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Clinical Study

A reproducible and reliable localization technique for lumbar spine surgery that minimizes unintended-level exposure and wrong-level surgery

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Abstract

BACKGROUND CONTEXT: Exposure of unintended levels (defined as a spinal segment outside the intended surgical levels) is unnecessary and potentially adds to operative time and patient morbidity. Wrong-level surgery (defined as decompression, instrumentation, or fusion of a spinal segment not part of the intended surgical procedure) clearly adds to morbidity as well as putting the surgeon at medicolegal risk.

PURPOSE: To describe a localization technique for posterior lumbar spine surgery to minimize both unintended-level exposure and wrong-level surgery.

STUDY DESIGN: Consecutive case series.

PATIENT SAMPLE: One thousand nine hundred and eighty-six consecutive posterior lumbar operations performed from January 2010 to January 2017 using this technique were reviewed.

OUTCOME MEASURES: The primary outcome measure was the incidence of unintended-level exposure and wrong-level surgery.

METHODS: This localization technique was consistently used for determination of skin incision, soft tissue dissection, and identification of spinal levels for all patients undergoing posterior lumbar surgery during the time interval noted. Two spinal needles are inserted under sterile technique 3 cm lateral to the midline before incision at the approximate cranial and caudal aspects of the anticipated incision based on external landmarks. A cross-table lateral X-ray before incision is obtained and the actual incision is adjusted based on the location of the spinal needles. Once dissection is carried down to the facet capsules, spinal needles are then placed in adjacent facets, and a second cross-table lateral film is obtained to confirm appropriate levels. A retrospective review of all posterior lumbar cases was performed to determine the incidence of unintended-level exposure and wrong-level surgery using this technique.

RESULTS: There were no wrong-level surgeries during this time period. There were six (0.30%) cases of unintended-level exposure.

CONCLUSIONS: The technique described provides surgeons with a reliable, accurate, and easily reproducible method for localizing surgical levels during posterior lumbar spine surgery while minimizing exposure of uninvolved areas. This technique offers distinct advantages over previously proposed protocols and may lead to a widely accepted system for intraoperative spinal level identification.

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Introduction

Current literature reflects a heterogeneous grouping of intraoperative protocols to identify the correct surgical level in posterior lumbar spine surgery [1–5]. In addition, Mody et al. have shown that there is variable use of these protocols within the spine surgery community [6]. These variable and potentially unreliable techniques can result in incorrect spinal level localization. This can result in exposure of an unintended spinal level during dissection and, more significantly, wrong-level decompression or instrumentation.

A recent systematic review by Devine et al. listed the incidence of wrong-level spine surgeries in the literature ranging from 0.09 to 4.5 per 10,000 surgeries [7]. Such an error can have a social and emotional impact on the patient–doctor relationship as well as serious medicolegal implications [8,9]. More importantly, wrong-level surgery may fail to address the patient's symptoms for which they pursued operative treatment in the first place.

Unintended-level exposure, in which a surgeon dissects down to a spinal level that was not part of the original surgical plan, has been reported to occur in anywhere from 1.3% to 15% of cases [10,11]. Though exposing an unintended level can be corrected intraoperatively and is distinct from wrong-level surgery, unintended-level exposure in itself carries potential morbidity including increased length of incision, increased operative time, and greater soft tissue dissection. Although it may be unavoidable in some circumstances, measures to decrease its incidence would be useful.

In this study, we present a detailed description of an efficient localization technique and its results when used in posterior lumbar spine surgery (both decompressions and fusions). Our goal is to devise a reliable standard for proper level identification and thereby minimize unintended-level lumbar spine exposure and wrong-level surgery.

Materials and methods

Localization technique

A standard method for localization was used for all patients that underwent a posterior lumbar spine surgery (both decompressions and fusions) since the method was initiated in January 2010. Patients are positioned prone on the operating room table. Preoperative imaging is printed, hung in the rooms, and visible to all staff. The correct levels for the consented surgery are clearly identified and marked by the attending surgeon on anterior–posterior and lateral radiographs as well as sagittal magnetic resonance imaging cuts. The planned skin incision is also marked on the preoperative lateral radiograph. In accordance with World Health Organization procedures, the circulating nurse initiates a time-out procedure before incision, which allows all providers in the room to introduce themselves and confirms the patient's name, medical record number, procedure, and surgical site, including spinal level and side that is indicated on the patient's consent form [12].

