Value of Single-position Surgery using Robotic Guidance—A Surgeon's Perspective

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A published article by Khan et al, "Comparing Next-Generation Robotic Technology with 3-Dimensional Computed Tomography Navigation Technology for the Insertion of Posterior Pedicle Screws", found both technologies had high accuracy rates with percutaneous approaches to insert pedicle screws.[3]

		Robotic Guided	Navigated	P-value (*significant)
Number of Screws (Patients)		190 (50)	165 (49)	
Accuracy	Grade I	99.5%	95.1%	0.14
	Grade II	0.5%	4.9%	
	Grades III & IV	0	0	
Mean Minutes per Screw Placement*		3.7 ± 1.8	6.8 ± 0.9	<0.001*

*Time-per-screw placement was only recorded for 61 screws in the robotic- guided group and 75 screws in the navigation group.

A significant difference was found in fluoroscopy time, but not radiation dose. Results were also tracked for length of stay, operation time, blood loss, and ASA class+. Of these, only length of stay was found to have a significant difference.

A key challenge of any lateral procedure is patient positioning. To place posterior supplemental fixation after the lateral portion of the surgery, the patient must be repositioned from lateral to prone position. Repositioning requires a significant amount of time in the operating room[1], or the operation can be staged across multiple days.[2]

The amount of time needed to reposition a patient, in addition to the cost of re-draping materials, has led to the adoption of single-position spine surgeries where the pedicle screws are placed with the patient in a lateral position which can be ergonomically challenging for the surgeon. One method of easing the ergonomic constraints of inserting pedicle screws in the lateral position is to use a robotic guidance system like the Mazor™ robotic guidance platform.

Dr. Greg Poulter with OrthoIndy in Indianapolis, whose cases are presented in the article, has performed more than 158 spine cases using Mazor™ robotic guidance and more than 80 single-position surgeries with the system. The cases presented here were performed using the Mazor X Stealth Edition™ robotic guidance platform. Since these cases were performed, the 5.0 software version of the Mazor™ robotic guidance platform has launched, which has improved clinical efficiency with the introduction of the the Midas Rex™ Mazor™ drill that has reduced the potential for skive when placing pedicle screws.

Case One

History and Examination

A 55-year-old male presented with degenerative disc disease at L5/S1 leading to herniation and radiculopathy; he had significant pain in his left leg for more than one year prior to surgery and was unresponsive to steroid injections. Comorbidities included heart disease and diabetes, leading to an American Society of Anesthesiologists (ASA) score of two. The patient also had mild scoliosis, but because it was asymptomatic in nature, surgical correction was not recommended.

Surgical Plan

The primary goal of this procedure was to restore lordosis to the lumbar spine and to decompress the spine anteriorly to achieve 20° of lordosis and provide stability using posterior instrumentation leading to spinal fusion.

Procedure

The patient was placed in the right lateral decubitus position throughout the procedure, providing access to both the posterior and anterior portions of the spine. In addition, care was taken to ensure the patient was positioned on the OR table as posterior as possible to provide trajectory access for bilateral screw placement. The Mazor™ robotic guidance platform was used to place four CD Horizon™ Solera™ Voyager™ 5.5/6.0mm Awl Tap Screws (ATS) at L5 and S1 in accordance with the surgical plan. As the patient would remain in the same position for the entire procedure, no flip or re-draping was required, allowing the procedure to continue with minimal disruption. After an access surgeon provided a pathway to the disc space, a discectomy was performed, and a 12° Sovereign™ interbody cage was inserted into the disc space.

Outcomes

Total operative time was two hours and 10 minutes. Adequate decompression was achieved during the anterior portion of the case. Dr. Poulter determined all four screws were placed successfully per the operative plan based on a visual comparison of the surgical plan to postoperative images.

Case Two

History and Examination

The second case involved a 76-year-old male with degenerative disc disease leading to a collapsed disc and radiculopathy at L5/S1; his symptoms presented as a persistent pain in his back that radiated to his legs, leading him to pursue surgical options. The patient had high blood pressure and cholesterol, which in combination with his advanced age, contributed to an ASA score of two. As such, less time under anesthesia was desired.

Surgical Plan

Much like the first case, the primary goal of this procedure was to decompress the nerves surrounding the collapsed disc. The preferred strategy was to decompress the disc space anteriorly, but plans were also made to use the METRx™ system for a posterior decompression if the osteophytes detected preoperatively reduced visibility and an adequate decompression could not be achieved from the front.

Procedure

The patient was positioned similarly to the patient described in the case one, with access confirmed to the oblique corridor and the planned pedicle screw trajectories. The Mazor™ robotic guidance platform was used to place four CD Horizon™ Solera™ Voyager™ ATS screws at L5 and S1 in accordance with the surgical plan.

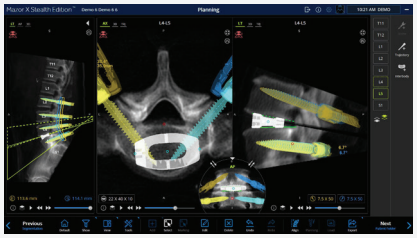
Once again, the surgical team was able to leave the patient in the lateral position throughout the procedure, avoiding the re-positioning time and expense of re-draping the patient. After an access surgeon provided a pathway to the disc space, a discectomy was performed, and a 12° Sovereign™ interbody cage was inserted into the disc space.

