ABSTRACT

Introduction: To describe the outcomes of retropupillary iris fixation of an iris claw Artisan Myopia intraocular lens (IOL), and to review literature on retropupillary iris fixation of iris claw models for myopia for the correction of aphakia and IOL dislocation in eyes with extremely high myopia.

Methods: Single-center, retrospective case series. Three patients (three eyes) with pathological myopia underwent retropupillary iris fixation of the iris claw Artisan Myopia model 204 for the correction of aphakia and IOL dislocation. After IOL power calculation, we found that the Artisan Aphakia IOL was not available for these patients. One patient had a history of previous extracapsular cataract extraction and two patients exhibited IOL–bag complex dislocation. The target lens power was calculated using ultrasound biometry and the Sanders–Retzlaff–Kraff theoretical and T2 formulae, with an A-constant of 103.8. All surgeries were performed by a single surgeon. Visual outcomes were assessed at 12–48 months after surgery.

Results: The mean axial length was 34.33 ± 0.21 mm. The power of the implanted Artisan IOLs ranged between −4.00 and −3.00 diopter. The corrected distance visual acuity, measured in logarithm of the minimum angle of resolution units, improved after surgery in all eyes, from 0.60 ± 0.36 logMAR before surgery to 0.40 ± 0.43 logMAR after surgery at 12 months postoperatively and remained stationary thereafter. There were no postoperative complications.

Conclusions: Retropupillary iris fixation of Artisan Myopia IOLs may be a safe and effective surgical treatment option for the correction of aphakia and IOL dislocation in patients with extremely high myopia.

Keywords: Aphakia; Artisan Myopia; High Myopia; IOL Dislocation; Retropupillary; Retropupillary Iris Fixation
Key Summary Points

Why carry out this study?
To provide the outcomes of retropupillary iris fixation of an iris claw Artisan Myopia intraocular lens (IOL), and to review literature on retropupillary iris fixation of iris claw models for myopia for the correction of aphakia and IOL dislocation in eyes with extremely high myopia.

What was learned from the study?
Retropupillary iris fixation of Artisan Myopia IOLs may be a safe and effective surgical treatment option for the correction of aphakia and IOL dislocation in patients with extremely high myopia.

INTRODUCTION

The surgical treatment of aphakia and intraocular lens (IOL) dislocation has remained a challenge, particularly for eyes with high myopia [1]. Options for IOL implantation in the absence of capsular support include anterior chamber IOL (ACIOL), scleral fixation of posterior chamber IOL (PCIOL), and iris fixation of PCIOL [2]. Because ACIOL is in close proximity to the cornea, there is an increased risk of bullous keratopathy, glaucoma, and peripheral anterior synchiae [3]. Scleral fixation of PCIOL requires a longer surgical duration and results in several complications such as IOL tilting and ocular inflammation [4]. Recently, the Artisan Aphakia IOL (Ophtec BV, Groningen, the Netherlands), in which the haptics are fixated to the iris with clips on both sides of the optic, was introduced [5]. Retropupillary iris claw IOL implantation has been considered a safe and predictable technique with minimal complications [6].

Of late, the prevalence of high myopia has been increasing [7]. According to a previous study, high myopia is a major risk factor for late IOL dislocation [8]. Scleral fixation of PCIOL may be challenging in these patients, with a high probability of complications [9]. An iris claw IOL is one of the recommended options for exchange of the dislocated IOL–bag complex in patients with high myopia [10, 11]. However, this may not be feasible in several cases of high myopia, considering that the power of commercially available Artisan Aphakia IOLs ranges between $+2.00$ diopter (D) and $+30.00$ D. Recently, a case report presented the results of retropupillary fixation of an iris claw Artisan Myopia IOL in a patient with high myopia [10], which resulted in the successful correction of aphakia. However, reports of more cases are necessary to confirm the feasibility, safety, and effectiveness of this technique and consider it as a reliable treatment option.

