# Effect of high pressurization versus normal pressurization on changes in intraocular pressure immediately after clear corneal cataract surgery

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**PURPOSE:** To compare changes in intraocular pressure (IOP) immediately after clear corneal incision (CCI) cataract surgery between eyes in which IOP was adjusted to a high or normal range at the conclusion of surgery.

**SETTING:** Hayashi Eye Hospital, Fukuoka, Japan.

**DESIGN:** Comparative case series.

**METHODS:** Either eye of patients scheduled for phacoemulsification was randomized to 1 of 2 groups as follows: eyes that were to be adjusted to (1) high IOP (22 to 40 mm Hg) or (2) normal IOP (10 to 21 mm Hg). The IOP was measured using a rebound tonometer preoperatively; at the conclusion of surgery; and 15, 30, 60, 120, and 180 minutes and 24 hours postoperatively. The Seidel test and anterior segment optical coherence tomography (AS-OCT) were performed.

**RESULTS:** The mean IOP at the conclusion of surgery was 31.3 mm Hg in the high IOP group and 17.1 mm Hg in the normal IOP group. The IOP decreased to approximately 15 mm Hg by 15 minutes and did not change until 60 minutes in either group. The mean IOP did not differ significantly between groups throughout the observation period ($P \geq .0634$). Hypotony of 5 mm Hg or less was not detected in any eye. The Seidel test was negative and based on AS-OCT, the wound was closed at 60 minutes in all eyes.

**CONCLUSIONS:** After adjusting IOP to a high or normal range, the IOP normalized within 15 minutes postoperatively and was stable for 24 hours. The wound was closed within 60 minutes postoperatively.

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Clear corneal incisions (CCIs) are a well-known significant risk factor for endophthalmitis after cataract surgery.[1–4] Previous studies[5–8] found that the inflow of ocular surface fluid occurs through CCIs after cataract surgery at an incidence between 57% and 100%. This inflow could lead to anterior chamber contamination. More recent studies using anterior segment optical coherence tomography (AS-OCT) showed the structural integrity of clear corneal wounds[9–11] and that the wounds are compromised when intraocular pressure (IOP) is decreased.[12–15] In particular, McDonnell et al.[15] report that reduced IOP is associated with the loss of wound apposition and inflow of ocular surface fluid. Based on these findings, hypotony due to wound leakage through incompetent CCIs in the immediate postoperative period is considered to be a major risk factor for anterior chamber contamination.



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In some studies,[16,17] IOP was measured only once, soon after cataract surgery. Shingleton et al.[16] measured IOP 30 minutes after CCI cataract surgery; hypotony of 5 mm Hg or less occurred in approximately 20% of eyes. Rhee et al.[17] showed that IOP decreased to the normal range by approximately 25 minutes postoperatively, even after supranormal pressurization. However, transient or intermittent hypotony due to eye blinking or eye squeezing may cause anterior chamber contamination.[6–8] Accordingly, to prevent anterior chamber contamination, the IOP must be continuously maintained within the normal range until the clear corneal wound is closed. Based on these previous findings, we assessed the longitudinal changes in IOP immediately after CCI cataract surgery.

The purpose of the present study was to evaluate the temporal changes in IOP in the immediate period after CCI cataract surgery and to evaluate the wound integrity of CCIs using AS-OCT. In particular, to evaluate the effect of high or normal pressurization on maintenance of the IOP, 1 eye was adjusted to a high IOP with stromal hydration at the conclusion of surgery while the fellow eye was adjusted to a normal IOP.

## PATIENTS AND METHODS

A clinical research coordinator began to screen all patients who were scheduled to consecutively have bilateral cataract surgery at Hayashi Eye Hospital on September 5, 2012. Exclusion criteria were pathology of the cornea, vitreous body, or macula; pseudoexfoliation; glaucoma or ocular hypertension; eyes scheduled for planned extracapsular cataract extraction; a history of ocular surgery or inflammation; diabetes; patient refusal; and anticipated difficulties with the examination or analysis because of factors including a markedly thin or thick cornea, a high degree of irregular corneal astigmatism, or marked senile arcs. Eyes that were included in another study were also excluded from the present study. Screening was continued until 30 patients were recruited (November 6, 2012).

This research adhered to the tenets of the Declaration of Helsinki. Institutional review board/ethics committee approval was obtained. All patients provided written informed consent.

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### Randomization

All enrolled patients were randomly assigned to 1 of 2 groups the day before surgery as follows: (1) left eyes that were to be adjusted to a high IOP (22 to 40 mm Hg; high IOP group) and right eyes that were to be adjusted to a normal IOP (10 to 21 mm Hg; normal IOP group) by stromal hydration at the conclusion of surgery and (2) left eyes that were to be adjusted to a normal IOP and right eyes that were to be adjusted to a high IOP. The clinical research coordinator for this trial generated a randomization code with equal numbers (1:1 ratio) using random-number tables and assigned each patient to 1 of the 2 groups according to the randomization code. The coordinator informed 1 of the operating room staff to which group the patient had been assigned. All data were collected by the coordinator at Hayashi Eye Hospital. To ensure allocation concealment, the coordinator kept the assignment schedule concealed until all data were collected. All patients, examiners, and the data analyst were unaware of the group to which the patients had been assigned. Because the procedures of treatment, anesthesia, and surgery were the same between groups, the patients were unaware of which eye was adjusted to a high IOP. The examiners were unaware of which eyes had been adjusted to a high IOP because the ocular and wound appearances were the same. Because the coordinator concealed the assignment schedule until all data were collected (November 20, 2012), the data analyst did not know which eyes were adjusted to a high IOP.

### Surgical Technique

All surgeries were performed by the same surgeon (K.H.) using previously described procedures.[18] To equalize the effect of local anesthesia on IOP reduction between groups and to avoid high lid pressure due to the patient's tension, a 2 mL retrobulbar injection of lidocaine hydrochloride 2.0% (Xylocaine) was given in all eyes before preoperative measurement of IOP. For phacoemulsification, the surgeon made a CCI horizontally in eyes with against-the-rule or oblique corneal astigmatism and superiorly in eyes with with-the-rule astigmatism. A continuous curvilinear capsulorhexis measuring approximately 5.5 mm in diameter was created using a bent needle through a 0.6 mm side port. A 2.4 mm single-plane CCI was made using a stainless steel keratome (CCR-24AGF, Kai Medical, Inc.). After hydrodissection, endocapsular phacoemulsification of the nucleus and aspiration of the residual cortex were performed. The lens capsule was inflated with sodium hyaluronate 1.0% (Healon), after which a single-piece hydrophobic acrylic intraocular lens (IOL) (Acrysof SN60WF, Alcon Laboratories, Inc.) was placed in the capsular bag using a Monarch II injector (Alcon Laboratories, Inc.). After IOL insertion, the ophthalmic viscosurgical device was thoroughly evacuated.

At the conclusion of surgery, the IOP was adjusted to a high or normal range with stromal hydration according to the randomization code. An examiner who had been trained in the use of a rebound tonometer (Icare Tiolat, Icare Finland Oy) measured the IOP using the rebound tonometer. The IOP was adjusted by injecting a balanced salt solution around the main wound and side ports and by leaking the anterior chamber fluid through a side port using the cannula. The preoperative and postoperative medication, anesthesia, and surgical procedures were the same in the 2 groups, as were the ocular and wound appearance.