The patient's lumbar skin is then disinfected and prepped with DuraPrep surgical solution (3M, St. Paul, MN, USA) in the standard fashion. Based on external anatomic landmarks such as the top of the iliac crest, two spinal needles are then inserted using sterile gloves through the skin into the paraspinal muscles (Fig. 1). These needles are directed perpendicular to the floor, approximately 3 cm lateral to the spinous processes to avoid inadvertent dural puncture, and placed at the levels corresponding to the estimated proximal and distal extents of the skin incision desired for the given operation. A cross-table lateral radiograph is then taken with the two needles in place before draping (Fig. 2). The image is reviewed and printed for the room, confirming both spinal needles, sacrum, and indicated surgical levels are visible in the image. The estimated cranial and caudal aspects for an appropriate skin incision are then marked on the lateral radiograph image before draping (Fig. 3). The patient is then draped in standard sterile fashion. The location of the needles is marked with a line perpendicular to the spine (Fig. 4) before removing the needles and covering the surgical site with Ioban (3M, St. Paul, MN, USA). Based on the location of the needles on the cross-table image, we then determine or adjust the exact skin incision that corresponds to the proposed incision that was marked on the lateral radiograph preoperatively (Fig. 5). The skin is incised and dissection is then carried down through fascia to the facets of interest, leaving the facet capsule completely intact. On one side (ie, either left or right), a spinal needle is then placed superficially ($\leq$1 mm deep) in one or two facet joints. One needle is sufficient for a one level decompressive procedure; two consecutive needles are placed for multilevel decompressions or when performing one or more level fusions. This time, the needles are ideally placed parallel to the corresponding disc space, so that on imaging the needles will "point" to the operative level(s) of interest. A second cross-table lateral radiograph is then taken to include both needles in the facet joints, the sacrum, and the indicated surgical spinal levels. The correct level in the lumbar spine is then confirmed by identifying the facet joints in which the spinal needles are placed. The facet joints

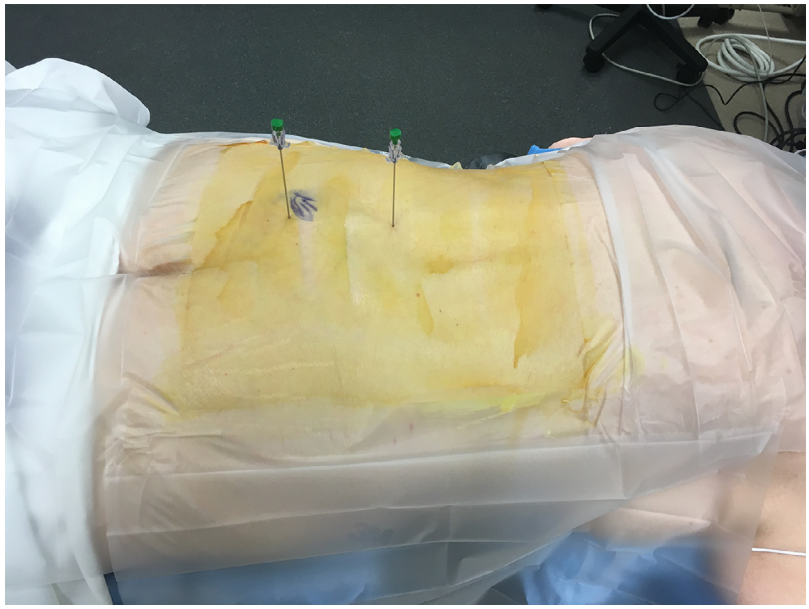

Fig. 1. Two spinal needles are then inserted using sterile gloves through the skin into the paraspinal muscles.

Fig. 2. Cross-table lateral radiograph is then taken with the two needles in place before draping.

are then clearly marked with a surgical pen, the spinal needles are removed, and the case proceeds for exposure, decompression, and/or instrumentation.

Methods

After obtaining approval from the institutional review board, all patients who underwent posterior lumbar or thoracolumbar decompression or instrumentation by a single surgeon at an academic institution between January 1, 2010 and January 1, 2017 were identified by ICD-9-CM and Current Procedural Terminology (CPT) codes. Thoracic levels were only included in the study if part of a thoracolumbar fusion. In these cases, the localization protocol was carried out strictly at lumbar levels. We excluded patients who did not have a cross-table lateral radiograph of the spinal needles in the facet capsule available for review in the medical record, likely caused by errors in saving the images. Medical charts were reviewed for patient demographics (age and gender) and operative plan.

