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Secondary intraocular lens (IOL) implantation: Anterior chamber versus scleral fixation long-term comparative evaluation

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PURPOSE. *To compare the long-term efficacy of a secondarily implanted flexible angle supported anterior chamber (AC) intraocular lens (IOL) with sclerally fixated IOL as a secondary procedure in patients with aphakia.*

METHODS. *Sixty patients with aphakia were recruited for this study. The patients were randomly divided into two groups: Group I patients underwent secondary implantation with AC IOL (Kelman Z type multiflex Domi classic AC IOL) and Group II patients underwent secondary implantation with scleral fixated IOL (Hanita lens with two eyelets). Postoperatively, the patients were followed up at 1 week, monthly for 6 months, and at twice yearly intervals for 5 years (mean follow-up was 3 years).*

RESULTS. *Best-corrected visual acuity of 6/18 or better was achieved in 36.6% (11/30) of patients in Group I and 30% (9/30) of patients in Group II after a mean follow-up of 3 years. The complication rate was higher in Group II as compared to Group I. The authors encountered a total of 23 complications in the sclerally fixated group and 11 in the AC IOL group (p=0.004). Uveitis and ciliary tenderness were the most common complications in Groups I and II, respectively.*

CONCLUSIONS. *For secondary implantation of IOL in aphakic patients, Kelman Z type multiflex Domi classic AC IOL is a better rehabilitation modality as compared to the scleral fixated Hanita IOL. (Eur J Ophthalmol 2003; 13: 627-33)*

KEY WORDS. *Aphakics, Anterior chamber intraocular lens, Scleral fixated intraocular lens*

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INTRODUCTION

Secondary implantation of an intraocular lens (IOL) has a large role to play in the rehabilitation of patients with aphakia. However, many surgeons are reluctant to perform a second intraocular surgery because of the inherent danger involved in any surgical intervention on the globe, particularly when the previous surgery has been complicated by events such as posterior capsule rupture, vitreous loss, and damage to the cornea, and postoperative events such as bullous keratopathy and cystoid macular edema. In these patients, a second intervention might result in a decrease in best-corrected visual acuity (BCVA) of the aphakic eye. However, some patients cannot tolerate visual aids such as aphakic spectacles or contact lenses, and functional VA in that eye remains minimum although potentially good vision is possible.

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Anterior chamber (AC) IOL were considered to be viable options in cases that were unsuitable for posterior chamber IOL implantation (1). However, various complications such as uveitis, glaucoma, hyphema, endothelial decompensation, and macular edema have been described after the use of closed loop AC IOL (2, 3). The superiority of scleral fixation IOL has been reported by many authors (4, 5). On the other hand, various complications after scleral fixation have also been described (6). Furthermore, with the use of open loop IOL, lesser complications and better results have been obtained (7-12).

Although a number of workers have studied the individual results of primary or secondary implantation with these two lens types in eyes with a ruptured posterior capsule, no study has directly compared the results with secondary implantation of these two types of lenses in patients with long-term follow-up (1, 9, 13). We undertook this study to compare the long-term efficacy of secondary implantation of Kelman Z type multiplex Domi classic AC IOL with the scleraly fixated Hanita IOL in eyes with failed primary implantation of posterior chamber IOL, to restore eyesight qualitatively and to find a safe and effective procedure for secondary IOL implantation in aphakic patients.

MATERIALS AND METHODS

Sixty patients (35 male, 25 female) (age range, 10 to 62 years) were selected for this study. The criteria for selection of patients were unilateral aphakia with failure to wear, adjust to, or afford contact lenses (n=26); unilateral aphakia with pseudophakia in the other eye (n=21); aphakia with traumatic corneal scarring (n=9); and desire of the patient because of his or her professional requirements (n=4).

The exclusion criteria were any relevant health problem, other additional ocular surgery, poor corneal endothelial status (endothelial cell count <1500 /mm^2), glaucoma and iridocyclitis, diseased posterior segment, amblyopia, one-eyed patients, and pregnant women.

