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Biomechanical Assessment of a Novel Sharp-Tipped Screw for 1-Step Minimally Invasive Pedicle Screw Placement Under Navigation

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ABSTRACT

Background: The objective of this study was to assess the pullout force of a novel sharp-tipped screw developed for single-step, minimally invasive pedicle screw placement guided by neuronavigation compared with the pullout force for traditional screws.

Methods: A total of 60 human cadaveric lumbar pedicles were studied. Three different screw insertion techniques were compared: (A) Jamshidi needle and Kirschner wire without tapping; (B) Jamshidi needle and Kirschner wire with tapping; and (C) sharp-tipped screw insertion. Pullout tests were performed at a displacement rate of 10 mm/min recorded at 20 Hz. Mean values of these parameters were compared using paired *t* tests (left vs right in the same specimen): A vs B, A vs C, and B vs C. Additionally, 3 L1-L5 spine models were used for timing each screw insertion technique for a total of 10 screw insertions for each technique. Insertion times were compared using 1-way analysis of variance.

Results: The mean pullout force for insertion technique A was 1462.3 (597.5) N; for technique B, it was 1693.5 (805.0) N; and for technique C, it was 1319.0 (735.7) N. There was no statistically significant difference in pullout force between techniques ($P > 0.08$). The average insertion time for condition C was significantly less than that for conditions A and B ($P < 0.001$).

Conclusions: The pullout force of the novel sharp-tipped screw placement technique is equivalent to that of traditional techniques. The sharp-tipped screw placement technique appears biomechanically viable and has the advantage of saving time during insertion.

Clinical Relevance: Single-step screw placement using high resolution 3-dimensional navigation has the potential to streamline workflow and reduce operative time.

Level of Evidence: 5.

Biomechanics

Keywords: Biomechanics, insertion time, MIS, navigation, pullout, sharp-tipped screw

INTRODUCTION

Screw loosening remains a recognized complication following posterior spinal fixation, particularly in complex spinal reconstruction and deformity correction procedures. Successful fusion is correlated with desirable clinical outcomes, whereas complications such as pseudarthrosis and instrumentation loosening that require revision are often associated with recurrent or persistent back pain.^{1,2} Ensuring good pedicle screw placement with adequate technique is essential for obtaining appropriate bone purchase, providing adequate perfusion stability, and helping to prevent mechanical complications and revision surgery.

Recently, a combination of highly technical tools has allowed pedicle screw placement with high accuracy

in a less invasive approach. Pedicle screw placement using minimally invasive surgery (MIS) consists of multiple imaging-guided steps, which start with a Jamshidi needle (BD, Franklin Lakes, NJ), followed by a Kirschner wire (K-wire), then tapping, and finally, screw placement. The purpose of the Jamshidi needle and K-wire during MIS procedures is to maintain the screw trajectory under 2-dimensional (2D) fluoroscopy while tapping prepares the trajectory for a good screw-bone interface. However, the influence of these steps on the ultimate fixation strength of the screw after insertion is not well understood. High-resolution stereotactic navigation with a 3-dimensional (3D) imaging system is associated with lower rates of pedicle screw misplacement and greater rates of accuracy compared with 2D

fluoroscopic image guidance.^{3,4} Real-time localization of the surgical anatomy in multiple views has the potential to eliminate steps from the traditional MIS pedicle screw placement technique.⁵ It can simplify the procedure for the surgeon and scrub technician, facilitating the workflow and the traffic of surgical instruments in and out of the surgical field.

A novel screw insertion approach was developed that obviates the need for Jamshidi needles, K-wires, and tapping procedures. A sharp-tipped screw with no cannula is placed directly at the desired insertion point guided by navigation. The screw is then advanced directly into the pedicle via 3D stereotactic image guidance, cutting the bone and initiating and formulating its trajectory in real time. The relative fixation strength of a screw inserted using this technique compared with traditional methods is also unknown, as well as the effects of skipping the other traditional steps. The objective of this study was to assess the pullout force of a novel sharp-tipped screw developed for single-step, minimally invasive pedicle screw placement, guided by neuronavigation compared with the pullout force of conventional screws placed using traditional methods.

