

A Systematic Review of Robot-assisted vs Manual Vitreoretinal Surgery: Is it Feasible?

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ABSTRACT

Introduction and Objectives: Vitreoretinal surgery requires high precision and fine manipulation of instruments, which can be challenging due to human physiological barriers such as tremors, jerks, and low-frequency drifts. Robotic assistance carries the potential to overcome these limitations by providing better stability and filtering involuntary movements, therefore improving safety and future opportunities for this complex procedure. This review aims to compare the feasibility and safety of robot-assisted and manual vitreoretinal surgery.

Methods: A comprehensive literature search was performed on 4 online databases: PubMed, Cochrane, ProQuest, ScienceDirect, and hand searching. Human studies comparing robot-assisted and manual vitreoretinal surgery, English language, and full-text journal available were included in this review. We identified the feasibility, safety, and duration of the robot-assisted approach for vitreoretinal surgery as the main outcome measurements.

Results: Three randomized controlled trials (RCTs) with a total of 45 adults were evaluated. Robotic assistance was performed on various different vitreoretinal surgery procedures, including subretinal injection of tissue plasminogen activator (TPA), peeling of epiretinal membrane (ERM), and internal limiting membrane (ILM), with one study performed both procedures. All three studies showed surgical steps carried out with robotic assistance were successfully performed without clinical complications observed. The duration was longer in robot-assisted surgery compared

to manual surgery. The number of retinal microtrauma was less frequent in robot-assisted surgery compared to manual surgery.

Conclusion: Even though the duration of surgery took longer in the robot-assisted group, all studies show the feasibility and safety of robotic assistance in vitreoretinal surgery. However, further studies with larger samples are needed.

Keywords: robot-assisted surgery, manual surgery, vitreoretinal surgery

INTRODUCTION

Since its first demonstration by Machemer in 1970, vitreoretinal surgery has been indicated for various ophthalmic conditions, including retinal detachment, vitreous hemorrhage, macular hole, and epiretinal membrane. [1,2] Vitreoretinal surgeries involve the insertion of fine surgical instruments through small incisions in the sclera. Conventionally, 3-port access is used, incorporating an infusion line, a light source, and task-specific instruments. Surgeons then manipulate these instruments delicately within the patient's eye. Visualization of the posterior pole is achieved through a microscope with a magnifying lens positioned above or on the cornea. [2,3]

Despite significant advancements in recent decades, vitreoretinal surgery remains one of the most challenging procedures in microsurgery. Surgeons are required to do extremely precise motion within the eye's

limited and delicate workspace, which can be hindered by human physiological limitations.^[1,4] Physiological tremor of human hands, with average amplitude of 100µm, makes it challenging to precisely position the instrument relative to the surgical target site, which is typically within 10µm.^[2,3] Consequently, performing surgical maneuvers like subretinal injections and membrane peeling becomes even more challenging in the presence of tremor. The lack of force perception during vitreoretinal surgery is attributed to the absence of force feedback during manipulations, as it falls below the threshold of human tactile perception. This limitation increases the risk of retinal microtrauma due to excessive manipulation of the tissue.^[2,3]

Robotic assistance holds the potential to overcome human physiological limitations. It offers better stability and suppresses involuntary movements, such as tremor, jerks, and low frequency drifts. Additionally, robotic systems integrate force-sensing tools to reduce iatrogenic retinal microtrauma during surgery.^[4,5] It can enhance accuracy and safety of this complex procedure, thereby expanding future possibilities and treatment options.^[1,2,4] However, there have been relatively few studies on this topic. This review aims to compare the feasibility and safety of robot-assisted and manual vitreoretinal surgery.

MATERIALS & METHODS

This review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guideline.^[6] Studies meeting the following criteria were included: (1) human studies comparing robot-assisted and manual vitreoretinal surgery, (2) English language, and (3) full-text journals available. Review studies and animal or eye model studies were excluded.

