LABORATORY SCIENCE

Semiautomated optical coherence tomography-guided robotic surgery for porcine lens removal

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Purpose: To evaluate semiautomated surgical lens extraction procedures using the optical coherence tomography (OCT)–integrated Intraocular Robotic Interventional Surgical System.

Setting: Stein Eye Institute and Department of Mechanical and Aerospace Engineering, University of California, Los Angeles, USA.

Design: Experimental study.

Methods: Semiautomated lens extraction was performed on postmortem pig eyes using a robotic platform integrated with an OCT imaging system. Lens extraction was performed using a series of automated steps including robot-to-eye alignment, irrigation/aspiration (I/A) handpiece insertion, anatomic modeling, surgical path planning, and I/A handpiece navigation. Intraoperative surgical supervision and human intervention were enabled by real-time OCT image feedback to the surgeon via a graphical user interface. Manual preparation of the pig-eye models, including the corneal incision and capsulorhexis, was performed by a trained cataract surgeon before the semiautomated lens extraction procedures. A scoring system was used to assess surgical complications in a postoperative evaluation.

Results: Complete lens extraction was achieved in 25 of 30 eyes. In the remaining 5 eyes, small lens pieces ($\leq$1.0 mm^3) were detected near the lens equator, where transpupillary OCT could not image. No posterior capsule rupture or corneal leakage occurred. The mean surgical duration was 277 seconds $\pm$ 42 (SD). Based on a 3-point scale (0 = no damage), damage to the iris was 0.33 $\pm$ 0.20, damage to the cornea was 1.47 $\pm$ 0.20 (due to tissue dehydration), and stress at the incision was 0.97 $\pm$ 0.11.

Conclusions: No posterior capsule rupture was reported. Complete lens removal was achieved in 25 trials without significant surgical complications. Refinements to the procedures are required before fully automated lens extraction can be realized.

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Worldwide, approximately one third of cases of blindness and one sixth of cases of vision impairment are caused by cataract.[1] Innovative technologies developed for cataract surgery, such as the laser-assisted corneal incision,[2] capsulorhexis,[A] and lens fragmentation,[3] have improved specific surgical steps. However, lens extraction, during which the majority of complications occur,[4] continues to be manually performed and represents the most critical step of cataract surgery. If incomplete, vision recovery is limited; if improperly performed, surgical complications can occur.

Posterior capsule rupture occurs when the phacoemulsification or irrigation/aspiration (I/A) handpiece uses excessive vacuum force in close proximity to the capsule; it occurs in 1.8% to 4.4% of cases.[5] Every year, more than 70 000 patients in the United States and 352 000 patients worldwide suffer from posterior capsule rupture.[5] Posterior capsule rupture increases the incidence of retinal detachment, macular edema, intraoperative lens dislocation, and endophthalmitis.[6,7] Eliminating posterior capsule rupture would decrease the vision-threatening complications of cataract surgery. However, the posterior capsule is invisible and delicate, with a thickness of approximately 5 to 10 μm and an allowable displacement of only hundreds of micrometers.[8] With the limited reaction time of a human surgeon (360 ms),[9] the posterior capsule can rupture before the

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surgeon is able to react. On the other hand, incomplete lens extraction occurs if the surgeon is too conservative.

Systems that have been developed to improve surgery include teleoperated robotic platforms for assisting in vitreoretinal surgery[10,11]; however, the state of the art in cataract surgery remains limited. To date, no system for cataract surgery (automated or otherwise) has received U.S. Food and Drug Administration approval or been used to perform studies of human volunteers. Unresolved issues include (1) aligning the robot-guided I/A handpiece with the corneal incision, (2) registering anatomic structures for surgical path planning, and (3) accounting for the dynamic nature of the surgical environment to safely navigate within the eye.

In this study, semiautomated lens extraction was evaluated in pig-eye models using the Intraocular Robotic Interventional Surgical System.[12,13] This robotic system is guided by optical coherence tomography (OCT) with a minimal degree of human intervention.[14] The OCT image feedback enables automated procedures such as I/A handpiece alignment, anterior segment modeling, generation of an I/A handpiece surgical path, and real-time supervision and intervention.