The aim of the present study was to describe the outcomes of retropupillary fixation of the iris claw Artisan Myopia model 204 (Ophtec BV, Groningen, the Netherlands) (Fig. 1), and to review literature on retropupillary iris fixation of iris claw models for myopia, which were originally designed to correct myopia with iris fixation in the anterior chamber, for correction of aphakia and IOL dislocation in eyes with extremely high myopia. Because model 204 IOLs are available with a power range of $-1.00$ D to $-15.50$ D, emmetropia could be achieved by retropupillary iris fixation.

METHODS

This study included patients with pathological myopia who underwent retropupillary fixation of the iris claw Artisan Myopia model 204 for the correction of aphakia without sufficient capsular support at Yonsei University Gangnam Severance Hospital from April 2017 through December 2017. All patient data were retrospectively assessed. This study followed the tenets of the Declaration of Helsinki. The protocol of the study was approved by the Institutional Review Board of the Gangnam Severance Hospital (IRB approval number 3-2021-0459). We included patients with an observation period of at least 48 months, attending follow-up visits at 1 week and 1, 6, 12, 24, 36, and

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48 months after surgery. All patients underwent preoperative slit-lamp examination of the anterior segment. Fundus photography and retinal optical coherence tomography were also performed. The target lens power was calculated using ultrasound biometry and the Sanders–Retzlaff–Kraff theoretical (SRK/T) and T2 formulae. The IOL manufacturer recommended the use of these formulae with an A-constant of 103.8 for retropupillary fixation of Artisan Myopia IOLs. Optic power calculation was based on a target of emmetropia. All preoperative assessments were performed 1 day before surgery.

Under local or general anesthesia, pars plana vitrectomy or anterior vitrectomy was performed in all cases. A 6.2-mm sclerocorneal tunnel incision was placed at the 12 o’clock position, and two horizontal paracenteses were created at the 2 o’clock and 10 o’clock positions. In two cases with IOL–bag complex dislocation, the complex was removed through the sclerocorneal tunnel using forceps after performing vitrectomy to free the dislocated IOL–bag complex. After injection of the viscoelastic substance in the anterior chamber, the Artisan Myopia IOL was inserted through the sclerocorneal tunnel into the anterior chamber, with the vaulted optic leading posteriorly. The lens was rotated in the horizontal position using a micro-hook, and was placed behind the iris through the pupil. The bimanual technique was used to enclavate a bite of the iris in the clips (claw mechanism) of the lens haptic using an enclavation needle and the Artisan lens holder. After the same procedure was performed with the second haptic, the viscoelastic substance was flushed from the anterior chamber through irrigation. The wound was secured with one or two 10–0 nylon sutures. All surgeries were performed by a single surgeon (MK).

**RESULTS**

In total, three eyes of three patients (two men and one woman) with high myopia received retropupillary iris fixation of Artisan Myopia IOLs. After IOL power calculation, we found that Artisan Aphakia IOLs were not available for these patients. A brief summary of each case is presented in Table 1. The mean age of the patients was 57.3 ± 3.79 years. The mean axial length was 34.33 ± 0.26 mm. The corrected distance visual acuity (CDVA), measured in logarithm of the minimum angle of resolution (logMAR) units, improved from 0.60 ± 0.44 before surgery to 0.40 ± 0.53 after surgery. All patients were followed up for at least 12 months, and there were no perioperative complications during the follow-up periods. Representative anterior segment photographs before and after surgery are shown in Fig. 2. The mean specular endothelial cell count was
2328 ± 739 cells/mm² before surgery and 1911 ± 784 cells/mm² at 12 months postoperatively. Clinical manifestations and pre- and postoperative data are shown in Table 2. We present a summary of the relevant case reports in Table 3.

Case 1

A man in his 50s presented with sudden-onset blurred vision in the left eye and was found to have an in-bag inferiorly displaced PCIOL. CDVA was 0.3 logMAR (Snellen equivalent 20/40) and manifest refraction was +2.00 − 1.25 × 120 D. He had undergone initial cataract surgery in the left eye 17 years back. Biometry and keratometry performed at the current presentation revealed an axial length of 34.60 mm, K1 of 43.50 D, and K2 of 43.75 D, with an axis of 44°/C176. The specular endothelial cell count was 2364 cells/mm².

