Does the apodized diffractive intraocular lens Acrysof ReSTOR Natural™ interfere with FDT Matrix perimetry results?

A lente difrativa apodizada Acrysof ReSTOR Natural™ pode interferir nos resultados da perimetria por FDT Matrix?

Karine Duarte Bojikian[1]
João Brasil Vita[2]
Catia Potira Dal Forno[3]
Alfredo Tranjan Neto[4]
Christiane Rolim de Moura[5]

ABSTRACT

Purpose: To compare the effect of an apodized diffractive intraocular lens (IOL) (Acrysof ReSTOR Natural™) and its yellow counterpart (Natural IQ™) on frequency doubling technology (FDT) perimetry results. **Methods:** This study included 37 eyes from 22 patients at the "Centro Oftalmológico Tranjan" who had undergone uncomplicated phacoemulsification and intraocular lens implantation (17 Acrysof ReSTOR Natural™, 20 Natural IQ™) performed by the same surgeon, at least three months prior to the study. Patients were subject to frequency doubling technology Matrix Perimeter testing. **Results:** The patients were between 41 to 79 years old (mean, 70.78 ± 9.83) in the Natural IQ™ and 49 to 81 years old (mean, 67.11± 11.48) in the Acrysof ReSTOR Natural™ group, and the mean IOP was 13.64 ± 2.02 mmHg in the Natural IQ™ 12.94 ± 1.39 mmHg in the Acrysof ReSTOR Natural™ group. The mean pupillary diameter under scotopic conditions was 6.63 ± 1.16 mm in the Natural IQ™ group and 7.20 ± 1.8 mm in the Acrysof ReSTOR Natural™ group (p=0.20). The mean deviation was -1.83 ± 3.46 dB in the Natural IQ™ group and -1.77 ± 3.94 dB in the Acrysof ReSTOR Natural™ group (p=0.28). The pattern standard deviation was 3.49 ± 0.79 dB in the Natural IQ™ group and 3.20 ± 0.86 dB in the Acrysof ReSTOR Natural™ group (p=0.27). **Conclusion:** There was no difference in the results of FDT Matrix perimetry in eyes that received apodized diffractive IOLs implant or eyes that received monofocal intraocular lens implant.

Keywords: Cataract; Lenses, intraocular; Perimetry; Glaucoma; Lens implantation, intraocular; Contrast sensibility; Phacoemulsification

Trabalho realizado no Departamento de Oftalmologia da Universidade Federal de São Paulo - UNIFESP - São Paulo (SP) - Brazil.

[1] Mestre pela Universidade Federal de São Paulo - UNIFESP - São Paulo (SP) - Brazil. Centro Oftalmológico Tranjan - São Paulo (SP) - Brazil.
[2] Mestre pela UNIFESP - São Paulo (SP) - Brazil. Centro Oftalmológico Tranjan - São Paulo (SP) - Brazil.
[3] Mestre pela UNIFESP - São Paulo (SP) - Brazil. Centro Oftalmológico Tranjan - São Paulo (SP) - Brazil.
[4] Mestre pela UNIFESP - São Paulo (SP) - Brasil. Centro Oftalmológico Tranjan - São Paulo (SP) - Brazil.
[5] Mestre pela UNIFESP - São Paulo (SP) - Brazil. Centro Oftalmológico Tranjan - São Paulo (SP) - Brazil.

Correspondence address: Karine Duarte Bojikian. Rua Pensilvânia, 888/83 - São Paulo (SP)
CEP 04564-002
E-mail: karine@oftalmo.epm.br

Recebido para publicação em 03.07.2009
Última versão recebida em 24.09.2009
Aprovação em 04.11.2009

Nota Editorial: Depois de concluída a análise do artigo sob sigilo editorial e com a anuência do Dr. Rui Barroso Schimiti sobre a divulgação de seu nome como revisor, agradecemos sua participação neste processo.

