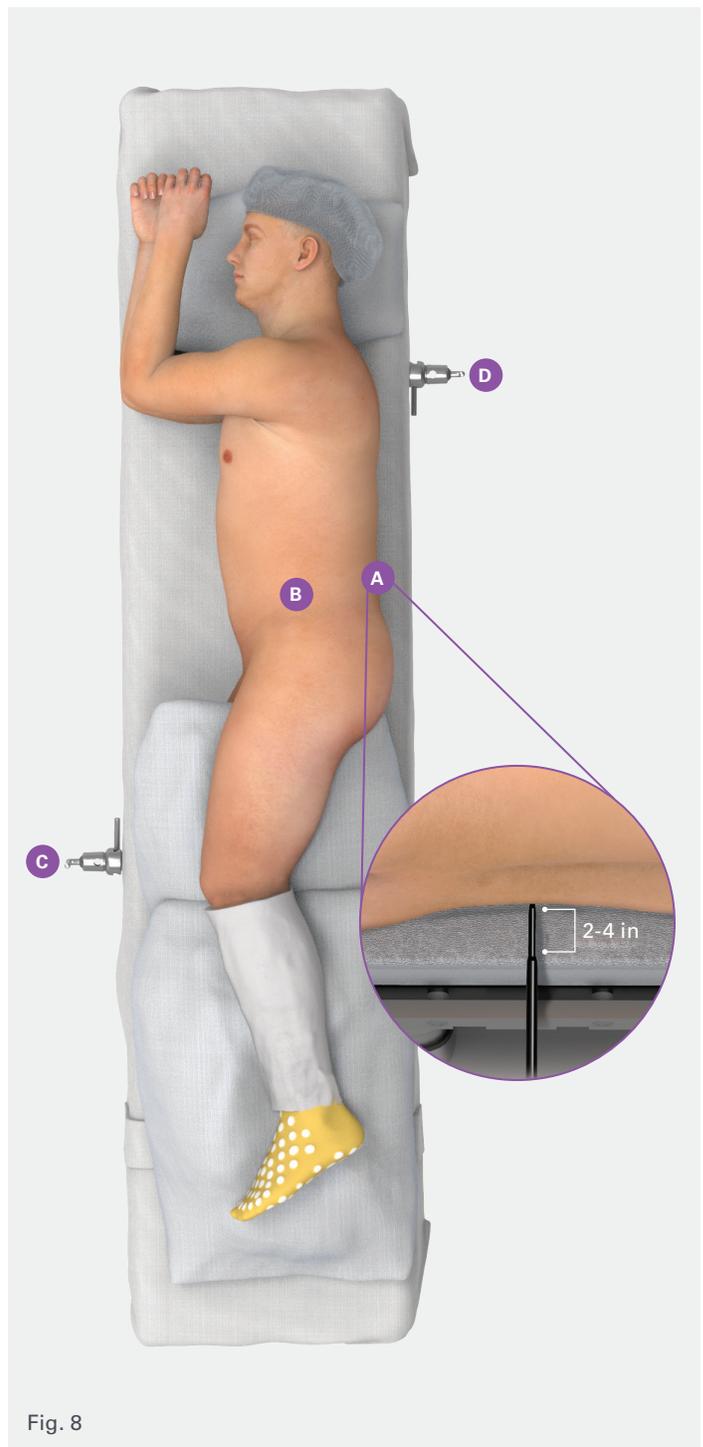


Fig. 8

- AP Fluoroscopy (Fig. 9):

- The spinous process centered between pedicles
- Clean, crisp endplates at operative level

- Lateral Fluoroscopy (Fig. 10):

- Superimposed pedicles
- Clean, crisp endplates at operative level



Fig. 9



Fig. 10

Patient Positioning and Taping (cont.)

Step 3

Secure the Patient to the Bed (Fig. 11)

Secure the patient's hips/pelvis to the table with tape. **(A)**

- Begin anterior at the mid-thigh and extend the tape over the patient's iliac crest and secure to the table on the posterior side of the patient
- Tape directly onto the skin unless there is a patient specific reason that will not allow for this

Note: Consult with the access surgeon to confirm the tape will not interfere with the XALIF exposure.

