Early experience of placing image-guided minimally invasive pedicle screws without K-wires or bone-anchored trackers

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OBJECTIVE Image guidance for spine surgery has been reported to improve the accuracy of pedicle screw placement and reduce revision rates and radiation exposure. Current navigation and robot-assisted techniques for percutaneous screws rely on bone-anchored trackers and Kirchner wires (K-wires). There is a paucity of published data regarding the placement of image-guided percutaneous screws without K-wires. A new skin-adhesive stereotactic patient tracker (SpineMask) eliminates both an invasive bone-anchored tracker and K-wires for pedicle screw placement. This study reports the authors’ early experience with the use of SpineMask for “K-wireless” placement of minimally invasive pedicle screws and makes recommendations for its potential applications in lumbar fusion.

METHODS Forty-five consecutive patients (involving 204 screws inserted) underwent K-wireless lumbar pedicle screw fixation with SpineMask and intraoperative neuromonitoring. Screws were inserted by percutaneous stab or Wiltse incisions. If required, decompression with or without interbody fusion was performed using mini-open midline incisions. Multimodality intraoperative neuromonitoring assessing motor and sensory responses with triggered electromyography (tEMG) was performed. Computed tomography scans were obtained 2 days postoperatively to assess screw placement and any cortical breaches. A breach was defined as any violation of a pedicle screw involving the cortical bone of the pedicle.

RESULTS Fourteen screws (7%) required intraoperative revision. Screws were removed and repositioned due to a tEMG response < 13 mA, tactile feedback, and 3D fluoroscopic assessment. All screws were revised using the SpineMask with the same screw placement technique. The highest proportion of revisions occurred with Wiltse incisions (4/12, 33%) as this caused the greatest degree of SpineMask deformation, followed by a mini midline incision (3/26, 12%). Percutaneous screws via a single stab incision resulted in the fewest revisions (7/166, 4%). Postoperative CT demonstrated 7 pedicle screw breaches (3%; 5 lateral, 1 medial, 1 superior), all with percutaneous stab incisions (7/166, 4%). The radiological accuracy of the SpineMask tracker was 97% (197/204 screws). No patients suffered neural injury or required postoperative screw revision.

CONCLUSIONS The noninvasive cutaneous SpineMask tracker with 3D image guidance and tEMG monitoring provided high accuracy (97%) for percutaneous pedicle screw placement via stab incisions without K-wires.

https://thejns.org/doi/abs/10.3171/2017.7.SPINE17528

KEY WORDS K-wireless; image guidance; navigation; neuromonitoring; pedicle screw; percutaneous; surgical technique

Lumbar pedicle screw-rod fixation for interbody fusion or supplemental posterior fixation traditionally uses open anatomical landmarks for screw entry points and pedicle cannulation. The evolution of minimally invasive spine surgery (MISS) has removed these visible anatomical landmarks and is instead reliant on 2D fluoroscopy for pedicle cannulation and Kirchner wire (K-wire) placement.5,16 K-wires can break, pull out, or advance during pedicle screw insertion and potentially cause neural, vascular, or visceral injury.6 A “K-wireless” technique using 2D fluoroscopy has been described.17 The development of intraoperative 3D fluoroscopy and...
spinal navigation has further improved the accuracy of pedicle screw placement and provides significant occupational safety and technical benefits.\textsuperscript{7,19} The surgical team benefits from reduced radiation exposure and avoids wearing heavy protective lead aprons for the duration of the operation. The navigation images provide axial, coronal, and sagittal plane visibility, allowing accurate screw sizing and pedicle screw placement, and reduced neurological injury.\textsuperscript{15}

Current 3D spinal navigation techniques rely on K-wires and bone-anchored spinal tracking through either iliac crest bolts or spinous process clamps.\textsuperscript{21,22} However, bone-anchored trackers require an additional incision, often have difficulty anchoring the tracker to bone in obese patients, possibly impair the desired instrument trajectory in deformity cases, and lose visibility due to obstruction by instruments. Recently, a noninvasive spinal patient tracker called SpineMask (Stryker Navigation) was developed (Fig. 1). A skin-adhesive tracker utilizing light-emitting diode (LED) tracking technology is placed on the patient’s thoracolumbar region and enables real-time spinal navigation for MISS procedures.\textsuperscript{11} No method for the placement of pedicle screws without K-wires using 3D navigation has been previously described.

