Perspective on robotic spine surgery: Who’s doing the thinking?

Nancy E Epstein MD

Clinical Professor of Neurological Surgery, School of Medicine, State U. of NY at Stony Brook, NY and ½ Dr. Marc Agulnick, 1122 Franklin Avenue Suite 106, Garden City, NY 11530, USA.

E-mail: *Nancy E Epstein - nancy.epsteinmd@gmail.com

*Corresponding author: Nancy E. Epstein, M.D., Clinical Professor of Neurological Surgery, State University of New York at Stony Brook, NY, and Dr. Marc Agulnick, 1122 Franklin Avenue Suite 106, Garden City, NY 11530, United States nancy.epsteinmd@gmail.com

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ABSTRACT

Background: Robotic assisted (RA) spine surgery was developed to reduce the morbidity for misplaced thoracolumbar (TL) pedicle screws (PS) resulting in neurovascular injuries, dural fistulas, and/or visceral/other injuries. RA is gaining the attention of spine surgeons to optimize the placement of TL PSs, and to do this more safely/effectively versus utilizing stereotactic navigation alone, or predominantly free hand (FH) techniques. However, little attention is being focused on whether a significant number of these TL RA instrumented fusions are necessary.

Methods: RA spine surgery has been developed to improve the safety, efficacy, and accuracy of minimally invasive TL versus open FH PS placement.

Results: Theoretical benefits of RA spine surgery include; enhanced accuracy of screw placement, fewer complications, less radiation exposure, smaller incisions, to minimize blood loss, reduce infection rates, shorten operative times, reduce postoperative recovery periods, and shorten lengths of stay. Cons of RA include; increased cost, increased morbidity with steep learning curves, robotic failures of registration, more soft tissue injuries, lateral skiving of drill guides, displacement of robotic arms impacting accurate PS placement, higher reoperation rates, and potential loss of accuracy with motion versus FH techniques. Notably, insufficient attention has been focused on the necessity for performing many of these TL PS instrumented fusions in the first place.

Conclusion: RA spinal surgery is still in its infancy, and comparison of RA versus FH techniques for TL PS placement demonstrates several potential pros, but also multiple cons. Further, more attention must be focused on whether many of these TL PS instrumented procedures are even warranted.

Keywords: Complications, Free hand: Pedicle screw placement, Morbidity, Robotic spine surgery: Neuronavigational, Skiving, Unnecessary fusions, Unwarranted surgery

INTRODUCTION

Robotic assisted (RA) spinal surgery was developed to reduce the frequency of neurological, vascular, visceral, and other injuries resulting from thoracolumbar (TL) pedicle screw (PS) fusions.[6] By 2019, the United States Food and Drug Administration had already approved 7 spinal RA devices manufactured by 4 companies for placing TL PS.[8] Potential pros for RA TL PS placement included; enhanced screw location/accuracy (i.e. improved visualization, dexterity), reduced morbidity, less surgeon/staff radiation exposure, and shorter operative times amongst others.[6-8,10-13] However, cons also included; the increased cost of RA, screw skiving resulting in inaccurate screw placement,
potential displacement of the robotic arm with patient motion, higher reoperation rates, and steep learning curves.\textsuperscript{[1,2,5,9,11,13,16]} Here, we have compared the pros and cons for TL PS placement utilizing spinal RA versus predominantly free hand (FH) techniques. Additionally, we have raised the question as to why and whether a significant subset of these procedures should be performed in the first place.

HISTORY OF RA FOR SPINE SURGERY

In 2004, the FDA approved the first RA device for spinal surgery in the USA; Mazor Robotics Ltd. (Caesarea, Israel).\textsuperscript{[2,13]} RA was developed to reduce the incidence of TL PR-related complications seen with FH techniques.\textsuperscript{[1,2,6-16]} Fan et al. (2018) summarized the incidence of FH lumbar PS complications as ranging from 5% to 41%, while the range for misplaced thoracic screws varied from 3% to 55%.\textsuperscript{[6]}

COMPARISON OF ACCURACY OF RA VERSUS FH TL PEDICILE SCREW PLACEMENT

Different studies compared the safety/efficacy and pros/cons of RA versus FH transpedicular screw placement in the thoracic or lumbar spine.\textsuperscript{[6,10,11,12,13]}

SUPERIORITY OF FH OVER RA PLACEMENT OF PS IN THE LUMBAR SPINE

In a prospective randomized single center study, Ringel et al. (2012) looked at the safety/efficacy of PS placement for one or two-level lumbar fusions utilizing RA versus FH techniques [Table 1].\textsuperscript{[12]} Postoperative CT studies used Grades A-E to document the accuracy of PS screw placement; Grade A: no cortical violation; Grade B < 2 mm breach all the way to Grade E: >/= 6 mm pedicle violation. Of 298 PS placed in 60 patients (FH, 152; RA, 146), 90% of FH, versus a lower 85% of RA screws were optimally placed (i.e., defined as Grades A/B).

