Robotic and computer-assisted techniques in ear surgery

Fujita, Takeshi ; Ito, Taku ; Uchida, Masaya ; Koyama, Hajime ; Takahashi, Masahiro ; Nakazawa, Takara ; Fujiwara, Takashi ; Matsumoto…

(Citation)
Auris Nasus Larynx,52(4):496-501

(Issue Date)
2025-08

(Resource Type)
journal article

(Version)
Version of Record

Auris Nasus Larynx 52 (2025) 496–501

Contents lists available at ScienceDirect

Auris Nasus Larynx

journal homepage: www.elsevier.com/locate/anl

Robotic and computer-assisted techniques in ear surgery

Takeshi Fujita [a,*], Taku Ito [b], Masaya Uchida [c], Hajime Koyama [d], Masahiro Takahashi [e], Takara Nakazawa [f], Takashi Fujiwara [g], Nozomu Matsumoto [h], Tadao Yoshida [i], Naohiro Yoshida [j], Seiji Kakehata [f], Manabu Komori [k], Naohito Hato [l]

[a] *Department of Otolaryngology - Head and Neck Surgery, Kobe University Graduate School of Medicine, Hyogo 650-0017, Japan*
[b] *Department of Otorhinolaryngology, Institute of Science Tokyo, Tokyo 105-0011, Japan*
[c] *Department of Otorhinolaryngology Tracheoesophageal Surgery, Japanese Red Cross, Kyoto Daini Hospital, Kyoto 602-8026, Japan*
[d] *Department of Otolaryngology and Head and Neck Surgery, Faculty of Medicine, University of Tokyo, Tokyo 113-8655, Japan*
[e] *Department of Otorhinolaryngology, Jikei University School of Medicine, Tokyo 105-8461, Japan*
[f] *Department of Otolaryngology, Endoscopic Middle Ear Surgery Center, Ota General Hospital, Kanagawa 210-0852, Japan*
[g] *Department of Otolaryngology, Kurashiki Central Hospital, Okayama 710-8602, Japan*
[h] *Department of Otorhinolaryngology, Graduate School of Medical Sciences, Kyushu University, Fukuoka 812-8582, Japan*
[i] *Department of Otorhinolaryngology, Nagoya University Graduate School of Medicine, Nagoya 466-8550, Japan*
[j] *Department of Otolaryngology-Head and Neck Surgery, Jichi Medical University Saitama Medical Center, Saitama 330-8503, Japan*
[k] *Department of Otolaryngology, St. Marianna University School of Medicine, Kanagawa 216-8511, Japan*
[l] *Department of Otolaryngology, Head and Neck Surgery, Ehime University School of Medicine, Ehime 791-0295, Japan*

ARTICLE INFO

Keywords:
Robotic ear surgery
Cochlear implantation
Augmented reality
Virtual reality
Artificial intelligence

ABSTRACT

Robotic and computer-assisted systems for ear surgery are receiving growing attention as tools to overcome the challenges intrinsic to the delicate, restricted operative field of the middle and inner ear. This review highlights recent advances in robotic platforms, clinical outcomes, and emerging technologies such as augmented reality (AR), virtual reality (VR), and artificial intelligence (AI). Multiple groups worldwide have introduced robotic devices that aid or automate tasks like mastoid drilling, stapes footplate fenestration, and cochlear implant (CI) electrode insertion. Seminal studies involving systems such as HEARO, iotaSoft, and RobOtol reveal sub-millimeter accuracy and minimized trauma during CI, suggesting the potential to reduce postoperative complications and improve hearing preservation.

Although these technologies have progressed from proof-of-concept prototypes to early clinical usage, significant barriers remain before they become routine. Cost is a key concern, given the relatively small patient population for otologic procedures compared to other surgical fields. Regulatory pathways also require strict safety validations, particularly for semi-autonomous or fully autonomous functions. Nevertheless, FDA and European CE approvals for certain robotic systems illustrate their growing feasibility. Meanwhile, AR- and VR-based navigation is improving intraoperative visualization by overlaying critical structures such as the facial nerve onto the surgeon's field, while AI-driven algorithms for instrument tracking and real-time monitoring offer further enhancements in safety and precision. In addition, simulation-based training in VR environments can accelerate surgical expertise and reduce learning curves.

Larger-scale clinical trials that directly compare robotic and conventional approaches are still needed to quantify benefits related to complication rates, operative times, and long-term auditory outcomes. Ongoing innovations in software integration and miniaturized hardware are likely to broaden the range of feasible robotic tasks within the ear's narrow anatomical boundaries.

* Corresponding author at: Department of Otorhinolaryngology Head and Neck Surgery, Kobe University Graduate School of Medicine, 7-5-1 Kusunokicho, Chuoku, Kobe, Hyogo, 650-0017.