METHODS

Sample

A total of 30 fresh frozen adult cadaver lumbar vertebrae were obtained from a tissue bank, 6 vertebrae of each level from L1 to L5, totaling 60 pedicles studied from a total of 8 donors. Of the cadavers, 2 were men and 6 were women, and they had a mean age of 45.0 years (SD 13.0). Some donors contributed all 5 lumbar vertebrae, while others contributed only 1 out of 5 because some vertebrae had pre- or postmortem fractures or were not intact. All donor medical records were carefully reviewed before the vertebrae were acquired to exclude systemic diseases interfering with calcium and bone metabolism. Plain radiographs were reviewed to ensure there were no fractures or bone abnormalities. Direct visual and manual inspections were performed to exclude those with tissue disruption and flaws. Finally, dual-energy x-ray absorptiometry was performed to exclude those with osteoporosis. Before testing, intact specimens were stored in a -20°C freezer and thawed in a room-temperature saline solution for a few hours before the test. Once fully thawed, each vertebra was carefully disarticulated, and all soft tissues were removed. Each vertebral body was then embedded in a fast-curing resin (Smooth-Cast 300-Q, Smooth-On, Inc., Macungie, PA) for rigid fixation in the test frame.

A flexible metal strip was looped through the spinal canal, involving the whole vertebral body, and embedded on the potting material. This technique was done to reinforce the potting and ensure the vertebra remained fixed in the potting material. The pedicles of all specimens remained exposed to allow unimpeded access to the sites necessary for proper screw insertion and direct visualization of the pedicle to ensure there were no cortical breaches. The resin did not encapsulate the pedicle itself and provided no support to improve the purchase of the screw.

Instrumentation and Conditions Tested

Three different pedicle screw insertion techniques were compared: (A) insertion of the pedicle screw (6.5×40 mm, Reline MAS, NuVasive, San Diego, CA) using a Jamshidi needle and K-wire without tapping; (B) insertion of the pedicle screw (6.5×40 mm, Reline MAS, NuVasive, San Diego, CA) using a Jamshidi needle and K-wire with tapping before screw placement; and (C) insertion of a novel single-step, self-tapping sharp-tipped pedicle screw (6.5×40 mm, Reline Prototype Sharp-Tipped Screw, NuVasive, San Diego, CA) (Figure 1) with no Jamshidi needle, K-wire, or tapping. Two different techniques were used in each vertebra, 1 on each pedicle with overall balance for left vs right pedicle and lumbar level placement for each technique. All techniques used axial vertebral radiographic images to verify the trajectory during each procedure and provide direct visualization of the pedicle to ensure no breaches.

Tests, Parameters, and Analysis

All tests were conducted in a standard uniaxial servohydraulic material testing system (858 Mini Bionix, MTS Systems Corporation, Eden Prairie, MN). Each specimen was secured using an angle vise clamped to the bottom of the test frame. A 5.5-mm titanium rod segment about 60-mm long (NuVasive, San Diego, CA) was attached to the screw head and secured with a set screw. A set of carabiners attached to the piston via chains was looped onto each end of the rod segment and used to pull out each screw from the pedicle. Specimens were carefully repositioned in the vise before each test, which involved pulling the screw in line with the axis of the piston to ensure an even distribution of the tensile force on both sides of the screw head. The displacement rate was set to 10 mm/min, with force and displacement data recorded at 20 Hz using a linear variable differential transformer.

