Comparison of biometric predictability and final refraction expected in phacoemulsification surgery with and without trabeculectomy

Comparação da previsibilidade biométrica e refração final esperada em cirurgia de facoemulsificação com e sem trabeculectomia

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Abstract

Objective: *The main purpose of this article is to compare the predictability of biometric results and final refractive outcomes expected in patients undergoing cataract surgery through phacoemulsification with and without associated trabeculectomy.* ***Methods:*** *Cataract patients who have undergone phacoemulsification surgery alone (control group) or associated with trabeculectomy (study group) screened. All surgeries were performed following standard protocol. For enrollment, biometrics calculated by IOL Master (Carl Zeiss Meditec, Inc.) biometry, refraction and intraocular pressure (IOP) before and after surgery were required. Data was compared between groups in addition to the correlation between variation of IOP and final refraction.* ***Results:*** *Thirty eyes per group were enrolled. Only prior IOP (p <0.001), IOP post-surgery (p = 0.01) and the difference in IOP (p <0.001) were statistically significant. Axial length, IOL diopter used, expected spherical refraction by biometrics and astigmatism pre- and post-surgery were similar in both groups (p=0.1; 0.4; 0.4; 0.5 and 0.3, respectively). Spherical predictability by biometrics within 0.25 diopters was noted in both the control group (range 0.06 ± 0.45) and study group (range 0.25 ± 0.97, p = 0.3). There was no statistical significance between groups for the difference between final cylinder and corneal astigmatism (p = 0.9), and the difference between axis of refractive and corneal astigmatism (p = 0.7).* ***Conclusion:*** *The biometric predictability in phacoemulsification surgery and the expected final refraction are significant, andare not modified by trabeculectomy in the combined surgeries.*

Keywords: *Ocular refraction; Cataract; Glaucoma; Phacoemulsification; Trabeculectomy*

Resumo

Objetivo: Comparar a previsibilidade dos resultados refracionais e da biometria em pacientes submetidos à cirurgia de catarata por facoemulsificação com e sem trabeculectomia (Trec) associada. **Métodos:** Pacientes com catarata submetidos à cirurgia de facoemulsificação isolada (grupo controle) ou associada a Trec (catarata + glaucoma, grupo estudo) foram consecutivamente selecionados. Todas as cirurgias foram feitas seguindo protocolo padrão. Para inclusão, era necessário apresentar biometria calculada pelo biômetro IOL Master (Carl Zeiss, Meditec, Inc), refração e pressão intraocular (Pio) pré e pós-operatórios. Os dados foram comparados entre os grupos, além da correlação entre a variação da Pio e a refração final. **Resultados:** Foram incluídos 30 olhos por grupo. Na comparação, apenas a Pio prévia (p<0,001), Pio pós cirurgia (p=0,01) e a diferença de Pio pré-pós cirurgia (3,8 ± 4,4mmHg vs. 15,5 ± 9,3mmHg, grupos controle e estudo, respectivamente, p<0,001) foram estatisticamente significativos. Diâmetro axial, dioptria da Lio utilizada, dioptria esperada pela biometria e astigmatismo prévio e pós- cirurgia foram estatisticamente semelhantes entre os grupos (p=0,1; 0,4; 0,4; 0,5 e 0.3, respectivamente). Notou-se previsibilidade esférica pela biometria dentro de 0,25 dioptrias, tanto no grupo controle (variação de 0,06 ± 0,45), quanto no grupo estudo (variação de 0,25 ± 0,97, p=0,3). Não houve significância estatística entre os grupos para a diferença entre o cilindro final e o astigmatismo corneano em dioptrias (p=0,9), e diferença entre o eixo do astigmatismo refracional e corneano (p=0,7). **Conclusão:** A previsibilidade biométrica e a refração na cirurgia de facoemulsificação aferida pelo biômetro IOL Master é significativa, e não sãoalteradas na cirurgia combinada com trabeculectomia.

Descritores: Refração ocular; Catarata; Glaucoma; Facoemulsificação; Trabeculectomia

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The authors declare no conflict of interests.
Received for publication 03/07/2017 - Accepted for publication 21/10/2017.