The intraoperative cross-table lateral radiographs were reviewed to determine the incidence of unintended-level

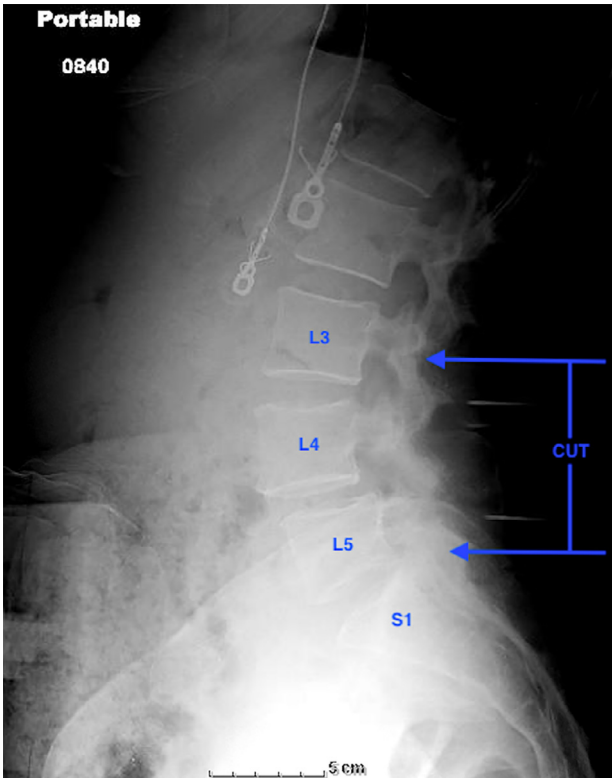

Fig. 3. Image is reviewed and printed for the room, confirming both spinal needles, sacrum, and indicated surgical levels are visible in the image for a L4–L5 fusion for spondylolisthesis.

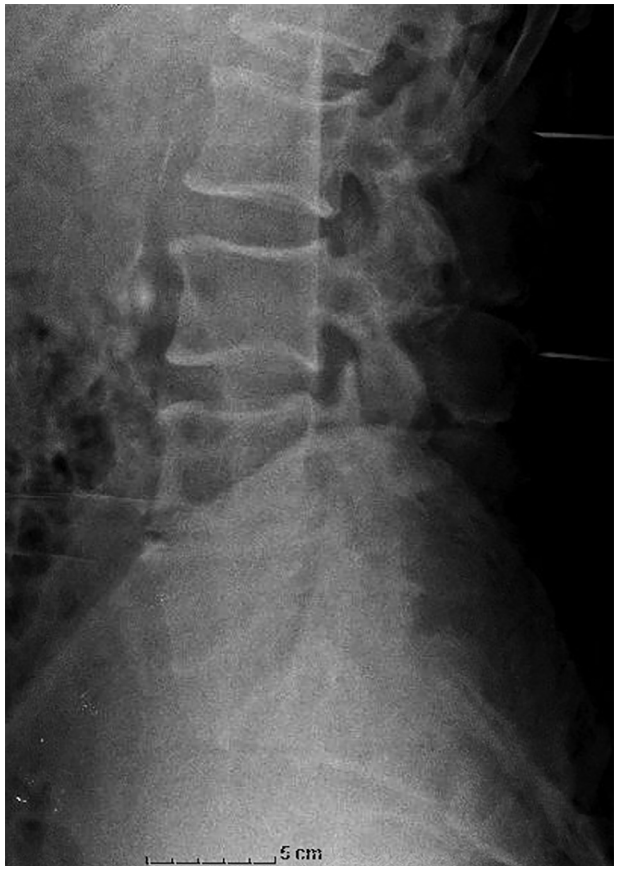

Fig. 5. Example of superficial localization cross-table lateral radiograph in a patient undergoing posterior lumbar fusion with instrumentation of L2–L3, allowing the surgeon to adjust their planned incision for the intended operative levels.