MATERIALS AND METHODS

Figure 1 shows the overall system setup. Table 1 shows the relevant engineering metrics.

Semiautomated Lens Extraction

The procedures for semiautomated lens extraction[14] can be divided into preoperative, intraoperative, and postoperative stages (Figure 2). During the preoperative planning stage, the robotic system was automatically initialized and self-calibrated to ensure the precision and accuracy of its motion. The location and orientation of the corneal incision were determined from an OCT volume scan of the incision. These measurements enabled automated robot alignment and insertion of the I/A handpiece, where the robot system autonomously aligned its remote center of motion to the corneal incision and inserted the I/A handpiece through it.

After the I/A handpiece was aligned to the eye, the system autonomously constructed an anatomic model of the anterior segment from OCT volume scans. Using this model, a workspace was defined for I/A handpiece navigation and surgical safety margins were established (1.5 mm from any part of the iris; 0.1 mm from the corneal endothelium; 3.5 mm to the posterior capsule). Irrigation/aspiration forces were delivered to the I/A handpiece through the robotic platform and automatically regulated according to the proximity of the I/A handpiece to the posterior capsule. During the autonomous lens extraction phase, the robotic system autonomously tracked the preoperatively planned lens extraction trajectory. To accommodate for the variable surgical environment, a graphical user interface was used to allow the surgeon to monitor and override the automated lens extraction procedure, including the lens extraction trajectory, the applied I/A forces, and the predefined workspace and surgical safety margins. In addition, an OCT-based progress assessment was performed by the surgeon every 2 minutes during lens extraction. If no visible lens material remained in the capsular bag, the surgery was concluded and postoperative evaluation performed. If the second trajectory concluded but small piece(s) ($\leq$1.0 mm^3) of lens material remained, the robotic system was directed to the location of the remaining lens material by the surgeon via the graphical user interface. Otherwise, the robotic system would continue tracking the lens extraction trajectory until the subsequent progress assessment.

Preparation of Pig-Eye Model and Surgical Instruments

The semiautomated lens extraction was validated on postmortem pig eyes (Sioux-Preme Packing, Sioux City, Iowa, USA) pinned into a custom polystyrene holder. Manual preparation of each eye was performed by a trained cataract surgeon (A.A.F.) under a surgical microscope (M840, Leica Microsystems GmbH). The surgeon created a uniplanar corneal incision with a 2.8 mm keratome knife, made a 5.0 mm diameter continuous curvilinear capsulorhexis, and performed hydrodissection and hydrodelamination of the lens with a balanced salt solution. As the final preparation step, the anterior segment was filled with an ophthalmic viscosurgical device (sodium hyaluronate 1.0%) to prevent collapse of the anterior chamber.

A straight-tip I/A handpiece with a side aspiration port (Table 1) was installed with an irrigation sleeve and mounted on the robotic system. The I/A handpiece was connected to a modified ACCURUS surgical system (model 800CS, Alcon Laboratories, Inc.) to provide robot-controlled I/A for lens extraction and intraocular pressure (IOP) regulation with a maximum vacuum force of 600 mm Hg.

