Development of an Enhanced Recovery After Surgery (ERAS) approach for lumbar spinal fusion

Michael Y. Wang, MD,1 Peng-Yuan Chang, MD,1 and Jay Grossman, MD2

Departments of 1Neurological Surgery and 2Anesthesiology, University of Miami Miller School of Medicine, Miami, Florida

OBJECTIVE Over the past decade, Enhancing Recovery After Surgery (ERAS) programs have been implemented throughout the world across multiple surgical disciplines. However, to date no spinal surgery equivalent has been described. In this report the authors review the development and implementation of a “fast track” surgical approach for lumbar fusion.

METHODS The first 42 consecutive cases in which patients were treated with the new surgical procedure were reviewed. A combination of endoscopic decompression, expandable cage deployment, and percutaneous screw placement were performed with liposomal bupivacaine anesthesia to allow the surgery to be performed without general endotracheal anesthesia.

RESULTS In all cases the surgical procedure was performed successfully without conversion to an open operation. The patients’ mean age (± SD) was 66.1 ± 11.7 years, the male/female ratio was 20:22, and a total of 47 levels were treated. The mean operative time was 94.6 ± 22.4 minutes, the mean intraoperative blood loss was 66 ± 30 ml, and the mean hospital length of stay was 1.29 ± 0.9 nights. Early follow-up showed a significant improvement in the mean Oswestry Disability Index score (from 40 ± 13 to 17 ± 11, p = 0.0001). Return to the operating room was required in 2 cases due to infection and in 1 case due to cage displacement. An iterative quality improvement program demonstrated areas of improvement, including steps to minimize infection, improve postoperative analgesia, and reduce cage osteolysis.

CONCLUSIONS ERAS programs for improving spinal fusion surgery are possible and necessary. This report demonstrates a first foray to apply these principles through 1) a patient-focused approach, 2) reducing the stress of the operation, and 3) an iterative improvement process.

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KEY WORDS minimally invasive; spondylolisthesis; lumbar spine; interbody fusion; bone morphogenetic protein; BMP; expandable cage; endoscopy; anesthesia; pedicle screw; percutaneous; ERAS
the immune response after surgery and new approaches to prevent postoperative inflammation, including the proper selection of anesthetic agents, goal-directed fluid therapy, and the application of minimally invasive surgery.

Another aspect of ERAS has been its data-driven quality improvement approach. This has allowed for iterative improvements in surgical care based upon a continuous examination of the effects of changes to the surgical protocol. Thus, ERAS processes are always undergoing revision in a quest to optimize procedures and practices. In a sense, procedures undergo a constant and directed evolution toward improvement from multiple perspectives, including the patient, surgeon, hospital, payor, and regulatory stakeholders.

The success of ERAS has been obvious and well demonstrated by the proliferation of programs both geographically and by specialty. Although the movement began in Western Europe, it has now spread to virtually all industrialized nations in one form or another. Similarly, ERAS initiatives have been developed for numerous surgical subspecialties. There is now an international ERAS conference, and a society has been founded to assist centers in implementing or improving their programs.

Nevertheless, to date there have been no spine ERAS programs implemented. Given that spinal fusion surgeries can be painful, morbid, and costly, the implementation of a spine ERAS program would be most welcome. In our institution we have been developing a lumbar spinal fusion program incorporating the principles of ERAS in an effort to improve patient outcomes and reduce complications. This report summarizes our initial experience with the first iteration of our program.

Methods
ERAS Program Components

The development of an ERAS protocol at the University of Miami began with an exploration of steps along the patient’s journey through a surgical procedure. This includes not only the procedure itself but also aspects of the preoperative and postoperative journey as shown in Table 1 and Fig. 1. In our initial development (Version 1.0) of a fast-track spinal fusion procedure, we chose to focus on the operative intervention itself. We focused on developing a modified minimally invasive transforaminal interbody fusion (MIS TLIF) operation due to the widespread application of this technique, its versatility for treating diverse lumbar spine pathologies, and its existing development as a minimally invasive surgery (MIS) approach. The first iteration of the ERAS MIS TLIF differed from standard open surgery because of 6 technological components. These components, as well as their potential advantages, disadvantages, and Food and Drug Administration (FDA) labeling, are shown in Table 2. Although pre- and postoperative components of a mature ERAS program are an integral portion of a complete program, we have only recently begun to explore this important area, and this series does not incorporate any specific changes in these areas.