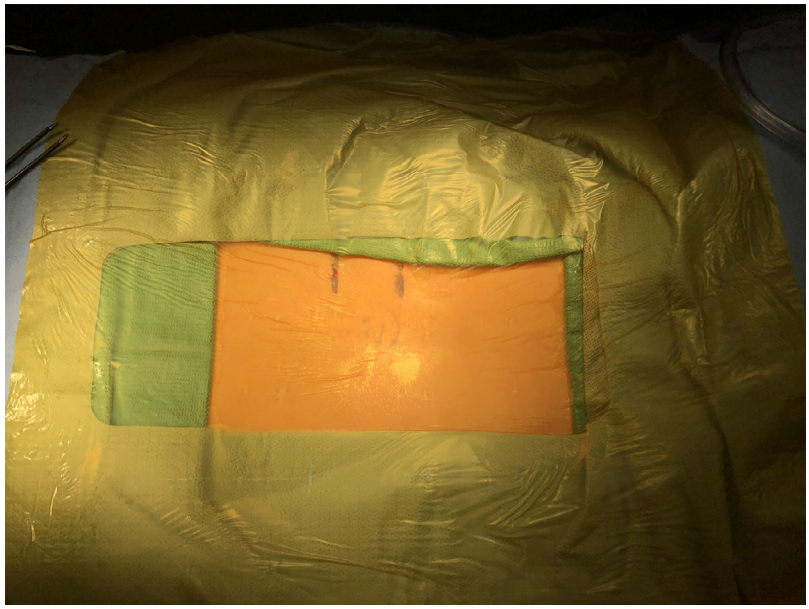

Fig. 4. Location of the needles is marked with a line perpendicular to the spine before removing the needles and covering the surgical site with Ioban.

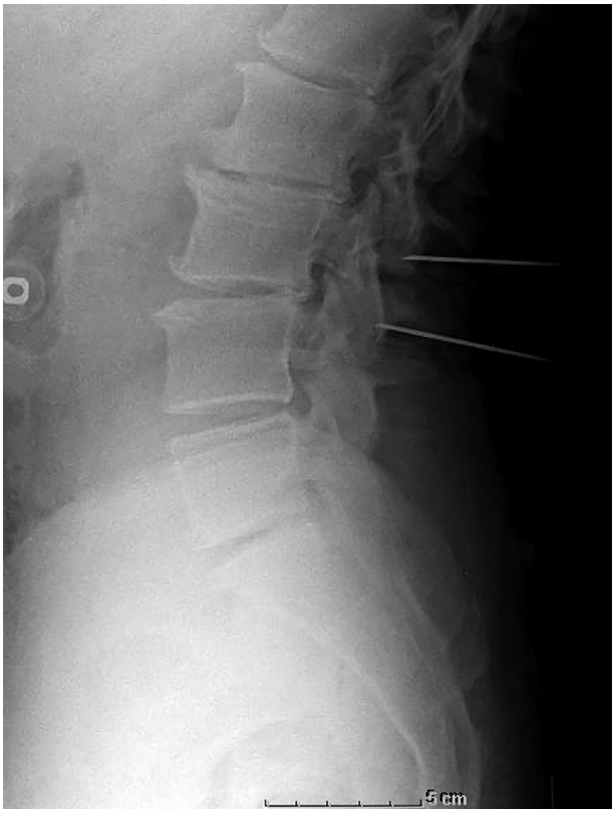

Fig. 6. Example of correct deep localization cross-table lateral radiograph with spinal needles inserted into the L2/L3 and L3/L4 facet capsules in a patient undergoing lumbar decompression of L3–S1, because the L3–L4 facet is at the level of the caudal needle.

