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EXPERT OPINION

Informed Consent for Spine Procedures: Best Practice Guideline from the American Society of Pain and Neuroscience (ASPN)

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Introduction: The evolution of treatment options for painful spinal disorders in diverse settings has produced a variety of approaches to patient care among clinicians from multiple professional backgrounds. The American Society of Pain and Neuroscience (ASPN) Best Practice group identified a need for a multidisciplinary guideline regarding appropriate and effective informed consent processes for spine procedures.

Objective: The ASPN Informed Consent Guideline was developed to provide clinicians with a comprehensive evaluation of patient consent practices during the treatment of spine pathology.

Methods: After a needs assessment, ASPN determined that best practice regarding proper informed consent for spinal procedures was needed and a process of selecting faculty was developed based on expertise, diversity, and knowledge of the subject matter. A comprehensive literature search was conducted and when appropriate, evidence grading was performed. Recommendations were based on evidence when available, and when limited, based on consensus opinion.

Results: Following a comprehensive review and analysis of the available evidence, the ASPN Informed Consent Guideline group rated the literature to assist with specification of best practice regarding patient consent during the management of spine disorders.

Conclusion: Careful attention to informed consent is critical in achieving an optimal outcome and properly educating patients. This process involves a discussion of risks, advantages, and alternatives to treatment. As the field of interventional pain and spine continues to grow, it is imperative that clinicians effectively educate patients and obtain comprehensive informed consent for invasive procedures. This consent should be tailored to the patient's specific needs to ensure an essential recognition of patient autonomy and reasonable expectations of treatment.

Keywords: informed consent, best practice, clinical guideline, pain medicine, spine intervention, spine surgery

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Introduction

Informed consent is an ethical and legal process involving active communication between a healthcare provider and patient to provide the patient with necessary information to make knowledgeable healthcare decisions. Since the 1900s, the principles of informed consent in medical treatment settings within the United States have evolved in response to several key judicial decisions.[1–4] As a core component of the shared decision-making process, the 1957 case Salgo v. Leland Stanford Jr University Board of Trustees specified the requirement for elaboration of potential benefits and risks of any medical procedure.[5] Notably, this case first coined the term "informed consent". These early judicial decisions set the foundation for the modern informed consent process within the United States, emphasizing the ethical principle of patient autonomy.

In its current form, the basis of informed consent in clinical settings essentially is to provide the patient with 1) the nature of the illness, natural history and consequences of no treatment, 2) the proposed treatment impact on natural history and associated common complications, and 3) alternative treatment options with their general advantages and disadvantages.[6] Additionally, the American Medical Association has recommended specific elements that providers should discuss with patients during the informed consent process, including:[7]

1. Disclosure of the patient's diagnosis or potential pathology.
2. Nature and purpose of the recommended procedure.
3. Discussion of risks and expected benefits of the recommended procedure.
4. Discussion of reasonable alternatives including forgoing treatment, and the risk and benefits of discussed alternatives.
5. Evaluation of the patient's ability to comprehend the relevant information of the involved discussion to make an independent, voluntary decision.
6. Documentation of the informed consent discussion and the patient's decision.

The formal process of this discussion provides a structure for patients' and providers' mutual understanding of the situation and subsequent actions. This requires more than the administrative action of obtaining a signature, but rather an essential recognition of patient autonomy and reasonable expectations of treatment. As it is therefore legally and ethically of paramount importance, only certain exceptions to this process exist, most notably 1) when the patient is incapacitated and unable to provide consent, 2) in emergencies with insufficient time to obtain consent for treatments which are lifesaving or prevent permanent disability, and 3) when the patient has voluntarily waived the right to provide consent. When a patient's capacity is in question, further evaluation or a surrogate decision-maker, as appointed by the patient or in hierarchical manner in accordance with state laws, may be necessary to obtain informed consent.

Despite the legally defined process of informed consent, the basic components tend to provide only general guidance and not specifications to spinal procedures, including progressively novel injections, neuromodulation, and minimally invasive surgical techniques. Treatment of spinal pathology is a notably complex medicolegal process, as evidenced by the high rate of malpractice litigation associated with spinal surgery.[8] A study conducted on medical malpractice cases among individuals who received spinal surgery from 1984 to 2015 determined that nearly two-thirds of the lawsuits were primarily due to failure to obtain informed consent or had lack of informed consent listed as a secondary allegation.[9] Failure to adequately explain the risks and adverse effects of surgery or alternative treatment options were most prominently featured in these lawsuits.