SUPERIORITY OF RA VERSUS FH TECHNIQUES FOR TL PEDICILE SCREW PLACEMENT

Several studies documented the superiority of TL PS placement using RA-based versus FH techniques [Table 1].\textsuperscript{[6,7,9,11-14,16]} In 2017, Joseph et al. considered RA for spine surgery to be in its infancy.\textsuperscript{[9]} The Gertzbein and Robbins grading system revealed an overall 85–100% accuracy of screw placement (i.e. accuracy as determined by Grades A or B: Grade A-no pedicle breach, Grade B-minimal pedicle breach). In a meta-analysis of 10 articles (2011–2016) involving 597 patients, 12 cadavers and 2937 screws, Fan et al. (2018) demonstrated more accurate screw placement for RA versus FH techniques as confirmed on postoperative CT-studies (i.e. pedicle breach of ≤3 mm).\textsuperscript{[6]} When Ghasem et al. (2018) reviewed 32 RA versus FH articles for TL PS instrumentation, the accuracy was at least comparable if not superior using the RA techniques.\textsuperscript{[7]} Khan et al. (2019) retrospectively evaluated the accuracy for lumbar PS placement in 20 patients with/without degenerative spondylolisthesis using the Mazor X (Mazor Robotics Ltd, Caesarea, Israel) RA device, and employed the Grade I-IV scale (i.e. Grade I [no pedicle breach], to Grade IV [breach >4 mm]) [Table 1].\textsuperscript{[10]} They found that 74 (98.7%) of screws were optimally placed (Grade I) placed at 24 spinal levels, only one screw (1.3%) was Grade II (medial <= 2 mm), and there were no adverse events.

MINIMAL LEARNING CURVE AND PROS FOR RA VERSUS FH TL PS PLACEMENT

Minimal learning curve for RA versus FH screw placement

Two studies clearly documented a minimal learning curve for accurately placing TL PS using RA spinal techniques [Table 1].\textsuperscript{[10,15]} When Khan et al. (2019) performed lumbar PS placement in 20 patients using the Mazor X (Mazor Robotics Ltd, Caesarea, Israel) RA device, 74 (98.7%) screws were optimally placed (Grade I: no breach), only one screw (1.3%) was in Grade II (medial breach <= 2 mm), and there were no adverse events.\textsuperscript{[10]} Vardiman et al. (2020), using the minimally invasive RA CT-based Gertzbein and Robbins system found that 600 screws placed in the TL spine showed no/minimal breach (Grades A/B) in 98.7% of cases when they were placed by an experienced attending surgeon, and a 97.67% accuracy for the inexperienced resident’s RA spinal cases.\textsuperscript{[15]} Further, only 9 screws (1.5% of 600) in Grade C required intraoperative repositioning (Grade C), while none were in Grade D.

Pros for RA versus TL PS Placement

Potential benefits for RA placement of TL PS included; greater safety/efficacy/accuracy of PS placement, reduced complications, the ability to adapt RA to intraoperative navigational techniques, less radiation exposure (i.e. to the patient, surgeon, and staff), shorter operative/postoperative recovery times, a shorter average length of stay, smaller incisions, reduced blood loss, and lower infection rates [Table 1].\textsuperscript{[2,6,7,9,11-14,16]} Further, future RA techniques could be applied to; the resection of spinal tumors, ablations, vertebroplasties, spinal deformity, bony decompressions, dural closures, and pre-planned osteotomies.\textsuperscript{[2,7,13,14,16]}

