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Penetrating Keratoplasty and Verisyse Iris-Claw Lens – is it Safe for Corneal Graft?

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A B S T R A C T

The loss of the corneal endothelial cells, especially in a first postoperative year, has been observed in patients who underwent penetrating keratoplasty (PK). The implantation of new generation of »iris claw« phakic IOL (Verisyse) in refractive cases has been shown to cause clinicaly insignificant endothelial cell loss. In our prospective case series we investigated the endothelial cell loss and clinical outcome in patients that either underwent PK and implantation of PCIOL or PK and implantation of Verisyse IOL. In the first group of 9 patients scheduled for PK, implantation of Verisyse was performed due to the absence of the posterior capsule support. 2 of these patients had angle supported ACIOL, 4 patients were aphakic and 3 had posttraumatic cataract with ruptured posterior capsule. The second group of 12 patients had standard »triple« procedure (PK + ECCE + PCIOL). BCVA of both groups of patients prior the operation was hand movement in 12 patients, light perception in 7 patients and 0,05 in 3 patients. The preoperative endothelial cell count of the donor grafts obtained from the eye bank was 2800 cells/mm^2 on average. The follow up was 6–10 months. Six months after the operation all »Verysise« patients maintained transparent graft. Postoperative visual acuity improvement was recorded in 18 out of 21 eyes (85,7 %). Best spectacle corrected visual acuity of ≥0,3 was achived in 55,5% in the Verisyse group and in 50,0% of »triple procedure« group. The endothelial cell count and morphology were estimated on the specular microscope on a monthly basis. Mean endothelial cells loss in patients with PK and Verysise was 40± 8% and in patients with »triple« procedure was 42±12% at 10 postoperative months. There was no significant difference in the endothelial cell loss and clinical outcome between the group of patients who had PK and Verysise as compared to those with implanted PCIOL.

***Key words**: penetrating keratoplasty, Verisyse IOL, »triple procedure«, endothelial cell loss*

Introduction

Combined penetrating keratoplasty and extracapsular cataract surgery with intraocular lens implantation (»triple« procedure) has been performed with increasing success for patients with corneal disease and cataract. It has several advantages, such as single procedure, rapid visual rehabilitation and no additional endothelial trauma. However, open sky procedure may be accompanied by uncontrollable vitreous pressure followed by posterior capsule rupture and difficulty of IOL implantation, while the worst complication may be expulsive hemorrhage[1].

Posterior chamber intraocular lens (PCIOL) offers several advantages and many authors recommend it even in eyes lacking capsular or zonular support. Scleral fixation of PCIOL is a method to overcome lack of capsular support but is technically more difficult, has high complication risk and is time-consuming compared to ACIOL implantation. A recent study with long-term follow up has shown that scleral-fixated PCIOLs may be associated with high rates of postoperative complications and reoperation[1]. If some remnants of capsular bag persist in some cases IOL can be implanted in the posterior chamber on these remnants, but if significant capsular support is lost or extensive vitreous surgery is required, it is advisable to fixate an IOL to the iris or to the sclera. Iris fixation is preferable due to its rapidity, ease, reversibility and safety. Scleral fixation is used if there is inadequate iris to provide support and an ACIOL is contraindicated.

The implantation of new generation of »iris claw« Verisyse lenses has been shown to cause insignificant endothelial cell loss in a refractive surgery cases. The de-

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vice is a single-piece, elliptical, polymethylmethacrylate (PMMA) lens with a slight anterior vault. It is designed for implantation into the anterior chamber of the phakic and aphakic eye. Proper fixation requires about 1 mm of iris tissue. An advantage of the lens is its ease of attachment and detachment. It can be repositioned during surgery or easily removed, if necessary. It is available in two sizes, 6 mm and 5 mm, each with a different diopter range. Because the lens attaches to a relatively immobile part of the iris, the pupil can be dilated[2–4]. Verisyse Aphakia IOL are lenses for primary or secondary implantation after ICCE, ECCE and Phacoemulsification. Complications such as iris chafing, pigment dispersion, pupillary block and dislocation are rare with this technique.