Fundus examination showed an encircled retina with degenerative myopia. IOL power calculation using the SRK/T formula revealed that an Artisan Aphakia IOL with a power of −7.0 D was required to achieve emmetropia; however, IOLs with this power are not commercially available. Fundus examination showed posterior staphyloma and degenerative myopia. The patient underwent IOL removal with pars plana vitrectomy, followed by retropupillary iris fixation of the Artisan Myopia model 204 with a power of −4.0 D. CDVA at 12 months after surgery was 0.0 logMAR (Snellen equivalent 20/20), with manifest refraction of +0.50 − 1.50 × 110 D. The specular endothelial cell count was 2410 cells/mm² at 12 months after surgery. The target powers calculated using the SRK/T and T2 formulae were +0.06 D and −0.29 D, respectively; both were accurate with regard to the achievement of emmetropia. His left eye vision

### Table 1 Demographic and clinical characteristics of three patients with extremely high myopia

| Patient No | Sex | Age | Clinical presentation |
|------------|-----|-----|-----------------------|
| 1          | Male | 50s | Incomplete IOL–capsular bag complex dislocation with vitreous prolapse |
| 2          | Male | 50s | Aphakia due to previous extracapsular cataract extraction. Previously underwent scleral encircling for retinal detachment and strabismus surgery for esotropia |
| 3          | Female | 60s | Incomplete IOL–capsular bag complex dislocation. Previously underwent strabismus surgery for esotropia. Known amblyopia due to esotropia and myopic macular degeneration |

IOL: intraocular lens
remained good; CDVA at 48 months after surgery was 0.1 logMAR (Snellen equivalent 20/25).

Case 2

A man in his 50s presented with a CDVA of 0.4 logMAR (Snellen equivalent 20/50) and manifest refraction of $-3.50 - 0.25 \times 112$ D and requested for the correction of pathological myopia in the right eye. He had undergone extracapsular cataract extraction and scleral encircling for retinal detachment approximately 20 years back. His ocular history included strabismus surgery for esotropia performed 7 and 22 years back. At the current presentation, aphakia and vitreous prolapse into the anterior chamber were observed. Biometry and keratometry revealed an axial length of 34.30 mm, $K_1$ of 43.25 D, and $K_2$ of 43.50 D, with an axis of 166°. The preoperative specular endothelial cell count was 3215 cells/mm². Fundus examination showed an encircled retina with degenerative myopia. IOL power calculation using the SRK/T formula revealed that an Artisan Aphakia IOL with a power of $-6.5$ D was required to achieve emmetropia; however, IOLs with this power are not commercially available. He underwent pars plana vitrectomy and retropupillary iris fixation of the Artisan Myopia model 204 with a power of $-3.5$ D. CDVA at 12 months after surgery was 0.2 logMAR (Snellen equivalent 20/32), with manifest refraction of $-0.25 - 1.00 \times 125$ D. The specular endothelial cell count was 2519 cells/mm². Target powers calculated using the SRK/T and T2 formulae were $0.08$ D and $-0.19$ D, respectively; both were accurate with regard to the achievement of emmetropia. CDVA at 48 months after surgery was 0.5 logMAR (Snellen equivalent 20/63).