As the field of interventional pain and spine continues to evolve with new interventions and surgeries, it is prudent that providers educate and obtain adequate informed consent prior to proceeding with these procedures. Currently, there is a lack of guidance regarding best practice for informed consent for interventional spine procedures and surgery. The goal of this article is to provide recommendations for interventional pain physicians and spine surgeons on effective and appropriate education and informed consent practices for spine procedures.

Methods

Development Process

Given the rapid pace at which the field of interventional pain and spine is evolving, the American Society of Pain and Neuroscience (ASPN) determined the need for a best practice guideline for informed consent for interventional procedures and surgery. A thorough needs-based assessment performed by ASPN concluded that while medical societies and state medical boards have published guidelines and best practices for informed consent, these tend to provide only general guidance. There is a paucity of literature for informed consent relating to spinal injections, neuromodulation, and minimally invasive spine surgical procedures, despite unique considerations associated with these interventions.

ASPN elected to address this deficit by convening a multidisciplinary panel consisting of anesthesiologists, physiatrists, interventional radiologists, orthopedic surgeons, a neurosurgeon, a psychologist/medical ethicist and advanced practice providers (APPs) to author a comprehensive best practice review. Selection of authors was made to ensure intentional collaboration between a diverse set of providers. This study was exempt from IRB approval as it purely involved literature review and no patient information was analyzed.

Literature Search Method

A formal search of all publicly available medical and legal literature was performed in which web pages, guidelines, and publications relevant to informed consent for medical procedures were collected. Searches were completed using PubMed, Google Scholar, Web of Science, and Ovid MEDLINE. Keywords used were: "informed consent + physician", "informed consent + advanced practice provider", "informed consent + spine", "informed consent + pain", "informed consent + best practice", and "informed consent + elective surgery".

Evidence Ranking and Consensus Development

The ASPN best practice guideline working group and the authors of this manuscript opted to publish recommendations on which a consensus was reached by all members. Based upon the available literature, the working group elected to assign United States Preventative Services Task Force (USPSTF) evidence ranking with letter grading for strength of recommendation along with the strength of consensus, ranging from strong to moderate to weak (Table 1 and Table 2).

Table 1 Evidence Ranking Using United States Preventative Services Task Force Criteria Modified for Informed Consent

Grade	Definition	Suggestions for Practice
A	ASPN recommends this activity. There is high certainty that the net benefit is substantial.	Perform this activity.
B	ASPN recommends this activity. There is high certainty that the net benefit is moderate or that there is moderate certainty that the net benefit is moderate to substantial.	Perform this activity.
C	ASPN recommends selectively offering or providing this activity. There is at least moderate certainty that the net benefit is small.	Perform this activity for selected circumstances.
D	ASPN recommends against performing this activity. There is moderate to high consensus that this activity has no benefit or that the risks significantly outweigh the benefits.	Discourage this activity.
I	ASPN concludes that consensus could not be reached regarding the balance of benefits and harms of this action.	If the activity is performed, the performing provider should understand the uncertainty about the balance of benefits and harms.

Table 2 Strength of Consensus

Strength of Consensus	Definition
Strong	The available evidence includes legal precedent requiring that this activity be performed and consistent recommendations from state medical boards and medical societies advocating for this activity need to be heeded.
Moderate	The available evidence includes inconsistent legal requirement but consistent recommendations from state medical boards and medical societies advocating for this activity need to be adopted.
Weak	The available evidence includes insufficient or inconsistent legal requirement and inconsistent recommendations from state medical boards and medical societies advocating for this activity to be adopted.

Best Practice

Discussion of Pathology, Natural Progression of Disease, and Explanation of Proposed Procedure

The best practice process for obtaining informed consent should consist of a counseling session that includes at minimum: a description of the procedure, risks and benefits of the procedure in general and in particular to the individual patient, advantages and disadvantages of alternative treatments including no treatment, and confirmation of the patient's or the patient's legal representative's comprehension of these elements. This process requires a continuing dialogue between physician and/or APP and the patient or patient's legal representative. There must be recognition of individual patient differences in perception of concepts and principles of decision-making. Informed consent should begin with the establishment of a diagnosis of the patient's condition. This should also include a detailed discussion of the pathology's natural progression. As the etiology of a patient's symptoms may be multifactorial, the proposed initial treatment will often include elaboration of potential subsequent evaluation and testing. While this discussion may occur during clinical care, preferably prior to requesting formal informed consent, it is essential that patients understand their pain etiology and have appropriate expectations regarding ongoing treatment when informed consent is obtained.

