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Robotic-Assisted Needle Insertion System for Percutaneous Renal Access: Accuracy and Safety Testing

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ABSTRACT

Background: Percutaneous nephrolithotomy depends on safe, accurate needle access to the target renal calyx, yet conventional freehand fluoroscopic or ultrasound-guided puncture is highly operator-dependent and associated with multiple attempts, prolonged radiation exposure, and access-related complications, particularly among less experienced operators. Objective: This narrative review synthesizes published accuracy and safety testing of robotic-assisted needle insertion systems developed for percutaneous renal access. Methods: We reviewed engineering and clinical studies spanning early remote-center-of-motion robotic arms, electromagnetic and optical tip-tracking navigation systems, and contemporary CT- and ultrasound-guided robotic platforms, focusing on quantitative targeting accuracy, needle attempts, procedure time, and complication and success rates reported in phantom, animal, cadaveric, and human studies. Findings: Robotic platforms integrated with volumetric imaging achieve targeting accuracies of approximately 1.6 to 3.4 millimeters in phantom and animal models, generally matching or exceeding manual technique with substantially lower variance, while reducing needle attempts, shortening procedure time in most studies, and eliminating or markedly reducing operator radiation exposure; early human randomized and cadaveric data corroborate fewer punctures and lower access failure rates, with the largest benefit observed among novice operators. Conclusions: Robotic-assisted needle insertion systems demonstrate consistent accuracy and safety advantages over manual percutaneous renal access across the preclinical and early clinical literature, positioning the technology to narrow the experience-dependent performance gap as larger multicenter trials mature.

Keywords: *robotic-assisted needle insertion; percutaneous renal access; percutaneous nephrolithotomy; image-guided surgical robotics; targeting accuracy and safety testing*

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Introduction

Percutaneous nephrolithotomy (PCNL) remains the standard of care for large or complex renal calculi, and the success of the entire procedure hinges on a single early step: obtaining safe, precise percutaneous access to the desired renal calyx. The multicenter Clinical Research Office of the Endourological Society (CROES) Global Study, which classified complications across a large PCNL cohort, underscored that access-related events—hemorrhage, adjacent organ injury, and pleural or vascular complications—remain among the most consequential adverse outcomes of the procedure, and that access quality is a major determinant of overall morbidity [1]. Conventional access is achieved by manual, freehand needle insertion under fluoroscopic or ultrasound guidance, a technique that is highly operator-dependent: it typically requires years of case experience to master, exposes both patient and surgeon to ionizing radiation when fluoroscopy is used, and is associated with a measurable rate of multiple puncture attempts, extended access times, and access failure, particularly among trainees and less experienced operators [2]. This dependence on manual dexterity and spatial reasoning under two-dimensional or hand-held imaging has motivated three decades of engineering effort toward robotic and navigation-assisted systems intended to make renal access more accurate, more reproducible, and less reliant on operator experience.

The resulting literature spans several technological lineages. The earliest efforts, beginning in the 1990s at Johns Hopkins University, adapted remote-center-of-motion robotic arms originally developed for other percutaneous applications to guide a needle toward a fluoroscopically or ultrasonographically

defined renal target [3]. A second lineage, emerging in the 2010s, replaced or augmented the robotic arm with electromagnetic or optical tracking of the needle tip relative to a pre-acquired or intraoperative image, allowing conventional handheld insertion to be guided by real-time three-dimensional feedback rather than fluoroscopic projection alone [4,5]. A third and more recent lineage has combined image-guided robotic arms with modern cross-sectional imaging—computed tomography (CT), cone-beam CT, and three-dimensional ultrasound—to achieve sub-centimeter and, in several reports, sub-5-millimeter targeting accuracy in phantom, cadaveric, and live animal models, with early human feasibility and randomized comparative data now beginning to appear [6]. This narrative review synthesizes the published accuracy and safety evidence across these three lineages, focusing specifically on quantitative targeting accuracy, number of needle attempts, procedure time, and complication and success rates reported in individually verified studies of robotic-assisted needle insertion for percutaneous renal access.

