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Flanged Intrascleral Intraocular Lens Fixation with Double-Needle Technique

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Purpose: To report the clinical outcomes of a new technique for transconjunctival intrascleral fixation of an intraocular lens (IOL).

Design: Prospective, noncomparative, interventional case series.

Participants: One hundred eyes of 97 consecutive patients with aphakia, dislocated IOL, or subluxated crystalline lens who underwent posterior chamber sutureless implantation of an IOL were studied.

Methods: Two angled incisions parallel to the limbus were made by 30-gauge thin-wall needles. Haptics of an IOL were externalized with the needles and cauterized to make a flange of the haptics. The flange of the haptics were pushed back and fixed into the scleral tunnels.

Main Outcome Measures: Best-corrected visual acuity (VA), corneal endothelial cell density, IOL tilt, and complications were determined.

Results: The IOLs were fixed with exact centration and axial stability. The mean preoperative best-corrected VA was 0.25 logarithm of the minimum angle of resolution (logMAR) units; after surgery, it improved significantly to 0.11 logMAR, 0.09 logMAR, 0.12 logMAR, and 0.04 logMAR at 6, 12, 24, and 36 months, respectively ($P < 0.01$, $P < 0.01$, $P = 0.03$, and $P = 0.10$, respectively). The mean corneal endothelial cell density decreased from 2341 cells/mm^2 before surgery to 2313 cells/mm^2, 2240 cells/mm^2, 2189 cells/mm^2, and 2244 cells/mm^2 at 6, 12, 24, and 36 months, respectively ($P < 0.01$, $P < 0.01$, $P < 0.01$, and $P = 0.17$, respectively). The mean IOL tilt was 3.4°±2.5°. The postoperative complications included iris capture by the IOL in 8 eyes (8%), vitreous hemorrhage in 5 eyes (5%), and cystoid macular edema in 1 eye (1%). There were no incidents of postoperative retinal detachment, endophthalmitis, or IOL dislocation.

Conclusions: We have developed a new technique for intrascleral IOL fixation. The flanged IOL fixation technique is a simple and minimally invasive method for achieving good IOL fixation with firm haptic fixation. *Ophthalmology 2017;■:1–7 © 2017 by the American Academy of Ophthalmology*

Supplemental material available at www.aaojournal.org.

Surgical techniques for secondary intraocular lens (IOL) implantation in the absence of capsular support have been accomplished by using an anterior chamber IOL, an iris-fixed IOL, and a transscleral sutured posterior chamber IOL.[1–12] The transscleral IOL suture technique has advantages over the other techniques, which can cause corneal endothelial cell loss, glaucoma, and peripheral anterior synechiae.[13–16] However, suture erosion and breakage remain significant concerns when using a transscleral IOL suture. Suture breakage was observed in 27.9% of cases 6 years after IOL suturing using 10-0 polypropylene sutures.[17] Some surgeons have used Gore-Tex (W. L. Gore & Associates, Elkton, MD) sutures to decrease the risk of suture breakage.[18,19]

The intrascleral IOL fixation technique was reported by Gabor and Agarwal et al[21] as a sutureless technique for IOL fixation.[20] This technique can overcome the risk of suture-related complications, but has a potential risk of postoperative hypotony. In the above reports, the sclerotomy is made by a 24- or 25-gauge needle, and the vertical sclerotomy that is created by a 25-gauge needle usually requires suturing for wound closure. There have also been reports of a modified intrascleral IOL fixation technique.[22–25] We have developed a double-needle technique that can minimize the sclerotomy to 27 gauge and decrease the risk of postoperative hypotony.[22] Totan and Karadag[23] developed a transconjunctival technique using a 25-gauge trocar and achieved completely sutureless surgery.

