Prospective, Double-masked, Randomized Trial Comparing Lidocaine Gel to Tetracaine Drops in Femtosecond Laser-assisted LASIK

Despite the use of topical anesthetics, patients report intra- and/or postoperative pain and discomfort during LASIK, particularly during flap creation and during the first several hours after LASIK. Evidence suggests that gel preparations of topical anesthetics may be more effective than aqueous-based drops, due to their prolonged contact with the ocular surface and deeper penetration into the aqueous humor. A prior study in eyes undergoing LASIK with a microkeratome found decreased pain in the eye that received supplementary lidocaine 2% gel compared to the eye that received 0.5% proparacaine alone. We designed the first study (to our knowledge) comparing the anesthetic efficacy and surgical outcomes between lidocaine 2% gel and tetracaine 0.5% drops in patients undergoing bilateral femtosecond laser-assisted LASIK.

This University of Miami, IRB-approved, prospective, single-center, randomized, double-masked, paired-eye comparison intended to include 80 eyes from 40 healthy adults not taking pain medications. However, the study was halted after 22 eyes from 11 patients were enrolled due to patient safety concerns (ie, when 1 patient developed irregular, thin flap in the eye receiving lidocaine 2% gel). A 0.25-inch application of 2% lidocaine gel was administered 10 minutes prior and again at 5 minutes prior to LASIK with a supplement of 0.5% tetracaine administered at time 0 in 1 eye, selected at random by a data allocation sheet. For the fellow eye, 2 drops of 0.5% tetracaine were given at 10 and 5 minutes prior to and at the time of LASIK.

Main outcome measures included baseline and postoperative pain scores (1 indicating no pain and 4 indicating severe pain for 12 different pain descriptions) assessed immediately after and 1 hour following LASIK; uncorrected (UDVA) and corrected distance visual acuity (CDVA) measured at 1 day and 1 month postoperatively; and intended versus actual flap thickness. The study was in compliance with Good Clinical Practices, the Declaration of Helsinki (1996), ClinicalTrials.gov (Trial# NCT01383200), and informed consent (US 21 CFR part 50) and HIPAA regulations.

The study found no difference in visual acuity and showed similar pain levels between the treatment arms. However, we found that the femtosecond laser flaps were significantly thinner than intended in eyes that received lidocaine gel compared to those that received tetracaine drops. When comparing the intended flap thickness to the actual flap thickness, eyes receiving lidocaine gel were a mean of $10 \pm 22.71 \mu m$ thinner than intended, compared to the tetracaine drop eyes, which were $8.6 \pm 27.87 \mu m$ thicker ($P=.04$).

These differences in flap difference may be related to the formation of a thin gel layer on the surface of the cornea, which can induce scatter and thus affect the precision of the femtosecond laser beam. Our final patient developed an irregular, thin flap, likely caused by a remaining gel–cornea interface that affected the depth of the femtosecond laser beam (Fig). However, it may be possible to use a gel interface for therapeutic applications with the femtosecond laser in cases of irregular corneal surfaces. Furthermore, this study suggests that a small residual gel layer may remain following copious rinsing with balanced saline solution, reinforcing the practice that antiseptics for endophthalmitis prophylaxis prior to cataract surgery need to be administered prior to the gel anesthetic in patients undergoing cataract surgery. Thus, our study suggests that using anesthetic gel with the femtosecond laser for flap creation may not be the ideal alternative to tetracaine drops for femtosecond laser-assisted LASIK, due to the potential risk for flap complications.

![Figure](image_url)
Development of a Wide-field, Binocular, Open-view Type Electronic Pupillometer

Recently, the number of pupil-dependent refractive surgeries and presbyopia correction surgeries being performed has increased.\(^1\)\(^5\) It is well known that pupil size is greatly affected by the measurement conditions, with the pupil size becoming smaller as the environmental illumination increases. Therefore, it is important to establish the measurement conditions prior to measuring the pupil size (pupillometry). We believe that pupillometry should be performed under conditions as close to natural viewing as possible, given the fact that daily routines involve bright (photopic) environments with a binocular open view.

The new pupillometer comprises a main unit that is connected to a personal computer (PC) that is responsible for controlling the measurements (Fig A). Two infrared cameras (resolution 768×494) are built into the main unit, which makes it possible to image both eyes simultaneously. In each imaged eye, a black circle above a set threshold is first detected (the pupil), after which the horizontal and vertical diameters of the detected pupil are then measured in pixel units. The PC controls when the measurement period begins, receives the pupil size data (horizontal and vertical diameters) from the pupillometer, and then, via use of a measurement program, converts the pupil size to absolute units. This pupillometer is calibrated on the basis of the actual value of shot range, which photographed the pupil with the infrared camera.

Ten healthy individuals aged 20 to 22 years (mean age: 20.7±0.7 years) were tested with an eye shield that completely covered their eye, and then with eye shields that contained various hole sizes in the center. All measurements were collected over a specified time period, with the horizontal and vertical pupil diameters used to calculate the mean values.

Pupil size was measured by the new pupillometer device using eight different fields of view that included: one eye completely covered; monocular field of views of 20°, 30°, 40°, 50°, 60°, and 70°; and no covering of the eye, which provided horizontal and vertical viewing angles of 120° and 90°, respectively, by fixing the head of each patient in a head and chin-support frame. This study followed the tenets of the Declara-
tion of Helsinki. All applicable institutional regulations concerning the ethical use of human volunteers were followed during this research.

As the monocular field of view narrowed, the pupil size increased. Compared to the “no covering” values, the results were significantly larger when the monocular viewing angles were ≤50° (Fig B). These findings indicate that measurement viewing angles can affect pupil size measurements. Much of our daily environment involves bright (photopic) exposures with a binocular open view. Thus, when planning for refractive surgery, pupil size measurements need to be performed under conditions as close to natural viewing as possible. This is also important from the perspective of the patient’s postoperative satisfaction. Therefore, we believe the wide-field, binocular, open-view electronic pupillometer will be an important and clinically useful device in the future.

Tomoya Handa, CO, PhD
Nobuyuki Shoji, MD, PhD
Takushi Kawamorita, CO, PhD
Kimiya Shimizu, MD, PhD
Sagamihara, Japan
Ryo Kawamura
Noriyoshi Shimizu, PhD
Osaka, Japan

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