Historical Development of Robotic Platforms for Percutaneous Renal Access

The conceptual foundation for robotic percutaneous renal access was established by Cadeddu and colleagues, who described a passive, remote-center-of-motion (RCM) mechanical arm—subsequently developed into the Percutaneous Access to the Kidney (PAKY) system—that constrained a needle driver to pivot about a fixed skin entry point while an operator directed fluoroscopic targeting, demonstrating in early bench and preclinical testing that the mechanism could reproduce the trajectory precision of an experienced surgeon's hand while reducing fluoroscopic exposure to the operator [3]. This PAKY-RCM platform was subsequently evaluated in a prospective clinical comparison by Su and colleagues, who found that robotically assisted percutaneous access achieved needle-to-target accuracy and single-pass success comparable to standard manual access performed by experienced endourologists, while allowing the responsible surgeon to stand outside the direct fluoroscopic beam during needle advancement—establishing, for the first time in a clinical population, that a percutaneous renal access robot could match manual performance without sacrificing safety [7]. Extending this platform toward telesurgery, Bauer and colleagues demonstrated that the automated PAKY-RCM system could be operated remotely over a network connection to achieve percutaneous renal access in an animal model, successfully separating the operating surgeon's physical location from the patient and the fluoroscopy suite, an early proof of concept for tele-robotic percutaneous intervention that anticipated later interest in remote and mentor-assisted endourologic procedures [8].

These first-generation systems established two principles that persisted through later platform generations: first, that mechanically constraining the needle to a fixed pivot point can reproduce or exceed the geometric accuracy of a skilled human hand, and second, that decoupling the operator from direct beam exposure is an achievable and clinically meaningful safety benefit independent of any gain in targeting accuracy. However, PAKY-RCM and its direct successors remained fundamentally tied to two-dimensional fluoroscopic guidance, meaning that out-of-plane errors—depth misjudgment along the fluoroscopic viewing axis—remained a persistent limitation not fully addressed by the robotic arm itself. This limitation, more than any deficiency in the mechanical actuation, motivated the shift toward three-dimensional tracking and cross-sectional image guidance described in the following section, and later toward integrating robotic actuation directly with CT and ultrasound volumes, discussed subsequently.

Selected robotic and navigation-assisted platforms for percutaneous renal access: guidance modality, evaluation stage, and key reported result.

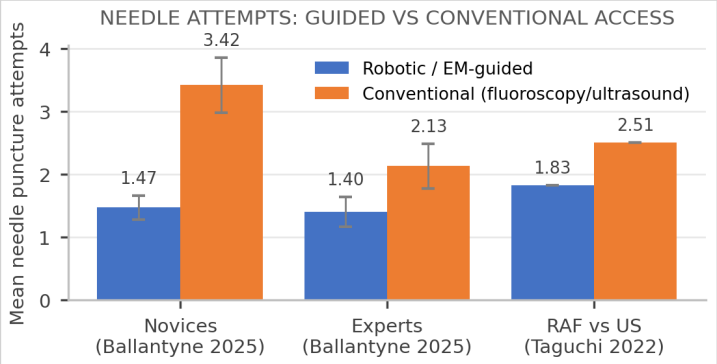
Platform / Study	Guidance modality	Evaluation stage	Key reported result
PAKY-RCM (Cadeddu et al. 1997)	Fluoroscopy, remote-center-of-motion arm	Bench / preclinical	Mechanically constrained trajectory reduced surgeon fluoroscopic exposure
PAKY-RCM (Su et al. 2002)	Fluoroscopy, remote-center-of-motion arm	Clinical	Accuracy and single-pass success comparable to manual access
Telesurgical PAKY-RCM (Bauer et al. 2001)	Fluoroscopy, remote telerobotic control	Animal model	Successful remote (networked) percutaneous renal access
Optical-tracker robot (Zhang et al. 2013)	Ultrasound + optical tracking, robotic servoing	Bench / ex vivo	Feasibility of closed-loop optical registration and servoing
CT-guided robot (Hiraki et al. 2017)	CT fluoroscopy, robotic needle driver	Phantom + swine	1.6 mm (phantom) / 3.2 mm (animal) mean accuracy; 0 uSv operator dose
CT-guided robot (de Baere et al. 2022)	CT, robotic needle driver	Swine (n=2, 8 trajectories)	2.8 +/- 1.3 mm accuracy; 100% first-attempt success