INTRODUCTION

Multifocal intraocular lenses (IOLs) are emerging as useful tools for cataract and refractive surgeons[1-2]. A recent addition to the market of presbyopia-correcting IOLs is Acrysof ReSTOR Natural™ (Alcon Laboratories, Inc, Fort Worth, TX), which was approved by the Food and Drug Administration (FDA) on March 21, 2005. The Acrysof ReSTOR Natural™ IOL employs both refractive and diffractive technologies. A unique feature of the ReSTOR lens is the apodized diffractive optics. Apodization refers to the gradual transition of optical properties from the center of a lens to its periphery. Specifically, apodization is the gradual tapering of diffractive steps from the center to the outside edge of the lens to create

a smooth transition between the distant, intermediate, and near focal points[3]. Previous studies have shown that although this type of IOL enhances distant and near visual acuity (VA), it may reduce contrast sensitivity[4-8].

Frequency doubling technology (FDT) perimetry is based on the frequency doubling illusion[9]. The test stimulus is a series of white and black bands that flicker at 25 Hz[10]. The FDT perimetry is thought to be mediated by a subset of large diameter ganglion cells, called MY ganglion cells, which project to the magnocellular visual pathway[11]. These cells are sensitive to motion and contrast and may be considered vulnerable to damage from glaucoma[12].

Based on this observation, FDT has been developed as a novel psychophysics test to detect early glaucoma damage. Apodized diffractive IOLs can cause contrast sensitivity changes and therefore visual field testing with FDT could theoretically be negatively influenced to some extent. Patients with apodized diffractive IOLs may develop glaucoma in the future; therefore, it is important to assess the influence of an apodized diffractive IOL on the outcome of FDT[13-15].

The aim of this study was to compare the effect of an apodized diffractive IOL (Acrysof ReSTOR Natural™) and its yellow counterpart (Natural IQ™ [Alcon Laboratories, Inc, Fort Worth, TX]) on FDT Matrix perimetry results.

METHODS

Thirty seven eyes from 22 patients that were subjected to uncomplicated phacoemulsification and IOL implantation with either Acrysof ReSTOR Natural™ or Natural IQ™ were selected. The procedures were performed by the same surgeon at least 3 months prior to this study. The study was approved by the Ethics Committee of the Federal University of São Paulo, and informed consent was obtained from each patient prior to examination. Inclusion criteria were: uncorrected VA of 20/30 and J2; no previous eye surgery; no other eye disease; normal intraocular pressure (IOP); and a normal optic disc. Patients that met the inclusion criteria were trained with the screening Matrix program 30 minutes prior to the normal 24-2 full-threshold strategy FDT perimetry (Humphrey Matrix Perimeter™, Carl Zeiss Meditec, Dublin, California) testing. The technician was not aware which kind of IOL each patient received. Both in the training exam and in the 24-2 FDT perimetry, the right eyes were usually initially tested. The pupillary diameter was measured by a technician using the Matrix Perimeter's video eye monitoring feature. The reliability criteria for the Matrix test included fixation losses less than 20%, and false-negative and false-positive responses less than 33%, according to the manufacturer's recommendation[16]. FDT Matrix exams do not require an eye patch, and trial lenses are only required beyond ± 3 diopters. Patients were not corrected when performing FDT Matrix testing because they already had a J2 of 33 cm without correction.

Statistical analysis

Pupillary diameter, mean deviation (MD), and pattern standard deviation (PSD) were compared between the two groups using the t-test corrected for interocular correlation[17]. Both eyes were included whenever possible. A $p<0.05$ was considered to be statistically significant.

RESULTS

Of the 37 eyes from the 22 patients, 20 received the Natural IQ™ IOL (8 patients received bilateral implants) and 17 received the Acrysof ReSTOR Natural™ IOL (7 patients received bilateral implants). There were 15 women and 7 men, aged 41 to 79 years old (mean, 70.78 ± 9.83) in the Natural IQ™ and 49 to 81 years old (mean, 67.11 ± 11.48) in the Acrysof ReSTOR Natural™ group (p=0.40). The mean IOP in right eyes (OD) was 13.64 ± 2.2 mmHg in the Natural IQ™ group and 12.88 ± 1.53 mmHg in the Acrysof ReSTOR Natural™ group (p=0.41) and in left eyes (OS) was 13.60 ± 1.9 mmHg in the Natural IQ™ group and 13.00 ± 1.82 mmHg in the Acrysof ReSTOR Natural™ group (p=0.27). The pupillary diameter was measured under scotopic conditions and was 6.63 ± 1.16 mm in the Natural IQ™ group and 7.20 ± 1.8 mm in the Acrysof ReSTOR Natural™ group (p=0.20). The final refractive error in the Natural IQ™ group was -0.1 ± 0.58 spherical equivalents (SE) and in the Acrysof ReSTOR Natural™ group was 0.05 ± 0.18 EE. FDT reliability indices for all patients in this study were good; fixation losses, false-negative, and false-positive findings were all less than 33%. The MD was -1.83 ± 3.46 dB in the Natural IQ™ group and -1.77 ± 3.94 dB in the Acrysof ReSTOR Natural™ group (p=0.28) (Figure 1). The PSD was 3.49 ± 0.79 dB in the Natural IQ™ group and 3.20 ± 0.86 dB in the Acrysof ReSTOR Natural™ group (p=0.27) (Figure 2).