Steep learning curves and cons for RA spinal surgery

Cons for RA spinal surgery included; steep learning curves, greater cost, and technique-related difficulties compromising surgical accuracy [Table 1].\textsuperscript{[9,12,13]} Ringel et al. (2012) found significant weaknesses in the robotic spinal system; “One of
| Author Reference Year | Study Type | Numbers of Patients | Other Data | Other Data | Outcomes |
|-----------------------|------------|---------------------|------------|------------|----------|
| Epstein: Perspective on robotic spine surgery: Who’s doing… | | | | | |
| | | | | | |
| Ringel et al. | RCT; FH versus RA | LS ScP 298 PS in 60 PT; Randomized 1: 1 FH versus RA for PS Fluoro FH 152 versus RA 146 Results Check Postop CT Grades PScP: Screw A: no Breach, B: cortical breach <2 mm; C: ≥2 mm to <4 mm; D: ≥4 mm to <6 mm; E: ≥6 mm). | Grade Local Screws A–E >Accuracy FH>RA 93% GP (A or B) in FH 83% GP (A or B) RA | MalS LAT AE SKIV Shorter OR FH 84 min versus RA 95 min | AE: 10 RA Screws Intraop Con to FH 1 FH SR |
| Joseph et al. | Analysis 25 studies Using 2 Robots Gertzbein and Robbins | Accuracy Screw Placement: Screw A-Screw E Good Grades A/B 85-100% | 10 Studies RTE 1.3 to 34 seconds per screw Impact of RA on RTE Not Clear | 9 Studies SLC | 12 Studies AE Registration Failure Lateral Skiv Accuracy PScP Appears High AE for RA - Screw Skiv Conclude RA As Accurate as FH if not better |
| Ghasem et al. | Review-32 Articles RA versus FH PS | RA Findings: Trend Less RTE But SLC | RA Longer Or Time | RA Trend Reduce LOS | |
| Fan et al. | 2011-2016-1682 Robot Assisted versus 1255 FH PSC-597 PT; 12 Cadavers-2937 Screws | Theory Advantages RA: Lower AE, Shorter RTE, Shorter LOS, Smaller incision, Decreased EBL, Fewer Infections, SLC Meta-analysis 10 Articles Risks Misplaced Screws Damage: Neurological, Vascular, Dural Tear, Visceral | Defined: Perfect Screw Placement: 100% within pedicle Clinically Acceptable; <3 mm outside pedicle without significant injury | Accuracy Better experience | Range misplaced screws FH-5-41% Rate lumbar; 3-55% Thoracic Cited Paper by Ringel et al. RA 85% versus 93% FH and 10 required Revision |
| D’Sousa et al. | Accuracy ScP 92–98.3% MalR 0.7%, 3.9% versus 5.6% | Robot Aims:< RTE IF 10–12 X >RTE RA May Reduce RTE by 30% | Potential to Reduce AE Skiv MalS | Longer OR RA199.1 min versus 119 min without Decreased Recovery Time RA High Cost SLC High Cost-SLC |
| Staub and Sadrameli | Increase Accuracy ScP - Risk SLC | 2004 Mazor Spine Assist Robot (First) | Limited PScP | |
| Kochanski et al. | Theoretical Advantage PScP with RA Greater Accuracy | Decreased MalR P Unknown Clinical Outcome | Deformity Complex Anatomy TL PScP | Future Tumor Resection | Reduce RTE Surgeon Staff Concerns; Cost, Work Flow, OR Time, LOS |
| Khan et al. | Next Generation RA Lumbar PScP-20 Patients-75 Screws-24 Levels | Feasibility Safety Learning Curve Mazor Z | Accuracy PScP Grade I No Breach Grade II Breach <2 mm Grade III Breach 2–4 mm Brace IV Breach >4 mm | 74/75 Screws Grade I (98.7%) 1 Screw Grade II (Medial 1.3%) Mean Time per Screw 3.6 min Mean Fluoro time 13.1 s Mean RTE Does 29.9 mGy | RA After IF for DDD ± DegS Safe Reliable Accurate Minimal Learning Curve |
| Staub and Sadrameli | J Spine Surg 2019 | |
| Khan et al. | Oper Neurosurgery (Hagerstown) 2019 | |

(Contd...)
In 2019, Kochanski et al. reviewed 12 studies, found additional failures regarding RA spine surgery; registration failure, soft-tissue hindrance, and lateral skiving of the drill guide. Crawford et al. added to these RA risks: "skiving of the tool on bone, displacement of the robotic arm, or patient movement."[12]

### TIMES FOR PREPARATION, SURGERY, AND RADIATION EXPOSURE WITH RA VERSUS FH

Comparable or shorter times for preparation, surgery, and radiation exposure using RA vs. FH techniques