The aims of this study were to report our early experience with the use of a noninvasive tracker (SpineMask) for K-wireless placement of minimally invasive pedicle screws and make recommendations for its potential applications in lumbar fusion.

**Methods**

We conducted a prospective study of consecutive patients treated with SpineMask by a single surgeon (G.M.M) from October 2015 to March 2017 at Epworth Hospital. IRB approval was obtained. No patient refused to participate in this study, and informed consent was obtained for all patients.

**Inclusion and Exclusion Criteria**

Patients were treated with SpineMask if they required minimally invasive 1) 1- to 2-level posterior or transforaminal lumbar interbody fusion (PLIF or TLIF) with or without decompression, or 2) posterior supplementary pedicle screw-rod fixation as a second stage to anterior or lateral lumbar interbody fusion (ALIF or LLIF). Patients who required multilevel open decompression or PLIF/TLIF were not treated with SpineMask, as the spinous process was accessed for a bone-anchored clamp. All patients treated with SpineMask were included in this study; no patients were excluded.

**SpineMask**

The SpineMask is a rectangular skin-adhesive stereotactic patient tracker (Fig. 1) that integrates with 3D spinal navigation (Stryker Spine Map 3.0) using automatic intraoperative mask registration. SpineMask registration is not compatible with 2D fluoroscopy. The SpineMask is a sterile packaged, single-use, disposable, battery-powered device that spans 4–5 adult lumbar vertebrae and costs approximately US $200. SpineMask does not require a bone-anchored tracker, fiducial-based registration, or image merging.

**Operating Room Workflow**

After general anesthesia and endotracheal intubation, the patient is positioned prone on a radiolucent operating table. The SpineMask is templated (outline marked on the skin) prior to skin preparation. The skin is prepared with antisepsic and Ioban 2 (3M) draping that must smoothly adhere to the skin (Fig. 1). The SpineMask is placed in the premarked templated position with care taken not to deform the SpineMask on the skin. For patients with obesity or pronounced skin hypermobility, the skin was tensioned proximally and distally in the longitudinal axis by taping (Leukoplast Sleek, BSN Medical) prior to placing the SpineMask. The SpineMask is registered and LEDs captured in position. For registration to proceed, 28 of the 31 LEDs on the SpineMask must be visible. A 3D fluoroscopic spin is then performed with the Arcadis Orbig 3D (Siemens AG) C-arm.

**Surgical Techniques**

Patients comprised 3 groups: 1) percutaneous screws via 13-mm stab incisions, to accommodate the screws and the countertorque tube (final tightening device), supplementing ALIF or LLIF as a staged procedure (Fig. 2A); 2) bilateral Wiltse incisions for pedicle screws and posterolateral bone grafting (Fig. 2B); and 3) percutaneous screws via stab incisions with decompression via midline incision for laminectomy, facetectomies with or without PLIF, or TLIF (Fig. 2C).

**Pedicle Screw Insertion Technique**

No K-wires were needed. Pedicle screws were placed with integrated navigated instrumentation (Fig. 3) in a stepwise fashion: 1) the awl was used to puncture the cortex; 2) with the awl docked into bone, the entry point was annotated on the navigation screen; 3) the annotation point was used as a return reference for each pedicle cannulation; 4) the trajectory of the pedicle probe was mapped with the

![FIG. 1. SpineMask noninvasive skin tracker.](image)
navigation; 5) the mapped trajectory was then used for screw insertion, with a virtual tip representing the screw visible on the navigation screen; and 6) the screw was visible to the surgeon upon insertion in the coronal, axial, and sagittal planes on the navigation screen. Screws requiring revision were replaced using this same technique.

