



# Comparison of robot-assisted vitreoretinal surgery and manual surgery in different preclinical settings: a randomized trial

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**Background:** Progress in the field of surgical robotics has the potential to allow surgeons to reduce the limitations of human hands and has substantially improved the dexterity and accuracy of surgery. This study aimed to compare robot-assisted vitreoretinal surgery with manual surgery in a simulated setting involving donor porcine eyes.

**Methods:** A randomized controlled trial was conducted involving 10 experienced vitreoretinal experts and 10 residents. Participants were randomized to start with either manual or robot-assisted surgery (n=5 in each group). Participants completed 3 tests consisting of 2 vitreoretinal modules on a virtual-reality simulator and microcannulation in donor porcine eyes. The primary outcome measures were as follows: test completion time, surgical accuracy and tremor control provided by the simulator, and the feasibility of microcannulation in donor porcine eyes.

**Results:** Robot-assisted surgery supported better accuracy and tremor control than manual surgery for vitreoretinal experts (P=0.028 and P=0.002, respectively) and residents (P=0.025 and P<0.001, respectively). Residents improved their microcannulation performance with the assistance of the robot (P=0.038) to a level comparable to that of experts (P=0.49). Robot-assisted surgery was less time-efficient than manual surgery for both residents (P<0.001) and vitreoretinal experts (P<0.001).

**Conclusions:** Compared with manual surgery, robot-assisted vitreoretinal surgery improves the stability of instrument handling and the accuracy of surgery. Robot-assisted surgeries have the potential to shorten the learning curve for residents and improve surgical performance.

**Keywords:** Vitreoretinal surgery; robot-assisted surgery; manual surgery; tremor control; accuracy

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## Introduction

Progress in the field of surgical robotics has allowed surgeons to reduce the limitations of human hands and has substantially improved the dexterity and accuracy of surgery (1-4). The most widespread and commercially available robotic surgical system is the da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA, USA), the introduction of which in the operating room has revolutionized several specialties. Robot-assisted surgery is mainly applied in the field of laparoscopic and thoracoscopic procedures; however, to date, it has been rare in ophthalmic surgery (5-7).

Vitreoretinal surgery is one of the most technically challenging microsurgeries (8,9). Fine, precise motions are essential for surgery on extremely delicate tissue within the small, constrained interspace of the eyeball, often requiring forces that are below the level of human tactile perception (10). Vitreoretinal surgery requires some of the most delicate instruments in the field of microsurgery. However, to date, the theoretical advantages of surgical robots in terms of tremor filtering and accuracy have not been evaluated in intraocular surgery.

In recent years, research on robots dedicated to intraocular surgery has increased (11-13). Technically challenging processes such as microcannulation in the retinal vessel may benefit from robotic surgery (14,15). Due to the small size of retinal vessels, these operations are either at or beyond the limitations of many vitreoretinal surgeons due to physiological tremors. The application of surgical robots in vitreoretinal surgery requires multidimensional and objective assessment.

A surgical simulator incorporates virtual reality (VR) technology into a bionic eyeball to create a dummy surgical scenario (16). The simulator can externalize comprehensive clinical characters with sophisticated programming, interactively react to the operator, and independently supply surgical evaluation and feedback (17,18). With its automatic and objective evaluation process, the simulator establishes a secure and standardized test setting, which provides quantifiable data regarding surgical performance. Therefore, surgical simulator tests are suitable options for the preclinical evaluation of surgical robots.

This study aimed to investigate robot-assisted vitreoretinal surgery compared with manual surgery performed by both residents and experienced vitreoretinal experts in a VR surgical simulator using donor porcine eyes. We present the following article in accordance with the CONSORT reporting checklist (available at <https://atm.amegroups.com/article/view/10.21037/atm-22-1315/rc>).

