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VIPER PRIME™ System Cadaver Time Study

White Paper

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1. INTRODUCTION

Minimally invasive surgical techniques to perform spinal stabilization have gained popularity in recent years due to the demonstration of reduced complications, less blood loss, and less perioperative muscular damage during the procedure compared to conventional open spine surgery.[1-3] Additionally, these techniques yield less postoperative pain, less narcotic usage, a shorter hospitalization, and a quicker recovery than traditional open surgery.[1,2] A number of minimally invasive systems have been developed to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine. Although the benefits of traditional minimally invasive techniques for spinal stabilization are substantial, there are a number of compromises that the surgeon may have to make to achieve these benefits. For example, most minimally invasive techniques have steep learning curves and a limited visual field requiring different cognitive, psychomotor, and technical skills to achieve procedure success.[1,3] Additionally, depending on the surgeon's experience and the type of procedure being performed, minimally invasive techniques may take a longer time to perform than conventional open spine surgery and often require surgeons to navigate small channels involving several procedural steps, instrument passes, and management of guidewires.[1]

In December 2016, DePuy Synthes received FDA clearance to market a new minimally invasive system called the VIPER PRIME™ Spine System. This system is designed to facilitate a posterior percutaneous approach with minimally invasive instrumentation and provide immobilization and stabilization of spinal segments as an adjunct to fusion.[4] More specifically, this system is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (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, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.[4] The VIPER PRIME Spine System is a *streamlined* approach to traditional minimally invasive pedicle screw placement procedures that has been designed to provide a number of procedural benefits including:

- Reduction in time to complete screw insertion
- Reduction in procedural steps
- Less operating room supplies (i.e., reduction in number of trays for sterile processing)
- Elimination of the need for Jamshidi needles, guidewires, awls and taps
- Reduction in number of instruments and instrument passes to insert a percutaneous screw

To evaluate the hypothesis that the VIPER PRIME Spine System may lead to a reduction in time to complete screw insertion compared to traditional minimally invasive techniques, DePuy Synthes performed a cadaver time study to compare the screw insertion times associated with the VIPER PRIME System technique compared to the traditional Jamshidi/guidewire technique in a one-level percutaneous pedicle screw procedure.[5] This white paper describes the methods and results of this cadaveric study.

2. METHODS

The objective of this cadaver time study was to evaluate and compare the screw insertion times for the traditional Jamshidi/guidewire percutaneous screw placement technique and the VIPER PRIME System percutaneous screw placement technique.[5] This study was done at the Johnson & Johnson Institute in Raynham MA in December 2016. Eight surgeons participated in this study. Each surgeon placed seven pedicle screws via the traditional Jamshidi/guidewire technique and seven pedicle screws via the VIPER PRIME System technique for a total of 14 screws. Screws were implanted into five lumbar levels and two thoracic levels for each cadaver. Start and stop times (in minutes) were recorded for each of the steps involved in screw placement based on the technique outlined in the protocol (Table 1):

Table 1. Cadaver Time Study Protocol

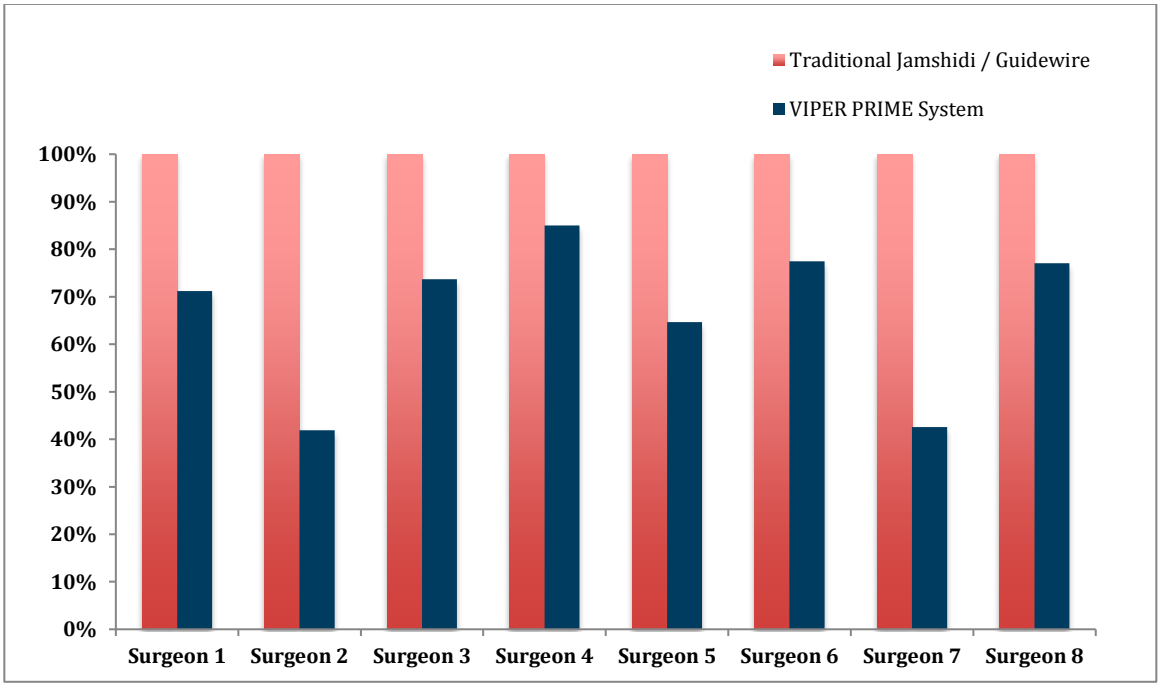
Jamshidi/Guidewire Technique	VIPER PRIME System Technique
(1) Create incision (2) Insert Jamshidi into incision and target pedicle (3) Insert Guidewire (4) Remove Jamshidi (5) Insert tap over guidewire. (6) Remove tap over guidewire (7) Insert screw over guidewire (8) Remove guidewire (9) Remove polydriver from screw	(1) Create incision (2) Insert VIPER PRIME Screw Driver assembly into incision and target pedicle (3) Advance Stylet (4) Drive pedicle screw (5) Remove VIPER PRIME Screw Driver assembly