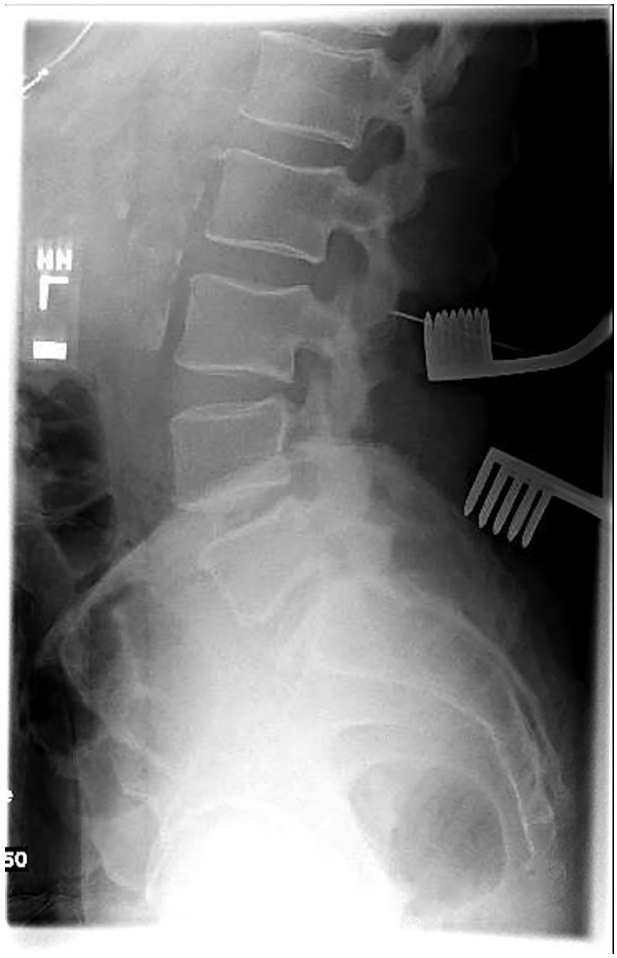

Fig. 7. Example of a unintended-level exposure with spinal needle inserted into the facet capsule of L2/L3 in a patient undergoing lumbar decompression of L4–L5, because the needle does not mark an area that is within the intended surgical field.

exposure. A correct level exposure was defined by at least one needle being in an appropriate facet capsule given the intended operative plan (Fig. 6). An unintended-level exposure was defined by no spinal needles placed into appropriate facet capsules for the operative plan (Fig. 7). If one needle was placed into the facet of an intended motion segment but the other was outside of the intended field, this situation was not considered an unintended-level exposure (eg, one needle in the L2–L3 facet and the other in the L3–L4 facet for an L3–L5 decompression).

Routine postoperative upright anterior–posterior and lateral radiographs of the lumbar spine were obtained on all instrumented patients after mobilization with physical therapy and before discharge in order to verify treatment of the correct spinal level. Patients who underwent decompression without instrumentation had postoperative radiographs at the 6-week follow-up whereas fusion procedures had a minimum of 6-month radiographs. The respective postoperative imaging for every patient was reviewed and compared with the original procedure description in the operative report in order to determine the incidence of wrong-level surgery. A wrong-level surgery was defined as decompression, instrumentation, or fusion at a level not designated in the procedure description section of the operative report.

Results

In total, 2,073 posterior lumbar or thoracolumbar operations using the technique described qualified for inclusion in this study. Of these, 87 cases did not have a cross-table lateral radiograph saved into the on line viewing system and were excluded from the study. There were 1,986 cases included in the final analysis.

The surgically treated levels were as follows: T2 in 1 procedure, T3 in 4 procedures, T4 in 9 procedures, T5 in 9 procedures, T6 in 10 procedures, T7 in 10 procedures, T8 in 11 procedures, T9 in 14 procedures, T10 in 50 procedures, T11 in 64 procedures, T12 in 76 procedures, L1 in 137 procedures, L2 in 447 procedures, L3 in 914 procedures, L4 in 1,620 procedures, L5 in 1,789 procedures, and S1 in 735 procedures (Fig. 8).

There were six (0.30%) cases in which no facet-level spinal needle was at the intended operative level, indicating unintended-level exposure. There were zero wrong-level decompressions or instrumentations during this time period as determined by the postoperative

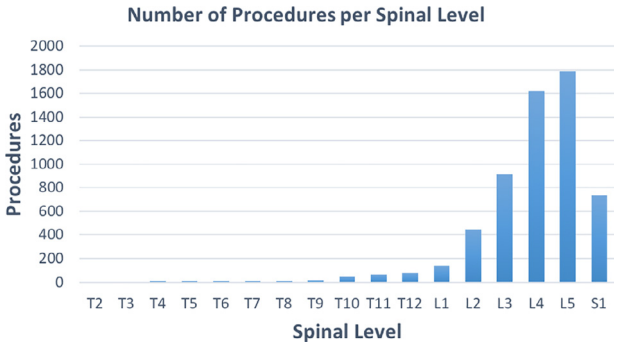

Fig. 8. Graphical representation of the number of procedures per spinal level included in the case series.

radiographs. All 1,986 patients had postoperative radiographs that confirmed the correct levels. None were lost to follow-up in that regard.

