



Contents lists available at ScienceDirect

## North American Spine Society Journal (NASSJ)

journal homepage: [www.elsevier.com/locate/xnsj](http://www.elsevier.com/locate/xnsj)

## Commentaries

## The use of image intensifier during scoliosis surgery: Perhaps not medico-legally obligatory; probably still the best practice

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In this edition of NASSJ, the authors present the results of a survey directed to scoliosis surgeons in the U.K. exploring their opinions regarding the intraoperative use of image intensifier [1]. Although 68% of the respondents affirmed they always use image intensifier during scoliosis surgery, 66% mentioned that, in their opinion, such a practice is not medico-legally mandatory.

Overall, such results are quite interesting insofar as they reveal a natural reluctance by the part of most surgeons to consider even practices that are an integral part of their routine as standards which should be universally applied to other practitioners.

First, it must be highlighted that, because only a low percentage of surgeons actually responded to this survey (36.5% response rate with a total of only 34 surgeons), the generalizability of this study's findings may be quite limited, even inside the U.K.

Second, although the authors emphasize that the current literature demonstrates similar rates of neurological complications between free-hand technique, fluoroscopy-assisted and navigation-assisted pedicle screw insertion [2,3], it is also true that the best available evidence on the issue demonstrates a significant difference between overall accuracy rates at each step of the ladder from free-hand technique to fluoroscopy-assisted screw placement and finally to navigation-guided techniques, especially in the thoracic spine [2,4,5,6].

As emphasized by the authors, there are three main reasons why spine surgeons may choose to employ an image intensifier during scoliosis surgery. First, to confirm the levels to be instrumented; second, to assist during screw placement or to confirm the accuracy of placed screws; and third, for evaluation of the obtained curve correction. Personally, I believe the first of these reasons constitutes the most compelling argument for obtaining at least one radiographic image during such type of complex surgeries. Taking into account the incidence rates of wrong-level surgery as revealed by the current spine surgery literature [7,8] (clearly an unacceptable occurrence which should be actually a "never event"), at least in the U.S, it seems an almost universal practice to obtain intra-operative x-rays before starting a laminectomy, even for simple pathologies such as a lumbar disc herniation. The third reason (namely, verifying the obtained correction of the scoliotic curve) seems to be another quite persuasive argument for obtaining at least one intra-operative fluoroscopic image, especially as, according to the literature, the success of scoliosis surgery in terms of long-term clinical

outcomes seems be strongly correlated with proper restoration of sagittal and coronal balance [9,10].

Finally, although I acknowledge that there is some evidence that surgical experience may significantly increase accuracy rates of free-hand pedicle screw placement [11], not obtaining at least one fluoroscopic image at the end of the case for verification of screw placement seems a quite extreme position, which likely reveal an excessive level of confidence, especially taking into account the fact that the accuracy rates of the free-hand technique in scoliosis surgery described in the literature are far from 100% [12,13]. Although it has been demonstrated that intra-operative plain radiographs may still fail to diagnose up to 5% of the screws which, according to a CT-scan, may be considered misplaced [14], such a technique is able to properly identify almost all grossly misplaced screws, which are the ones that may eventually require revision.

Although it seems undeniable that there is an emerging body of literature focused on the deleterious effects of radiation exposure both to the surgical staff as well as to patients [15,16], it should be noted that the vast majority of patients with scoliosis are already submitted to multiple radiographs pre-operatively, either to evaluate their curves as well as sagittal and coronal alignment, or as part of the pre-operative anesthesiological evaluation, which typically includes chest x-rays especially when considering elderly patients. Taking into account that the whole surgical staff (except, possibly, for the radiology technician) could leave the room during a one-shot fluoroscopic image or while obtaining a plain radiograph, it seems, at least to me, that justifications based on concerns regarding exposure of the surgical staff to radiation seem quite weak in this case. Ultimately, a future study focused on a cost-benefit analysis of the use of intraoperative fluoroscopy in scoliosis surgery would be quite interesting, especially if employing a meticulous methodology which differentiates between how many times intra-operative radiographic images are obtained, and which includes a careful comparison between the available rates of revision surgeries with each technique as well as an estimation of the incremental risk of deleterious radiation effects upon patients and surgical staff for each millisievert (mSv) of radiation exposure.