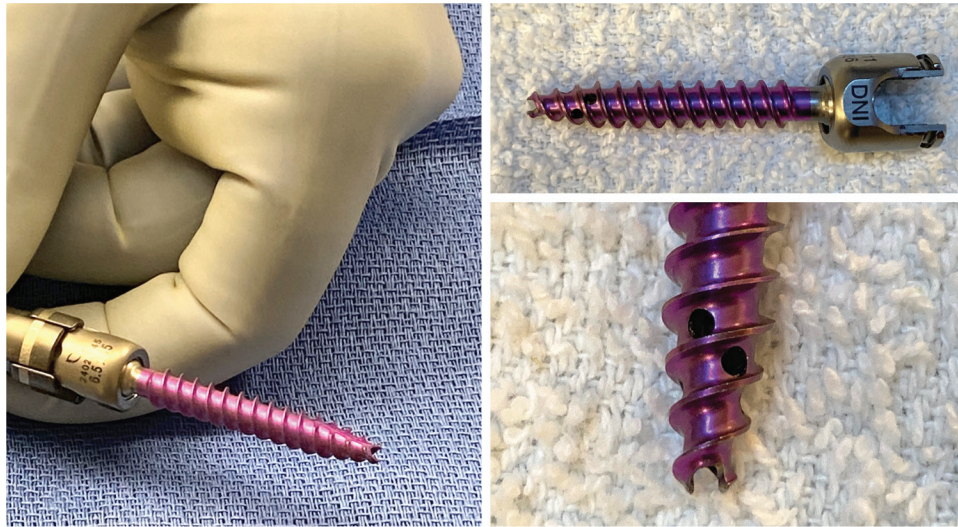


Figure 1. Images of sharp-tipped, self-tapping pedicle screw used for single-step, minimally invasive 3-dimensional navigation-guided pedicle screw placement (group C). Insets are enlarged to show detail. Used with permission from Barrow Neurological Institute, Phoenix, Arizona.

Loads vs displacement curves were analyzed to evaluate fixation stiffness and peak load at failure (pullout force) (Figure 2). The fixation stiffness was determined from the slope of the linear portion of each force-displacement curve. The pullout force was determined by finding the peak force on the curve. Mean (SD) values of peak load at failure, fixation stiffness, and displacement at failure were compared using paired *t* test analysis (left vs right in the same specimen): groups A vs B, A vs C, and B vs C.

Timing

A second and separate phase of the study focused on the time involved for each insertion technique using 3 lumbosacral (L1-sacrum) spine models (Sawbones, Pacific Research Company, Vashon, WA). The proximal

and distal ends of each model were potted in a fast curing resin and firmly attached to a surgical table using 2 vises. One model was used for each insertion technique, including the right and left pedicles of L1 through L5. Two neurosurgeons (1 resident and 1 fellow) took turns inserting screws at each level (ie, each surgeon did 5 insertions per technique and model, totaling 10 insertions per condition). The time was recorded from the start to the end of screw placement when the screwdriver was detached from the screw. Data from both surgeons were pooled, and the mean insertion times for the 3 insertion techniques (groups A, B, and C) were compared using 1-way analysis of variance.

RESULTS

The Table summarizes all results for bone mineral density (BMD), pullout force, stiffness, and mean displacement to achieve pullout for each pedicle of each specimen. It also includes *P* values for comparisons between each insertion technique (group).

The mean BMD for all specimens was 0.731 g/cm² (SD 0.194), and the mean BMD values for all groups were equivalent (*P* = 0.854). The mean pullout force for group A was 1462.3 N (SD 597.5); for group B, it was 1693.5 N (SD 805.0); and for group C, it was 1319.0 N (SD 735.7). The mean stiffness for group A was 671.5 N/mm (SD 198.7); for group B, it was 645.5 N/mm (SD 268.5); and for group C, it was 563.2 N/mm (SD 312.2).

There were no statistically significant differences in pullout force between groups A and B (*P* = 0.27), A and C (*P* = 0.32), and B and C (*P* = 0.08). There were no statistically significant differences in stiffness between

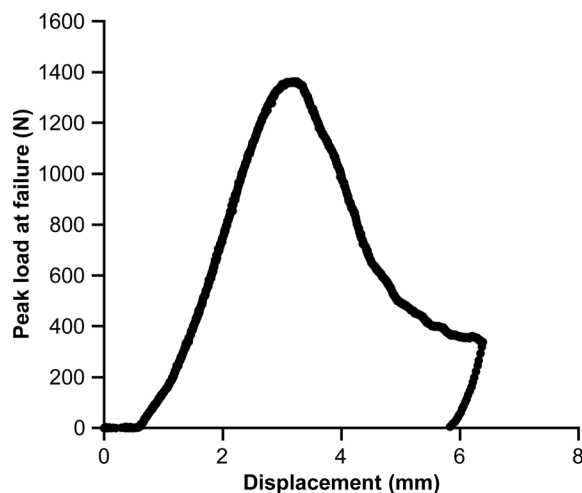


Figure 2. Typical example of peak load at failure vs displacement curve. Used with permission from Barrow Neurological Institute, Phoenix, Arizona.