Information regarding medical treatment should be conferred to the patient in his/her preferred form of communication style and level of understanding. In addition to open discussion with the treating provider, explanation of the procedure may include printed educational materials, procedural videos, or demonstrations by the provider or device manufacturer's representative using synthetic models. However, adaptation of vernacular and prolonged discussions with the healthcare provider are the most effective means for improving patient understanding.[10]

Best Practice Recommendation #1: It is strongly recommended to discuss the determined or potential pathology that may be contributing to the patient's symptoms. Patients should be informed that the natural progression of their disease may evolve and require further evaluation and procedures. The discussion should be tailored to meet the patient's individual needs in order to effectively convey the information.

Strength of Recommendation: A

Discussion of Risk, Benefits, Alternatives and Recovery

The consent process will ideally strike a balance between the risks inherent to the procedure and the expected benefits. Establishment of realistic, beneficial outcomes is necessary for appropriate patient understanding of both diagnostic and therapeutic procedures. At one end of the spectrum of a balanced discussion lies the patient knowing and understanding possible risks associated with the procedure. Critics of this line of thought state that this would merely confuse the patient, as without the proper medical background, patients may not comprehend this information. Therefore, this would lead to clouded judgement and an unbalanced decision process. The other end of this spectrum is reminiscent of the abolition of the patient's right to autonomy; that due to this lack of knowledge by the patient, the provider becomes the sole decision-maker. Risks which would affect the decision-making process of a reasonable patient should be elaborated, including anything that poses potential grave adverse consequences.[11,12] With these rare occurrences, objective data regarding these risks should also be presented to the patient. Presenting such risks in forms of proportions (eg, 1 in 1000) rather than percentages (eg, 0.1%) may be beneficial to patient understanding.[13] This discussion should also include an explanation of the safeguards against adverse consequences and steps to address concerns that may arise.

As previously discussed, alternatives to the proposed procedure should be addressed in this discussion. This includes the risk of potential harms associated with receiving no treatment for patients' established diagnoses. Alternatives should include the spectrum of possible treatments for their diagnosis, from no intervention to the most invasive option possible. For example, spinal stenosis is a common spine pathology that produces back and leg symptoms. Some treatment options for spinal stenosis include physical therapy, epidural steroid injections, percutaneous image-guided lumbar decompression, spinous process spacers, and open surgical decompression with or without fusion/instrumentation. When discussing the recommended treatment options with patients, it is highly advisable to present the alternative options on a spectrum of risks while discussing the potential benefits and drawbacks of the treatment options. Patients may be referred for consultation to another provider who has expertise in the proposed alternative treatment option.

Patients should also be made aware of expectations in the immediate post-operative/post-procedural period. This should include potential post-procedural pain levels, restrictions or limitations, and planned follow-up appointments, and how to address concerns should they arise. The anticipated timeline of each of these should be communicated, as well.

Best Practice Recommendation #2: It is strongly recommended that the risks and benefits of the proposed treatment against natural history are discussed. Risks that would affect the decision-making of a rational patient should be elaborated, as well as anything that poses potentially grave adverse consequences. If objective data are available regarding the associated risks, it is recommended to present them in the form of proportions rather than percentages.

Strength of Recommendation: A

Best Practice Recommendation #3: It is strongly recommended to discuss the alternatives, including no intervention, for the established diagnosis. Alternatives should be presented on a spectrum from least-invasive to most invasive options. Referral to appropriate providers is encouraged to further discuss available alternative treatment options.

Strength of Recommendation: A

Discussion of Trainee Involvement

The provider should ensure that the patient is aware of and consents to special circumstances. One of which is whether medical trainees, including medical students, residents and fellows, are observing or participating in the procedure. Disclosure of trainee participation in surgical procedures yields a high rate of patient acceptance.[14] Although a majority of patients are willing to allow trainees to participate in the procedure, it should not be assumed the patient has provided consent for such.

The thought of having a trainee involved in the procedure can be concerning for some patients, particularly if the trainee is less experienced or if the procedure is complex. It is recommended to have this discussion prior to the procedure, preferably at the pre-operative encounter, to allow for sufficient time for the patient to consider the involvement of trainees and ask any questions prior to the procedure. Physicians should also explain the value of involving trainees, including improved patient outcomes, potentially more personalized care, and an opportunity for trainees to develop proficiency.

