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## The future is now: How AI is reshaping spine care

Eric J. Muelbauer<sup>a</sup>, Mohammed Ali Alvi, MD, MS<sup>b,c</sup>, David J. Kennedy<sup>d</sup>,  
Michael G. Fehlings, MD, PhD<sup>b,c,e,\*</sup><sup>a</sup> Executive Office, North American Spine Society, 1000 N. Northwest Highway, Suite 150, Park Ridge, IL 60068, United States<sup>b</sup> Division of Neurosurgery and Spine Program, Department of Surgery, University of Toronto, 149 College Street, Toronto, ON M5T 1P5, Canada<sup>c</sup> Institute of Medical Science, Temerty Faculty of Medicine, University of Toronto, King's College Cir, Toronto, ON M5S 3K3, Canada<sup>d</sup> Department of Physical Medicine and Rehabilitation, Vanderbilt University Medical Center, 1211 Medical Center Drive, Nashville, TN 37232, United States<sup>e</sup> Division of Neurosurgery, Krembil Neuroscience Centre, Toronto Western Hospital, University Health Network, 399 Bathurst Street, Toronto, ON M5T 2S8, Canada

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## ABSTRACT

**Introduction:** Artificial intelligence (AI) is rapidly reshaping spinal care, transitioning from experimental algorithms to operational tools embedded in clinical workflows. This narrative review explores the evolving role of AI across the spine care continuum, including diagnostic imaging, surgical planning, intraoperative navigation, predictive analytics, and digital therapeutics.**Methods:** Using a mixed-methods approach, we synthesized insights from peer-reviewed literature, regulatory documents, press releases, and grey sources published between 2017 and 2025.**Results:** AI-enabled imaging platforms now assist in detecting spinal pathologies and extracting quantitative metrics such as disc heights and Cobb angles, improving diagnostic consistency and reducing inter-rater variability. In surgical planning, decision-support systems and robotics-integrated platforms offer personalized guidance and enhanced precision. Intraoperative tools using 2D–3D fusion and volumetric reconstruction are enabling hardware-light navigation, particularly in ambulatory settings. Predictive models for survival, reoperation risk, and patient-reported outcomes are emerging, though external validation remains limited.

Digital therapeutics and wearable technologies are expanding the reach of spine care beyond the clinic, offering scalable solutions for rehabilitation and postoperative monitoring. Meanwhile, regulatory and legal frameworks are evolving to address transparency, data governance, and intellectual property concerns. Recent FDA guidance and landmark legal cases underscore the need for disciplined collaboration and responsible deployment.

**Conclusions:** AI in spine care is no longer theoretical and is operational. Its integration promises enhanced precision, efficiency, and personalization, but also demands rigorous validation and ethical oversight. This review highlights the multifaceted impact of AI and calls for continued alignment between clinicians, developers, and regulators to ensure safe, equitable, and sustainable innovation.

## Introduction

Artificial intelligence (AI) is rapidly transforming spine care across the continuum. In today's evolving landscape of spine medicine, AI is becoming an everyday tool in diagnostics, surgical planning, and postoperative care. Whether in the operating room (OR) or reviewing a patient's imaging, AI is helping spine specialists work more efficiently, precisely, and proactively. While early applications focused on proof-of-concept algorithms, recent advances have yielded FDA-cleared tools, commercially deployed platforms, and real-world clinical integrations. This review explores the evolving landscape of AI in spine care, highlighting

key technological milestones, regulatory developments, and practical implications for clinicians. By synthesizing diverse sources, including peer-reviewed literature, press releases, and industry reports, we aim to provide a comprehensive overview of how AI is reshaping clinical workflows and decision-making in spinal medicine.

## Methods

This mixed-methods narrative review draws from a wide range of sources, including peer-reviewed publications, conference proceedings, press releases, grey literature, and regulatory documents. We included

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\* Corresponding author. Michael G. Fehlings, MD, PhD, FRCSC, FACS, Toronto Western Hospital, 399 Bathurst Street, Suite 4WW-449, Toronto, ON M5T 2S8, Canada.