E-mail address: fujitake@med.kobe-u.ac.jp (T. Fujita).

https://doi.org/10.1016/j.anl.2025.06.013
Received 3 April 2025; Accepted 30 June 2025
Available online 25 July 2025

1. Introduction

Ear surgeries (including tympanoplasty, stapes surgery, cochlear implantation (CI), and endoscopic approaches) demand extreme precision due to the minute anatomy and proximity of delicate structures (such as the facial nerve and ossicles). Traditionally, these microsurgeries rely on the surgeon's skill under a microscope or endoscope. In recent years, there has been a surge in research exploring robotic assistance and advanced surgical support systems to overcome human limitations such as hand tremor and restricted dexterity [1].Robotic technology, widely adopted in fields like urology and neurosurgery, is now making inroads into otologic surgery – albeit slowly, owing to the unique challenges of the middle and inner ear's confined space and the required sub-millimeter precision.

This review summarizes the latest research trends in robot-assisted ear surgery, current clinical applications and outcomes, the key features of emerging robotic systems, developments in surgical navigation and augmented reality (AR)/virtual reality (VR) support, and the future prospects and challenges for this field.

2. Latest research trends in robotic ear surgery

Research into robotic and computer-assisted ear surgery has accelerated over the past decade. Numerous engineering and clinical groups worldwide are developing systems to assist or automate parts of otologic procedures. For example, Lim et al. introduced a semi-manual mastoidectomy system using human–robot collaboration that selectively protects critical structures (such as the facial nerve) [2]. Early proof-of-concept studies have likewise demonstrated the feasibility of robotic keyhole drilling in cochlear implantation [3,4]. Broadly, these experimental surgical robots fall into three categories: (a) co-manipulated systems where the surgeon and robot jointly handle instruments, (b) teleoperated systems where the surgeon controls instruments via a master console, and (c) (semi)autonomous systems that execute surgical actions under surgeon supervision [1].

Key technical trends include improving accuracy of bone drilling, reducing tremor in microsurgery, and minimizing trauma during implant insertion. For example, robot-assisted keyhole drilling approaches have been developed to access the cochlea with sub-millimeter accuracy, avoiding critical structures like the facial nerve [5]. Another active area is enhancing the precision of stapedotomy (opening the stapes footplate) and ossiculoplasty (ossicular reconstruction), where even minor hand tremors can cause inner ear damage. Researchers have introduced handheld robotic micromanipulators that cancel tremor and scale down surgeon movements for these delicate steps [6].

In parallel, there is growing interest in leveraging artificial intelligence (AI) and AR in the operating room: AI algorithms are being studied for real-time tracking of surgical tools and identification of anatomical landmarks [7], while AR systems can overlay critical structures onto the surgeon's view to guide navigation. The number of scientific publications on AR in otologic surgery, for instance, has steadily increased from 2007 through 2022 [8], reflecting broader enthusiasm for integrating these technologies. Importantly, recent literature reviews highlight that we are transitioning from pure engineering development to early clinical evaluation.

Riojas and Labadie noted that current trials in otologic robotics focus on enhancing the accuracy of stapes surgery, enabling minimally invasive cochlear access, and achieving less traumatic cochlear implant insertions [1]. Another review by Sheppard et al. observed that multiple robotic prototypes for middle ear surgery have been reported, but only a couple have reached initial clinical use so far [9].

In summary, the research trend over the last ten years has moved from concept prototypes towards translation, with first-in-human studies of robotic ear surgery now reported. The field is at a pivotal "edge of clinical application," where pioneering surgical series are testing the feasibility and safety of these systems in patients. This sets the stage for broader clinical trials and eventual adoption if these technologies prove their value.

3. Current clinical applications and outcomes

Despite the extensive research, robotic ear surgery is still in its infancy clinically. A few specialized centers in Europe and the United States have begun integrating robotic systems for select ear procedures, under clinical trial or pilot settings. The current applications and findings can be summarized by surgical procedure:

3.1. Cochlear implantation

The most notable clinical translation has been in cochlear implant (CI) surgery. In 2017–2018, the first robot-assisted cochlear implantation procedures were performed in Europe using a system called HEARO (developed by CASCINATION AG) [5]. HEARO performs a planned "keyhole" mastoidectomy, drilling a narrow (1.8–2.5 mm) trajectory toward the cochlea while avoiding critical structures such as the facial nerve. In an initial Swiss clinical trial, nine patients successfully underwent this minimally invasive robotic approach, and no facial nerve injuries or other major adverse events were reported. In six of these nine patients, the surgical team proceeded with full robotic access to the round window for electrode insertion, yielding hearing outcomes comparable to conventional CI. More recently, the first case of fully robotic cochlear implantation—including automated electrode insertion—was also performed with HEARO, demonstrating a safe procedure and audiometric results equivalent to manual surgery [10].

A second system, the iotaSoft (iotaMotion Inc., USA) robotic inserter, has been tested under an FDA investigational trial. It is designed to automate electrode insertion while still allowing the surgeon to pause, retract, or adjust technique as needed. In a single-center study with 21 adult CI patients, the iotaSoft device achieved a 95.2 % success rate in fully advancing electrodes, with no device-related adverse events. Postoperative outcomes indicated stable device function and no major complications [11].