## Methods

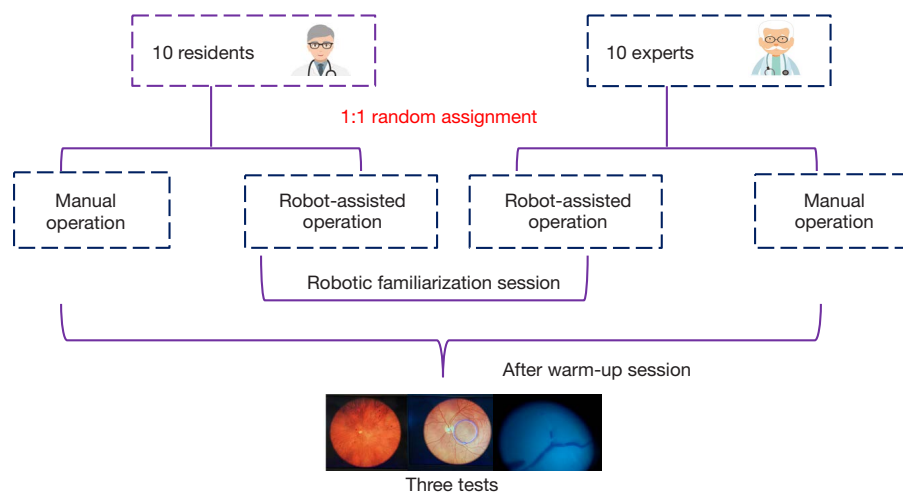
A single-center, randomized controlled trial (balanced randomization at a 1:1 ratio) was conducted. Data were collected at the Zhongshan Ophthalmic Center (ZOC), Sun Yat-sen University, between April 2021 and January 2022. The ethics committee of ZOC adjudicated that ethics review approval was not needed for this study. The full trial protocol was provided under the Footnote section. The principles outlined in the Declaration of Helsinki (as revised in 2013) were followed throughout the study.

### *Participants*

Participants consisted of experienced vitreoretinal experts (10–15 years of experience) and residents without intraocular surgical experience (first- or second-year residents) from ZOC. After prior examination to reach an agreement of operating level, 10 participants in each group were included in the study. Experts and residents who had trained for more than 2 hours on the Eyesi Simulator (VRmagic, Mannheim, Germany) during the past 6 months were not eligible to partake in the research. All participants gave written content before being included in the research.

### *Robotic system*

The robot (Oculotronics Medical Instrument, Guangzhou, China) consisted of 3 parts: a three-dimensional (3D) force sensor attached to the tool holder, a hybrid parallel-serial micromanipulator, which could change the remote center of motion (RCM) point during the motion process, and an RCM adjustment strategy based on online learning. The force sensor could obtain the force produced by the instrument in real-time, and the force value was used to decide the RCM strategy for the surgical system. Control of the RCM was implemented by the hybrid parallel-serial micromanipulator, which included 3 translations and 2 angles on its end-effector. Additionally, the surgeon could control the manipulator with the robot controller, which had 3 dimensions to control the rotation angle  $\theta_1$ , the rotation angle  $\theta_2$ , and the deep distance  $Z$  of the end effector. Accuracy was 10  $\mu\text{m}$  in all 3 directions. In addition, the RCM adjustment strategy provided a compensation approach to adjust the RCM point and reduce the force of the system. This strategy achieved satisfying performance in trajectory deformation and force reduction. Moreover, dynamic motion scaling, tremor filtering, and freeze positioning were integrated into the surgical system, and



**Figure 1** Research workflow.

these extra features were implemented using a software program, which provided an operator interface.

### **Intervention**

The 10 residents and 10 vitreoretinal experts were randomly divided into the robot-assisted and manual surgery groups. A computer-generated list of random numbers was used to randomly assign participants to the 2 conditions (manual or robot-assisted surgery) by following a balanced permutation (computer-generated random numbers). Thus, there were 4 groups in total, and each group comprised 5 participants. Group 1 included residents operating manually; Group 2 comprised residents operating with robot assistance; Group 3 included experts operating manually; and Group 4 comprised experts operating with robot assistance. Participants in Groups 2 and 4 needed to familiarize themselves with the robotic surgery until they could control the robotic instrument manipulator according to instructions provided by the researchers. All participants completed a warm-up session involving 10 min of introduction and 1 familiarization session consisting of either robot-assisted or manual surgery before the data collection process was initiated. The warm-up term was used to familiarize participants with the equipment and procedure. One of the researchers introduced the performance and procedural targets of each test. The data collection procedure comprised 3 repetitions of the test (*Figure 1*).