Discussion

Wrong-level spine surgery is a relatively rare occurrence but can be more difficult to prevent than wrong-site surgeries in other surgical fields. Especially in the setting of increased body mass, transitional lumbar vertebral segments, severe spondylosis or deformity, and revision lumbar operations, identifying the appropriate surgical level is seemingly straightforward but in actual practice can at times be very challenging. Our goal is for the proposed protocol to serve as a reliable and easily reproducible method of level localization that will improve upon the protocols described below, namely in its ability to minimize unintended-level exposure and wrong-level surgery. Using this technique, the occurrence of unintended-level exposure was 0.3% and that of wrong-level surgery was 0%.

Comparison to other protocols

There have been several previously proposed protocols to address the issue of wrong-level and wrong-side spine surgeries. However, we believe that our novel technique offers distinct advantages. Mitchell et al. proposed the "knife check strategy," where the scrub nurse verifies the surgical site with the surgeon just before incision [4]. Jhawar et al. suggested the use of the "ABCD pause" method, which involves a preincision review of the operative schedule and diagnostic imaging by the entire surgical team [3]. Notably, this time-out does not address the issue of wrong-level error. The Joint Commission on the Accreditation of Healthcare Organizations instituted a universal surgical protocol consisting of a three-step process where the operative plan is verified with the patient preoperatively, the operative site is marked, and a surgical time-out is executed before starting the procedure [1]. Although these protocols have been effective in outlining the importance of preoperative site verification, none of them incorporate the use of intraoperative radiography, which is essential in the setting of spine surgery in order to verify not only the correct region (ie, the posterior lumbar spine), but also the correct level(s) (eg, L4–L5).

Ebraheim et al. demonstrated that reliance solely on palpation of anatomic landmarks is an unreliable method for level identification in posterior lumbar spine surgeries [13]. The use of anatomic landmarks is only further complicated when operating on obese patients. The importance of incorporating intraoperative imaging for localization of the correct level in spine surgery has been recognized by several studies [14–16,11]. Ammerman et al. found a 15% incidence of unintended-level exposure in the lumbar spine without the use of confirmatory radiograph [10].

Some protocols exist that integrate the use of intraoperative imaging. Wong et al. established the "Sign, Mark, and X-ray" program, shortened to SMaX. This protocol consists of signing the surgical site preoperatively, marking the level with a radiopaque marker, and confirming the correct level with a radiograph of the spine with the marker in place. A comprehensive surgical time-out is also included [5]. In 2010, Irace et al. proposed the IRACE method, which incorporates components of both the SMaX program and the "knife check strategy." In this method, a wire is placed in the cranial spinous process of the appropriate spinal level and lateral fluoroscopy is used to confirm the correct level. Following confirmation, the superficial aspect of the wire is cut and a surgical time-out process is employed in which the level and side of the procedure are verified. Additional fluoroscopic confirmation is only used in cases of challenging anatomy or when a subtotal arthrectomy is planned [2].

When comparing the technique proposed in this paper with the aforementioned protocols, we believe that our technique offers several advantages. First, we recognize the importance of the detailed surgical time-out process and encourage the use of a refined method similar to the World Health Organization Surgical Safety Checklist or the one proposed by Irace et al. [12,2] Our technique focuses upon improvement of intraoperative spinal level confirmation via the use of intraoperative imaging. Our technique uses lateral radiographic confirmation using spinal needles as radiopaque markers at both the level of the skin and the facet joints, as opposed to the IRACE method, which only uses routine fluoroscopic imaging at the level of the skin. Our protocol serves as a second line of defense against wrong-level error. It also avoids the potential complications involved in using a buried wire as a guide for dissection as described in the IRACE method, which include mobilization of the wire during dissection and unintentional retention of the wire postoperatively. The 0% incidence of wrong-level surgeries across the 1,986 posterior lumbar spine cases performed in this study demonstrates the efficacy and reliability of this technique for spinal level localization. Additionally, this technique does not add to intraoperative time. The spinal needles can be inserted in a few seconds and the cross-table lateral radiograph can be obtained whereas the surgeons are scrubbing. The use of

cross-table radiographs rather than C-arm fluoroscopy allows for more detailed evaluation of bony structures for a clearer interpretation of levels and comparison to preoperative radiographs.

