

# Stryker Power Tools for Pedicle Screw Insertion: Results of Testing



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## Introduction

Surgeons face numerous occupational hazards and exposures in the operating room including radiation, smoke, noise, and poor ergonomic conditions. Several researchers noted that spine surgeons may be at particular risk because of the intense physical demands of performing spinal deformity corrections.<sup>1</sup> Spine surgeons are at particular risk, since much of their career requires completing long surgeries involving repetitive manual tasks, using tools that require a large amount of physical force, and standing for prolonged periods in mechanically disadvantageous positions of the neck, back, and upper extremities.<sup>1,2</sup> Maintaining a surgeon's physical health is necessary to ensure career longevity, quality surgical performance, on-going patient care, and personal well-being. Over half of all surgeons over the age of 50 reported having at least one major medical problem, presumably a result of their work environment.<sup>3</sup>

Previous studies have shown that work environments that require an awkward or extreme posture increase the amount of force required to complete a task.<sup>4</sup> Spine surgeons often work in difficult physical positions, especially when inserting pedicle screws during spinal deformity corrections. In a study of surgeons who were members of the North American Spine Society, it was demonstrated that the risk for developing carpal tunnel syndrome was two times higher for spine surgeons as compared to nonsurgical medical practitioners, with 32% reporting that the carpal tunnel caused interference with their ability to work. Additionally, exposure to long surgical hours and the use of Kerrison Rongeurs were major risk factors for the development of carpal tunnel.<sup>2</sup>

The first study to examine the occurrence of musculoskeletal disorders (MSD) in spine surgeons was conducted as a survey among members of the Scoliosis Research Society. The study revealed a higher prevalence of MSD in spine surgeons as compared to disease estimates in the general population. Spine surgeons experienced pain in a variety of areas, with a prevalence of: 62% low back pain, 59% prevalence of neck pain, 49% shoulder pain, 28% elbow pain, 25% wrist pain, and 31% finger pain.<sup>1</sup> Upper limb MSD were also present in spine surgeons who reported a self diagnosis rate of 24% for rotator cuff symptoms and 18% for lateral epicondylitis. These rates significantly exceeded that of the general population, but, are similar to highly exposed workers, defined as individuals whose work requires repetitive manual tasks.<sup>1,5,6</sup>

Overall, 32% of spine surgeons reported that they were forced to take time off from work because of a MSD.<sup>1</sup> The authors attributed the forceful use of instrumentation during spine surgery, especially during dissection and insertion, to developing "spine-stripper's elbow." Additional risk factors included the number of work hours, total spine caseload, practicing for less than five years, obesity, and the use of Kerrison Rongeurs.<sup>1</sup> Auerbach and colleagues suggested that the incidence of MSD may be decreased in spine surgeons by modifying instruments and techniques. They suggested that the use of power to insert pedicle screws is one way in which the torque placed on the upper limbs may be reduced, thereby mitigating the risk of MSD for spine surgeons.<sup>1</sup>

Stryker Spine (Allendale, NJ) offers instrumentation that allows for both corded and cordless power screw insertion of pedicle screws, targeted for use by neurosurgeons and orthopedic surgeons with diverse levels of experience. In this unpublished testing protocol, both the accuracy and the quality of pedicle screw insertion demonstrated no significant difference between manual and power screw insertion. Additionally, this testing demonstrated there is no significant difference between the baseline Xia® 3 pedicle screw system as compared to Mantis® and Radius® pedicle screw systems (Stryker Spine, Allendale, NJ) when using the power insertion method, as well as demonstrating that surgeon experience level is not significant in the successful use of power insertion.



## Materials and Methods

### Screwdriver

Four surgeons were directed on the assembly and use of the power adaptor to be used with either the RemB Universal Driver Corded Hand Piece or the CD3 Cordless Hand Piece paired with the Hudson® Modified Trinkle Adaptor (Stryker Instruments, Kalamazoo, MI). The CORE unit controller was set at 1500 RPM with the ability for the surgeon to modify the speed from 0-100% of the output capabilities at their discretion. (Figure 1)



Figure 1.