When Ringel et al. (2012) evaluated 298 screws (FH 152, RA 146) placed in 60 patients, the preparation time, operating times, and intraoperative radiation exposure times were similar for both populations [Table 1]. In 2019, Kochanski et al., after comparing RA versus Image-Guided Navigation for performing TL PS instrumentation in deformity/complex spine procedures, noted that both procedures reduced radiation exposure requirements.[11]
Longer times for preparation, surgery, and radiation exposure for RA vs. FH techniques

Several authors documented that RA spinal procedures required longer operative times, and higher doses/longer duration of radiation exposure versus FH techniques [Table 1]. However, a learning curve effect was noted for RA surgery, wherein initially longer operations, longer radiation exposure times, and longer duration of operations decreased with experience. Additionally, Ghasem et al. cautioned that “screw trajectories should be checked,” as “drilling pathways (were/could be) altered by soft tissue pressures, forceful surgical application, and bony surface skiving.”

NEED TO RECONSIDER AND ACKNOWLEDGE HIGH RATE OF UNNECESSARY TL PS SPINE FUSIONS UTILIZING RA VERSUS FH TECHNIQUES

Future studies may better document that RA offers technological advantages over FH procedures for placing TL PS. Nevertheless, one should exercise better clinical judgment as to whether and when these procedures are warranted [Table 2]. Here, we defined unnecessary surgery as operations recommended to patients by another surgeon for pain alone, without significant neurological deficits, or significantly abnormal X-ray, MR, or CT findings. In 2011, Epstein found that 47 (17.2%) of 274 patients coming in for second opinions were scheduled for unnecessary spinal surgery; 21 (23.1%) of 91 were scheduled for unnecessary cervical procedures/fusions, and 26 (14.2%) of 183 for unnecessary single/2-5 level lumbar interbody fusions. This 2011 review article also focused on the incidence of overly extensive spine operations being offered to patients age 65 and older. Further, in 2013, out of 183 second opinions performed by Epstein over a 20 month period, 111 (60.7%) needed no surgery, 61 (33.3%) were told to have the wrong surgery, and 11 (6%) were told to have the right operation.

CONCLUSION

RA spinal procedures are still in their infancy as confirmed by the continued controversy regarding the relative safety/efficacy and pros/cons of RA versus FH techniques for TL PS placement/instrumentation [Tables 1, 2]. Clearly, more attention needs to be focused on whether and when to utilize TL PS instrumented fusion procedures, and how to better analyze/determine if they are warranted.

Table 2: Summary of Epstein's Articles on Unnecessary Spine Surgery.

| Author Reference Journal | Study Aims | Definitions and Study Design | Study Findings | Conclusion |
|--------------------------|------------|------------------------------|----------------|------------|
| Epstein[3] SNI 2011      | Unnecessary spinal surgery: One year study on one surgeon's experience | Definition; told needed spinal surgery by another surgeon but had pain alone no neurological deficits and no significant abnormal X-ray/MR/CT findings | Unnecessary lumbar surgery 26 (14.2%) of 183 patients: Told to undergo single/multilevel lumbar interbody fusions 13-1 Level 7-2 Levels 3-3 Levels 4-2 Levels 1-5 Levels | Unnecessary cervical surgery 21 (23.1%) of 91 patients: 1-4 Level ACDF (18 Pts.) 1 Lam/Fusions (2 Pts.) Posterior discs (1 Pt.) One year 47 (17.2%) of 274 spinal consultations scheduled for unnecessary spine surgery |
| Epstein[4] SNI 2011      | Increased frequency unnecessary spine surgery patients ≥65-years-old | Unnecessary: Too many instrumented fusions | Quoted 2010 report 28 X increase ACDF: >Comorbidities >>Postop Complications | Quoted study 40% complication rate for decompressions/Limited fusions (average age 70.4) versus 56% complication rate for full curve Fusions (average age 62.5) |
| Epstein[5] SNI 2013      | Quoted 2012 Gamache findings 69 (44.5%) of 155 second opinion cases told by outside surgeons needed surgery seen over 20 months | 183 second opinion cases told by outside surgeons 111 (60.7%) needed no surgery 61(33.3%) were told to have the wrong surgery 11 (6%) told the have the right operation |

ACDF: Anterior cervical disectomy/fusion, SNI: Surgical neurology international, Pts.: Patients, PLIF: Posterior lumbar interbody fusion, Postop: Postoperatively.
Declarations of patient consent

Patient’s consent not required as there are no patients in this study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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COMMENTARY 1