**Intraoperative Neuromonitoring**

Multimodality intraoperative neuromonitoring (NIM-Eclipse Spinal System, Medtronic Inc.) assessing motor and sensory responses with triggered electromyography (tEMG) was performed by a surgical neurophysiology specialist (Neuro-Monitoring Services Australia). Total intravenous anesthesia with muscle relaxant, only for intubation, was used to provide optimal monitoring conditions. tEMG responses corresponding to the likelihood of pedicle breach are provided in Table 1.

**Intraoperative Screw Position Review**

Screws were removed based on tactile feedback, neuromonitoring (tEMG response < 13 mA), intraoperative 3D fluoroscopic assessment, and the surgeon’s clinical interpretation. A 3D fluoroscopic spin was performed, registering the SpineMask, and the screw was repositioned using the same methodology described above. Revised screws were then checked with an intraoperative 3D spin.

**Intraoperative Radiation Dose**

After each case a radiation summary report generated by the Siemens Orbic was used to record the cumulative fluoroscopic time and cumulative area dose product.

**Postoperative CT Scans**

High-definition CT scans (Somatom Definition Flash,
Siemens AG) were performed 2 days postoperatively to assess instrumentation and screw position. Targeted CT at the operative level only—and not full lumbar CT—was performed to reduce radiation exposure. A pedicle breach was defined as any violation, in millimeters, of a pedicle screw with the cortical bone of the pedicle as graded by the Gertzbein-Robbins classification. A pedicle breach was defined as any violation, in millimeters, of a pedicle screw with the cortical bone of the pedicle as graded by the Gertzbein-Robbins classification. All patients consented to CT examination. An independent radiologist from within the treating institution assessed the CT scans.

Results

The SpineMask tracker was used for 45 consecutive patients with 204 screws inserted. The demographic and treatment information for these patients is provided in Table 2.

The total intraoperative screw revision rate was 14/204 (7%); all screws were revised using the SpineMask with the same screw placement technique. One hundred sixty-six screws were placed percutaneously via stab incisions with an intraoperative revision rate of 4% (7/166). Twenty-six screws were placed via mini-open midline incisions and 12 were placed via Wiltse incisions, with intraoperative revision rates of 12% (3/26) and 33% (4/12), respectively (Table 3). Screws were removed and repositioned due to 3 factors: 1) a tEMG response < 13 mA, 2) tactile feedback, and 3) 3D fluoroscopic assessment. The overall intraoperative accuracy rate was 93% (190/204).

The median number of 3D spins with the Siemens Oribic was 2 (range 1–3) per case. Mean fluoroscopic time, as measured by the x-ray unit, was 141 seconds (range 69–309 seconds) and the mean cumulative area dose product was 246.7 mGy (range 217.3–359.9 mGy) per case.

Postoperative day 2 CT demonstrated 7 (3%) radiological pedicle screw breaches, with 5 (2%) lateral breaches (Fig. 4A), 1 (0.5%) medial breach (Fig. 4B), and 1 (0.5%) superior breach (Fig. 4C). All 7 breaches occurred with percutaneous stab incisions (7/166, 4%) and were classified as minor (< 2 mm violation from the pedicle cortex). This provided a radiological accuracy rate of 97%, with 197 of 204 screws being inserted without a cortical breach. No patient required a return to the operating room for screw revision. There were no neural, vascular, or visceral injuries.

Discussion

The traditional open pedicle screw misplacement rate, assessed by postoperative CT, has been reported to be as high as 40%. Conventional fluoroscopy alone improved screw accuracy to 86.6%–94.9%, and when combined with EMG monitoring, accuracy was further improved to 90.2%–97.5%. MISS techniques have reduced incision size, postoperative pain, length of hospital stay with earlier mobilization, and return-to-work time. For the surgeon, MISS necessitates a learning curve to master radiological spinal anatomy. Intraoperative K-wires facilitate percutaneous pedicle screw insertion accuracy but require fluoroscopic guidance to reduce the risk of inadvertent K-wire advancement and the potential for CSF leak and neural, vascular, and visceral injury.