### Screws

For the first phase of this project, Xia 3 polyaxial screws (Stryker Spine, Allendale, NJ) in various sizes (4.5 x 25mm, 4.5 x 35mm, 4.5 x 40mm, 4.5 x 45mm, 5.5 x 40mm, 6.5 x 45mm, 7.5 x 45mm) were used for pedicle screw insertion determined by size of the vertebra at the level of insertion. In the second phase of the project, power insertion of Xia 3 polyaxial screws was compared to other Stryker pedicle screw systems. Screws of varying sizes as determined by the level of insertion were selected from multiple Stryker Spine systems: Xia 3 (4.5 x 25mm, 4.5 x 35mm, 4.5 x 40mm, 4.5 x 45mm, 5.5 x 40mm, 6.5 x 45mm), Mantis (6.5 x 40mm), and Radius Rapid (5.65 x 40mm). (Figure 2)



Figure 2.

All screws used in this project had common design elements that allowed the tulip to interface with a rod and the shank of the bone screw anchoring the system to the spine. The screws interfaced with the screwdriver's inner shaft to transfer torque, thereby engaging the bone screw into the pedicle. The outer sleeve of the screwdriver, with a threaded tip, joined with the tulip threads. The sleeve then pulled the bone screw tight, keeping engagement between torque transmission features during screw insertion. (Figure 3) All systems used in this testing are available with both monoaxial and polyaxial screws. Since the polyaxial screws have a more complex connection with the screwdriver, featuring a ball socket screw tip that may result in toggle during insertion, they were selected for worst-case scenario testing.



**Figure 3.**

### **Lab Technique**

Five fresh human cadaver spines of ages ranging from 70-94 years (three males, two females) were used in this project. Cadavers were pre-screened to verify for acceptable anatomy. Exclusion criteria included no prior spine surgery and no contraindications that would prevent the cadaver from lying in a neutral-prone position. The spines were anatomically exposed to simulate a long deformity correction surgery prior to testing; therefore, it was not necessary to remove the facet joints or other bony material. Cadavers were placed prone on a radiolucent table and multiple lateral and anterior-posterior (AP) images were taken from T4-iliac to document the initial condition of the spine.

Four surgeons participated in this project, two with over 15 years of experience and two with less than 15 years of experience. For the first part of the testing, surgeons began at the T4 or T6 level by preparing the entry point with an awl, followed by probing to create a pathway into the pedicle for the appropriate screw length. Modular taps were used to make a hole undersized by 1mm as per the screw diameter assigned to that level. Holes for the 4.5mm screws were not tapped, as the probe provided sufficient hole preparation. Depending on the side of the vertebra, a single or double-beaded wire was placed inside the prepared pedicle for side identification and to define the axis of the hole. Lateral and AP images were taken using a C-arm including the two adjacent vertebral bodies. (Figure 4)



**Figure 4.**

Screw size and insertion method, randomized between power and manual at each level, were determined via a pre-defined diagram given to the surgeons based upon the size of the vertebra for each level. Once the screws were inserted, lateral and AP images of the final pedicle screw placement were taken. If a pedicle screw was placed in a manner that was deemed clinically unacceptable, this data point was excluded. Screws were also excluded due to image quality issues including inability to visualize the head of the screw, missing images, or excessive vertebral rotation.

In the second part of the testing, a comparison to show equivalence between Stryker pedicle screw systems, as well as a risk assessment, was completed. Screws and insertion method (power vs. manual) were randomized across the levels. Surgeons followed a provided surgical technique guide that was in accordance with the pedicle screw system used at that level. Levels T2-S1 were used in the risk assessment evaluation. Surgeons were asked to insert Xia 3 screws using power bilaterally into both tapped and untapped holes, allowing the power insertion to bottom out (compressed as far as possible). Lateral and AP images were taken using a C-arm including the two adjacent vertebral bodies, and surgeon commentary was collected.

### **Revision**

In an effort to ensure that all power-inserted screws could be removed manually, surgeons were asked to revise screws at T6, T7, L1, L2, S1, and ilium. The revision attempt consisted of a minimum of one turn and a maximum of two turns backing the screw out. Success rate was recorded and screws were manually rotated back to their original location.

### **Bleaching**

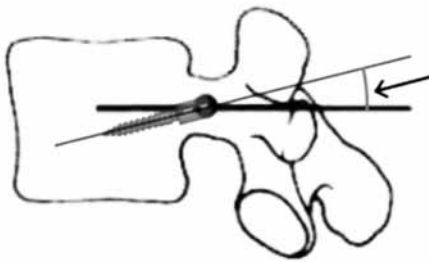
The spine was removed from the cadaver and placed in a 50% bleach solution. Every 4-6 hours the bleach solution was replaced until all the fatty deposits and soft-tissue were removed and the vertebrae could be easily separated. The spine was rinsed with detergent and allowed to dry. Once dry, the vertebrae were separated. The left and right pedicle of each vertebra was observed for breaching of the pedicle wall. If a breach was observed, the location (medial, lateral, cranial, or caudal) was recorded as was the magnitude of the breach in millimeters. (Figure 5)