DISCUSSION

Diffractive lenses are the only therapeutic option for overcoming the loss of accommodation following cataract surgery. The disadvantages of the multifocal strategy are primarily theoretical in nature and are attributed to the division of incoming light between several focal points. In addition, there are clinically relevant disadvantages[18-19]; for example, there is a slight reduction in sensitivity to black and white contrast, and halos arise when looking at a bright light source by night. A considerable amount of contrast sensitivity testing has been performed to determine the extent of image quality gained from multifocal implants. In most cases, only minimal impairment has been verified in relation to middle spatial frequencies, which are physiologically the most sensitive[20-22].

A new version of FDT perimetry, called Matrix, has been recently introduced into clinical practice. A recent cross-sectional study determined that Matrix provided the best diagnostic power for early glaucoma when compared with single

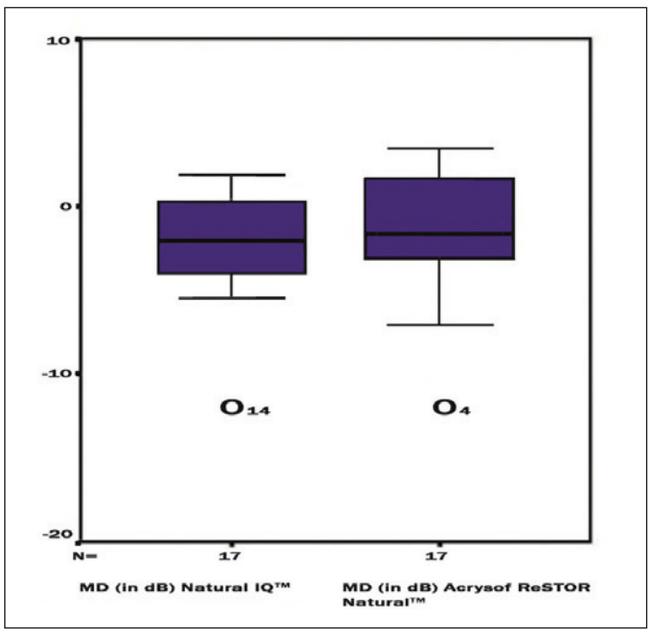

Figure 1 - MD (in dB) of eyes that received Acrysof ReSTOR Natural™ and Natural IQ™ IOLs

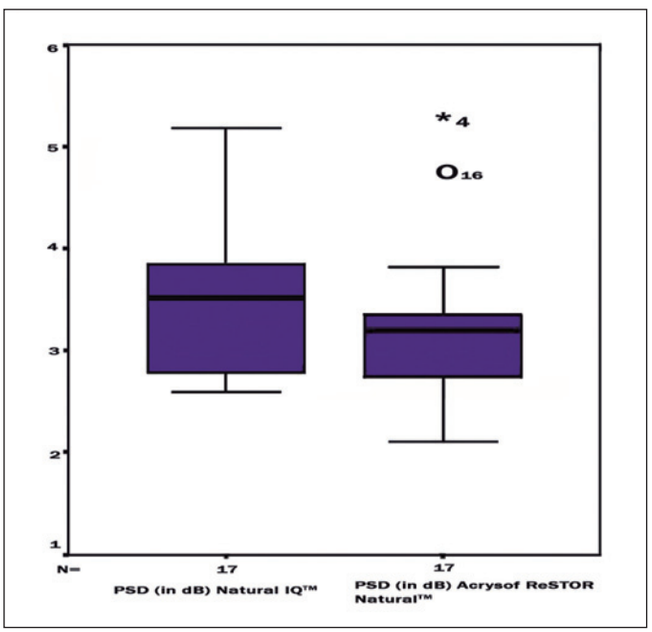

Figure 2 - PSD (in dB) of eyes that received Acrysof ReSTOR Natural™ and Natural IQ™ IOLs

morphological tests including scanning laser polarimetry, Optical Coherence Tomography, and retinal nerve fiber layer photography[23]. Previous reports have suggested that the FDT Matrix learning effect could be easily ruled-out by excluding the first test from analysis[24]. In this study, all patients were pre-trained with the Matrix screening program, and the FDT reliability indices for all patients were good.