A third system, the teleoperated micro-robot RobOtol (Collin Medical, France), initially developed for middle ear surgery (for example, stapedotomy, tympanoplasty), has also been investigated for cochlear implantation [12,13]. RobOtol is equipped with six degrees of freedom—three linear and three rotational axes—and features two interchangeable arms: an endoscope holder enabling two-handed transcanal procedures, and a micro-instrument holder for tremor suppression and tools such as lasers or cochlear implant insertion instruments [12,13]. In a 2021 pilot report, RobOtol demonstrated stable micro-instrument handling and no robot-related complications when assisting CI surgery [12]. That same year, another study described the first use of RobOtol in pediatric recipients, confirming the feasibility and safety of robot-assisted electrode insertion in younger patients as well [13]. More recently, a 2023 intra-individual study comparing robot-assisted versus manual CI insertion found equivalent speech recognition outcomes, supporting the feasibility of robotic assistance [14]. In addition, an ongoing clinical trial (NCT05696171) is evaluating RobOtol-based CI insertion in adults against the conventional manual approach to further assess safety and postoperative hearing outcomes [15].

3.2. Stapes surgery

Stapedotomy or stapedectomy for otosclerosis is already highly successful using conventional techniques, with excellent hearing outcomes and low complication rates [9]. Nevertheless, sub-millimeter precision in footplate fenestration has driven research into robotic assistance to further reduce surgical variability. The teleoperated RobOtol system, for example, has been applied not only in cochlear implantation but also in middle ear procedures such as laser stapedotomy, demonstrating stable instrument handling with no robot-related complications in a pilot series [12]. Another micro-manipulator, the MMS-II (Micro Manipulator System II) in Germany, tested in a 2016 preclinical study, showed potential for precise footplate drilling, though its limited degrees of freedom may limit broader clinical use [16]. While these early results suggest that robotic assistance is technically feasible and safe, larger-scale trials are needed to establish whether it provides tangible benefits—such as even fewer complications or more consistent hearing outcomes—over standard manual stapes surgery.

3.3. Tympanoplasty and chronic ear surgery

Robotic assistance in tympanoplasty and chronic ear surgery has primarily focused on stabilizing endoscopes and microinstruments to improve surgical precision. In one pilot series using the teleoperated RobOtol system for endoscopic procedures in 37 patients, no robot-related complications were noted, and hearing outcomes were comparable to conventional techniques [17]. Similar feasibility studies have tested RobOtol or comparable systems for graft placement and ossicular chain repair, reporting stable visualization and bimanual access [12] but acknowledging the need for larger trials to confirm cost-effectiveness and workflow benefits over standard manual surgery.

4. Types of robotic systems and their features

Robotic systems for ear surgery vary in design and mode of interaction with the surgeon. Here we compare the main types of robots and assistive devices being developed, along with examples and their key characteristics:

4.1. Co-manipulated and handheld active robots

These systems provide real-time motion stabilization and tremor filtering while allowing the surgeon to hold the instrument directly. A notable example is Micron, developed at Carnegie Mellon/Pitt [6], which detects involuntary hand tremors and compensates instantly. In ex vivo stapedotomy tests, Micron significantly improved footplate fenestration accuracy. These so-called "steady-hand" robots maintain the surgeon's tactile feedback but enhance precision via features like motion scaling and virtual boundaries [18]. Another example is the Steady-Hand Robot from Johns Hopkins, originally for eye surgery but now considered for otology [3]. Although they do not automate procedures, co-manipulated robots excel in microsurgical tasks requiring sub-millimeter accuracy.

4.2. Teleoperated master-slave robots

Teleoperated robots physically execute surgical actions but are controlled by the surgeon via a console, joystick, or similar interface. In otologic procedures, this approach allows motion scaling (large hand movements become microscopic tool movements) and tremor filtering, enabling precise manipulation in narrow spaces while improving surgical ergonomics. The trade-off is limited tactile feedback and potentially complex setup; moreover, large robotic arms designed for abdominal surgery are often too bulky for the confined area around the ear.

A notable example is the RobOtol system (Collin Medical, France), which features a remote-center-of-motion (RCM) mechanism tailored to the ear canal. By pivoting around a fixed point at the canal's entrance, RobOtol can position instruments or an endoscope without damaging canal walls [19]. In preclinical and pilot clinical studies, it has been shown capable of handling tasks like laser stapedotomy and endoscopic middle ear surgery [12]. Another teleoperated prototype, the MMS-II micromanipulator (Germany), was designed specifically for stapes footplate drilling and prosthesis placement [16]. Although it demonstrated precise control in a 2016 preclinical trial, its limited range of motion restricts broader application.

Overall, specialized teleoperated systems like RobOtol and MMS-II highlight the potential of remote-control robotics in otologic microsurgery, offering enhanced precision and stability in procedures that demand sub-millimeter accuracy.

4.3. Semi-Autonomous and autonomous systems

Fully autonomous robots remain rare in ear surgery, but semi-autonomous workflows have been introduced for select tasks—such as image-guided cochlear access and controlled electrode insertion—under surgeon oversight. Systems like HEARO [5,10] and iotaSoft [11] rely on preoperative CT planning, calibration, and safety checks to execute pre-defined actions (for example, drilling a narrow tunnel or advancing an electrode) with sub-millimeter precision. This can reduce human variability, enable motion profiles beyond normal dexterity, and potentially lessen cochlear trauma [10]. However, autonomy also requires robust fail-safes and faces strict regulatory hurdles, with major surgical steps unlikely to become fully automated in the near term [1]. Currently, these robots are used for specific subtasks rather than entire procedures, reflecting the need for further validation before broader clinical adoption.

