A new paradigm for staging pedicle screw–based spinal procedures: rationale, feasibility, safety, and efficacy

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Object. The aims of this study were to present the rationale for and the evolution of a staged, two-procedure paradigm for spinal surgery requiring pedicle screw instrumentation, and to evaluate the feasibility, safety, and efficacy of the technique.

Methods. The rationale for the new algorithm is presented for consideration in the form of unproven hypotheses subject to verification by subsequent studies. The first stage of the two-staged algorithm, performed in an interventional radiology (IR) setting, involves percutaneous placement of either headless pedicle screws or K-wire fragment placeholders of the trajectory for pedicle screws. The second stage, performed days or weeks later, involves open surgical completion of instrumentation placement and other surgical objectives. The techniques for IR percutaneous K-wire fragment and percutaneous screw placement evolved over the duration of the study.

Instrumentation was placed in 126 pedicles in 25 patients. Efficacy was equated to the accuracy of screw placement, which was evaluated using computed tomography (CT). Algorithms incorporating correction for metal artifact were developed to determine deviation of the screws and K-wire fragments from proper position. Over 1500 measurements were made to evaluate K-wire fragment and screw position in the 116 instrumented pedicles for which CT data were available.

Results. Accuracy of placement (relative to both cortical and pedicle breaches or to only pedicle breaches) was 98 to 100% for K-wire fragments, 96 to 98% for screws following K-wire fragments, and 100% for percutaneous screws. The only adverse consequence of pedicle screw placement by this method was one infection that occurred 8 months postoperatively.

Conclusions. The staged, two-procedure paradigm for pedicle screw placement proved, within the limits of this study, to be feasible, safe, and effective; therefore, the unproven rationale behind the new paradigm merits further evaluation in a larger cohort of patients with randomized, matched controls. (DOI: 10.3171/SPI-07/11/521)

KEY WORDS • accuracy • blindness • complication • pedicle screw • percutaneous surgery • staging

Complex pedicle screw–based spinal procedures are associated with long duration of anesthesia. Prolonged anesthesia time has been associated with increases in the incidence and severity of postoperative medical complications and postoperative infections, the increased incidence of intraoperative technical errors, blood loss, and postoperative mortality.1,3,5–9,11,12,14–16,20–25,27,29–32,35 Staging may offer a logical means of reducing the time patients spend in a state of anesthesia for any one procedure.

We have, therefore, developed a staged, two-procedure algorithm for pedicle-based spinal surgery. Our main goal in developing this algorithm was to significantly diminish the time patients spend in a state of anesthesia at any one stage. Other objectives were to have flexibility in the timing of the second stage, to preserve the high level of accuracy currently achieved in the placement of pedicle screws, to achieve broad application in pedicle screw–based surgery, to avoid the introduction of expensive new technology and the use of time-consuming and expensive computer-aided imaging, to limit radiation exposure, and to avoid introducing any new procedure-related complications.

After the implementation and apparent success of this approach at our institution, publications appeared in the anesthesia literature suggesting staging of spinal surgical procedures that are performed with the patient in the prone position and are likely to exceed 6 hours in duration.2,19,33 Staging was proposed in order to decrease the time patients spend in a state of anesthesia for any one stage of a procedure in an effort to reduce the incidence of blindness fol-
lowing prone spinal surgery. These reports served to further emphasize the potential importance of the staging algorithm that we have developed.

Our approach is quite simple. The first stage is the percutaneous placement of K-wire fragments as placeholders of pedicle screw position or the percutaneous placement of only the screw portion of a Click’X (Synthes) pedicle screw. This first stage is performed in an IR setting. The remainder of the procedure is completed on an elective basis, days or weeks later, in open surgery. The approach is universally applicable for any pedicle screw–based procedure, regardless of the level of complexity; however, one would expect maximum benefit in cases in which a large number of screws must be placed, there is a high degree of difficulty in pedicle screw placement, and the procedure is generally more complex. Under these circumstances, the spine surgeon could approach the open surgical procedures with all screws already placed and known to be in excellent position. In this initial study, the concept has been developed and evaluated in less complex situations. It remains to be tested under more complex circumstances, such as severe, combined coronal and axial plane spinal deformities at multiple levels.

The primary purpose of this preliminary report is to relate the rationale for and to describe the feasibility, safety, and efficacy of this staged, two-procedure algorithm. A secondary purpose is to document the evolution of the techniques for K-wire fragment and headless screw placement. Feasibility, safety, and efficacy must be demonstrated and techniques must be developed to their final form before use of the procedure can be expanded to a larger patient cohort in a study with matched controls. One could then measure all the necessary variables, under stable procedural parameters, and attempt to document all the other potential advantages of the approach. These potential advantages, which constitute the rationale for proposing the new algorithm, remain, at this point, unproven hypotheses. Of these advantages, the most beneficial would be a significant reduction in anesthesia time during the open stage, with the expected attendant reduction in surgical morbidity and mortality rates. Other advantages might include: decreased radiation exposure for staff members and the patient, because no radiography is required for screw placement in the OR and because radiation exposure may be better controlled in the IR setting; greater accuracy in pedicle screw placement in situations where screw placement is difficult; diminished cost; and improved economy in utilization of OR time for the spine surgeon. Again, at this point, these potential advantages remain hypothetical, but they have provided compelling reasons for us to begin to evaluate the proposed new algorithm.

Clinical Material and Methods

Because the new paradigm represented a significant departure from our standard clinical practice, in addition to obtaining approval from our institutional review board we also obtained approval to proceed with the new approach from both the governing body of our institution and the OR oversight committee. All patients were told that the new approach was a significant departure from standard clinical practice, and all gave informed consent for our use of the new paradigm.