Source: DePuy Synthes, Data on File. Protocol for VIPER PRIME Cadaver Study. Report 103327910 REV 1.

3. RESULTS

The results of the analysis showed that the duration of time for screw placement was shorter using the VIPER PRIME System technique compared to the traditional Jamshidi /guidewire technique for each surgeon (Figure 1). More specifically, the duration of time for screw placement with the VIPER PRIME System technique was approximately 33% shorter (on average) than the traditional Jamshidi/guidewire technique when analyzing the cumulative screw placement times for all surgeons and for all screws (Figure 2). Surgeons #2 and #7 achieved the greatest reductions in screw placement times using the VIPER PRIME System technique versus the traditional Jamshidi/guidewire technique with a 58.1% reduction and 57.4% reduction, respectively (Figure 1).

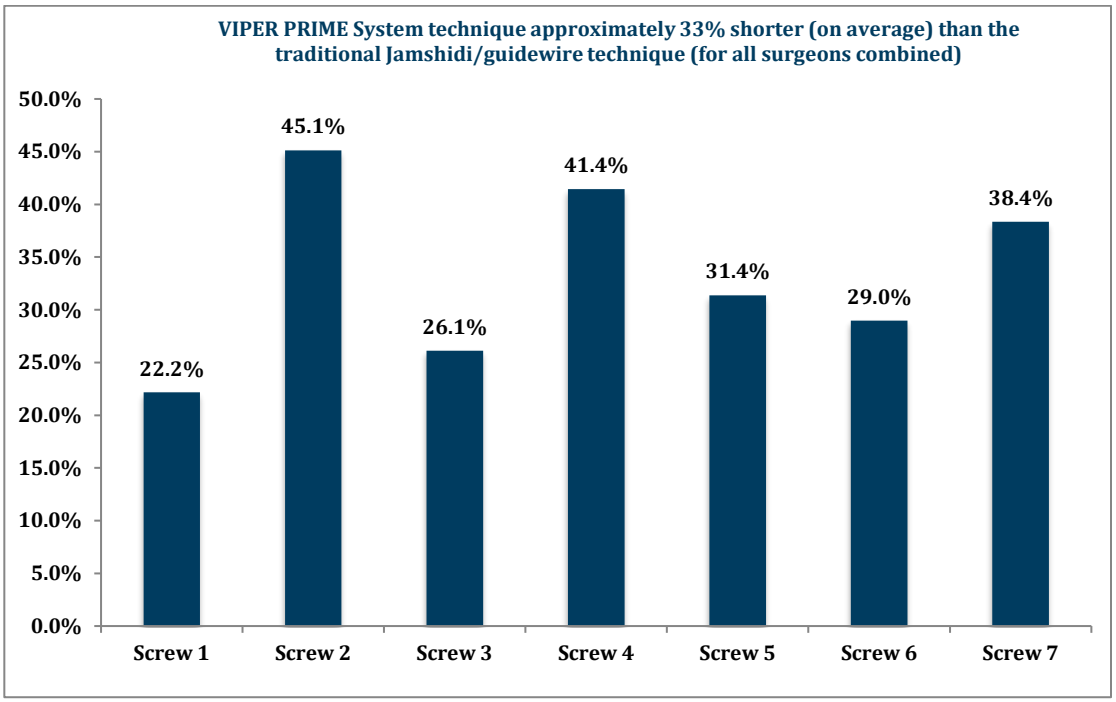
Figure 1. Percent Improvement in Screw Placement Times for the VIPER PRIME System Technique Compared to the Traditional Jamshidi/Guidewire Technique (*Averages for Each Surgeon)*



Note: All Jamshidi/Guidewire Technique screw times were normalized to 100% for graphical purposes.