E-mail address: [Michael.Fehlings@uhn.ca](mailto:Michael.Fehlings@uhn.ca) (M.G. Fehlings).<https://doi.org/10.1016/j.xnsj.2025.100825>

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**Table 1**  
AI applications across the spine care continuum.

Domain	AI use cases	Representative tools/platforms	Key benefits
Diagnostic imaging	Detection of herniations, stenosis, fractures; quantitative metrics	SpineNet, Aidoc	Faster diagnosis, improved consistency
Imaging analytics	Automated measurements (disc height, Cobb angles); segmentation, alignment	SpineNet, Neurospine-reviewed frameworks	Standardization, reduced inter-rater variability
Surgical planning	Decision support for approach selection, implant design	Agada Medical (Spine Oracle™)	Personalized planning, reduced unnecessary surgery
Intraoperative navigation	Real-time guidance using 2D→3D fusion, volumetric reconstruction	VUZE Medical, See All AI	Hardware-light precision, ambulatory compatibility
Robotics integration	Assistive robotic systems for screw placement and navigation	Mazor X, ROSA ONE Spine	Workflow standardization, enhanced accuracy
Digital therapeutics	App-based rehab for low back pain	Rise-uP trial apps	Scalable adjuncts, cost-effective outcomes
Wearables	Monitoring mobility, sleep, stress postop	Smartwatches, IMUs	Passive tracking, longitudinal recovery insights
Predictive analytics	Risk modeling for survival, reoperation, PROMs. Trajectory based analysis.	SORG models, registry-trained algorithms	Outcome forecasting, personalized care

materials published between 2017 and 2025 that describe AI applications in spine care, with emphasis on diagnostic imaging, intraoperative guidance, predictive analytics, and digital therapeutics. Selection was guided by relevance to clinical practice, technological innovation, and regulatory impact. No formal meta-analysis was conducted. Instead, findings were synthesized thematically to reflect current trends and future directions.

## Results

We present the various applications of AI not covered in other studies in this section including (1) advances in imaging analytics, (2) use of AI in digital therapeutics and wearables, and (3) predicting outcomes and personalizing care (Table 1).

### AI-powered imaging analytics in spine care

AI is dramatically enhancing the interpretation of spinal imaging, facilitating quicker and more accurate diagnosis. Tools powered by machine learning now assist in detecting disc herniations, spinal stenosis, scoliosis, and fractures with speed and accuracy. Beyond detection, they provide objective measurements (disc height, curvature, vertebral alignment) that improve diagnostic consistency. Platforms like SpineNet and Aidoc are already streamlining radiologic workflows with automated reads that rival manual interpretation [1].

The Spinal Cord Toolbox (SCT), an open-source software suite tailored for spinal cord MRI, exemplifies this shift through its integration of advanced segmentation and registration algorithms powered by DL [2].

Recent versions of SCT incorporate convolutional neural networks for spinal cord, gray matter, and lesion segmentation (eg, sct\_deepseg\_sc, sct\_deepseg\_gm, sct\_deepseg\_lesion), outperforming traditional deformable models and atlas-based methods. These models are trained on diverse datasets and leverage frameworks likeivadomed, allowing researchers to deploy custom segmentation pipelines for specific pathologies, scanner types, or populations—including pediatric and animal models.

The importance of AI-driven automation lies in its ability to standardize analysis across sites, reduce operator variability, and accelerate biomarker discovery. In conditions like multiple sclerosis, spinal cord injury, and degenerative cervical myelopathy, automated quantification of atrophy, lesion burden, and tract-specific metrics can support diagnosis, monitor progression, and evaluate treatment response with unprecedented precision.

### Extending care beyond the OR and clinic: digital therapeutics and wearables

App-based programs for nonspecific low back pain demonstrate clinically meaningful pain reduction versus usual care/physiotherapy in

randomized studies, and 12-month real-world evaluations suggest favorable clinical and economic signals when embedded in primary care pathways. While these are not substitutes for surgical care, they represent scalable adjuncts for perioperative conditioning and postoperative rehabilitation [3].

