To Compare Changes in Intraocular Pressure in Glaucomatous and Non Glaucomatous Subjects Pre and Post Phacoemulsification

Akanksha Nirala¹, Vimlesh Sharma², Shanti Pandey³, Nitin Mehrotra⁴

¹Post Graduate Junior Resident 3rdyear, Ophthalmology Department, Government Medical College, Haldwani, Nainital, Uttarakhand, India

²Associate Professor, Ophthalmology Department, Government Medical College, Haldwani, Nainital, Uttarakhand, India

³Associate Professor, Ophthalmology Department, Government Medical College, Haldwani, Nainital, Uttarakhand, India

⁴Assistant Professor, Ophthalmology Department, Government Medical College, Haldwani, Nainital, Uttarakhand, India

Abstract: <u>Background and objectives</u>: Cataract and glaucoma are the first and second leading cause of blindness worldwide¹⁻³. Intraocular pressure is the only known modifiable risk factor in management of glaucoma³. This prospective observational study was done to study changes in intraocular pressure in glaucomatous and non glaucomatous eyes undergoing phacoemulsification with intraocular lens implantation. <u>Methods</u>: 75 glaucomatous and 75 non glaucomatous subjects were evaluated in the eye OPD of tertiary care centre from January 2020 to September 2021. Evaluation included assessment of intraocular pressure in the eye undergoing phacoemulsification pre and post operatively on day 1, day 7, 1 month, 3 month and 6 month along with collection of basic information like age, sex. <u>Results</u>: The mean intraocular pressure at day 1, Day 7, 1 month, 3 month and 6 month was significantly more among glaucomatous. <u>Interpretation & Conclusion</u>: Phacoemulsification results in IOP reduction. In cases of higher preoperative IOP, phacoemulsification and Intraocular lens implantation is a reliable option for IOP control.

Keywords: Cataract, Glaucoma, Intraocular pressure, Phacoemulsification

1. Introduction

Cataract and glaucoma are the first and second leading cause of blindness worldwide¹⁻³. The incidences of both cataract and elevated intra ocular pressure (IOP), with or without glaucoma, increases with age⁴. IOP is the only known modifiable risk factor in management of glaucoma³. A decrease in intraocular pressure (IOP) after cataract surgery has been reported in both glaucomatous and nonglaucomatous eyes⁵.Normal intraocular pressure, in nonglaucomatous eyes, varies in the population between 10 to 21 mm Hg.6. The widespread general belief that cataract extraction alone lowers IOP 2-4 mmHg is slowly evolving towards an understanding of a larger and more sustained IOP reduction, especially in patients with higher preoperative IOP⁷⁻⁹. Cataract surgery seems to be emerging as a safe to lower IOP in patients with mild to moderate glaucoma while avoiding morbidity of traditional glaucoma surgery¹⁰. IOP can be controlled in 20% of patients with open angle glaucoma (OAG) without drops following cataract surgery.¹¹ Although the physiological reasons for decreased IOP after cataract surgery remain speculative, the facility of out-flow is known to increase after cataract surgery.¹² The angle width does not change in normal or OAG patients after cataract surgery suggesting improved function of trabecular meshwork itself rather than improved aqueous access to the trabecular meshwork.¹³

As the eye ages the crystalline lens increases significantly in volume. This may initiate a series of anatomical changes, that ultimately leads to increase in IOP observed with aging .The lens can incur angle narrowing by pushing the

peripheral iris anteriorly, which the effect will be more marked if the lens is cataractous¹⁴⁻¹⁵.

As the lens grows, the anterior lens capsule is displaced forward causing the zonules to place anteriorly directed traction on the ciliary body and uveal tract, which in turn compresses the canal of Schlemm and trabecular meshwork, as the ciliary body is displaced forward by the enlarging lens the tendons relax and the space between trabecular plates becomes narrowed.¹⁶ Phacoemulsification typically induces low grade inflammation in the immediate postoperative period.¹⁷ This may lowers IOP by either decreasing aqueous production of ciliary body as seen in uveitis; or it could increase outflow similar to the mechanism of selective laser trabeculoplasty or prostaglandin analogues. An additional explanation is that high flow of fluid and high IOP (up to 90 mmHg) experienced during cataract surgery forces fluid through the trabecular meshwork into the canal of Schlemm and episcleral veins.^{18,19} Forcing this large amount of fluid through the drainage system may increase patency and promote flow. Again, there is little evidence to support or refute this hypothesis.