A comprehensive literature search was performed on 4 online databases: PubMed, Cochrane, ProQuest, and ScienceDirect. The search was done by 3 independent

reviewers. The search used the following terms “Robotic Surgical Procedures” and “Vitreoretinal Surgery”. No filter based on year of publication and language was applied. Additional search was also performed by hand-searching of relevant studies. The search was concluded in February 2023. We assessed the feasibility and safety of the robot-assisted approach for vitreoretinal surgery by analyzing duration of surgery as the primary measurements and post-surgery complications as the secondary measurements. The duration of surgery was defined as the interval between the insertion of the first trocar into the sclera and the injection of subconjunctival antibiotics before the removal of the eyelid speculum (from instruments being inserted to being removed).

Rayyan, an online-based tool, was used to conduct the screening process.^[7] Three reviewers conducted the screening independently based on title and abstract. Blinding of each reviewer's decision was turned on until the screening process was finished. Disagreements between reviewers were resolved through discussion.

The risk of bias assessment was performed using RoB 2.0.^[8] The assessment was performed by 3 reviewers independently and conflicting results were decided through deliberation. Data from included studies were extracted independently and then cross-verified by 3 reviewers.

RESULT

The initial search according to the inclusion criteria resulted in 146 articles. The reviewers then conducted an automated process of duplicate elimination using Rayyan tool, followed by manual duplicate verification, abstract screening, and full paper selection. Finally, a total of 3 articles were included in the final analysis as shown in Figure 1. The risk of bias assessment showed a low risk of bias in all domains except for domains 1 and 2, where the randomization process was inadequately described and lack of adjustment for missing data in the analysis was found.

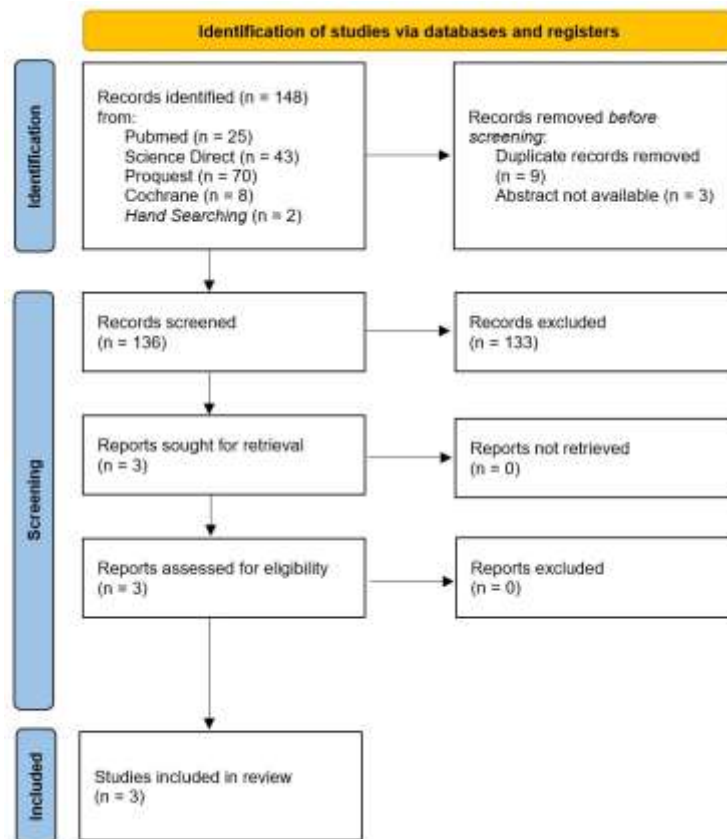


Figure 1. PRISMA flow chart

The baseline characteristics of this research are presented in Table 1. Two studies were conducted in the United Kingdom and one study was conducted in the Netherlands. The general inclusion criteria were as follows: patients requiring peeling of an epiretinal membrane (ERM) or internal limiting membrane (ILM), or subretinal tissue plasminogen activator (TPA) injection. Patients needed to be fit for either general or local anesthesia, as determined by the assessing ophthalmologist. Subjects were randomly assigned to receive either robot-assisted or manual surgery intervention in all included literatures.