Wearables (IMUs, smartwatches) are increasingly used to capture mobility, sleep, and physiologic stress as longitudinal endpoints that correlate with recovery trajectories. Their widespread availability enables passive, low-burden monitoring but also raises analytic and privacy considerations; prospective protocols should prespecify data quality thresholds and handling of missingness [4].

### Predicting outcomes, personalizing care

Predictive analytics, powered by AI, is offering a new level of personalization. These systems assess risk, anticipate complications, and forecast outcomes using large datasets [5].

Prognostic models now span survival in metastatic disease, reoperation risk, and patient-reported outcomes (PROMs) after decompression or fusion. The SORG group's 30-day mortality model after surgery for spinal metastasis (2019) is a representative exemplar: trained on national registries, externally reported, and deployed as a usable web tool. Subsequent reviews catalog dozens of models for degenerative indications, while emphasizing gaps in external validation and calibration reporting that must be addressed before routine bedside use [6,7].

Beyond survival and perioperative risk prediction, AI and machine learning are increasingly being applied to understand the heterogeneity of recovery after spinal cord injury (SCI) and degenerative cervical myelopathy (DCM). Traditional outcome measures often assume uniform recovery trajectories, but recent work demonstrates that patients follow distinct, data-driven patterns of neurologic improvement. For example, trajectory-based modeling of large SCI cohorts has revealed reproducible subgroups that are not apparent from baseline severity alone. These models integrate demographic, injury-level, and physiologic variables to probabilistically assign patients to recovery trajectories, offering a more nuanced framework for prognostication and trial design. By identifying patients most likely to benefit from early interventions, such approaches move beyond static classification systems like AIS grades toward dynamic, personalized recovery forecasting [8,9].

In parallel, unsupervised learning has been applied to DCM populations to uncover latent phenotypes with distinct symptom clusters and long-term outcomes. Using clustering algorithms such as k-means and latent profile analysis, investigators have identified reproducible subgroups, including “motor-dominant,” “pain-dominant,” and “severe multimodal impairment” phenotypes, that differ not only in baseline presentation but also in functional recovery after surgery. These AI-derived phenotypes outperform single scales like the mJOA by capturing multidimensional symptom burden, including pain and disability, and linking them to quality-of-life outcomes. Such stratification holds

promise for tailoring surgical decision-making, counseling patients on expected recovery, and designing phenotype-specific therapeutic strategies [9].

Together, these advances illustrate how AI-driven prognostic modeling is reshaping the landscape of spine care. By leveraging large multicenter datasets and sophisticated analytic techniques, machine learning can parse heterogeneity, anticipate individualized recovery patterns, and ultimately guide precision medicine approaches in SCI and DCM. The challenge ahead lies in external validation, integration into clinical workflows, and ensuring interpretability so that these tools can be trusted and adopted at the bedside.

#### Legal landscape for AI in spine care: staying ahead of risk

##### IP and data-use risk: copyright, fair use, and training data

U.S. copyright law's fair-use doctrine (17 U.S.C. §107) remains the central defense for model training that incorporates copyrighted material. Courts weigh purpose and character, nature of the work, amount used, and market effects; none is dispositive. Recent rulings suggest an increasingly skeptical view of unlicensed ingestion that targets the same market as the rightsholder. In *Thomson Reuters v. ROSS Intelligence* (D. Del., Feb 11, 2025), the court granted partial summary judgment for Thomson Reuters, rejecting ROSS's fair-use defense where Westlaw headnotes had been used to build a competing legal research tool—emphasizing market substitution and lack of sufficient transformation. The decision is one of the first U.S. rulings squarely against “training as fair use” and is already shaping industry risk assessments [10–12].

News-publisher litigation is also advancing. In *The New York Times v. Microsoft & OpenAI* (S.D.N.Y.), the court (April 2025) allowed core copyright claims to proceed while trimming some Digital Millennium Copyright Act (DMCA) claims—confirming that large portions of the case will move into discovery and potentially trial. Taken together with ROSS, this underscores that commercial developers relying on proprietary text for training face material litigation exposure absent clear licenses. Clinician-developers and hospitals partnering with vendors should therefore verify provenance and licensing of training corpora [13–15].