A thorough history followed by a complete ophthalmic checkup, including BCVA, gonioscopy, intraocular pressure, state of cornea, pupil, anterior and posterior synechia, vitreous phase, and posterior segment, was done. Keratometry and IOL power calculation were also done. The interval between the primary surgery and secondary IOL implantation for all eyes ranged from 1 to 8 years.

The patients were randomly divided into two groups. Group I patients underwent secondary IOL implantation with Kelman Z type multiflex Domi classic AC IOL and Group II patients underwent scleral fixation of IOL (Hanita lens with two eyelets).

Preoperatively, the patients were prepared with systemic antibiotics, oral acetazolamide, and intravenous 350 cc mannitol and an adequate ocular massage following peribulbar block with 5 cc of 2% lidocaine and 5 cc of 2% bupivacaine. Secondary AC IOL implantation was performed as follows. After conjunctival peritomy, a 5.5- to 6-mm groove was made 1 to 2 mm posterior to the limbus. The incision was carried forward to the peripheral cornea and the AC was entered with a 2.8 mm incision. Synechiolysis was done in eyes with adherent leucoma and pupilloplasty was done in patients with iris abnormalities like sector iridectomy. The administration of acetazolamide along with mannitol caused shrinkage of the vitreous phase in a majority of eyes. However, in appropriate eyes, anterior vitrectomy followed by insertion of air bubble was done, to settle the vitreous phase. Under the air bubble, the Kelman Z type multiflex Domi classic AC IOL was introduced with its inferior haptic first, followed by the placement of the superior haptic into the AC angle. A peripheral iridectomy was performed if it had not been done previously. The corneo-scleral incision was closed with continuous shoelace 10-0 silk sutures. The total surgical time was about 10 to 15 minutes.

Scleral fixation of IOL was done with Hanita lens with two eyelets. After conjunctival peritomy, triangular scleral flaps were created at 10 o'clock and 4 o'clock positions. The triangular flaps were dissected toward the limbus at one half thickness up to surgical limbus. A 7 mm corneo-scleral groove was made avoiding damage to the surgical limbus. A 3 mm entry wound was made into this groove. Anterior vitrectomy was done, if required. An air bubble was introduced into the AC to push back the vitreous phase. The limbal incision was enlarged to 7 mm. An 8-0 double-armed Prolene suture with 8 mm needles at both ends (Ethicon NW8703) was divided into two equal parts. The cut ends of these two sutures were inserted into two 27-G disposable needles through the bevel

ends and brought out through the base. The disposable needles were curved with a needle holder. One Prolene suture threaded through 27-G needle was introduced through the scleral bed, underneath the scleral flap at 4 o'clock, about 1 mm posterior to the surgical limbus. The needle was directed perpendicular to the sclera for the first 2 mm and was then directed parallel to the back of iris until it reached the pupillary center. A curved fine forceps was introduced through the limbal incision. The suture loop at the tip of needle was grasped with the forceps and brought out through the limbal incision and kept at one end of the wound. The 27-G needle was withdrawn from the eye and sutured through the cut end. The procedure was repeated at the 10 o'clock position. The loop of Prolene suture was passed through the eyelets of the haptic and secured over the haptic. Optic of the IOL was inserted through the wound and the IOL was pushed behind the iris. Once the IOL was behind the iris, the Prolene suture was pulled externally. The curved needles attached at the other end of Prolene suture were passed through the scleral bed beneath the respective scleral flaps, close to the limbus, and tied and secured over the implant. The sutures were cut long to prevent the suture end eroding through the scleral flap cover. The limbal incision was closed with interrupted 10-0 nylon sutures and the scleral flaps were closed with interrupted 10-0 nylon suture. The total surgical time was about 45 to 70 minutes.

Following the secondary AC IOL or scleral fixated IOL implantation, a subconjunctival injection of 0.5 cc gentamicin and 0.5 cc dexamethasone was given. Postoperatively, all the patients were placed on systemic antibiotics, analgesics, and oral acetazolamide for 3 to 5 days and frequent topical steroid-antibiotic drops for 4 to 6 weeks.