Robot-assisted surgery was performed in vitreoretinal procedures such as ERM or ILM peeling and subretinal TPA injections. All ERM and ILM peeling procedures were performed under general anesthesia, while subretinal TPA injection procedures were conducted under local anesthesia. All studies use Preceyes Robotic Surgical System (PRSS). Cehajic-Kapetanovic et al and Edwards et al utilized the same TPA solution (Alteplase, Boehringer Ingelheim) with a consistent volume of TPA injected into the subretinal space, guided by the size of the hemorrhage, ranging between 0.025 and 0.10 mL.

Table 1. Baseline characteristics

Author	Year/ Setting	Study Design	Total Samples	Treatment	Anesthesia	Age (SD)		Baseline BCVA (SD) ^a	
						RAS	MS	RAS	MS
Faridpooya et al	2022/ Rotterdam Eye Hospital, The Netherland	RCT	15	ERM or ILM peeling	GA	74.0 (3)	73.0 (4)	0.5 (0.21)	0.6 (0.22)
Cehajic-Kapetanovic et al	2021/ Oxford Eye Hospital, United Kingdom	RCT	12	Subretinal injection of TPA	LA	75.0 (6.5)	87.5 (4.9)	1.74 (0.87-2.30)	2.30 (1.98-2.30)
Edwards et al	2018/ Oxford Eye Hospital, United Kingdom	RCT	18	ERM or ILM peeling (12) Subretinal injection of TPA (6)	GA for ERM or ILM peeling LA for subretinal TPA injection	62.0 (10)	72.0 (8)	NA	NA

SD: standard deviation; RAS: Robot-assisted surgery; MS: Manual Surgery; RCT: Randomized controlled trials; ERM: Epiretinal membrane; ILM: Internal limiting membrane; TPA: Tissue plasminogen activator; GA: General anesthesia; LA: Local anesthesia; NA: Not available

^alogMar

Table 2. Study result

Author	Treatment	Duration			Retinal Microtrauma			BCVA post surgery ^a	
		RAS	MS	P value	RAS	MS	P value	RAS	MS
Faridpooya et al	ERM or ILM peeling	56 mins, (SD 12)	24 mins (SD 5)	NA	NA	NA	NA	0.1 (0.12)	0.2 (0.11)
Cehajic-Kapetanovic et al	Subretinal injection of TPA	42.7 mins (95% CI 26.0-59.3)	46.9 mins (95% CI 33.0-60.8)	p = 0.61	0.0 (0.0-2.5)	1.0 (0.0-2.0)	p = 0.87	1.30 (0.18-1.90)	1.62 (0.50-2.00)
Edwards et al	ERM or ILM peeling	55 mins (95% CI 51-60)	31 mins (95% CI 27-35)	p < 0.0001	0 (0 – 2)	1 (0 – 2)	p = 0.2	NA	NA
	Subretinal injection of TPA	5.7 mins ^b	4.8 mins	NA	NA	NA	NA	NA	NA

RAS: Robot-assisted surgery; MS: Manual Surgery

^alogMar. BCVA at the last visit; Faridpooya et al at 6 months post-surgery; Cehajic-Kapetanovic et al at 1 month post surgery

^bInjection phase of surgery for one patient was completed manually due to development of cataract

All studies demonstrated that the robot-assisted surgical techniques are feasible, safe, and well-tolerated for all patients. In 2 studies, robot-assisted ERM or ILM peeling procedures required a longer duration compared to manual surgery, with 1 study showing statistical significance. However, in subretinal TPA injection procedures, the duration required by the robot and manual techniques were comparable, as shown in Table 2, Edwards et al only included the duration of subretinal TPA injection procedure, not the total duration of the surgery. In this study, the second patient treated with subretinal TPA injection in the robot-assisted surgery group switched to manual injection procedure due to the development of cataract which precluded a clear view of the cannula tip against the retina. Faridpooya et al also found that the duration of the surgery declined with increasing numbers of surgery performed. The recorded number of microtraumas on the retina in both studies was lower in the robot-assisted group. However, Faridpooya et al did not provide the total number of microtraumas on the retina; instead, they stated that there were no postoperative adverse events or complications.