Note: Capturing the pelvis is crucial to help prevent patient movement during the case and may reduce migration of the medial blade during the XALIF portion of the case.

Secure the patient's chest to the table with tape. **(B)**

- Begin anterior by the arms and extend the tape over the chest and secure to the table on the posterior side of the patient
- Place a protective covering between the tape and the patient's nipples

Secure the patient's legs to the table with tape. **(C, D)**

- From the greater trochanter to the knee, and then secured to the table with padding placed between knees
- From the table to the knee, past the ankle, and then secured to the table

Step 4

Obtain LessRay Baselines

- Take full-dose fluoroscopy images with the patient in the true lateral position, both AP and Lateral
- Learn each of these images as baselines in LessRay for future use in the case

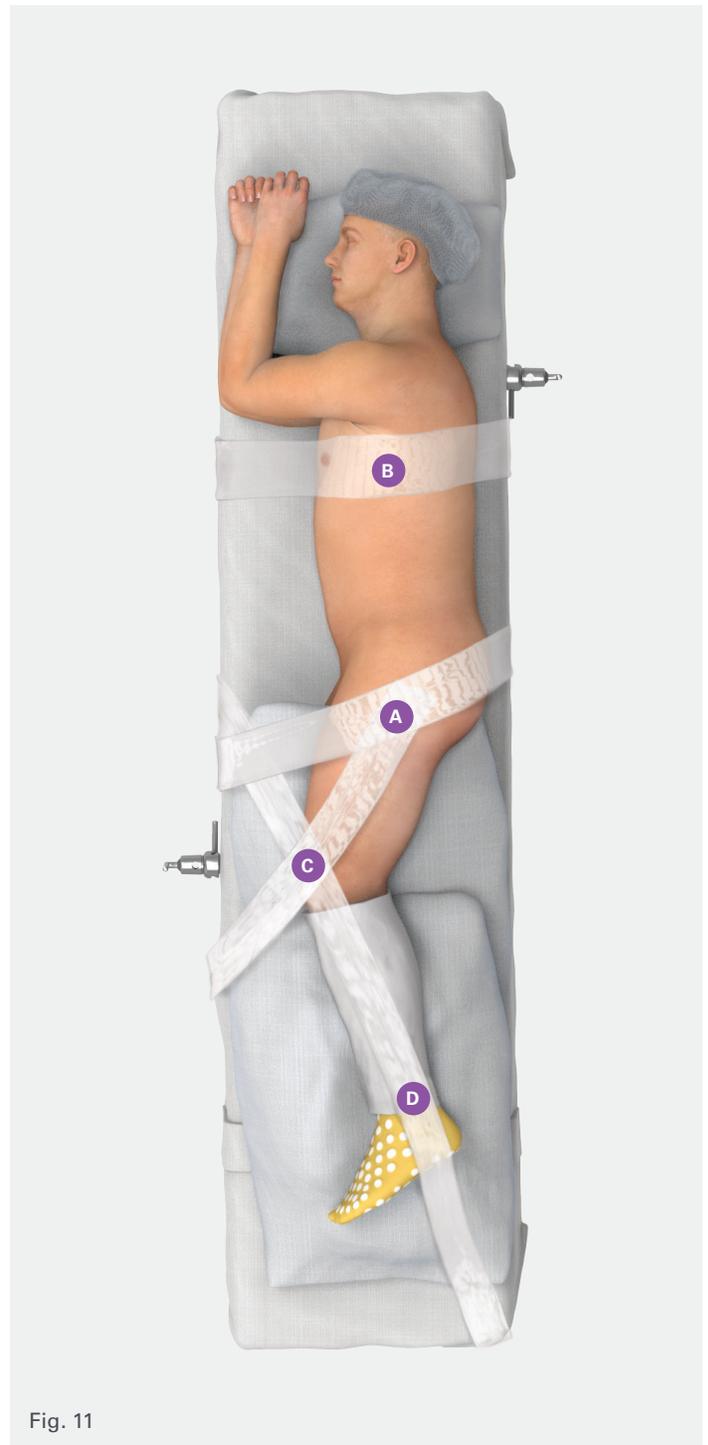


Fig. 11

Marking and Draping

Targeting for XLIF (Fig. 12)

Use the targeting tool to mark the following anatomical landmarks at the operative level with the assistance of lateral fluoroscopy:

- ALL (A)
- PLL (B)
- Posterior 3rd of the disc space (C)
- Disc angle (C)

Note: Extending this transverse mark anterior serves as a visual reference to both the surgeon and C-arm operator.

