Refractive lensectomy outcomes and complications for myopia and hyperopia: A 15-year review of results

Corresponding Author:

Karl Stonecipher, M.D.
1. Director, The Laser Center--Greensboro, NC, USA.[1]
2. Clinical Associate Professor, University of North Carolina, Department of Ophthalmology

E-mail: StoneNC@aol.com

1. Laser Defined Vision
1002 N. Church Street, Suite 101
Greensboro, NC 27401, USA

Matej Polomsky, M.D.
E-mail: matej.polomsky@gmail.com
Megan Stonecipher
E-mail: mnstonenc@aol.com
Kody Stonecipher
E-mail: kgstonenc@aol.com
Kristen Dunn, B.S.
E-mail: Kristentaylor_dunn@aol.com

No author has any financial or proprietary interest in any material or method mentioned in this manuscript.

ABSTRACT

Purpose: To investigate the type and rate of ophthalmic complications that may occur following refractive lensectomies.

Methods: This is a retrospective consecutive case series exploring the incidence of complications in 437 eyes that received refractive lensectomies by a single surgeon from 1993 to 2000. All participants had a clear crystalline lens and a best-corrected visual acuity (BCVA) of 20/40 or better prior to the lens exchange. Main outcome measures included uncorrected visual acuity (UCVA) and BCVA after clear lensectomy, the rate of posterior capsular fibrosis formation, and retinal complications such as retinal detachments (RD) and cystoid macular edema (CME).

Results: Following the refractive lensectomy, all subjects experienced an improvement in UCVA and BCVA as compared to pre-operative levels ($p<0.05$). During the greater than 15-year follow-up period, 36% of subjects experienced posterior capsule opacification (PCO) requiring a Neodymium-doped yttrium aluminum garnet laser (Nd:YAG) capsulotomy, 0.23% experienced retinal detachments, and 0.46% experienced cystoid macular edema. The overall rate of retinal complications following refractive lensectomy was 0.69%. All patients with complications were treated appropriately with good outcomes.

Conclusion: This series demonstrated excellent visual acuity outcomes following refractive lensectomy. Although studies suggest that refractive lensectomy leads to high rates of retinal complications and detachments, with modern surgery it can be a safe option for patients seeking refractive surgery. Careful and continuous follow-up is essential.

Brief Summary Statement: In this retrospective case series, the incidence of ocular complications was assessed in 437 eyes that have undergone refractive lensectomies with up to 15 years of follow up. Our results show that refractive lensectomies have a superior efficacy and safety profile, with a 0.69% overall rate of retinal complications, including retinal detachments and cystoid macular edema.

Key Words: Refractive Lensectomy, Cystoid Macular Edema, Nd:YAG Capsulotomy, Posterior Capsule Opacification.

1.0 INTRODUCTION

Refractive lensectomy or clear lens exchanges have been growing in popularity, with the advent of smaller incision surgery and new surgical techniques, for patients with high myopia and hyperopia. Refractive lensectomies are usually considered in these patients when alternative refractive procedures are not feasible and spectacle or contact lenses are unacceptable alternatives. The procedure can provide patients with good visual rehabilitation and acuity without the risk of corneal ectasia or irregular astigmatism, which may occur with excessive excimer laser treatments. Despite these benefits, refractive lensectomies still remain controversial given the increased risk of complications [1,2]. Primary complications include PCO, CME and RD. Previous studies report that the average rate of RD following refractive lensectomies is as high as 7.3% – 8.1%[1,3]. The purpose of this retrospective study is to clarify the type and rate of post-operative complications following refractive lensectomies in a large refractive surgery practice.

2.0 MATERIALS AND METHODS

This study is a retrospective consecutive case series assessing subjects who received refractive lensectomies by one surgeon (Karl Stonecipher, M.D.) at one center, Greensboro, North Carolina, USA, from 1993 to 2000. Patients were selected based on the following inclusion criteria: pre-operative myopia greater than -12 D or hyperopia greater than +6 D, and did not qualify for laser vision correction, radial keratotomy or automated lamellar keratoplasty (LASIK, PRK, RK, or ALK) based on their pre-operative refractive error, anatomy, keratometry readings, topography findings, pupil size, pachymetry readings, systemic health conditions, or pre-existing ocular conditions such as dry eye. Furthermore, all subjects had to have a best-corrected visual acuity (BCVA) of 20/40 or better and a clear crystalline lens on examination.