The aim of this prospective study was to evaluate postoperative results and the endothelial cell loss in the patients that underwent penetrating keratoplasty (PK) and implantation of »iris claw« Verisyse IOL as compared to PK and implantation of PCIOL (standard »triple« procedure).

Materials and methods

We prospectively studied 21 patients undergoing penetrating keratoplasty combined with either: a) Verisyse IOL implantation (n=9) or b) posterior chamber IOL implantation (n=12) between February 2009 and June 2009. In the first group of 9 patients scheduled for PK, implantation of Verisyse Aphakia IOL (AMO, USA) was performed due to the absence of posterior capsule support. Two of these patients had angle supported ACIOL, 4 patients were aphakic and 3 had posttraumatic cataract without sufficient capsular support for PCIOL. The second group of 12 patients had standard »triple procedure« (PK+ ECCE+ PCIOL).

BCVA of patients prior to the operation was hand movement in 12 patients, light perception in 7 patients and 0.05 in 3 patients. The follow-up was 6–10 months. All surgeries were done by the same surgeon (I.D.). There were 7 women and 14 man. The mean age at the time of penetrating keratoplasty was similar between groups: 51 years in Verisyse group and 54 in »triple group« (ranged from 10 to 80 years). Corneal patologies included bullous keratopathy, preperforated corneal ulcer, corneal scar after perforative injury, corneal leucoma, sy Steven-Johnson, rejected graft, keratoconus and keratoglobus. Indications for penetrating keratoplasty in our group of patients are shown in Table 1.

Preoperative evaluation

Preoperatively all patients underwent a complete ocular examination which included visual acuity assessment, intraocular pressure measurement, slit lamp (CSO Digital vision, Italy) and dilated fundus examination (if possible), A and B-scan ultrasonic examination (Ultrascan Imaging System, Alcon, USA), anterior segment imaging (Visante™ OCT, Carl Zeiss, Germany and Wavelight Allegro Oculyzer, Germany). Intraocular lens (IOL) power was calculated echographically, using the Sanders-Retzlaff-Kraff II (SRK-II) formula. If the fellow eye was healthy and anamnestic data suggested similar prepatology situation in both eyes IOL Master calculation (IOL MASTER, Carl Zeiss Meditec AG, Germany) was made for a fellow eye to double check IOL power that was calculated echographically[5].

Surgical technique

All penetrating keratoplasties were done by the same experienced surgeon, under general anesthesia or with parabulbar block with sedation. Standard PK surgical technique was used throughout. The donor corneal button was trephined from the endothelial surface of the corneoscleral button (Barron Vacuum Trephine, Katena Product USA). The donor button was 0.5 mm larger in diameter than the planned diameter of the host, to facilitate watertight closure, minimize postoperative flattening (to obtain deeper anterior chamber) and reduce possibility of postoperative glaucoma. The average donor trephanation size range from 7.50–9.00 mm. The Ophtec corneal trephane system was used for trephination of the recipient cornea. The average recipient trephination size range from 7.00–8.50 mm. In a »triple« cases the lens nucleus was extracted and the cortical remants carefully aspirated (Infiniti, Alcon, USA), leaving behind an intact posterior capsule. The PCIOL was than inserted. Visco-

TABLE 1
INDICATIONS FOR PENETRATING KERATOPLASTY COMBINED WITH VERISYSE IOL IMPLANTATION OR WITH POSTERIOR CHAMBER IOL IMPLANTATION (»TRIPLE«)

Corneal pathologies	Number of eyes	Percentage (%)	No of eyes per surgical procedure	
			»Verisyse«	»Triple«
Bullous keratopathy	6	28,5	4	2
Preperforated corneal ulcer	4	19	1	3
Corneal scar after perforative injury	3	14,3	2	1
Corneal leucoma	2	9.5	1	1
Sy Steven-Johnson	2	9,5	0	2
Rejected graft	2	9,5	1	1
Keratoconus	1	4,7	0	1
Keratoglobus	1	4,7	0	1

TABLE 2
DONOR TISSUE CHARACTERISTICS

Donor tissue	Verisyse Aphakia IOL (n=9)	PCIOL group (n=12)
Average donor age (years)	50±12	53±27
Mean preoperative endothelial cell density (cells/mm^2)	2709±180	2905±210
Mean preservation time (days)	10±2	12±3

elastic was used to separate the anterior and posterior lens capsules to facilitate »in the bag loop« placement. In a Verisyse group, ACIOL or cataract remnants were extracted, vitrectomy was performed until we had a »clear« pupil zone, myostatic was applied and then Verisyse IOL was attached to the iris. Peripheral iridectomy was performed at the 12 o'clock meridian to prevent postoperative IOP elevation.