The patients were followed up at 1 week, monthly for 6 months, and twice yearly for 5 years. During the follow-up, eyes were examined for BCVA; intraocular pressure; state of cornea, pupil, AC, and posterior segment; and postoperative complications. Chi-square test was used for statistical analysis.

TABLE I - PREOPERATIVE STATUS OF THE POSTERIOR CAPSULE, VITREOUS PHASE, AND PUPIL

Characteristic	Group I	Group II
Ruptured or absent posterior capsule	30/30 (100)	30/30 (100)
Vitreous in anterior chamber	9/30 (30)	14/30 (36.6)
Vitreous bulge in anterior chamber	8/30 (26.6)	7/30 (23.3)
Adherent leucoma	5/30 (16.6)	4/30 (13.3)
Sector iridectomy	4/30 (13.3)	4/30 (13.3)

Values are n (%)

TABLE II - INTRAOPERATIVE COMPLICATIONS AND PROCEDURE PERFORMED

Complications	Group I	Group II
High intraocular pressure	5/30 (17.3)	7/30 (23.3)
Iris trauma	3/30 (10)	4/30 (13.3)
Hyphema	1/30 (3.3)	1/30 (3.3)
Excessive manipulation	–	4/30 (13.3)
Pupil deformation	2/30 (6.6)	3/30 (10)
Anterior vitrectomy	9/30 (30)	20/30 (66.6)
Pupilloplasty	4/30 (13.3)	4/30 (13.3)
Synechiolysis	5/30 (16.6)	4/30 (13.3)
Peripheral iridectomy	6/30 (20)	3/30 (13.3)

Values are n (%)

RESULTS

Sixty patients (35 male, 25 female) (age range, 10 to 62 years; mean 36 years) who had a failed primary implantation of a posterior chamber IOL were included in this study. The average time interval between the primary surgery and secondary implantation of IOL was about 4 years. Preoperatively, the groups had similar abnormalities, which could complicate secondary implantation of an AC or a sclerally fixated IOL (Tab. I).

The total surgical time for Group I was about 10 to 15 minutes and for Group II was about 45 to 70 minutes. The most common intraoperative complication associated with scleral fixation of IOL was excessive manipulation required to fixate the IOL (i.e., more than one puncture for the needle to emerge in the desired position). Other peroperative complications are listed in Table II. Intraocular procedures associated with secondary IOL implantation included anterior vitrectomy, pupilloplasty, synechiolysis, and peripheral iri-

dectomy (Tab. II). Postoperatively, the patients were followed up at 1 week, monthly for 6 months, and twice yearly for 5 years. However, for the purpose of the study, the results were analyzed at the end of 3 years or the patient's most recent visit. The eyes were examined for BCVA, intraocular pressure, AC reaction, ciliary tenderness, and condition of pupil, cornea, and posterior segment. At 3 years of follow-up, in Group I, 36.66% (11/30) of patients had a BCVA of 6/18 or better. In Group II, 30% (9/30) of patients had a BCVA of 6/18 or better; VA at 3 months was better as compared to 3 years (Tab. III). Postoperative complications are listed in Table IV. The total number of complications was significantly higher in Group II as compared to Group I (23 *vs* 11) (p=0.004).

TABLE III - VISUAL ACUITY AT 3 MONTHS AND 3 YEARS AFTER SURGERY

Best-corrected visual acuity				
	Group I		Group II	
	3 months	3 years	3 months	3 years
6/60–6/24	15	19	16	21
6/18–6/12	10	7	9	6
6/9–6/6	5	4	5	3

Values are number of patients

TABLE IV - POSTOPERATIVE COMPLICATIONS

Complications	Group I, n =30	Group II, n =30
Cystoid macular edema	2 (6.6)	4 (13.2)
Pseudophakic bullous keratopathy	2 (6.6)	2 (6.6)
Intraocular lens decentration	—	1 (3.3)
Pupillary capture	1 (3.3)	—
Uveitis	6 (20)	—
Secondary glaucoma	—	4 (13.2)
Ciliary tenderness	—	9 (30)
Retinal detachment	—	1 (3.3)
Suture extrusion	—	1 (3.3)
Vitreous hemorrhage	—	1 (3.3)