- A secondary incision marking can be made on the posterolateral side of the patient and assist with accessing the retroperitoneal space (D)

Note: Typically, this is a finger length's distance from the posterior third marking and just lateral to the erector spinae muscles.

Skin Incision(s) for XLIF (Fig. 13)

- The primary skin incision will be a transverse incision from ALL to PLL along the disc space (E)
- The secondary skin incision will be a transverse incision on the posterolateral side of the patient, large enough for a finger to enter the retroperitoneal space (F)

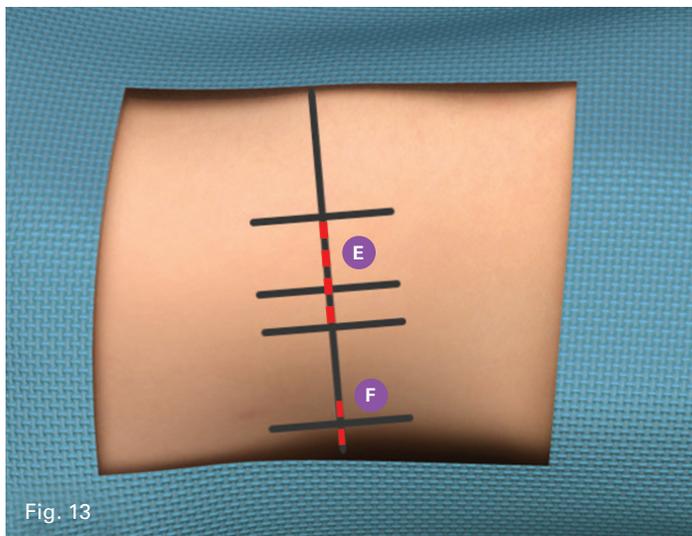


Fig. 13

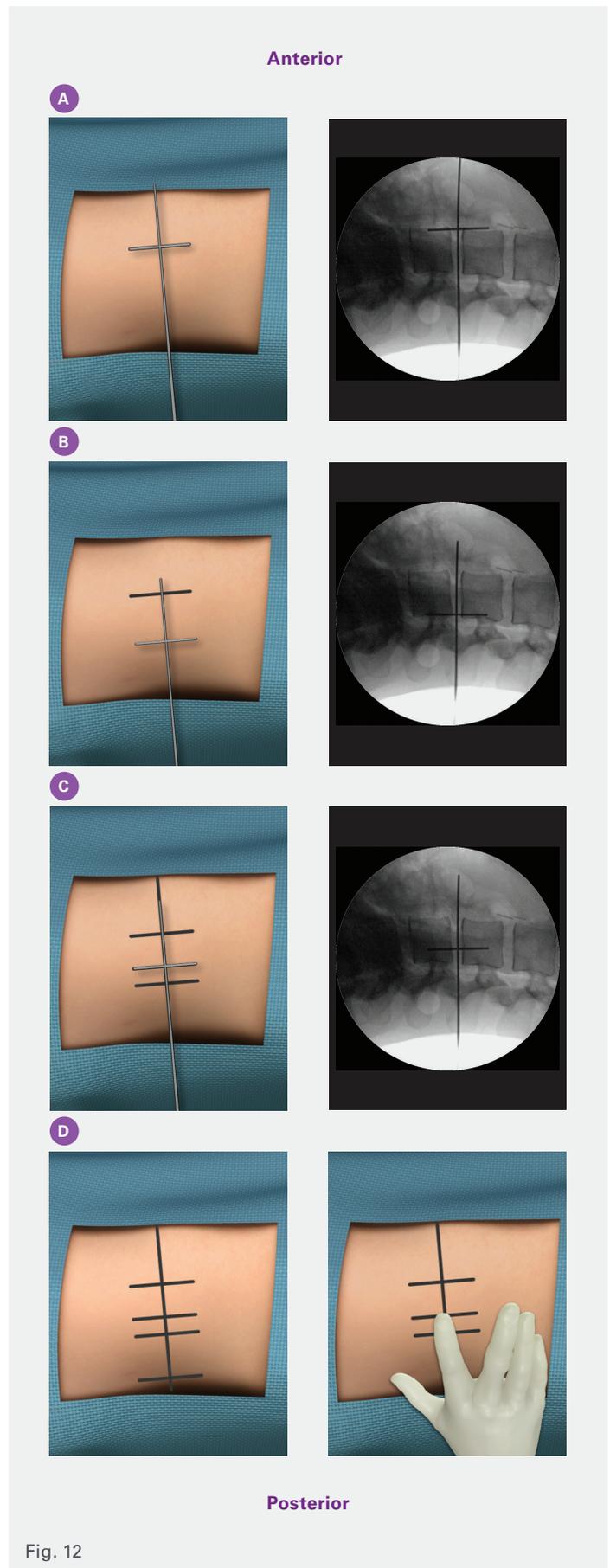


Fig. 12

Marking and Draping (cont.)

Targeting for XALIF (Figs. 14, 15)

