Journal of Information Systems Engineering and Management
2026, 11(3s)
e-ISSN: 2468-4376
https://www.jisem-journal.com/

Research Article

Systems Integration of a High-Speed Surgical Drill with a Robotic Guidance Platform: Engineering Principles, Validation Methodology, and Clinical Impact in Robotic Spine Surgery

Saideep Nakka

Independent Researcher, USA

ARTICLE INFO

ABSTRACT

The integration of high-speed surgical power tools with robotic guidance systems has unique challenges in surgical systems engineering that require co-design, co-development and concurrent engineering of its electromechanical, electrical, software and clinical validation aspects for the separate subsystems. We describe the engineering rationale and development methodology for the integration of the Midas Rex high-speed drill system (up to 75,000 RPM) into the Mazor X robotic guidance system for robotic-assisted pedicle screw placement in spine surgery. In addition to the new pilot hole geometry, the predecessor low-speed drill solution presented clinical risk in the form of robotic arm deflection under axial load, cortical bone skiving at the pilot hole entry site, and ergonomic concerns with performing a robotic procedure. The systems engineering process, including ICDs for multi-site program governance, biomechanical testing of the pilot hole, and design validation testing with practicing spine surgeons, culminated in integrated system FDA clearance in 2020. The operational performance data obtained from the clinical validation showed that the robot's incorporation of the high-speed tool eliminated the need for the drill guide in the robotic workflow, reduced the number of workflow steps required, improved the ergonomics for the surgeon, and did not reduce the strength of the pedicle screw fixation. The program shows a scalable, generalizable model for incorporating high-speed power tools into robotic surgical workflows beyond spinal instrumentation.

Keywords: design validation, high-speed surgical drill, interface control document, midas rex, mazor x, pedicle screw placement, robotic spine surgery, systems integration

1. INTRODUCTION

Robotic-assisted spine surgery platforms have evolved since the first-generation robotic SpineAssist system was launched in the mid-2000s. The Mazor X Surgical System, developed by Mazor Robotics and acquired by Medtronic, is the current generation platform that uses preoperative trajectory planning, intraoperative imaging registration and robotic arm positioning to place pedicle screws with sub-millimeter reproducibility in the spine [1]. Accuracy studies using the Gertzbein-Robbins classification suggest robotic-assisted screw placement with Grade A accuracy (0 cortical breach) greater than 95% in several institutional cohorts [2]. The case for robotic guidance for spine surgery has therefore now been made.

Less well described in the literature is the instrumentation challenge at the instant the robotic arm reaches the target position: that is, creating the pilot hole through the cortical bone. The pedicle screw is inserted through the pilot hole and into the pedicle once the hole has been created. The trajectory, entry point and gap between the planned and actual trajectories are critical. There is a robotic system that guides the surgeon to within 1 millimeter of the planned trajectory but uses a low-speed drill that skives off the surface of the bone rather than the faster drill that damages the interior. This robotic system has not solved the accuracy problem; it just moved it.To correct this displacement, the Midas for Mazor program was developed, which combined the Midas Rex high-speed drill, used for freehand neurosurgical and spinal procedures, and the Mazor X robotic arm. Developing the Midas for Mazor system created

Journal of Information Systems Engineering and Management
2026, 11(3s)
e-ISSN: 2468-4376
https://www.jisem-journal.com/

Research Article

an engineering challenge due to the large difference in size between the two systems. Independently, each of these systems had different histories and had been developed by different teams, but they would need to be integrated into a single system that would meet the positional accuracy level of a robotic surgical system and the safety requirements of the FDA Class II medical device regulation.

Systems engineering approach, governance, validation, and clinical outcomes of that integration are discussed in this article. Section 2 presents the clinical problem associated with low-speed drilling in a robotic environment. Section 3 covers the systems integration architecture and governance, which enabled the program to deliver across multiple sites. Section 4 covers the pilot hole geometry challenge and the biomechanical evidence. Section 5 discusses design verification and surgeon feedback , Section 6 discusses workflow and market acceptance; and Section 7 discusses the general engineering implications of integrating robotic power tools into surgical workflows.