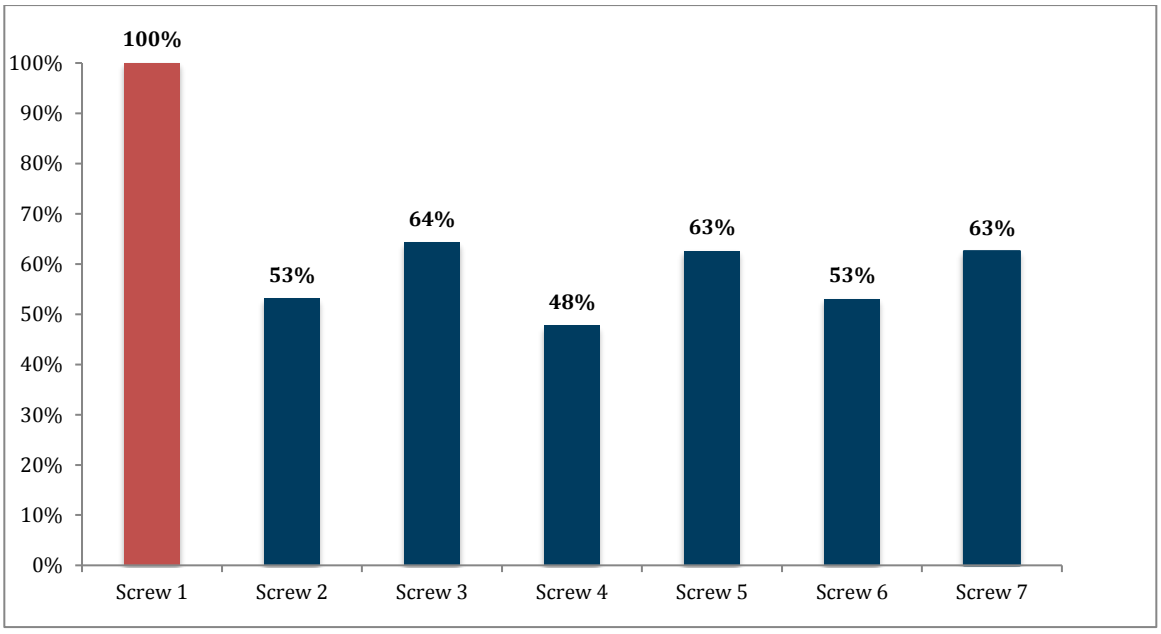
Similarly, when evaluating the results for all surgeons combined, the analysis showed that the duration of time for screw placement was shorter for the VIPER PRIME System technique compared to the traditional Jamshidi/guidewire technique for each screw (Figure 2).

Figure 2. Percent Reduction in Screw Placement Time Achieved Using the VIPER PRIME System Technique Compared to the Traditional Jamshidi/Guidewire Technique
(Averages for All Surgeons Combined)



When analyzing the results for the VIPER PRIME System technique alone, the placement of screw #1 took longer than each of the other screw placements (Figure 3). For example, the placement of screw #2 took approximately 53% of the time it took to place screw #1. These results are likely attributable to a learning curve since screw #1 was the first screw placed using the VIPER PRIME System technique and the screws were placed in sequential order.