The optical profile for the ReSTOR lens provides an equal distribution of light between the two primary images, near and far, for pupil diameters up to 3.6 mm, but as the pupil becomes larger, more of the light is directed to the far lens power. The concept here is that near tasks generally require more illumination, and the accommodative reflex enables constriction of the pupil for near tasks[3]. In this study, the mean pupillary diameter was greater than 3.6 mm in both the Acrysof ReSTOR Natural™ and Natural IQ™ groups, and this parameter did not differ significantly between the two groups.

Previous reports using FDT after cataract surgery have suggested that cataracts affect the FDT measurement, and PSD may serve well as a measure of localized abnormality irrespective of the presence of glaucoma[25-26].

Some authors studied 44 patients with normal ophthalmic examinations, with the exception of cataracts, that were scheduled to undergo phacoemulsification and posterior chamber lens implantation. All participants underwent FDT perimetry using the full-threshold C-20 strategy. Both eyes were tested 1 month before cataract surgery and for 3 months after surgery. The fellow eyes that were not surgically manipulated served as controls. The authors concluded that a cataract has an adverse effect on MD but not on PSD in FDT perimetry. The MD correlates significantly with VA in eyes that have visually significant cataracts. Following cataract surgery, the change in VA significantly correlates with the adjusted change in MD[25]. Kook et al. performed FDT threshold C20-1 and Humphrey Swedish Interactive Threshold Algorithm (SITA)-fast programs 1 month before and 2 months after phacoemulsification in 52 consecutive nonglaucomatous patients. They showed that cataract surgery, irrespective of clear or yellow IOL implantation, resulted in a significant improvement in MD but not PSD in FDT or SITA-fast. Furthermore, both MD and PSD did not differ significantly between clear and yellow IOLs[26]. Other authors studied 26 cataractous eyes in 26 patients who underwent phacoemulsification and IOL implantation. The intraoperatively IOL implanted cohort was randomly selected from clear (VA60BB, HOYA) and yellow-tinted lenses (YA60BB, HOYA). Three months postoperatively, the FDT 24-2 threshold test was performed three times. MD but not PSD had improved significantly in postoperative eyes as compared to preoperative eyes. Furthermore, there was no significant change in MD or PSD between clear and yellow IOLs. Therefore, when interpreting FDT results, the effect of cataracts must be considered, but the IOL color does not require consideration[27].

In all studies above, the authors did not observe any substantial changes in PSD after cataract surgery and IOL implantation (independent of the type of IOL), and this was similar to the results that were found herein. In our point of view, this is an important finding since increasing of PSD may be one indicator of glaucoma visual field progression, and one of the reasons that we do not implant diffractive IOLs in patients with glaucoma diagnosis is the fact that it might negatively impact the visual field result.

Some authors studied 40 eyes of 20 patients in a blue-light filtering fellow-eye controlled study. After cataract surgery, each patient received a yellow-tinted IOL (Acrysof Natural) implant in one eye and a non-yellow-tinted IOL (Acrysof SA60AT) in the fellow eye. Three months postoperatively, monocular contrast sensitivity function was measured with the CSV 1000-E contrast sensitivity chart at a distance, and color discrimination was assessed with the Farnsworth-Munsell 100 Hue test. The contrast sensitivities were similar in the eyes implanted with blue-light filtering IOLs as in the fellow eyes implanted with non-yellow-tinted IOLs. However, due to the small sample size, further studies will be required to evaluate this relationship[28]. This may be used to reinforce our results and our assumption that Acrysof ReSTOR Natural™ IOLs do not cause any contrast sensitivity changes and therefore FDT Matrix testing would not be negatively influenced by that.

In this study, the effect of an apodized diffractive IOL (Acrysof ReSTOR Natural™ and it yellow counterpart, Natural IQ™) on FDT perimetry was evaluated. There were no statistically significant differences in the MD or PSD.