In order to evaluate the safety and accuracy of the new approach to the staging of procedures involving pedicle screw instrumentation, we conducted a retrospective review of the medical records and imaging studies of all patients who had undergone transpedicular place holder K-wire fragment or screw placement in an IR setting between September 2, 2004, and June 16, 2006. This comprises all of the patients from our institution treated according to the staged two-procedure approach through June 15, 2006. The end date of the study was selected before case review and coincided with the beginning date of the research fellowship of the lead author (M.J.R.). Because this group was the initial set of patients treated under the new protocol at our institution, the techniques used evolved over the course of the study period. In the period between the end of data collection and the writing of this paper, no events occurred that would change the conclusions or results. Further evolution of the technique has occurred, however, and it is described in the Discussion. The retrospective review included patient demographics, presentations, pathological conditions treated, feasibility (as indicated by the ease of implementing the protocol in our institution), safety (as indicated by complications of screw or K-wire placement), and efficacy (as indicated by measures of the accuracy of screw and K-wire placement). We did not believe that it would be meaningful to attempt to measure variables related to technique (such as various times, radiation exposure, or interprocedure pain control) because the technique was evolving during the study period. Nor did we believe it would be meaningful to evaluate outcome variables by comparison against matched controls before the algorithm had been finalized or proved to be feasible, safe, and effective.

Due to the evolution of the IR procedure, patients in our study population were treated with one of two procedural sequences (identified in this article as Sequences 1 and 2). Each sequence consisted of two procedures: an outpatient interventional radiological procedure, and an inpatient open surgical procedure. The first 19 patients were treated under Sequence 1, in which transpedicular K-wire fragments were placed percutaneously in an IR setting as placeholders for pedicle screws, and pedicle screws and rods were placed days to weeks later in an open procedure in the OR. The technique of K-wire fragment placement, as described here, evolved during the treatment of these 19 patients. The last six patients were treated under Sequence 2, in which percutaneous pedicle screws without the rod-holding 3D head were placed in an IR setting, and the rod-holding head and rods were placed days to weeks later in an open procedure in the OR. The technique of placement of headless percutaneous screws in an IR setting, as described here, evolved during the treatment of these latter six patients. The number of days between IR and OR procedures was noted. A single interventional radiologist (L.J.F.) performed all IR procedures, and one of two neurosurgeons (H.G.S. or K.T.W.) performed each of the open surgeries. To guard against infection when implanting spinal hardware outside of the OR environment, a protocol for aseptic technique in the IR suite was developed in concert with hospital infection control and the OR oversight committee. This protocol mandated that: 1) the room be cleaned according to OR standards before a procedure; 2) these procedures be the first procedures on any given day; 3) traffic be limited in the IR suite; 4) air flow in the IR suite be con-
trolled; 5) implants or K-wires be individually packaged and unopened until immediately before implantation; and 6) intravenous antibiotics be administered before the procedure.

**Sequence 1: Surgical Technique**

Patients were positioned prone on the radiolucent table of the IR suite. Using an isocentric C-arm fluoroscope (Multistar T.O.P., Siemens) and vertebroplasty/kyphoplasty imaging technique with off-angle oblique images through the pedicles, the pedicles of interest were located and their corresponding skin entry points were marked. A sterile surgical field was then prepared using standard antisepctic technique. Before incision, general anesthetic was supplemented with injections of 1% buffered xylocaine in the skin and subcutaneous tissues down to the periosteal surfaces. In patients in whom general anesthesia was not induced, these injections of xylocaine were the only source of anesthesia. A small skin incision (less than 5 mm long) was made, and an 11-guage Jamsheedi-type bone biopsy needle (Osteocyte Bone Biopsy needle, No. G12373, Cook Inc.) was advanced under fluoroscopic guidance through the pedicle until the tip was positioned near the junction of the posterior or third and anterior two thirds of the VB. Next, a 1.6-mm-diameter K-wire was cut to a length that would allow it to extend from the tip of the bone biopsy needle to a few millimeters posterior to the site of entry into the bone. The posterior protrusion of the K-wire was intended to facilitate its finding and removal during the subsequent open surgical procedure. After the trocar was removed from the bone biopsy needle, the precut K-wire fragment was passed through the empty bone biopsy needle and tapped into the VB with a blunt-ended pusher (part of the Osteocyte Bone Biopsy needle set). The bone biopsy needle was then removed, leaving the precut K-wire fragment in place. To avoid confusion, these precut K-wires are referred to as “placeholder K-wire fragments.” The small skin incisions at each site were closed with Steri-Strips (3M Co.), and a postprocedure CT scan was obtained using one of two scanners (Somatom Sensation 4 or Somatom Sensation 16, Siemens) to assess the position of each placeholder K-wire fragment and determine an appropriate size for the pedicle screw to follow. This CT scan replaced the preoperative surgical planning CT scan routinely used by the primary surgeon (H.G.S.) to measure for screw diameter and length at each level at which instrumentation is to be placed. The CT scan in Fig. 1 left shows a typical placeholder K-wire fragment implantation.

The open surgical procedure for screw placement and posterior fixation followed within days to weeks of placeholder K-wire fragment placement. General anesthesia was induced in all cases. The small skin incisions for placeholder K-wire fragment placement served as guides for the open surgery incisions, thereby obviating the need for radiographs for this purpose. For thoracic and thoracolumbar cases, a midline incision was employed, and the placeholder K-wire fragments were identified visually. In the lumbar area, a bilateral paramedical approach was also used, with incisions made slightly medial to and in line with the entry points used earlier for the placeholder K-wire fragment placement. When the lumbar paramedical approach was used, minimally invasive finger dissection separated the paraspinous muscles down to the level of the placeholder K-wire fragments, which were easily identified by palpation. Identification of these K-wire fragments at open surgery with any approach required no more than a few minutes. One simply had to dissect to the insertion point indicated on CT, and the protruding portion of the K-wire was immediately obvious. Once located, each placeholder K-wire fragment was removed and its hole was tapped to within one size of the screw to be used. This was accomplished using a series of taps, beginning with a tap featuring a K-wire–mimicking elongation of its tip to allow for accurate tracking of the placeholder K-wire fragment hole (Fig. 2) (Axis Tap, Synthes). Pedicle screws of the required diameter and length, as determined on the basis of the CT scan obtained after K-wire fragment placement, were then allowed to follow the tapped holes, and rods were placed accordingly. Generally, no radiographs were required during placement of the pedicle screws or for localization of the incision at open surgery. Standard wound closure and dressing completed the procedure. As a matter of convention, the screws placed by this procedure will be referred to as “open screws.” A CT scan performed after the open surgery confirmed the position of the open screws. The primary surgeon routinely obtains a postsurgical CT scan in all pedicle screw cases. Thus, each patient in this sequence underwent two CT scans, the same number as if pedicle screws had been placed in the usual fashion.
Sequence 2: Surgical Technique