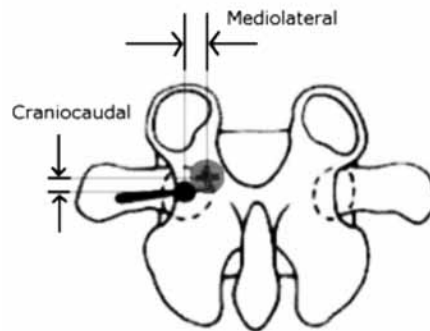
**Figure 5.**

## Imaging/Measurement Definition and Success Criteria

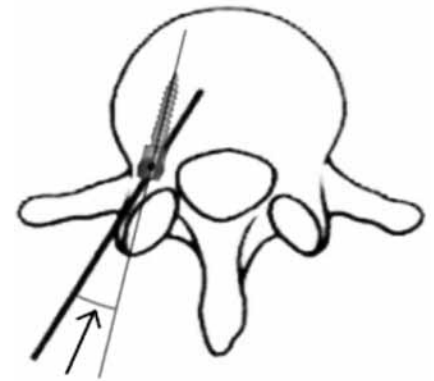
After screw insertion, each vertebra was situated so the endplate was parallel to the film surface to obtain an axial x-ray for analysis. A randomized, blinded analysis was conducted by Medical Metrics, Inc. In the first measure of accuracy, the sagittal screw orientation was measured in the sagittal plane from the lateral fluoroscopic image to assess the difference in angulations between the pilot-hole and the longitudinal axis of the pedicle screw. The sagittal screw measurement was stabilized by using QMA software and was performed separately for the left and right pedicles; screw orientation was reported in units of degrees. (Figure 6) Similarly, in a second and third measure of accuracy, the offset of screw entrance point was measured for the mediolateral and the craniocaudal components in the coronal plane using AP/PA fluoroscopic images. This enabled the objective assessment of the actual entry point relative to the pilot hole, and was measured as a percent of the diameter of the head of the pedicle screw. (Figure 7) Finally, to measure quality, the extent of the axial screw breach was measured in the axial plane as the ratio of the longest distance between the pedicle and the edge of the screw and the screw diameter. The extent of the axial breach was reported as a percentage of the superior endplate length. (Figure 8)



**Figure 6. Sagittal Screw Orientation**



**Figure 7. Offset Screw Entrance Mediolateral and Craniocaudal**



**Figure 8. Axial Screw Orientation**

## Statistical Analysis

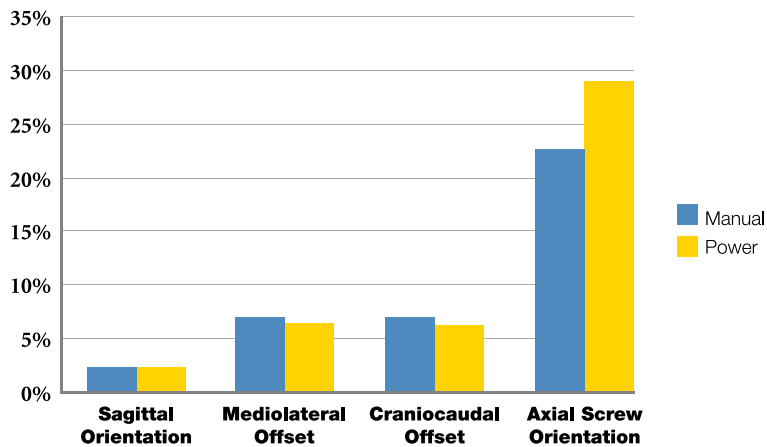
Data comparing manual pedicle screw insertion to power pedicle screw insertion were analyzed using a paired t-test for the four variables: deviation of the final pedicle screw orientation in the sagittal plane, deviation of the final pedicle screw entry point from the planned entry point in the mediolateral and cranial-caudal planes, and breach of the pedicle screw through the outer border of the pedicle. An ANOVA was used to detect any differences between the screw systems.

## Additional Surgeon Input

A questionnaire was distributed as part of the design input to gather information from the participating surgeons. Of particular interest was the ease of use of the system, the physical expenditure of the surgeon, visibility, current use of power to insert pedicle screws, precautionary statements, and general commentary.