Procedural Steps

The procedure has been described in a previous publication. With the patient prone on a Jackson table, careful monitoring by the anesthesiologist is necessary during the operation. Supplemental oxygen is given via face mask or nasal cannula, but no laryngeal access is used. No Foley catheter is placed. The patient is sedated with a combination of propofol and ketamine administered intravenously, titrating to moderate sedation. No narcotic medications are given, and no spinal, epidural, or regional analgesia is used.

Kambin’s triangle is unilaterally entered using a spinal needle with the assistance of local injections of Marcaine (bupivacaine hydrochloride and epinephrine). This allows successive dilation of the access site to a final 8-mm outer diameter working channel ( JoiMax Inc). The traversing and exiting nerve roots are identified using the working channel endoscope, and any compressive bony or cartilaginous pathology can be removed under direct visualization. The endoscope does allow for direct removal of disc material, osteophytes, part of the superior articular process of the facet, and ligamentum flavum. The disc space is cleaned, and the bony endplates are prepared for interbody fusion. This is accomplished utilizing a combination of pituitary rongeurs, curettes, and stainless steel brushes.

Following disc removal, 2.1 mg of rhBMP-2 (recombinant human bone morphogenetic protein–2, InFuse, Medtronic Sofamor Danek) is placed into the anterior disc space as far away from any neural structures as possible. This is followed by placement of an Optimesh (Spineology) cage. The mesh expandable cage is filled internally with premachined allograft matrix to increase interbody height and reduce any spondylolisthesis (Fig. 2). Bilateral pedicle screws are then inserted percutaneously under fluoroscopic guidance. The 4 or 6 (for a 2-level fusion) access sites for the pedicle screws are first injected with a total of 20 ml of Exparel. This is diluted 1:2 to 40 ml of total volume, then divided evenly between the 4 screw insertion tracts. The pedicle screws are then connected using bilateral rods placed subfascially. Each of the 5 small incisions are then closed with Monocryl suture. It should be noted that the use of InFuse, Optimesh, and Exparel in this application is off-label for the US FDA.

Patient Series

A consecutive case series involving the first 42 patients treated with the ERAS MIS TLIF was analyzed retrospectively. Selection criteria did not change for these patients as compared with standard open or conventional MIS TLIF. All patients had either a spondylolisthesis or a severely degenerated disc with nerve root impingement. In addition, all patients had some component of radiculopathy from neural compression as well as back pain from instability. Patients who would otherwise have been treated without fusion were not candidates for this procedure.

All data were collected prospectively. The patients were evaluated for baseline demographics, Charlson Comorbidity Index, pathology being treated, surgical level, blood
loss, hospital length of stay, and perioperative complications. Clinical metrics included Oswestry Disability Index (ODI), SF-36, and EQ-5D scores, which were obtained before surgery and at 6 weeks, 3, 6, 12, and 24 months postoperatively. Preoperative and postoperative metrics were analyzed. Iterative improvement protocols were instituted based upon outcomes and complications during the perioperative (1st 2 weeks) and early (1st 3 months), intermediate (1 year), and long-term (2 years) follow-up periods.