### **Outcomes of the simulator tests**

The vitreoretinal interface of the Eyesi Simulator can provide automated assessments to test surgical performance. Two tests performed on the Eyesi Simulator were included in this study. Test 1 involved the navigation module, and Test 2 involved antitremor training. Detailed descriptions and characteristics of the 2 tests are shown in *Table 1*. We selected 4 outcomes for this study: the efficiency of operation, which was (I) the time taken following instrument insertion until test completion (min) and (II) the distance traveled by the instrument tip as measured by an odometer (mm); (III) the accuracy of operation, determined by whether the instrument slipped out of the target sphere (red ball in the vitreous); and (IV) the performance of tremor control, determined by the instrument tip exceeding the tolerance percentage.

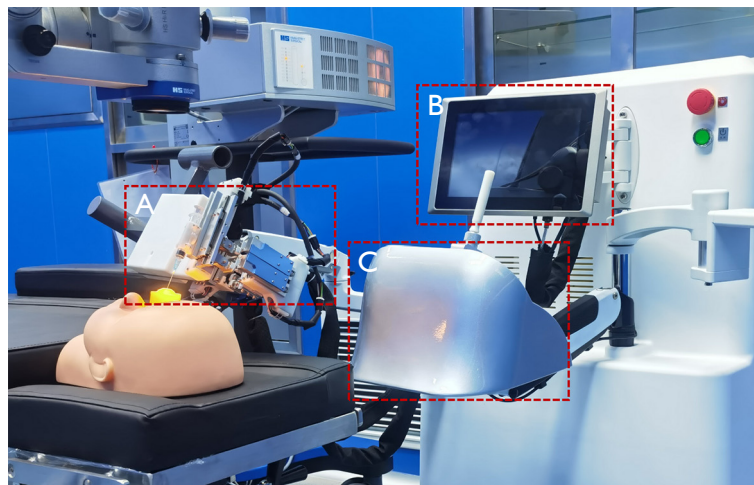
### **Feasibility test in donor porcine eyes**

This test was performed in harvested porcine eyes stuck on the orbital fossa of a facial model (*Figure 2*). A fabricated microneedle with an outer diameter of 50  $\mu\text{m}$  and an inner diameter of 20  $\mu\text{m}$  was used to pierce the retinal vein. When the microneedle was connected to a 1-mL syringe containing a sterile saline, the solution could be injected into a vessel. Each participant performed surgery 3 times, and the performances of the surgeries were recorded. Successful injection was defined as injecting 1-mL

**Table 1** Overview of the research tests

Test	Setting	Name	Description	Difficulty level*	Main outcomes
1	Eyesi simulator	Navigation training	Move the instrument tip into the center of the green sphere and hold until the sphere turns green	Level 4 out of 4	Efficiency, accuracy
2	Eyesi simulator	Anti-tremor training	Keep the handle tip inside the sphere and guide the sphere to follow a circular trajectory until the destination is reached	Level 5 out of 7	Efficiency, tremor control
3	Harvested porcine eyes	Feasibility test	Perform retinal endovascular surgeries with microneedles	Hard for residents	Feasibility

\*, level 1 is the easiest, and the difficulty increases at higher levels.



**Figure 2** Robot-assisted surgery setup. (A) Robot instrument manipulator. (B) Robot controls display. (C) Robot motion controller.

sterile saline at one time. In addition, the participant and 2 ophthalmologist recorders judged the performance of the surgeries, and the majority opinion was taken as the final result. The porcine eyes were slaughterhouse materials. Experiments were performed under a project license (No. 2019-146) granted by the Institutional Animal Care and Use Committee of ZOC, in compliance with the Association for Research in Vision and Ophthalmology guidelines for the care and use of animals.