Image-Guided Navigation and Electromagnetic Tracking Systems

A parallel and partly independent line of development pursued three-dimensional navigation of the needle tip rather than, or in addition to, mechanical constraint of the needle shaft. Zhang and colleagues developed an optical-tracker-based registration and visual servoing method that coupled a robotic manipulator to real-time ultrasound imaging for percutaneous renal access, using optical markers to register the robot's coordinate frame to the ultrasound image plane and thereby allow closed-loop correction of needle trajectory as the ultrasound probe or patient moved, a design intended to solve the registration drift problem that limits purely image-based or purely mechanical approaches used in isolation [9]. Li and colleagues took a complementary, lower-cost approach by reporting single-center clinical experience with the SonixGPS electromagnetic needle-tracking and ultrasound-fusion navigation system for real-time ultrasonography-guided PCNL, in which an electromagnetic sensor embedded in the needle is tracked relative to a co-registered ultrasound volume and projected as a real-time trajectory overlay, without a robotic arm constraining the needle itself—demonstrating that electromagnetic tip-tracking alone,

without mechanical actuation, could improve first-attempt success in routine clinical practice [10].

Mean number of needle puncture attempts required to achieve percutaneous renal access with robotic or electromagnetic (EM) guidance versus conventional fluoroscopic or ultrasound-guided technique, across a cadaveric novice/expert study and a randomized clinical trial (error bars are reported standard deviations, where available).



Electromagnetic navigation without ultrasound fusion has also been evaluated directly against fluoroscopy-guided freehand technique. Huber and colleagues reported an initial clinical experience navigating renal puncture using electromagnetic tracking referenced to a preoperative CT dataset, describing successful calyceal targeting with the navigation system in a small clinical series and identifying registration accuracy and tracking of respiratory renal motion as the principal technical challenges to be solved before wider adoption [4]. Lima and colleagues subsequently reported the first clinical experience, under an IDEAL Stage 1 evaluation framework, of a novel electromagnetic guidance navigation system that combined a flexible ureteroscope-mounted electromagnetic sensor with an external tracked needle to allow ureteroscopy-assisted percutaneous access, in which the endoscopist inside the collecting system helps guide the percutaneous needle to the target calyx under real-time electromagnetic co-registration—an approach designed explicitly to reduce the number of puncture attempts and the reliance on fluoroscopic depth estimation [5]. In a subsequent pilot outcomes study using a comparable electromagnetic guidance platform, Borofsky and colleagues compared access outcomes across surgeons and trainees of varying experience levels and found that electromagnetic guidance narrowed, though did not fully eliminate, the performance gap between experienced and less-experienced operators, suggesting that navigation technology alone can partially substitute for years of freehand experience but that operator skill continues to influence outcomes even with tracking assistance [11].

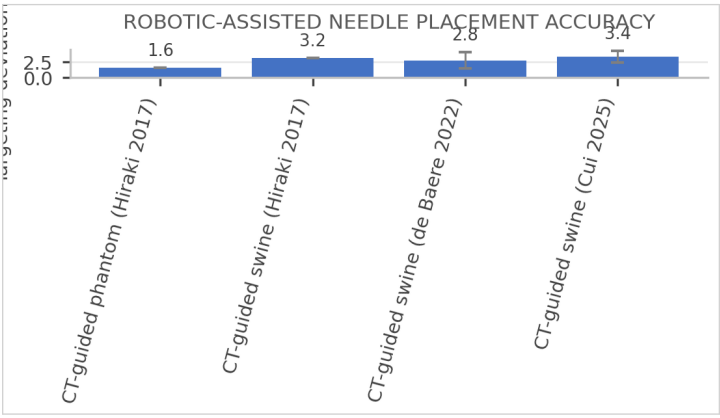
Taken together, this body of navigation-focused literature demonstrates that three-dimensional tracking of the needle tip—whether by optical marker, electromagnetic sensor, or ureteroscope-referenced coordinate frame—can meaningfully reduce the geometric uncertainty inherent to two-dimensional fluoroscopic or freehand ultrasound guidance, and that these gains are realizable even without a robotic arm physically constraining the needle. This sets up a natural convergence point: pairing electromagnetic or optical navigation-derived positional accuracy with robotic mechanical constraint of the needle trajectory, which is the approach taken by the majority of the most recent systems reviewed in the following section.