## Results

Pedicle screws were placed bilaterally into 56 vertebrae, randomized between power and manual screw insertion. A few screws could not be evaluated due to image quality issues, including inability to adequately visualize the head of the screw, missing images, or excessive vertebral rotation. A paired, two-tailed t-test was used to compare manual and power pedicle screw insertion. There was no significant difference found between the sagittal screw orientation ( $p=.9$ ), offset of screw entrance point in the mediolateral plane ( $p=.41$ ), offset screw entrance point in the craniocaudal plane ( $p=.45$ ), or the axial screw orientation ( $p=.20$ ). (Graph 1)



**Graph 1. Mean Values for Test Variables**

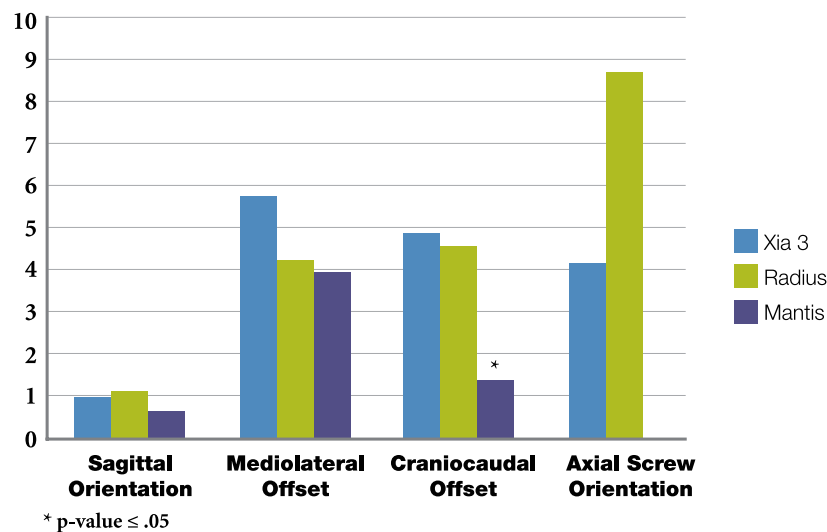
Using a paired t-test, there was no significant difference when comparing power and manual pedicle screw insertion completed by surgeons with experience defined as less than fifteen years of experience versus having more than fifteen years of experience. (Table 1)

Years of Experience	P-Value	
	≤ 15 yrs	≥ 15 yrs
Sagittal Screw Orientation	.49	.7
Offset Screw Entrance Point: mediolateral plane	.64	.47
Offset Screw Entrance Point: craniocaudal plane	.12	.85
Axial Screw Orientation	.48	.25

**Table 1. Power Screw Insertion by Years of Experience**



Concerning the equivalence of the pedicle screw systems, comparisons were analyzed between other Stryker Spine screws, specifically, Radius and Mantis, as compared to Xia 3 for sagittal orientation, mediolateral and craniocaudal offset, and axial orientation. It was determined that there was no significant difference between the control group Xia 3 and the Radius and Mantis groups for the sagittal orientation ( $p=0.44$ ), mediolateral offset (4.19), and the axial screw orientation ( $p=0.48$ ). For the craniocaudal data set, there was a statistical difference between the means ( $p=0.03$ ). When examining the craniocaudal offset data, Mantis had a very low (favorable) mean of 1.36 as compared to the rest of the group, which ranged from 4.52-7.26. When using an MIS approach with k-wire there was less offset than with systems that did not use a k-wire. When examining the axial orientation with Mantis excluded from the data set because there were no instances of pedicle breach, there was no significant difference between Xia 3 and Radius for the craniocaudal offset ( $p=0.71$ ). (Graph 2)



**Graph 2. Equivalence Comparison between Stryker Screws**

The questionnaire commentary confirmed that the adaptor allowed the screws to be inserted using power, the use of power reduced the perceived physical exertion of the surgeon, and after power insertion manual removal of the screws was possible. Overall surgeons found that using power for pedicle screw insertion was a viable option for use in spinal deformity surgery.

## Discussion

Stryker has developed a power adaptor which, when used in conjunction with the Hudson Modified Trinkle Adaptor, allowed for power pedicle screw insertion. This testing protocol was designed to validate that Stryker's power screw instrumentation was non-inferior to manual screw insertion based upon measures of accuracy as measured by sagittal screw orientation and offset screw orientation in the mediolateral and craniocadual planes, as well as in quality as measured by pedicle breach. The results also demonstrated that there is no significant difference between power and manual pedicle screw insertion between surgeons of different experience levels. Additionally, this protocol showed that the Stryker Systems, Radius, and Mantis were found to be equivalent to the Xia 3 control group.

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