2.1 Exclusion Criteria

Exclusion criteria included subjects with any pre-operative systemic pathology such as diabetes or hypertension; corneal pathology such as guttata with or without Fuch’s endothelial dystrophy or if they had pre-existing retinal pathology such as diabetic retinopathy, and drusen with or without age-related macular degeneration. Any patient with retinal holes or tears was evaluated preoperatively and either excluded from surgery or included in the study population. Any retinal conditions observed preoperatively required the independent evaluation by either one of two retinal specialists in the investigator’s practice to confirm the diagnosis and assist with management and determination of whether they were suitable for surgery or not.

2.2 Surgical Procedure

The surgical procedure was identical in all cases. Preoperative axial length measurements and keratometry measurements were made with the IOLMaster Optical Biometer (*Zeiss Instruments Version 1-3*) and an appropriate intraocular lens (IOL) was selected for a goal of emmetropia. Subjects who had near **plano sphero-equivalent refractive** errors with mixed astigmatism required implantation of toric IOLs (STARR, approved 1998). To achieve higher dioptric power corrections, three patients received piggyback IOLs. A standard coaxial cataract technique was utilized with a 4.00 mm clear corneal incision, and an Alcon *Legacy*® device was used for phacoemulsification.

2.3 Post-Surgery Protocol

Subjects were followed on day 1, week 1, and 2 to 3 months after the surgery. Topical steroids and antibiotics were given post-operatively. A manifest refraction was performed two to three months after surgery. Patients were then followed yearly with careful dilated examinations. A 4– 5 mm round Nd:YAG capsulotomy (Coherent laser, Santa Clara, CA, USA) was performed when indicated. Retinal complications were managed promptly and referred to a retinal specialist for further treatment. All patients with pre-existing retinal pathology were excluded from the study and referred for retinal evaluation.

2.4 Analysis

A detailed informed consent was obtained from all patients. Gender, age, pre-operative data and post-operative data including complications were recorded throughout the term of the study. The data were collected using SurgiVision® Data Link, a proprietary software program.

3.0 RESULTS

The total number of eyes included in the study was 437 from 317 patients. The age of the patients ranged from 26 to 80 years. All subjects had pre-operative BCVAs of 20/20 with the exception of 3 subjects who presented with mild amblyopia, but no worse than 20/40. It should be noted that the 80-year-old patient included in this analysis presented with a BCVA of 20/20 (Figure 1).

Total population	437 eyes (317 patients)
Range of surgery	1993–2000
Range of spherical equivalent	-21.5 to 11.5 D
Range of cylinder	0 to 5.75 D
Range of axial length	20.28 to 29.7 mm
Range of age	26–80
Range of intraocular lens/ lens combination	4–36 D

Figure 1: Patient characteristics

With regard to the sphero-equivalent refractive errors, 65% (284/437) of the subjects were myopic, 33% (144/437) were hyperopic, and 2% (9/437) presented with mixed astigmatism. The spherical equivalent refractive error of these subjects ranged from -21.50 D to +11.50 D and the cylinder error ranged from 0.00 to 5.75 D. The axial lengths ranged from 20.28 to 29.70 mm. The IOL powers used in these patients ranged from 4.00 to 30.00 D (Figure 1). Three subjects required piggyback lens placement.

All subjects underwent an uneventful refractive lensectomy without intraoperative complications. All 317 patients were available for the 15-year examination if surgery was performed that far out. No patients were lost to follow-up except for in the case of death.

3.1 Visual acuities

In decimal acuities, the average pre-operative uncorrected visual acuity (UCVA) and standard deviation was 0.179 ± 0.16. The average post-operative UCVA and standard deviation improved to 0.705 ± 0.24 ($p<0.05$). The average post-operative BCVA of 0.848 ± 0.19, improved as compared to the average pre-operative BCVA of 0.703 ± 0.19 ($p<0.05$). The average pre-operative BCVA was equivalent to the average post-operative UCVA and statistically insignificant (Figure 2, 3).

