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Advanced Technologies for Outpatient Lumbar Fusion: Barriers and Opportunities

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ABSTRACT

Background: In recent years, there has been increasing interest in outpatient spine surgery. Minimally invasive techniques have created an opportunity for ambulatory lumbar fusion, and these techniques increasingly involve advanced technologies such as navigation and robotics.

Objective: To explore the barriers, advantages, and future predictions for such technology in the context of outpatient lumbar fusions.

Methods: This is a narrative review of studies examining the advantages, limitations, and cost-effectiveness of navigation and spinal robotics in conjunction with the outcomes and costs of outpatient lumbar fusion.

Results: Outpatient lumbar fusion is a growing trend with ample evidence of its safety, favorable patient outcomes, and cost savings. Navigation and spinal robotics are associated with improved instrumentation accuracy and fewer complications, and the long-term cost savings can make these technologies financially practical in the outpatient setting. Future capabilities with robotics will only increase their value.

Conclusions: Advanced technologies such as navigation and robotics are strategic long-term investments in the context of outpatient lumbar fusion.

Clinical Relevance: The favorable outcomes and costs associated with navigation and robotics will be relevant to any spine surgeon interested in developing an outpatient lumbar fusion program.

Level of Evidence: 5.

New Technology

Keywords: lumbar fusion, outpatient, ambulatory, outpatient lumbar fusion, ambulatory surgery center, ASC, navigation, robotic navigation, robotics, technology

INTRODUCTION

In the United States, an increasing proportion of spine surgeries are being performed on an outpatient basis. There was a 5-fold increase between 1994 and 2006, and since that time, the shift away from the inpatient setting has only continued.[1] Spinal decompression procedures and anterior cervical discectomy and fusions (ACDFs) are responsible for the majority of this trend, whereas lumbar fusions have lagged behind.[2–5] As a case in point, one study reported that the incidence of outpatient lumbar fusions was stagnant between 2008 and 2018.[6] In recent years, however, multiple studies have demonstrated favorable outcomes after outpatient lumbar fusion—particularly with the use of minimally invasive techniques.[7]

In conjunction with the shift toward outpatient procedures, spine surgeons have also been adopting image guidance and robotic technologies.[8] These technologies limit radiation exposure to the surgeon by reducing the reliance on fluoroscopy during minimally invasive procedures while also increasing the accuracy of instrumentation.[8–10] We are therefore faced with 2 concurrent trends in spine surgery that are seemingly at odds with one another. Outpatient procedures represent a commitment to cost containment, given that the widespread use of ambulatory surgery centers (ASCs) could potentially save more than $100 million annually.[11] On the other hand, navigation and robotic technology have historically required significant capital expenditures. The acquisition of expensive equipment, which is not absolutely critical to the execution of spine procedures, runs counter to the philosophies of efficiency and value-based care that underpin outpatient care.

In this review, we explore these 2 trends and their intersection. We discuss the opportunities and barriers for navigation and robotics in the context of outpatient spine surgery. We also make predictions for the future of these enabling technologies in the ambulatory space.

OUTPATIENT LUMBAR FUSION

Outpatient spine surgery is receiving significant attention as health care stakeholders—from payers, to employers, to patients—seek to reduce the costs of care. One study examined more than 40,000 lumbar discectomies and found that outpatient facility charges were less than half of inpatient charges.[12] A similar observation has been made with ACDFs, wherein overall charges in the inpatient setting are more than double that of the ambulatory setting.[13] Interestingly, the financial impact may be even deeper. There is evidence suggesting that ASCs are associated with a reduction in adverse events after spine surgery.[14] Complications, readmissions, and reoperations are significant sources of excess costs, and the potential to reduce them in the outpatient setting provides an opportunity for savings that goes beyond a simple reduction in fees. To this end, many studies have reported on the feasibility of ACDF, cervical arthroplasty, posterior cervical foraminotomy, and lumbar decompression in the outpatient setting.[2–5,15]

Only in the past few years, however, can the same be said for lumbar fusions. In 2013 and 2014, the first 3 case series of outpatient transforaminal lumbar interbody fusions (TLIFs) were published.[16–18] From 2016 to 2018, 6 retrospective cohort studies were published that demonstrated comparable or superior safety profiles and patient-reported outcomes after outpatient lumbar fusion. Some of the studies examined the TLIF, while others focused on the lateral lumbar interbody fusion or the posterior lumbar fusion sans interbody.[6,19–23] And finally, in the year 2020 alone, 5 studies were published that again showed favorable outcomes for outpatient lumbar fusion.[24–28] The anterior lumbar interbody fusion was also included in these retrospective analyses.