In addition to these categories, some robotic systems are designed specifically for endoscope positioning in ear or sinus procedures. By stabilizing the endoscope via a controlled arm, these devices free the surgeon's hands for bimanual instrument manipulation and potentially improve procedural ergonomics. For example, Michel et al. describe a robotic holder with an integrated safety device based on a parallelogram mechanism, designed to prevent unintentional movement and injury during ear and sinus surgery [20]. Meanwhile, Fujita et al. developed a compact, bed rail-mounted endoscope manipulator featuring yaw and pitch control via gimbal-based linkages plus a linear guide rail for insertion. Their cadaver and model simulations demonstrated positional accuracy under 0.1 mm even under load, and they found that less experienced surgeons benefited from more consistent performance when using the robot compared to manual endoscope handling [21]. Additionally, the Intelligent Surgeon's Arm Supporting System (iArmS), introduced for neurosurgical procedures and endoscopic sinus surgery [22,23], is now being adapted for otologic endoscopic surgery, providing surgeon arm stabilization that can reduce operator fatigue and enhance precision in confined middle ear spaces. These developments suggest that purpose-built endoscope holders—and supportive systems like iArmS—can maintain a steady operative view while reducing surgeon fatigue, potentially enhancing safety and efficiency—especially in transcanal endoscopic ear surgery (TEES) where workspace is highly constrained.

To illustrate the landscape of current systems, below is a summary of notable robotic technologies for ear surgery and their features (Table 1).

5. Advances in surgical navigation, AI, and AR/VR for ear surgery

Technological advancements in surgical navigation, AI, and AR/VR are significantly transforming otologic surgery. These innovations enhance surgical precision, intraoperative visualization, and decision-making, offering improved safety and efficiency in both conventional and robotic-assisted procedures.

5.1. Image-guided surgery / surgical navigation

Surgical navigation has greatly enhanced otologic procedures by providing real-time instrument tracking and facilitating the identification of critical anatomical structures, such as the facial nerve and cochlea, even in cases of distorted anatomy [24]. In cochlear implantation, navigation-assisted techniques have achieved submillimeter accuracy (~0.9–1 mm), ensuring safer electrode insertions, particularly in complex anatomical cases [25]. AR overlays can further assist endoscopic

Table 1
Comparison of current robotic systems for ear surgery.

System / Concept	Country	Type	Year	Key Features	Status / Remarks
Micron Handheld Robot (Carnegie Mellon/Pitt)	USA	Co-manipulated (Handheld)	Early 2010s [6]	Active tremor cancellation; Sub-micron motion control; Integrated sensing/actuation	Validated in ex vivo studies; Not yet in clinical use
MMS-II (Munich)	Germany	Teleoperated (Master-Slave)	2016 [16]	Stapes footplate drilling; Prosthesis placement; Limited DOF design	Limited clinical testing; Development discontinued
RobOtol (Collin)	France	Teleoperated (Master-Slave)	2010–2021 [12,13,19]	RCM-based design; Multi-instrument compatibility; Motion scaling capability	CE-marked; >30 clinical cases completed; Active use in stapes/tympanoplasty and CI electrode insertion.
HEARO (CASCINATION)	Switzerland	Semi-autonomous (Image-guided)	2019 [5]	Image-guided drilling; Automated electrode insertion; Safety constraint system	CE-marked; Clinical trial completed (n = 9); Commercial evaluation ongoing
iotaSoft (iotaMotion)	USA	Semi-autonomous (Insertion Tool)	2023 [11]	CI electrode insertion; Force/speed control; Surgeon override function	FDA approved (Class II); Clinical trial: 95 % success (n = 21); Under continued evaluation
Endoscope Holders	Various	Teleoperated / Assistive	2022–2025 [20,21]	Stable endoscope positioning; Multiple control options; Compact design	Early clinical testing; Various prototypes in development

RCM = Remote Center of Motion; DOF = Degrees of Freedom; CI = Cochlear Implant.

approaches by projecting pathologies like cholesteatoma onto the surgical view [26].

For intraoperative imaging, noninvasive registration methods, including STAMP or 3D-printed templates, simplify workflow and reduce invasiveness [27,28]. Meanwhile, robotic systems build on navigated drilling concepts and have shown promise in "keyhole" cochlear implantation; however, technical complexity sometimes necessitates reverting to conventional approaches [29]. Regardless of whether robotic or manual, these navigation-assisted techniques aim to improve precision in stapes surgery, tympanomastoidectomy, and cochlear implantation—particularly in challenging anatomies. Ultimately, image-guided and computer-assisted methods serve as valuable adjuncts, complementing surgical expertise rather than replacing it.