Case 3

A woman in her 60s presented with sudden-onset decreased vision in the left eye and was found to have an in-bag inferiorly displaced PCIOL. She had undergone initial cataract surgery in both eyes 6 years back, followed by YAG
laser posterior capsulotomy in the left eye 2 months later. She had an ocular history of strabismus surgery for esotropia 20 years ago and amblyopia in the left eye. At the current presentation, she exhibited a CDVA of 1.1 logMAR (Snellen equivalent 20/250) and manifest refraction of $-2.00 \text{ D}$. Biometry and keratometry revealed an axial length of 34.09 mm, K1 of 41.50 D, and K2 of 45.25 D, with an axis of 144°. The preoperative specular endothelial cell count was 1406 cells/mm², and corneal guttata were found. Fundus examination and OCT for the left eye showed posterior staphyloma and degenerative myopia. Because of the risk of bullous keratopathy associated with a relatively long surgical duration, iris claw IOL implantation was recommended. IOL power calculation using the SRK/T formula revealed that an Artisan Aphakia IOL with a power of $-6.0 \text{ D}$ was required to achieve emmetropia; however, IOLs with this power are not commercially available. Therefore, the Artisan Myopia model 204 with a power of $-3.0 \text{ D}$ was chosen for retropupillary fixation. The patient was informed about limited visual acuity improvement after surgery due to previously diagnosed amblyopia, and agreed to the operation. The patient underwent IOL–bag complex removal with pars plana vitrectomy, followed by retropupillary iris fixation of the Artisan IOL. CDVA at 6 and 12 months after surgery was 1.0 logMAR (Snellen equivalent 20/200), with manifest refraction of $+3.00 - 6.00 \times 45 \text{ D}$. The specular endothelial cell counts were 921 and 805 cells/mm² at 1 and 12 months after surgery, respectively. The target powers calculated using the SRK/T and T2 formulae were $-0.16 \text{ D}$ and $-0.46 \text{ D}$, respectively. Despite low endothelial cell counts, her left eye vision remained stationary; CDVA at 48 months after surgery was 1.0 logMAR (Snellen equivalent 20/200).

DISCUSSION

In the present study, we evaluated data for three eyes of three patients with extremely high myopia who successfully underwent retropupillary iris fixation of an Artisan Myopia IOL, without any complications, for the correction of aphakia and IOL dislocation. To our knowledge, this is the first case series on the retropupillary iris fixation of an iris claw Artisan Myopia IOL (model 204) in patients with high myopia who present with IOL dislocation.

A longer eyeball in eyes with high myopia is strongly associated with dislocation of the IOL–bag complex [12]. A previous study reported the need for IOL exchange in children with pseudophakic eyes because of myopic shift resulting from axial elongation [13]. In eyes with high myopia, IOL–bag complex dislocation may occur because of progressive over-stretching of fibers and zonule degeneration [14]. However, we found little published information about IOL fixation for the treatment of

| Author, year | Case Age | Axial Length (mm) | Ophthalmic treatment | Pre-op vision (Snellen) | Post-op vision (Snellen) |
|--------------|----------|------------------|----------------------|-------------------------|-------------------------|
| Huerva, 2014 | 75-year-old, female | 31.44 | Retropupillary implantation of Artisan Myopia $-3.0 \text{ D}$ (OS), no surgical complications | 20/100 | 20/100 at 3 months |
| Faria et al., 2016 | 72-year-old, male | – | Retropupillary implantation of Artiflex Myopia model 401 $-5 \text{ D}$ (OS), no surgical complications | 20/200 | 20/100 at 12 months |
aphakia and IOL dislocation in eyes with high myopia. Of late, angle-support IOL implantation is not recommended because it may significantly reduce the number of corneal endothelial cells through corneal decompensation [3]. PCIOL with scleral fixation may produce lens tilting and decentration and is often associated with endophthalmitis and suture-related complications such as suture breakage [4]. Retropupillary fixation of an iris claw IOL has emerged as one of the treatment options for many cases of IOL–bag complex dislocation and aphakia. There are very few publications regarding retropupillary IOL implantation using iris claw models for myopia, which were originally designed to correct myopia with iris fixation in the anterior chamber, for correction of aphakia and IOL dislocation in eyes with extremely high myopia, and we present a summary of the relevant case reports in Table 3.

Even though Artisan Myopia IOLs are similar to Artisan Aphakia IOLs and are single-piece all-pmma lenses, several differentiating factors should be noted. The Artisan Myopia model 204 exhibits a slightly larger optic size (6.0-mm optic body) than the Artisan Aphakia model 205 (Ophtec BV, Groningen, the Netherlands), which exhibits a 5.4-mm optic body and is generally used to correct aphakia via retropupillary iris fixation; therefore, a larger tunnel incision is required for the former. In accordance with previous reports about Artisan Myopia IOLs for the correction of myopia, we created a 6.2-mm sclerocorneal tunnel incision. For implantation of Artisan Aphakia IOLs, a 5.5 to 6.0-mm-wide sclerocorneal incision is required according to previous studies [16]. The shape of the fixation haptic is also different between the two lens types, with the Artisan Myopia model 204 exhibiting a smaller fixation haptic. When the bimanual technique was used during surgery in our patients, a greater compressive force was required to enclavate a knuckle of the iris.

