Intraocular Pressure and Wound Status in Eyes Immediately After Scleral Tunnel Incision and Clear Corneal Incision Cataract Surgery

KEN HAYASHI, TADATOSHI TSURU, MOTOAKI YOSHIDA, AND AKIRA HIRATA

• PURPOSE: **To compare intraocular pressure (IOP) and wound architecture immediately after cataract surgery using a scleral tunnel incision or clear corneal incision.**
• DESIGN: **Prospective randomized clinical trial.**
• METHODS: **Bilateral eyes of 64 patients undergoing phacoemulsification were randomized to 2 groups: 2.4 mm scleral tunnel incision or 2.4 mm clear corneal incision. IOP was adjusted upon completion of surgery to between 15 and 30 mm Hg. The wound was hydrated in 87.5% of eyes in the clear corneal incision group. IOP was measured using a rebound tonometer preoperatively; at the conclusion of surgery; and at 5, 10, 15, 30, and 60 minutes postoperatively. The Seidel test and anterior segment optical coherence tomography (AS OCT) were performed at 30 minutes postoperatively.**
• RESULTS: **In the scleral tunnel incision group, mean IOP decreased to the preoperative level within 15 minutes postoperatively and did not change significantly for up to 60 minutes. In the clear corneal incision group, IOP decreased to lower than the preoperative IOP at 30 minutes postoperatively. Mean IOP was significantly higher in the scleral tunnel incision group than in the clear corneal incision group throughout the postoperative period ($P \leq .0339$). Hypotony (< 10 mm Hg) was observed in 7 eyes (10.9%) that underwent clear corneal incision and in no eyes that underwent scleral tunnel incision ($P = .0131$). Wound leakage and loss of wound coaptation were not observed in any eyes.**
• CONCLUSIONS: **IOP was significantly higher immediately after scleral tunnel incision without hydration than after clear corneal incision with hydration, and both incisions closed within 30 minutes postoperatively without leakage based on AS OCT. (Am J Ophthalmol 2014;158:232–241. © 2014 by Elsevier Inc. All rights reserved.)**

ENDOPHTHALMITIS OCCURS MORE FREQUENTLY after clear corneal incision cataract surgery than after scleral tunnel incision cataract surgery.[1–3] Previous studies revealed that bacteria-sized particles flow into the anterior chamber through the clear corneal incision at a high incidence in the immediate or early postoperative period when intraocular pressure (IOP) is reduced.[4–7] Further, recent studies using anterior segment optical coherence tomography (AS OCT) showed that a low IOP in the immediate postoperative period is associated with incomplete clear corneal incision wound closure.[8–12] Thus, hypotony immediately or early after cataract surgery is a major risk factor for anterior chamber contamination.

Some studies evaluated IOP immediately after clear corneal incision cataract surgery. Shingleton and associates[13] reported that hypotony occurs in approximately 20% of eyes at 30 minutes after clear corneal incision. Our previous study demonstrated that the IOP normalizes and stabilizes within 15 minutes after clear corneal incision, and clear corneal wounds close within 60 minutes based on AS OCT.[14] No studies to date, however, have examined the temporal changes in IOP and wound architecture immediately after scleral tunnel incision cataract surgery. Corneal shape changes are smaller after scleral tunnel incision than after clear corneal incision when the incision length is greater than 2.5 mm.[15] Furthermore, Ernest and associates[16] reported, using cadaver eyes, that wound strength of a square scleral tunnel incision is stronger than that of a rectangular clear corneal incision. Accordingly, we assumed that the IOP fluctuation would be less and wound tightness more secure after scleral tunnel incision than after clear corneal incision.

The purpose of the present study was to compare the longitudinal changes in IOP and wound integrity between eyes after scleral tunnel incision and eyes after clear corneal incision. Adjustment of the IOP to normal range was achieved by corneal wound hydration and injection of irrigating solution in eyes that underwent clear corneal incision, whereas eyes that underwent scleral tunnel incision did not undergo corneoscleral wound hydration.

METHODS

• PATIENTS: This study was a prospective randomized clinical trial. A clinical research coordinator began screening all consecutive patients scheduled for bilateral cataract surgery at the Hayashi Eye Hospital on May 10,

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From Hayashi Eye Hospital, Fukuoka, Japan.
Inquiries to Ken Hayashi, Hayashi Eye Hospital, 4-23-35 Hakataekimae, Hakata-Ku, Fukuoka 812-0011, Japan; e-mail: hayashi-ken@hayashi.or.jp

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2013. Exclusion criteria were eyes with any pathology of the cornea, vitreous body, macula, or optic nerve; eyes with glaucoma or ocular hypertension; eyes with pseudoexfoliation syndrome; eyes scheduled for planned extracapsular cataract extraction; a history of previous ocular surgery or inflammation; patients with diabetes; patient refusal; and any anticipated difficulties with examination or follow-up. Eyes that were included in another study were excluded from the present study. Screening was continued until 64 patients were recruited on December 9, 2013. This research adhered to the tenets of the Declaration of Helsinki. The Institutional Review Board (IRB)/Ethics Committee of the Hayashi Eye Hospital, Fukuoka, Japan, at which the present study was conducted, approved the study protocol, and all patients provided written informed consent to participate in the present study.