Introduction

The association of cataract with glaucoma is frequent.[1] Ocular hypotensive medication and reduced intraocular pressure (IOP) can also be identified as inducers of cataract in patients with glaucoma.[2-3]

For a safer surgerywithcombined procedures involving phacoemulsification and trabeculectomy (TRAB), with a more diffuse bleb with thicker walls, one of the modifications suggested in the original technique, among others, was toincreasing the size of the scleral flap.[4] This change may cause astigmatism on the incision site to increase the corneal meridian in this position and allow the flow of aqueous humor towards the filtering bleb. On the other hand, tighter scleral flap or conjunctival sutures could also induce astigmatism, increasing the curvature of the corneal axis. In addition, it is possible that reduction of IOP to safe considered levels in TRAB could coincide with a decrease in the anterior-posterior ocular diameter, which can be theoretically more pronounced when higher levels of IOP are found preoperatively in relation to the final IOP.

These confounding factors could affect the predictability of biometry to artificially modify two important variables in the formulas used, keratometry and ocular axial length, making it possible to assume the need for prior correction. [5-6] This study aims to compare the predictability of biometric results and final refractive outcomes expected in patients undergoing cataract surgery through phacoemulsification with andwithout associated trabeculectomy.

Methods

The study was conducted after approval by the Research Ethics Committee of the Federal University of Goiás (UFG) and VER Hospital. One or both eyes of all patients who underwent cataract surgery,by phacoemulsification associated with TRAB (study group) or phacoemulsification only(control group) performed by the same experienced surgeon (LM), were consecutively screened, from January 2013. The study aimed to enroll 30 eyes per group, in accordance with predetermined criteria and matched by type of IOL.

The inclusion criteria for both groups were: patients of both sexes, one or both eyes with cataract and spectacle-corrected visual acuity (SCVA) of 20/40 or less, and inadvertent phacoemulsification with IOL implantation within the capsular bag. In the control group, patients were required to have IOP <21 mmHg and an examination with no signs of glaucoma.[7] In the study group, the recommendation of filtration surgery, which also should have been performed without any problem, occurred when the target intraocular pressure was not achieved even with the use of ocular hypotensive agents, when the patient had been on three ocular hypotensive medications or, in case of severe glaucoma, on two medications. Furthermore, IOP reduction of at least 30% without using ocular hypotensive medication was required for inclusion in the study group.

Patients were excluded if they had irregular astigmatism in the computerized corneal keratometry, pterygium, prior anterior and/or posterior segment surgery, any corneal pathology that could affect the accuracy of biometry, absence of IOL Master biometry, and amblyopia. Any intraoperative complications, such as posterior capsule rupture or vitreous loss during any procedure, was considered an exclusion factor.

Pre and postoperative routine consisted of medical historicaland complete eye examination, including best corrected visual acuity, biomicroscopy, applanation tonometry with the same calibrated Goldmann tonometer, gonioscopy with Goldmann4-mirrorlens in the glaucoma group, ophthalmoscopy, corneal keratometry (Orbscan, Baush& Lomb, Inc. San Dimas CA, USA), specular microscopy (Topcon Medical Systems, Oakland, NJ), ultrasound (Alcon Ultra scan, Fort Worth, TX, USA) and optical biometry (IOLMaster, Carl-Zeiss Meditec, Germany). According to the axial length, the following formulas were used in the biometry: Hoffer-Q if ≤22 mm, Holladay I if >22 mm and ≤24.50 mm and SRK-T if >24.50 mm. Clinical examinations were performed by the same surgeon. Complementary examinations were performed by an experienced technician, except for ultrasound, which was performed by a certified ophthalmologist.

All phacoemulsification surgeries were performed with the "Phaco-Chop" technique and Infiniti phacoemulsification system (AlconLabs, Fort Worth, TX, USA) under topical anesthesia.[8]The phacoemulsification incision was performed on the 140o axis in all patients with a disposable 2.2-mm scalpel and paracentesis with a 15º disposable scalpel on the 20º axis. The postoperative regimen in these patients consisted of a combination of Moxifloxacin and Dexamethasone (Vigadexa®), Alcon Labs, Fort Worth, TX, USA) QID and nepafenac 0.1% (Nevanac®, Alcon Labs, Fort Worth, TX , USA) TID for 15 days.