*What fair use is (and isn't).* Statutorily, fair use permits limited, context-dependent uses for criticism, comment, news reporting, teaching, scholarship, or research; the analysis is case-specific and turns heavily on market harm and the use's purpose. For clinical adopters, the key translation is practical: do not assume that “training on the open web” is per se lawful—especially if the training materials are paywalled, curated, or substitute for the original service. Reference the statute directly in Methods/Ethics sections when describing data sources and licensing [11].

##### Contract, trade-secret, and collaboration disputes

Healthcare AI projects frequently hinge on complex R&D agreements. In *ChemImage Corp. v. Johnson & Johnson / Ethicon* (S.D.N.Y.), a dispute over AI-enabled surgical imaging culminated in a July 2025 order awarding ~\$76.6 M to ChemImage after the court found Ethicon breached aspects of the parties' agreement; earlier orders had already narrowed available damages despite ChemImage's initial >\$1.5B claim. The case illustrates that termination rights, milestone definitions, and IP reversion terms can decide outcomes years later—especially for software-first surgical platforms [16,17].

Presuit discovery fights are also emerging around AI components embedded in devices. In *re Acclarent, Inc.* (Tex. Ct. App. 2024), the appeals court curtailed presuit Rule 202 discovery sought to probe an alleged defect associated with an AI-augmented navigation system, signaling the courts' reluctance to allow expansive fishing expeditions without specific need. For providers, this underscores the value of disciplined documentation of AI changes and supplier roles [18].

##### FDA's evolving framework for AI/ML devices

For tools that meet the definition of Software-as-a-Medical Device (SaMD) or AI-enabled device software functions, the Food and Drug Administration has moved from principles to concrete expectations:

- *AI/ML SaMD Action Plan (2021)* established a total-product-lifecycle lens and set the stage for targeted guidance. Entrepreneurs are recommended to cite this plan to orient readers to current regulatory theory [19].
- *Good Machine Learning Practice (GMLP) guiding principles:* Jointly with Health Canada and MHRA, these stress data quality, monitoring, and human-AI team performance; these are increasingly referenced in marketing submissions and postmarket plans [20].
- *Transparency principles for ML-enabled devices (2024):* These highlight user-facing information needs (intended use, data scope, performance, updates) that are directly relevant to informed consent and clinical governance [21].
- *Predetermined Change Control Plans (PCCPs):* The FDA has now issued guidance on including PCCPs in submissions so that future model updates (eg, dataset refreshes) can occur without resubmission, provided they remain within predefined bounds. Reference the most recent PCCP guidance when discussing any adaptive functionality [22].
- *AI-Enabled Device List:* Clinicians can verify whether a product is authorized, the pathway used, and summary safety/effectiveness. This resource is useful when comparing vendors' regulatory status in the manuscript [23].

##### Privacy, marketing, and “AI-washing” enforcement

Outside HIPAA-covered environments, AI tools in musculoskeletal care (eg, wellness, remote monitoring) often fall under state consumer-health-data laws. HHS's OCR (Office of Civil Rights) has warned that use of online tracking technologies can trigger HIPAA obligations for covered entities and business associates—risking violations if analytics pixels or SDKs touch protected health information. Meanwhile, states such as Washington (My Health My Data Act) and California (CMIA updates; CCPA/CPRA exemptions) impose additional duties when handling consumer health data in non-HIPAA contexts. Manuscripts should acknowledge these overlapping regimes whenever digital data leave the EHR [24–26].

Regulators are also targeting *deceptive AI marketing*. The FTC's “Operation AI Comply” and guidance to “keep your AI claims in check” caution against overstating capabilities or bias-mitigation. The SEC has brought actions for “AI-washing” in securities disclosures. These trends matter for clinician-entrepreneurs and hospital innovation arms making performance claims for navigation, triage, or prediction tools [27–29].