• **SAMPLE SIZE:** The study sample size was determined to have a statistical power of more than 90% to detect a clinically meaningful magnitude of difference in IOP between eyes after scleral tunnel incision and eyes after clear corneal incision. Assuming that an IOP difference of 1 mm Hg was clinically meaningful, we calculated that 51 eyes per group were necessary based on standard deviation of previous study.[14] Assuming a possible 20% loss to follow-up, we calculated that 64 eyes were required for each group.

• **RANDOMIZATION:** All enrolled patients were randomly assigned to 1 of 2 groups the day before surgery: (1) left eyes that were to undergo a 2.4 mm scleral tunnel incision group and right eyes that were to undergo a 2.4 mm clear corneal incision group, and (2) right eyes that were to undergo scleral tunnel incision and left eyes that were to undergo clear corneal incision. The clinical research coordinator for this trial generated a randomization code with equal numbers (1:1 ratio) using computer software, and assigned each patient to 1 of the 2 groups according to the computer-generated randomization code. The group to which the patients were assigned was directly communicated by the coordinator to a member of the operating room staff who prepared the intraocular lens (IOL). The surgeon was informed about the type of surgery just before surgery. Data were collected by the coordinator at the Hayashi Eye Hospital. To ensure allocation concealment, the coordinator kept the assignment schedule until all data were collected (December 12, 2013). All patients, examiners, and the data analyst were unaware of the group to which the patients had been assigned.

• **SURGICAL TECHNIQUES:** All surgeries were performed by a single surgeon (K.H.) using the surgical procedures described previously.[14,15] To equalize the effect of local anesthesia on IOP reduction between groups and to avoid eyelid pressure owing to patient tension, each eye received a 2 mL retrobulbar injection of 2% xylocaine prior to the preoperative measurement of IOP. For phacoemulsification surgery, the surgeon made a horizontal incision in eyes having against-the-rule or oblique corneal astigmatism, and a superior incision in eyes having with-the-rule astigmatism.

Scleral tunnel incision cataract surgery. For the scleral tunnel incision, 2 side ports were first created with a 0.6 mm diamond knife approximately 90 degrees away from the center of the main incision. Through 1 side port, a continuous curvilinear capsulorrhexis measuring about 5.5 mm in diameter was accomplished using a bent 25 gauge needle. After dissection of the conjunctiva and before incision, wet-field cauterization was gently applied at the bleeding sites of the superficial episcleral vessels. The surgeon then made a 2.5 mm straight incision that was 1.5 mm posterior to the limbus, and a scleral tunnel was dissected up to 1.0 mm anterior to the limbus with a diamond crescent knife. The anterior chamber entry was created with a 2.4 mm steel keratome. The intended length of the scleral tunnel incision was approximately 2.5 mm. After hydrodissection, phacoemulsification of the nucleus and aspiration of residual cortex was performed. The lens capsule was inflated with 1% sodium hyaluronate (Healon; Abbott Medical Optics, Santa Ana, California, USA), after which a single-piece hydrophobic acrylic IOL (SN60WF; Alcon Laboratories, Fort Worth, Texas, USA) was placed into the capsular bag using a Monarch II injector with a C cartridge (Alcon). At the conclusion of surgery, balanced saline solution was injected into the anterior chamber using a cannula through a side port, and the IOP was measured using a rebound tonometer (ICare; Tiolat, Helsinki, Finland). The side ports were hydrated at the conclusion of surgery. An examiner, trained in using the ICare tonometer, measured the IOP. Because the IOP was 15 mm Hg or higher in all eyes, wound hydration was not performed. Finally, the IOP was adjusted to range between 15 and 30 mm Hg by reinjection of balanced saline solution, or by removing anterior chamber fluid through a side port using a cannula.

Clear corneal incision cataract surgery. For the clear corneal incision, 2 side ports were first created with a 0.6 mm diamond knife at approximately 90 degrees away from the center of the main incision. Through a side port, a continuous curvilinear capsulorrhexis was accomplished using a bent needle. Then, a 2.4 mm single-plane clear corneal incision was created from the posterior margin of the cornea with a stainless steel keratome for phacoemulsification and implantation of the IOL. The intended length of the clear corneal incision was approximately 1.5 mm. At the conclusion of surgery, balanced saline solution was injected through a side port into the anterior chamber, and the IOP was measured. Eyes in which the IOP did not reach at least