As with Sequence 1, the first stage of Sequence 2 took place in the IR setting, and the second stage of this sequence was an open surgical procedure that took place days to weeks later. The facilities, patient preparation procedures, and surgical technique used for the first stage of Sequence 2 were identical to those of the first stage of Sequence 1 through the removal of the trocar from the transpedicularly placed bone biopsy needle. At this point, a 480-mm-long, 1.6-mm-diameter K-wire (02.606.001, Synthes) was passed through the bone biopsy needle and secured in the VB at the depth of the tip of the bone biopsy needle or slightly beyond. To differentiate from the wire used in Sequence 1, we will refer to a K-wire used to pass a cannulated screw as a “long K-wire.” The depth of the long K-wire reflected the desired depth of the cannulated screw to follow. The needle was then removed, leaving the long K-wire protruding from the skin. Next, blunt soft-tissue dilators (03.610.001, 03.610.002, Synthes) of increasing diameter were passed over the long K-wire down to the bone cortex at the site of needle entry until a working cannula of sufficient size to accommodate the screw was in position. This technique, of course, required a larger skin incision than was required for placeholder K-wire fragment placement. The incisions were somewhat larger than they needed to be, because the final dilator supplied by Synthes was not a tight fit on the nonthreaded terminus of the Click’X screw without the 3D head. A cannulated Click’X pedicle screw (Fig. 3: 04.606.033–04.606.36, 04.606.44–04.606.46, Synthes) of predetermined size (without the 3D head) was then threaded over the long K-wire and advanced by hand with the aid of a cannulated screwdriver (03.606.011, Synthes). The Click’X screw system was chosen because of its multistage assembly, which allowed the screw to be implanted without the 3D head (498.571, Synthes) attached. This gave the implanted screw a low profile of projection beyond the posterior cortex, decreasing concerns of painful irritation during the intraoperative period. At the time of this study, the cannulated Click’X screw system was not generally available and was supplied to us specifically for the study. These screws meet all of the mechanical requirements of the standard Click’X system, and have been approved by the US Food and Drug Administration. As a matter of convention, these screws will be referred to as “percutaneous screws.” Progress of the screw was monitored with intermittent lateral fluoroscopy. Once the screw was in position, the long K-wire and working cannula were removed. Sutures and Steri-Strips were used to close each incision, and a postprocedure CT scan was obtained to assess the accuracy of screw placement. Figure 1 right shows the typical appearance of a cannulated Click’X screw without the 3D head after percutaneous placement. Like the CT obtained after K-wire fragment placement, this CT study replaced the CT scan routinely used by the pri-
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mary surgeon (H.G.S) for preoperative planning, and represented no additional radiation exposure for the patient. As in Sequence 1, the open surgical procedure for rod placement and completion of posterior fixation followed within days to weeks of the IR procedure. Facilities and patient preparation for this procedure mimicked those described for Sequence 1, and exposure via minimally invasive bilateral paramedian incisions was once again used when possible in lumbar procedures. Once exposure of the posterior vertebral elements was accomplished, the previously placed pedicle screws were promptly and easily identified visually or by palpation. Identification of these screws required no more than a few minutes of surgical time. The 3D heads, rods, and locking caps were placed, other surgical objectives were achieved, and wound closure was carried out according to standard procedure. Generally, no radiographs were required for the placement of posterior instrumentation or for localization of the skin incision. A postoperative CT scan, as is routinely obtained by the primary surgeon after placement of thoracolumbar instrumentation, was taken to assess hardware position and correction of deformity, as well as to determine whether other surgical objectives had been achieved. For both percutaneous and open screws, the frequent need for anterior correction of sagittal deformity, posterior decompression, or multilevel fixation prevented the authors from expanding the scope of the IR procedure to include rod placement.