Given this growing body of supportive evidence, there is reason to believe that the United States is currently at an inflection point with respect to outpatient lumbar fusion. Surgeons who perform other spine procedures at ASCs are already aware of the increased control, fewer bureaucratic hurdles, specialized staff, and financial opportunities inherent to that setting. Patients often see the benefits as well in the form of convenience and customer experience. There is evidence to suggest that satisfaction rates after spine surgery are increased in the outpatient setting.[14] The development that is most relevant, however, is a recent change in policy by the Centers for Medicare & Medicaid Services. The Centers for Medicare & Medicaid Services has removed posterior lumbar interbody fusion from its list of "inpatient-only" procedural codes, and commercial payers are also providing reimbursements outside the hospital setting. This will surely catalyze significant growth in outpatient lumbar fusion in the years to come.

NAVIGATION AND ROBOTICS

Advantages Over Traditional Techniques

The growing popularity and benefits of intraoperative navigation have been thoroughly described in the literature.[29–33] There is ample evidence that navigation improves the accuracy of pedicle screw placement when compared with fluoroscopy and freehand techniques.[34] Pedicle screw misplacement rates are reported to be as high as 15% to 20% with the freehand technique, 13% with fluoroscopy,[29] and 2% to 6% with navigation.[34] Navigation is particularly useful for minimally invasive procedures, wherein traditional bony landmarks cannot be directly visualized. One study compared navigation with fluoroscopy for pedicle screw placement specifically in minimally invasive TLIFs and reported a 96% accuracy rate with the former and a 92% accuracy rate with the latter.[35] It should also be noted that image guidance can be helpful not only during instrumentation, but also during the decompression and interbody phases of procedures.[36] Another significant advantage of navigation is a reduction in radiation exposure to the surgeon and operating room staff. Multiple studies have borne this out, specifically with minimally invasive techniques.[9,37,38] Although the patient often receives additional radiation—especially when intraoperative computed tomography (CT) is used for image registration—the total exposure is routinely less than that of a typical outpatient lumbar CT.[39]

Not surprisingly, spinal robotics also carries advantages with respect to pedicle screw accuracy and radiation exposure. Four meta-analyses have compared robot-assisted screw placement with the freehand technique—3 of the studies reported superior accuracy with robot assistance, and the fourth study showed an equivalence.[10,40–42] A study by Laudato et al demonstrated a 79% screw accuracy rate with the robot, as compared with 70% with navigation only. Similarly, Roser et al reported a 99% accuracy rate with the robot as compared with a 92% accuracy rate with navigation.[43] Multiple randomized trials have also demonstrated a lower risk of superior facet joint violation with robot-assisted screw placement, when compared against freehand or fluoroscopy-based placement.[44–46]

As expected, the use of a robot reduces radiation exposure to the surgeon and staff, just as intraoperative navigation does.[10] One criticism of spinal robotics is the assumption that it increases operative time; however, this has not been consistently proven in the literature. For example, a cadaveric study reported similar times for minimally invasive pedicle screw placement when performed with fluoroscopy vs robot assistance.[47] A second criticism, which is particularly germane for outpatient lumbar fusion, is that navigation and robotics are not worth the additional costs. This issue deserves focused attention.

Cost-Effectiveness

Although discussions around the cost of robotic systems naturally focus on the initial capital expenditure, which can reach $1 million at times, it is important to consider the indirect savings that can be achieved. A study of 557 thoracolumbar procedures by Menger et al found that minimally invasive operations with robotic assistance took 3.4 fewer minutes than nonrobotic cases, leading to projected annual savings of $5713. Robot assistance on all appropriate cases would have avoided nearly 10 reoperations, leading to cost savings of $314,661. Moreover, the robot would have converted 49 patients from open to minimally invasive procedures. This would have saved 140 hospitalization days ($251,860) and roughly 2 surgical infections ($36,312). All told, the use of a surgical robot would have yielded $608,546 in savings over the course of 1 year at an academic center.[48]

Early results from the prospective MIS ReFRESH study are consistent with these findings.[49] Surgeries performed with robotic assistance were associated with fewer complications and reoperations, both of which lead to significant costs. Another study demonstrated that patients undergoing robot-assisted procedures had shorter lengths of stay, in addition to fewer revision surgeries.[50] Again, these differences translate into indirect savings for hospitals. In a review of this topic, Fiani et al echo these observations and suggest that, although robotic technology is expensive, reductions in operative time and complications may result in long-term financial gains.[51]

Notably, the evidence is not unanimously supportive of this conclusion. A single study found that, after accounting for complications, revisions, and capital expenditures, robot-assisted lumbar fusions were more costly than nonrobotic cases.[52] The cost per quality-adjusted life year was also higher for robot-assisted cases ($29,785.64) as compared with nonrobotic ones ($5,824.71). However, the authors do point out that the cost per quality-adjusted life year with robotics remains well below acceptable "willingness-to-pay" thresholds.

