

Abstract 45

ROBOT-ASSISTED SUBRETINAL DRUG DELIVERY: FIRST-IN-HUMAN STUDY

Oral

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Purpose:

To report the results of a first-in-human study using a robotic device to assist subretinal drug delivery in patients undergoing vitreoretinal surgery for macular haemorrhage.

Methods:

This was double-armed, randomized controlled surgical trial (ClinicalTrials.gov: NCT03052881) performed at the Oxford Eye Hospital, Oxford University Hospitals NHS Foundation Trust, Oxford, United Kingdom. In total, 12 participants with acute sub-foveal haemorrhage were recruited. After standard vitrectomy, subretinal injection of tissue plasminogen activator (TPA) was performed by either robot-assisted or conventional manual technique under local anaesthesia. The robotic part of the procedure involved advancement of a cannula through the retina and stabilizing it during foot-controlled injection of up to 100 µL of TPA solution. We assessed surgical success, duration of surgery, adverse events, and tolerability of surgery under local anaesthesia.

Results:

The procedure was well tolerated by all participants and safely performed in all cases. Total duration of surgery, time taken to complete the injection, and retinal microtrauma were similar between the groups and not clinically significant. Subretinal haemorrhage was successfully displaced at 1-month postintervention, except for 1 control subject, and the median gain in visual acuity was similar in both arms.

Conclusions:

This first-in-human study demonstrates the feasibility and safety of high-precision robot-assisted subretinal drug delivery as part of the surgical management of sub-macular haemorrhage, simulating its potential future application in gene or cell therapy.