Evaluation of Placeholder K-Wire Fragment and Screw Placement

Screws and placeholder K-wire fragment positions were evaluated using the post–K-wire fragment placement, the post–percutaneous screw placement, and the postoperative CT scans with axial and sagittal reconstructions made coplanar with the screw and placeholder K-wire fragment major axes. As noted previously here, two CT scans were performed in each patient, the same number as would have been done had they not been involved in this study. Postprocessing of CT data was performed with Voxel Plug ‘n’ View 3D, version 3.0 (Voxar Limited). A research fellow (M.J.R.) trained in reading spinal CT scans performed all measurements on postprocessed CT scans, in accordance with techniques that he developed. The postprocessing and measurement techniques were reviewed and approved by an independent radiologist experienced in reading spinal CT scans (M.A.N.). The surgeons did not participate in the measurement process. Several other conventions were used to ensure consistency, including making adjustments to the window to minimize metal artifacts and using the known dimensions of the implant instead of its visible boundaries as measurement endpoints. For example, the actual lateral and medial boundaries of a screw of known diameter were determined by perpendicular measurement from the center of the shaft of the screw on a postprocessed axial image coplanar with the screw. Even with window adjustment, the apparent boundary, due to metal artifact, might extend beyond the true boundary determined by measurement. Screw length was determined in a similar manner. The boundary between the pedicle and VB was defined as the arc of an ellipse made to fit the border of the VB in the axial plane using filmless radiology software’s elliptical tool (Synapse, FUJIFILM Medical Systems). Figure 4 illustrates the measurements used to identify the position of the implanted screw or placeholder K-wire fragment within the vertebrae. The perpendicular distance from the surface of the implant to the pedicle cortex in four directions—medial, lateral, superior, and inferior—determined the relative position of the implant within the pedicle. These measurements were taken at the point of their smallest value, which often, but not always, occurred at the isthmus of the pedicle. The ratio of screw penetration into the VB to the trans-VB distance was used to determine the position of the screw within the VB. These measurements were taken along the major axis of the screw in the axial plane. All of these linear measurements incorporated the correction for metal artifact described previously. Finally, the angle between the implant and the anteroposterior vertebral midline in the axial plane (axial implant angle) and the angle between the implant and the superior vertebral endplate in the sagittal plane (sagittal implant angle) were used to determine the implant’s overall trajectory. The trajectory of each open screw was compared with that of the placeholder K-wire fragment that preceded it to assess how well the screw could track the intended trajectory of the placeholder K-wire fragment hole. The threshold condition for a positive tracking event was established as the agreement of trajectories within ± 4˚ in both the axial and sagittal planes—roughly twice the measurement error. This tolerance was chosen to reflect the authors’ opinion of a visually significant deviation of paths, a judgment that was made before the results of the study were analyzed. All measurements were taken with a precision of 0.01 mm and 1˚, as dictated by the software measurement tools. In all, more than 1500 individual measurements were made to evaluate accuracy of screw and placeholder K-wire fragment placement.

Cases of cortical perforation were assigned letter grades to reflect the severity of protrusion beyond the cortex: A = protrusion of less than 2.00 mm; B = protrusion between 2.00 and 3.99 mm; and C = protrusion of 4.00 mm and greater. Examples of Grades A, B, and C protrusions are shown in Fig. 5. When the border of a pedicle was obscured by a perforation, the location of this border, for measurement purposes, was determined by comparison with postprocessed preinstrumentation images, with the opposite pedicle on a postprocessed image, and by extrapolation of the visible ends of the obscured border on a postprocessed image. All perforations were measured at the point of greatest compromise, with borderline cases routinely downgraded (from A to B, for example). Perforations were further classified by their location (left pedicle, right pedicle, vertebral endplate, or anterior vertebral cortex) and direction of penetration (medial, lateral, superior, or inferior). Screws or placeholder K-wire fragments with no perforation or Grade A perforation were considered to be accurately placed, whereas those with Grade B or C were considered misplaced. For example, engagement of the cortex of the pedicle at its isthmus by the threads of a screw would be a Grade A breach of the pedicle. Even when screws have a very accurate trajectory, the number of Grade A breaches of the pedicle will increase if one attempts to closely match the size of a screw to the narrowest dimension of a pedicle.

A random sample representing 10% of the implants was subjected to remeasurement in order to assess the level of measurement variability. The two sets of data were compared to determine the mean difference between measure-
ments in both degrees and millimeters, and to calculate the coefficient of variation for length measurements. The Fisher exact test was used to analyze all categorical data.

Safety of the procedures was evaluated based on the complications related to placeholder K-wire fragment or pedicle screw placement. The protocol for postoperative management was to follow the clinical course of each patient until the instrumented levels were judged to be stable and all postoperative issues were resolved.

Results

The patient population was diverse, including 11 male and 14 female patients (median age 60 years, range 16–75 years). The mean length of postoperative follow-up was 6.6 months (range 0.1–17.8 months). Five patients presented with spinal claudication, five with radiculopathy, five with traumatic spinal fractures, and the remainder with low back, buttock, or leg pain. The primary diagnoses in our patients were as follows: 1) lumbar degenerative or post-laminectomy single-level listhesis L-3–4 to L5–S1 in 14 patients (Grade II in five, Grade I in nine); 2) marked hyperlordosis of the sacrum with a Grade I listhesis at L-4 to L-5 and L-5 to S-1 in one patient; 3) adjacent-level disease with Grade II listhesis at L-1 to L-2 in one patient and severe spinal stenosis at L-4 to L-5 in another; 4) spinal stenosis at T-10 to T-11 in one patient; 5) spinal stenosis at L-3 to L-4 and a degenerative Grade I listhesis at L-4 to L-5 in one patient; and 6) traumatic fractures at L-2 in three patients, at T-8 in one patient, at T-12 in one patient, and at L-3 in one patient. There were no cases of significant coronal or axial plane deformity. As noted above, all significant deformities were in the sagittal plane.

The number of days between stages ranged from 1 to 41 (median 5 days). For the IR stage of both surgical sequences, general anesthesia was induced in 17 patients, and local anesthesia was induced in eight. One surgeon (H.G.S.) performed 24 of the 25 open surgeries. No patients were lost to follow-up during the postoperative period. Even though OR time was not tracked as a variable in this study because of evolution of both the technique and the algorithm itself, it was obvious to all involved staff members that there was a marked shortening of the OR time of open surgeries performed according to the reported protocol compared with those performed using the standard approach.