Intraoperative 2D navigation improved the accuracy of pedicle screw placement compared with conventional fluoroscopy. The development of 3D fluoroscopy and spinal navigation has further improved pedicle screw accuracy by providing real-time coronal, axial, and sagittal reconstructions for the surgeon. Three-dimensional guidance is advantageous in cases of deformity and for S-1 pedicle cannulation, which are not always well visualized using fluoroscopy. Navigation eliminates the need for on-

**TABLE 1. Triggered electromyography thresholds**

<table>
<thead>
<tr>
<th>tEMG Threshold (mA)</th>
<th>Response</th>
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<tbody>
<tr>
<td>≥13</td>
<td>Unlikely breach: proceed</td>
</tr>
<tr>
<td>9–12</td>
<td>Possible breach: attempt redirection</td>
</tr>
<tr>
<td>≤8</td>
<td>Likely breach: neural tissue at risk</td>
</tr>
</tbody>
</table>

**TABLE 2. Patient demographic and treatment information**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>45</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>60.8 ± 12.7 Range 36–85</td>
</tr>
<tr>
<td>Male</td>
<td>29 (64)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>28.4 ± 4.5 Range 21–39</td>
</tr>
<tr>
<td>Primary diagnosis</td>
<td></td>
</tr>
<tr>
<td>Degenerative disc disease</td>
<td>10 (22)</td>
</tr>
<tr>
<td>Scoliosis</td>
<td>4 (9)</td>
</tr>
<tr>
<td>Spondylolisthesis</td>
<td>23 (51)</td>
</tr>
<tr>
<td>Stenosis</td>
<td>8 (18)</td>
</tr>
<tr>
<td>Incision</td>
<td></td>
</tr>
<tr>
<td>Mini midline w/ percutaneous screws</td>
<td>6 (13)</td>
</tr>
<tr>
<td>Percutaneous stab</td>
<td>37 (82)</td>
</tr>
<tr>
<td>Wiltse</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Screws*</td>
<td>204</td>
</tr>
<tr>
<td>L-2</td>
<td>6 (3)</td>
</tr>
<tr>
<td>L-3</td>
<td>26 (13)</td>
</tr>
<tr>
<td>L-4</td>
<td>66 (32)</td>
</tr>
<tr>
<td>L-5</td>
<td>74 (36)</td>
</tr>
<tr>
<td>S-1</td>
<td>32 (16)</td>
</tr>
</tbody>
</table>

BMI = body mass index. All data given as number of patients (%) unless otherwise indicated.

* Left and right.

**TABLE 3. Summary of screw revisions**

<table>
<thead>
<tr>
<th>Incision</th>
<th>Revisions (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mini-open midline w/ percutaneous screws</td>
<td>3/26 (12)</td>
</tr>
<tr>
<td>Percutaneous stab</td>
<td>7/166 (4)</td>
</tr>
<tr>
<td>Wiltse</td>
<td>4/12 (33)</td>
</tr>
<tr>
<td>Total</td>
<td>14/204 (7)</td>
</tr>
</tbody>
</table>
going intraoperative 2D fluoroscopy, thus reducing radiation exposure for the patient and surgical team by negating the need for protective lead glasses and heavy aprons. A surgeon’s tactile feedback is maintained throughout the navigated pedicle cannulation.

Three-dimensional navigation relies on bone-anchored spinal tracking through either iliac crest bolts or spinous process clamps. The challenges we identified with bone-anchored tracking were 1) difficulty attaching the tracker clamp to bone in large and obese patients; 2) artifact from the tracker after 3D spin, affecting image quality; 3) obstruction of desired instrument trajectory in deformity cases; 4) impacting the tracker with instruments and/or movement from deep muscle retraction intraoperatively, reducing accuracy; 5) visibility challenges in navigation of tracker LEDs blocked by instrumentation; and 6) tracker movement when using the mallet with the pedicle awl and pedicle probe. These challenges are similar to those in other authors’ experiences.