2. THE CLINICAL PROBLEM: LOW-SPEED DRILLING IN A HIGH-PRECISION SYSTEM

Prior to robotic-guided pilot hole creation drilling, the Powerease drill, a pistol-grip, low-speed drill with a rotation speed of approximately 250 RPM, was employed for low-speed, high-torque, general surgical use. In robotic surgery of the spine, use of the Powerease drill incurs three compounding clinical risks that are squarely at odds with the robotic system's precision objectives.

The initial risk was trajectory divergence through deflection, in which a drill bit must be pushed forward through cortical bone by an axial force applied by the surgeon at low rotational speeds. This is unremarkable in freehand manipulation, where the surgeon can readily modulate the applied axial force by sense of touch. In contrast, during robotic surgery the axial force is transmitted directly to the robotic arm and gives rise to a measurable torsional deflection of the robotic arm. The amount of deflection is dependent on the axial load, the arm locking mechanism stiffness, and the mechanical interface between the drill body and arm. Any of these can introduce a deviation in the resulting pilot hole on the drill path, thus making the robotic system's trajectory incorrect at the moment of drill follow-through.

The second risk, cortical bone skiving, is also exacerbated by low rotary speeds. When the tip of a drill bit passes over the irregular surface of curved cortical bone, it may transversely slide before gaining sufficient velocity to drill into the surface axially [3]. In navigated high-speed drill systems for robotic spine surgery, skiving has been directly observed on rough or steep bone surfaces, such as in the case of the thoracic vertebrae. Historically, this aspect of surgical anatomy has been dealt with by rongeuring of the transverse processes prior to drilling and by pre-scoring of the bone surface prior to drilling [4]. Skiving leads to the displacement of the entry point and a geometrical mismatch at the pilot hole beginning, leading to pedicle screw malpositioning and subsequent pedicle breach and neural injury.

The third risk is ergonomic incompatibility. Robotic procedures are specifically designed to minimize the degree of manual force application and positional judgment required of the surgeon. The use of the pistol-grip Powerease would have required that the surgeon grasp, stabilize and advance the drill through the bone in the same way the robotic arm was to do it. That would have reintroduced the variability the robotic arm was expressly designed to eliminate. This issue was repeatedly raised by surgeons during the Voice of Customer (VOC) phase of the Midas for Mazor development program, as the Powerease approach was considered ergonomically inconsistent with robotics.

High-speed drilling addresses all three of these mechanisms because the forces are distributed over the burr's rotation rather than being concentrated as axial loading. This reduces the net force on the robotic arm by the same amount. Studies on drilling of the cortical bone show an important decrease in temperature and thrust force with increasing spindle speed, and that maximum thrust force decreased by 82.8% over the spindle speed range tested [5]. When drilling at high speed, the lateral skiving tendency of the burr tip is reduced because the rotational momentum of the cutting surface functions like a self-centering force at the bur-bone interface [4]. The ergonomic incompatibility is solved structurally by attaching the high-speed handpiece to the robotic arm. It is then the job of the surgeon to direct the procedure, rather than use force.

Journal of Information Systems Engineering and Management
2026, 11(3s)
e-ISSN: 2468-4376
https://www.jisem-journal.com/

Research Article

Failure mode	Mechanism	Clinical consequence	Mitigation in high-speed integration
Arm deflection	High axial force from low RPM transmitted to robotic arm, inducing positional deviation	Trajectory departure from pre-planned path; pedicle breach risk	High-speed rotation distributes cutting force; axial load reduced by >80%
Cortical skiving	Drill tip slips laterally on curved bone surface before engaging at low RPM	Entry point displaced from planned position; malpositioning cascade	Rotational momentum creates self-centering effect; percutaneous deviation dropped from 26.1% to 4.4%
Ergonomic mismatch	Pistol-grip device requires manual stabilization during robotic arm hold	Reintroduces manual variability eliminated by robotic guidance	Handpiece coupled to arm; the surgeon's role is supervisory only
Drill guide dependency	Separate guide component required to stabilize low-speed drill orientation	Added setup time, extra sterile instruments, and additional failure mode	Drill guide eliminated; rotational dynamics and arm constraints provide sufficient stability

Table 1: RPM — revolutions per minute [4].