No other previous study comparing the effect of an apodized diffractive IOL (Acrysof ReSTOR Natural™) on FDT Matrix perimetry came to our knowledge.

However more studies with larger samples are required to confirm these results.

ACKNOWLEDGEMENTS

The authors thank Augusto Paranhos MD for assistance with the statistical analysis.

CONCLUSIONS

Compared to monofocal IOLs, apodized diffractive IOLs do not appear to cause any difference in the results of FDT Matrix testing.

RESUMO

Objetivo: Comparar o efeito da lente difrativa apodizada (Acrysof ReSTOR Natural™) e da lente de mesma plataforma amarela (Natural IQ™) sobre os resultados da perimetria de dupla frequência (FDT). **Métodos:** O estudo incluiu 37 olhos de 22 pacientes do Centro Oftalmológico Tranjan que foram submetidos a cirurgia de facoemulsificação e implante de lentes intraoculares (17 Acrysof ReSTOR Natural™, 20 Natural IQ™) sem complicações, realizadas pelo mesmo cirurgião, pelo menos três meses antes do estudo. Pacientes foram submetidos à perimetria FDT Matrix. **Resultados:** A idade dos pacientes variou de 41 a 79 anos (média, 70,78 ± 9,83) no grupo Natural IQ™ e 49 a 81 anos (média, 67,11± 11,48) no grupo Acrysof ReSTOR Natural™ , a PIO média foi 13,64 ± 2,02 mmHg no grupo Natural IQ™ e 12,94 ± 1,39 mmHg no grupo Acrysof ReSTOR Natural™. O diâmetro pupilar sobre condições escotópicas foi 6,63 ± 1,16 mm no grupo Natural IQ™ e 7,20 ± 1,8 mm no grupo Acrysof ReSTOR Natural™ (p=0,20). O MD foi de -1,83 ± 3,46 dB no grupo Natural IQ™ e -1,77 ± 3,94 dB no grupo Acrysof ReSTOR Natural™ (p=0,28). O PSD foi de 3,49 ± 0,79 dB no grupo Natural IQ™ e 3,20 ± 0,86 dB no grupo Acrysof ReSTOR Natural™ (p=0,27). **Conclusão:** Não houve diferenças nos resultados da perimetria com FDT Matrix em olhos que receberam implante de lentes intraoculares difrativas apodizadas ou olhos que receberam LIOs monofocais.

Descritores: Catarata; Lentes intraoculares; Perimetria; Glaucoma; Implante de lentes intraoculares; Sensibilidade de contraste; Facoemulsificação