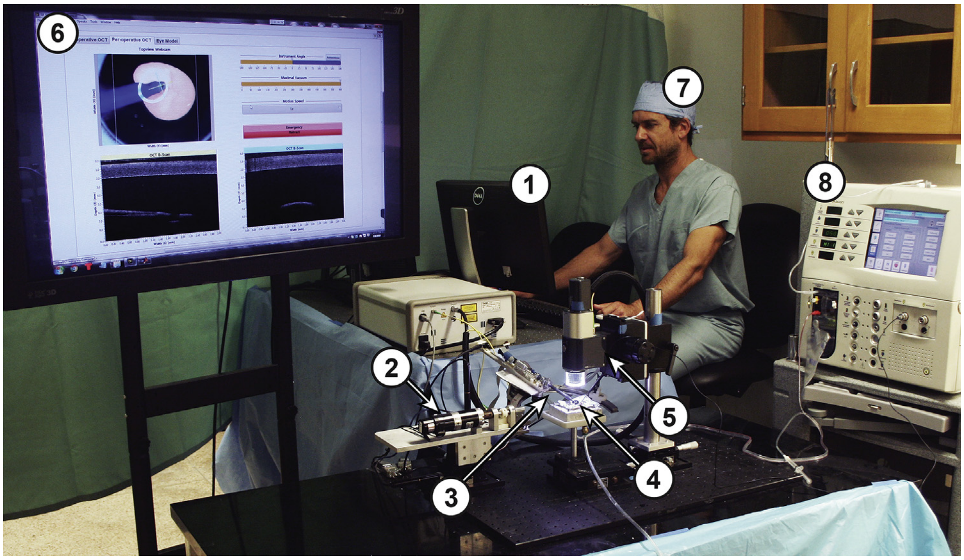

Figure 1. Overall system setup. Numbers indicate major system components and correspond to the elements illustrated in Figure 2. These elements are (1) the control software, (2) intraocular robotic interventional surgical system, (3) irrigation/aspiration handpiece, (4) pig-eye model, (5) optical coherence tomography with integrated complementary metal oxide semiconductor camera, (6) graphical user interface, (7) surgeon, and (8) the phacoemulsification unit.

Table 1. Engineering metrics of the robotic and OCT systems.

System/Metric	Value/Description
Robotic[12,13]	
Positional precision* (µm)	27 ± 2
Positional accuracy† (µm)	205 ± 3
Robot-to-eye alignment time (min)	<1
Mounted tool	8172 UltraFLOW straight-tip irrigation/aspiration handpiece with side aspiration port (Alcon)
OCT	
Detection scheme	Spectral domain
Model	Telesto II 1060LR with objective lens LSM04BB (ThorLabs)
Central wavelength (nm)	1060
Volume scan dimensions (mm)	10.0 × 10.0 × 9.4
Volume scan acquisition time (s)	33.2
Axial resolution (in air) (µm)	9.18
B-scan acquisition and display rate (Hz)	4.65

OCT = optical coherence tomography

*Ability to repeatably touch the same point

†Ability to exactly touch a specified point

Evaluation of the Procedure

A postoperative histological examination was performed by the cataract surgeon using the surgical microscope. The evaluation metrics were as follows: posterior capsule rupture (yes/no); lens extraction (complete, near-complete, incomplete); iris damage (damage level 0 to 3); cornea damage (damage level 0 to 3); incision stress (stress level 0 to 3).

For assessing lens extraction, the surgeon examined the entire capsular bag (including the equator) to search for remaining lens material. If none was found, the procedure was considered complete. If particles were found, they were assessed for size. If all found particles were smaller than 1.0 mm^3, the procedure was considered near-complete. If any particle was larger than 1.0 mm^3, the procedure was considered incomplete. Damage and stress levels were qualitatively defined according to Table 2. Finally, the surgical duration of aspiration (the amount of time the I/A handpiece was in the eye) was recorded for each trial.

RESULTS

Semiautomated lens extraction was performed on 30 postmortem pig eyes. The mean harvested pig-eye pupil diameter was recorded as 8.50 mm ± 0.59 (SD).

Figure 3 shows the results of the postoperative histological examination. No posterior capsule rupture was encountered in any of the 30 trials. Lens extraction was assessed as complete in 25 trials, near-complete in 5 trials, and incomplete in zero trials. In the 5 trials with near-complete lens extraction, the small lens particles ($\leq$1.0 mm^3) were adhered to the lens equator.

The mean surgical duration was 277 ± 42 (SD) seconds. In all trials, preparation of the eye by the surgeon required approximately 5 minutes; automated alignment of the robotic system to the eye required less than 1 minute. The mean iris damage level was 0.33 ± 0.20 (SD), the mean cornea damage level was 1.47 ± 0.20 (SD), and the mean incision stress level was 0.97 ± 0.11 (SD).