For the study group, the axis of phacoemulsification incisions was always the same (140o), with the glaucoma surgery being performed in the upper nasal quadrant of the right eye and in the superior temporal quadrant of the left eye, about 90° away from the phacoemulsification incision. The combined surgeries were performed under peribulbar anesthesia.

TRAB was performed with fornix-based conjunctival opening, light cauterization of any bleeding spots, marking the scleral flap with a disposable 11-blade (Feather Safety Razor, Ohyodo-Minami, Japan) measuring about 4 mm horizontally by 3 mm vertically and application of mitomycin C 0.4 mg/ml for 2 minutes using 3 parts of a Merocel sponge soaked in adjuvant, two placed on the bottom area of the bag, and one extended to the delineated flap. Then, flushingoff the area with about 2-3 ml of BSS and dissection of the scleral flap with the same 11-blade towards the corneal limbus to about 1 mm was performed. Phaco-Chop phacoemulsification was then performed, followed by penetration into the anterior chamber with a 2.2-mm blade, centrally on the flap. Removal of trabecular tissue was performed using the Kelly-Descemet Punch with 0.75 mm measurement and iridectomy with the use of Vannas scissors. The scleral flap was sutured with two fixed stitches about 45° lateral to the scleral flap edge with 10-0 mononylon tightened to the desired filtration. A third central point, 90° of the scleral incision, was to be performed if the filtration was in excess. Then the conjunctiva/tenon was closed using 10-0 Nylon, two-side stitches tightening the incision and a central stitch in "U".

The stitches from the scleral flap could be removed with Diode laser and Hoskins lens according to the postoperative need of IOP reduction, from the third day after surgeryon, and was not considered a complication. The three external stitches were removed as they were loosening, causing discomfort to the patient after at least seven days following surgery or thirty days after surgery. Postoperative regimen in the study group included the use of Prednisolone 1% eye drops (Predfort®, Allergan Labs, Irvine, CA, USA) every two hours, with weekly reduction, for six weeks, gatifloxacin 0.5% eye drops (Zymar XD®, Labs Allergan, Irvine, CA) every twelve hours for ten days and Ketorolac trometamol 0.45% eye drops (Acular CMC®, Labs Allergan, Irvine, CA, USA) every twelvehours for twenty days.

The IOP used for calculation purposes was assessed on the same day the refraction was performed, after at least forty-fivedays for patients in the study group and at least thirty days for patients in the control group.

All statistical tests were performed with SPSS 15.0 (SPSS Inc, Chicago, IL, USA). The unpaired Student t-test was used when comparing pairs. Correlation between IOP variation and refraction found was performed with Pearson's Correlation. In this study, p values <0.05 were considered statistically significant.

Results

Eighteen patients (30 eyes) in the control group (10 women, 15 right eye, 15 left eye) and 20 patients (30 eyes) in the study group (12 men, 18 right eye, 12 left eye) were enrolled. The mean age was 70.9 ± 5.9 years-oldfor the control group and 66.6 ± 7.4 years-oldfor the study group, p = 0.01. There was a similar distribution of IOL types implanted between groups (p = 1.0) (Table 1).

Patients in the study group decreased the number of ocular hypotensive medications preoperatively from 2.2 ± 0.8 to 0.05 ± 0.3 in the last postoperative assessment (p <0.001). Suture lysis of the scleral flap was required in thirteen eyes, 1 suture lysis in 10 eyes, two suture lysis (2 stitches) in 2 eyes and 3 suture lysis (3 stitches) in one eye. Preoperative spectacle-corrected visual acuity (SCVA) (LogMAR) was 0.4 ± 0.2 for the control group and 0.4 ± 0.3 for the study group (p = 0.9), and the postoperative one was 0.1 ± 0.3 and 0.2 ± 0.3, respectively (p = 0.2).