##### Practical implications for clinicians and research teams

Given these challenges in the current landscape, physicians and research groups should

- Demand traceable licenses for training and fine-tuning data and avoid “black-box” provenance claims. They should also be cautious to map vendor data flows to HIPAA/state law boundaries and confirm business associate agreements (BAAs) where applicable [30].
- Verify regulatory posture: request FDA decision summaries, PCCP scope, postmarket monitoring plans, and alignment with GMLP/Transparency principles before deployment [23].
- Structure collaborations with exit ramps: define milestones, change-control, IP ownership on improvements, and data-return obligations to mitigate ChemImage-style disputes [16].

##### Cautions and limitations of AI in spine care

Despite accelerating enthusiasm for artificial intelligence in health-care, and surgical care in particular, adoption should proceed with caution (Table 2). Many systems remain constrained by issues of general-

**Table 2**  
Regulatory and legal landscape.

Area	Key developments	Implications for clinicians/developers
Copyright & fair use	Rulings in <i>Thomson Reuters v. ROSS</i> and <i>NYT v. OpenAI</i>	Training data must be licensed; fair use defenses narrowing
Contract & IP disputes	<i>ChemImage v. Ethicon</i> awarded \$76.6 M over breached AI collaboration	Define milestones, IP terms, and exit ramps in R&D agreements
FDA guidance	SaMD Action Plan, GMLP, PCCPs, Transparency Principles	Align submissions with lifecycle, monitoring, and update protocols
Privacy & data governance	HIPAA, state laws (WA, CA), OCR tracking tech warnings	Map data flows, confirm BAAs, avoid unlicensed SDKs
Marketing & enforcement	FTC/SEC actions against “AI-washing” and deceptive claims	Ensure truthful, evidence-backed performance claims

**Table 3**  
Limitations and cautions in AI deployment.

Challenge	Description	Recommended mitigation
Generalizability	Poor external validation across sites, scanners, populations	Conduct internal–external validation, report calibration
Dataset shift & performance decay	Drift over time or across settings affects model reliability	Implement drift detection and periodic re-verification
Automation bias	Over-reliance on AI outputs reduces clinician vigilance	Design challenge–response workflows, train for verification
Regulatory Clearance ≠ Benefit	FDA approval does not guarantee clinical impact	Use CONSORT-AI guidelines, conduct rigorous trials
Transparency & change management	Users often unaware of training data, failure modes, update policies	Disclose PCCPs, align with GMLP and transparency principles

izability, data provenance, and incomplete external validation. Importantly, their real-world performance can drift as patient populations and workflows change. These limitations do not diminish the promise of AI, but they underscore the need for rigorous evaluation, transparent reporting, and disciplined implementation (Table 3).

*Generalizability*

Many clinical prediction and imaging models are under-validated outside their development data; external validation and calibration are often incomplete, hampering transportability across hospitals, scanners, and populations. Contemporary guidance stresses internal–external validation and transparent calibration reporting, but adherence is inconsistent [31–33].

*Dataset shift and performance decay are real in practice*

Prospective monitoring studies show clinically meaningful shifts across sites and over time and demonstrate that drift-triggered adaptation or transfer learning can be necessary to sustain performance. Imaging-specific work likewise documents the need for robust drift detection in real-world pipelines. Your service plan should include label-agnostic drift monitoring and periodic verification [34,35].

*Automation bias and over-reliance can create new failure modes*

Even when average performance improves, clinicians may over-trust system outputs, suppressing vigilance and verification, an effect demonstrated across clinical-decision-support (CDS) tasks and reviewed specifically for AI-enabled CDS systems (CDSS). Human factors and “challenge–response” behaviors (eg, mandatory verification steps) should be designed and trained explicitly [36,37].

*Regulatory clearance does not prove clinical benefit*

FDA clearance/authorization assures conformity to a specific intended use and safety/effectiveness standards, but robust impact evidence and guideline-concordant reporting vary. Recent evaluations of AI RCTs show incomplete adherence to CONSORT-AI items, underscoring the need for rigorous trial design and reporting [38].