### Statistical analysis

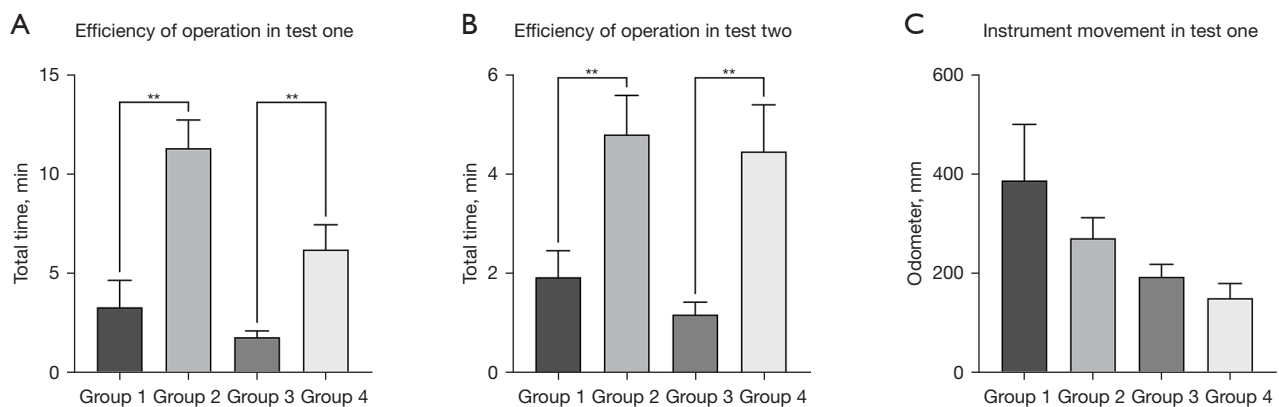
The researchers who undertook the outcomes assessment were blinded to group assignment. Data compilation processes and analyses were conducted using SPSS 26.0 statistical software (IBM Corp., Armonk, NY, USA). One-way analysis of variance (ANOVA) and Bonferroni's tests were used to analyze the differences in the 3 outcomes

of the simulator tests among the 4 groups. A chi-squared test was used to compare the feasibility tests. Values were shown as mean  $\pm$  SD. All reported P values are 2-tailed, and statistical significance was defined at the  $\alpha=0.05$  level.

## Results

### Time efficiency of operations

After random assignment, there were 4 groups in total, with 5 participants in each group. The total time for completing Test 1 and Test 2 operations was recorded. In Test 1, Group 2 spent more time than Group 1 ( $P<0.001$ ), and Group 4 spent more time than Group 3 ( $P<0.001$ , *Figure 3A*). In Test 2, Group 2 was slower than Group 1 ( $P<0.001$ ), and Group 4 was slower than Group 3 ( $P<0.001$ , *Figure 3B*). The time efficiency of robot-assisted operation was less than that of manual operation. *Figure 3C* shows the intraocular odometer of the instrument for the 4 groups. There were



**Figure 3** Efficiency of operation. (A) Time consumption levels during Test 1. (B) Time consumption levels during Test 2. (C) Instrument odometer during Test 1. Group 1: residents operating manually; Group 2: residents operating with robot assistance; Group 3: experts operating manually; Group 4: experts operating with robot assistance. \*\*,  $P < 0.001$ .

**Table 2** Outcomes of the simulator tests

Group	Test one (SD)			Test two (SD)	
	Total time, min	Odometer, mm	Instrument slipped out of sphere, times	Total time, min	Out of tolerance percentage, %
1	3.29 (1.36)	388.10 (113.38)	11.40 (4.16)	1.95 (0.54)	77.90 (4.63)
2	11.31 (1.42)	271.40 (41.42)	4.80 (2.05)	4.83 (0.79)	45.40 (5.02)
3	1.78 (0.31)	193.30 (25.27)	9.20 (3.77)	1.19 (0.25)	40.90 (7.09)
4	6.20 (1.25)	150.30 (29.68)	2.70 (1.89)	4.49 (0.94)	21.10 (10.01)

Group 1: residents operating manually; Group 2: residents operating with robot assistance; Group 3: experts operating manually; Group 4: experts operating with robot assistance.

no significant differences between the robot-assisted and manual groups in either Test 1 or Test 2 (Table 2).