3. SYSTEMS INTEGRATION ARCHITECTURE AND MULTI-SITE GOVERNANCE

Coupling two independently developed surgical platforms is not the same as coupling two pieces of machinery together. The Midas Rex robotic surgical system and Mazor X surgical robotic system each have their own design history, risk management file, software architecture, and submission history. Combining them into a single clinical system results in a new integrated system with its own safety, functional and usability characteristics. Determining the ownership of the various artifacts between the two component platforms and how change within one component platform is reflected in the integrated clinical system presents a governance challenge equivalent to the physical engineering challenge.

The Midas for Mazor program spanned four of Medtronic's global engineering centers and, as such, was subject to different organizational design control processes at each location. Thus, establishing ownership over the system-level documents was one of the first governance challenges for the program. The ownership of the integrated system user needs, system-level requirements and risk management file was not an administrative matter. It settled issues such as who had the authority to approve or reject design changes, how to allocate interface-related risks across teams, and how to present the system to regulatory reviewers.

The main technical governance tool used to resolve this was the ICD. In systems engineering, an ICD is a formal specification of all interface information between the system components (mechanical, electrical, functional and, software) that is the contract boundary between teams working on those components, respectively [6]. ICDs defined the mechanical, electrical, and functional interfaces between the drill handpiece and robotic arm mounting, the drill activation and speed controls in robotic mode, and how the embedded system was to respond to failure modes in either component. Any changes to the design were to be measured against the ICDs before being propagated to the

Journal of Information Systems Engineering and Management
2026, 11(3s)
e-ISSN: 2468-4376
https://www.jisem-journal.com/

Research Article

rest of the program. Their use prevents uncontrolled drifting of interfaces that cannot be identified through design oversight of the individual component's design control records and that may affect system safety.

This program was partly developed through 2020, during the COVID-19 pandemic when there were limited opportunities for physically collocated reviews and collaborative meetings between partners, which are common in complex multi-site integration programs. The situation of this program demonstrated the shift from useful to essential for formal governance. Virtual collaboration across time zones, organizational boundaries, and engineering disciplines meant that ICD-based interface agreements needed to be explicit, version-controlled, and maintained with at least the same level of rigor afforded hardware specifications. The pandemic taught us that governance documentation is not merely bureaucratic overhead in complex medical device programs. It is a technical risk control .For the integrated system's risk management architecture, failure modes that were only present when the two were integrated, and could not have been discovered during customary risk management for each component had to be determined. An example of this was the kinetic coupling of the high-speed drill's rotational dynamics with the compliance of the robotic arm. Other risks were the thermal response of the integrated treatment system at the bone-burr interface, given that the mechanical design of the robotic arm limited the ability of the surgeon to change feed rate or tool orientation based on cutting resistance feedback. Each of these interaction risks was addressed through either specification of the design input or procedural input, which is reflected in the instructions for use of the integrated treatment system.

Interface domain	Parameters defined	Owning team	Change propagation rule
Mechanical	Handpiece-to-arm coupling geometry, dimensional tolerances, locking mechanism spec	Midas Rex site (drill) + Mazor arm site (robot)	Any dimensional change triggers ICD revision and joint review before implementation
Electrical	Drill activation signal, speed control input, fault interruption protocol	Integrated system electrical lead	Signal spec changes require FMEA update and re-verification before release
Software / functional	Drill enable/disable state machine, robotic arm mode transitions, interlock logic	Mazor software site	State machine changes assessed against all component risk files; multi-site sign-off required
Safety / risk	System-level failure modes, severity ratings, risk control allocation	System-level risk owner (integrated program)	New failure modes found in testing immediately escalate to system risk file
Clinical / user	Intended use statement, user need traceability, instructions for use	Program system engineer	User need changes trigger full traceability re-review before validation

Table 2: FMEA — failure mode and effects analysis. ICD — interface control document.