DISCUSSION

Vitreoretinal Surgery with Robot-assisted

In our study, two RCTs compared the feasibility and safety of robot-assisted and manual peeling of ERM or ILM. The choice of ERM or ILM peeling as a test model stemmed from its significance as one of the most delicate maneuvers in vitreoretinal surgery and common vitreoretinal procedures that are familiar to all vitreoretinal surgeons, making it an ideal candidate for assessing the feasibility and safety of integrating robotic assistance into ophthalmic operating theaters. The procedures involved well-defined, high-precision steps, making them suitable for evaluation through RCTs. [4,9] Faridpooya et al employed robot-assisted surgery from ILM staining up to the fluid-air exchange, whereas Edwards et al used robotic

assistance for lifting a flap of ERM or ILM away from the macula surface. Despite Edwards et al utilization of robotic assistance in only one step, we analyzed the potential application of robot-assisted techniques, as stated in Table 2.

Moreover, as the field of gene and cell therapy for retinal degenerative diseases rapidly evolves, precise and prolonged delivery of therapeutic substances into the subretinal space becomes crucial. Cehajic-Kapetanovic et al and Edwards et al attempted to simulate the potential future application of robot-assisted subretinal gene therapy. Their studies involved robot-assisted subretinal injections of tissue plasminogen activator (TPA). [4,5] Cehajic-Kapetanovic et al emphasized robot-assisted surgery ability to apply dynamic motion scaling with subretinal injection. This allowed for low scaling and larger tool-tip directional motion perpendicular to the retina in the center of the eye. Simultaneously, high motion scaling (ratio 1:25) and standby mode was used to restrict movements to increments of 10 μm when the cannula tip was in proximity to the retina and provide stable position during penetration into the subretinal space. [5]

The Preceyes Robotic Surgical System (PRSS) used in the included studies implements hybrid nature which allows seamless transitions between manual and robot-assisted segments of the procedure, ensuring minimal disruption to the surgical flow. [5] This system aligns with the teleoperated robotic surgery category outlined by Gerber et al, wherein surgeons manipulate a robotic system through joysticks, directly translating to robotic motion, while relying on an optical microscope or digital heads-up display for visual feedback. [10] Channa et al assert that the ideal system might take the form of a computer-assisted robot rather than a fully automated setup. The robot or computer would receive input from the surgeon and the eye. From the surgeon, it would gather intricate details about the surgical maneuver, allowing the computer to

mitigate tremors, optimize movement velocity, force generation pace, and guide movement direction and amplitude. From the patient's eye, the computer could receive real time visual measurements and or physiological information.^[11]

The PRSS offers several distinctive features that facilitate its effective and secure application in retinal surgery. Its precision, characterized by a tool-tip positional resolution of 10 μm , empowers it to navigate a pig retinal venule with a diameter of merely 60 μm and deliver therapeutic substances into its lumen. The "dynamic motion scaling" feature adapts based on the instrument's position within the eye, utilizing lower motion scaling ratios (1:5) for larger eye movements at the center of the eye and higher ratios (1:25) as the instrument tip approaches the retina. The operator can establish and adjust the "virtual boundary" distance relative to the retina, effectively constraining instrument movement beyond the specified boundary and thereby significantly reducing the risk of inadvertent retinal microtrauma.^[4,5] The "return to position" function allows the injection cannula to revert to a predetermined safe position within the eye, facilitating necessary adjustments to the eye's positioning and the instrument tip's trajectory. Furthermore, this function, combined with the ability to "store specific coordinates" for future use, could potentially enable the cannula tip to re-enter the same retinotomy, maintaining consistent size, in a two-stage subretinal injection approach. Surgeons also retains direct tactile feedback through the second handheld instrument (light pipe) throughout the procedure. In instances of compromised safety, the surgeon can swiftly trigger the "automatic retract" feature of the robot-held instrument along its current axis, an action completed in under 500 ms. A "standby mode" provides a stable position for gradual drug infusion into the subretinal space, lasting 15-20 minutes.^[4,5] These functionalities ensure system stability in the face of power loss or system malfunction. Additionally,