Finally it should be pointed that the very concept of "medico-legally necessity" is quite unclear and vague. From a legal perspective, at least in U.K and U.S. common-law systems, there is no cause of action unless

DOI of original article: [10.1016/j.xnsj.2020.100024](https://doi.org/10.1016/j.xnsj.2020.100024)E-mail address: [tobias.mattei@health.slu.edu](mailto:tobias.mattei@health.slu.edu)<https://doi.org/10.1016/j.xnsj.2020.100027>

Received 8 September 2020; Accepted 8 September 2020

Available online 10 September 2020

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there is an objective injury which can be traced to medical negligence in a causative manner. Therefore, from a practical standpoint, no adjuvant surgical technique (including the use of microscope or fluoroscopy) is *per se* “medico-legally necessary”, as long as the surgery occurs without any complications and the outcomes are favorable. In terms of medical litigation, a more relevant question is: Are there standard practices which, in the case of known and well-described complications of spine surgery procedures, may significantly reduce the chances of a successful malpractice litigation against the physician insofar as their use denote an adequate level of prudence which matches the definition of compliance with the “standard of care”?

Ultimately, it should be recognized that the question about the influence of certain medical practices upon the outcomes of medical malpractice litigation, both in U.K. as well as in the U.S., is an empirical one, which can only be answered by a comprehensive analysis of the past behavior of courts in such matters. According to the current legal system guiding medical malpractice litigation in both countries, the standard of care is defined neither by the results of a survey responded by a few spine surgeons, nor by society guidelines or even by the best available data according to evidence-based medicine standards. In both countries, the standard of care during a specific medical malpractice case depends exclusively on what a medical expert witness is willing to acknowledge as being, according to his personal opinion, the standard of care. The practice of subordinating objective scientific evidence to the personal testimony and opinion of a qualified expert witness has a long tradition in the English common-law, dating back all the way to the case *Collier v. Simpson* (1831), where the English courts determined that the defendant physician was not allowed to read from authoritative textbooks, but could only use information contained in such material as evidence to support and justify his own personal opinions on the issue [17]. According to the classic principles of legal realism, best represented by H.L.A. Hart’s *magnum opus* “The Concept of Law” [18], the validity of a law is an empirical and not a philosophical matter, which in the end depends entirely on the customary and collective practices of the courts of a certain jurisdiction.

From a patient safety perspective, the central question is: Taking into account the available evidence on the increased accuracy rates of fluoroscopic-assisted pedicle screw placement and its proven role in preventing wrong-level surgery as well as in detecting grossly misplaced instrumentation, does it seem reasonable to not obtain at least one intra-operative radiographic due to radiation exposure concerns? I would personally argue that no, although I agree that reasonable people may thoughtfully disagree with my viewpoint. Considering the low cost and easy access of fluoroscopy worldwide, from a legal perspective the ultimate question is: In the case of a post-operative complication or suboptimal surgical outcome involving misplaced screws or wrong-level surgery, does the lack of any intraoperative fluoroscopic image increase the chances that a medical expert witness would be willing to testify that there was a deviation of the standard of care? Again, in my humble opinion the answer seems to be definitely in the affirmative, although an empirical and systematic evaluation of such a specific question based on the historical records of U.S or U.K.’s courts would provide a more scientific answer to it.

It seems clear that the choice about using (or not) any intra-operative visualization technology in spine surgery seems to depend first and foremost on the overall experience as well as the personal risk aversion profile of each surgeon. From a system perspective, avoiding wrong-level surgery and reducing revision rates for misplaced hardware are clearly important values. From a personal perspective, although I believe that concerns about litigation should not be the determinant factor in choosing to employ or not such techniques, every surgeon has an undeniable personal interest in avoiding unnecessary litigation related to an excessive and unjustified level of personal confidence, especially when pre-

vention strategies are readily available. In such a scenario, it seems that obtaining at least one radiographic image during scoliosis surgery for any of the three reasons previously discussed, could be hardly classified as defensive medicine. I personally would consider it a prudent and reasonable standard practice which, in the game theory vernacular could be described as a classic “minimax strategy” [19], namely a risk-averse approach focusing on avoiding the worst possible outcome.

Such considerations lead me to conclude that, although the use of image intensifier during scoliosis surgery (regardless of how often and through which method such radiographic images are obtained) may perhaps not be “medico-legally obligatory” (whatever that means...), it is probably still the best practice.

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