BARRIERS FOR ADVANCED TECHNOLOGIES

Of the 14 published studies that report on outpatient lumbar fusion, only 1 explicitly described the use of navigation for pedicle screw placement.[16] None of the studies described the use of robot assistance. In the vast majority of cases, the screws in these cohorts were placed percutaneously or through Wiltse incisions, and so 2-dimensional (2D) fluoroscopy was the mainstay. The question then becomes, what are the barriers to adoption of navigation and robotics for outpatient lumbar fusion, and do the benefits outweigh the financial and nonfinancial costs?

Cost of Acquisition/Maintenance

The most obvious hurdle for the utilization of robotics (and navigation, but to a lesser extent) is the cost of acquisition and maintenance. Costs are a particular concern in hospital outpatient departments (HOPDs) and ASCs because these sites rely on reduced expenses to maintain healthy operating margins in the setting of lower facilities fees. As previously mentioned, 3 studies have examined the financial viability of spinal robotics—2 concluded that the use of a robot can be cost-effective, while the other suggested that it may not be (in its current form).[48,49,52] This begs the question—what is the true cost for utilizing a robotic system?

When the Mazor Renaissance system first came onto the market a few years ago, the price tag was nearly $1,000,000. The second-generation system, the Mazor X, was launched at a price point of $550,000—inclusive of hardware and installation, but exclusive of implants and disposables.[49] These examples suggest that, while the initial cost can be quite high, robotic systems are likely to become less expensive (and more practical) over time. Perhaps more importantly, robotic systems need not be acquired purely through large, 1-time capital expenditures. ASCs and HOPDs can agree to "earn out" agreements with vendors, whereby the robotic system is paid for by committing to use a certain quantity of the company's other implants over a period of time. Another avenue is to lease the technology rather than make an out-right purchase. These options make robotic systems more accessible to entities that do not have the budget for significant expenditures. It should also be noted that increased surgical volume, through the use of a robotic system, could allow the technology to pay for itself. Hospitals typically charge somewhere between $40,000 and $80,000 for lumbar fusions, such that revenue from 10 to 12 of those operations would theoretically cover the initial costs of a robot.[49] Spinal robotics has become a marketable asset for practices and hospitals, so it is quite conceivable to anticipate an expansion of business with the technology.

The Learning Curve

A second barrier to the adoption of navigation and robotics in the outpatient setting is the perception of a steep learning curve.[53] HOPDs and ASCs are designed to be very efficient environments, where all members of the operative and perioperative team work together seamlessly to provide a smooth patient experience. Studies have demonstrated that operative times for lumbar fusions are reduced in the outpatient setting as compared with traditional hospitals.[21] This is not surprising, given that ASCs must be even more cost-conscious than traditional hospitals, and every additional minute of surgery detracts from operating margins. In an unforgiving environment such as this, it is no surprise that surgeons are hesitant to incorporate new technology into their workflow.

Several studies have examined the "learning curve" for spinal robotics. Kam et al studied their own series of consecutive patients and found that robot-assisted screw placement was highly accurate, with short placement times and low complication rates. There was no significant difference in accuracy or operative times between the initial phase of robot utilization and later phases, suggesting that there was a very short learning curve.[54] Backer et al found that the time for anesthesia, surgery, and robot usage decreased over time, but also concluded that there was no major learning curve.[55] Urakov et al have also examined this issue and only found a (nonsignificant) trend toward improved efficiency with instrumentation as more cases were performed.[56]

Taken as a whole, one can conclude that the learning curve for robot-assisted pedicle screw placement is quite shallow. Surgeons who have already become accustomed to 3-dimensional (3D) navigation will likely find adoption of a robot to be even easier.

Lack of Utility

A third barrier to the adoption of navigation or robotics in the outpatient setting is the notion that they do not provide sufficient value to the surgeon or to patients. As value-based care becomes the norm, and lumbar fusions shift to the outpatient environment, technologies will only be considered if they provide unique and unequivocal benefits. It is important to document the advantages of navigated spinal robotics, beyond pedicle screw accuracy, which should be considered by ASCs and HOPDs.