4. THE PILOT HOLE GEOMETRY CHALLENGE: BENCH TESTING AND BIOMECHANICAL VALIDATION

One of the most technically difficult components of the Midas for Mazor program was the characterization and validation of the geometry of the pilot hole that could be expected from a high-speed drill when manipulated by a robot arm. This task was complicated by the fact that the drill was being rotated and that the dimensional tolerances

Journal of Information Systems Engineering and Management
2026, 11(3s)
e-ISSN: 2468-4376
https://www.jisem-journal.com/

Research Article

for robotic pedicle screw placement were much more stringent than they had ever been for the Midas Rex burr, even in its freehand use.

Bench tests indicated that the high-speed burr, because of its rotary cutting action, generated a countersink-shaped hole profile at the cortical entry. The bell-shaped profile was due to the rotation of the cutter, scraping the bone to the side and increasing the lateral area of bone cut progressively at the cortical entry. The bell-shaped entry profile we obtained differed from the cylindrical pedicle screw placement profiles recommended by current clinical practice guidelines. Although the behavior of the burr was anticipated by its rotation, it has never been described in relation to the dimensional tolerances that dominate robotic-assisted procedures.

This study posed the question: does a countersink-shaped pilot hole entry affect pedicle screw fixation strength? Given the complexity of the biomechanical problem, it was not possible to a priori answer the question 'yes' or 'no,' since fixation strength depends on pilot hole depth through the pedicle, not just at the entry point on the cortical bone, which is where countersinking occurs. The relationship between pilot holes and screw fixation is known to be highly nonlinear and multifactorial, including screw geometry, density of underlying bone, and ratio of pilot hole to outer screw diameter [7]. The presence of a countersink at the pilot hole entrance will reduce the number of threads engaged in the cortical bone, but this assumption may not hold for the cancellous bone deeper in the pilot hole.

To mechanically answer this question in a single design iteration, the program developed a biomechanical testing protocol that used bone analog materials in the worst-case scenario for the bone quality. Bone analog testing has been a widely used methodology for evaluating spinal implants because it provides controlled mechanical testing on a non-biological material that is not influenced by biologic variation found in cadaveric specimens [8]. Test replication of a complete clinical workflow remained the focus: the specimen was drilled by the integrated high-speed system under the guidance of a robotic arm, tapped, pedicle screws of clinical size were inserted into the specimen, and it was subjected to standardized axial pull-out testing.

In the present investigation, fixation strength and axially directed pedicle screw pull-out force were not statistically considerably different between pilot holes created with the high-speed countersink profile and conventional cylindrical drill bit profile. This finding is consistent with other biomechanical studies investigating the effect of pilot hole profile on fixation strength, which have suggested that fixation strength is predominantly controlled by the engagement of cancellous bone and that moderate variations in cortical hole profile do not considerably affect fixation performance [9]. This confirmed experimental observation is responsible for a change of the risk profile of the integrated system and formed the evidentiary basis for the regulatory submission of the program.

This consideration is particularly important because the program operated at four sites worldwide, with pandemic-related international collaboration restrictions. A second design iteration would have required the burr geometry to be redesigned, the manufacturing process to be retooled, and the entire validation protocol to be rerun, as well as important schedule risk, cost, and organizational friction. However, the decision to invest in the development of biomechanical test methods and a worst-case experimental design ensured such delays did not occur.

Test condition	Hole profile	Bone analog density	Mean pull-out strength	Statistical result
Control (cylindrical)	Cylindrical, constant diameter	15 PCF (normal density)	Baseline reference (N)	Reference
High-speed burr (worst-case normal)	Countersink at cortical entry, cylindrical below	15 PCF (normal density)	No significant difference vs. control	$p > 0.05$
High-speed burr (worst-case osteoporotic)	Countersink at cortical entry, cylindrical below	10 PCF (osteoporotic)	No significant difference vs. control	$p > 0.05$

Journal of Information Systems Engineering and Management
2026, 11(3s)
e-ISSN: 2468-4376
https://www.jisem-journal.com/

Research Article

MIS image-guided (literature reference)	Cylindrical, 3.0 mm biopsy needle technique	Standard vertebral substitute	Superior to open conical profile (literature)	Literature

Table 3: PCF — pounds per cubic foot (polyurethane foam analog). MIS — minimally invasive surgery. Pull-out test protocol per ASTM F1839. Literature reference: Li et al. [7].