5.2. Augmented reality (AR) in otologic surgery

AR technology superimposes digital data onto the surgeon's real-world view, enhancing intraoperative visualization. In otologic procedures, AR can project patient-specific anatomical details—such as the facial nerve's course from preoperative CT data—directly onto the microscope or endoscope display. A 2023 scoping review by Chen et al. identified 18 studies in otology/neurotology, with most focusing on AR for surgical navigation and drill guidance [8]. For example, Hussain et al. developed a microscope-integrated AR system that improved landmark identification during middle ear surgery [30]. Similarly, Tsuchida et al. demonstrated that AR-assisted TEES could delineate cholesteatoma boundaries, thereby aiding precise bone removal [26]. Recently, Uchida et al. proposed "image-guided percutaneous endoscopic ear surgery (IGPEES)," combining AR navigation with a minimal keyhole mastoidectomy to enhance accuracy and reduce invasiveness for middle ear pathologies. Their retrospective analysis of 11 cases showed improved precision (registration error ~0.25 mm) without major complications, suggesting the feasibility of AR-assisted keyhole approaches in otologic surgery [31]. A study by Ito et al. (2024) introduced a novel AR system that projects 3D holographic images onto surgical footage without requiring head-mounted displays. This approach significantly lowered cognitive load and improved surgical orientation during cochlear implant surgeries [32]. Additionally, the same group reported a VR/MR-based navigation system using only commercially available devices for lateral temporal bone resection [33], and also demonstrated the usefulness of patient-specific VR/MR in both anatomy education and surgical planning for complex temporal bone cases [34]. AR is also proving valuable in education; its overlays help trainees visualize hidden structures—like the cochlea behind the promontory—without diverting attention from the operative field. Moreover, Hadida Barzilai et al. conducted a randomized controlled trial using an AR-guided mastoidectomy simulator, demonstrating that AR training significantly improved surgical proficiency, especially among less experienced surgeons [35]. Although challenges remain—such as achieving sub-millimeter registration accuracy and dynamically updating overlays—advances in tracking algorithms and hardware promise to further integrate AR into both surgical navigation and training in otologic surgery [8,36].

5.3. Artificial intelligence and automation aids

AI in the context of ear surgery is being applied in a few ways. One area is intraoperative video analysis – using computer vision to recognize surgical instruments and anatomic structures in real-time. For example, researchers at Mass. Eye and Ear demonstrated an AI model that can accurately track the surgical drill in endoscopic mastoidectomy videos in near real-time [7]. This capability could enable automated monitoring of the drilling process, warning the surgeon or even stopping an autonomous robot if the drill gets too close to a critical structure. AI-based detection of the facial nerve or sigmoid sinus on the surgical field video could serve as an additional safety layer. Another AI application is in preoperative planning: using machine learning to analyze CT scans to identify optimal mastoid drilling paths or predict which patients are suitable for certain minimally invasive approaches. For instance, algorithms have been developed to automatically segment the facial nerve and other key structures on temporal bone CT, which can then feed into a navigation or robotic planning system [15].

In cochlear implantation, AI has been used to evaluate insertion techniques – one study trained a model on force and motion data to distinguish between smooth vs. problematic electrode insertions, which could help a robotic inserter adapt its strategy. Moreover, in the domain of diagnostics, AI models have shown high accuracy in recognizing middle ear pathologies (for example, identifying otitis media on endoscopic ear images) [37]. While not directly surgical, this could eventually integrate with surgical decision support (for example, an AI suggesting the presence of ossicular erosion that requires reconstruction). Overall, AI in otologic surgery is still emerging; unlike fields such as radiology where AI is more mature, here it is mostly in experimental stages here. The vision is that in the future, AI could provide a form of "smart assistance" – for example, guiding a surgeon's instrument along an optimal path, optimizing a robot's speed based on tissue feedback, or predicting complications during a case. Any AI deployed in surgery must be thoroughly validated for reliability, as errors could have serious consequences. So far, the controlled environment of simulators and labs has been the main proving ground for these algorithms.

5.4. Virtual reality (VR) and simulation for training and planning

VR has emerged as a powerful tool for surgical training in otology.

High-fidelity temporal bone simulators—such as the Voxel-Man system and others—provide 3D representations of skull anatomy and haptic feedback during mastoid drilling, enabling trainees to practice mastoidectomy and related procedures in a risk-free environment [38–41]. Building on these systems, several groups have developed VR modules specifically for robotic ear surgery. For example, Kazmitcheff et al. introduced a VR simulator integrated with a teleoperated robot that allows trainees to plan a robotic cochlear implant trajectory and simulate robotic endoscope control during middle ear procedures [40].

Beyond training, VR is increasingly used for preoperative planning: surgeons can perform a "virtual rehearsal" by navigating patient-specific VR models derived from CT scans, thereby identifying potential challenges—such as canal-wall-up vs. canal-wall-down mastoidectomy—before entering the operating room [36]. Furthermore, recent work by Andersen et al. demonstrated that VR-based rehearsal can correlate with actual postoperative outcomes in cochlear implantation [42], while Talks et al. provided evidence that VR simulation improves surgical skill acquisition [43]. Finally, mixed reality approaches are being explored to enable remote expert guidance during challenging cases, further underscoring VR's growing role in otologic surgery.

