INTRODUCTION

At our refractive surgery unit, the rejection rate for laser in situ keratomileusis (LASIK) is 25.4%. The most common reasons for rejection are suboptimal corneal thickness, high myopia, keratoconus and forme fruste keratoconus (keratoconus suspect). Alternatives to LASIK for the correction of moderate to high myopia include clear lens extraction (CLE) and implantation of a phakic intraocular lens (PIOL). CLE and PIOL are the most common surgical procedures for correcting severe myopia. The main disadvantage of CLE is the complete loss of accommodation in young individuals and it theoretically increases the risk of retinal detachment.

Relatively moderate myopia and severe myopia are increasingly being treated with PIOL. One of the most commonly used PIOL is the posterior chamber Visian implantable collamer lens (ICL) (STAAR Surgical, Monrovia, CA, USA).

ABSTRACT

Introduction: To evaluate the vitreoretinal complications in myopes after Visian implantable collamer lenses (ICL) implantation.

Materials and Methods: This is a retrospective, observational, non-comparative clinical study that evaluated 617 consecutive myopes who underwent ICL implantation at the Department of Refractive Surgery, Yemen Magrabi Hospital, Sana’a, Yemen between July 2006 and May 2010. Follow up ranged from 6 months to 40 months. Preoperative and postoperative patient evaluation included manifest and cycloplegic refractions, uncorrected (UCVA) and best spectacle-corrected visual acuity (BSCVA), slit-lamp biomicroscopy, intraocular pressure and dilated retinal examination. Investigations included corneal topography, central corneal thickness, anterior chamber depth and white to white diameter. Retinal diseases and complications were recorded and analyzed preoperatively and postoperatively.

Results: Preoperatively, 61 (9.9%) eyes had posterior segment pathology requiring prophylactic laser photocoagulation. One eye developed spontaneous rhegmatogenous retinal detachment (RRD), one eye developed traumatic retinal detachment and two eyes required laser treatment postoperatively. The overall retinal detachment rate post-ICL was 0.32%.

Conclusions: Posterior segment complications are rare after ICL implantation but dilated vitreoretinal assessment is important before and after the procedure. Patients with suspicious retinal lesions need a comprehensive vitreoretinal evaluation by a retinal specialist. If a patient develops floaters or blurry vision he/she requires further assessment by a vitreoretinal specialist.

Key words: Myopia, Phakic Implantable Collamer Lens, Retinal Detachment, Retinal Hole
The majority of published studies on the ICL have shown good predictability, efficacy stability, a high level of safety and low complication rates for the treatment of moderate to high myopia.7,8 These outcomes indicate its viability as a surgical option for the treatment of myopic eyes.7,8

However, the increasing number of patients undergoing these procedures has led to awareness of the potential risks and complications of these surgeries. ICL implantation is safe with regard to immediate visual and refractive results. The short-term clinical benefit and lack of immediate surgical complications are impressive. However, the increase in anterior chamber flare, endothelial cell loss, decrease in crystalline lens transmittance, and the crystalline lens-ICL contact are findings that suggest caution regarding the long-term safety of this lens implant. Most of the reported complications are related to the refractive outcome or to anterior segment injury.9,10

Posterior segment complications are rarely reported. This clinical study was performed to retrospectively evaluate the characteristics of vitreoretinal complications and retinal detachment in a consecutive series of patients with mild to severe myopia who underwent Visian ICL implantation.

MATERIALS AND METHODS

Between July 2006 and May 2010, 617 Visian ICL implantations (model V4) were performed for 352 patients at the refractive surgery unit in Yemen Magrabi Hospital, Sana’a, Yemen. This study retrospectively evaluated the retinal lesions and retinal detachment in 617 eyes that received a posterior chamber phakic ICL to correct myopia. All patients in the study period who underwent ICL implantation for myopia and astigmatism were included and patients who had other refractive procedures were excluded from the study. Patients who have keratoconus, pellucid marginal degeneration, previous refractive surgery or corneal graft surgery were excluded.

Inclusion criteria were: age ranging from 18 to 45 years; stable myopia for at least one year; patient not suitable for laser refractive surgery; normal anterior segment; anterior chamber depth (ACD) greater than 2.8 mm; normal peripheral retina or areas of lattice degeneration, atrophic holes, or flap tears were treated with argon laser photocoagulation.

At the initial examination, all patients received complete ophthalmic examination, including manifest and cycloplegic refraction, uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), slit-lamp biomicroscopy of the anterior segment (Haag Streit, Switzerland), Goldmann applanation tonometry (Haag Streit, Switzerland); central corneal thickness (CCT) (Nidek US1000 pachymeter, Gamagori, Japan), corneal topography (TMS-2, Tomey Co), anterior chamber depth (ACD) (Nidek US1000 or IOL master, Zeiss, Jena, Germany) and white to white measurement (WTW) (IOL master, Zeiss, Germany). Endothelial cell counts were not performed because a specular microscope is not available in Yemen.