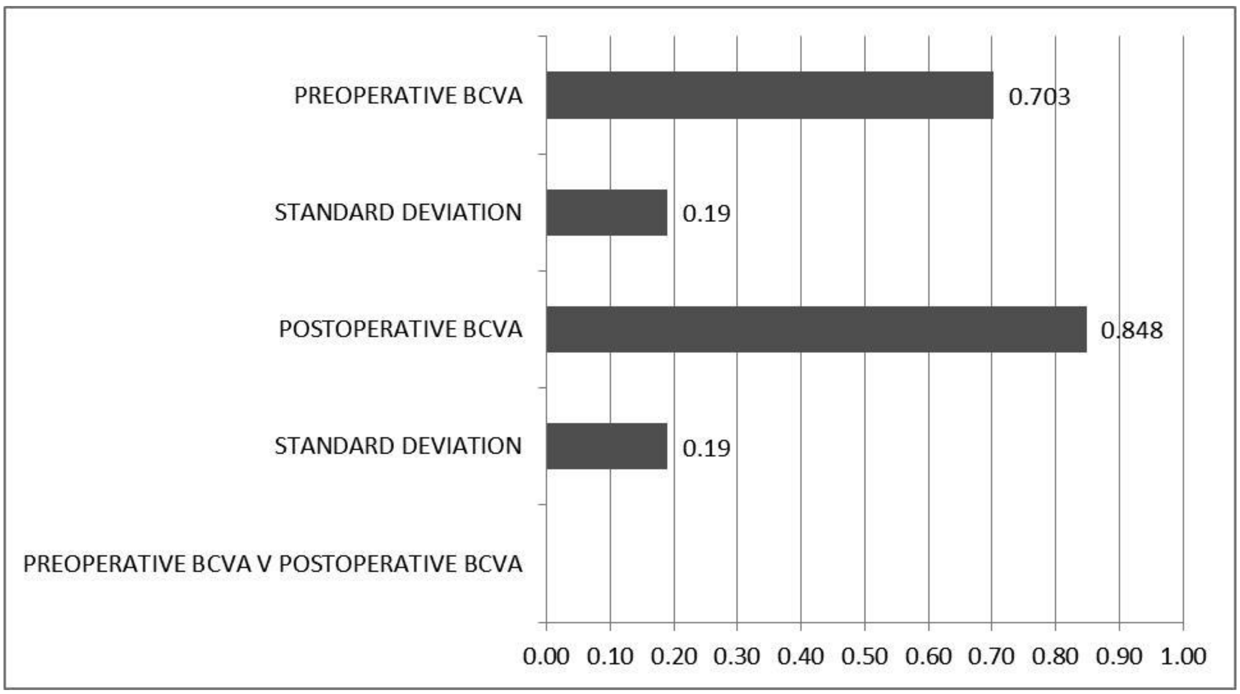

Figure 2: Statistically significant improvement in post-operative best-corrected visual acuity (BCVA) as compared to pre-operative BCVA.

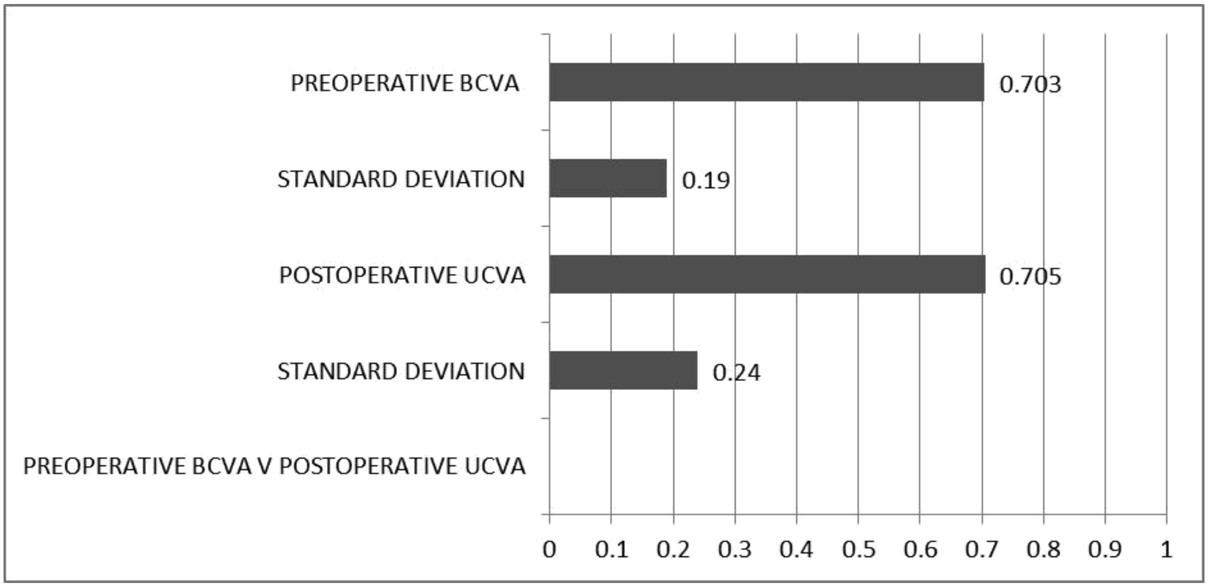

Figure 3: Average pre-operative BCVA was equivalent to the average post-operative UCVA for both groups.