*Transparency and change management are still maturing*

Regulators have issued GMLP principles and dedicated transparency guidance for ML-enabled devices, emphasizing the performance of the human–AI team, user-facing disclosures, and real-world monitoring. Manuscripts and SOPs should state what users learn about training data, known failure modes, and how updates are governed (eg, PCCP) [20,21].

*Domain-specific realities*

In spine, adoption spans triage of cervical spine fractures, quantitative imaging, navigation/robotic guidance, and perioperative risk modeling; limitations noted by recent spine reviews include heterogeneous labels, small external datasets, and uneven reporting of patient-important outcomes [39–41].

**Conclusion**

Artificial intelligence has transitioned from theoretical promise to practical utility in spine care. Across diagnostic imaging, surgical planning, prognostication, and rehabilitation, AI-enabled tools are now actively shaping clinical workflows and decision-making. The integration of these technologies offers enhanced precision, efficiency, and personalization. These benefits are increasingly evident in both academic and commercial settings. However, as adoption accelerates, so too does the need for responsible deployment. Clinicians, developers, and regulators must collaborate to ensure transparency, equity, and safety in AI applications. Rigorous validation, clear documentation, and ethical data governance are essential to avoid unintended consequences and maintain trust. Looking ahead, the future of spine care will likely be defined by hybrid intelligence, where human expertise and machine learning coalesce to deliver better outcomes. This review underscores that AI is no longer experimental, it is operational, and its thoughtful integration will be critical to advancing the field responsibly and sustainably.

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The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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**References**

[1] Jamaludin A, Kadir T, Zisserman A. SpineNet: Automated classification and evidence visualization in spinal MRIs. *Med. Image Anal.* 2017;41:63–73.  
 [2] Valošek J, Cohen-Adad J. Reproducible spinal cord quantitative MRI analysis with the Spinal Cord Toolbox. *Magn. Reson. Med. Sci.* 2024;23(3):307–15.