Both 3D navigated and the recently developed robot-assisted pedicle screw placement systems require an incision for bone anchoring. The cutaneous noninvasive tracker (SpineMask) eliminates the need for bone-anchored fixation that may cause increased operative time and morbid-ity. Registration with SpineMask can be transferred to a bone anchor, without requiring another 3D spin, as a salvage option.

Bone-anchored trackers may be knocked or dislodged from bone. The SpineMask is a skin-based marker and may be susceptible to any skin distortion, which could affect registration accuracy. Factors that may impact accuracy include greater posterior adipose tissue, larger subcutaneous mobility, on-table patient positioning, and movement. We advocate using adhesive tape to mitigate skin movement that would cause SpineMask deformation.

The SpineMask is approved for use with the 3D fluoroscopic units Arcadis Orbic 3D (Siemens AG), O-Arm (Medtronic Navigation), and BodyTom CT Scanner (Neurologica). We prefer 3D fluoroscopy to CT given the versatility of the C-arm to be used as a conventional 2D machine, speed of use, and lower radiation doses. The spinal navigation software has additional cranial, orthopedic joint replacement, and ear, nose, and throat applications.

Navigated pedicle screw placement using the Siemens Orbic demonstrates lower radiation doses (152 mGy) than CT-based (432 mGy) and 2D fluoroscopic (1091 mGy) navigation. The higher mean radiation dose of 246.7 mGy in our study reflects the author’s preference to also check screw placement intraoperatively.

In our study a total of 14 screws (7%) required intraoperative revision; all screws were revised using the SpineMask with the same screw placement technique. These screws were removed and repositioned due to a low tEMG response (< 13 mA), confirmed by another 3D fluoroscopic spin. Wiltse incisions caused the greatest degree of SpineMask deformation and, as a result, had the highest proportion of screw revisions (4/12, 33%) compared with percutaneous stab incisions (7/166, 4%). The mini-open midline incision caused SpineMask deformation by the midline retractor, resulting in screws being placed superiorly in 3 (12%) of 26 pedicles. This was mitigated by closure of the midline wound after decompression, restoring the integrity of the SpineMask before stab incisions were made and percutaneous screws inserted. When TLIF or PLIF was indicated, interbody cages were inserted prior to SpineMask application for second-stage percutaneous screws. This reduced anatomical inaccuracy given the change in segmental disc height and lordosis after interbody fusion.

Postoperative day 2 CT in our study identified 7 pedicle screw breaches (3%). All breaches were minor (grade 1, < 2 mm) with no major pedicle violations (grade 2, 2–4 mm, and grade 3, screw outside of pedicle). These included intentional breeches based on challenging pedicular anatomy, such as narrow and deformed pedicles. We demonstrated a screw placement accuracy rate of 97%. This was consistent with other recent publications reporting accuracies of 92.7%–96.6% using image guidance and 95.3%–96.2% using image guidance with EMG neuromonitoring.

Five of our 7 screw breaches were lateral. Lateral screw breaches are the most common misplacement type. These included intentional breaches based on challenging pedicular anatomy, such as narrow and deformed pedicles. We demonstrated a screw placement accuracy rate of 97%. This was consistent with other recent publications reporting accuracies of 92.7%–96.6% using image guidance and 95.3%–96.2% using image guidance with EMG neuromonitoring.

Five of our 7 screw breaches were lateral. Lateral screw breaches are the most common misplacement type.
intraoperative tEMG consistent with the position of the exiting nerve root in the adjacent foramen. A surgeon's tactile feedback and experience still remains paramount in pedicle cannulation. Higher rates of laterally misplaced screws were also found in robot-assisted pedicle screw systems, which reflects the surgeon's concern of medial breach and greater risk of neural injury.