In total, 126 thoracic and lumbar pedicles were instrumented in this study. One hundred two placeholder K-wire fragments, 92 open screws, and 24 percutaneous screws were placed. The median number of placeholder K-wire fragments placed per patient was six (range three–12), the median number of open screws per patient was four (range three–11), and the median number of percutaneous screws per patient was four (range two–six). The distribution of instrumentation by vertebral level for the population is presented in Table 1. Four of the placeholder K-wire fragments were not evaluated because of the lack of a postprocedure CT scan; thus, for the purpose of statistical analysis, only 98 placeholder K-wire fragments were considered. The discrepancy between the number of placeholder K-wire fragments and open screws (10 screws were not placed after a placeholder K-wire fragment implantation) is due to the following situations: 1) a wire that perforated anteriorly (shown in Fig. 5C) was removed and was not replaced by a screw; 2) the radiologist was dissatisfied with the K-wire placement in the left L-5 pedicle in a patient with a degenerative Grade I spondylolisthesis, and placed a second K-wire with an improved trajectory; 3) two patients with L3–4 spondylolisthesis, one of which was Grade II degenerative and the other Grade I congenital, were instrumented with K-wires at L-2, L-3, and L-4 (because of excellent reduction by an anterior approach, only L3–L4 instrumentation was placed)—the additional K-wires in each patient were removed at the open surgery; and 4) four K-wires were placed at L-4 to L-5 in a patient with Grade I degenerative spondylolisthesis, and the patient subsequently decided against surgery (the K-wires were removed percutaneously). The placeholder K-wire fragment with Grade C anterior perforation shown in Fig. 5C was removed via a transpedicular approach and not replaced with a screw. Other than the case of an anterior perforation shown in Fig. 5C, there were no cases in which a K-wire was placed but a screw could not be placed at surgery or in which a K-wire was left but a screw was not placed.

Within the standard 30-day postoperative window, there were no cases of infection related to placeholder K-wire fragment or screw placement, although one patient developed an infection of the VB at an instrumented level after
an incident of septicemia—following an episode of pneumonia—8 months postoperatively. We recognize that this could be delayed infection due to contamination of the implanted placeholder K-wire fragment or screw. Removal of the implanted hardware was required. No other adverse consequences related to pedicle screw or placeholder K-wire fragment placement occurred.

The randomized repeated measurements conducted to determine variability resulted in a coefficient of variation of 7.1% for distance measurements, corresponding to a mean difference of 0.14 mm. This difference was considered to be negligible relative to the 2-mm intervals of the perforation grading scale. The mean difference in angle measurements was less than 2°.

The location and extent of pedicle/VB perforations are also provided in Table 1. Ninety-six of the 98 placeholder K-wire fragments (98%) were accurately placed (no perforation or Grade A perforation). All of the placeholder K-wire fragment breaches were anterior and clearly related to the learning curve. Eighty-eight (96%) of the 92 open screws were accurately placed. The only two significant (Grade B or C) breaches of the pedicle were by open screws, both of which were Grade B breaches of the medial pedicle. All 24 percutaneous screws were accurately placed. Thus, relative to the pedicles, the accuracy rates were 100% for placeholder K-wire fragment placement, 98% for open surgical screw placement, and 100% for percutaneous screw placement. No cases of clinical sequelae were linked to misplaced placeholder K-wire fragments, open screws, or percutaneous screws.

Figure 5B shows the worst case of penetration of the medial pedicle wall, and Fig. 5C shows the worst case of penetration of the anterior cortex. The worst-case medial pedicle wall penetration (Fig. 5B) did not result in neurological deficit or symptoms, and the screw was not removed. The worst-case placeholder K-wire fragment penetration of the anterior cortex into the mediastinum (Fig. 5C) occurred in our first case, and was due to a technical error in which excessive pressure was applied to the placeholder K-wire fragment while removing the bone biopsy needle from the pedicle. There was no penetration of the esophagus, trachea, or great vessels. After CT angiography and endoscopic visual inspection of the esophagus and trachea, the placeholder K-wire fragment was removed by a transpedicular approach. The patient suffered no adverse effects. This complication should be noted by others who might wish to test this technique. When holding the placeholder K-wire fragment in place and removing the bone biopsy needle, it is best to avoid excessive pressure on the K-wire and to use fluoroscopy to be certain that the placeholder K-wire fragment is not advanced through the VB as the needle is removed.

A comparison of the critical (Grade B or C) perforation rates for open screw placement and percutaneous screw placement revealed no significant difference (p = 0.579). A comparison of the total perforation rates for open screw placement and percutaneous screw placement also revealed no significant difference (p = 0.240). A larger sample size might have favored percutaneous screw placement in both situations.

Thirty-two (38%) of 85 open screws tracked the trajectory of their preceding placeholder K-wire fragment holes according to the previously established tolerance (± 4° in both axial and sagittal planes). Applying a more lenient tolerance of ± 6° to the data still resulted in only 54 (64%) open screws tracking the trajectory of their preceding placeholder K-wire fragment, and applying a tolerance of ± 8° resulted in a finding of 66 (78%) open screws tracking the trajectory of their preceding placeholder K-wire fragment. Interestingly, the amount of trajectory discrepancy between a placeholder K-wire fragment and its corresponding screw did not correlate with the likelihood of cortical perforation.

On average, open screws penetrated 66% into the VB (posterior to anterior), and percutaneous screws penetrated 65%. Based on their experience with conventionally placed screws, both surgeons observed that, in comparison, the percutaneous screws and the open screws both tended to follow a more oblique trajectory. This oblique trajectory made these screws or placeholder K-wire fragments more difficult to expose surgically through a midline incision than screws surgically implanted by standard techniques. This was especially true at the L-4, L-5, and S-1 levels, and not significant at higher levels.

**Discussion**

As previously noted, the purpose of this initial report is to present the rationale and evolution of technique for—and to document the feasibility, safety, and efficacy of—a new staged, two-procedure approach to pedicle screw–based spinal surgery. This is an alternative method for minimizing OR time and placing instrumentation in a minimally invasive manner.