Table. Results for BMD, pullout force, stiffness, and mean displacement to achieve pullout for each pedicle of each specimen; *P* values are for the paired *t* test analysis (L vs R in same specimen and level): A vs B, A vs C, B vs C.

Specimen	BMD (g/ cm ²)	Level, Side	Group	Fixation			Specimen	Level, Side	Group	Pullout Force (N)	Stiffness (N/ mm)	Displacement From Start (mm)
				Pullout Force (N) ^a	Stiffness (N/ mm) ^b	Displacement from Start (mm) ^c						
1043	0.883	L1, L	A	2348	929	4.6	1043	L1, R	B	2063	526	4.7
1057	0.885	L2, L	A	2151	397	5.8	1057	L2, R	B	1864	403	5.7
1088	0.810	L3, L	A	1423	879	2.0	1088	L3, R	B	1088	862	2.8
1076	0.795	L4, L	A	1335	630	3.6	1076	L4, R	B	1730	443	4.8
1076	0.795	L5, L	A	740	258	4.4	1076	L5, R	B	1001	377	3.8
1164	0.885	L1, R	A	2153	1003	2.9	1164	L1, L	B	3057	1050	4.0
1243	0.644	L2, R	A	1436	610	3.5	1243	L2, L	B	1482	731	4.0
1243	0.644	L3, R	A	1364	742	3.2	1243	L3, L	B	1195	571	3.9
1164	0.885	L4, R	A	2643	568	6.0	1164	L4, L	B	3343	958	6.0
1068	0.815	L5, R	A	1452	787	2.4	1068	L5, L	B	1075	554	2.1
1241	0.585	L1, L	A	1966	786	4.6	1241	L1, R	C	2411	754	4.3
1076	0.795	L2, L	A	1561	684	3.8	1076	L2, R	C	1561	542	2.7
1246	0.651	L3, L	A	924	791	2.2	1246	L3, R	C	906	759	1.2
1079	1.002	L4, L	A	1727	784	1.8	1079	L4, R	C	2157	1423	3.0
1121	1.137	L5, L	A	1347	757	2.8	1121	L5, R	C	1328	380	2.8
1211	0.419	L1, R	A	880	815	1.3	1211	L1, L	C	622	259	2.6
1211	0.419	L2, R	A	640	476	1.8	1211	L2, L	C	612	368	2.2
1164	0.885	L3, R	A	1827	683	4.3	1164	L3, L	C	2686	265	9.1
1211	0.419	L4, R	A	515	319	2.4	1211	L4, L	C	302	289	1.3
1043	0.883	L5, R	A	813	534	2.1	1043	L5, L	C	780	383	2.0
1113	0.713	L1, L	B	2101	1062	3.1	1113	L1, R	C	1884	715	3.5
1043	0.883	L2, L	B	3201	562	6.0	1043	L2, R	C	2477	450	5.6
1076	0.795	L3, L	B	1350	944	3.1	1076	L3, R	C	1139	903	1.8
1068	0.815	L4, L	B	1413	1189	1.8	1068	L4, R	C	1684	1149	2.0
1057	0.885	L5, L	B	1462	382	4.2	1057	L5, R	C	1552	657	3.0
1243	0.644	L1, R	B	1219	493	3.0	1243	L1, L	C	655	380	2.3
1164	0.885	L2, R	B	2226	550	7.7	1164	L2, L	C	1702	542	10.5
1211	0.419	L3, R	B	500	389	2.3	1211	L3, L	C	359	321	1.2
1043	0.883	L4, R	B	1230	558	3.6	1043	L4, L	C	873	346	3.8
1211	0.419	L5, R	B	458	308	2.2	1211	L5, L	C	690	377	2.4

Abbreviations: BMD, bone mineral density; L, left; R, right.

Note: Table arranged for paired *t* test analysis (L vs R in same specimen and level): A vs B, A vs C, B vs C.