DISCUSSION

We believe that this work represents the first success in performing semiautomated lens extraction guided by a transpupillary OCT imaging system for cataract surgery. The semiautomated procedures, which address challenges of OCT-guided surgical automation, proved safe and effective for (1) the alignment of the robot-guided I/A handpiece to the corneal incision, (2) the reconstruction of intraocular anatomical structures for surgical path planning, and (3) the ability to accommodate the dynamic nature of the surgical environment to ensure surgical safety and outcomes.

The automated image segmentation and modeling algorithm was able to reconstruct the anatomic model from OCT scans of the anterior segment. Without requiring the manual labeling of tissue, the algorithm establishes

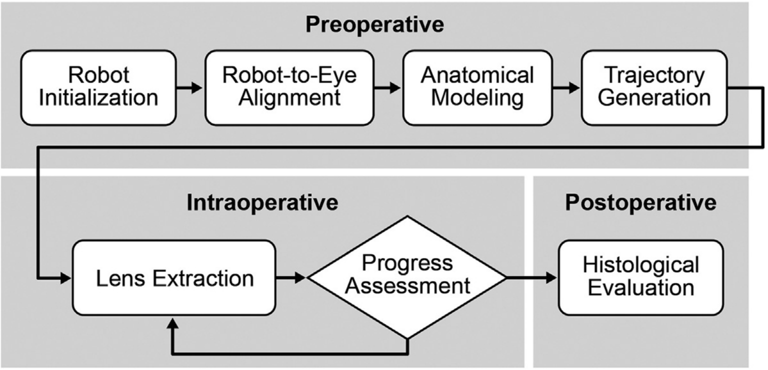

Figure 2. Procedures for semiautomated lens extraction divided by stage.

Table 2. Definition of postoperative evaluation scores.

Description	Score
Iris damage	
No iris contact	0
Iris contact without damage	1
Iris contact and damage in a single location	2
Iris contact and damage in multiple locations	3
Cornea damage	
No evidence of endothelial or stromal defect	0
Mild Descemet folds; no stromal defect	1
Descemet fold and mild corneal edema	2
Opaque cornea	3
Incision stress	
Preserved incision	0
Mild opening of the incision; does not compromise sealing	1
Opening of the incision; compromised sealing	2
Widening of the incision with compromised sealing	3

the anatomic model and generates the I/A handpiece trajectory for lens extraction. The mean accuracy of posterior capsule modeling was 79.6 ± 23.3 (SD) μm, which was approximately 40 times smaller than the surgical safety margin between the I/A handpiece trajectory and the posterior capsule (3.5 mm).

The OCT imaging system allows for real-time surgical supervision and intervention. The user interface was designed for modification of the programmed lens extraction trajectory so that the dynamic surgical environment could be accommodated if required. The surgeon was not required to handle the I/A handpiece or manual controls during the operation. If necessary, the robot could be commanded by clicking on the displayed images acquired from the OCT and its integrated camera. This feature eliminated reliance on the surgeon's dexterity and familiarity with the robotic system. This development represents a milestone toward fully automated lens extraction, especially because real-time OCT image segmentation remains challenging.

The self-navigated I/A handpiece brushed the iris in 9 of the 30 trials, primarily because of the limited dilation of the porcine eye model as well as submillimeter shifting of the eye. These complications could be mitigated by improving dilation, implementing eye tracking, or increasing the surgical safety margin around the iris. Damage to the cornea was expected because of the accumulated tissue dehydration and natural degradation of the pig eyes, which were shipped overnight from the slaughterhouse. The cornea damage was proportional to the surgical duration (mean surgical duration of trials with cornea damage level of 1 was 220.6 seconds; 333.5 seconds for trials with cornea damage level of 2) and resulted from air exposure and the initiation of dehydration. Aside from the corneal incision, the I/A handpiece never touched the corneal endothelium during the trials; therefore, contact with the I/A handpiece was not a source of damage. Last, the incision stress was minimal (level 1 in almost every trial) as a result of the automated alignment and adherence of the I/A handpiece motion about the robotic remote center of motion.