Training

The issue of what training is appropriate for RA surgery is an on-line course, a weekend course, incorporation of RA training within a spine fellowship, or the presence of the robotics representative for every case. Ideally, patients with significant polytrauma and multiple complex TL fractures will be treated in a tertiary care or trauma center. These tertiary centers are more likely to have a fellowship trained spine surgeon on staff, and a robot. This would allow for the volume needed to solve the problem of a steep learning curve, and enough familiarity with complex fractures, spinal biomechanics, and RA surgery to trouble shoot difficult cases such as highly unstable fractures which may move with patient positioning. The use of RA surgery could instill a false sense of confidence in those surgeons who typically don’t do complex spine surgery to leave their comfort zone; this is concerning for the performance of inappropriate surgeries or unnecessarily long constructs.

Monitoring

Who monitors the accuracy of the robots-the surgeons, the robot representatives, or operating room personnel? Equipment that is moved for every case and potentially bumped multiple times is bound to lose accuracy over time. Accuracy should be checked between cases, not just when there is a miss or malfunction. From a medical-legal perspective, if the equipment is owned by the hospital, it would be their responsibility to ensure the equipment is checked unless a purchase agreement included a lifetime representative. It is also concerning that any instrumentation can be used with a given robotic system. Or, on the other hand, does this force the surgeon to use the specific spinal instrumentation that is manufactured or distributed with the robot. This creates a situation of monopoly with the robot/instrumentation company, and risks having a surgeon use instrumentation that they are less familiar with which can increase the incidence of inadvertent mistakes, and additional OR time.
Costs

Does the potential accuracy of thoracic screw placement replace the need for intraoperative monitoring, or just add an additional cost of increased OR time and disposables? Does bundling of the robot and the spinal instrumentation increase the price of the spinal instrumentation in efforts to decrease the cost of the robot? Will RA be demanded by patients for all lumbar cases since it is a potential marketing tool? All these factors must be accounted for when determining the value and efficacy in spinal surgery, otherwise we are driving costs up without added benefit.

Prof. Jamie Baisden MD
MCW-Neurosurgery
HUB 4th Floor
8701 Watertown Plank Rd
Milwaukee, WI 53226
Cell 262 902 0059
Phone: 414 248-4997

COMMENTARY 2

My impression before reading Nancy’s paper was that there was a substantial “learning curve” for the use of robotics and that Free Hand placement was very good in experienced surgeons hands.

How much time did the new technology take, was technical help necessary to run the equipment, did the equipment fail, was the final placement of the screws accurate, was there a higher infection rate because of the use of the technology, will the surgeon’s judgment be better because of the technology, or will his/her abilities be the same using the technology? In using navigation technology for brain surgery, I have found that the technology failed 1/3 of the time because of new people using it who were unfamiliar with it.

Her paper says just that. There is an impression being formed that robotic surgery will take over as a technology for spine surgery, which will make the manufacturers money. It is a new product from the manufacturer. They need to have new products. The learning curve is not important to them; that is the doctors’ problem, not theirs.

What you might want to consider is how many patients will be required to be successfully done using robotic technology to overcome the “learning curve”? Its’ complications should be counted as misplacement in the physician’s data and included in the reporting of results. For example, if a surgeon is doing a procedure and has 1 death, he/she needs to do 99 without any deaths to make the mortality rate 1%!

By “learning curve”, who plays the price? The patient. The reporting of complications can be questioned. For example, the interventionists only record complications for 24 hours! What about delayed rupture of an aneurysm, which I have seen, a week after the procedure, because of improper coiling. Isn’t that a complication? The “learning curve” complications in patients should be reported as complications, not as a “learning curve”.

How do people define complications? If the “learning curve” is used and discarded, or no complications are recorded after 24 hours, what does that mean compared to complication reporting as in the past. In previous times, all complications after the procedure, defined up to 30 days, were counted against the procedure or treatment. These complications would not have occurred if the procedure was not done; so, they are all attributed to the choice of treatment.

I support new technology and ideas. But “compared to what?” is the question. There are ways to diminish the “learning curve” for new procedures. It is the physician’s responsibility to learn how to use the technology. This learning can be accomplished by practicing the new procedure in a laboratory, or morgue to diminish complications. Yes, that takes extra time and money, but that is what is best for the patient.

This is a different world. People are playing by different rules, their own rules to fit their agenda. That is not the actual TRUTH. But for some, truth does not matter. It is all about perception… and money.

James I. Ausman, MD. Ph.D.
Emeritus Editor-In-Chief
Surgical Neurology International

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