6. Future perspectives and challenges

6.1. Regulatory and safety considerations

Surgical robots must clear stringent regulatory thresholds to ensure that benefits outweigh risks. In the United States, the FDA has established specific regulatory pathways for surgical robots based on their intended use and risk level. For example, the iotaSoft system is the first semi-autonomous robotic surgical support device in otology to receive marketing authorization through the FDA's De Novo classification [11]. The FDA determined that iotaSoft is a novel device with no existing predicate, yet concluded it did not present a high enough level of risk to require a PMA, thus classifying it as Class II via De Novo. If similar medical devices are developed in the future, the iotaSoft device could serve as a predicate, potentially allowing a 510(k) submission [44].

In Europe, the CE marking under the Medical Device Regulation (MDR 2017/745) requires manufacturers to demonstrate comprehensive safety data, risk management processes, and clinical evidence [45]. Robotic systems like RobOtol and HEARO have achieved CE marking [5, 12], requiring them to meet essential requirements including mechanical reliability, sterilization validation, software verification, and thorough documentation of safety features. In Japan, the Pharmaceuticals and Medical Devices Agency (PMDA) applies similar stringent standards, with surgical robots typically requiring extensive preclinical and clinical data for approval [46].

Common safety requirements across jurisdictions include:

1. Redundant monitoring systems (for example, electromyographic facial nerve monitoring during mastoid drilling)
2. Emergency stop mechanisms and backup operational modes
3. Fail-safe features that prevent uncontrolled movements
4. Sterility maintenance throughout the procedure
5. Comprehensive validation of software controlling automated movements

The pathway to approval typically involves rigorous testing, from preclinical validation through carefully monitored first-in-human trials [45,47]. Most developers adopt a stepwise strategy: securing approval first for semi-autonomous or assistive functions, then gradually expanding autonomy as clinical experience grows [48]. This approach has proven successful, as evidenced by the FDA clearance of powered insertion systems [11,49] and CE marking of image-guided platforms [5, 50]. As robotic technologies evolve, regulatory frameworks continue to adapt, particularly regarding AI integration and human-robot interaction safety, requiring ongoing collaboration among engineers, clinicians, and regulators.

6.2. Cost and economic viability

The financial challenge of robotic ear surgery is substantial. Designing and manufacturing specialized robotic platforms for a relatively small market—compared to general surgery or orthopedics—drives up costs, which hospitals must weigh against potential benefits [48]. Because most payers still reimburse robotic otologic procedures at the same rate as conventional surgery, institutions often bear the additional expense of capital equipment, disposables, and maintenance. In Japan, for instance, robotic procedures gained traction only after select surgeries (for example, prostatectomy) secured reimbursement; similar coverage gaps now limit broader adoption in otology [46].

Demonstrating clear clinical advantages—such as reduced complication rates, improved hearing preservation, or shorter hospital stays—remains key to justifying investment. Some early studies suggest that robotic systems can mitigate insertion trauma or enhance surgical precision; if validated in larger trials, these benefits may translate to fewer postoperative complications and eventual cost savings [50]. Over the long term, the market could expand if developers introduce more versatile "modular" robots that address multiple ENT or skull base procedures, distributing expenses and improving utilization. As pioneering centers publish positive outcomes, it may prompt insurers to cover these procedures, increasing financial feasibility. Until then, cost-effectiveness analyses and health technology assessments will continue to shape how quickly robotic ear surgery becomes standard practice [48].

7. Conclusion

Over the past decade, robotic and computer-assisted techniques in ear surgery have rapidly progressed from proof-of-concept to initial clinical application. Early studies involving cochlear implantation and stapes surgery suggest these technologies can be both safe and highly precise, with navigation, AR/VR, and AI further enhancing surgical capabilities. However, challenges remain: high costs, technological refinement, and the need for large-scale clinical trials to establish definitive evidence. Looking ahead, broader adoption of robotic ear surgery may help reduce complications, shorten recovery times, and improve hearing outcomes.

Author contributions

Each author made substantial contributions to the conception, drafting, and revision of this manuscript. TF prepared the overall manuscript draft. All other authors reviewed and revised the respective sections of the article, contributed critical feedback, and approved the final version of the manuscript for submission.

Declaration of competing interest

All authors declare that they have no conflicts of interest related to this work.

References

[1] Riojas KE, Labadie RF. Robotic ear surgery. Otolaryngol Clin North Am 2020;53(6): 1065–75.
[2] Lim H, Matsumoto N, Cho B, et al. Semi-manual mastoidectomy assisted by human-robot collaborative control - A temporal bone replica study. Auris Nasus Larynx 2016;43(2):161–5.
[3] Rothbaum DL, Roy J, Stoianovici D, Berkelman P, Hager GD, Taylor RH, et al. Robot-assisted stapedotomy: micropick fenestration of the stapes footplate. Otolaryngol Head Neck Surg 2002;127(5):417–26.
[4] Miroir M, Nguyen Y, Szewczyk J, Sterkers O, Bozorg Grayeli A. Design, kinematic optimization, and evaluation of a teleoperated system for middle ear microsurgery. ScientificWorld J 2012;2012:907372.

