

Reduction of Nd:YAG Capsulotomy Rates After Implantation of a Single-Piece Acrylic Hydrophilic Intraocular Lens With 360° Squared Optic Edge: 24-Month Results

Rashmi G. Mathew, MRCOphth; Andrew G. A. Coombes, FRCOphth

■ **BACKGROUND AND OBJECTIVE:** Posterior capsule opacification remains a significant problem following cataract surgery. The aim of the study was to evaluate the incidence of symptomatic posterior capsule opacification requiring Nd:YAG capsulotomy in patients who underwent cataract extraction and implantation of the Rayner C-flex 570C intraocular lens (IOL) (Rayner Intraocular Lens, Ltd., Sussex, UK).

■ **PATIENTS AND METHODS:** A retrospective study of 3,461 eyes that underwent cataract extraction and insertion of the Rayner C-flex IOL from January 2004 to December 2005. The cases that received Nd:YAG capsulotomies were evaluated.

■ **RESULTS:** Over a 24-month period, 3,461 Rayner C-flex IOLs were implanted. Nd:YAG capsulotomy was performed in 58 of these cases. The rate of Nd:YAG capsulotomy was 0.6% at 12 months and 1.7% at 24 months. The mean time to Nd:YAG capsulotomy was 9.3 months (range: 1.3 to 22.7 months). The follow-up period was 5.3 to 29.0 months.

■ **CONCLUSION:** The incidence of symptomatic posterior capsule opacification with the Rayner C-flex IOL is low.

[*Ophthalmic Surg Lasers Imaging* 2010;41:651-655.]

INTRODUCTION

Posterior capsule opacification remains a significant problem following modern cataract surgery. In

recent years, advances in intraocular lens (IOL) design and surgical technique have significantly reduced the incidence and severity of posterior capsule opacification following surgery.¹

From Broomfield Hospital (RGM), Chelmsford; Moorfields Eye Hospital (RGM), London; and St. Bartholomews Hospital (AGAC), London, United Kingdom.

Originally submitted March 2, 2010. Accepted for publication July 29, 2010. Posted online September 29, 2010.

The authors have no financial or proprietary interest in the materials presented herein.

Address correspondence to Rashmi G. Mathew, MRCOphth, Moorfields Eye Hospital, 162 City Rd., London EC1V 2PD, United Kingdom. E-mail: rashmi.mathew@doctors.org.uk

doi: 10.3928/15428877-20100929-04

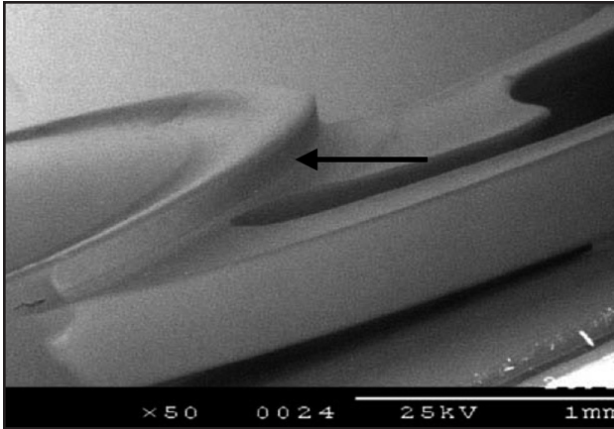


Figure 1. Scanning electron photograph C-flex 570C (Rayner Intraocular Lens, Ltd., Sussex, UK) with 360° square-edge profile (arrow).

Nd:YAG capsulotomy is the definitive treatment for posterior capsule opacification; thus, an indirect method of studying symptomatic posterior capsule opacification is to look at Nd:YAG capsulotomy rates with a particular IOL. Nd:YAG capsulotomy is not without complications, which include post-procedure intraocular pressure spike, damage to the IOL optic, cystoid macular edema, and retinal detachment.² Prevention of posterior capsule opacification would avoid the complications associated with Nd:YAG capsulotomy and reduce the economic burden on the healthcare system.³ Furthermore, developing countries may not have access to Nd:YAG laser therapy.

The role of squared optic edges in reducing posterior capsule opacification is well documented.⁴⁻⁶ However, the influence of IOL material on posterior capsule opacification continues to be controversial. A limitation of many previous studies is that they assessed hydrophilic IOLs with round-edged optics and compared them to square-edged hydrophobic IOLs.⁷⁻⁹ Thus, true comparative data on the performance of hydrophilic acrylic IOLs are lacking.