^aThe *P* value for pullout force between groups A and B was *P* = 0.27, between groups A and C was *P* = 0.32, and between groups B and C was *P* = 0.08.

^bThe *P* value for stiffness between groups A and B was *P* = 0.66, between groups A and C was *P* = 0.27, and between groups B and C was *P* = 0.28.

^cThe *P* value for displacement to achieve pullout between groups A and B was *P* = 0.11, between groups A and C was *P* = 0.50, and between groups B and C was *P* = 0.82.

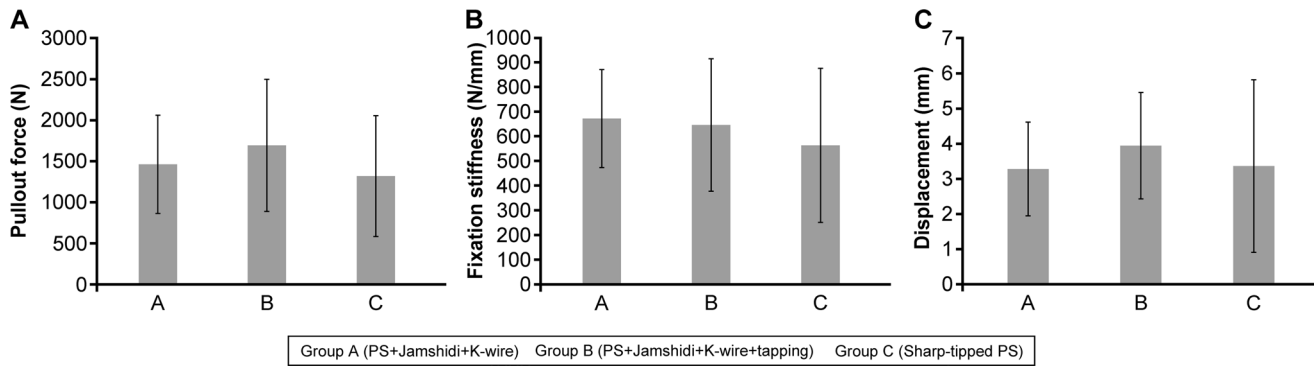


Figure 3. Comparison for various biomechanical parameters between insertion groups. Mean (A) pullout force, (B) fixation stiffness, and (C) displacement of the screw to produce pullout for group A (insertion using the Jamshidi needle and a K-wire with no tapping), group B (insertion using the Jamshidi needle and a K-wire with tapping), and group C (sharp-tipped screw insertion without use of a Jamshidi needle, K-wire, or tapping). Whiskers show SDs. Abbreviation: PS, pedicle screw. Used with permission from Barrow Neurological Institute, Phoenix, Arizona.

groups A and B ($P = 0.66$), A and C ($P = 0.27$), and B and C ($P = 0.28$). The mean displacement to produce pullout for group A was 3.3 mm (SD 1.3); for group B, it was 3.9 mm (SD 1.5); and for group C, it was 3.4 mm (SD 2.5). There were no statistically significant differences in displacement to achieve pullout between groups A and B ($P = 0.11$), A and C ($P = 0.50$), and B and C ($P = 0.82$) (Figure 3).

There were significant and positive correlations between both pullout force vs BMD ($R = 0.40$, $P = 0.001$) and stiffness vs BMD ($R = 0.30$, $P = 0.02$) when including data from all 3 groups (A, B, and C: $n = 60$). The same correlations remained significant only for group C (pullout force vs BMD: $R = 0.47$, $P = 0.04$, Figure 4).

The mean (SD) pedicle screw insertion time for group A was 55.0 (6.7) seconds; for group B, it was 118.0 (20.2) seconds; and for group C, it was 25.9 (4.2) seconds. Pedicle screw insertion in group C demanded significantly less time for the entire insertion technique than in groups A and B ($P < 0.001$). Pedicle screw insertion in group B demanded significantly more time than in groups A and C ($P < 0.001$).