[5] Caversaccio M, Wimmer W, Anso J, Mantokoudis G, Gerber N, Rathgeb C, et al. Robotic middle ear access for cochlear implantation: first in man. PLoS One 2019; 14(8):e0220543.
[6] Vendrametto T, McAfee JS, Hirsch BE, Riviere CN, Ferrigno G, De Momi E. Robot assisted stapedotomy ex vivo with an active handheld instrument. Annu Int Conf IEEE Eng Med Biol Soc 2015;2015:4879–82.
[7] Liu GS, Parulekar S, Lee MC, El Chemaly T, Diop M, Park R, et al. Artificial intelligence tracking of otologic instruments in mastoidectomy videos. Otol Neurotol 2024;45(10):1192–7.
[8] Chen JX, Yu SE, Ding AS, Lee DJ, Welling DB, Carey JP, et al. Augmented reality in otology/neurotology: a scoping review with implications for practice and education. Laryngoscope 2023;133(8):1786–95.
[9] Sheppard SC, Caversaccio MD, Anschuetz L. Endoscopic and robotic stapes surgery: review with emphasis on recent surgical refinements. Curr Otorhinolaryngol Rep 2022;10:34–9.
[10] Abari J, Heuninck E, Topsakal V. Entirely robotic cochlear implant surgery. Am J Otolaryngol 2024;45(5):104360.
[11] Gantz JA, Gantz BJ, Kaufmann CR, Henslee AM, Dunn CC, Hua X, et al. A steadier hand: the first Human clinical trial of a single-use robotic-assisted surgical device for Cochlear implant electrode array insertion. Otol Neurotol 2023;44(1):34–9.
[12] Vittoria S, Lahlou G, Torres R, Daoudi H, Mosnier I, Mazalaigue S, et al. Robot-based assistance in middle ear surgery and cochlear implantation: first clinical report. Eur Arch Otorhinolaryngol 2021;278(1):77–85.
[13] Jia H, Pan J, Gu W, Tan H, Chen Y, Zhang Z, et al. Robot-assisted electrode array insertion becomes available in pediatric cochlear implant recipients: first report and an intra-individual study. Front Surg 2021;8:695728.
[14] Maheo C, Marie A, Torres R, Archutick J, Leclère JC, Marianowski R. Robot-assisted and manual Cochlear implantation: an intra-individual study of speech recognition. J Clin Med 2023;12(20):6580.
[15] Hospital Guillaume Rene Laennec. Clinical evaluation of robot-assisted cochlear implant insertion in adults using robotol® compared to manual insertion [Internet]. ClinicalTrials.gov Identifier; 2025. NCT05696171.[cited 2025 Feb 11]. Available from: https://www.centerwatch.com/clinical-trials/listings/NCT05696171/.
[16] Peschka A, Berger T, Maier T, Scholz M, Lüth TC, Strauß G. Evaluation eines Mikromanipulators für die Mittelohrchirurgie: eine präklinische studie [Evaluation of a Micro-Manipulator for Middle Ear Surgery: a Preclinical Trial]. Laryngorhinootologie 2016;95(2):112–7.
[17] Veleur M, Lahlou G, Torres R, Daoudi H, Mosnier I, Ferrary E, et al. Robot-assisted middle ear endoscopic surgery: preliminary results on 37 patients. Front Surg 2021;8:740935.
[18] Becker BC, Maclachlan RA, Hager GD. Riviere CN. Handheld micromanipulation with vision-based virtual fixtures. IEEE Int Conf Robot Autom 2011;2011:4127–32.
[19] Miroir M, Nguyen Y, Szewczyk J, Sterkers O, Bozorg Grayeli A. RobOtol: from design to evaluation of a robot for middle ear surgery. In: 2010 IEEE/RSJ International Conference on Intelligent Robots and Systems; 2010. p. 850–6.
[20] Michel G, Bordure P, Chablat D. A new robotic endoscope holder for ear and sinus surgery with an integrated safety device. Sensors (Basel) 2022;22(14):5175.
[21] Fujita T, Yokoyama K, Kawai T, Uehara N, Yamashita T, Kamakura T, et al. A robot for transcanal endoscopic ear surgery with gimbal-based rotational linkage and linear guide rail mechanisms. Adv Biomed Eng 2025;14:146–54. https://doi.org/10.14326/abe.14.146.
[22] Goto T, Hongo K, Ogiwara T, Nagm A, Okamoto J, Muragaki Y, et al. Intelligent surgeon's arm supporting system iArmS in microscopic neurosurgery utilizing robotic technology. World Neurosurg 2018;119:e661–5.
[23] Okuda H, Okamoto J, Takumi Y, Kakehata S, Muragaki Y. The iArmS robotic armrest prolongs endoscope lens-wiping intervals in endoscopic sinus surgery. Surg Innov 2020;27(5):515–22.
[24] Kohan D, Jethanamest D. Image-guided surgical navigation in otology. Laryngoscope 2012;122(10):2291–9.
[25] Stelter K, Ledderose G, Hempel JM, Morhard DF, Flatz W, Krause E, et al. Image guided navigation by intraoperative CT scan for cochlear implantation. Comput Aided Surg 2012;17(3):153–60.
[26] Tsuchida K, Takahashi M, Nakazawa T, Kurihara S, Yamamoto K, Yamamoto Y, et al. Augmented reality-assisted transcanal endoscopic ear surgery for middle ear cholesteatoma. J Clin Med 2024;13(6):1780.