- [3] Priebe JA, Kerkemeyer L, Haas KK, et al. Medical app treatment of non-specific low back pain in the 12-month cluster-randomized controlled trial Rise-up: Where clinical superiority meets cost savings. *J. Pain Res.* 2024;17:2239–55.
- [4] Dunn J, Runge R, Snyder M. Wearables and the medical revolution. *Per. Med.* 2018;15(5):429–48.
- [5] Karhade AV, Thio QCBS, Ogink PT, et al. Development of machine learning algorithms for prediction of 30-day mortality after surgery for spinal metastasis. *Neurosurgery* 2019;85(1):E83–91.
- [6] Lubelski D, Hersh A, Azad TD, et al. Prediction models in degenerative spine surgery: A systematic review. *Global Spine J* 2021;11(1\_suppl):79S–88S.
- [7] Yahanda AT, Joseph K, Bui T, et al. Current applications and future implications of artificial intelligence in spine surgery and research: A narrative review and commentary. *Global Spine J* 2025;15(2):1445–54.
- [8] Badhiwala JH, Wilson JR, Kulkarni AV, et al. A novel method to classify cervical incomplete spinal cord injury based on potential for recovery: A group-based trajectory analysis. *Neurosurgery* 2020;67(Supplement\_1).
- [9] Jaja BNR, Badhiwala J, Guest J, et al. Trajectory-based classification of recovery in sensorimotor complete traumatic cervical spinal cord injury. *Neurology* 2021;96(22):e2736–48.
- [10] [https://www.ded.uscourts.gov/sites/ded/files/opinions/20-613\\_5.pdf?utm\\_source=chatgpt.com](https://www.ded.uscourts.gov/sites/ded/files/opinions/20-613_5.pdf?utm_source=chatgpt.com). Accessed December 3, 2025.
- [11] 17 U.S. Code § 107 - limitations on exclusive rights: fair use. *LII /Legal Information Institute* [https://www.law.cornell.edu/uscode/text/17/107?utm\\_source=chatgpt.com](https://www.law.cornell.edu/uscode/text/17/107?utm_source=chatgpt.com). Accessed December 3, 2025.
- [12] Thomson Reuters wins AI copyright 'fair use' ruling against one-time competitor. *Reuters* 2025.
- [13] Judge explains order for New York Times in OpenAI copyright case. *Reuters* 2025.
- [14] <https://nysd.uscourts.gov/sites/default/files/2025-04/yf>. Accessed December 3, 2025.
- [15] Fischer, S. NYT case against OpenAI and Microsoft can advance. *Axios* [https://www.axios.com/2025/04/01/nyt-openai-microsoft-lawsuit-advances?utm\\_source=chatgpt.com](https://www.axios.com/2025/04/01/nyt-openai-microsoft-lawsuit-advances?utm_source=chatgpt.com) (2025). Accessed December 3, 2025.
- [16] Whooley, S. Judge says Johnson & Johnson Ethicon owes \$76.6M to ChemImage after failed partnership. *MassDevice* [https://www.massdevice.com/judge-ethicon-76m-chemimage-failed-partnership/?utm\\_source=chatgpt.com](https://www.massdevice.com/judge-ethicon-76m-chemimage-failed-partnership/?utm_source=chatgpt.com) (2025). Accessed December 3, 2025.
- [17] ChemImage Corporation v. Johnson & Johnson et al., No. 1:2024cv02646 - document 64 (S.D.N.Y. 2024). *Justia Law* [https://law.justia.com/cases/federal/district-courts/new-york/nysdce/1:2024cv02646/619123/64/?utm\\_source=chatgpt.com](https://law.justia.com/cases/federal/district-courts/new-york/nysdce/1:2024cv02646/619123/64/?utm_source=chatgpt.com). Accessed December 3, 2025.
- [18] In re Acclarent, Inc. Appeal from 67th district court of tarrant county (memorandum opinion). *Justia Law* <https://law.justia.com/cases/texas/second-court-of-appeals/2024/02-24-00228-cv.html>. Accessed December 3, 2025.
- [19] [https://www.fda.gov/media/145022/download?utm\\_source=chatgpt.com](https://www.fda.gov/media/145022/download?utm_source=chatgpt.com). Accessed December 3, 2025.
- [20] Good machine learning practice for medical device development: guiding principles. *US Food and Drug Administration* [https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles?utm\\_source=chatgpt.com](https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles?utm_source=chatgpt.com) (2025). Accessed December 3, 2025.
- [21] Transparency for machine learning-enabled medical devices: guiding principles. *US Food and Drug Administration* [https://www.fda.gov/medical-devices/software-medical-device-samd/transparency-machine-learning-enabled-medical-devices-guiding-principles?utm\\_source=chatgpt.com](https://www.fda.gov/medical-devices/software-medical-device-samd/transparency-machine-learning-enabled-medical-devices-guiding-principles?utm_source=chatgpt.com) (2024). Accessed December 3, 2025.
- [22] Center for Devices & Radiological Health. Artificial intelligence-enabled device software functions: lifecycle management and marketing submission recommendations. *US Food and Drug Administration* [https://www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing?utm\\_source=chatgpt.com](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing?utm_source=chatgpt.com) (2025). Accessed December 3, 2025.