All cases scheduled for myopic ICL implantation were referred for a comprehensive dilated retinal examination by two experienced vitreoretinal surgeons (SA and NT). Patients presenting with postoperative retinal complications or complaining of floaters, flashes of light and/or photopsia were also referred to the vitreoretinal unit. Data collected included detailed descriptions and fundus drawings of retinal lesions in all four quadrants of the globe.

Although the majority of the patients with lattice or retinal breaks in this series were asymptomatic, they all underwent immediate prophylactic argon laser photocoagulation to seal the retinal lesion. The laser was applied by the two retinal specialists treating any peripheral retinal lesions predisposing to the development of RRD, such as lattice degeneration, atrophic holes, or flap tears. The breaks were surrounded completely with the photocoagulation treatment for at least three to five rows of photocoagulation marks or U-shaped photocoagulation for breaks extending anteriorly into the ora serrata. Those who underwent photocoagulation had the ICL implantation at least two weeks later after re-examination by the retinal surgeon to check the effect of the laser on the retina.

The ICL implantation was performed by five experienced refractive surgeons (MB, MS, HM, ME and MA). Most had the implantations performed with a temporal approach but some cases underwent a superior approach on the steepest axis. The procedures were performed under topical anesthesia or general anesthesia upon patient request.

Postoperative examinations were conducted at day 1 and 3 then 1, 3, 6 and 12 months, and, thereafter, once a year. The minimum follow-up period was six months and range (range, 6 to 40 months). Twenty-seven patients were lost to follow-up. The majority of these cases lived in the Gulf countries and came to Yemen to visit their relatives.

All patients who had preoperative and postoperative prophylactic retinal laser photocoagulation and patients who presented with postoperative vitreoretinal complaints and complications were included in the study. Table 1 presents the patient demographics and ocular characteristics. Descriptive analysis was performed on the data using a Microsoft Excel® spreadsheet (2003, Microsoft Corporation, Redmond, WA., USA).

The study was approved by the Research and Ethics Committee of Yemen Magrabi Hospital and the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional).
This study adhered to the Declaration of Helsinki, 1975, as revised in 2000. The risk of the surgery was fully explained to the patients in accordance with the Declaration of Helsinki, and written informed consent was obtained.

RESULTS

Two hundred sixty-five patients underwent bilateral implantation and 87 underwent unilateral implantation. Majorities were females and most had myopic ICL but a number of eyes had toric myopic ICL [Table 1]. Table 2 presents the characteristics of eyes that underwent ICL implantation during the study period.

In the preoperative retinal assessment, 61 eyes (9.9%) had retinal holes or breaks requiring prophylactic retinal laser photocoagulation. Of these breaks, 26 were identified as atrophic holes, 22 as flap tears and 13 lattice degenerations. Prophylactic argon laser photocoagulation was performed in all cases before the ICL implantation. The refractive procedure was performed at least two weeks later. In the postoperative follow-up period, four eyes developed posterior vitreous detachment (PVD). Two eyes developed the PVD three months postoperatively and one eye six months and one eye one year postoperatively. Two of these cases had retinal holes at the peripheral retina that required prophylactic laser therapy to seal the breaks.

Two eyes of two patients developed rhegmatogenous retinal detachment (RRD). The first was the right eye of a male aged 25 years with high myopia (−12.00 D) and the second was the right eye of a female aged 24 years with high myopia (−14.00 D). The overall retinal detachment rate post-ICL was 0.32%. RRD developed spontaneously 10 months post-ICL in the male patient and 37 months post-ICL in the female patient after trauma to the eye. Retinal detachment surgery was performed and anatomic success was achieved after one surgery in first case and the final BSCVA was 20/200. The second female patient travelled abroad for the retinal detachment repair and was lost follow up. Both cases had a documented pre-ICL retinal examination by the retinal surgeon. Table 3 presents data on eyes that underwent laser photocoagulation and eyes with RRD.

DISCUSSION

Phakic ICL for the correction of myopia and astigmatism is increasing in popularity and is used to treat moderate to high myopia. The outcomes of the FDA study supported the safety, efficacy, and predictability of ICL surgery to treat moderate to high myopic refractive errors. At 3 years, 94.7% had 20/40 or better UCVA and 88.2% were within ± 1.00 D of predicted refraction. Cumulative three-year corneal endothelial cell loss was under 10%. Only 0.6% reported dissatisfaction and the incidence of patient symptoms, such as glare, halos, double vision, night vision problems, and night driving difficulties decreased or remained unchanged postoperatively.
In recent studies, the ICL was found to be a safe and effective procedure and it seems to be a viable alternative to corneal refractive excimer surgery in the treatment of low and moderate myopia. In this study, the majority of eyes were high myopes (53.9%) and moderate myopes (39.2%). Low myopes only accounted for 4.9% of the treated eyes (Table 1).