There was no statistically significant difference between characteristics of the groups studied, except for pre-surgery IOP (p <0.001), post-surgery IOP (p=0.01) and difference in pre- vs. post-surgery IOP (3.8 ± 4.4 mmHg vs. 15.5 ± 9.3 mmHg, control and study groups, respectively; p <0.001). Axial length, IOL diopter used, expected spherical refraction by biometry and astigmatism pre- and post-surgery were similar between groups (Table 2).

Table 1
IOL used for each group (p=1.0)

	Acrysof IQ	Akreos MI	B-Lens	Envista	Tecnis ZCB00	Total
Control Group	2	6	4	1	17	30
Study Group	2	6	4	2	16	30
Total	**4**	**12**	**8**	**3**	**33**	**60**

. IOL used for each group (p=1.0)

Table 2
Comparison between groups (Control Group; Study Group).

		Control Group n=30	Study Group n=30	"p"(between groups)
Preoperative IOP (mmHg)	Average	15.5	25.2	<0.001
	Standard Deviation	4.2	9.1	
Postoperative IOP (mmHg)	Average	11.7	9.7	0.01
	Standard Deviation	2.4	3.5	
Spherical Refraction	Average	-0.12	-0.14	0.85
Expected by Biometry (D)	Standard Deviation	0.41	0.43	
Final Spherical Refraction (D)	Average	-0.05	0.1	-0.42
	Standard Deviation	0.6	0.9	
Final Cylinder Refraction (D)	Average	-0.9	-1.05	0.37
	Standard Deviation	0.5	0.7	
K2 - K1 (D)	Average	-0.99	-1.14	0.5
	Standard Deviation	0.7	0.9	
Final Cylinder Axis (°)	Average	97.15	111.93	0.22
	Standard Deviation	44.4	49.1	
Corneal Astigmatism Axis (°)	Average	94.5	104.23	0.49
	Standard Deviation	51.5	57.8	
K1 (D)	Average	43.51	42.78	0.04
	Standard Deviation	1.5	1.5	
K2 (D)	Average	44.51	43.92	0.11
	Standard Deviation	1.6	1.6	
Axial length – AL (mm)	Average	23.16	23.58	0,1
	Standard Deviation	1	1.1	
IOL diopter used	Average	22.31	21.81	0,4
	Standard Deviation	2.4	2.8	

Comparison between groups (Control Group; Study Group).

Pre-corneal mean astigmatism (as measured by IOL Master) in the control group was -0.99 ± 0.78 D and -1.14 ± 0.93D in the study group, p= 0.5. Time between surgery and refraction was 71.5 ± 70.0 days for the control group and 59.9 ± 35.6 days for the study group, p= 0.4.

Spherical predictability for biometry within 0.25 diopters was noted in both the control group (0.06 ± 0.45) and the study group (0.25 ± 0.97, p = 0.3). There was no statistical significance between groups for the difference between final measured cylinder and corneal astigmatism in diopters (0.09 ± 0.7 vs. 0.09 ± 1.2, p = 0.9), and the difference between the refrationalaxis and pre-corneal astigmatism (2.6 ± 49.2º vs. 7.7 ± 66.3º, p = 0.7). The change in IOP after surgery was neithercorrelated with the spherical nor cylindrical difference found (r = 0.242, p = 0.06, r = -0.075, p = 0.5, respectively), northe variation of the astigmatic axis (r = 0.089, p = 0.5) (Figure1).

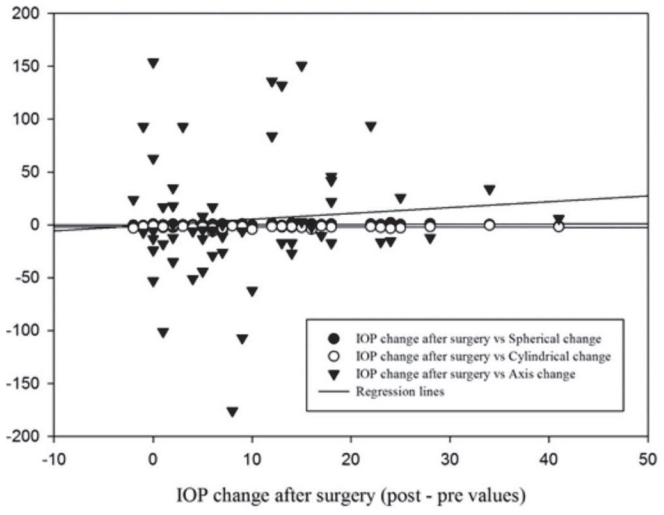

Figure 1: Correlation between change in IOP after surgery and the spherical or cylindrical difference found, or variation of the astigmatic axis.