[27] Matsumoto N, Oka M, Cho B, Hong J, Jinnouchi M, Ouchida R, et al. Cochlear implantation assisted by noninvasive image guidance. Otol Neurotol 2012;33(8):1333–8.
[28] Yamashita M, Matsumoto N, Cho B, Komune N, Onogi S, Lee J, et al. Registration using 3D-printed rigid templates outperforms manually scanned surface matching in image-guided temporal bone surgery. Int J Comput Assist Radiol Surg 2016;11(11):2119–27.
[29] Labadie RF, Balachandran R, Noble JH, Blachon GS, Mitchell JE, Reda FA, et al. Minimally invasive image-guided cochlear implantation surgery: first report of clinical implementation. Laryngoscope 2014;124(8):1915–22.
[30] Hussain R, Guigou C, Lalande A. Bozorg Grayeli A. Vision-based augmented reality system for middle ear surgery: evaluation in operating room environment. Otol Neurotol 2022;43(3):385–94.
[31] Uchida M, Matsumoto Y, Morioka S, Hori R, Mizutari K. Efficacy of image-guided percutaneous endoscopic ear surgery: a novel augmented reality-assisted minimally invasive surgery. Otol Neurotol 2025. https://doi.org/10.1097/MAO.0000000000004488. Published online March 10.
[32] Ito T, Fujikawa T, Takeda T, Mizoguchi Y, Okubo K, Onogi S, et al. Integration of augmented reality in temporal bone and skull base surgeries. Sensors (Basel) 2024; 24(21):7063.
[33] Ito T, Kawashima Y, Yamazaki A, Tsutsumi T. Application of a virtual and mixed reality-navigation system using commercially available devices to the lateral temporal bone resection. Ann Med Surg (Lond) 2021;72:103063.
[34] Yamazaki A, Ito T, Sugimoto M, et al. Patient-specific virtual and mixed reality for immersive, experiential anatomy education and for surgical planning in temporal bone surgery. Auris Nasus Larynx 2021;48(6):1081–91.
[35] Hadida Barzilai D, Tejman-Yarden S, Yogev D, Vazhgovsky O, Nagar N, Sasson L, et al. Augmented reality-guided mastoidectomy simulation: a randomized controlled trial assessing surgical proficiency. Laryngoscope 2025;135(2):894–900.
[36] Guigou C, Hussain R, Lalande A, Bozorg Grayeli A. Augmented reality based transmodiolar Cochlear implantation. Otol Neurotol 2022;43(2):190–8.
[37] Koyama H, Kashio A, Yamasoba T. Application of artificial intelligence in otology: past, present, and future. J Clin Med 2024;13(24):7577.
[38] Arora A, Lau LY, Awad Z, Darzi A, Singh A, Tolley N. Virtual reality simulation training in otolaryngology. Int J Surg 2014;12(2):87–94.
[39] Bolton L, Young K, Ray J, Chawdhary G. Virtual temporal bone simulators and their use in surgical training: a narrative review. J Laryngol Otol 2024;138(4):356–60.
[40] Kazmitcheff G, Nguyen Y, Miroir M, Péan F, Ferrary E, Cotin S, et al. Middle-ear microsurgery simulation to improve new robotic procedures. Biomed Res Int 2014; 2014:891742.
[41] Sethia R, Wiet GJ. Preoperative preparation for otologic surgery: temporal bone simulation. Curr Opin Otolaryngol Head Neck Surg 2015;23(5):355–9.
[42] Andersen SAW, Hittle B, Värendh M, Lee J, Varadarajan V, Powell KA, et al. Further validity evidence for patient-specific virtual reality temporal bone surgical simulation. Laryngoscope 2024;134(3):1403–9.
[43] Talks BJ, Lamtara J, Wijewickrema S, Collins A, Gerard JM, Mitchell-Innes AM, et al. Developing an evidence-based surgical curriculum: learning from a randomized controlled trial of surgical rehearsal in virtual reality. J Int Adv Otol 2023;19(1):16–21.
[44] US Food and Drug Administration. De novo classification request for iotaSOFT insertion system (DEN190055) [Internet]. Silver Spring (MD): FDA; 2021 [cited 2024 March 24]. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf19/DEN190055.pdf.
[45] Regulation (EU). 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. Off J Eur Union 2017. L117:1.
[46] Nishimura K. Current status of robotic surgery in Japan. Korean J Urol 2015;56(3):170–8.
[47] Food and Drug Administration (FDA). Medical devices; ear, Nose, and throat devices; classification of the Powered Insertion System for a Cochlear implant electrode array. Fed Regist 2023;88(4):977–9.
[48] De Seta D, Russo FY, Ferrary E, Bernardeschi D, Nguyen Y, Sterkers O. Robotics, automation, active electrode arrays, and new devices for cochlear implantation: a contemporary review. Hear Res 2022;414:108425.
[49] O'Connell BP, Hunter JB, Wanna GB. Comparative analysis of robotics-assisted and manual insertions of cochlear implant electrode arrays. Otol Neurotol 2022;43(10):1155–61.
[50] Auinger AB, Muck S, Illing RB, et al. Robot-assisted cochlear implant surgery in a patient with partial ossification of the cochlea: a technical note. Clin Otolaryngol 2022;47(4):949–54.