As noted, the rationale consists of a set of untested, unproven hypotheses regarding the potential benefits of staging complex, pedicle screw–based spinal surgery with one shorter IR procedure for placement of headless screws or K-wire fragments, and a delayed, second, longer open procedure for completion of the surgical objectives and instrumentation. The use of percutaneously placed K-wire fragments or headless cannulated screws provides a logical break point for staging. The underlying assumption is that, if the second, longer, open procedure is delayed long enough, the complication rate for both procedures together will reflect only the duration of anesthesia of the second open procedure. It is assumed that this should hold true, even if the total duration of anesthesia for both procedures done in two stages is the same or even slightly greater than if they were done in one stage. Under these assumptions, clearly, the more screws required and the more difficult the screw placement, the greater the potential benefit from the proposed paradigm. How long and complex must a procedure be before a patient will benefit from this approach? Put another way, when is the inconvenience of two procedures for the patient outweighed by the benefits of staging? How long should one allow between stages to gain these proposed advantages? The answers to all of these questions are, of course, unknown. We suspect that the expected time of a planned procedure must certainly exceed 3 hours, and that it probably must exceed 6 hours before significant benefit from staging, as we have proposed, will be achieved. We also suspect that the minimum time between stages is 1 week, and that 2 weeks or more is probably better. Another question is whether the paradigm is justified simply because it represents a better way to place pedicle screws.
Under these circumstances, for short cases, the time interval between procedures would not be important. In such cases, inconvenience would be outweighed by improved accuracy. All of these issues must be addressed in a more comprehensive study, but first a foundation for such a study must be established. Such a foundation will have been established when procedural techniques have evolved to a stable point and when feasibility, safety, and effectiveness (accuracy of screw placement) have been established.

The goal of this study was to explore whether such a foundation could be established. We believe that the results reported here, achieved in relatively straightforward cases involving patients with primarily sagittal deformity, establish just such a foundation for moving ahead with a larger study, with matched historical controls as a validation-of-concept study. If the concept is shown to be valid in such a study, then a comprehensive, multicenter, randomized, controlled trial of the reported paradigm should be performed as proof of concept. Both of these studies should involve a set of more complex cases in which the expected duration of surgery is longer than 6 hours and there are multilevel coronal and axial deformities. We have begun planning such studies on the basis of the results of the current study.

Feasibility is attested to by the fact that no obstacles were encountered in implementing the proposed paradigm in our institution.

Safety is attested to by the fact that there were no neurological or vascular complications as a consequence of placeholder K-wire fragment or screw placement, and that there were no postoperative infections (that is, infections occurring in the first 30 days after surgery) attributable to placeholder K-wire fragment or screw placement. As noted, one debilitated patient experienced osteomyelitis of an instrumented VB 8 months after surgery and 2 months after an episode of pneumonia. At that time, this patient also had a partially treated septicemia due to the same organism as the one that subsequently caused the osteomyelitis of the instrumented VB. Radiographs obtained 2 months before the episode of septicemia had not revealed any abnormality of the VB that later became infected. It is, nevertheless, possible that the osteomyelitis was a delayed infection from an organism that was implanted at the time of the IR procedure or at surgery, and not related to bacterial seeding of the instrumented vertebrae when the patient had pneumonia and septicemia. If this case were included as a postoperative infection, the incidence rate for infection in our case series would be 4%. The questions are whether the risk of infection is greater with two procedures than with one, and whether placing hardware or placeholder K-wire fragments in the IR suite poses a greater risk of infection than does open surgery. Numerous published studies support the notion that there is a direct relationship between the incidence of postoperative infection and the duration of general anesthesia.

Therefore, unless the percutaneous stage in IR carries a high risk of infection, a decrease in the time of the open surgery stage should decrease the risk of infection. Controlled studies in a larger patient cohort with matched controls will be needed to determine whether the infection rate in staged procedures of the type reported here is different from the infection rate in those that are not staged. Anyone implementing this paradigm should institute appropriate infection control measures in the IR setting, and should carefully monitor the infection rate. Controlled studies in a larger patient cohort with matched controls will be needed to determine whether the infection rate in staged procedures of the type reported here is different from the infection rate in those that are not staged. Anyone implementing this paradigm should institute appropriate infection control measures in the IR setting, and should carefully monitor the infection rate. We believe that our initial data related to infection justify proceeding with the staged, two-procedure paradigm, with careful prospective auditing of the infection rate.

One might argue that, even though there were no major

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**TABLE 1**

**Total pedicle screw placements and breaches by placement technique and grade**

<table>
<thead>
<tr>
<th>Vertebral Level</th>
<th>K-Wire Fragments</th>
<th>Open Screws</th>
<th>Percutaneous Screws</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total Breaches/ Grade B or C Breaches Placed</td>
<td>No.</td>
<td>Total Breaches/ Grade B or C Breaches Placed</td>
</tr>
<tr>
<td>T-4</td>
<td>2/1 (AC, Grade C)†</td>
<td>1</td>
<td>0/0</td>
</tr>
<tr>
<td>T-5</td>
<td>1/1 (AC, Grade C)</td>
<td>2</td>
<td>0/0</td>
</tr>
<tr>
<td>T-6</td>
<td>0/0</td>
<td>2</td>
<td>0/0</td>
</tr>
<tr>
<td>T-7</td>
<td>0/0</td>
<td>0</td>
<td>0/0</td>
</tr>
<tr>
<td>T-8</td>
<td>0/0</td>
<td>0</td>
<td>0/0</td>
</tr>
<tr>
<td>T-9</td>
<td>4/0</td>
<td>4</td>
<td>0/0</td>
</tr>
<tr>
<td>T-10</td>
<td>8 (10)§</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>T-11</td>
<td>6</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>L-1</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>L-2</td>
<td>12</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>L-3</td>
<td>18 (20)§</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>L-4</td>
<td>24</td>
<td>22</td>
<td>0</td>
</tr>
<tr>
<td>L-5</td>
<td>16</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>total</td>
<td>98 (102)§</td>
<td>92</td>
<td>20</td>
</tr>
</tbody>
</table>