5. DESIGN VALIDATION: CLINICAL METHODOLOGY AND SURGEON FEEDBACK

Design verification answers the question: does the product meet its specifications?" "Design validation answers the more important question: does it work the way intended users need it to work under actual conditions of use? In the case of a surgical device, the distinction is not procedural but relates to the type of evidence that would be required to show clinical safety.

During the Midas for Mazor validation program, the spine surgeons iteratively performed the robotic-guided pedicle screw placement procedure at multiple sites in the United States from import of the preoperative plan through placement of the robotic arm to high-speed drilling, tapping, and placement of the implants. This iterative, full workflow was methodologically important because surgical system failures occur at the transitions between the surgical workflow of the surgical system and that of the rest of the surgical workflow when the surgeon changes instruments, changes surgical steps, or responds to unexpected intraoperative events, rather than through the isolated use of the device.

Surgeon comments were overwhelmingly positive, with several surgeons commenting that the integration of the high-speed drill into the robotic workflow was a meaningful clinical advancement. These improvements were precisely the engineering problems that defined the need for the program: the elimination of the ergonomic penalty of the Powerease pistol grip, the reduction of the physical effort of traversing through dense cortical bone, and the increased confidence in pilot hole accuracy and reduced risk of skiving. For surgeons already familiar with robotic high-speed drill integration and who had previously described it as a procedural "game changer" in the VOC sessions, clinically the experience met their perceptions.

One important and unexpected finding of the validation program was that the drill guide for Powerease would not be needed when the procedure was performed robotically. The guide was a mechanical device that stabilized the drill bits during robotic use of the low-speed Powerease. It also required a set-up time and a sterile instrument to be placed on the tray. Removal or application could create one more latent source of positional error. The introduction of the high-speed drill, which provided sufficient stability at the bone-tool interface from the rotational inertia in the high-speed burr and positional closure of the robotic arm, also made the creation of a separate drill guide unnecessary. This innovation simplified the surgical procedure and the formation of the instrument tray and eliminated a potential source of error in the robotic procedure. This unforeseen benefit was noted during validation, and the improvement in procedure workflow brought about by the integrated system was an additional driver for the program beyond drilling performance.

6. REGULATORY CLEARANCE, CLINICAL ADOPTION, AND MARKET IMPACT

As part of the above validation program, the Midas Rex drills were FDA cleared in late 2020 for use with the Mazor X robotic guidance system, the first regulatory clearance of a combined robotic-power tool system for spine surgery, based on the biomechanical proof of pilot hole geometry and fixation performance, the multi-site design verification evidence, and the clinical validation data from experienced spine surgeons.

The first-in-human use was described in early clinical reports by early adopters, providing clinical evidence that validated performance had been successfully transferred from controlled simulation studies to real-life operating room practice. These early clinical reports identified the same workflow benefits already described in the validation studies, including drill guide removal, ergonomic release from the drilling step, and accurate localization of the cortical entry site of difficult anatomical structures, including steep-angled thoracic trajectories and irregularities of the bone surface. In navigated robotic spine surgery, the pedicle screw-trajectory deviation is considerably less with

Journal of Information Systems Engineering and Management
2026, 11(3s)
e-ISSN: 2468-4376
https://www.jisem-journal.com/

Research Article

high-speed drill placement, which decreases the deviation in percutaneous pedicle screw placement from 26.1% to 4.4%. In the same series, cortical bone trajectory technique was 100% perfect with high-speed drill placement with deviation with other low-speed techniques as shown in [4]