Donor age ranged from 26 to 70 years with mean of 47 years. The preoperative endothelial cell count of the donor graft which was obtained from the certified eye bank was at least 2300 cells/mm^2. Average Donor tissue characteristics are shown in Table 2.

Postoperative care

Postoperatively, all patients recieved topical steroids, antibiotics and artificial tears. If needed steroid and cycloplegic combination was administered subconjuctivally. In a first postoperative week examinations were made each day for first 7 days, then weekly for first month and monthly thereafter. Postoperative examinations consisted of visual acuity assesment, slit-lamp examination, intraocular pressure measurement, endothelial cell count (Specular mycroscope CSO, Italy), anterior segment imaging, fundus and ultrasonic examinations.

Statistical methods

Since we compared three different parameters before and after surgery, we used student t-test with significance value of 0.05.

Results

Patients in Verisyse group (Figure 1.) and 11 out of 12 in »triple« group maintained transparent graft. Postoperative BCVA in the group of patients with Verisyse IOL (n=9) and »triple cases« (n=12) is presented in Table 3. Postoperative visual acuity improvement was recorded in 18 out of 21 eyes (85,7%). Low BCVA <0.1 in both groups was associated with accompanied eye diseases or earlier eye surgeries causing retinal pathology (macular oedema n=2) and postoperative IOP elevation (n=2). Best spectacle corrected visual acuity of ≥0,3 was achived in 55,5 % in the Verisyse group and in 50,0 % of »triple procedure« group.

Elevated intraocular pressure (IOP) occured in 2 out of 9 patients (22,2%) with Verisyse IOL, and in 1 of 12 (8%) patients with PCIOL. Those 3 patients had IOP>25 mm Hg occuring on a first postoperative day. In one patient from Verisyse group high IOP persisted beyond 20 days after surgery and was regulated by trabectulectomy. After trabeculectomy IOP remained =14 mm Hg for next 6 months. Second Verisyse patient and one »triple« case with IOP >25 responeded well to topical anti glaucoma drops and remained on topical treatment for following 4 months with IOP <16 mm Hg. Mean postoperative IOP at the 6 months follow up for Verisyse group was 15,2±6 mm Hg and for »triple group« was 14,6±5 mm Hg

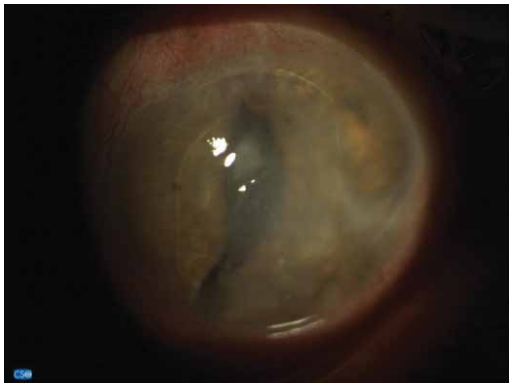

Fig. 1. Patient who had bullous keratopathy A. Preoperatively B. After PK, explantation of ACIOL and implantation of Verisyse IOL (jpg files).

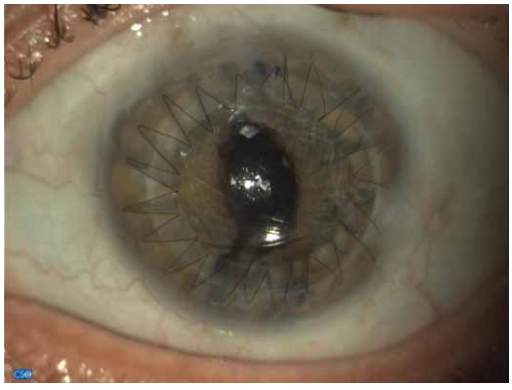

Fig. 2. Visante OCT measurment of anterior chamber depth after PK and Verisyse IOL implantation (jpg files).