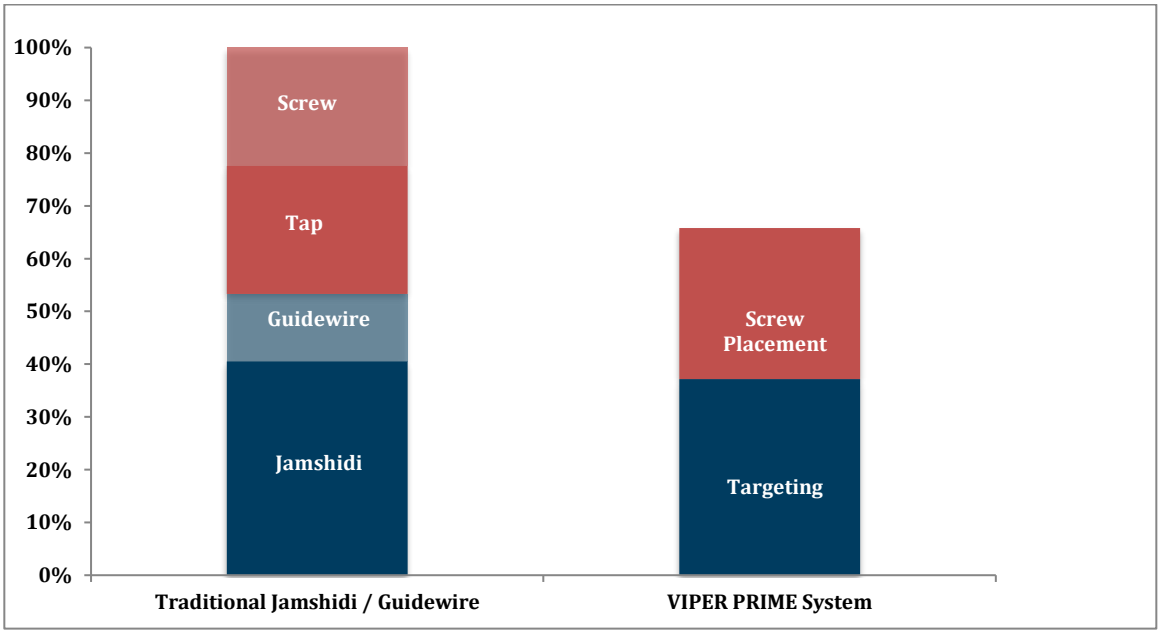
Figure 3. VIPER PRIME Screw Placement Time for Screw#1 Compared to All Other Screws
(Averages for All Surgeons Combined)



When examining individual screw placement times for the VIPER PRIME System technique *by surgeon*, five of the eight surgeons spent the longest amount of time placing screw #1 compared to the other screws. This trend shows that the majority of surgeons in this study were more efficient with placing subsequent screws, after the first screw was completed.

For the traditional Jamshidi/guidewire technique, the cumulative times for each step in the screw placement procedure were analyzed. The steps included insertion and placement of the Jamshidi, guidewire, tap and screw. The analyses of the individual procedural steps showed that the cumulative time for the insertion of the Jamshidi was the longest step followed by the insertion and removal of the tap from the guidewire (Figure 4). Similarly, for the VIPER PRIME System technique, the cumulative times for each step in the screw placement procedure were analyzed. The two main steps included targeting and screw placement. The analyses of the individual procedural steps showed that the cumulative time for targeting was longer than the cumulative time for screw placement (Figure 4).

Figure 4. Cumulative Time (by Percentage) for Each Step in the Jamshidi/ Guidewire Technique Compared to the VIPER PRIME System Technique *(Average for All Surgeons Combined)*



Note: The "Screw + Tap" steps are analogous to the "Screw Placement" step. The "Jamshidi + Guidewire" steps are analogous to the "Targeting" step. All Jamshidi/Guidewire Technique screw times were normalized to 100% for graphical purposes.

The results of a comparative analysis of the two techniques demonstrated that the cumulative time for "screw placement" using the VIPER PRIME System technique was 39% shorter than the cumulative time for the analogous "tap + screw placement" steps for the Jamshidi/Guidewire technique. Similarly, the cumulative time for the "targeting" step using the VIPER PRIME System technique was 30% shorter than the cumulative time for the analogous "Jamshidi + Guidewire" steps (Figure 4).

4. DISCUSSION / CONCLUSION

The results of this study showed that the VIPER PRIME System technique is a streamlined, *time saving* approach compared to traditional minimally invasive pedicle screw placement using the Jamshidi/guidewire technique. More specifically, the results showed that the cumulative screw placement times were shorter for the VIPER PRIME System technique compared to the traditional Jamshidi /guidewire technique across *all* eight surgeons participating in this study. As with any new surgical technique, a learning curve is necessary to become proficient in the technique. This is particularly the case for minimally invasive spine techniques which can be technically demanding and often require surgeons to navigate small channels involving several procedural steps and instrument passes. The results of this study showed that there was an initial learning curve with the VIPER PRIME System technique during the placement of the first screw but that all of the surgeons in this study were more efficient with placing subsequent screws, after the first screw was completed. Additionally, this study showed that the cumulative times for each of the individual steps were shorter for the VIPER PRIME System technique compared to the traditional Jamshidi /guidewire technique across all surgeons. Overall, the results of this cadaver time study demonstrate that the VIPER PRIME System technique leads to a reduction in procedural steps and a reduction in the time to complete screw insertion when compared to the traditional Jamshidi/guidewire technique for a one-level percutaneous pedicle screw procedure. Since pre-clinical testing is not necessarily predictive of clinical performance, research in the clinical setting should be done to evaluate these placement times.

5. REFERENCES

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