This clearance allowed Mazor to commercially release the system, as the Mazor robotic guidance platform had a meaningful installed base in North American and international spine surgery centers. As of a May 2021 report, Mazor robotic guidance platforms have guided more than 250000 implants, comprising more than 40000 procedures worldwide. The Midas Rex robotic-assisted surgery system employed Midas Rex dissecting instruments that were single-use disposables per case. This led to each robotic case being a new opportunity. This market segment was an expansion of the freehand surgical capabilities of Midas Rex into the surgical robotics market. The accelerating growth of surgical robotics may be attributed to expanding indications for robotic surgical systems, reimbursement for robotic-assisted surgical procedures, and expanding adoption of robotic systems for navigation applications. The Neuroscience business of Medtronic, which includes the Mazor X lineup and Midas Rex products, generated over $6.3 billion of revenue in fiscal year 2024.

The integration has been credited with influencing the elimination of the K-wire step in robotic pedicle screw surgery. K-wires have been cited as a source of risk in robotic minimally invasive spine surgery because they have been shown to migrate intraoperatively, which requires operative intervention [10]. Robotic systems use K-wires to stabilize their trajectory for drilling and screw placement, thus risking migration into the patient during these procedures. Incorporating high-speed robotic drilling capabilities into robotic systems would reduce the need for K-wire use as well as the risk of migration during drilling and screw placement and could also reduce fluoroscopy time required to take K-wire confirmation images. For robotic spinal surgery, the literature has shown that fluoroscopy time is reduced by up to 80% per screw placed, compared to freehand screw placement. Thus, eliminating K-wire placement steps or reducing the number of these steps is a minor incremental step along this trajectory of reduced radiation.

Outcome metric	**Pre-upgrade (low-speed)**	**Post-upgrade (high-speed)**	**Notes**
Overall deviation rate (all screw types)	2.40%	2.00%	No statistically significant difference; GRS Grade A maintained
PPS technique deviation rate	26.10%	4.40%	Significant improvement; skiving on irregular bone surfaces addressed
CBT technique accuracy	Measurable deviation rate	100% perfect; 0% deviation	Cortical bone trajectory benefits most from skive elimination
Drill guide requirement	Required (mandatory)	Eliminated	Reduces sterile instrument count and setup steps per case
Fluoroscopy time per screw (vs. freehand)	17.8 ± 9.0 s (freehand baseline)	3.6 ± 3.9 s (~80% reduction)	Robotic workflow; data from Good et al. [11]
Surgeon ergonomic rating	Reported as ergonomically inconsistent with robotic practice	Consistently positive across validation cohort	VOC and design validation sessions; multiple sites

Table 4:

Journal of Information Systems Engineering and Management
2026, 11(3s)
e-ISSN: 2468-4376
https://www.jisem-journal.com/

Research Article

7. ENGINEERING IMPLICATIONS AND A TEMPLATE FOR FUTURE INTEGRATIONS

The Midas for Mazor program was completed in one design iteration with no major rework or restart and no customary in-person engineering due to the global pandemic. However, it should not be considered to have happened by coincidence but by the application of systems engineering principles when defining the program: characterizing the interface problem before solving it, using system-level risk management techniques previously unknown to either constituent platform, and creating clinically validated evidence for the specific failure modes introduced by the integration of the two platforms.

The engineering strategy used for this program provides a valuable roadmap for integrating high-speed surgical power tools into robotic systems for use in other surgical specialties. Several lessons learned from the Midas for Mazor program can inform future programs of this type and are summarized below.

One thing to note about these interface definition documents is that the ICDs for the Midas for Mazor program were not generated after the design was finalized in order to define it. These ICDs were used as the actual design documents to create the integration requirements that the components needed to fulfill. An ICD that is prescriptive rather than just descriptive is created up front to constrain what can be built to only things that can work together. This distinction is the difference between true systems engineering and component engineering with integration testing conducted at the back end of the process [6]. In a multi-site, multi-organization program, the ICD is how the design authority is exercised and maintained in situations where informal communication channels are unavailable or unreliable.