### Surgical accuracy

One essential index for evaluating instrument handling in Test 1 was the number of times that the instrument slipped out of the target sphere. The fewer times the instrument slipped out of the target sphere, the more accurate the surgery. The number of times that the instrument slipped out of the target sphere in Group 2 was less than that in Group 1 ( $P = 0.025$ ), and likewise, the number of slips in Group 4 was less than that in Group 3 ( $P = 0.028$ ). This shows that robot-assisted operation is more precise than manual operation (Figure 4A, Table 2).

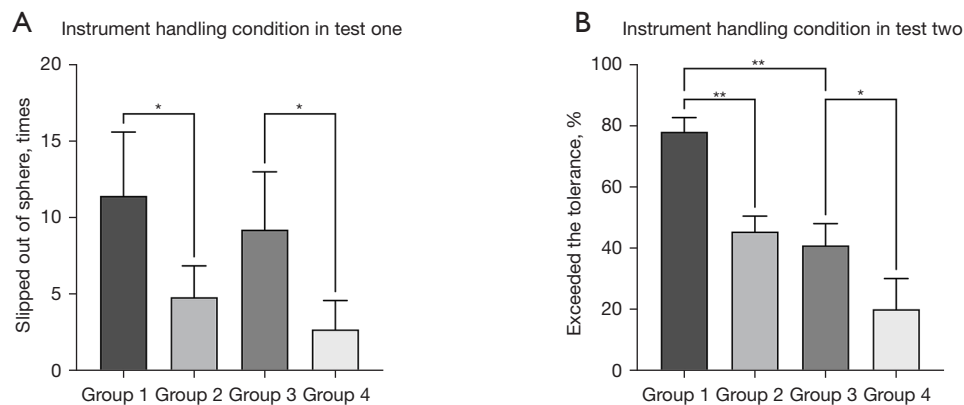
### Performance of tremor control

The percentage of instrument tips exceeding the tolerance

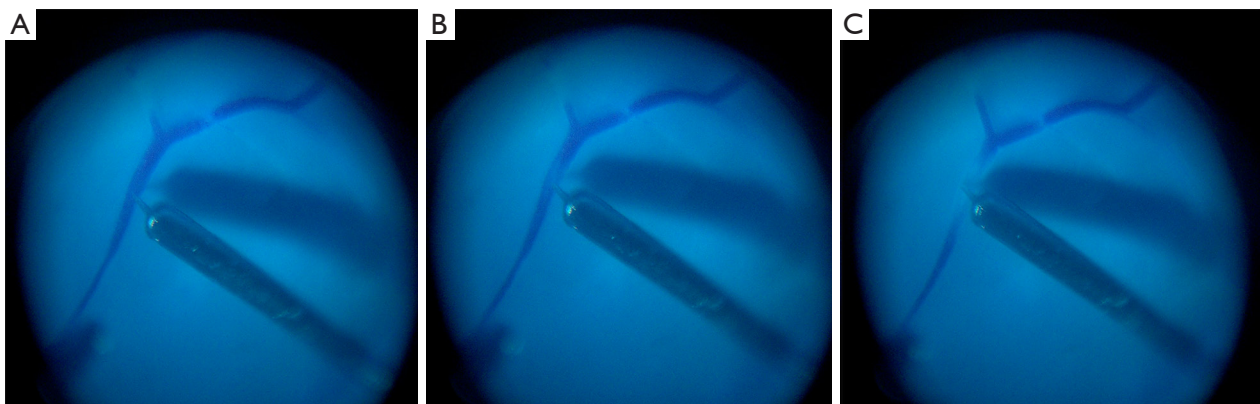
was a vital index for evaluating tremor control of operators in Test 2. The lower the excess degree of tolerance percentage, the better the tremor control performance. Figure 4B shows that the degree to which the instrument tip exceeded the tolerance percentage in Group 2 was less than that in Group 1 ( $P < 0.001$ ), and likewise, the degree in Group 4 was less than that in Group 3 ( $P = 0.002$ ). In addition, the difference between Group 1 and Group 3 was significant ( $P < 0.001$ ), yet Group 2 and Group 3 were not significantly different ( $P = 1.0$ , Table 2). This finding demonstrates that the residents seemed to improve their ability to control tremors with the assistance of the robot and achieved a performance comparable to that of experts.