REFERENCES

1. Walkow L, Klemen UM. Patient satisfaction after implantation of diffractive designed multifocal intraocular lenses in dependence on objective parameters. Graefes Arch Clin Exp Ophthalmol. 2001;239(9):683-7.
2. Kohnen T, Allen D, Boureau C, Dublineau P, Hartmann C, Mehdorn E, et al. European multicenter study of the AcrySof ReSTOR apodized diffractive intraocular lens. Ophthalmology. 2006;113(4):584 e1.
3. Solomon R, Donnenfeld E. Refractive intraocular lenses: multifocal and phakic IOLs. Int Ophthalmol Clin. 2006;46(3):123-43.
4. Lesueur L, Gajan B, Nardin M, Chapotot E, Arne JL. [Comparison of visual results and quality of vision between two multifocal intraocular lenses. Multifocal silicone and bifocal PMMA]. J Fr Ophtalmol. 2000;23(4):355-9. French.
5. Pieh S, Weghaupt H, Skorpik C. Contrast sensitivity and glare disability with diffractive and refractive multifocal intraocular lenses. J Cataract Refract Surg. 1998;24(5):659-62.
6. Rocha KM, Chalita MR, Souza CE, Soriano ES, Freitas LL, Muccioli C, et al. Postoperative wavefront analysis and contrast sensitivity of a multifocal apodized diffractive IOL (ReSTOR) and three monofocal IOLs. J Refract Surg. 2005; 21(6):S808-12.
7. Souza CE, Muccioli C, Soriano ES, Chalita MR, Oliveira F, Freitas LL, et al. Visual performance of AcrySof ReSTOR apodized diffractive IOL: a prospective comparative trial. Am J Ophthalmol. 2006;141(5):827-32.
8. Solomon R, Donnenfeld E. Refractive Intraocular Lenses: Multifocal and Phakic IOLs. Int Ophthalmol Clin. 2006;46(3):23-143.
9. Kelly DH. Frequency doubling in visual responses. J Opt Soc Am 1966;56: 1628.
10. Alward WL. Frequency doubling technology perimetry for the detection of glaucomatous visual field loss. Am J Ophthalmol. 2000;129(3):376-8.
11. Maddess T, Goldberg I, Dobinson J, Wine S, Welsh AH, James AC. Testing for glaucoma with the spatial frequency doubling illusion. Vision Res. 1999;39(25): 4258-73.
12. Quigley HA. Neuronal death in glaucoma. Prog Retin Eye Res 1999;18(1):39-57.
13. Brusini P, Salvetat ML, Zeppieri M, Tosoni C, Parisi L, Felletti M. Visual field testing with the new Humphrey Matrix: a comparison between the FDT N-30 and Matrix N-30-F tests. Acta Ophthalmol Scand. 2006;84(3):351-6.
14. Kara-Junior N, Jardim JL, de Oliveira Leme E, Dall'Col M, Junior RS. Effect of the AcrySof Natural intraocular lens on blue-yellow perimetry. J Cataract Refract Surg. 2006;32(8):1328-30.
15. Mastropasqua L, Brusini P, Carpineto P, Ciancaglini M, Di Antonio L, Zeppieri MW, et al. Humphrey matrix frequency doubling technology perimetry and optical coherence tomography measurement of the retinal nerve fiber layer thickness in both normal and ocular hypertensive subjects. J Glaucoma. 2006; 15(4):328-35.
16. Brusini P. Frequency doubling technology staging system 2. J Glaucoma 2006; 15(4):315-20.
17. Katz J. Two eyes or one? The data analyst's dilemma. Ophthalmic Surg. 1988; 19(8):585-9.
18. Post CT Jr. Comparison of depth of focus and low-contrast acuities for monofocal versus multifocal intraocular lens patients at 1 year. Ophthalmology. 1992; 99(11):1658-63; discussion 1663-4.

19. Weghaupt H, Pieh S, Skorpik C. Visual properties of the foldable Array multifocal intraocular lens. J Cataract Refract Surg. 1996;22(suppl 2):1313-7.
20. Olsen T, Corydon L. Contrast sensitivity as a function of focus in patients with the diffractive multifocal intraocular lens. J Cataract Refract Surg. 1990;16(6):703-6.
21. Olsen T, Corydon L. Contrast sensitivity in patients with a new type of multifocal intraocular lens. J Cataract Refract Surg. 1990;16(1):42-6.
22. Pieh S, Weghaupt H, Skorpik C. Contrast sensitivity and glare disability with diffractive and refractive multifocal intraocular lenses. J Cataract Refract Surg. 1998;24(5):659-62.
23. Hong S, Ahn H, Ha SJ, Yeom HY, Seong GJ,Hong YJ. Early glaucoma detection using the Humphrey Matrix perimeter, GDx VCC, Stratus OCT, and retinal nerve fiber layer photography. Ophthalmology. 2007;114(2):210-5.
24. Centofanti, M, Fogagnolo, P, Oddone, F, Orzalesi N, Vetrugno M, Manni G, et al, Learning effect of Humphrey matrix frequency doubling technology perimetry in patients with ocular Hypertension. J Glaucoma. 2008;17(6):436-41.
25. Tanna AP, Abraham C, Lai J, Shen J. Impact of cataract on the results of frequency-doubling technology perimetry. Ophthalmology. 2004;111(8):1504-7.
26. Kook MS, Yang SJ, Kim S, Chung J, Kim SG, T, Tchah H. Effect of cataract extraction on frequency doubling technology perimetry. Am J Ophthalmol 2004;138(1):85-90.
27. Ueda T, Ota T, Yukawa E, Hara Y. Frequency doubling technology perimetry after clear and yellow intraocular lens implantation. Am J Ophthalmol. 2006; 142(2):856-8
28. Rodriguez-Galietero A, Montes-Mico R, Munoz G, Albarrán-Diego C. Comparison of contrast sensitivity and color discrimination after clear and yellow intraocular lens implantation. J Cataract Refract Surg. 2005;31(9):1736-40.