DISCUSSION

Minimally invasive thoracic and lumbar fusion approaches can decrease soft tissue disruption, improve patient postoperative pain, and decrease recovery time. However, they involve increased radiation exposure to

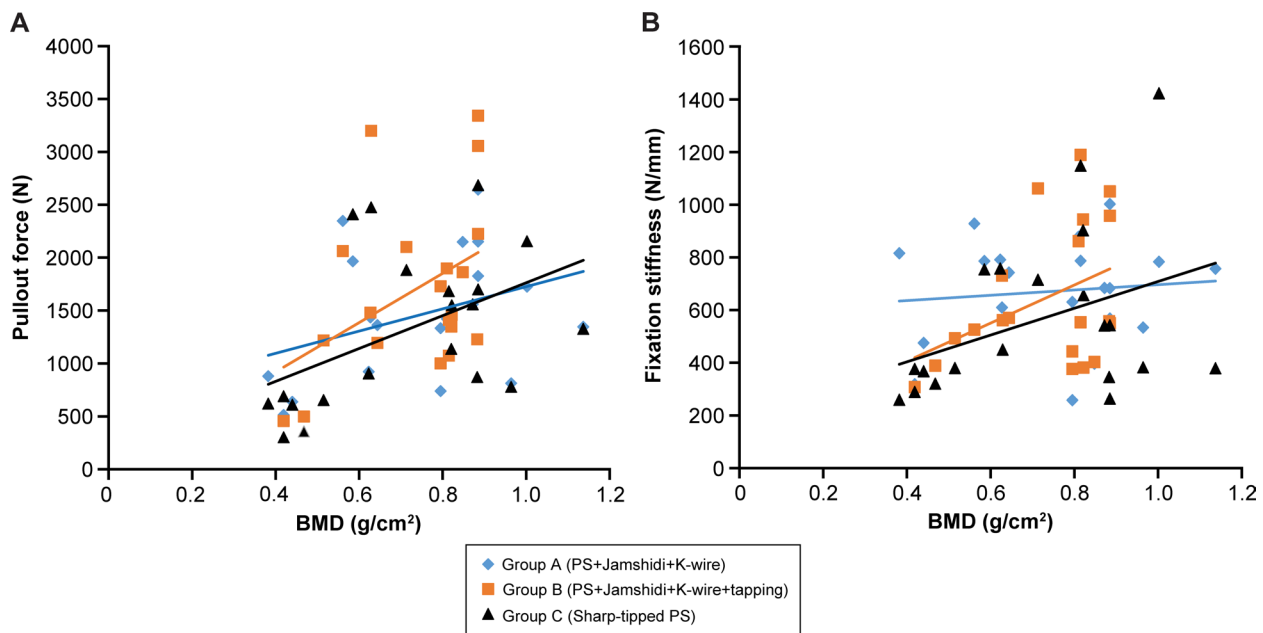


Figure 4. Linear correlations between (A) pullout force and (B) fixation stiffness vs bone mineral density (BMD). Abbreviation: PS, pedicle screw. Used with permission from Barrow Neurological Institute, Phoenix, Arizona.

the surgeon, staff, and patient in the operating room compared to traditional open surgery.⁶⁻⁹ Pedicle screw placement through a traditional 2D fluoroscopic-guided MIS approach requires multiple steps to prepare the trajectory and ensure reasonable positioning. Since concerns about radiation exposure have been raised, new imaging technologies have been developed to mitigate this exposure, such as the 3D spinal navigation system. Studies that compared radiation exposure in both MIS and open procedures for the placement of pedicle screws have shown decreased radiation exposure with navigation-assisted techniques.¹⁰ The 3D navigational guidance improves accuracy and allows surgeons to place pedicle screws confidently through a mini-open approach, and it provides a more precise trajectory in case of anatomical distortion.^{3,4,11} Furthermore, the introduction of navigation permitted the elimination of 1 or more steps during MIS pedicle screw placement.