### Feasibility performance in donor porcine eyes

Retinal endovascular surgeries with microneedles in harvested porcine eyes were used to evaluate the feasibility of robot operations in real eyeballs. The targeted retinal



**Figure 4** Accuracy and tremor control of surgeries. (A) Number of times the instrument slipped out of the target sphere was used as an index for accuracy of the surgeries. The fewer times the instrument slipped out of the target sphere, the more accurate the surgeries. (B) Percentage of the instrument exceeding the tolerance was an index used to determine tremor control of the surgeries. The lower the excess degree of tolerance percentage, the better the tremor control performance. Group 1: residents operating manually; Group 2: residents operating with robot assistance; Group 3: experts operating manually; Group 4: experts operating with robot assistance. \*,  $P < 0.05$ ; \*\*,  $P < 0.001$ .



**Figure 5** Robotic system assisted in performing the microcannulation surgery in harvested porcine eyes. The targeted retinal vessels had inner diameters of approximately  $100 \mu\text{m}$ . The outer diameter of the tip of the microneedle was  $50 \mu\text{m}$ . (A) Tip of the microneedle approaching the vessel. (B) Cannulation. (C) Holding and injection.

vessels had inner diameters of approximately  $100 \mu\text{m}$ . The tip was made with an outer diameter of  $50 \mu\text{m}$ . The feasibility performances of microcannulation in Group 2 were higher than those in Group 1 ( $P = 0.038$ ), yet Groups 3 and 4 were not significantly different ( $P = 0.291$ ). The manual performances of microcannulation of residents (Group 1) and vitreoretinal experts (Group 3) were significantly different ( $P = 0.01$ ). With the assistance of the robot, residents seemed to perform this surgery as well as vitreoretinal experts ( $P = 0.49$ ). Moreover, during robot-assisted operations, the microneedle was more stable during injections (Figure 5).

## Discussion

Our research investigated the feasibility and potential advantages of robot-assisted surgery from multiple dimensions: a surgical simulator was utilized to test (I) performance accuracy (II) and antitremor performance, and harvested porcine eyes were used to test (III) the feasibility of microcannulation. Compared with manual surgery, robot-assisted vitreoretinal surgeries were more precise and stable, although robot-assisted surgery was slower than manual surgery. In particular, the performance of residents

significantly improved with robot-assisted vitreoretinal surgery.

During intraocular surgery, experts operate on tiny, delicate tissues, which require delicate manipulation and steady hand movements (19). Therefore, it is considered one of the most challenging microsurgery procedures. For the past 30 years, robot-assisted surgical devices have focused on overcoming these challenges. Several systems have been developed to improve microsurgical accuracy by eliminating hand tremors and facilitating faster, safer, and more effective microsurgeries (20,21).

The robot in our research moved with 5 degrees of freedom and possessed a displacement accuracy of 10  $\mu\text{m}$ . A novel master-slave remote control system was embedded in the robot. The slave-side robotic arm could handle different surgical instruments to perform various operations, and the operator used the master side for control. It has been reported that through the master-slave robotic system, tremor filtering, amplified force feedback, reduced motion mapping, and stable instrument handling could be improved to enhance the safety of surgical operations (22,23). In addition, intraocular surgery requires complex manipulation in a small, confined space through a scleral trocar. In robot-assisted retinal surgery, the RCM allows the surgical instrument to rotate around a distal fixed point without any lateral translations (24). The RCM is a mechanical property in the case of a hardware-based and/or mechanical RCM or a control approach in the case of a software-based RCM; it acts as a rotational fulcrum and restricts the translation of the end effector along the trocar axis except for the depth of penetration (25,26). This robotic system was designed with a unique software-based RCM, with a trocar as the virtual point position of the RCM, thereby reducing scleral traction, compression, and related complications caused by surgical instruments. In addition, to realign the RCM, the calculation of the new RCM took about 5 ms, and the communication time from the force sensor to the control board was less than 1 ms. During the master-slave control period, the new RCM point used at the next step was calculated using the force value, and the positions of the joints were read at the previous step. Thus, the lag time of the RCM realignment was only 6 ms, which could hardly influence the whole control loop.