Accuracy and Safety Testing of Contemporary Robotic Access Platforms

Human and near-clinical comparative studies of robotic or navigation-assisted versus conventional percutaneous renal access.

Study	Population / design	Comparator	Principal finding
Taguchi et al. 2022	71 patients, randomized single-blind trial	Ultrasound-guided manual access	1.83 vs 2.51 punctures (p=0.025); 0% vs 14.3% access failure
Ballantyne et al. 2025	15 participants (10 novice, 5 expert), cadaveric	Fluoroscopy-guided manual access	Novices: 100% vs 70% success; 97% vs 37% first-pass accuracy
Bazzani et al. 2025	17 participants (4 experts, 13 residents), phantom	Manual insertion	Zero failed robotic insertions vs multiple resident failures
Taguchi et al. 2020	1 patient, first clinical case	N/A (feasibility)	Robot-assisted fluoroscopic access feasible during combined ECIRS
Knoedler et al. 2026	Early clinical series, MONARCH platform	N/A (early safety/efficacy)	Early clinical safety and efficacy of integrated robotic access system

Reported robotic-assisted needle placement accuracy across representative phantom and animal studies of image-guided robotic percutaneous renal access, expressed as mean targeting deviation from the intended target in millimeters (error bars are reported standard deviations, where available).



The most recent generation of robotic percutaneous renal access systems integrates a mechanically actuated needle driver with volumetric CT, cone-beam CT, or three-dimensional ultrasound guidance, and a growing number of these systems have now been subjected to quantitative accuracy and safety testing in phantom, cadaveric, animal, and early human studies. Hiraki and colleagues evaluated a CT-fluoroscopy-integrated needle insertion robot in both phantom and live swine experiments, reporting a mean targeting accuracy of 1.6 mm for robotic insertion versus 1.4 mm for manual insertion in phantom testing (a difference that was not clinically meaningful), and an overall mean accuracy of 3.2 mm across robotic insertions into liver, kidney, lung, and hip muscle targets in the animal experiments; critically, the effective radiation dose to the physician was 0 μSv for every robotic insertion, compared with a mean of 5.7 μSv for manual insertion, establishing operator radiation elimination as a reproducible and clinically significant safety benefit of CT-guided robotic needle

placement independent of any targeting accuracy advantage [12]. De Baere and colleagues subsequently tested a dedicated CT-guided robotic assistance system specifically for percutaneous kidney access in a live swine model, reporting a mean three-dimensional Euclidean targeting deviation of 2.8 ± 1.3 mm (lateral deviation 2.3 ± 1.2 mm, depth deviation 0.7 ± 1.7 mm) across eight needle trajectories to fiducial targets in two animals, with 100 percent of insertions successful on the first attempt and a median procedure time of 21 minutes from system activation to post-insertion imaging verification, without any needle readjustment required [13].

Direct head-to-head comparisons between robot-assisted and manual insertion under the same cross-sectional imaging modality have produced some of the most compelling safety and efficacy data. Cui and colleagues compared an optical-navigation robot-assisted CT-guided puncture system against manual CT-guided puncture across 24 kidney punctures in six swine, finding a targeting accuracy of 3.40 ± 0.91 mm for the robotic group versus 14.96 ± 12.42 mm for the manual group, a first-puncture success rate of 100 percent (12/12) for robotic insertion versus 33.3 percent (4/12) for manual insertion, and a mean procedure time of 3.92 ± 0.90 minutes for the robotic group versus 8.00 ± 4.22 minutes for the manual group, with the robotic group requiring zero needle adjustments compared with a mean of 1.00 ± 0.85 adjustments in the manual group [14]. Grüne and colleagues similarly compared robotic-assisted against manual Uro Dyna-CT-guided puncture in an ex-vivo kidney phantom model, reporting that robotic assistance improved puncture precision and reduced the number of control imaging acquisitions required relative to manual technique, reinforcing the accuracy advantage observed with live-tissue models in a controlled bench setting [15].

