Trial protocol

Objective

This study aims to compare robot-assisted vitreoretinal surgery with manual surgery in a simulated setting involving an animal model.

Participants

The participants will consist of experienced vitreoretinal experts (10-15 years of experience) and residents with no previous intraocular surgical experience (first- or second-year residents) from ZOC. After prior examination for the agreement of operating level, ten participants for each group will be included in the study. Experts and residents who had trained for more than 2 hours on the Eyesi simulator (VRmagic, Mannheim, Germany) in the past six months will not be eligible to participate in the study.

Intervention

Residents and vitreoretinal experts will be randomly divided into either robot-assisted or manual surgery groups. A computer-generated list of random numbers will be used to randomize participant assignment to the two operations (manual and robot-assisted operation) by following a balanced permutation (computer-generated random numbers). Thus, there will be four groups in total. Group 1 will include residents operating manually; Group 2 will contain residents operating with robot assistance; Group 3 will include experts operating manually; and Group 4 will contain experts operating with robot assistance.

Outcomes

(1) the efficiency of operation, which is the time taken following instrument insertion until test completion (minutes) and the distance traveled by the instrument tip as measured by an odometer (mm); (2) the accuracy of operation, determines by whether the instrument slipped out of the target sphere; and (3) the performance of tremor control, determines by the instrument tip exceeding the tolerance percentage; (4) the feasibilities of the microcannulation in harvested porcine eyes.

Statistical analysis

The processes of outcomes assessment will be blinded to group assignment. Data compilation processes and analyses will be conducted using SPSS 26.0 statistical software (SPSS Inc. Chicago, IL, USA). One-way ANOVA and Bonferroni's tests will be used to analyze the differences in the three outcomes of the simulator tests among the four groups. A chi-squared test will be used to compare the feasibility tests. Values are shown as the mean $\pm$ SD. All reported p values are 2-tailed, and statistical significance will be defined at the α = 0.05 level.