Cataract surgery is a very common and highly refined surgery with a favourable risk/benefit profile including improved visual acuity and visual field.²⁰ The widespread general belief that cataract extraction alone lowers IOP 2-4 mmHg is slowly evolving towards an understanding of a larger and more sustained IOP reduction, especially in patients with higher preoperative IOP.²¹⁻²³ Even though cataract surgery alone lowers IOP, combined cataract/glaucoma surgery lowers IOP more with fewer postoperative pressure spikes.²²⁻²⁴ Cataract surgery to lower

IOP may be especially beneficial in developing countries or where the close follow-up necessitated by traditional glaucoma surgery is difficult. Nonetheless, cataract surgery seems to be emerging as a safe to lower IOP in patients with mild to moderate glaucoma while avoiding morbidity of traditional glaucoma surgery.²⁵

The objective of this study was to evaluate the effect of phacoemulsification on intraocular pressure in glaucomatous eye and non glaucomatous eye.

2. Material and Methods

This prospective observational study was conducted according to the principles of the Declaration of Helsinki and was approved by the Institutional Ethics Committee, Government Medical College, Haldwani, Nainital (Uttarakhand) in the outpatient department of ophthalmology at tertiary care centre from January 2020 to September 2021 in which 150 subjects were included .75 patient were glaucomatous and 75 were non-glaucomatous. Intraocular pressure was measured by Goldmann applanation tonometer.

Inclusion criteria-

- 1) Patient who had phacoemulsification with posterior chamber intraocular lens implantation.
- Glaucoma patients with medically controlled open angle glaucoma (pre operative IOP <22 mm Hg under medication) attending glaucoma clinic .
- 3) Glaucoma has been diagnosed in cases where glaucomatous visual field defect matched optic disc changes.
- 4) Healthy subjects from general ophthalmology clinic. Criteria is normal anterior segment on slit lamp examination, IOP between 10 and 21 mm Hg, cup to disc ratio of <0.6, no retinal nerve fiber layer(RNFL), defects in red free RNFL photographs and no glaucomatous VF defects.
- 5) Primary angle closure suspect
- 6) Primary angle closure glaucoma

Exclusion Criteria

- 1) Primary angle closure attack
- 2) Ophthalmic disease (other than cataract) that could affect IOP
- 3) Secondary glaucoma such as lens induced glaucoma, neovascular glaucoma
- 4) Patient has undergone any non glaucoma related surgical or laser procedure such as laser capsulotomy following phacoemulsification
- 5) Patient having traumatic cataract.

3. Results

Table 1: Distribution of Mean age among study population

	Age					
	Moon	Std.	Mean	t-test	p-	
	Mean	Deviation	Change	value	value	
Glaucomatous	63.99	12.74	1.05	0.510	0 604	
Non-Glaucomatous	62.93	12.10	1.05	0.519	0.004	
Over-all	63.46	12.39				

The mean age of study population among Glaucomatous group was 63.99 ± 12.74 years, Non-Glaucomatous was 62.93 ± 12.10 years and Over-all study population was 63.46 ± 12.39 years.



Figure 2: Distribution of Mean age among study population

 Table 2: Distribution of Gender among study population

Gender	0	Total	
	Glaucomatous Non-Glaucomatous		
Male	42	38	80
	56.0%	50.7%	53.3%
Female	33	37	70
	44.0%	49.3%	46.7%
Total	75	75	150
	100.0%	100.0%	100.0%

There were 80 (53.3%) males and 70 (46.7%) females among study population.



Figure 2: Distribution of Gender among study population

Volume 11 Issue 2, February 2022 www.ijsr.net

International Journal of Science and Research (IJSR) ISSN: 2319-7064 SJIF (2020): 7.803