3.2 Post Operative Complications

When we consider the postoperative complications to refractive lensectomies, two main outcomes stand out as the most common. First, is opacification of the posterior capsule and second are retinal complications, which include CME and RD. These are seen occurring at a similar rate as with Cataract Extraction with IOL.

3.2.1 Fibrosis of Posterior Capsule

Figure 4 shows the rate of Nd:YAG capsulotomies performed for posterior opacification following refractive lensectomies. During the 15-year follow-up period, 40% (175/437) of eyes with pre-operative spherical equivalent emmetropia, 16% (245/437) of eyes with pre-operative spherical equivalent hyperopia, and 42% (184/437) of eyes with pre-operative myopia required Nd:YAG laser capsulotomies. The overall rate of Nd:YAG capsulotomies needed in this study population following refractive lensectomy was 36% (157/437) (Figure 4).

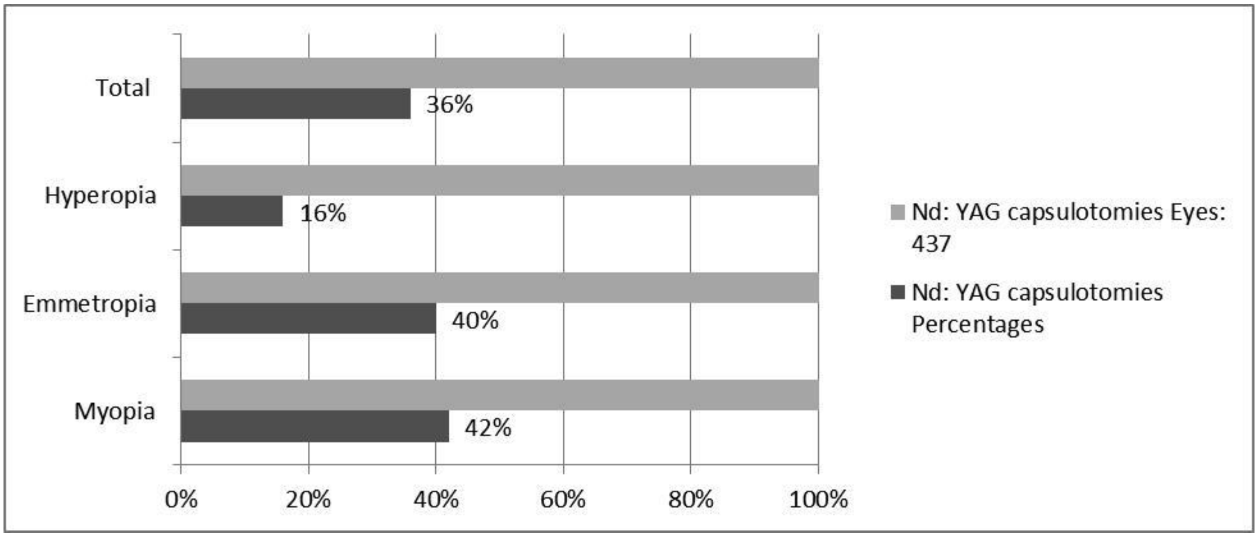

Figure 4: Demonstrated percentage of Nd:YAG capsulotomies in the various refractive groups.

3.2.2 Retinal complications

The two most prevalent retinal complications noted after refractive lensectomy in this study population were CME and RD. Two eyes out of 437 (0.46%) of subjects experienced CME and one eye out of 437 (0.23%) experienced a RD during the up to 15-year follow-up period. The patients were treated with topical steroids and visual acuity was recovered to baseline in both cases. The RD occurred in a 42-year-old man who presented with a retinal tear nine months after the lensectomy. He was promptly treated by a retina specialist and regained an uncorrected visual acuity of 20/30 when last seen in 2015. The overall percentage of subjects who experienced retinal complications following refractive lensectomy was 0.69% (3/437) (Figure 5).

Of the 317 patients who were in the study population, 4.5% (28 eyes of 14 patients) were treated by a retina specialist for pre-existing retinal pathology, such as lattice or atrophic holes, and were then cleared to proceed with surgery. Of the 28 eyes, 16 were treated by argon, green, or red retinal photocoagulation laser (Figure 5).