No posterior capsule rupture was diagnosed, and complete lens extraction was achieved in 25 of 30 trials. In the 5 trials in which near-complete lens extraction was achieved, only small pieces (≤ 1.0 mm^3) of lens material were discovered near the lens equator during the postoperative assessment. Nevertheless, we consider these trials successful because the equatorial area hidden by the iris remained invisible during the entire procedure; this represents a deficiency of the sensing modality, not the developed automated procedures. An improved or augmented means to visualize the lens equator is required to enable complete lens extraction.

To allow implementation of the semiautomated procedures in future preclinical trials, several refinements are currently underway. First, inclusion of an additional imaging modality that can visualize the lens equator and detect lens material posterior to the iris will improve the completion of lens extraction. Second, regulation of the IOP via active irrigation control will stabilize the intraocular tissues and reduce the risk for surgical complications. Third, the application of artificial intelligence can prove beneficial toward resolving the challenging problem of real-time image segmentation of

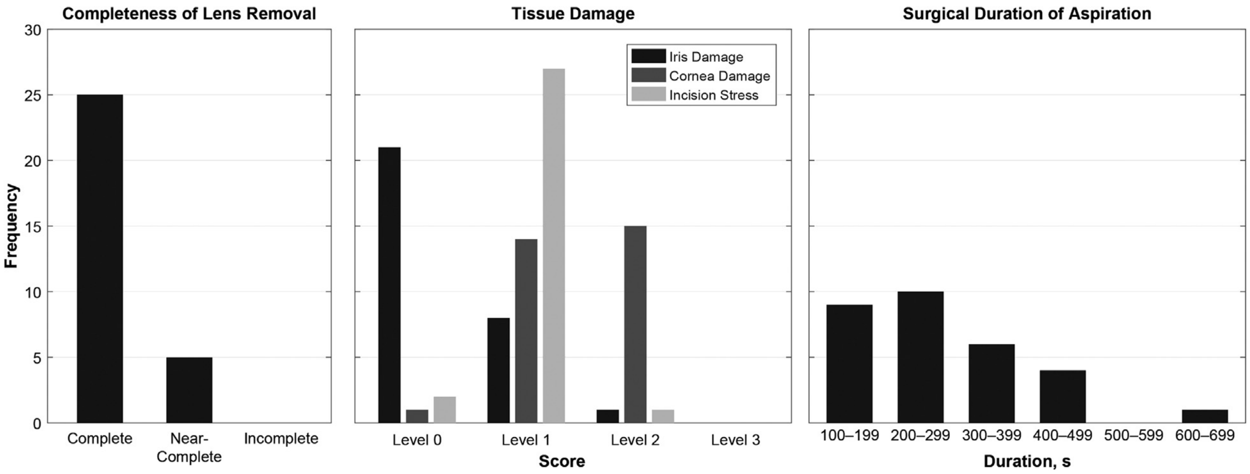

Figure 3. Results of the semiautomated lens extraction trials.

OCT data and allow for development of a real-time OCT-based tissue-tracking algorithm that can be used to update the anatomical model and adjust the navigation strategy. Finally, we will continue to pursue fully automated lens extraction and cataract surgery by combining a femtosecond laser system with the Intraocular Robotic Interventional Surgical System.

WHAT WAS KNOWN

- The most critical step of cataract surgery, lens extraction, remains a manual operation to remove the lens nucleus and cortical material from the capsular bag. Surgical complications such as posterior capsule rupture and incomplete lens extraction occur during this stage.
- Transpupillary optical coherence tomography (OCT) images have been used in preoperative diagnosis and surgical planning. However, no existing system applies transpupillary OCT data to intraoperative lens extraction.

WHAT THIS PAPER ADDS

- Semiautomated lens extraction on postmortem pig eyes was performed using a robotic system integrated with an OCT imaging system.
- Automated steps included alignment of the irrigation/aspiration (I/A) handpiece to the corneal incision, anatomic modeling, trajectory generation, and I/A handpiece insertion. Lens extraction was partially automated in the sense that surgeon intervention was permitted during the otherwise fully autonomous lens extraction operation.

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