we showed that the robot can be used as a 'third hand' by holding a light pipe in a required position.^[9] Improved 'hands-free' lighting sources allow the introduction of bimanual manipulation techniques in challenging cases.^[12]

Duration of Surgery

The duration of surgery in robot-assisted surgery was significantly longer than in manual surgery, as found in the study conducted by Edwards et al and Faridpooya et al.^[4,9] These findings align with the study conducted by Jacobsen et al who compared manual and robot-assisted vitreoretinal surgery using a virtual reality surgical simulator.^[10] This study reported that robot-assisted surgery is significantly slower compared to manual surgery in both novice and vitreoretinal surgeons.

Several factors could contribute to these findings. The preparation time for robot-assisted surgery was four times longer than for manual surgery due to the need to initialize and calibrate the PRSS. Additionally, more time was required to assemble the sterile instrument holder and apply drapes. Manual screwing of the instrument clamp was necessary every time the instrument needed to be changed. Furthermore, downscaling of movement also extended the time required for each motion.^[9] A compartmentalized movement pattern emerges when using robotic motion controllers, primarily due to the repeated need to disengage the clutch and readjust the position of the motion controller to move the instrument tip across the retina. This continuous cycle of regrasping and readjustment throughout the surgery contributes to an increased surgical duration.^[13]

However, Faridpooya et al found that the duration of the surgery declined with increasing numbers of surgery performed. Decline of surgical time in robot-assisted group during the second repetition was also noted in the study by Jacobsen et al.^[13] The reason for both these findings is likely due to a familiarization effect or learning curve

as the surgeon becomes more accustomed to the robot, which enhances the integration of workflow and increases surgical speed.^[9,13] Similarly, Maberley et al found that robot-assisted surgery for membrane peeling in simulated setting was slower than manual surgery. In Maberley et al study, the PRSS was compared to manual ILM peeling using the Eyesi surgical simulator. Even though the participating surgeons only performed robot-assisted ILM peeling for the first time in the study, Maberley et al expected that shorter surgical time would be possible as surgeons adapted and gained experience with the system.^[14]

Cehajic-Kapetanovic et al found that there was no significant difference between the duration of subretinal TPA injection and the total duration of surgery in the robot-assisted group compared to the manual group. This demonstrate that PRSS robot can be used to safely perform subretinal TPA injection without compromising duration of surgery.^[5] This result can enhance the future potential of robot-assisted subretinal delivery of gene and stem cell therapy in the treatment of inherited retinal diseases, which has similar technique with subretinal drug delivery. The slow and accurate delivery of gene therapy vectors can be accommodated by the “standby mode” of the robotic instrument tip, which can remain in a stable position in the subretinal space for a 15–20-minute period that is not possible with manual approach.^[4,5]

Although most of the studies state that precision and safety should take priority over speed due to the novelty of this procedure demonstrated in humans, increased cost of time resulting from prolonged duration of surgery may become a concern. Thus, providing high precision, accuracy, and speed remains a current challenge in the development of robot-assisted surgery. Hybrid systems are considered to be one solution to reduce setup time, where the robot is placed on an existing surgical table and used for tasks that require high precision, while it can

remain in place during other stages of surgery.^[4,15] The use of motion scaling which make the robot have multiple modes of motion, such as rapid motion in extraocular or distant areas from retinal surface and slower motion in intraocular or near the target, can significantly increase both speed and safety when moving the instrument toward the target. However, it is still time-consuming to switch between modes.^[15,16] Physiological barriers also contribute to the longer duration of the surgery. Sensing devices, such as optical coherence tomography (OCT) can be equipped to the instrument to help detect distance beyond surgeon’s depth perception. Once this is achieved, it is hoped that increased speed and safety of the procedure can be obtained.^[4,15]