Results

Patient Population

A total of 42 patients were treated over a 22-month period. Clinical and demographic data are shown in Table 3. All patients underwent either a 1- or 2-level unilateral TLIF surgery successfully and without conversion to an open surgery. The average age was 66.1 ± 11.7 years (range 28–87 years). The male/female ratio was 20:22. All patients had severe disc height collapse, and 60% had a Grade I spondylolisthesis. Given the predominance of degenerative spondylolisthesis cases in this study, L4–5 was the most commonly treated level. The mean operative time (± SD) was 94.6 ± 22.4 minutes (range 60–140 minutes), and intraoperative blood loss was 66 ± 30 ml (range 30–190 ml). The mean hospital length of stay was 1.29 ± 0.9 nights. The mean operative time (± SD) was 94.6 ± 22.4 minutes (range 60–140 minutes), and intraoperative blood loss was 66 ± 30 ml (range 30–190 ml). The mean hospital length of stay was 1.29 ± 0.9 nights. The vast majority of patients were discharged on postoperative Day 1. However, there were exceptions such as 1 patient who had no family or social support and thus was not discharged home for 5 days. One patient was lost to follow-up, and the mean duration of follow-up was 10 months.

Clinical Outcome Measures

All patients underwent surgery without any intraoperative events related to anesthesia, over-sedation, medical events, or sentinel surgical events. All patients were able to tolerate the entirety of the procedure. Postoperatively, pain control was successful with standard regimens of narcotic analgesics, and all patients were ambulatory on either the day of surgery or the day after surgery. Preoperative scores on clinical outcome measures were compared with scores

<table>
<thead>
<tr>
<th>TABLE 1. Spinal ERAS recommendations</th>
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<tr>
<td><strong>Items</strong></td>
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<tr>
<td>Preadmission counseling</td>
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<tr>
<td>Preoperative enteral nutrition</td>
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<tr>
<td>Preoperative fasting &amp; carbohydrate loading</td>
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<tr>
<td>Antimicrobial prophylaxis &amp; skin preparation</td>
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<tr>
<td>Anesthesia protocol</td>
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<tr>
<td>Local analgesia</td>
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<td>Minimally invasive spinal surgery</td>
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<tr>
<td>Osteobiologics</td>
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<tr>
<td>Surgical drainage</td>
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<tr>
<td>Avoiding hypothermia &amp; hypotension</td>
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<tr>
<td>Fluid balance</td>
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<tr>
<td>Urinary drainage</td>
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<td>Postop analgesia</td>
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<td>Postop nutrition</td>
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<tr>
<td>Early mobilization</td>
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<td>Audit</td>
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MRSA = methicillin resistant Staphylococcus aureus; NPO = nil per os.
at 3 months’ follow-up, as complete data were available for 76% of patients at this early time point. The mean ODI score improved from $40 \pm 13$ to $17 \pm 11$ ($p = 0.0001$), and this change was statistically significant.

Radiographic Results
Radiographic imaging included flexion-extension radiographs at 3, 6, and 12 months following surgery. While CT scanning was not obtained in all cases to demonstrate arthrodesis, patients were observed clinically to assess for any signs or symptoms of a nonunion, including persistent or worsening back pain. Any radiographic evidence suggestive of a nonunion, such as hardware loosening or ab-

normal motion was investigated with CT scanning. Using these criteria, there were no cases of delayed nonunion. There was no hardware loosening, breakage, or dislodgement. However, 1 patient had an early graft migration at 2 months after surgery, which was treated with a revision operation via the anterior approach.

Complications
In this series there were no intraoperative complications related to anesthesia. However, 3 patients required a return to the operating room. The first was the case of cage displacement described above. The other two were patients early in the series who developed an infection.

<table>
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<tr>
<th>TABLE 2. Lumbar spine fusion ERAS components</th>
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<tr>
<td><strong>Component</strong></td>
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<tr>
<td>Working channel endoscope</td>
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<td>Anesthesia w/o intubation</td>
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<tr>
<td>Expandable cage</td>
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<tr>
<td>BMP</td>
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<tr>
<td>Small-caliber percutaneous screws</td>
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<tr>
<td>Liposomal bupivacaine</td>
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BMP = bone morphogenetic protein; NSAID = nonsteroidal anti-inflammatory drug.
of the interbody graft. The presentation was with sepsis, which was treated effectively with an incision and drainage followed by intravenous antibiotic therapy. Other complications included 1 case of atrial fibrillation, treated medically, and 1 case of an upper-extremity deep venous thrombosis, treated without anticoagulation. Two patients developed transient radiculitis due to manipulation of exiting nerve roots during surgery.