One advantage is an oblique (or perhaps direct) lateral approach to the spine that is performed at the same time as posterior lumbar instrumentation. Pham et al have described 2-surgeon, simultaneous, single-position surgery—oblique lumbar interbody fusion and posterior fixation—using a robotic platform.[57] This type of surgery would not be practical without robotic assistance and enables a level of efficiency that was previously not possible. A second, related advantage is the ability to place pedicle screws in the lateral position.[58] This can be challenging when done manually due to unfamiliar ergonomics and angles, but robotic assistance adds real value—particularly for the "downside" screws. Here again, robotics enables a level of operative efficiency that would otherwise be difficult to achieve. Changing a patient's positioning from lateral to prone to perform a minimally invasive procedure can be a cause for hesitation when considering surgeries in an ASC of HOPD. The prospect of single positioning, by virtue of robotics, may increase the number of lumbar fusions that can be performed on an outpatient basis.

A third potential advantage of robotics, which was briefly touched on earlier, is a reduction in postoperative complications. Liounakos et al conducted a prospective study comparing lumbar fusions performed with robotic vs fluoroscopic guidance, and found that the robot was associated with an 86.3%, 83.2%, and 69.4% cumulative reduction in complication rates at 30 days, 90 days, and 1 year after surgery.[59] Robotic assistance was also associated with a 92.6% reduction in the reoperation rate at 90 days and a 66.1% reduction in the reoperation rate at 1 year. Outpatient lumbar fusion is growing in popularity due to an overarching prioritization of cost containment, and robotics appear to be consistent with that philosophy by helping avoid adverse events that are incredibly costly.

THE FUTURE OF TECHNOLOGY IN THE OUTPATIENT SETTING

Although certain advantages of robotics have been outlined here, the fact remains that the bar for investing in expensive technologies is high in the outpatient setting. Widespread adoption of navigated spinal robotics in ASCs and HOPDs is therefore likely contingent upon significant upgrades to the systems' capabilities. As of now, robot assistance is mostly utilized for pedicle screw placement. In the future, it is probable that robotic systems may be able to guide bony cuts, neural decompression, decortication, spinal reductions, and even wound closure.

Robot-assisted decompressions will become possible once magnetic resonance imaging (MRI) registration becomes feasible. Proof-of-concept studies have demonstrated some encouraging preliminary results, suggesting that MRI could be converted to synthetic 3D CT images that are then utilized by image guidance systems.[60] If robotic software could process a patient's MRI, it is quite plausible that a robotic arm with a burr could assist in the removal of compressive bony structures. Decortication of facets and other cortical bone could also be accomplished with a robot-assisted burr that is integrated with CT imaging. Furthermore, reduction of a spondylolisthesis during a minimally invasive TLIF could be aided by robotic software that helps select the optimum cage size and rod contour to achieve optimum results. Even now, it is possible to preoperatively plan the ideal placement of an interbody cage, and then use robotic assistance to deliver the cage in a manner that matches that plan. Additional capabilities such as these will accelerate the adoption of advanced technology in the outpatient setting.

One inadvertent consequence of the trend toward outpatient lumbar fusion will be the decentralization of surgical delivery. Lumbar fusion surgery is currently concentrated in high-volume, traditional hospitals where other spine surgeries and nonspine surgeries are also performed. As ASCs and HOPDs assume more of these cases, there will be a geographic dispersal that will make data sharing more challenging. Robotics will likely provide an elegant solution to this problem. Robotic software will soon be able to quantify and track the movements of the Computer Numerical Control (CNC) arm and its end effectors as various steps of lumbar fusion procedures are performed. This will allow unique data on the thoroughness of decompressions and arthrodesis, as well as the positioning of implants, to be stored and pooled across various sites. By sharing data between robotic workstations that are geographically separated, outpatient surgeons will be able to maintain collective operative databases that overcome the limitations of distance.

CONCLUSIONS

Outpatient lumbar fusion is a growing trend which, at face value, can seem at odds with the adoption of newer technologies such as 3D navigation and robotics. A careful analysis reveals, however, that these technologies can provide financial gains in the outpatient setting if indirect costs are taken into account. Robotics in particular can also increase the efficiency of certain lumbar fusion procedures, making them eligible for ASCs and HOPDs when they may not have been otherwise. Furthermore, future developments in robotic technology will likely increase its advantages, as the costs of the systems come down. Novel payment schemes are also emerging which will increase the accessibility of spinal robots. For all these reasons, it is safe to conclude that advanced technologies will likely become a mainstay of outpatient spine surgery.

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