A recent innovative movement to eliminate steps during navigation-guided MIS pedicle screw placement involves the tubular percutaneous or mini-open approach. Reducing the number of steps required for MIS screw placement facilitates the workflow for the surgeon and scrub technician, avoids crowding of surgical instruments, and optimizes the attention spent on each step. However, this pace optimization coexists with concerns about maintaining a good bone purchase and trajectory accuracy. The use of K-wires can be eliminated without complications and with good accuracy.^{5,12} Kleck et al¹³ described a 1-step screw technique using navigation, performed in 8 patients for a total of 48 pedicle screws, that had good accuracy but still used an integrated K-wire that was removed after advancement of the screw. Avoiding K-wire protrusion through the cannulated screw tip can help to prevent accidents and organ injury complications. Sadrameli et al¹⁴ described a retrospective review of 42 consecutive patients who underwent a stereotactic-guided wireless lumbar pedicle screw placement with relative safety and good accuracy. Schmidt et al¹⁵ described a prospective case series in patients who underwent pedicle screw placement using a novel single-step system without a K-wire that showed relative safety and accuracy. They employed a system that used a short stylet within the tip of the screw to dock the entry point that was then retracted.

Many studies have assessed the accuracy and complication rates of 1-step MIS screw placement. However, little is known about the biomechanical effects on the bone-screw interface or the effects of not tapping the screw trajectory before the placement.

Pedicle screw loosening is one of the most frequently reported complications of thoracolumbar posterior fixation. Although there is no evidence that this complication is related to the screw insertion technique, surgeons still need to ensure a good bone anchorage and optimize the screw-bone interface, particularly in osteoporotic patients for whom the failure rate can reach up to 60%.^{16,17} The present study describes a sharp-tipped screw that allows single-step, minimally invasive pedicle screw placement. It assesses the pullout force, stiffness, and displacement through traditional pullout tests. At the very tip of the screw, the threads extend outward to form 2 short, sharp prongs that provide the self-drilling and self-tapping features. Assessment of the pullout force, stiffness, and displacement to achieve pullout provides information about the bone-screw interface quality.

The BMD was homogeneous between the groups in the present study and therefore not a confounding factor. Additionally, statistical analyses performed were paired for 2 different conditions in 2 different pedicles within the same vertebra, further reducing the potential effects of confounding factors. Although the analysis demonstrated a positive correlation between stiffness and pullout force with BMD, the results for pullout force, stiffness, and displacement to achieve pullout did not differ statistically, and the 3 conditions were equivalent.

Minimally invasive pedicle screw placement using a 1-step sharp-tipped screw has the same screw-bone interface quality as conventional screws placed with traditional techniques. Furthermore, skipping the tapping step did not significantly affect the screw pullout force. The sharp-tipped screw design with 2 sharp prongs at the tip and tapered flute, which create a self-tapping and self-drilling feature, does not positively or negatively interfere with the bone-screw interface. These results provide a biomechanical basis for surgeons to eliminate traditional steps during navigation-guided minimally invasive pedicle screw placement with Jamshidi needle, K-wire, and tapping. Single-step screw placement simplifies the workflow for the surgeon and scrub technician and decreases the number of times that the surgeon needs to switch instruments. Although an evaluation of operative time was not an objective of this study, the second phase of this study demonstrated that this technique can reduce operative time. Further studies are necessary to address this matter. Nonetheless, eliminating steps drives the surgeon to rely more on the navigation system; thus, the accuracy of the navigation frame should be carefully monitored throughout the procedure.

Our study has certain limitations. Variables including screw trajectory and the diameter of the screw can influence the pullout force.¹⁸ For example, if the trajectory of the screw within the isthmus of the pedicle is closer to the cortical bone, the screw may have better mechanical anchorage. The insertions were performed by a single surgeon using the same technique throughout the study to decrease the effect of these variables, and the same screw size was used for all insertions. We analyzed the pullout force and the bone-screw interface characteristics in a hypothetical immediate postoperative scenario, which can be reproduced in vitro. Different factors can affect the screw pullout force and screw-bone interface integrity in vivo. Such factors include pseudarthrosis, failure to re-establish the spinal alignment, remodeling of the bone surrounding the screw microfractures, screw-bone interface overloads, and stress shielding.¹⁷ Further studies are necessary to evaluate the performance of the single-step pedicle screw placement technique in clinical conditions.

CONCLUSION

The pullout force and stiffness for the novel sharp-tipped screw and placement technique are equivalent to those of conventional screws and traditional placement techniques. Tapping did not significantly affect the final pullout force. The 1-step, sharp-tipped screw placement technique appears biomechanically viable, demands less time for its insertion, and has the potential to decrease operative time.

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