Given the various levels of training throughout medical education, it can be challenging for patients to fully understand the role and expertise of residents and fellows. Providers should emphasize the credentials, level of training, and involvement of the trainees who will participate in the procedure. Most importantly, reassurance should be provided regarding the level of supervision the trainees will receive during the procedure. This is particularly important in instances in which surgeons utilize overlapping surgical procedure models that may depend on trainee, surgical assistant and/or APP involvement. The use and rationale for overlapping surgical procedures in itself should be points of disclosure during the consenting process. Ultimately, the patient has the right to refuse the involvement of trainees during the procedure, and as healthcare providers, it is imperative that we are respectful of the patient's preferences.

Best Practice Recommendation #4: It is strongly recommended to disclose the involvement of trainees prior to the procedure. Providers should emphasize the credentials, level of training, and involvement of the trainees who will participate in the procedure. Reassurance should be provided regarding the level of supervision during the procedure.

Strength of Recommendation: A

Role of Advanced Practice Providers, Nurses, and Other Team Members

All members of the multidisciplinary team have roles in the informed consent process. This team-based approach provides uniform and cohesive patient and caregiver understanding. APPs, such as nurse practitioners (NPs) and physician assistants (PAs), perform numerous medical procedures in diverse settings, and as licensed independent providers (LIPs), they are held to the same medicolegal standards as physicians for obtaining consent for procedures performed within their scope of practice.[15] In some institutions and states, when the APP is not performing the procedure, APPs may act as delegates to obtain certain aspects of consent on behalf of their physician colleagues. The APP's scope of practice is set by the state; therefore, APPs must be aware of state-specific regulations or limitations to consent practices.[15] For example, in 2017, courts in Pennsylvania ruled that informed consent cannot be delegated, and the performing LIP is responsible for ensuring a patient's understanding of the risks involved in a treatment.[16] Therefore, informed consent discussion should be between the patient and the provider performing the treatment.

Although non-LIPs may not obtain consent, many other healthcare providers such as nurses educate patients about procedures and care. The American Nursing Association's Code of Ethics tasks nurses to ensure patients' rights to self-determination and to verify that informed consent is obtained. This may include witnessing consent conversations and promoting a culture of safety.[15,17] LIPs are able to delegate the task of obtaining patient signatures on consent forms to nurses, but the informed consent discussion should remain the role of the LIP.[15] Finally, all other non-LIP healthcare members involved in the patient's care similarly cannot obtain consent, but may act as advocates for the patient and ensure that patients receive the information they need, augmenting the communication between patient and provider.

Best Practice Recommendation #5: It is strongly recommended that informed consent is obtained by the provider who will be performing the procedure.

Strength of Recommendation: A

Special Circumstances: Utilization of Photography and Videography for Medical Education and Social Media

Photography or videography are sometimes used to capture a portion of the procedure for future clinical review, medical education, or research. This is commonly evidenced in cases with unique pathology that are often published in medical journals. Other uses include educational settings with colleagues, medical trainees, and other audiences. The use of any portion of the patient's medical course, including media obtained during a procedure, must be disclosed and consented by the patient. Verbal consent is not sufficient. It is strongly recommended to obtain written consent prior to disseminating any patient-related content.[18] Additional recommendations for social media and professional conduct have been published and provide guideline for providers when disseminating patient-related content on social media.[18]

Best Practice Recommendation #6: It is strongly recommended to obtain written consent prior to the use of any portion of the patient's medical course, including photography and videography.

Strength of Recommendation: A

Timing of Informed Consent

Consent is commonly obtained either in the provider's office before the date of the procedure or on the day of the procedure. As informed consent constitutes more than obtaining a signature, the associated discussion should be progressive. As previously highlighted, all members of the healthcare team contribute to the patient's knowledge base. There is no established optimal time for obtaining consent. However, we suggest that this occurs at a time and a location in which neither the provider nor the patient feels pressured to immediately complete the process, thus facilitating adequate time for questions and further discussion. Ideally, the informed consent process should be initiated at the pre-operative encounter to allow sufficient time for the patient to internalize the discussed information and formulate questions. Follow-up questions and discussion may be necessary and are often recommended. Since the informed consent process is an ongoing discussion, some providers may wait until the day of the procedure for the patient to sign the consent form.