- [23] Center for Devices & Radiological Health. Artificial intelligence-enabled medical devices. *US Food and Drug Administration* [https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-enabled-medical-devices?utm\\_source=chatgpt.com](https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-enabled-medical-devices?utm_source=chatgpt.com) (2025). Accessed December 3, 2025.
- [24] The EU's AI act: what it means for the medical device industry. [https://www.dekra.com/en/eu-ai-act-medical-device-industry/?utm\\_source=chatgpt.com](https://www.dekra.com/en/eu-ai-act-medical-device-industry/?utm_source=chatgpt.com). Accessed December 3, 2025.
- [25] Washington my health my data act: requirements and exceptions. [https://www.irmi.com/articles/expert-commentary/washington-my-health-my-data-act-requirements-and-exceptions?utm\\_source=chatgpt.com](https://www.irmi.com/articles/expert-commentary/washington-my-health-my-data-act-requirements-and-exceptions?utm_source=chatgpt.com) (2023). Accessed December 3, 2025.
- [26] State of California. Frequently asked questions (FAQs). [https://cppa.ca.gov/faq.html?utm\\_source=chatgpt.com](https://cppa.ca.gov/faq.html?utm_source=chatgpt.com). Accessed December 3, 2025.
- [27] FTC announces crackdown on deceptive ai claims and schemes. *Federal Trade Commission* [https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-announces-crackdown-deceptive-ai-claims-schemes?utm\\_source=chatgpt.com](https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-announces-crackdown-deceptive-ai-claims-schemes?utm_source=chatgpt.com) (2024). Accessed December 3, 2025.
- [28] Coldewey D. FTC warns tech: 'keep your AI claims in check. *TechCrunch* 2023.
- [29] SEC charges two investment advisers with making false and misleading statements about their use of artificial intelligence. [https://www.sec.gov/newsroom/press-releases/2024-36?utm\\_source=chatgpt.com](https://www.sec.gov/newsroom/press-releases/2024-36?utm_source=chatgpt.com). Accessed December 3, 2025.
- [30] The EU's AI act: what it means for the medical device industry. [https://www.dekra.com/en/eu-ai-act-medical-device-industry/?utm\\_source=chatgpt.com](https://www.dekra.com/en/eu-ai-act-medical-device-industry/?utm_source=chatgpt.com). Accessed December 3, 2025.
- [31] Riley RD, Snell KIE, Archer L, et al. Evaluation of clinical prediction models (part 3): calculating the sample size required for an external validation study. *BMJ* 2024;384:e074821.
- [32] Collins GS, Dhiman P, Ma J, et al. Evaluation of clinical prediction models (part 1): from development to external validation. *BMJ* 2024;384:e074819.
- [33] Riley RD, Archer L, Snell KIE, et al. Evaluation of clinical prediction models (part 2): how to undertake an external validation study. *BMJ* 2024;384:e074820.
- [34] Subasri V, Krishnan A, Kore A, et al. Detecting and remediating harmful data shifts for the responsible deployment of clinical AI models. *JAMA Netw. Open.* 2025;8(6):e2513685.
- [35] Kore A, Abbasi Bavi E, Subasri V, et al. Empirical data drift detection experiments on real-world medical imaging data. *Nat. Commun.* 2024;15(1):1887.
- [36] Lyell D, Coiera E. Automation bias and verification complexity: a systematic review. *J. Am. Med. Inform. Assoc.* 2017;24(2):423–31.
- [37] Abdelwanis M, Alarafati HK, Tammam MMS, et al. Exploring the risks of automation bias in healthcare artificial intelligence applications: A Bowtie analysis. *J. Saf. Sci. Resil.* 2024;5(4):460–9.
- [38] Martindale APL, Llewellyn CD, de Visser RO, et al. Concordance of randomised controlled trials for artificial intelligence interventions with the CONSORT-AI reporting guidelines. *Nat. Commun.* 2024;15(1):1619.
- [39] Pollen, A. A clinical use-case: the clinical impact of ai for triaging c-spine fractures. *Healthcare AI | Aidoc Always-on AI*. [https://www.aidoc.com/learn/blog/clinical-impact-ai-triaging-c-spine-fractures/?utm\\_source=chatgpt.com](https://www.aidoc.com/learn/blog/clinical-impact-ai-triaging-c-spine-fractures/?utm_source=chatgpt.com) (2019). Accessed December 3, 2025.
- [40] Lee S, Jung J-Y, Mahatthanatrakul A, et al. Artificial intelligence in spinal imaging and patient care: A review of recent advances. *Neurospine* 2024;21(2):474–86.
- [41] Ambati VS, Saggi S, Dada A, et al. Has artificial intelligence in spine surgery lived up to the hype? A narrative review of recent approaches, current challenges, and the path forward. *Artif. Intell. Surg.* 2025;5(1):53–64.