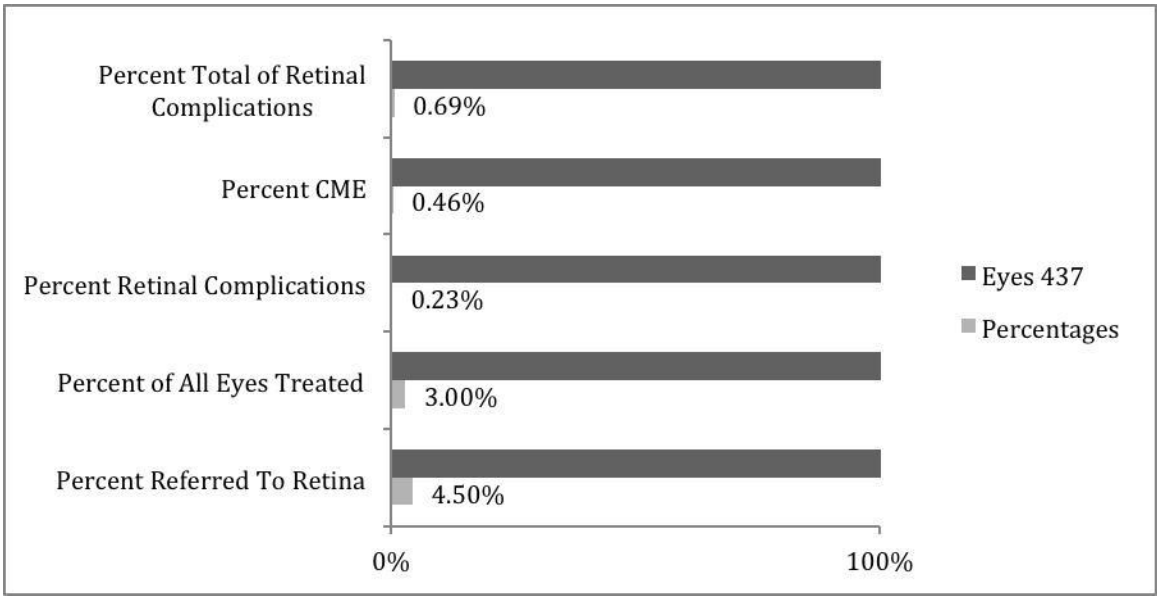

Figure 5: Depicted percentage of post-operative retina complications and the percentage of patients referred to and treated by a retina specialist.

4.0 DISCUSSION

Although refractive lensectomies can help patients achieve emmetropia without the need of excessive excimer treatments, the procedure remains controversial given the potential risk of retinal complications reported in the literature[1,3]. Colin *et al*.[1] report a retinal detachment rate of 8.1% in a 7-year follow-up of 41 eyes that had undergone refractive lensectomies[1]. More recent studies showed an improvement, but still a significant risk of RD following cataract surgery, ranging from 0.71–4.0% with young high myopes demonstrating the greatest risk[2,4]. Neuhann *et al*.[2] also reported a much lower rate of RD of 1.5–2.2% in eyes with greater than 27.00 mm axial length. Our study demonstrated an equally low rate of RD of 0.3% in 437 eyes that had undergone refractive lensectomies. One reason for our low rate of RD was the pre-treatment of patients with lattice or atrophic holes by the retina specialist, and thorough screening practices. The patient in our series who had an RD was 42 years of age. This corresponds to the increased risk of RD in younger myopes reported previously[4]. Older myopes typically have undergone a posterior vitreous detachment, which may serve as a protective factor for their RD risk.

4.1 Complication Rates

The results of this study demonstrated a slightly higher rate of development of PCO, 36%, following refractive lensectomies than with cataract surgery. The current Nd:YAG laser capsulotomy rate is approximately 10% with modern cataract surgery. However, the literature of our study time period, from 1993 to 2000, supports a PCO formation rate of approximately 32.7% at five years following surgery[5]. This number coincides with the rate we found in our analysis. In addition, the younger age of our study population, as compared to the average age of cataract surgery patients, helps explain why our PCO rate was higher[6] . Interestingly, Figure 4 shows a 3-fold decrease in Nd:YAG laser capsulotomies in hyperopic patients when compared to the myopic and mixed astigmatic groups. This may be attributed to a contracted capsular bag in hyperopes, which inhibits the remaining lens epithelial cells in the periphery from migrating centrally. Despite the increased rate of PCO formation in our series, all patients achieved good BCVAs after uneventful Nd:YAG capsulotomies.