* Grade A, < 2 mm; Grade B, 2 to 4 mm; Grade C, greater than 4 mm. Abbreviations: AC = anterior cortex breach; MP = medial pedicle breach.
† See Fig. 5C.
‡ See Fig. 5B.
§ Parenthetical values include cases in which K-wire fragments were placed but no CT scan was obtained.
|| See Fig. 5A.
neurological or vascular complications, safety is hardly
proven when there was an anterior perforation of the mag-
nitude demonstrated in Fig. 5C. Even though this perfora-
tion occurred in our first patient, and we are convinced that,
by altering the technique, we have made this complication
entirely preventable, this point is well taken. Now that the
technique and algorithm are stable, the absence of such
anterior perforations will need to be demonstrated in a larg-
er series, such as the ones planned to follow this report.
The efficacy of the paradigm was measured by its ability
to achieve a high rate of accurate pedicle screw place-
ment. As revealed in Results, high rates of accuracy (98% for
placeholder K-wire fragment placement, 96% for open
screws, and 100% for percutaneous screws) were achieved
with both surgical sequences. Considering only pedicle
violation, our accuracy was 100% for placeholder K-wire
fragments, 98% for open screws, and 100% for percuta-
neous screws. Conventional techniques used to achieve
accurate pedicle screw placement in the thoracolumbar
spine, including the use of posterior anatomical landmarks,
pedicle probes, pedicle exposure via partial laminotomy,
visual estimation, and intraoperative fluoroscopy, have
been associated with misplacement rates (determined by
various means and in both cadaver and clinical studies)
ranging from 6 to 72.4%.\(^{4,10,13,17,34}\) Rampersaud and col-
leagues\(^{28}\) noted corresponding rates of clinical sequelaes
ranging from 0 to 7%. From a clinical perspective (H.G.S.),
the rate of significant pedicle perforation in spine surgery
today, with standard techniques, is likely to be much lower
than the rates cited here, and the incidence of significant
sequelaes from screw perforation of the pedicles is proba-
ably very low. Nevertheless, even though complications as
a result of pedicle screw misplacement may be uncommon,
they are potentially devastating. To our knowledge, the
only prospective, randomized study undertaken to compare
the accuracy of conventional pedicle screw placement
methods with accuracy of image-guided, computer-assisted
surgical methods was reported by Laine et al.\(^{18}\) These
authors considered only breaches of the pedicle. When con-
sidering perforations of 2.0 mm and greater—those
deemed significant by those authors and by us—they found
a rate of 4.0% for conventional methods and 0.9% for
image-guided methods. Powers and associates\(^{26}\) have
recently reported a pedicle breach rate of 0.35% in 287 per-
cutaneously placed screws. These authors employed an
intraoperative fluoroscopic approach similar to that used
here in IR, but they did not obtain postoperative CT scans
on all patients, nor did they employ a rigorous algorithm for
evaluation of breaches. Nevertheless, their data are impres-
sive. In comparison, we found pedicle breach rates of 0.0% for
placeholder K-wire fragments, 2.0% for open screws,
and 0.0% for percutaneous screws. It should be noted that,
even though our data represent the initial part of the learn-
ing curve for the staged, two-procedure paradigm, our rates
compare quite favorably with these published rates of sig-
nificant screw misplacement. We make this comparison
with caution because of the smaller sample size in our
study. The efficacy achieved in our preliminary study sup-
ports continued use of the staged, two-procedure paradigm,
and suggests that a larger series could show improved ac-
curacy over standard techniques—probably equivalent to the
accuracy achieved with image-guided, computer-assisted
surgical techniques. If this is the case, the approach sug-
gested here could obviate the need for expensive and time-
consuming, image-guided, computer-assisted surgical
approaches. If a newer, inexpensive, readily available, high-
ly accurate technology (for example, some inexpensive
version of real-time 3D computer imaging of pedicle screw
insertion) becomes available for placing pedicle screws,
then it would replace the technique reported here for plac-
ing the percutaneous K-wire fragments or percutaneous
headless pedicle screws. The pedicle instrumentation tech-
nique we have reported would then simply be outdated.
Even then, however, the proposed, potentially powerful,
two-staged algorithm would remain intact for the long
complex cases in which outcomes are possibly improved
by staging. In such cases, the first stage of the new algo-
rium would simply be performed using the improved
equipment.

Although we found that open screws (that is, those
inserted along the holes left by the image-guided placeholder
K-wire fragments, were placed with a high degree of
accuracy (98%),) it was also determined that they did not
necessarily track the placeholder K-wire fragment holes as
closely as expected. To our knowledge, this is the first
attempt to study the ability of a screw (pedicle screw or oth-
erwise) to track a pretapped hole of intended trajectory. We
were surprised at the level of discrepancy between the tra-
jectories of the pedicle screws and their guide holes, with
agreement of only 38% given a tolerance of \(\pm 4°\) in both
the axial and the sagittal planes, and of only 64% given a
tolerance of \(\pm 6°\).

It is unclear why this deviation occurred. It may be that
the tap was forced to deviate from the guide hole by the
geometry of the cortical bone of the pedicle. The inability
of a pedicle screw to follow a hole of preplanned trajecto-
ry has implications for procedures beyond our own. Both
conventional and image-guided techniques often rely on a
screw’s ability to closely follow a guide hole of preplanned
trajectory.