Gladeomatous and Non-Gladeomatous									
IOP	G	Glaucomatous		-Glaucomatous	Mean Difference	t-test value	p-value		
	Mean	Std. Deviation	Mean	Std. Deviation					
Pre-operative	14.89	3.64	13.36	2.40	1.53	3.046	0.003*		
Day 1	13.25	3.34	11.52	2.32	1.73	3.693	0.001*		
Day 7	13.17	2.94	11.59	1.91	1.59	3.916	0.001*		
1 month	13.19	2.73	11.73	1.85	1.45	3.818	0.001*		
3 months	13.04	2.69	11.61	1.78	1.43	3.829	0.001*		
6 months	12.99	2.66	11.60	1.82	1.39	3.720	0.001*		
Difference at Day 1	1.64	2.40	1.84	2.46	-0.20	-0.504	0.615		
Difference at Day 7	1.72	2.10	1.77	1.65	-0.05	-0.173	0.863		
Difference at 1 month	1.71	1.89	1.63	1.37	0.08	0.297	0.767		
Difference at 3 months	1.85	1.81	1.75	1.39	0.11	0.405	0.686		
Difference at 6 months	1.91	1.73	1.76	1.22	0.15	0.601	0.548		

Table 3: Comparison of mean IOP at pre-operatively and post-operatively Day 1, Day 7, 1 month, 3 months and 6 months, Difference at Day 1, Difference at Day 7, Difference at 1 month, Difference at 3 months and Difference at 6 months between Glaucomatous and Non-Glaucomatous

The mean IOP at pre-operatively, day 1, Day 7, 1 month, 3 months and 6 months, Difference at Day 1, Difference at Day 7, Difference at 1 month, Difference at 3 months and Difference at 6 months was compared between Glaucomatous and Non-Glaucomatous using the unpaired t-test. The mean IOP at day 1, Day 7, 1 month, 3 months and

6 months was significantly more among Glaucomatous group. There was no significant difference in mean reduction in IOP at day 1, at day 7, at 1 month, at 3 months and at 6 months between Glaucomatous and Non-Glaucomatous groups.





Volume 11 Issue 2, February 2022

<u>www.ijsr.net</u>

Licensed Under Creative Commons Attribution CC BY

International Journal of Science and Research (IJSR) ISSN: 2319-7064 SJIF (2020): 7.803



Figure 3: Comparison of mean IOP at pre-operatively and post-operatively Day 1, Day 7, 1 month, 3 months and 6 months, Difference at Day 1, Difference at Day 7, Difference at 1 month, Difference at 3 months and Difference at 6 months between Glaucomatous and Non-Glaucomatous

4. Discussion

This study was performed to evaluate if there is a change in intraocular pressure (IOP) after cataract surgery with phacoemulsification. The mean age of study population among Glaucomatous group was 63.99 ± 12.74 years, Non-Glaucomatous was 62.93 ± 12.10 years and Over-all study population was 63.46 ± 12.39 years. This was in similarity to the study by *Ali et al*,²⁶ the mean age of patients was 62.87 ± 7.90 years.

There were 53.3% males and 46.7% females among study population in the present study. This was in similarity to the study by *Ali et al*,²⁶ there were 57.89% males and 42.11% females and *Prathapan et al*,²⁷ there was predominance (51.1%)of males.

The mean IOP at day 1, Day 7, 1 month, 3 months and 6 months was significantly more among Glaucomatous group. There was no significant difference in mean reduction in IOP at day 1, at day 7, at 1 month, at 3 months and at 6 months between Glaucomatous and Non-Glaucomatous groups. Ramli et al²⁸ showed significant reduction of IOP at one week and one month afterphacoemulsification, with mean IOP reduction of 1.77 mmHg at one month postoperatively. The present findings were similar to previous studies conducted innon-glaucomatous patients, which showed a reduction in IOP between 1.26 mmHgand 2.82 mmHg.²⁹⁻³¹.Our study was similar to the findings by Sambhav K and Sasidharan A,³² the mean preoperative IOP was 14.17±3.47 mmHg and Al Anazi NM et al.,³³ the mean preoperative IOP was 14.12 mmHg. The mean postoperative IOP in the study by Sambhav K and Sasidharan A^{32} was 13.24±3.66 mmHg and in Al Anazi NM et al.,33 was 13.5 mmHg. The mean reduction in IOP after phacoemulsification in the study by Sambhav K and Sasidharan A^{32} and Al Anazi NM et al.,³³ where it was 0.93 and 0.6 mmHg, respectively.

Zamani et al^{34} observed a significant reduction in IOP in eyes with open angles and both normal or high IOP, 1 and 6 weeks after phacoemulsification and IOL implantation. IOP

reduction was proportional to preoperative IOP, i.e. the higher the preoperative IOP, the greater the reduction in postoperative IOP.Different Studies have reported that cataract extraction alone lowers IOP two to four mm Hg which correlates with our results.