Best Practice Recommendation #7: Although there is no established optimal time for obtaining consent, the authors strongly recommend initiating the informed consent discussion at the pre-operative encounter. This allows adequate time for the patient to process the information and the opportunity to formulate and ask questions.

Strength of Recommendation: A

Documentation of Informed Consent Discussion

An informed consent form often serves as a system-level check to ensure that the consent process has occurred and is integrated into the safety check process at most healthcare institutions. In order to ensure an efficient process, the form should be brief, and language should be easily understood.[19] In addition to improved documentation, patients are more open to consent and experience reduced anxiety when the consent forms are simplified.[20] The form often requires a signature from the patient, provider, and a witness who is often another team member, such as a nurse or medical assistant.

Since the informed consent form does not include the content of the consent discussion, it is imperative that providers document in the patient's chart that informed consent was obtained, and that it describes the pertinent components of the associated discussion of risks, benefits, and alternatives prior to signing the form. If there were follow-up questions or discussions, it is also important to document the content of those.

Best Practice Recommendation #8: It is strongly recommended to document the content of informed consent discussion in the patient's medical records, including questions the patient asked and the patient's understanding of the procedure risks, benefits, and alternatives.

Strength of Recommendation: A

Other Considerations to Enhance Informed Consent Process

An important component of informed consent is determining the patient's comprehension of the discussion. Patients' recall of risks and complications has been determined to be as low as 21%.[11,21] Poor health literacy may be a primary reason why patients often fail to recall information subsequent to consent discussions. One proposed solution is to maintain a sixth-grade reading level for any patient education and informed consent documents. Additionally, the use of other mediums such as audio-visual aids and interactive digital content has been determined to increase patient comprehension of the informed consent discussion by 56% and 85%, respectively. Various multimedia consent interventions such as videos, online learning, and computerized presentations have been studied in diverse patient populations, with increased recall and patient satisfaction noted.[21–24]

Rowbotham and colleagues demonstrated increased patient comprehension of risks and increased satisfaction when the consent process included an interactive tablet-based video followed by a consent form and post-test.[24] In a study of patients undergoing laparoscopic urologic surgery, 95% of patients found it useful to watch a video of the proposed surgery, 81% of patients recommended that all future patients watch the videos, and 75% of patients requested recordings of their own surgeries.[21] Another study obtained video records of the consent conversation which were emailed to patients who were undergoing spine surgery.[2] Over 80% of patients watched the videos with friends and family and reported that the video was helpful in decision-making, and 100% of patients recommended the videos for others undergoing surgery.

As new multimedia-enhanced informed consent processes emerge for spine procedures, there are several benefits, as previously discussed, to incorporating these into current practice. These multimedia processes should not replace the traditional informed consent discussion but rather, when used to supplement the standard process, they can increase patient comprehension and satisfaction, and further individualize the process. Although there is limited evidence in the literature, we believe that a multimedia-enhanced informed consent process may assist patients with vision or hearing impairments.

Best Practice Recommendation #9: It is strongly recommended that informed consent documents be written at a sixth-grade reading level.

Strength of Recommendation: A

Best Practice Recommendation #10: As the informed consent process continues to evolve, it is strongly recommended to incorporate multimedia to increase patients' understanding of the discussion.