There has been some doubt about whether sufficient haptic fixation power could be achieved by simple insertion into the scleral tunnel. Postoperative IOL dislocation after intrascleral IOL fixation is not common; however, there is a potential risk.[26–28] We have developed a new surgical procedure that can be carried out via the conjunctiva in which the haptics of the IOL are fixed strongly to the sclera without using suture or glue. We have named this technique *flanged IOL fixation* because we create a flange at the end of the haptic for firm fixation. In this article, we report this technique and its clinical results.

Methods

The study protocol was approved by the Institutional Review Committee at the Yokohama City University Medical Center. All clinical procedures were conducted according to the principles of

http://dx.doi.org/10.1016/j.ophtha.2017.03.036
ISSN 0161-6420/17

the Declaration of Helsinki. Informed consent was obtained from all patients after the study protocol, the procedure, and its possible complications had been explained. The inclusion criteria were aphakia, a dislocated IOL, a subluxated crystalline lens, and agreement with the study protocol. The exclusion criteria were retinal disease requiring treatment, such as retinal detachment or macular pucker; preoperative intraocular pressure (IOP) of 25 mmHg or more while receiving treatment with eye drops; scleritis; age younger than 20 years; and postoperative follow-up for less than 6 months. All surgeries were performed by a single surgeon (S.Y.) at the Yokohama City University Medical Center between May 2013 and January 2016.

All of the patients underwent a standard ophthalmologic examination including measurements of uncorrected and best-corrected visual acuity (VA) with a Landolt chart at 5 m, slit-lamp examination, measurement of IOP, and dilated indirect slit-lamp biomicroscopy at all preoperative and postoperative visits. Early and late postoperative complications were defined as surgical complications developing within and beyond 1 month after surgery, respectively.[27] Postoperative hypotony and IOP elevation were defined as an IOP of less than 6 mmHg and an IOP of more than 25 mmHg, respectively. The corneal endothelial cell density was measured using a specular microscope (FA-3809; Konan Medical, Inc, Nishinomiya, Japan) before surgery and at 6, 12, 24, and 36 months after surgery.

Surgical Procedure

A 25-gauge or 27-gauge pars plana vitrectomy was performed using a Constellation Vision System (Alcon Laboratories, Inc, Duluth, GA) under retrobulbar anesthesia. Phacoemulsification cataract extraction was performed for the subluxated crystalline lens. If the dislocated IOL was made of soft material, it was cut into 2 or 3 pieces and extruded from the 3.0-mm sclerocorneal incision. If the dislocated IOL was made of polymethyl methacrylate, it was extruded from the 6.0-mm sclerocorneal incision.

A 3-piece IOL (X-70 [Santen, Osaka, Japan]; Tecnis ZA9003 [Abbott Medical Optics, Santa Ana, CA]; PN6A [Kowa, Tokyo, Japan]; or MA60MA [Alcon Laboratories, Inc]) was inserted into the anterior chamber using an injector, and the trailing haptic was kept outside to prevent the IOL from falling into the vitreous cavity. An angled sclerotomy was made through the conjunctiva using a 30-gauge thin-wall needle (TSK ultra-thin wall needle; Tochigi Seiko, Tochigi, Japan) at 2 mm from the limbs (Fig 1A; Video 1, available at www.aaojournal.org). The leading haptic was threaded into the lumen of the needle using a forceps (Fig 1B; Video 2, available at www.aaojournal.org). A second sclerotomy then was made with a 30-gauge thin-wall needle that was 180° from the first sclerotomy. The trailing haptic was inserted into the lumen of the second needle while the first needle was put on the eye lid (Fig 1C; Video 3, available at www.aaojournal.org). Both haptics were externalized onto the conjunctiva using the double-needle technique (Fig 1D; Video 4, available at www.aaojournal.org). The ends of the haptics were cauterized using an ophthalmic cautery device (Accu-Temp Cautery; Beaver Visitec, Waltham, MA) to make a flange with a diameter of 0.3 mm (Fig 1E; Video 5, available at www.aaojournal.org). The flange of the haptics was pushed back and fixed into the scleral tunnels (Fig 1F; Video 6, available at www.aaojournal.org). A peripheral iridotomy was performed using the vitrectomy cutter after miosis to avoid iris capture of the IOL.