4.2 Cystoid Macular Edema

CME is not uncommon and can present 6 to 10 weeks after cataract surgery. The current incidence of CME following modern cataract surgery is 0.1%–2.35% and most cases resolve independently or with topical non-steroidal anti-inflammatory drug (NSAID) and corticosteroid therapy[7]. Our series demonstrated a CME rate of 0.46%, which is similar to the rate reported in the literature.

4.3 Findings and Limitations

Our series demonstrated a statistically significant increase in post-operative BCVA when compared to pre-operative BCVA. An explanation for this finding may be that patients are benefiting from magnification as they become emmetropic at the corneal-lenticular plane. Another explanation that can account for the improvement in vision is that patients may have visually significant lenticular changes despite having clear lenses on examination.

Some of the limitations of our study include the sample size and length of follow-up. Prior studies which assessed the risk of retinal detachment in cataract surgery have a large sample size with thousands of patients; however, most studies that specifically address refractive lensectomies have fewer samples, 30–69 eyes[1,3,8,9]. To our knowledge we provide the largest sample of eyes undergoing refractive lensectomy, 437 eyes.

5.0 CONCLUSION

In summary, refractive lensectomy or clear lens exchange is a safe and effective procedure. Our series showed no difference in the development of CME as compared to standard cataract extraction procedures; however, the rate of PCO formation was higher. Using modern small incision coaxial phacoemulsification and proper patient screening, the risk of RD can be mitigated. Until a large prospective trial can be established which specifically elucidates the risks, careful planning and a proper informed consent explaining such risks is a must for all patients undergoing refractive lensectomy.

Author contributions:

Karl Stonecipher, MD
Primary surgeon, data collection, manuscript editing, and manuscript preparation. Matej Polomsky, MD
Data collection, manuscript editing, and manuscript preparation. Megan Stonecipher
Data collection, manuscript editing, and manuscript preparation. Kody Stonecipher
Data collection, manuscript editing, and manuscript preparation. Kristen Dunn
Data entry, manuscript editing, and manuscript preparation.
Competing interests: None
Grant information “None

Acknowledgements:

Donald P. Maxwell, MD
Retina Associates of Oklahoma City, Private Practice, Oklahoma City, OK, USA Dr. Maxwell reviewed the retinal data and provided insight for data interpretation. John Matthews, MD
Dr. Matthews treated patients involved in the series. John Harriot,MD
Dr. Harriot treated patients involved in the series.

REFERENCES

1. Colin J, Robinet A, Cochener B. Retinal detachment after clear lens extraction for high myopia: seven-year follow-up. *Ophthalmology*. 1999 Dec;106(12):2281-4.

2. Neuhann IM, Neuhann TF, Heimann H, Schmickler S, Gerl RH, Foerster MH. Retinal detachment after phacoemulsification in high myopia: analysis of 2356 cases. *J Cataract Refract Surg*. 2008 Oct;34(10):1644-57.

3. Barraquer C, Cavelier C, Mejía LF. Incidence of retinal detachment following clear-lens extraction in myopic patients. Retrospective analysis. *Arch Ophthalmol*. 1994 Mar;112(3):336-9.

4. Alio JL, Ruiz-Moreno JM, Shabayek MH, Lugo FL, Abd El Rahman AM. The risk of retinal detachment in high myopia after small incision coaxial phacoemulsification. *Am J Ophthalmol*. 2007 Jul;144(1):93-98.

5. Ando H, Ando N, Oshika T. Cumulative probability of neodymium: YAG laser posterior capsulotomy after phacoemulsification. *J Cataract Refract Surg.* 2003 Nov;29(11):2148-54.

6. Dholakia SA, Vasavada AR, Singh R. Prospective evaluation of phacoemulsification in adults younger than 50 years. *J Cataract Refract Surg.* 2005 Jul;31(7):1327-33.

7. Zur D, Fischer N, Tufail A, Monés J, Loewenstein A. Postsurgical cystoid macular edema. *Eur J Ophthalmol.* 2010 Nov 11;21(S6):62-68.

8. Pucci V, Morselli S, Romanelli F, Pignatto S, Scandellari F, Bellucci R. Clear lens phacoemulsification for correction of high myopia. *J Cataract Refract Surg*. 2001 Jun;27(6):896-900.

9. Fernández-Vega L, Alfonso JF, Villacampa T. Clear lens extraction for the correction of high myopia. *Ophthalmology*. 2003 Dec;110(12):2349-54.