Iterative Improvement of Surgery

The patient’s journey following a surgical procedure is outlined in Table 4. While it is imperative to have long-term follow-up for patients undergoing spinal fusion procedures, critical information can also be gleaned from earlier follow-up. Earlier follow-up can be arbitrarily divided into 4 time periods: perioperative (first 2 weeks), early (first 3 months), intermediate (1 year), and long term (2 years). Specific outcome measures and complications can be identified at each time period. In our study, targeted iterative improvements based on earlier outcomes (before 2 years) have already resulted in meaningful data to drive the improvement process.

During the perioperative period it was identified that the method of liposomal bupivacaine injection has a major impact on postoperative pain control. In cases in which injection of this agent was not under pressure, pain control was poor. These cases occurred when the pedicle screws were placed prior to injection. The soft tissue opening prevented injection under high pressure. Thus, this agent is now first injected while the soft tissue envelope is intact and not disrupted, allowing for a high-pressure injection along the screw tract. This was an important point because of the limited ability of liposomal bupivacaine to diffuse through soft tissues.

During the early follow-up period (first 3 months), it was identified that 2 patients had interbody-space infections. Examination of the central processing procedures revealed that potential improvements in cleaning and processing the endoscopic equipment could be instituted through education. We also began adding vancomycin (1 g) to the irrigant used during the endoscopic portion of the procedure. After the institution of these changes we saw no more interbody-space infections.

During the intermediate follow-up period (first year) we began observing some cases of interbody cage subsidence. This was not vertebral endplate subsidence, but rather dissolution of some of the interbody cage, which is composed largely of cadaveric allograft. In the early series, we combined rhBMP-2 with the allograft, which was placed inside the cage. Following the identification of this radiographic (but not clinically relevant) finding, we began placing the osteobiologic agent anterior to the cage. The evaluation of this intraoperative change is ongoing. Long-term follow-up data collection is ongoing.

Discussion

Why Is an ERAS Approach Necessary?

The impetus for the ERAS movement was a clear need to improve the efficacy, reduce the morbidity, and
minimize the costs associated with surgical interventions. While the initial efforts focused on colorectal surgery, the basic principles have now been applied to multiple surgical disciplines. These principles have included: 1) a focus on the patient and the patient experience; 2) a multidisciplinary team approach; 3) efforts to reduce pain, morbidity, and recovery time; and 4) a data-driven iterative improvement process. This report represents our initial foray into applying ERAS principles in spinal fusion. We have felt that such a program is desperately needed given the variability in outcomes, high costs of care, and negative perceptions of lumbar spinal fusion in general.

How Spinal ERAS Works

The core of the ERAS surgical paradigm, whether for removing an abdominal lesion or decompressing neural elements, is to minimize the stress (physiological, psychological, economic, and social) that surgery places on the patient.1,3,5,7 In spinal fusion surgery, two of the main stressors are the anesthesia and postoperative pain. We have attempted to avoid general anesthesia and use local analgesia in combination with deep sedation to mitigate the negative effects associated with general endotracheal anesthesia. These negative effects include hemodynamic instability, cardiac stress, memory loss, and postoperative nausea. With regard to postoperative pain, it is well understood that pain reduces mobility, increases anxiety, and requires significant pharmacotherapy. With the use of ultra-minimally invasive techniques to reduce tissue trauma,2,5,16 in concert with long-acting local analgesics, patients experience far less pain at the surgical site, mobilize quickly, and are discharged earlier.