Strength of Recommendation: A

Table 3 Summary of Consensus Recommendations for Each Best Practice Category

Best Practice Category	Consensus Recommendations
Discussion of Pathology, Natural Progression of Disease, and Explanation of Proposed Procedure	• It is strongly recommended to discuss the determined or potential pathology that may be contributing to the patient's symptoms. Patients should be informed that the natural progression of their disease may evolve and require further evaluation and procedures. The discussion should be tailored to meet the patient's individual needs in order to effectively convey the information.
Discussion of Risk, Benefits, Alternatives and Recovery	• It is strongly recommended that the risks and benefits of the proposed treatment against natural history are discussed. Risks that would affect the decision-making of a rational patient should be elaborated, as well as anything that poses potentially grave adverse consequences. If objective data are available regarding the associated risks, it is recommended to present them in the form of proportions rather than percentages. • It is strongly recommended to discuss the alternatives, including no intervention, for the established diagnosis. Alternatives should be presented on a spectrum from least-invasive to most invasive options. Referral to appropriate providers is encouraged to further discuss available alternative treatment options.
Discussion of Trainee Involvement	• It is strongly recommended to disclose the involvement of trainees prior to the procedure. Providers should emphasize the credentials, level of training, and involvement of the trainees who will participate in the procedure. Reassurance should be provided regarding the level of supervision during the procedure.
Role of Advanced Practice Providers, Nurses, and Other Team Members	• It is strongly recommended that informed consent is obtained by the provider who will be performing the procedure.
Special Circumstances: Utilization of Photography and Videography for Medical Education and Social Media	• It is strongly recommended to obtain written consent prior to the use of any portion of the patient's medical course, including photography and videography.
Timing of Informed Consent	• Although there is no established optimal time for obtaining consent, the authors strongly recommend initiating the informed consent discussion at the pre-operative encounter. This allows adequate time for the patient to process the information and the opportunity to formulate and ask questions.
Documentation of Informed Consent Discussion	• It is strongly recommended to document the content of informed consent discussion in the patient's medical records, including questions the patient asked and the patient's understanding of the procedure risks, benefits, and alternatives.
Other Considerations to Enhance Informed Consent Process	• It is strongly recommended that informed consent documents be written at a sixth-grade reading level. • As the informed consent process continues to evolve, it is strongly recommended to incorporate multimedia to increase patients' understanding of the discussion.

Conclusion

Obtaining effective informed consent is crucial in achieving proper outcomes and ensuring that patients are adequately educated. Although the process focuses primarily on the associated risks, benefits, and alternatives, it is important to tailor the discussion to suit each individual patient's specific needs. The consent process should entail an evolving discussion with the patient. Although this is not an exhaustive list, this best practice guideline by ASPN provides a framework for providers to use for their consent processes (Table 3). As the field of interventional pain and spine continues to grow, it is imperative that clinicians effectively educate and that patients are able to provide genuinely informed consent regarding invasive procedures. Further, it is important to tailor the consent process to individual needs to ensure an essential recognition of patient autonomy and reasonable expectations of treatment.

Disclosure

Dr Timothy Deer reports personal fees for consulting, research and/or stock options from Abbott, Vertos, SpineThera, Saluda, Mainstay, Nalu, Cornerloc, Ethos, SPR Therapeutics, Medtronic, Boston Scientific, PainTeq, Tissue Tech, Spinal Simplicity, Avanos, and Biotronik, outside the submitted work; In addition, Dr Timothy Deer has a pending patent to Abbott. Dr Ashley Bailey-Classen reports personal fees for consulting or speaker's bureau from Nevro, Medtronic, Biotronik, and Spinal Simplicity, outside the submitted work. Ms Ashley Comer reports personal fees for consulting from Abbott, NALU, PainTEQ, Saluda, SPR Therapeutics, and Vertos, outside the submitted work. Ms Zohra Hussaini reports consulting fees from Nevro, SPR, PainTeq, Averitas; advisory board for Vertos, outside the submitted work. Dr Nasir Khatri reports personal fees for consulting from Saluda Medical; personal fees, non-financial support for advisory board from Vertos Inc., outside the submitted work. Dr Melissa Murphy reports personal fees for speaking, research and/or consulting from Medtronic and Relievant, outside the submitted work. Dr Morteza Rabii reports personal fees from InFormed consent, LLC, Abbott, Spinal Simplicity LLC, Flowonix Medical, and Southern Spine, outside the submitted work. Dr Douglas Beall reports personal fees from Medtronic, Spineology, Merit Medical, Johnson & Johnson, IZI, Techlamed, Peterson Enterprises, Medical Metrics, Avanos, Boston Scientific, Sollis Pharmaceuticals, Simplify Medical, Stryker, Lenoss Medical, Spine BioPharma, Piramal, ReGelTec, Nanofuse, Spinal Simplicity, Pain Theory, Spark Biomedical, Micron Medical Corp, Bronx Medical, Smart Soft, Tissue Tech, RayShield, Stayble, Thermaquil, Vivex, Stratus Medical, Genesys, Abbott, Eliquence, SetBone Medical, Amber Implants, Cerapedics, Neurovasis, Varian Medical Systems, Companion Spine, DiscGenics, Discure, SpinaFX, PainTEQ, outside the submitted work. Dr Michael E Schatman is a research consultant for Modoscript, Scientific Steering Committee for Collegium Pharma, and AdComm for Syneos Health, outside the submitted work. Dr Timothy Lubenow reports personal fees from Abbott Labs, Boston Scientific, Nevro, and Pain Teq, outside the submitted work. The authors report no other conflicts of interest in this work.

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