The SRK/T and T2 formulae were used for calculation of the target IOL powers in the present study, because the manufacturer reported an estimated A-constant of 103.8 for
retropupillary fixation of Artisan Myopia IOLs. Both formulae provided reliable and predictable values for all cases. According to our experience, when the same IOL is inserted, the T2 formula predicts greater myopic refraction than does the SRK/T formula; in two of our three patients, the T2 formula provided more predictable results than the SRK/T formula. However, the better of the two formulae remains debatable. The T2 formula was developed to improve the refraction prediction accuracy of the SRK/T formula [17]. A previous research revealed that the T2 formula generally performed better than the SRK/T formula [18]. However, according to another previous report by Kane, the SRK/T formula showed better prediction for myopic eyes than did the T2 formula [19]. Since recent studies have shown that newly developed IOL power formulae perform better than the classic formulae, a new formula for retropupillary fixation of Artisan Myopia IOLs should be considered for more accurate prediction [20]. Moreover, some patients with extremely high myopia may not require an IOL as leaving the eye aphakic can be an option for achieving the target diopter in this select group of patients.

In the present study, all three patients demonstrated axial lengths that were greater than 32 mm, and two patients had a past history of esotropia due to heavy eye syndrome. Heavy eye syndrome is generally caused by an increase in the axial length [21]. One patient had a previous history of retinal detachment, which is also closely associated with high myopia [22]. But heavy eye syndrome and retinal detachment have not affected the surgery. Notably, one of our patients presented with a significant decrease in the endothelial cell count. Endothelial cell loss may be related to surgical trauma rather than the presence of a retropupillary iris-fixated Artisan Myopia IOL, and it was a predictable complication of corneal guttata. Several studies have demonstrated that retropupillary fixation of Artisan Aphakia IOLs does not result in a significant decrease in the endothelial cell count [6]. Because the mechanism of lens fixation and techniques are almost identical for Artisan Myopia and Artisan Aphakia IOLs, we can expect that retropupillary Artisan Myopia IOL implantation will not result in corneal endothelial cell loss.

There are several studies regarding interexaminer reproducibility of endothelial cell density measurement. de Sanctis et al. reported that endothelial cell density measurements by two examiners could differ by −17% to +14% [23], and Benetz et al. reported differences of 0–23% [24]. The changes in endothelial cell count at 12 months postoperatively in cases 1, 2, and 3 were +1.94%, −21.65%, and −42.75%, respectively. The significant decrease in endothelial cell count in case 3 was largely due to the corneal condition; however, the changes in cases 1 and 2 were in the range of measurement reproducibility. Choi et al. recently reported there was a reduction in endothelial cell count over a 24-month follow-up period after retropupillary iris claw IOL implantation for the treatment of IOL dislocation [25]. They suggested that the reduction might be due to stress caused by IOL removal through the scleral tunnel [25]. The decrease in endothelial cell count in case 2 at 12 months postoperatively may have been due to surgical stress, as discussed by Choi et al.

This study has several limitations. First, the retrospective nature of the study does not allow definitive superiority of the treatment, which can be obtained in a prospective and comparative study only. Second, the number of study patients was small. Although the preoperative visual acuity of all patients was retained, there was no statistical significance, and a larger sample is necessary to reach significance. Third, all surgeries were performed in a single center. A prospective multicenter study with multiple surgeons is required to confirm the effectiveness of this technique.

CONCLUSIONS

Our findings suggest that retropupillary iris fixation of Artisan Myopia IOLs can be used as a safe and effective management option for eyes with extremely high myopia. Further studies are warranted to confirm our findings.
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Compliance with Ethics Guidelines. This study followed the tenets of the Declaration of Helsinki. The protocol of the study was approved by the Institutional Review Board of the Gangnam Severance Hospital (IRB approval number 3-2021-0459).

Disclosures. Tae Keun Yoo, Seung Min Lee, Hansang Lee, Eun Young Choi and Min Kim confirm that they have no conflicts of interest to declare.

Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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