Clinical and cadaveric human data are now emerging alongside this preclinical evidence base. In a randomized, single-blind clinical trial, Taguchi and colleagues compared robotic-assisted fluoroscopic-guided renal access against conventional ultrasound-guided access in 71 patients undergoing PCNL (36 robotic-assisted, 35 ultrasound-guided), finding a significantly lower mean number of needle punctures in the robotic-assisted group (1.83 versus 2.51 punctures, $p = 0.025$), a shorter median needle puncture duration (5.5 versus 8.0 minutes, $p = 0.049$), and no access failures in the robotic-assisted group compared with a 14.3 percent access failure rate in the ultrasound-guided group, while overall complication rates and stone-free rates did not differ significantly between the two approaches [16]. Ballantyne and colleagues evaluated a robotic electromagnetic-guidance platform in a cadaveric study of ten novice and five expert urologists, finding that novice operators using robotic electromagnetic guidance achieved 100 percent access success versus 70 percent with conventional fluoroscopy, required substantially fewer attempts (1.47 ± 0.19 versus 3.42 ± 0.44), completed access faster (4.49 ± 0.96 versus 12.86 ± 2.41 minutes), and achieved markedly higher first-pass accuracy (97 percent versus 37 percent), while expert operators showed smaller but still favorable differences with robotic guidance—demonstrating that the greatest safety and efficiency benefit of robotic navigation accrues to less experienced operators, precisely the population for whom access-related complications are most concerning [17]. In a phantom-based feasibility study, Bazzani and colleagues found that an ultrasonographic-guided robotic-assistance platform eliminated failed needle insertions entirely among both experienced urologists and urology residents, whereas residents performing manual insertion experienced multiple failures and substantially longer probe travel distances before achieving target puncture, again indicating that the greatest gains from robotic assistance are realized among less experienced operators [18]. Taguchi and colleagues also reported the first clinical case of robot-assisted fluoroscopy-guided renal access performed during endoscopic combined intrarenal surgery, demonstrating feasibility of integrating a robotic access platform into a combined antegrade-retrograde procedural workflow in a single patient [19], while Singh and colleagues conducted a prospective multispecialty feasibility study of a robotic ultrasound-guidance platform for percutaneous access across multiple procedural indications, supporting cross-specialty translational potential of the technology beyond urology alone [20]. Most recently, Knoedler and colleagues reported an early clinical safety and efficacy evaluation of the MONARCH robotic platform for combined intrarenal surgery, representing an initial step toward integrating fully robotic renal access into a commercially developed surgical system [21].

Across this contemporary literature, several consistent findings emerge. First, robotic-assisted needle placement systems paired with volumetric imaging reliably achieve targeting accuracies in the 1.6 to 3.4 mm range in phantom and animal models, generally equal to or better than manual technique under the same imaging modality, and with dramatically tighter variance—the standard deviation of manual accuracy in several comparative studies exceeded the mean accuracy of the corresponding robotic arm. Second, robotic and navigation-assisted access consistently reduces the number of needle attempts and, in most but not all studies, shortens procedure time relative to manual technique, though the magnitude of benefit is generally larger for less experienced operators than for experts. Third, radiation exposure to the operating physician is reduced or eliminated in CT-guided and fluoroscopy-guided robotic systems, representing a safety benefit that is independent of, and arguably as clinically important as, any gain in targeting accuracy. Fourth, while overall procedural complication rates and stone-free rates have not consistently differed between robotic and manual access in the limited human comparative data available to date, access failure rates have been consistently lower with robotic or navigation assistance, particularly among trainees.