Of other postoperative complications epithelial defect (ED) developed 14 days after surgery in 2 cases. Patients were conservatively treated with subconjunctival steroids, artificial tears and therapeutic soft contact lens. Healing of the defect was obtained in both cases in 10 and 12 days.

Irregular pupil was seen in 2/9 (22,2%) of cases with implanted Verisyse IOL without any subjective com-

TABLE 3
COMPARISON OF 10 MONTH BCVA IN THE GROUP OF PATIENTS WITH CORNEAL GRAFT AND VERISYSE OR PCIOL (»TRIPLE«)

BCVA	Verisyse (n=9)	Percentage (%)	»Triple« (n=12)	Percentage (%)
<0,1	2	22.5	2	17
0.1–0.3	2	22.5	4	33
>0.3	5	55	6	50

TABLE 4
ENDOTHELIAL CELL LOSS IN PATIENTS THAT UNDERWENT PK COMBINED WITH VERISYSE OR PCIOL (»TRIPLE«)

Group	Mean preoperative endothelial cell density (cells/mm^2)	Mean postoperative cell loss (%)		
		1 month	5 month	10 month
Verisyse IOL (n=9)	2709±180	20.8±10	40.5±14	42±12
Triple procedure (n=12)	2905±210	15±11	38.3±12	40±8

plains from patients. Examination by slit-lam mycroscopy did not show any damage to the iris tissue.

Endothelial cell density (ECD) was continously checked up in both groups during the postoperative period (Table 4). Our results show that the largest percentage of cell loss is seen in first 5 months and remaines almost stable up to 10 months postoperatively. We haven't seen any significant difference in EC loss between Verisyse and »tripple« group after 10 months of follow up.

Each patient from Verisyse group underwent anterior segment OCT imaging to establish the distance between Verisyse lens and corneal graft. This distance was higher than 1 mm (peripherally) and higher than 1.5 mm (centrally) in all cases (Figure 2).

Discussion

In all PK procedures and especially in combined procedures all attempts should be made to minimize endothelial cell loss in the intraoperative and postoperative period. Intraocular lens implantation is arguably the most challenging step in this surgery[6].

Aphakia is defined by the absence of the natural crystalline lens in the eye. It is encountered in patients who undergone complicated surgery or trauma[7,8]. With the advent of modern cataract surgery and better training of cataract surgeons, aphakia has become less common over the years. Verisyse Aphakia IOL are lenses for primary or secondary implantation in aphakia. These intraocular lenses are substantially different from all pupil-supported lenses of the past. Verisyse IOL are peripheral »iris bridge« supported lenses, and not »iris/pupil supported« lenses as e.g. the Binkhorst lens or the Medallion lens of the past which were supported by loops placed in contact with the pupil border. IOL haptics (fixation arms) of this lens are attached to the midperipheral virtually immobile iris stroma, thus allowing the pupil unrestricted ability to dilate and constrict. The two diametrically opposed haptics ensure stable fixation to the iris, preventing pseudo-phakodonesis and the risk of post-operative decentration. The vaulting of Verisyse IOL provides optimum clearance between this ACIOL and the cornea as a free flow of aqueous is ensured by the vaulted lens design. It is important though to perform an iridectomy during the surgery to prevent elevation of IOP after surgery[7,9].

In eyes with insufficient or no capsular support, IOL implantation can be made in several manners. Anterior chamber or iris-fixated IOLs can be implanted, or, alternatively, a posterior chamber IOL can be fixated in the ciliary sulcus using transscleral suturing. The safety and long-term efficacy of a transsclerally sutured PCIOL are less than satisfactory. The transsclerally sutured IOL is associated with a steep learning curve and requires special steps that anterior surgeon may not use routinely. Transscleral suturing of an IOL has problems related to accurate suturing at the ciliary sulcus and can be complicated by intravitreal hemorrhage, retinal detachment, lens subluxation, and suture erosion[10–12]. In PK surgery, the conventional wisdom is to reduce the »open-sky« duration to as short as possible as there is an associated risk for expulsive hemmorage or choroidal effusion. IOL fixation to the iris reduce the chance of these dangerous events. Iris suturing may be technically difficult in aphakia cases and may cause iris haemorrhage. As the open-sky procedure in aphakia is often associated with anterior vitrectomy, the resultant hypotony makes suture placement and adjustment difficult. New generation of aphakia lenses such as Verisyse are simple to use in »open-sky« cases and shorten the surgery time significantly as comparing to scelar fixation or suturing of IOL. One of the complications that has been associated with iris-fixated IOLs is postoperative cell loss via potential mechanical contact between the IOL and corneal endothelium. In preliminary Scheimpflug biometry study, the distance between the Artiflex lens and the endothelium was determined to be well above the 1,00 mm centrally and peripherally. Another Scheimpflug study with 12 months of follow up confirmed sufficent distance between surrounding tissues and showed stability of the results[13,14]. In our study, we have demonstrated with