Werner et al.¹⁰ demonstrated reduced posterior capsule opacification formation after the use of a single-piece hydrophilic lens with enhanced 360° square optic edge (C-flex; Rayner Intraocular Lens, Ltd., Sussex, UK) in a rabbit model. In our study, we evaluated the incidence of symptomatic posterior capsule opacification in patients undergoing cataract surgery and implantation of the C-flex IOL by determining the proportion requiring Nd:YAG capsulotomy.



Figure 2. Photograph of the C-flex 570C intraocular lens (Rayner Intraocular Lens, Ltd., Sussex, UK), demonstrating the square-edge profile and large haptics, which allow centration and stabilization of the lens.

PATIENTS AND METHODS

The Rayner C-flex 570C IOL was used in our department from January 2004 to December 2005 (24 months). During this time, 3,461 C-flex 570C IOLs were implanted in patients undergoing phacoemulsification.

The C-flex IOL is a single-piece foldable, biconvex, hydrophilic acrylic (hydroxyethyl methacrylate/methyl methacrylate copolymer) IOL with 360° enhanced square optic edge (Fig. 1). It has a total length of 12.0 mm and an optic diameter of 5.75 mm. The refractive index is 1.46 and its water content is 26%. It has specially designed haptics that enhance IOL stability and centration (Fig. 2). Furthermore, the new injection system makes the lens easy to insert and therefore ideal for those learning cataract surgery.

A standard surgical procedure was adopted with a 2.8-mm temporal clear corneal incision. The anterior chamber was maintained with hydroxypropyl methylcellulose viscoelastic. A continuous curvilinear capsulorhexis was created, hydrodissection was performed with balanced salt solution, the lens nucleus was re-

moved by phacoemulsification, and the cortical material was aspirated. The capsular bag and anterior chamber were filled with hydroxypropyl methylcellulose to facilitate IOL implantation. The incision was enlarged to 3.2 mm and the IOL was implanted into the bag. The viscoelastic was removed and the anterior chamber was filled with balanced salt solution. Surgeries were performed by four different surgeons. Those patients with sulcus-placed IOL, vitreous loss, or capsular tear were excluded from the study.

Nd:YAG capsulotomy was performed for patients with symptomatic posterior capsule opacification. Symptomatic posterior capsule opacification was defined as subjective complaints of glare and reduced visual acuity (compared with postoperative best-corrected visual acuity), with evidence of posterior capsule opacification on dilated slit-lamp examination.

All data were input to Microsoft Excel (Microsoft Corporation, Redmond, WA), the number of eyes requiring Nd:YAG capsulotomy was determined, and the mean time and standard deviation from time of IOL implantation to capsulotomy was calculated. Statistical analysis was performed with SPSS 9.0 software (SPSS Inc., Chicago, IL). A Kaplan–Meier survival curve was then plotted to illustrate the probability of not receiving Nd:YAG capsulotomy as a function of time.

RESULTS

During the 24-month period, 3,461 Rayner C-flex 570C IOLs were implanted. The study patients had an average age of 76 years (range: 39 to 93 years). The female to male ratio was 1.8:1. Nd:YAG capsulotomy was performed on 58 of the Rayner C-flex 570C IOLs that were implanted. The capsulotomy rate was 0.6% at 12 months and 1.7% at 24 months. Mean time to Nd:YAG capsulotomy was 9.3 ± 5.5 months (range: 2.6 to 22.7 months). The follow-up period ranged from 5.3 to 29.0 months. Younger age and female sex were not associated with increased rates of posterior capsule opacification formation ($P = .10$ and $P = .76$, respectively).

DISCUSSION

The use of capsulotomy rates as a measure of visually significant posterior capsule opacification is well accepted in the absence of more sophisticated objective measures of posterior capsule opacification.¹¹ The mea-

sure of Nd:YAG capsulotomy rates as a surrogate for posterior capsule opacification provides an important functional measure of posterior capsule opacification, which is of primary importance in the clinical setting. This study method does have its limitations and tends to overlook those patients who have visually insignificant posterior capsule opacification.

Posterior capsule opacification can result in significant visual symptoms, including reduction in visual acuity, increased glare, impaired contrast sensitivity, and IOL malpositioning from mechanical traction.²

The pathogenesis of posterior capsule opacification is multifactorial. Factors that influence posterior capsule opacification formation include patient factors (age, diabetes), surgical technique (thorough cortical clean-up¹² and overlap of the capsulorrhexis and anterior IOL surface¹³), IOL design, and material.