Values are n (%)

DISCUSSION

In the past, scleral fixation of IOL was preferred over AC IOL because this technique better preserves the anatomy of the eye, does not damage the corneal endothelium, and minimizes the aniseikonia in the contralateral eye that is phakic or pseudophakic with posterior chamber IOL (1, 2, 6, 8, 14). However, the change of design of the closed loop AC IOL to a flexible open loop AC IOL has changed this opinion (7, 9, 11, 12, 15). There are claims and counterclaims about the superiority of one type of implantation over the other. Few studies have been conducted to compare the efficacy of secondary implantation of AC IOL with sclerally fixated IOL (1, 3, 8). Authors who studied the results of secondary implantation with these two types of IOL either enrolled only a small number of patients or lacked a sufficiently prolonged follow-up (1, 2, 4, 6, 8, 16, 17). To our knowledge, no study has compared the results of secondary implantation with the flexible open loop AC IOL with the sclerally fixated IOL with a long follow-up. Hence, this study was undertaken to compare the long-term results achieved with the secondary implantation of Kelman Z type multiflex Domi classic AC IOL and sclerally fixated IOL in aphakic eyes with specific indications as mentioned in Materials and Methods.

Different authors found different results in BCVA with secondary implantation of AC IOL or sclerally fixated IOL. After secondary implantation with AC IOL, Hann et al reported vision of 6/12 or better in 70% of patients (3). Many other authors were successful in achieving the preoperative visual status in as many as 60 to 93.8% of eyes of their patients, even after the second surgery of AC IOL implantation (4, 16, 18, 19). With secondary implantation of flexible open loop AC IOL, Rattigan et al obtained BCVA of 6/9 in 73% of patients, Bayramlar et al reported BCVA of 6/12 or better in 76% of eyes, and Lyle and Jin noted BCVA of 6/12 or better in 83% of eyes (1, 9, 13). In our study, 36.66% (11/30) of patients achieved BCVA of 6/18 or better in Group I after a mean follow-up of 3 years. There was no significant difference in the number of patients who achieved 6/18 or better VA at 3 months and 3 years in the groups. In secondary implantation with scleral fixated IOL, some workers achieved VA of 6/12 or better in 57 to 83% of eyes; others achieved even better results (1, 3, 6, 14, 16). In our study, on-

TABLE V - COMPARATIVE STUDIES ON SECONDARY LENS IMPLANTATION

Authors	Intraocular lens (n)	VA 6/12 or better, %	Cystoid macular edema, %	Retinal detachment, %	PBK, %	Glaucoma, %	IOL decentration, %
Wong et al, 1987 (25)	AC (35)	94	5.7	5.7	2.9	2.9	–
	PC (40)	98	0	2.5	2.5	–	–
Lyle et al, 1993 (1)	AC (234)	83.36	5.5	0.9	3.0	1.7	–
	PC (114)	81.6	6.1	3.5	0.9	0.9	–
Bellucci et al, 1996 (8)	AC (35)	—	3	3	3	3	–
	PC (33)		9	6	–	6	27
Current study	AC (30)	36.66	6.6	–	6.6	–	–
	PC (30)	30.00	13.2	3.3	6.6	13.2	3.3

VA = Visual acuity; PBK = Pseudophakic bullous keratopathy; IOL = Intraocular lens; AC = Anterior chamber; PC = Posterior chamber

ly 30% (9/30) of patients gained a VA of 6/18 or better in Group II. Lyle et al obtained 6/12 or better VA in 81% and 83% of patients and Wrong et al obtained 6/12 or better VA in 98% and 94% of patients with AC and posterior chamber IOL, respectively (Tab. V). We could not get better results than those stated above, probably because we selected patients with poor visual prognosis and continued to follow them up for a long time.