Most of the ICL complications are related to the refractive outcome or to anterior segment complications which are well documented. Approximately 6% to 7% of eyes develop anterior subcapsular opacities after 7 years following ICL implantation but only 1% to 2% progress to clinically significant cataract during the same period, especially very high myopes and older patients. Visual outcome following cataract extraction is usually good.

Refractive surgery candidates, particularly those with moderate to high myopia, are vulnerable to retinal problems. Myopia is a recognized predisposing factor for vitreoretinal complications, regardless of any surgical procedure. These patients have an inherently increased risk of peripheral retinal degeneration, such as lattice degeneration and retinal break, which renders the patient more susceptible to rhegmatogenous retinal detachment (RRD).

The rarity of vitreoretinal events after ICL implantation makes it difficult to examine the exact incidence and risk factors of vitreoretinal complications. Posterior segment complications including rhegmatogenous retinal detachment (RRD) after ICL surgery is infrequent yet it is a serious complication. Case reports of RRD after ICL have been published. However, the cases reported were a heterogeneous group from which no epidemiologic conclusion could be reached. The limited information concerning posterior segment complications after ICL and the possible effect of the ICL on posterior segment of the eye is not well known. There has been no definitive proof of a causal link between ICL procedures and vitreoretinal complications.

Martínez-Castillo et al., found that the incidence of RRD after posterior chamber phakic IOL implantation (PCP IOL) was 2.07%. Primary RRD developed in 16 eyes of 15 patients. Prophylactic laser photocoagulation was performed in 3 eyes of 3 patients (18.75%). Rhegmatogenous retinal detachment occurred from 1 to 70 months after posterior chamber phakic IOL (PCP IOL) implantation (mean, 29.12 months). Fourteen breaks (60.86%) were horseshoe tears and 9 (39.14%) were atrophic holes. Scleral buckling was performed in 10 eyes (62.5%). Pars plana vitrectomy alone was performed in 5 cases (31.25%) with posterior breaks.

In a study by Panozzo et al., four patients, two males and two females, aged 26 to 35 years, were referred for retinal detachments (RDs) occurring 4 to 8 months after uncomplicated PCP IOL implantation. The cause of RDs were: giant retinal tear in two patients, 4 clock hours wide; a retinal dialysis in one patient, 5 clock hours wide; and a horseshoe tear in one patient. In the case of giant tears and dialysis, reattachment was obtained by removal of PCP IOL, lensectomy, vitrectomy and implantation of intraocular lens in the posterior chamber, encircling buckle, and gas tamponade. The horseshoe tear–related RD was treated with a scleral buckle.

Overall, ICL implantation is associated with a low incidence of RRD. This is likely due to the fact that refractive surgery patients have preoperative examination that includes dilated fundus examination and in suspicious cases referral to the vitreoretinal surgeon. These cases usually receive treatment of any retinal lesion that can be a predisposing factor to the development of RRD. Our rate of 0.32% of retinal detachment after ICL implantation appears low and a possible explanation is that all myopic eyes scheduled for ICL implantation are routinely referred to the retinal specialist for detailed retinal evaluation. It must be noted, however, that these rates depend on the duration of follow-up, the age of patients and the severity of myopia.

Age and myopia are risk factors for RRD. The vitreous undergoes syneresis between 40 and 60 years of age and occurs earlier in myopic eyes, and a syneretic vitreous is a prerequisite for the occurrence of posterior vitreous detachment (PVD) and subsequent retinal breaks and retinal detachment. The number of publications on vitreoretinal complications have not risen proportionately to the increase in the total number of ICLs performed worldwide.

In our series, 61 eyes (9.9%) required some form of treatment by prophylactic laser photocoagulation preoperatively due to evidence of pathology predisposing to the development of retinal lesions. Two eyes had treatment postoperatively to treat weak areas in the peripheral retina after presenting with PVD.

The occurrence of retinal detachment in the two eyes in our series (0.32%) occurred spontaneously in one eye and after trauma in the other eye. The spontaneous RRD can be partly attributed to the presence of small atrophic holes or retinal tears that were missed during the preoperative examination by the retinal surgeon. Referring all cases to the retinal surgeon is very important due to the high rates of eyes requiring laser photocoagulation; however, there are added expenses to the patient.

Patients admitted for ICL should be informed that the refractive procedure is to correct the refractive power, and the inherent nature of retinal degeneration due to posterior pole elongation in patients with myopia remains unchanged.

CONCLUSIONS

ICL is a growing surgical procedure for treatment of moderate to high myopia worldwide. Most of its complications are related to high myopia.
to the refractive outcome or to anterior segment injury. Posterior segment complications are very rare but dilated vitreoretinal assessment is important before and after ICL procedures. Patients with suspicious retinal lesions need comprehensive vitreoretinal evaluation by a retinal specialist. If a patient develops floaters or blurriness of vision post-treatment, then a detailed assessment is warranted to exclude retinal tears or detachment. More studies are also needed to confirm whether aggressive prophylactic retinal therapy is indicated in myopic eyes seeking refractive surgery.

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REFERENCES