In spinal surgery, we have found that changes in the anesthesia protocol and minimally invasive surgical techniques work synergistically to improve the patient experience. For example, only a truly minimally invasive procedure can be safely performed without general anesthesia. This, in turn, reduces the negative effects of the anesthesia. For example, having the patient autoregulate blood pressure reduces the need for invasive blood pressure monitoring and additional pharmacological intervention to raise or lower the blood pressure. Such practices may be especially beneficial in patients with advanced age or multiple comorbidities.1,16,21

Previous Case Series

While rapid recovery following minimally invasive decompression surgery has been achieved, obtaining these results with fusion surgery has been more challenging. Previous reports have shown accelerated recovery after lumbar fusion surgery utilizing a combination of MIS with an aggressive pain management protocol.3 Some authors have attempted to use unilateral screw fixation in an effort to reduce pain and blood loss, thus allowing lumbar fusion to be performed as an outpatient procedure.4 Others have advocated using regional analgesia, such as spinal or epidural infusions.2,5,8,14 However, none of these methods has become popular, either because the surgical intervention might be viewed as compromised, or because the use of regional analgesia is viewed as impractical or as a limitation to neuromonitoring.

Regardless, these case series have largely been driven by attempts to move fusion surgery into the ambulatory surgery center. In this report, our approach has not been focused on early discharge, but rather on the ERAS philosophy of improving recovery and the patient experience. While the surgical procedure we describe can clearly be performed in an ambulatory surgery center, that is not our primary goal. We believe that the basic tenets of open surgery apply, including: 1) performing surgery in clearly indicated cases, 2) improving patient outcomes through neural decompression and spinal stabilization, 3) achieving a successful arthrodesis, and 4) minimizing complications.

### TABLE 4. Iterative improvement components

<table>
<thead>
<tr>
<th>Time period</th>
<th>Anesthetic protocol, postop nausea, pain control, time to mobilization, LOS</th>
<th>Wound infections, readmissions, hardware misplacement, implant migration, postop radiculitis</th>
<th>Findings</th>
<th>Changes implemented</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st 2 wks</td>
<td>No anesthetic complications, pain control dependent on method of liposomal bupivacaine injection</td>
<td>Deep infection in 2 patients, no unwarranted readmissions</td>
<td>No anesthetic complications, pain control dependent on method of liposomal bupivacaine injection</td>
<td>Continuation of propofol/ketamine protocol, injection of liposomal bupivacaine under high pressure for all screw tracts</td>
<td>More consistent postop analgesic usage</td>
</tr>
<tr>
<td>1st 3 mos</td>
<td>Excellent clinical improvement, mild subsidence seen in some cases</td>
<td>Placement of BMP anterior to instead of inside interbody graft</td>
<td>Education of staff on cleaning and sterilization of endoscopy equipment and use of vancomycin in endoscopic irrigation, continuation of postop education</td>
<td>Decreased infection rate</td>
<td>Pending</td>
</tr>
<tr>
<td>1st yr</td>
<td>Excellent clinical improvement, mild subsidence seen in some cases</td>
<td>Placement of BMP anterior to instead of inside interbody graft</td>
<td>Education of staff on cleaning and sterilization of endoscopy equipment and use of vancomycin in endoscopic irrigation, continuation of postop education</td>
<td>Decreased infection rate</td>
<td>Pending</td>
</tr>
<tr>
<td>&gt;2 yrs</td>
<td>Excellent clinical improvement, mild subsidence seen in some cases</td>
<td>Placement of BMP anterior to instead of inside interbody graft</td>
<td>Education of staff on cleaning and sterilization of endoscopy equipment and use of vancomycin in endoscopic irrigation, continuation of postop education</td>
<td>Pending</td>
<td>NA</td>
</tr>
</tbody>
</table>

ASD = adjacent-segment disease; NA = not applicable.
Initial Experience (Version 1.0)

This series represents our efforts to use a combination of several techniques and technologies to achieve a more rapid and less painful recovery after lumbar spinal fusion surgery. The use of endoscopy and percutaneous screws reduces the amount of soft tissue disruption to the extent that the intervention can be tolerated without general anesthesia. Expandable cages allow for efficient placement of an interbody device to allow for fusion through Kambin’s triangle. This also permits indirect neural decompression by restoring intervertebral height. Osteobiologics are necessary to promote fusion through such a small corridor. Use of conscious sedation avoids the more severe side effects of general anesthesia, and it also allows for live neurological monitoring through patient feedback. Finally, liposomal bupivacaine provides prolonged local analgesia during the first 3 days after surgery, which is typically the most painful time period. These component techniques have all been previously applied clinically with success, but it is the combination of them that makes this series unique.