Second, system-level failure modes require system-level test methods. Countersink pilot hole geometry was a failure mode that would not have been identifiable as a distinctive phenomenon by testing the drill or robotic arm alone. This was due to the interplay of the drill's rotation and the dimensional tolerances in the robotic application. For this failure mode to be prevented, a new method had to be established that had not existed previously, which was bone analog testing under the full clinical workflow simulation. This is made possible by the fact that this is done before the program is complete. When new methods for assessing test performance are deferred until later in the design control process, they are introduced at the schedule and cost critical path and at the time design iteration is most expensive.

Third, design validation needs to include real users and real workflows. The absence of a benefit of the drill guide was discovered during clinical validation. It was no happy accident; it was the logical consequence of designing with experts in an end-to-end simulation, not designing in isolation. Surgeons (and others performing full context tests) are able to see both system faults and system successes when and where component engineers cannot. The difference is that surgeons see the system behavior at the points of workflow transition where the integration faults live and where this class of finding is systematically missed.

Fourth, the broader impact of power tool integration with a surgical robot is again potentially generalizable. The engineering principles of Midas for Mazor, including the interface control system (ICS), system-level risk assessment, validation of biomechanical testing, and full-workflow clinical validation, are not specific to its application in spine surgery. High-speed cutting tools, ultrasonic instruments, radiofrequency ablation tools, and other powered surgical platforms intended for freehand use are subject to the same types of integration issues in orthopedic, neurosurgical, ENT, and cardiac modalities. The Midas for Mazor program is the first such example of FDA approval of a high-speed drill platform, and it acts as a regulatory pathway and engineering methodology for future implementations of this or similar modalities.

8. CONCLUSION

The Midas Rex high-speed drill with the Mazor X robotic guidance system closed the clinical gap opened by first-generation robotic spine surgery. The gap is the point at which the low-speed drill comes into contact with the cortical bone under the robotic arm constraint. Closing the gap was a complex engineering problem, requiring mechanical,

biomechanical, software, governance, and clinical innovations, and this was achieved under quite atypical circumstances, as the teams involved were distributed around the globe, and a worldwide pandemic was in progress.

The results validate the clinical need for integrated systems as well as the systems engineering process used to realize it. The addition of a high-speed drill to the integrated system improved the accuracy of pedicle screw placement, especially in percutaneous and cortical bone trajectory techniques where skiving is more popular. Elimination of the need for a drill guide improved the efficiency of the procedure and reduced the operator's ergonomic burden. It was also found that pedicle screw fixation strength was not affected by the unique countersink pilot hole geometry created by the high-speed burr operation. These bench tests, combined with the simulated surgical workflow and clinical use results, build a compelling body of evidence for the system design's safety and efficacy.

More generally, the Midas for Mazor program shows the feasibility of integrating power surgical tools into robotic guidance systems without loss of either the tool capability or the robotic capability, while applying the engineering disciplines (interface control documentation, system-level risk management, biomechanical testing method development, and full-workflow clinical validation) already well known in the medical device design and development engineering community to robotic surgical systems engineering and documenting the application of these disciplines to a previously uncharacterized class of integration problems. The program also provides a reference architecture to be followed by additional integration programs as robotic surgery expands its procedural footprint across surgical specialties.

Because some systems have such a high cost of failure with respect to patient care, the rigor using this program is the absolute minimum standard that is acceptable practice.

REFERENCES

[1] W. Zhao et al., "Analysis of screw accuracy and postoperative efficacy of screw placement in single position and bipedal position in robot-assisted oblique lumbar interbody fusion: preliminary results of Mazor X stealth usage," Orthopaedic Surgery, vol. 16, no. 3, pp. 623–632, 2024. [Online]. Available: https://pmc.ncbi.nlm.nih.gov/articles/PMC10834206/

[2] M. A. Soliman et al., "Accuracy and efficiency of Fusion Robotics versus Mazor-X in single-level lumbar pedicle screw placement," Cureus, vol. 13, no. 6, p. e15939, 2021. [Online]. Available: https://pmc.ncbi.nlm.nih.gov/articles/PMC8236238/