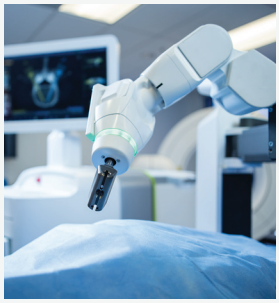
Outcomes

Total operative time was two hours and 47 minutes, with the time difference from Case One largely attributed to the difficulty of the anterior decompression. Despite this delay, Dr. Poulter determined that adequate decompression was achieved and that all four screws were placed with high accuracy to the preoperative plan.

About Mazor™ Robotic Guidance System

Mazor™ robotic guidance system delivers predictability of planning, precision of robotics-guidance, and the visibility of navigation in open, minimally invasive, or percutaneous procedures. Mazor™ system core technology delivers accurate pedicle screw placement (1.5mm accuracy)[6] and enables a minimally invasive approach to spine surgery, which has well-established benefits including less tissue trauma, blood loss, postoperative pain, and convalescence.[3-6]





Indications

The Sovereign™ Spinal System is indicated for use with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.. Additionally, the Sovereign™ Spinal System is indicated for use in patients diagnosed with deformity conditions as an adjunct to fusion. These patients should be skeletally mature and have had 6 months of non-operative treatment. The Sovereign™ Spinal System is intended to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with bone marrow aspirate. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique.

The Sovereign™ Spinal System may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the Sovereign™ Spinal System is intended to be used with 3 titanium alloy fixed or variable angle screws. The accompanying cover plate MUST be used anytime the device is used with any number of variable angle screws. If the physician chooses to use less than 3 or none of the provided screws, additional supplemental fixation in the lumbar spine must be used to augment stability. Implants with lordosis angles greater than 18° are intended to be used with supplemental fixation (e.g. facet screws or posterior fixation).

The CD Horizon™ Spinal System with or without Sextant™ instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (DDD - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD Horizon™ Spinal System titanium, cobalt chrome, and stainless steel implants may also be used for the same indications as an adjunct to fusion.

With the exception of DDD, the CD Horizon™ Legacy™ 3.5mm rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD Horizon™ Spinal System titanium, cobalt chrome, and stainless steel implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD Horizon™ Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD Horizon™ PEEK rods are intended to provide posterior supplemental fixation when used with an interbody fusion cage for patients diagnosed with DDD. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level. This device is intended for 1-2 level use in the lumbosacral spine (L2 – S1) in skeletally mature patients. The device is intended for use with an interbody fusion cage at the instrumented level and is not intended for stand-alone use.

The CD Horizon™ Spire™ plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: DDD (as previously defined), spondylolisthesis, trauma, and/or tumor.

In order to achieve additional levels of fixation, the CD Horizon™ Spinal System rods may be connected to the Vertex™ Reconstruction System with the Vertex™ rod connector. Refer to the Vertex™ Reconstruction System package insert for a list of the Vertex™ indications of use.

Mazor™ Robotic Guidance Platform Indications

The Mazor X™ system is indicated for precise positioning of surgical instruments or spinal implants during general spinal surgery. It may be used in either open or minimally invasive or percutaneous procedures.

Mazor X™ system 3-D imaging capabilities provide a processing and conversion of 2-D fluoroscopic projections from standard C-Arms into volumetric 3-D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3-D imaging of high contrast objects.

The Mazor X™ navigation tracks the position of instruments, during spinal surgery, in relation to the surgical anatomy and identifies this position on diagnostic or intraoperative images of a patient.

Important Information on the Medtronic Surgical Instruments for use with Mazor™ Robotic Guidance Platform

Description

Medtronic Surgical Instruments are non-sterile or sterile, single or re-usable instruments that may be used during the preparation and placement of various Medtronic spinal implants during spinal surgery. Medtronic Surgical Instruments are made of a variety of materials commonly used in orthopedic and neurological procedures which meet available national or international standards specifications. Single-use Medtronic Surgical instruments should never be reused under any circumstances.

The Medtronic Surgical Instruments are specifically designed for use in spinal procedures with MAZOR X Stealth Edition™. Medtronic Surgical Instruments can be navigated or non-navigated manual instruments that may or may not be guided through the MAZOR X Stealth™ Edition Arm Guide. Some Medtronic Surgical Instruments (e.g. drills, drivers, taps etc.) are also compatible with Medtronic's IPC™ POWEREASE™ System when connected to the POWEREASE™ Driver, these Medtronic Surgical instruments may or may not be guided through the MAZOR X Stealth Edition™ Arm Guide.

Medtronic surgical drills shall only be used through the MAZOR X Stealth Edition™ arm guides, Medtronic cannulas, and Medtronic drill guides. Placing Medtronic single-use sterile spheres on each of the NavLock™ Tracker passive stems allow MAZOR X Stealth Edition™ to track the Medtronic Surgical Instruments in the surgical field.

Enabling Technology Products: Please refer to product indication manual/package insert for instructions, warnings, precautions, and contraindications.

Potential Adverse Events

Adverse effects may occur when the device is used either with or without associated instrumentation. Risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include:

- Implant migration.
- Breakage of the device.
- Foreign body reaction to implants including possible tumor formation, auto immune disease, and/or scarring.
- Loss of proper spinal curvature, correction, height, and/or reduction.

References

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