Use the targeting tool to mark the following anatomical landmarks at the operative level with the assistance of lateral fluoroscopy:

- ALL (**A**)
- Disc angle—extend this transverse mark anterior along the belly of the patient to help determine the skin incision location (**B**)
- Iliac Crest—manual palpation can be used to identify the crest (**C**)

Skin Incision(s) for XALIF (Figs. 14, 15)

Make a transverse mark that meets the following requirements (**D**):

- Parallel to the disc angle line
- Half-way between the mid-line of the patient and the iliac crest

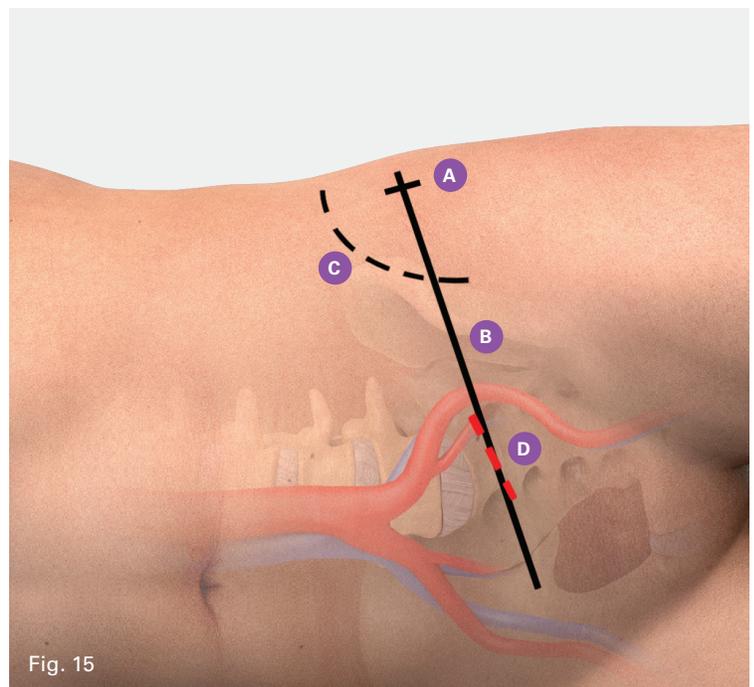
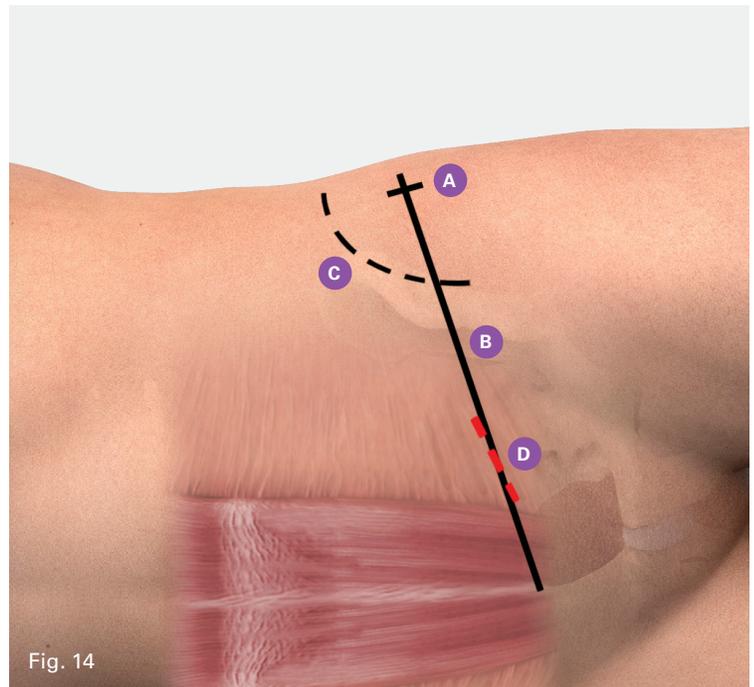
Note: This will put the incision lateral to the rectus muscle.