OCT measurments that there is no touch between the Verisyse IOL and endothelium and that there is no significant difference in postoperative endothelial cell loss between patients that underwent »triple« procedure and patients with Verisyse IOL.

Conclusion

According to our results, although in a small sample, Verisyse lens is safe and efficacious method to correct aphakia when combined with penetrating keratoplasty. No significant difference in graft survival rate, BCVA and postoperative endothelial cell density was found between Verisyse patients and those who underwent standard »triple« procedure.

Abbreviations: PK – Penetrating keratoplasty, IOL – Intraocular lens, ACIOL – anterior chamber intraocular lens, »Triple procedure« – penetrating keratoplasty + cataract extraction + posterior chamber intraocular lens, BCVA- best corrected visual acuity

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PENETRANTNA KERATOPLASTIKA KOMBINIRANA SA VERISYSE IRIS FIKSACIJSKOM LEĆOM – KOLIKO JE SIGURNA ZA PRESADAK?

SAŽETAK

Gubitak endotelnih stanica donorske rožnice je znana pojava nakon transplantacije rožnice. Ugradnja najnovijih modela »iris –fiksacijskih« leća (Verisyse) u refraktivnoj kirurgiji ukazuje na klinički neznatan gubitak endotelnih stanica. U našoj prospektivnoj studiji promatrali smo klinički učinak i gubitak endotelnih stanica u pacijenata koji su bili podvrgnuti transplantaciji rožnice u kombinaciji sa: a) ugradnjom iris-fiksacijske i b) implantacijom leće u stražnju kapsulu. U prvoj grupi od 9 pacijenata ugrađena je Verisyse afakična intraokularna leća (IOL) zbog nedostatka stražnje kapsule i nemogućnosti implantacije IOL-a u stražnju sobicu. Dva pacijenta iz ove grupe imali su »angle supported« IOL u prednoj očnoj sobici, četiri pacijenta su bila afakična a tri su imala posttraumatsku kataraktu sa puknutom stražnjom kapsulom. Drugoj grupi od 12 pacijenata učinjena je standardna »triple« operacija (KPP + ECCE+ PCIOL). Vidna oštrina prije operacije je bila mahanje rukom pred očima u 12 pacijenata, svjetlost projekcija u 7 pacijenata i 0,05 u 3 pacijenta. Preoperativni broj endotelnih stanica donorskoh rožnica bio je u prosjeku 2800 stanica/mm^2. Postoperativni period praćenja bio je 6–10 mjeseci. Šest mjeseci nakon operacije, svi pacijenti sa Verisyse IOL imali su bistar transplantat. Postoperativno poboljšanje vidne oštrine je zabilježeno u 18 od 21 operirana oka (85,7%). Vidna oštrina ≥0.3 je postignuta kod 55% pacijenata u Verisyse grupi te u 50% u »triple« grupi. Broj i morfologija endotelnih stanica praćena je spekularnim mikroskopom svaki mjesec postoperativno. Gubitak endotelnih stanica do 10-og postoperativnog mjeseca u Verisyse grupi bio je 42±12% te 40±8% u »triple« grupi. U našoj studiji nije uočena statistički značajna razlika u postoperativnom gubitku endotelnih stanica između grupe pacijenata sa KPP-om i ugradnjom Verisyse leće i grupe pacijenata sa KPP-om i ugradnjom leće u stražnju sobicu.