Dennis G. Crandall, MD

Spinal Reconstructive Surgery

Sonoran Spine Center | Mayo Clinic School of Medicine | University of Arizona School of Medicine

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Arizona Medical Board

[redacted]

Dear Board Members,

I have been asked to review the pertinent medical documents, imaging, and other pertinent medical records regarding the case of [redacted] the medical malpractice case resulting from the surgery on [redacted] I have agreed to perform an analysis from the perspective of local, regional, and national standards in spine care, with the understanding that I would honestly opine whether favorable or unfavorable. I am not currently and have never been a practice partner with Dr. Pitt. I have never traded call with him, or engaged with him socially. I know him as a colleague in the community.

The basis of my analysis comes from my experience as a past Arizona Board case reviewer, current Clinical Professor of Orthopedic Surgery at the University of Arizona School of Medicine in Phoenix, current Adjunct Associate Professor for the Mayo Clinic College of Medicine and Sciences, Head of Spine Surgery Education for the Mayo Clinic Orthopedic Surgery Residency Program, and a current Board Examiner for the American Board of Orthopedic Surgeons (ABOS). Through my experience in these areas or responsibility, I am well versed on what is currently taught to orthopedic surgery residents and fellows, the standards of care that are used to evaluate my spine surgery colleagues, and the standard of care required for Board Certification (as an ABOS board examiner).

On analysis of this case, I have identified **five potential points of accusation** from the plaintiff in this case against Dr. Pitt that appeared to be the major points upon which the case was argued during the medical malpractice trial. These five points include:

1.) the indication of surgery,
2.) whether C2-3 was ankylosed (which potentially could have made the surgery unnecessary),
3.) the complication of the esophageal tear, (is it a known complication?)
4.) the way the complication was handled postoperatively,
5.) The question of whether revision cervical spine surgery was appropriately performed at a surgicenter.

I will address each of these areas.

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1. Indication for Surgery

Adjacent level degeneration next to a fusion (such as C3 through 6 in this case) is a common complication. Tobert, et al (Clin Spine Surg 2017;30:94-101) occurs between 2 – 4% per year after a fusion and is a significant contributor to reoperation rates. Kong, et al (Medicine 2016; 95: E4171) described adjacent level cervical spine disease in a large meta-analysis looking at 83 different studies. The incidence appears to approach 3% per year of adjacent level degeneration on imaging, and 1.5% per year of symptomatic adjacent level disease. Adjacent level degeneration occurs even if a total disc replacement is performed (Nunley, et al. Spine J 2013; 13: 5-12). As noted in a series of 763 total disc arthroplasty patients enrolled in the FDA clearance study. Adjacent level disease occurs at similar rates in patients who underwent cervical fusions as patients who underwent cervical disc replacement (Miller, et al. Clin Spine Surg 2018;31:E98-E101). In our own database at Sonoran Spine Center in Tempe, Arizona consisting of approximately 8000 patients operated on since 2001, the radiographic adjacent level arthrosis is noted to approach 30% at ten years after surgery. In short, performing C2-3 anterior fusion for adjacent level degeneration is not unusual, is within the community standards, and is what is taught to orthopedic surgery residents and fellows and is the standard the American Board of Orthopedic Surgeons holds for board certification and recertification.

2. Was C2-3 ankylosed (auto-fused) or was it still mobile and a potential source of pain?

There was some opinion offered by the plaintiff's expert that C2-3 had gone on to ankylosis or auto-fusion. If that was the case, the surgery at C2-3 would not have been indicated in the first place. Lateral flexion-extension views of the cervical spine on 6/26/2014 show C2-3 moves and there is a vacuum sign within the degenerative joints. On the 3/22/2016 radiographs, the C2-3 facet joints are open and clearly visible (not ankylosed). My personal review of the CT scan of the cervical spine on 6/21/2016 notes the right sided C2-3 facet joint is severely arthritic, but is not ankylosed. The joint line is still apparent on multiple angles of CT images. In summary, the C2-3 segment was not ankylosed and would therefore be expected to be a predictable source of pain.