- Cranial to the inguinal crease

Ideally a transverse incision should be made co-linear to the angle of the disc space.

Note: This will help align the exposure to the disc space and reduce tissue that may impede direct access.

Note: In the case of a high pelvic incidence, this may not be possible and an incision just cranial to the inguinal crease will be adequate.



Marking and Draping (cont.)

Draping

- Confirm that the anterior (Fig. 16), lateral (Fig. 17), and posterior (Fig. 18) faces of the patient are prepped and draped
- C-arm or something similar can be used to help maintain sterility throughout the case

Note: Consult with the access surgeon to confirm the draping will not interfere with any of the exposures during the case.

Note: Appropriately drape the LessRay table array so it can be visualized by the camera and yet does not interfere with the sterile field.

Articulating Table Attachment Arms

Place the two articulating table attachment arms into the bed rails to prep for the exposure.

- The small arm (LATALIFARM) is on the anterior side of the patient and the knuckle joint will be parallel to the bed (A)
- The large arm (M4AARM) is on the posterior side of the patient and the knuckle joint will be perpendicular to the bed (B)

NVM5 Twitch Test

In order to assess how paralytics could be affecting the ability to acquire EMG signals later in the procedure, it is imperative that a Twitch Test be performed once the patient is positioned and the NVM5 electrodes are in place (see NVM5 Reference Manual for details). If the Twitch Test results are deemed unfavorable by the surgeon anesthesia should be instructed to reverse paralytics and muscle relaxants until an acceptable Twitch Test is conducted.

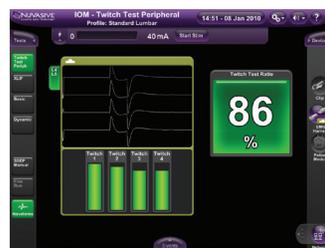
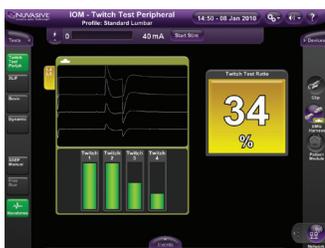