Our institution uses postoperative CT rather than radiography to check spinal instrumentation positioning. Targeted CT at the operative level only, and not full lumbar CT, is performed to reduce radiation exposure. All 5 lateral breaches evident on postoperative CT were not detected on tEMG given the distance of the exposed portion of the screw from the exiting nerve root. The authors will continue to use tEMG with the primary aim of avoiding medial breach. We had no neural, vascular, or visceral injuries, and no patient required a return to the operating room for screw revision.

At our institution the cost of the SpineMask was offset by eliminating disposable K-wires. The SpineMask is indicated for the placement of pedicle screws, but at our institution it has been used for anatomical localization, bone decompression, far lateral microdiscectomy, and spinal intradural tumor resection. Based on our early experience with the SpineMask tracker, we suggest the following guidelines for SpineMask use with tEMG in different posterior lumbar procedures. First, percutaneous screw placement with a stab incision provided the highest accuracy, and this is now our preferred method for pedicle screw insertion with SpineMask. Second, proceed with caution when using Wiltsie incisions, knowing registration can be transferred to bone-anchored tracker as an efficient salvage option. Third, mini-open midline incisions with percutaneous fixation showed that SpineMask is tolerant to this procedure, and we will continue to practice this method. For decompression only, the SpineMask is attached prior to an incision for laminectomy, with the midline wound closed prior to percutaneous stab incisions for pedicle screws to minimize distortion of SpineMask. If a midline incision is used for interbody fusion, we recommend SpineMask placement after cage insertion, given that the anatomical alteration after cage insertion would risk inaccuracy if the SpineMask were placed prior to cages. Close the midline wound after interbody fusion, and then attach the SpineMask and perform a 3D fluoroscopic spin for stab incisions for percutaneous pedicle screws. Fourth, for revisions and extension of constructs, use a bone-anchored spinous process tracker. And fifth, the described K-wireless technique can be used with a bone-anchored tracker and is not unique to SpineMask.

Adjuvant tEMG monitoring guides screw placement and intraoperative imaging. For high tEMG responses (≥13 mA) intraoperatively, use anteroposterior and lateral radiography only to check screw-rod construct. Low tEMG responses (≤12 mA) intraoperatively warrant an additional 3D fluoroscopic spin to check screw position.

Strengths of this study include a prospective evaluation by a single experienced surgeon with a consistent surgical technique from a single center. A senior surgical neurophysiologist monitored intraoperative tEMG. Postoperative CT rather than radiography assessed any pedicle screw breach, reported by an independent radiologist. No funding was received for our study, ensuring independence from industry. We do acknowledge limitations reporting our early experience with SpineMask in a small patient cohort. The majority of our patients received stab incisions for percutaneous screws as our technique evolved, with only small numbers in the Wiltsie and mini-open groups. These small patient sample sizes preclude meaningful statistical comparison between incision types. Additionally, intraoperative screw revisions were recorded, but no similar cohorts were available for comparison.

Conclusions

The noninvasive cutaneous SpineMask tracker with 3D image guidance and tEMG monitoring provides high accuracy for percutaneous pedicle screw placement via stab incisions without K-wires. The SpineMask demonstrated comparable accuracy to navigation systems using bone-anchored trackers. No patients suffered neural injury or required postoperative screw revision.

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technical pitfalls and their avoidance. Neurosurg Focus 36(3):E3, 2014


Disclosures
G.M.M. has received travel support from NuVasive and Stryker. R.M.P. has received travel support from NuVasive.

Author Contributions
Conception and design: Malham. Acquisition of data: Parker. Analysis and interpretation of data: Parker. Drafting the article: Malham. Critically revising the article: both authors. Reviewed the submitted version of manuscript: both authors. Approved the final version of the manuscript on behalf of both authors: Malham. Study supervision: Malham.

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