In this case series we were able to demonstrate that use of this multimodal method allowed patients to be discharged rapidly from the hospital following single-level MIS TLIF surgery. The hospital stay was reduced substantially. This reflects a reduction of over 2 hospital days on average (3.9 vs 1.29 days) compared with our previous publications of “standard” MIS TLIF.\(^{18,20}\) The blood loss was also reduced substantially, primarily through the use of working channel endoscopy to perform the neural decompression and discectomy.

Iterative Improvement Processes

A fundamental tenet of ERAS is a data-driven quality improvement (QI) process. Realizing the deficiencies that exist with present methods and technologies in spinal surgery, we were able to quickly apply this method to our surgical service. It should be recognized that long-term data are essential. However, the long cycle of follow-up and delayed feedback loop of any project requiring data to have a minimum of 2-year follow-up would in reality require iterative time periods on the order of a decade to provide meaningful recommendations, changes, and validation. In addition, it is clear that a wealth of clinical and radiographic data are available at the perioperative, early, and intermediate time periods, even for fusion operations (e.g., infection, length of stay, CSF leak). Thus, these earlier data are viewed as complementary to, and not as a substitute for, longer-term follow-up.

Within the first 2 years of our instituting this QI process, 3 substantive changes have already occurred. The first involved a process problem related to infection. This problem was resolved with a rigorous examination of sterile core processing procedures as well as use of antibiotics in the endoscopic irrigant fluid. The second was a surgeon technique problem related to the injection of liposomal bupivacaine. This problem was improved with an alteration to the injection method, which requires adequate pressure for dispersion through soft tissues. The third was related to osteobiologic-related osteolysis of the allograft and is currently under investigation. Due to the longer-term follow-up needed for this third problem, the final outcome requires a longer follow-up time period.

Ultimately, we plan to institute many of the other critical components that have made ERAS programs in other subspecialties successful. This will include patient education, preoperative nutritional supplementation, standardized mobilization practices, and monitoring of outcome measures beyond standard spine metrics.

Study Limitations

This study has significant limitations. It serves as the first English-language publication outlining an action plan for an ERAS spinal fusion protocol. Accordingly, however, the long-term follow-up data are insufficiently powered to draw definitive conclusions as to efficacy, safety, and fusion rates. Ultimately, this procedure must be able to achieve fusion rates equivalent to open lumbar fusion to be deemed acceptable, as a failure of arthrodesis will likely result in the ultimate failure of the procedure. Definitive confirmation of arthrodesis using 3D imaging (CT) would also be ideal for demonstrating efficacy. Finally, the generalizability of the procedure is important to ensure that it can be applied in diverse institutions, settings, and surgeons’ hands.

Conclusions

This report describes the first spinal fusion ERAS protocol, focusing largely on our intraoperative improvements. Using a combination of techniques and technologies, we were able to perform lumbar spinal fusions successfully without conversion to more standard methods. While still in its infancy, this technique, with modification, will likely reduce postoperative recovery times, complications, and acute care costs. Future reports will focus on the addition of the pre- and postoperative components of ERAS.

References

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Disclosures
Dr. Wang reports being a patent holder with and receiving royalty payments from DePuy Synthes Spine, Inc.; having a consultant relationship with DePuy Synthes Spine, JoiMax USA, K2M, and Aesculap Spine; being on the medical advisory board of Vallum; owning stock in Spincity; and receiving grants from the Department of Defense.

Author Contributions

Correspondence
Michael Y. Wang, Department of Neurological Surgery, Lois Pope Life Center, 1095 NW 14th Terrace, Miami, FL 33136. email: mwang2@med.miami.edu.