Fig. 16

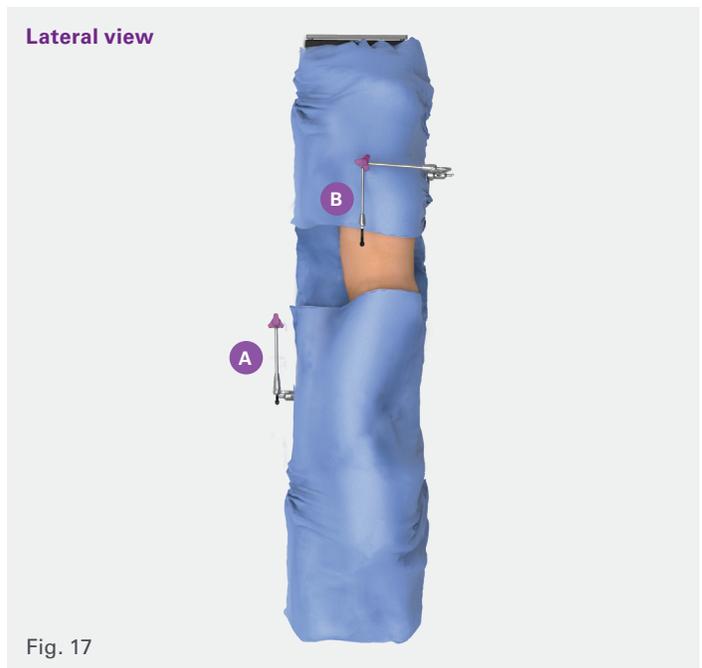


Fig. 17



Fig. 18

Optimized Surgical Workflow Powered by Surgical Intelligence

X360 Workflow	Surgical Intelligence Modalities
Pre-op iGA and Case Planning	NuvaLine
Patient Positioning and Taping	LessRay <ul style="list-style-type: none">• Baseline images• Image enhancement• Angle finder
Marking and Draping	Neuromonitoring and LessRay <ul style="list-style-type: none">• Twitch test• Image enhancement
XALIF	LessRay <ul style="list-style-type: none">• Image enhancement• C-arm tracking• Alternate image
XLIF	Neuromonitoring and LessRay <ul style="list-style-type: none">• Twitch test• EMG• TMAP• Image enhancement• C-arm tracking• Alternate image• Image stitching• NuvaMap O.R.
XFixation	Neuromonitoring and LessRay <ul style="list-style-type: none">• EMG• TMAP• Image enhancement• C-arm tracking• Alternate image• Image stitching• NuvaMap O.R.
Closure	
Post-surgical Confirmation	LessRay and NuvaLine

Post-Surgical Confirmation

LessRay iGA Confirmation

Prior to final closure, LessRay (Fig. 19) can be used for intra-operative assessment of spinopelvic alignment. The unique image stitching feature within the software allows surgeons to seamlessly capture all of the necessary anatomical landmarks through a series of lateral fluoroscopy images. Using these anatomical landmarks, the spinopelvic parameters can then be measured to confirm the preoperative plan was achieved.



Fig. 19

NuvaLine iGA Confirmation

NuvaLine (Fig. 20), a simple software application for tablet and mobile devices, may also be used for postoperative assessment of spinopelvic alignment. It allows the surgeon to calculate the spinopelvic parameters and evaluate the lordosis obtained from the X360 procedure after the surgical case has completed.

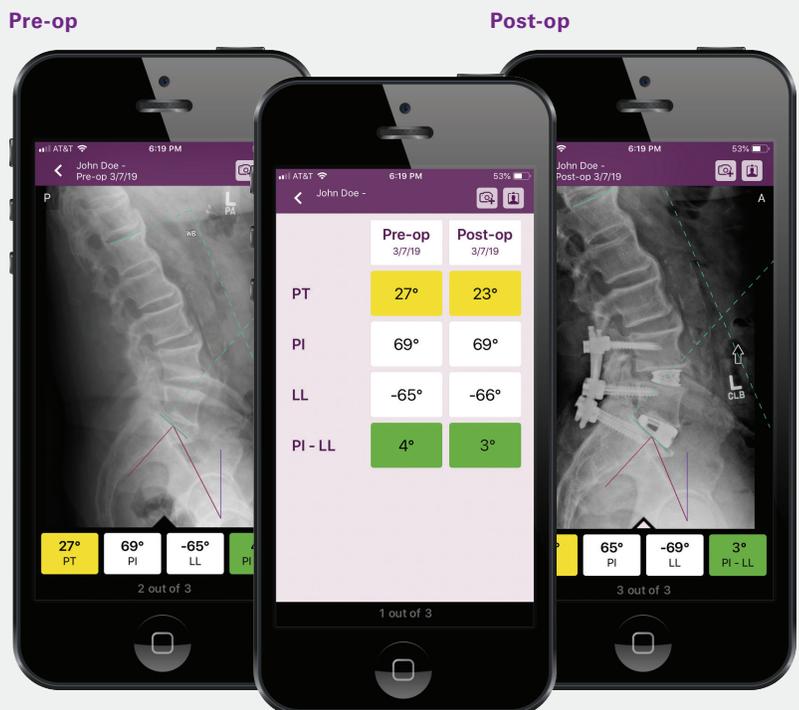


Fig. 20

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