Intraocular Lens Tilt Measurements

The angle of tilt of the IOL was measured as previously reported using swept-source optical coherence tomography (SS-1000 CASIA; Tomey Corporation, Nagoya, Japan) 3 months after surgery.[22] A standardized radial scan using swept-source optical coherence tomography was performed after the pupil was dilated. The radial scan acquired 512 A/B-scan images, each containing 128 B/C-scans with a length of 16 mm. The horizontal and vertical optical coherence tomography images were used to analyze the IOL tilt. A straight line passing through the iris−corneal angles on either side of the image was marked as a reference line. The angle between the reference line and the horizontal axis of the IOL was taken to be the IOL tilt. The IOL tilt was measured in both the vertical and horizontal planes. The average of the IOL tilt in the vertical and horizontal planes was defined as the mean IOL tilt.

Statistical Analyses

The decimal VA was converted to the logarithm of the minimum angle of resolution (logMAR) units for the statistical analyses. The Wilcoxon signed-rank test was used to determine the significance of any association between the preoperative and postoperative uncorrected VA, best-corrected VA, and corneal endothelial cell density. The Kruskal-Wallis test was used to evaluate the difference in refraction and IOL tilt among eyes with the 4 models of IOLs. The incidence of iris capture was compared between 2 types of IOLs using the Fisher exact test. The IOL tilt and age were compared between eyes with iris capture and those without using the Mann−Whitney U test. A P value of less than 0.05 was considered to be statistically significant. The statistical analyses were performed using Ekuseru-Toukei 2012 software (Social Survey Research Information Co, Ltd, Tokyo, Japan).

Results

The 100 eyes included in this prospective nonrandomized series were from 97 patients. No patient declined to undergo the procedure during the study period. Three eyes (3 patients) that underwent surgery during the study period were excluded because of combined surgery for macular pucker (1 eye) and short follow-up duration of less than 6 months (2 eyes). The mean patient age at the time of surgery was 68.3±12.7 years (range, 40−95 years). Sixty-eight eyes (70.1%) were from men and 29 eyes (29.9%) were from women. There were 21 aphakic eyes, 63 dislocated posterior chamber IOLs, and 16 subluxated crystalline lenses. The mean follow-up duration was 20.6±10.0 months (range, 6.0−42.9 months). The numbers of patients followed up for 6, 12, 24, and 36 months were 100, 86, 46, and 14, respectively. The patient characteristics are shown in Table 1.

The IOL was fixed well without conjunctival scarring or inflammation (Fig 2). Table 2 shows corrected VA, uncorrected VA, and corneal endothelial cell density. The mean preoperative best-corrected VA was 0.25 logMAR, and it improved to 0.11 logMAR, 0.09 logMAR, 0.12 logMAR, and 0.04 logMAR at 6, 12, 24, and 36 months, respectively ($P < 0.01$, $P < 0.01$, $P = 0.03$, and $P = 0.10$, respectively). The mean corneal endothelial cell density decreased from 2341 cells/mm^2 to 2313 cells/mm^2, 2240 cells/mm^2, 2189 cells/mm^2, and 2244 cells/mm^2 at 6, 12, 24, and 36 months, respectively ($P < 0.01$, $P < 0.01$, $P < 0.01$, and $P = 0.17$, respectively). The mean IOL tilt was 3.4°±2.5° and the mean refractive difference from the predicted value by the Sanders-Retzlaff-Kraff trial formula for in-the-bag fixation was −0.21±0.99 diopter (D).

Four models of IOLs were used in this study (Table 3). The mean refractive difference from the predicted value was significantly different ($P = 0.02$) among the 4 models, but IOL tilt did not differ significantly ($P = 0.17$). The rate of iris capture was 2.0% in eyes with an IOL with an optic diameter of 7 mm