3. The complication of the esophageal tear in revision cervical surgery

Esophageal injury in anterior cervical spine surgery is a known complication (Daniels et al. J Am Acad Ortho Surg 2008; 12: 729-738). Though the risk is small, the risk is higher in revision surgery. Other similarly rare complications that are known to occur in anterior cervical spine surgery include injuries to the trachea, the vertebral arteries, the carotid arteries, the jugular veins, hematoma, airway compromise, spinal cord injury, dural tear, dysphagia, dysphonia, Horner's syndrome, laryngeal nerve palsy, and graft

dislodgement. In a single surgeon large series of more than 1,000 patients published by Nanda, et al. (World Neurosurgery 2014; 82: 1380-87), an esophageal tear was encountered. Kostas, et al (Spine 2007; 32:2310-17) in a review of 1015 patients encountered esophageal tears in 0.3%. In summary, esophageal injuries are a known complication that has been taught by spine surgery Professors since the introduction of anterior cervical spine surgery by Smith and Robinson for decades. Delayed esophageal tears have also been described (Lee, et al. Spine J 2015;15:75-80).

4. Was the complication managed appropriately by Dr. Pitt?

I reviewed the way the surgical complication was handled by Dr. Pitt. When a complication such as this occurs, the surgeon must recognize the complication as promptly as possible, provide prompt care to handle the potentially negative outcomes from the complication, and keep open communication with the patient through the treatment pathway so the patient understands that the complication has occurred and what is happening to correct it. It appears that Dr. Pitt followed this "best practices" algorithm, even breaking scrub during the surgery to discuss the technique for esophageal rent repair with an otolaryngologist, and subsequently transferring the patient immediately to the care of that otolaryngologist at a hospital.

5. Is revision anterior cervical spine surgery appropriately performed in an ambulatory (same day surgery) Surgicenter?

Lastly, there was some discussion regarding whether patients should undergo revision cervical spine surgery at a surgicenter. In Arizona, such practices are not only common, but are standard. Chatterjee, et al (N Am Spine Soc J 2022; PMID 35783006) noted the increase in surgeons performing outpatient anterior cervical spine surgery led to a shift in case volumes (efficiency). Even three and four level surgeries appear to be safely performed (outcomes in 723 patients vs 2718 patients operated inpatient; Boddapati, et al. Spine J 2021;21:231-238). Lee, et al (Evid Based Spine Care J 2014;5:101-111) noted in 2014 that a review of 5 studies meeting inclusion criteria showed no difference in complications regardless of where surgery was done. Helseth, et al (Br J Neurosurg 2019;33:613-619) reviewed 1300 outpatient cervical spine surgery cases, with 1.2% major complications including major neurologic deterioration and other life threatening complications. The authors concluded outpatient surgery was safe, had a low complication rate, a low hospital admission rate, and a low re-operation rate at 1 year. Outpatient surgery was noted to be more cost efficient (less expensive) than inpatient surgery. Helseth also published the results of his series of 1449 consecutive cervical spine outpatient surgeries, noting feasibility and safe outcomes (Neurosurgery 2015;76:737-738). Ban, et al (Eur J Med Res 2016;21:34) in a meta-analysis or 12 articles noted similar risks, morbidity, but decreased cost with outpatient surgery. Similar studies were published by Adamson (J Neurosurg Spine 2016;24:878-884) of

1000 consecutive surgeries done outpatient who noted a 2.2% hospital readmission rate within 30 days, and similar results compared to inpatient surgery. The authors from Vanderbilt University noted the surgery "can be safely performed in the outpatient surgery setting without compromising surgical safety." Gennari (Orthop Traumatol Surg Res 2018;104:581-584) also noted cervical spine surgery can be safely performed in the outpatient setting.

A standard prerequisite for performing any spine surgery at an outpatient ambulatory surgery center is to have a patient transfer agreement with a major trauma center if any emergencies are encountered. This appears to have been in place in the surgery with [redacted]

Summary Analysis

From the standpoint of the surgical indications, this patient underwent an appropriate surgery for appropriate indications. She sustained a known though rare complication that was handled in the correct fashion, with care taken to maximize the outcome by including consultation and service transfer to otolaryngology after the complication had occurred. I am at a loss to explain the jury's verdict in this case. What I can explain, however, with full confidence, as an academic spine surgeon at two universities in the Phoenix area, and participating nationally as an Board Examiner with the American Board of Orthopedic Surgeons, Dr. Pitt did in fact meet the standards of care in this case. If this case was presented to the American Board of Orthopedic Surgeons Board Examiners for board recertification, Dr. Pitt would pass. I view the ultimate clinical result in this clinical case as a good. The patient had a rare complication. The surgery however was certainly indicated, and appropriately performed in a standard outpatient surgicenter venue, consistent with local and regional spine community patterns of care and consistent with the requirements of the American Board of Orthopedic Surgeons.

If I can provide any additional information regarding this case, please don't hesitate to get in touch with me.

Sincerely,

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