We encountered intraoperative complications such as excessive manipulation required to fixate the IOL (with scleral fixated IOL), high intraocular pressure, iris trauma, and hyphema. Other authors also encountered similar peroperative complications (8). As in our study, some other authors also encountered more intraoperative complications with the scleral fixated group, whereas others reported otherwise (8, 20). Only 65% of our patients needed anterior vitrectomy, whereas the meticulous execution of this procedure was considered as an essential prerequisite for good visual results in a greater number of patients in other studies (1, 9, 13, 17). This was perhaps because of the good preoperative preparation of our patients with oral acetazolamide and intravenous mannitol. Hence, we inserted the sclerally fixated lenses under an air bubble, whereas other authors had to do so after placing a viscoelastic agent in the AC (1). Similar to other workers, we performed intraocular procedures such as anterior vitrectomy, pupilloplasty, synechiolysis, and peripheral iridectomy (Tab. II). These procedures might cause poor vision.

We came across postoperative complications such as pupillary capture and uveitis in Group I patients. The Group II patients had complications such as secondary glaucoma, ciliary tenderness, vitreous hemorrhage, and retinal detachment. Complications common to both groups were cystoid macular edema and pseudophakic bullous keratopathy. The results were similar to those reported by some other authors (1, 7-9, 13, 21-23) with respect to the type and incidence of complications, but different from others (1, 17, 21, 24, 25). The most frequently reported complication of the scleral fixated group included IOL tilt or decentration and erosion of the overlying scleral flap by Prolene sutures, but we did not encounter similar complications (8, 17). This might be because of proper formation and deposition of the scleral flap. Ciliary tenderness was the most common complication observed by us. Cystoid macular edema has been found to be the most common complication following any type of secondary IOL implantation (1, 18, 19, 25). We also encountered this complication but it was not as common. Retinal detachment has been described after secondary IOL implantation surgery (16, 19, 25).

Few authors have compared the secondary implantation of AC IOL with scleral-fixated posterior chamber IOL (1, 7, 8). Lyle and Jin and Belluci et al found better results with open loop AC IOL and thus have recommended these types of IOL for elderly patients and for those who cannot cooperate during surgery because of health problems (1, 8). Equivalent long-term results with implantation of Kelman style flexible open-

loop AC IOL and sclerally fixated lenses, respectively, were found by Koenig et al (7) and Lyle and Jin (1) in their patients with penetrating keratoplasty and aphakia. Based on the visual results, Rhatigan et al also state that for secondary implantation, the flexible open loop AC IOL should be used as a first-choice technique (9). Davis et al (26) found a higher incidence of peripheral anterior synechiae and Hassan et al (27) found a higher incidence of elevated intraocular pressure in eyes with sclerally fixated lenses. Bayramlar et al also believed that scleral fixation of IOL requires elaborate skills and excessive intraocular manipulations whereas the flexible open-loop AC IOL are easier and faster to implant and vitreous manipulation is usually not required (13). Various authors state that scleral fixation of lenses should be restricted to those patients who have a damaged iris or extensive angle abnormalities (7, 17). In our series, we encountered 23 complications in the scleral fixation group as compared to 11 in the AC IOL group. When compared statistically, this difference was found to be significant (p=0.004). Moreover, earlier it was suspected that secondary glaucoma occurs more frequently after implantation of AC IOL, but we did not encounter it and even Bergman and Laatikainen in their series of 48 eyes concluded that semi-flexible open loop AC IOL had no effect on intraocular pressure and seemed to be a safe alternative in glaucomatous eyes (28). The various studies on secondary IOL implantation are presented in Table V. The major differences between our study and that of Belluci et al are that their study was not randomized, their follow-up was only 1 year, and we included only severe cases. The study by Lyle et al was a retrospective study.

With our long-term follow-up, we conclude that for secondary implantation of IOL in aphakic patients, Kelman Z type multiflex Domi classic AC IOL is a better rehabilitation modality as compared to scleral fixated IOL owing to the simplicity of the procedure, reduced time consumption, comparative visual results, and lesser rate of complications, especially sight-threatening ones (pseudophakic bullous keratopathy, cystoid macular edema, retinal detachment, and vitreous hemorrhage). We recommend further studies on a greater number of eyes in order to compare the efficacy of secondary implantation with Kelman Z type multiflex Domi classic AC IOL and sclerally fixated IOL in aphakic eyes.

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