Few studies on the efficacy of hydrophilic acrylic IOLs with square-edged optics have been published. Heatley et al.¹⁴ compared the Rayner Centerflex 570H IOL (Rayner Intraocular Lens, Ltd.) with the AcrySof SA60AT (Alcon Laboratories, Fort Worth, TX) in an attempt to evaluate posterior capsule opacification rates of the hydrophilic and hydrophobic single-piece lenses, respectively. They concluded that the lack of square edge at the optic–haptic junction on the Centerflex 570H IOL was a compounding factor and allowed migration of the lens epithelial cells on to the posterior capsule at this site. However, after 1-year follow-up there was no statistically significant difference in mean logarithm of the minimum angle of resolution visual acuity between the groups.

Vargas et al.¹⁵ found the results with the Centerflex 570H model comparable to the single-piece AcrySof lens in the rabbit model. In a further study, Vargas et al.¹⁶ overcame the lack of square edge at the haptic–optic junction in the Centerflex lens by implanting minus-powered lenses into rabbit eyes. Because of the biconcave nature of the minus lens, a 360° barrier was created, which subsequently prevented lens epithelial cell migration along the plane of the haptic. This study has been the basis for modification of the Rayner Centerflex 570H lens by incorporating a complete 360° barrier with a thicker square edge and also the basis of our study in humans using the new C-flex model.

In our study, the Nd:YAG capsulotomy rate was 1.7% after 24 months. This fares well with Nd:YAG

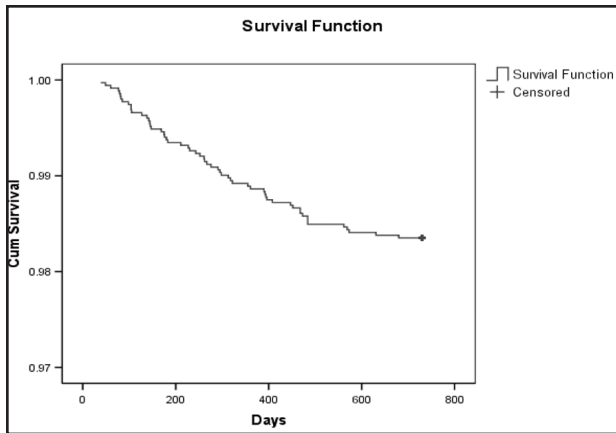


Figure 3. Kaplan–Meier survival graph demonstrating the probability of not receiving Nd:YAG capsulotomy.

capsulotomy rates of hydrophobic acrylic lenses, namely the AcrySof three-piece lens, which is considered a gold standard among IOLs. Mean follow-up time until capsulotomy was 9.3 ± 5.5 months (range: 2.6 to 22.7 months). The Kaplan–Meier survival curve demonstrates the survival of the IOL in relation to the development of posterior capsule opacification (Fig. 3).

Our results are comparable to the Nd:YAG capsulotomy rates of the AcrySof lenses. Mian et al.¹⁷ found the 24-month Nd:YAG capsulotomy rates of the AcrySof three-piece and one-piece lens to be 3.6% and 7.5%, respectively. In a postmortem study of 6,425 pseudophakic human globes, Schmidbauer et al.¹⁸ established a 3.3% capsulotomy rate with the AcrySof three-piece IOL. Beltrame et al.⁹ implanted 485 AcrySof lenses and found an Nd:YAG capsulotomy rate of 2.5%. Stordahl et al.⁸ performed Nd:YAG capsulotomy in 7.6% of patients with Stabibag lens (hydrophilic, round-edged acrylic) compared with 2.7% in AcrySof three-piece IOL.

Recent studies have concentrated on the effect of IOL design and biomaterial on the incidence of posterior capsule opacification formation. In terms of IOL design, the square optic edge appears to be of critical importance. Two theories exist as to how the square-edged optic inhibits posterior capsule opacification formation. Nishi and Nishi¹⁹ suggested that the square-edge profile of the IOL creates a discontinuous bend in the posterior capsule that initiates cellular contact inhibition between lens epithelial cells and prevents further migration and proliferation. The other theory postulated by Boyce et al.²⁰ was demonstrated using mathematical modeling of the forces between the IOL

and capsule and predicted that square-edged optics exert higher pressure on the capsule, forming a physical barrier to lens epithelial cell migration.