Clinical Translation, Limitations, and Future Directions

Despite this generally favorable accuracy and safety profile, several limitations temper enthusiasm for immediate widespread clinical adoption. Most of the quantitative accuracy data reviewed here derive from phantom, ex-vivo, or live animal models rather than human patients, and the animal and phantom kidney is a simplified surrogate for the more variable anatomy, respiratory motion, and tissue deformation encountered clinically, particularly in patients with prior renal surgery, staghorn calculi, or significant body habitus variation. Among the human studies identified, sample sizes remain modest—71 patients in the largest randomized trial and 15 participants in the largest cadaveric comparative study—and most systems have been tested at a single center by investigators closely associated with the device's development, raising the possibility of a Hawthorne-type performance effect not yet tested under independent, multicenter conditions. Complication and stone-free rate differences between robotic and manual access have generally not reached statistical significance in the human studies to date, likely reflecting both the modest sample sizes available and the fact that access-related

complications, while serious, remain relatively infrequent events that require substantially larger cohorts to detect a difference with adequate statistical power [16,1]. Cost, procedural workflow integration, and the additional equipment footprint required by CT-, cone-beam-CT-, or electromagnetic-tracking-based systems also remain practical barriers, particularly in resource-limited settings where PCNL access-related morbidity may be highest.

Looking forward, several trends observable across the reviewed literature suggest where the field is heading. The consistent finding that robotic and navigation assistance narrows, rather than eliminates, the performance gap between novice and expert operators points toward training and credentialing applications as an important near-term use case, potentially allowing less experienced surgeons and trainees to achieve access accuracy and safety approaching that of experienced operators [17,11,18]. The progressive integration of robotic actuation with increasingly sophisticated imaging—from two-dimensional fluoroscopy in the earliest PAKY-RCM systems, through electromagnetic and optical tracking, to full CT and three-dimensional ultrasound volumetric guidance in the most recent platforms—suggests that further accuracy gains will likely come from improved real-time deformable registration and respiratory motion compensation rather than from mechanical refinement of the needle driver itself, which has already achieved sub-millimeter reproducibility in bench testing [9,14]. Finally, the emergence of commercially developed integrated platforms such as the MONARCH system, alongside continuing academic development of CT- and ultrasound-guided robots, indicates that percutaneous renal access is likely to follow a translational trajectory broadly similar to that of robotic-assisted laparoscopic and endoscopic surgery, moving from single-center feasibility studies toward multicenter randomized comparative trials and, ultimately, broader commercial and regulatory adoption [21,20].

Conclusion

Three decades of engineering effort have progressively transformed robotic-assisted percutaneous renal access from a mechanically constrained fluoroscopic needle guide into an increasingly sophisticated family of systems that integrate electromagnetic or optical tracking, volumetric CT and ultrasound imaging, and closed-loop robotic actuation. Individually verified phantom, cadaveric, and animal studies consistently report robotic targeting accuracies in the low single-digit millimeter range, frequently with substantially lower variance than manual technique performed under identical imaging conditions, together with reduced numbers of needle attempts, shorter procedure times in most comparative studies, and, where fluoroscopy is used, elimination or marked reduction of operator radiation exposure [12,13,14,15]. Early human randomized and cadaveric comparative data corroborate these preclinical findings, showing fewer punctures, lower access failure rates, and disproportionately large benefits for less experienced operators, even though complication and stone-free rate differences have not yet reached statistical significance in the modestly sized trials completed to date [16,17,18]. As multicenter clinical evaluation of contemporary platforms such as MONARCH and ultrasound- and CT-guided robotic systems continues, robotic-assisted needle insertion is well positioned to become an increasingly standard component of safe, reproducible percutaneous renal access, particularly as a means of narrowing the performance gap between trainees and expert endourologists [21,20,6].

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Conflict of Interest

The authors declare no conflict of interest.

Author Contributions

Krajnc B conceived the review, conducted the literature search, and drafted the manuscript. Marchand C contributed to the literature screening, clinical framing, and critically revised the manuscript for important intellectual content. Karagiannis E contributed additional technical and engineering context and approved the final version for submission.

Ethics Statement

Not applicable. This is a narrative review of previously published literature and did not involve new experimental data, human participants, or animal subjects.

Data Availability

No new data were generated or analyzed for this review. All sources synthesized are cited in the reference list and are available through their original publishers.

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