Our method specifically avoids marking or considering the spinous processes, which we believe is a major cause of improper interpretation of level. For lumbar surgery, we believe that a marker on the facet is preferable to the spinous process for the following reasons. First, the facet complex represents the motion segment being operated upon and is co-linear with the disc, making it easy to verify the surgical level on a lateral X-ray. In addition, because the facet is immediately adjacent to the pedicle, marking the facet makes it easy to identify the pedicle being instrumented. In contrast, because the spinous process extends distally from its origin to overlap the lamina caudal to it, it is generally not co-linear with the motion segment being operated upon and has no reliable relationship to the pedicle, facet, or disc on a lateral X-ray. This variability in the relationship between the spinous process with the disc, facets, and pedicles can lead to confusion in interpreting intraoperative lateral X-rays, especially in the setting of severe degenerative changes or scoliosis. Second, the spinous process is often not well visualized on portable intraoperative X-rays, especially in larger patients, whereas the facets and discs are almost always radiographically visible.

There is theoretical risk for inflicting damage to the facet capsule when placing localization needles. However, we place the needles only very superficially into the capsule, such that the tip penetrates $\leq$1 mm. As such, we have not seen any traumatic injuries to the facets as a result of the technique. This is in contrast to inserting needles into disc spaces to localize during anterior surgery, which may be associated with traumatic disc injury, as shown in animal models.

Other anatomical landmarks that may be used for localization include the transverse process. A major advantage to using the facet, however, is the ability to use this landmark in decompression-only procedures where the transverse process does not need to be exposed. This allows a consistent protocol for all posterior lumbar cases, thereby decreasing the amount of variation in protocol between procedures. Additionally, because the facets are a relatively midline structure, one can limit exposure-related morbidity in case an unintended level is exposed. Therefore, we use the transverse process only when the facet method is equivocal, such as, in cases of severe scoliosis combined with massive facet overgrowth. In order to avoid any possibility of facet injury, another option may be to place needles into the lateral lamina just outside the facet capsules if there is available lamina medial to the capsule. However, individual patient anatomy does not always allow for this, whereas the facet joint method is virtually always possible.

An additional potential benefit to the proposed technique is the preoperative determination of approximate proximal and distal extent of the skin incision. The routine employment of two spinal needles to define these boundaries helps to guide dissection down to the desired levels, thereby decreasing the incidence of unintended-level exposure. Vitale et al. recently proposed a consensus-derived best practice guideline for the prevention of wrong-level spine surgery [17]. Although we agree with all of the included practices in their guideline, the use of a cross-table lateral radiograph before incision failed to reach the threshold consensus of 80% and was therefore not included in the guideline. This step is critical to the minimization of wrong-level exposure as it allows for accurate estimation of the extent of the planned incision. The current study reports a 0.30% incidence of unintended-level exposure compared with the reported values ranging from 1.3% to 15% in other studies, demonstrating the effectiveness of these additional steps [10,11].

When analyzing the six cases of unintended-level exposure, we found that only one facet-level needle was used in four of the cases. Inherently, using only one needle to localize the operative levels will be less accurate than using two. If these cases in which only one facet-level needle was used are excluded, the incidence of unintended-level exposure decreases to 0.1%. Therefore, we recommend the use of two facet-level spinal needles in every case with the exception of single-level decompression procedures in which only one level needs to be exposed. In another case of unintended-level exposure, the patient was obese with a body mass index of 38 kg/m^2, making the interpretation of imaging considerably more difficult. In all of these cases, the protocol allowed the surgeon to identify and correct the unintended-level exposure before going on to decompress or instrument the intended spinal levels.

The reproducibility of any proposed protocol is a necessary consideration. This series was carried out at an academic center, and the localizations were performed by a combination of junior residents, senior residents, fellows, and the single attending. We feel that the low wrong-level surgery and unintended-level exposure rates demonstrate the efficacy of this localization protocol when used by surgeons at any level of experience.

In a survey by Groff et al., to all of the members of the Joint Section on Disorders of the Spine and Peripheral Nerves, 88.6% of surgeons answered that they had exposed the unintended level at some point in their career [18]. Even if correctable intraoperatively, exposure of the wrong site can lead to increased operative time, incision length, and soft tissue injury. The proper determination of the proximal and distal extent of the skin incision before any deep dissection decreases the size of the skin incision and also soft tissue injury. By establishing a reliable, reproducible, and efficient technique for spinal intraoperative level identification, we have been able to minimize unintended-level dissections.

Conclusions

Unintended-level exposure and wrong-level surgery continue to occur despite adherence to current national guidelines. This study shows that our technique of localization is associated with a very low rate of unintended-level exposure and no wrong-level surgeries in a large series of posterior lumbar operations.

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