Safety of Robot-assisted Surgery

The safety profile results from our review showed that robot-assisted surgery can be safely performed without any serious adverse events or complications. No malfunctions occurred during any of the studies included. A lower number of retinal microtraumas were observed in robot-assisted surgery in two of our included studies.^[4,5] Faridpooya et al also described the movements of the robot-assisted surgery as considerably smoother and requiring less instrument movements compared to the manual group. Retinal surgery requires precise manipulation of delicate and non-regenerating tissue that is unforgiving to any trauma, including involuntary microtrauma. Gentler movement of the robot-assisted surgery improves precision, increases accuracy and potentially reduces the risk of tissue damage.^[9] These results are aligned with Channa et al study whose reported higher motion stability and better performance of the robotic system, which also led to fewer unnecessary forces being applied to the porcine eye and model eye.^[11] Supporting this outcome, Jacobsen et al noted that, compared with manual surgery, robot-assisted surgery improves precision in both novice and experienced surgeons, as

demonstrated by fewer instrument movements and reduced distance traveled by the instruments. However, significantly less tissue damage in the robot-assisted group is only noted in novice surgeons, not experienced vitreoretinal surgeons. This disparity occurs because experienced vitreoretinal surgeons did not experience significant tissue damage during manual surgery.^[13] Furthermore, the robot system also assists the procedure by filtering tremor and stabilizing the surgeon's movement. A review by Roizenblatt et al reported that while the human tactile threshold stands at 7.5 mN, a mere 6.1-12.4 mN of force can induce retinal tearing in a rabbit and porcine model. Given the remarkably thin and transparent nature of the innermost layer of the neurosensory retina (measuring 1–3 µm), physiological hand tremors can exceed the total thickness of the ILM.^[12]

Patients received either general or local anesthesia depending on safety considerations and the type of procedure required by the patient. Unanticipated head movement by patients during intraocular surgery poses substantial risks. Robot-assisted surgery integrates a conical dock to enhance ocular stability during robotic maneuvers, in addition to the immobilization achieved by anesthesia. Precaution measures involve taping the forehead to the headrest, and for robot groups involving membrane peeling, patients received general anesthesia. Notably, two studies also demonstrated the safety of precise robot-assisted subretinal therapeutic substance delivery under local anesthesia, emulating its potential applicability in subretinal gene or cell therapy.^[4,9] The success of executing this robotic procedure under local anesthesia holds notable implications for elderly individuals undergoing gene therapy for age-related macular degeneration, a demographic often unsuitable for general anesthesia. Such an approach promises to reduce the risk of ocular inflammation while optimizing precision.^[4]

Limitation

This review study has several limitations. Firstly, there is a scarcity of research regarding the comparative analysis between robot-assisted surgery and manual surgery within the vitreoretinal field. The studies included in our review utilized the same robotic surgical system (PRSS), limiting the diversity of robotic platforms assessed. All of the studies in this review were conducted in Western countries, potentially limiting the generalizability of the findings to a broader global population. Furthermore, the sample sizes in the studies were relatively small. Many of the studies we encountered were conducted using simulators, model eyes, or animal eyes, further highlighting the lack of human-centered investigations in this area.

CONCLUSION

This review has established that robot-assisted surgery is a feasible and safe procedure for application in vitreoretinal surgeries, particularly in ILM/ERM peeling and subretinal TPA injection procedures. Although the duration of surgery is longer in the robot-assisted group, the benefits of improved precision, tremor filtering and reduced retinal microtrauma are noteworthy. Due to the novelty of this robot-assisted surgery done in humans, safety should take priority over speed. It is expected that surgical time can be reduced with the integration of a learning curve. Further research on the application of robot-assisted surgery with larger sample sizes and a more diverse population is necessary for a more comprehensive investigation of this topic.

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