The “Sandwich” theory of posterior capsule opacification also provides an explanation as to why certain IOLs are associated with less posterior capsule opacification. Linnola et al.²¹ hypothesized that lens epithelial cell migration is hindered by strong adhesion of the IOL to the capsule (the “no space-no cells” phenomenon). The lens capsule is made of collagen and thus binds fibronectin and laminin found on certain IOLs. They found that the hydrophobic acrylic AcrySof lens bound best with fibronectin, relative to other IOL biomaterials. Incidentally, the hydrophilic acrylic Hydroview lens adhered to laminin best. From our experience with the Rayner C-flex lens, it also appears to subjectively bind well to the posterior capsule because these lenses have proven difficult to remove in lens exchange procedures. Radioactive labeling studies would need to be performed on this particular lens to establish its extracellular matrix protein binding properties.

The biocompatibility of IOLs or their ability to minimize host reactions is of paramount importance. Abela-Formanek et al.²² looked at uveal and capsular biocompatibility by studying the cellular reaction on the anterior surface of the IOL and the incidence and intensity of anterior capsule fibrosis. They found that hydrophobic IOLs had a higher affinity for foreign body giant cells than hydrophilic acrylic IOLs. This is an important feature to consider when selecting suitable IOLs for high-risk patients, such as children and patients with uveitis.²³ They also found that hydrophobic acrylic lenses had more anterior capsule fibrosis, although this was not associated with excessive anterior capsule fibrosis or complications. Lens epithelial cell outgrowth is seen with both biomaterials.

Much debate remains on the subject of IOL biocompatibility. Nishi et al.⁴ used the rabbit model to compare the efficacy of the square optic edge of the three-piece silicone CeeOn 911 IOL (Pharmacia Corp., Peapack, NJ) and the three-piece AcrySof IOL. They did not find a difference in posterior capsule opacification rates, suggesting that IOL biomaterial does not have a bearing on IOL efficacy in posterior capsule opacification prevention.

It would appear that IOL material, biocompatibility, and the square-edge design all have a role to play in the prevention of posterior capsule opacification. From

the literature, it appears that the efficacy of the square-edge design has the most important role in posterior capsule opacification prevention.

A constraint of this study is its retrospective design because a proportion of patients will invariably be lost to follow-up for various reasons, although the large study number takes this into account. Using Nd:YAG capsulotomy as a measure of symptomatic posterior capsule opacification has several limitations. It assumes that all patients with symptomatic posterior capsule opacification will present themselves. This may not be the case if the patient has macular pathology and is unable to appreciate the gradual deterioration in vision or whether the patient is generally too unwell from other comorbidities.

Clinically, the use of a lens with superior posterior capsule opacification profile has obvious immediate benefits. For patients with low posterior capsule opacification rates, it reduces the need for Nd:YAG capsulotomy and thus avoids the anxiety and inconvenience related to further interventional procedures and hospital appointments. It also limits any complications associated with Nd:YAG capsulotomy. As a clinician, one needs to bear in mind that most patients undergoing cataract surgery are elderly, live alone, and have multiple comorbidities; good vision and thus low posterior capsule opacification rates are paramount in this category of patients. Studies have shown that the biocompatibility of hydrophilic acrylic IOLs also reduces the postoperative inflammatory reaction, which is important in uveitis and pediatric cases and may also reduce the amount of topical steroid used postoperatively.

The Nd:YAG capsulotomy rate with the Rayner C-flex IOL is extremely low and shows results comparable with hydrophobic acrylic lenses with square-edged optic. The actual posterior capsule opacification rates must now be objectively measured in clinical studies.