A possible explanation for IOP reduction after cataract surgery in eyes with primary angle closure and narrow angles is widening of the angle and altered configuration of the ciliary body. *Nonaka et al*³⁵ found that ACD, angle opening distance at 500 microns anterior to the scleral spur and the trabecular- ciliary process distance increased significantly after cataract surgery. The authors concluded that cataract surgery attenuates anterior positioning of the ciliary processes and widens the anterior chamber angle in eyes with PACG.

A number of studies reported similar reductions in IOP after cataract surgery in patients with primary open angle glaucoma (POAG) and also in normal subjects^{36,11,13,19}. *Wang et al*³⁷suggested that phacoemulsification thins the iris and leads to smaller pupil diameters up to a year after the initial surgery. Potential mechanisms of iris thinning during routine phacoemulsification include direct trauma from the phaco probe and indirect damage to iris structures from the cavitation energy generated by the phaco tip.³⁸ While the exact effects of mechanical phacoemulsification energy on iris stroma are unknown, existing literature suggests that on a histopathological level, phaco-generated ultrasonic waves induce intracytoplasmic vacuolation within the sphincter and dilator muscles of both human and simian irises.^{39,40}

Phacoemulsification and IOL implantation reconfigures the anterior segment to its position earlier in life. By returning the anterior lens capsule to a more posterior location, the zonules exert posterior traction on the ciliary body and scleral spur. This results in expansion of the trabecular meshwork and Schlemm's canal. This expansion improves function of the trabecular meshwork and valves in Schlemm's canal. Ultimately, outflow facility increases and IOP decreases. The implanted artificial lens does not enlarge with time, hence IOP does not change postoperatively.³⁷

5. Conclusion

The mean age of study population among Glaucomatous group was 63.99 ± 12.74 years, Non-Glaucomatous was 62.93 ± 12.10 years and over-all study population was 63.46 ± 12.39 years with 53.3% males and 46.7% females.

The mean IOP at day 1, Day 7, 1 month, 3 months and 6 months was significantly more among Glaucomatous group $(14.89\pm3.64, 13.25\pm3.34, 13.17\pm2.94, 13.19\pm2.73, 13.04\pm2.69$ and 12.99 ± 2.66 respectively). There was no significant difference in mean reduction in IOP at day 1, at day 7, at 1 month, at 3 months and at 6 months between Glaucomatous $(1.64\pm2.40, 1.72\pm2.10, 1.71\pm1.89, 1.85\pm1.81$ and 1.91 ± 1.73 respectively) and Non-Glaucomatous $(1.84\pm2.46, 1.77\pm1.65, 1.63\pm1.37, 1.75\pm1.39$ and 1.76 ± 1.22 respectively) groups.

Phacoemulsification results in IOP reduction, which effect was lessened in healthy subjects and glaucoma patients over the course of a long-term follow up. In cases of higher preoperative IOP and young patients, phacoemulsification alone is a reliable option for IOP control. However, we also should consider the risk of early-phase IOP elevation and IOP failure. Above all, notwithstanding the fact that IOP reduction can be achieved after phacoemulsification in the early phase of follow up, long-term monitoring of IOP change is necessary, because the effect of IOP reduction cannot necessarily be maintained. We hope that our results will prove useful to physicians who are planning cataract management, especially for patients with glaucoma.

References

- [1] West S. Epidemiology of cataract :accomplishments over 25 years and future directions. Ophthalmic Epidemiol 2007; 14:173-8.
- [2] Quigley HA. Number of people with glaucoma worldwide. Br J Ophthalmol 1996; 80:389-93.
- [3] Babar TF, Saeed N, Masud Z, Khan MD. A two years audit of glaucoma admitted patients in Hayatabad Medical Complex Peshawar. Pak J Ophthalmol 2003; 19:32-40.
- [4] Rossetti L, Goni F, Denis P, Bengtsson B, Martinez A, Heijl A. Focusing on glaucoma progression and the clinical importance of progression rate measurement: a review. Eye (Lond) 2010;24 Suppl1:S1–S7.
- [5] Cinotti D., Fiore P.M., Maltzman B.A., Constad W.H., Cinotti A.A. Control of intraocular pressure in glaucomatous eyes after extracapsular cataract extraction with intraocular lens implantation. J Cataract Refract Surg 1998; 14:650-3.
- [6] Cibis, G., Anderson, R.E., Ferris, Fishman, L.F., Kardon, R.H., Palmberg, P. & Schmidt, D.W. Glaucoma, Lens, and Anterior Segment Trauma. American Academy of Opthalmology. San Fransisco, California.1990.
- [7] Siddiqui RMA, Khairy HA, Azuara-Blanco A. Effect of cataract extraction on SITA perimetry in patients with glaucoma. J Glaucoma. 2001; 16:205-8.
- [8] Poley BJ, Lindstrom RL, Samuelson TW. Long-term effects of phacoemulsification with intraocular lens

