VALUE OF SINGLE-POSITION OBLIQUE LATERAL INTERBODY FUSION AND BILATERAL PEDICLE SCREW FIXATION WITH MAZOR X STEALTH EDITION™ ROBOTIC GUIDANCE PLATFORM

Case Reports
of Mazor™ Core Technology

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Further, Together

MICHELSON TECHNOLOGY AT WORK

Introduction

A key challenge of any lateral procedure is that of patient positioning. In order to place pedicle screws after the lateral portion of the surgery, the patient must be moved to the prone position. This requires either a significant amount of time to be spent repositioning the patient in the operating room[1], or for the operation to be staged across multiple days.[2]

The amount of time needed to reposition a patient, in addition to the cost of re-draping, has led to the adoption of single-position surgeries, such as those with the pedicle screws inserted with the patient in a lateral position. One method of easing the ergonomic constraints of inserting pedicle screws in the lateral position is to utilize a robotic guidance system, such as the Mazor X Stealth Edition.

Prior to the cases discussed here, Dr. Poulter performed more than one hundred cases with the Mazor X Stealth Edition and more than fifty single-position surgeries with the system. As such, these cases reflect his experience after he has successfully navigated the learning curve for both the robotic system and inserting screws in a lateral position.

CASE 1

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 2. 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 twenty degrees of lordosis. In addition, posterior instrumentation was used to provide stability leading to fusion.

Procedure

The patient was placed in the right lateral decubitus position for the entire case, providing access to both the posterior and anterior portions of the patient. In addition, care was made to ensure the patient was placed as posterior as possible to provide optimal access for bilateral screw placement. Mazor X Stealth Edition was utilized to place four CD Horizon™ Solera™ Voyager™ 5.5/6.0 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 twelve-degree Sovereign™ Spinal System interbody cage was placed into the disc space.

Outcomes

Total operative time was 2 hours and 10 minutes, and adequate decompression was achieved during the anterior portion of the case. Dr. Poulter determined all four screws were placed successfully to plan based on a visual comparison of the surgical plan to post-operative images.

2 Hours 10 Minutes

Total Operative Time

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CASE 2

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 2. As such, a shorter amount of 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 utilize the METRx™ MicroDiscectomy System for a posterior decompression if the osteophytes detected preoperatively reduced visibility to where adequate decompression could not be obtained from the front.

Procedure
The patient was positioned similarly to the patient described in the first case, with access confirmed to the oblique corridor and the planned pedicle screw trajectories. Mazor X Stealth Edition was utilized 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 same position for the entire case, avoiding both the time of re-positioning and the expense of re-draping the patient. After an access surgeon provided a pathway to the disc space, a discectomy was performed, and a twelve-degree Sovereign Spinal system interbody cage was placed into the disc space.

Outcomes
Total operative time was 2 hours and 47 minutes, with the time difference from Case 1 largely attributed to difficulty in anterior decompression. Despite this, Dr. Poulter determined that adequate decompression was achieved and that all four screws were placed with high accuracy to plan.

In addition, both cases discussed here were performed on the same day, with **Dr. Poulter's staff able to go home at 4 p.m. on a Friday after completing two OLIF51 cases.**

2 Hours **47** Minutes

Total Operative Time

REFERENCES

1. Ziino, C., Konopka, J. A., Ajiboye, R. M., Ledesma, J. B., Koltsov, J. C., & Cheng, I. (2018). Single position versus lateral-then-prone positioning for lateral interbody fusion and pedicle screw fixation. *Journal of Spine Surgery*, 4(4), 717.

2. Kim, W. J., Lee, J. W., Park, K. Y., Chang, S. H., Song, D. G., & Choy, W. S. (2019). Treatment of Adult Spinal Deformity with Sagittal Imbalance Using Oblique Lumbar Interbody Fusion: Can We Predict How Much Lordosis Correction Is Possible?. *Asian Spine Journal*, 13(6), 1017.

INDICATIONS

The Sovereign™ Spinal System is indicated for use with autogenous bone graft 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 autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and oblique. The Sovereign™ interbody system may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the Sovereign™ interbody device 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.

INTENDED USE

Medtronic Surgical Instruments are intended to be used during the preparation and placement of Medtronic implants during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Surgical Instruments are specifically designed for use with the MAZOR X Stealth™ Edition, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. 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. Medtronic surgical drills shall only be used through the MAZOR X Stealth™ Edition arm guides, Medtronic cannulas, and Medtronic drill guides. Some of the Medtronic Surgical Instruments are also compatible with the IPC™ POWEREASE™ System.

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

Risks Include

Adverse effects may occur when the device is used either with or without associated instrumentation. The potential 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 but are not limited to:
- Implant migration.
- Breakage of the device(s).
- Loss of proper spinal curvature, correction, height, and/or reduction.
- Early or late loosening or movement of the device(s).

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

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Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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