Our results obtained during the simulator experiments demonstrated that the accuracy of robot-assisted surgery was significantly higher than that of manual surgery, both in the resident and vitreoretinal surgeon groups. Robot-assisted surgery also effectively reduced physiological

tremors and improved surgeons' control over the stability of the instrument tips. Experienced vitreoretinal surgeons acquire delicate microsurgical techniques through lifelong skills acquisition, which is reflected in the steep learning curve of junior ophthalmologists (27). Our results showed that robots helped residents to quickly achieve performance comparable to that of experts in terms of the stability of holding instruments, thereby improving their surgical skills and surgical safety.

There is some evidence that skills demonstrated on simulators correlate with real-life surgical performance (18). However, there is a large difference between a bionic eyeball in the simulator and a real eyeball. We cannot rule out that robot-assisted surgery will lead to different results in a simulated environment compared with real life. Therefore, we performed retinal vascularization with microneedles in harvested porcine eyes. The results showed that robots provided an efficient approach to sophisticated vitreoretinal surgeries, which might no longer be challenging for residents. Due to the high accuracy of the robot and the advantages of the RCM strategy, the robot's performance was more stable during the entire surgical process, especially during the injection process following intubation.

At present, the efficiency of robot-assisted surgery is still far lower than that of manual surgery. In Test 1 and Test 2, in both the vitreoretinal expert group and the resident group, robot-assisted surgeries took longer than manual surgery. This is mainly because when approaching the target area (such as the target sphere in Test 1), the displacement accuracy of each step of the robot was 10  $\mu\text{m}$ , which increased time consumption. Considering both accuracy and efficiency of robotic surgery, we set up multiple motion modes, such as intraocular and extraocular motion modes. Moreover, for intraocular motion the displacement speed was divided into 3 gears: high, medium, and low. However, even with these settings, the time it took to switch modes made robot-assisted surgery more time-consuming. In a clinical scenario, the more time a procedure takes, the more risks there are, such as the risks of anesthesia. Therefore, more research is needed on the efficiency of robotics-assisted surgery.

## Conclusions

Robots enhance a surgeon's ability to maintain the stability of instrument handling and the accuracy of surgery, especially for residents, but robot-assisted surgery is less

efficient than manual surgery. Robot-assisted surgeries have the potential to improve the precision and safety of surgery by overcoming the physiological limits of physicians.

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## Footnote

**Reporting Checklist:** The authors have completed the CONSORT reporting checklist. Available at <https://atm.amegroups.com/article/view/10.21037/atm-22-1315/rc>

**Trial Protocol:** Available at <https://atm.amegroups.com/article/view/10.21037/atm-22-1315/tp>

**Data Sharing Statement:** Available at <https://atm.amegroups.com/article/view/10.21037/atm-22-1315/dss>

**Peer Review File:** Available at <https://atm.amegroups.com/article/view/10.21037/atm-22-1315/prf>

**Conflicts of Interest:** All authors have completed the ICMJE uniform disclosure form (available at <https://atm.amegroups.com/article/view/10.21037/atm-22-1315/coif>). SL is the robot engineer in the Guangzhou Oculotronics Medical Instrument Co., Ltd. PY is the medical manager in Cloud Intelligent Care Technology (Guangzhou) Co., Ltd. The other authors have no conflicts of interest to declare.

**Ethical Statement:** The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Because of the intervention object was surgical simulator, the ethics committee of ZOC adjudicated that ethics review approval was not required for this study. The principles outlined in the Declaration of Helsinki (as revised in 2013) were followed throughout the study. The porcine eyes were slaughterhouse materials. Experiments were performed under a project license (No. 2019-146) granted by the Institutional Animal Care and Use Committee of ZOC, in

compliance with the Association for Research in Vision and Ophthalmology guidelines for the care and use of animals.

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