implantation in normotensive and ocular hypertensive eyes. J Cataract Refract Surg. 2008;34(5):735-42.

- [9] Friedman DS, Jampel HD, Lubomski LH, Kempen JH, Quigley H, Congdon N, et al.Surgical strategies for coexisting glaucoma and cataract: an evidence-based update. Ophthalmology 2002; 109:1902-13. Comment in: Ophthalmology 2004; 111:408-9.
- [10] Storr-Paulsen A, Pedersen JH, Laugesen C. A prospective study of combined phacoemulsificationtrabeculectomy versus conventional phacoemulsification in cataract patients with coexisting open angle glaucoma. Acta Ophthalmol Scand 1998; 76:696-9.
- [11] Hayashi K, Hayashi H, Nakao F, Hayashi F. Effect of cataract surgery on intraocular pressure control in glaucoma patients. J Cataract Refract Surg 2001; 27:1779-86.
- [12] Meyer MA, Savitt ML, Kopitas E. The effect of phacoemulsification on aqueous outflow facility. Ophthalmology 1997; 104:1221-7.
- [13] Hayashi K, Hayashi H, Nakao F, Hayashi F. Changes in anterior chamber angle width and depth after intraocular lens implantation in eyes with glaucoma. Ophthalmology 2000; 107:698-703.
- [14] Nomura H, Shimokata H, Ando F, Miyake Y, Kuzuya F. Age related changes in intraocular pressure in a large Japanese population: a cross-sectional and longitudinal study. Ophthalmology 1999; 106:2016-22.
- [15] Kashgarian M, Packer H, Deutsch AR, Deweese MW, Lewis PM. The frequency distribution of intraocular pressure by age and sex group. JAMA 1996; 197:611-4.
- [16] Tripathi RC. Uveoscleral drainage of aqueous humour. Exp Eye Res 1977; 25:305-8.
- [17] Dick HB, Schwenn O, Krummenauer F, Krist R, Pfeiffer N. Inflammation after sclerocorneal versus clear corneal tunnel phacoemulsification. Ophthalmology 2000; 107:241-7.
- [18] Zhao Y, Lix, Tao A, Wang J, Lu F. Intraocular pressure and calculated diastolic ocular perfusion pressure during three simulated steps of phacoemulsification in vivo. Invest Ophthalmol Vis Sci 2009; 50:2927-31. Epub 2009 Jan 24.
- [19] Khng C, Packer M, Fine IH, Hoffman RS, Moreira FB. Intraocular pressure during phacoemulsification. J Cataract Refract Surg 2006; 32:301-8.
- [20] Siddiqui RMA, Khairy HA, Azuara-Blanco A. Effect of cataract extraction on SITA perimetry in patients with glaucoma. J Glaucoma 2001; 16:205-8.
- [21] Poley BJ, Lindstrom RL, Samuelson TW. Long-term effects of phacoemulsification with intraocular lens implantation in normotensive and ocular hypertensive eyes. J Cataract Refract Surg 2008; 34:735-42.
- [22] Friedman DS, Jampel HD, Lubomski LH, Kempen JH, Quigley H, Congdon N, et al.Surgical strategies for coexisting glaucoma and cataract: an evidence-based update. Ophthalmology 2002; 109:1902-13. Comment in: Ophthalmology 2004; 111:408-9.
- [23] Vass C, Menapace R. Surgical strategies in patients with combined cataract and glaucoma. CurrOpinOphthalmol 2004; 15:61-6.
- [24] Storr-Paulsen A, Pedersen JH, Laugesen C. A prospective study of combined phacoemulsification-

Volume 11 Issue 2, February 2022

<u>www.ijsr.net</u>

Licensed Under Creative Commons Attribution CC BY

trabeculectomy versus conventional phacoemulsification in cataract patients with coexisting open angle glaucoma. Acta OphthalmolScand 1998; 76:696-9.