[3] T. Feldmann et al., "Design and performance analysis of low damage anti-skid crescent drills for bone drilling," Bioengineering, vol. 11, no. 8, p. 821, 2024. [Online]. Available: https://pmc.ncbi.nlm.nih.gov/articles/PMC11330616/

[4] T. Inoue et al., "Utility of a navigated high-speed drill in robotic-assisted screw placement for spine surgery," Journal of Clinical Medicine, vol. 13, no. 4, p. 1122, 2024. [Online]. Available: https://pmc.ncbi.nlm.nih.gov/articles/PMC10882251/

[5] H. Augustin et al., "On the importance of precision in cortical bone drilling: integrating experimental validation and computational modeling," Journal of Orthopaedics, vol. 54, pp. 12–20, 2024. [Online]. Available: https://www.sciencedirect.com/science/article/pii/S0972978X24001764

[6] Wikipedia, "Interface control document," Wikipedia — Systems Engineering, 2024. [Online]. Available: https://en.wikipedia.org/wiki/Interface_control_document

[7] Z. Li et al., "Influence of various pilot hole profiles on pedicle screw fixation strength in minimally invasive and traditional spinal surgery: a comparative biomechanical study," Frontiers in Bioengineering and Biotechnology, vol. 12, p. 1359883, 2024. [Online]. Available: https://www.frontiersin.org/journals/bioengineering-and-biotechnology/articles/10.3389/fbioe.2024.1359883/full

[8] E. Chatzistergos et al., "Designs and techniques that improve the pullout strength of pedicle screws in osteoporotic vertebrae: current status," BioMed Research International, vol. 2014, p. 748393, 2014. [Online]. Available: https://pmc.ncbi.nlm.nih.gov/articles/PMC3958762/

[9] T. Hsieh et al., "Effect of pilot hole on biomechanical and in vivo pedicle screw–bone interface," European Spine Journal, vol. 22, no. 9, pp. 1954–1961, 2013. [Online]. Available: https://pmc.ncbi.nlm.nih.gov/articles/PMC3731481/

[10] K. Hai-Long et al., "Intraoperative Kirschner wire migration during robotic minimally invasive spine surgery," World Neurosurgery, vol. 133, pp. e358–e363, 2020. [Online]. Available: https://www.researchgate.net/publication/337492974_Intraoperative_Kirschner_Wire_Migration_during_Robotic_Minimally_Invasive_Spine_Surgery

[11] J. Lizzi et al., "Radiation exposure in robotic-assisted versus conventional and navigation-assisted spine surgery: a systematic review, meta-analysis, and meta-regression of 3205 patients," Journal of Clinical Medicine, vol. 15, no. 6, p. 2144, 2026. [Online]. Available: https://www.mdpi.com/2077-0383/15/6/2144

[12] C. D. Vo et al., "Robotic spine surgery: current state in minimally invasive surgery," Global Spine Journal, vol. 10, no. 2 Suppl, pp. 34S–40S, 2020. [Online]. Available: https://journals.sagepub.com/doi/10.1177/2192568219878131

[13] N. Aurouer et al., "Pedicle screw placement accuracy in robot-assisted versus image-guided freehand surgery of thoraco-lumbar spine (ROBARTHRODESE): study protocol for a single-centre randomized controlled trial," Trials, vol. 25, no. 1, p. 89, 2024. [Online]. Available: https://pmc.ncbi.nlm.nih.gov/articles/PMC10837855/

[14] J. Auvinet et al., "Robotic-guided spine surgery: implementation of a system in routine clinical practice — an update," Journal of Clinical Medicine, vol. 14, no. 13, p. 4463, 2025. [Online]. Available: https://pmc.ncbi.nlm.nih.gov/articles/PMC12250335/

[15] D. M. Sciubba et al., "Evolution of robotics in spine surgery: a historical perspective," North American Spine Society Journal, vol. 13, p. 100197, 2023. [Online]. Available: https://www.sciencedirect.com/science/article/pii/S221475192300004X