As a result of these findings, we no longer use blind tap-
ning of the placeholder K-wire fragment hole as an
approach to pedicle screw placement. We may still use an
approach similar to Sequence 1 in the case of small pedi-
cles for which a cannulated headless screw may not be
available, or when we do not wish to use a cannulated
screw, but we will not use blind tapping of the placeholder
K-wire fragment hole. Instead, during the open stage, we
will remove the placeholder K-wire fragment and replace it
with a long K-wire. Then we will pass progressively larger
cannulated taps, up to near the desired screw diameter, over
the longer K-wire, after which we will pass a noncannulat-
ed screw down the pretapped hole. Another variation
would be to perform the tapping in the IR suite and place
an inexpensive plastic radiopaque, headless, threaded plug
as a placeholder for the later open surgery. As an aside,
using a placeholder K-wire fragment or radiopaque plug
allows very accurate determination of the length and the
diameter of the screw to follow at open surgery. This is the
case because, before the surgery, one can obtain CT images
that are coplanar with the placeholder K-wire fragment or
plug in both the axial plane and a vertical plane at an appro-
piate angle to the midsagittal plane. On this image, the
required screw length and diameter can be measured using
the exact path in which the screw will traverse the pedicle
and VB.
An incidental observation made during the study, likely to be peculiar to our institution, was that placeholder K-wire fragments and screws placed in the IR setting, according to the vertebroplasty/kyphoplasty technique employed in our medical center, tended to follow a more oblique trajectory in the axial plane than screws conventionally placed in open surgery with a midline incision. This oblique trajectory in the axial plane occurred because, when employing kyphoplasty/vertebroplasty technique in our center, the radiologist is accustomed to entering the lumbar pedicle at the junction between the lateral facet and the transverse process. At open surgery with a midline incision, surgeons in our institution usually enter the pedicle from a more medial location, resulting in less oblique trajectories in the axial plane. Whereas this was of little consequence when using bilateral paramedian exposure for open lumbar fixation only, it frustrated attempts at locating the implants and completing the placement of lumbar hardware when a midline incision was used. With bilateral paramedian lumbar incisions for both fixation and fusion, the oblique positions of the screws cause the 3D screw heads to lie over the transverse process, thereby preventing access for transverse process fusion.

We have since adapted our radiological techniques to allow for more vertically placed screws or placeholder K-wire fragments when needed. When possible, using a more lateral insertion point avoids invasion of the facet joint, which may be important at the upper and lower end of a construct. Obviously, close communication between the surgeon and the radiologist is required to obtain optimal screw or placeholder K-wire fragment position for particular surgical objectives.

Although both surgical sequences of the staged, two-procedure algorithm are widely applicable, a hyperlordotic lumbosacral segment may hinder the percutaneous approach taken during the interventional radiological procedure. In this situation, it is best to percutaneously place placeholder K-wire fragments or cannulated, headless screws at all other levels involved in the surgical plan, and then to place instrumentation at the lumbosacral level using laminotomy and pedicle exposure at the time of open surgery.

One of our goals was to avoid the introduction of any new procedure-related complications; unfortunately, we were not entirely successful. As part of the initial learning curve, we experienced two significant anterior cortical perforations by placeholder K-wire fragments. The worst of these is shown in Fig. 5C. This complication is completely preventable by fluoroscopic observation during the withdrawal of the bone biopsy needle as the placeholder K-wire fragment is left in place. Perforation of the heart, a major vessel, the esophagus, or an intraabdominal organ would be a devastating, life-threatening complication. Anyone wishing to employ our placeholder K-wire fragment technique should note this preventable complication. It should also be noted that there was no tendency for migration of the placeholder K-wire fragments.

Initially, in multilevel spine procedures, relatively large incisions were required for percutaneously place headless screws. By placing this incision between a superior pedicle and an inferior pedicle, it is possible to percutaneously place headless screws in two pedicles through one of these small incisions. With this approach, the small incisions do not limit options for location of the skin incision at the time of open surgery.

The paradigm we report raises many issues that should be addressed in future studies. Principal among these are the degree to which the length of the open surgical procedure can be reduced and the magnitude of the presumed associated reductions in postoperative medical complications, postoperative infections, complications related to increased blood loss from long surgery, technical errors related to long surgery, and operative mortality rates. Our impression from this limited preliminary experience is that, for complex pedicle screw–based cases, the time reduction in the open stage is likely to be quite significant and probably denominated in hours. Of course, anesthesia time at open surgery would be reduced in proportion to the number of screws one needs to place. We also believe that, for complex cases requiring many pedicle screws or difficult-to-place pedicle screws, this reduction in anesthesia time for the open surgical procedure will translate into a reduction in all of the above-noted postoperative and intraoperative adverse events. Another significant issue is the question of how long we must wait between stages so that the length of anesthesia during the first stage no longer counts in the generation of complications. We hypothesize that, for elective cases, several weeks may be sufficient. These issues must be addressed formally with large cohorts of patients in properly designed studies. Because blindness after spinal surgery is rare, it will be nearly impossible to determine if the incidence of this terrible complication is reduced by staging. Probably the best that can be hoped for is to find an approach that will reduce the length of complex, pedicle screw–based spinal surgeries to less than the 6-hour threshold reported in the literature.2,19,33 We believe that the approach reported here may help achieve this objective in many patients.

Other potential advantages of the staging algorithm proposed here may include improved accuracy of pedicle screw placement, reduction in radiation exposure, lack of limitation on the time interval between stages, cost savings, and improved OR utilization. As we stressed previously, these are unproven hypotheses. Future studies should address the shortcomings of the current study by including a proper control, larger patient populations, and a statistical comparison of results with those of competing techniques as found in the literature. If so validated, this staged, two-procedure approach could become the standard for lengthy, complex spinal procedures involving multilevel pedicle-based instrumentation. Finally, it should be noted that for this goal to be fully realized, an improvement on the currently available Click’X screw system (headless screws that allow delayed placement of the rod-holding heads) must be made to ensure that the system will withstand the stress of correction of long-segment, extensive deformities with simultaneous axial and coronal components. Such a screw system is currently being developed, and we plan to use it in these more demanding deformity types to test hypotheses stated here in relation to the reported staging algorithm.
Staging of spinal procedures

Conclusions

Within the limitations of this study, the proposed staged, two-procedure paradigm for pedicle screw placement is feasible, safe, and effective. It is reasonable to continue to study the merits of this paradigm in controlled settings and in larger, more complex patient cohorts with appropriate controls.

Disclosure

None of the authors has any commercial association that might represent a conflict of interest in relation to this article.

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