REFERENCES

- Apple DJ, Peng Q, Visessook N, et al. Eradication of posterior capsule opacification: documentation of a marked decrease in Nd:YAG laser posterior capsulotomy rates noted in an analysis of 5416 pseudophakic human eyes obtained postmortem. *Ophthalmology*. 2001;108:505-518.
- Apple DJ, Solomon KD, Tetz MR, et al. Posterior capsule opacification. *Surv Ophthalmol*. 1992;37:73-116.
- Steinberg EP, Javitt JC, Sharkey PD, et al. The content and cost of cataract surgery. *Arch Ophthalmol*. 1993;111:1041-1049.
- Nishi O, Nishi K, Wickström K. Preventing lens epithelial cell migration using intraocular lenses with sharp rectangular edges. *J Cataract Refract Surg*. 2000;26:1543-1549.
- Sacu S, Menapace R, Findl O, et al. Long-term efficacy of adding a sharp posterior optic edge to a three-piece silicone intraocular lens on capsule opacification: five-year results of a randomized study. *Am J Ophthalmol*. 2005;139:696-703.
- Hayashi K, Hayashi H. Posterior capsule opacification in the presence of an intraocular lens with a sharp versus rounded optic edge. *Ophthalmology*. 2005;112:1550-1556.
- Scaramuzza A, Fernando GT, Crayford BB. Posterior capsule opacification and lens epithelial cell layer formation: Hydroview hydrogel versus AcrySof acrylic intraocular lenses. *J Cataract Refract Surg*. 2001;27:1047-1054.
- Stordahl PB, Drolsum L. A comparison of Nd:YAG capsulotomy rate in two different intraocular lenses: AcrySof and Stabibag. *Acta Ophthalmol Scand*. 2003;81:326-330.
- Beltrame G, Salvetat ML, Chizzolini M, et al. Posterior capsule opacification and Nd:YAG capsulotomy rates after implantation of silicone, hydrogel and soft acrylic intraocular lenses: a two-year follow-up study. *Eur J Ophthalmol*. 2002;12:388-394.
- Werner L, Mamalis N, Pandey SK. Posterior capsule opacification in rabbit eyes implanted with hydrophilic acrylic intraocular lenses with enhanced square edge. *J Cataract Refract Surg*. 2004;30:2403-2409.
- Schaumberg DA, Dana MR, Christen WG, Glynn RJ. A systematic overview of the incidence of posterior capsule opacification. *Ophthalmology*. 1998;105:1213-1221.
- Peng Q, Apple DJ, Visessook N, et al. Surgical prevention of posterior capsule opacification. Part 2: enhancement of cortical cleanup by focusing on hydrodissection. *J Cataract Refract Surg*. 2000;26:188-197.
- Hollick EJ, Spalton DJ, Meacock WR. The effect of capsulorrhexis size on posterior capsule opacification: one-year results of a randomised prospective trial. *Am J Ophthalmol*. 1999;128:271-279.
- Heatley CJ, Spalton DJ, Kumar A, et al. Comparison of posterior capsule opacification rates between hydrophilic and hydrophobic single-piece acrylic intraocular lenses. *J Cataract Refract Surg*. 2005;31:718-724.
- Vargas LG, Peng Q, Apple DJ, et al. Evaluation of 3 modern single-piece foldable intraocular lenses: clinicopathological study of posterior capsule opacification in a rabbit model. *J Cataract Refract Surg*. 2002;28:1241-1250.
- Vargas LG, Izak AM, Apple DJ, et al. Implantation of a single-piece, hydrophilic, acrylic, minus-power foldable posterior chamber intraocular lens in a rabbit model: clinicopathologic study of posterior capsule opacification. *J Cataract Refract Surg*. 2003;29:1613-1620.
- Mian SI, Fahim K, Marcovitch A, et al. Nd:YAG capsulotomy rates after use of the AcrySof acrylic three piece and one piece intraocular lenses. *Br J Ophthalmol*. 2005;89:1453-1457.
- Schmidbauer JM, Vargas LG, Apple DJ, et al. Evaluation of neodymium:yttrium-aluminum-garnet capsulotomies in eyes implanted with AcrySof intraocular lenses. *Ophthalmology*. 2002;109:1421-1426.
- Nishi O, Nishi K. Preventing posterior capsule opacification by creating a discontinuous sharp bend in the capsule. *J Cataract Refract Surg*. 1999;25:521-526.
- Boyce JF, Bhermi GS, Spalton DJ, El-Osta AR. Mathematical modeling of the forces between an intraocular lens and the capsule. *J Cataract Refract Surg*. 2002;28:1853-1859.
- Linnola RJ, Sund M, Ylönen R, Pihlajaniemi T. Adhesion of soluble fibronectin, laminin, and collagen type IV to intraocular lens materials. *J Cataract Refract Surg*. 1999;25:1486-1491.
- Abela-Formanek C, Amon M, Schild G, et al. Uveal and capsular biocompatibility of hydrophilic acrylic, hydrophobic acrylic, and silicone intraocular lenses. *J Cataract Refract Surg*. 2002;28:50-61.
- Abela-Formanek C, Amon M, Schauersberger J, et al. Results of hydrophilic acrylic, hydrophobic acrylic, and silicone intraocular lenses in uveitic eyes with cataract: comparison to a control group. *J Cataract Refract Surg*. 2002;28:1141-1152.