- [25] Berdahl JP. Cataract surgery to lower intraocular pressure. Middle East Afr J Ophthalmol 2009; 16:119-22.
- [26] AliMS,Gupta RK. Early post-operative intraocular pressure rise between phacoemulsification and phacotrabeculectomy in primary open angle glaucoma patients: a comparison. International Journal of Contemporary Medical Research. 2017;4(3):781-4.
- [27] Prathapan M, Pambavasan N, Thampi SS, Nair S, George LS, Minu Maria Mathew. Effect of Phacoemulsification on Intraocular Pressure in Cataract Patients Attending a Tertiary Care Centre in Kerala-A Retrospective Cohort Study. Journal of Clinical and Diagnostic Research. 2021;15(1):NC06-9.
- [28] Ramli N, Chan LY, Nongpiur M, Samsudin A, He M, Zahari M. Anatomic predictors of intraocular pressure change after phacoemulsification: an AS-OCT study. Malaysian Journal of Ophthalmology. 2019;1:10-22.
- [29] Huang G, Gonzalez E, Peng PH, Lee R, Leeungurasatien T, He M, et al. Anterior chamber depth, iridocorneal angle width, and intraocular pressure changes after phacoemulsification: narrow vs open iridocorneal angles. Arch Ophthalmol. 2011;129(10):1283-1290.
- [30] Huang G, Gonzalez E, Lee R, Chen YC, He M, Lin SC. Association of biometric factors with anterior chamber angle widening and intraocular pressure reduction after uneventful phacoemulsification for cataract. J Cataract Refract Surg. 2012; 38(1):108-116.
- [31] Yang HS, Lee J, Choi S. Ocular biometric parameters associated with intraocular pressure reduction after cataract surgery in normal eyes. Am J Ophthalmol. 2013;156(1):89-94 e1.
- [32] Sambhav K, Sasidharan A. Analysis of change in intraocular pressure after phacoemulsification. Sudanese Journal of Ophthalmology. 2013;5(1):7-8.
- [33] Al Anazi N. M., Musallam N.A., Gikandi P.W, Mousa A., Al Muammar A.M. and Osman E.A. Impact of Axial Length and Preoperative Intraocular Pressure on Postoperative Intraocular Pressure Changes in NonGlaucomatous Eyes Following Phacoemulsification Surgery in a University Hospital. Austin J Public Health Epidemiol. 2016;3(2):1036.
- [34] Zamani M., Feghhi M., Azarkish A. Early changes in intraocular pressure following phacoemulsification. J Ophthalmic Vis Res. 2013;8(1):25-31.
- [35] Nonaka A, Kondo T, Kikuchi M, Yamashiro K, Fujihara M, Iwawaki T, et al. Angle widening and alteration of ciliary process configuration after cataract surgery for primary angle closure. *Ophthalmology* 2006;113:437-441.
- [36] Shingleton BJ, Pasternac JJ, Hung JW, O`Donoghue MW. Three and five year changes in intraocular pressures after clear corneal phacoemulsification in open angle glaucoma patients, glaucoma suspects, and normal patients. J Glaucoma 2006;15:494-498.
- [37] Wang Q, Perez CI, Masis M, Feinstein M, Mora M, Lin SC, Hsia YC. Post-phacoemulsification iris

changes in eyes with glaucoma or glaucoma suspect status. PLoS One. 2018;13(12):e0208776.

- [38] Zacharias J. Role of cavitation in the phacoemulsification process. J Cataract Refract Surg. 2008;34(5):846-52.
- [39] Komatsu M, Uga S, Oono S, Shimizu K, Kohara M. Histopathological study of the effect of phacoemulsification-aspiration on iris muscles. Ophthalmologica. 1998; 212(3):169-74.
- [40] Komatsu M, Oono S, Shimizu K. The effects of phacoemulsification-aspiration and intra-ocular lens implantation on the pupil: Pupillographic and pharmacologic study. Ophthalmologica. 1997;211(6):332-7.