Discussion

These results showed a statistically significant reduction of IOP for the patient group undergoing a combined surgery of phacoemulsification and TRAB. Control group had lower IOP reduction compared to the study group. These findings support what is found in literature, i.e. phacotrabeculectomy(PHACO-TRAB) results in lower average IOP compared to phacoemulsification alone in patients with glaucoma.[9-10] Additionally, patients undergoing PHACO-TRAB had a reduced need to use ocular hypotensive medication postoperatively within a short follow-up period. These data supports the study group in evaluating the influence of TRAB, and as a result, the influence of the higher IOP reduction in biometric calculation for patients undergoing PHACO-TRAB.

For combined surgeries, separate incision technique was used. This technique is easily reproduced, widely used and has good postoperative results, which is believed to induce less astigmatism. In single site surgeries, the movement of the phacoemulsification tip, and the heat emanating from it could alter the incision architectureand thus, induce astigmatism. Compared to single site surgery another bias would be that patients in the control group would have a corneal incision not performed in the study group, leading to a potential cause of variation in the corneal axis. For both groups, corneal incision during cataract surgery was performed in the same location and with the same dimensionsthus, neutralizing this factor. Therefore, only the influence of TRAB and the greater IOP reduction in the final results were checked for any differences found.

A decrease in axial length was shown by combined surgeries and TRAB only, however, it did not influence the expected spherical refraction provided by biometry.[11] The axial length variation was not subject to preoperative and postoperative comparison, since biometry was performed only before surgery. This can be considered as a limitation, or at least as a relative one. However, the objective of this study was the biometric predictability in relation to final refraction, so that this method, although subjective, was adopted as the standard for final comparison.

Although several corneal astigmatism evaluation methods are available, it is believed that the measurements obtained with IOL Master may be a significant representation of corneal astigmatism, therefore, it was used for this preoperative measurement. Since the goal of the study was to assess the expected refraction, a new keratometry measurement was not made; only the refractive astigmatism assessment was performed, and the data was used for both groups. Although the use of third generation formulas in the IOL calculation may be considered a weakness of the study, both groups used the same protocol to perform it thus, avoiding an inclusion bias. Additionally, the final spherical refraction was low and it was estimated preoperatively with high precision by IOL Master in the control group.

A previous paper showed a 0.44D induction of with-the-rule astigmatism[11], different from induced against-the-rule astigmatism in this study. This difference could be explained by the technique used, corneal suturing with phacoemulsification incision in the combined surgeries, associating the continuous sutures of the conjunctival flap, which may induce flattening of the vertical meridian of the cornea.

Studies on induction of corneal astigmatism after PHACO-TRAB and the comparison between them are limited due to the different surgical techniques used. Tzu et al reported a higher corneal induced astigmatism in combined surgery compared to PHACO only; in average 1.31 D of corneal astigmatism was induced by combined surgery.[12]There are reports suggesting that these corneal topography changes evolve in about 12 months. However, other authors have illustrated a stable keratometry postoperatively after about 2 months.[13] Thus, it is believed that the time taken to carry out the final calculations did not influence the results. However, it is possible that some modifications can be made after a few months.

In this study, the control group showed similar spherical results (0.06 ±0.4D) as estimated by biometry. In the study group, a small myopic tendency (-0.25D) was demonstrated, probably caused by the reduction in axial length when performing IOP control. Thus, a possible desired correction of the spherical refraction regarding biometry results can be suggested, as reported by Jonathan et al. who found a greater myopic value (-0.5D) for the group undergoing combined PHACO-TRAB surgery. However, in their analysis, surgeries were performed by different surgeons with no single surgery technique described for comparison, and therefore it was not homogeneous. Despite a slightly less precise predictability compared to this study, 74% of refractions were

obtained within the planned range regardless of possible changes induced by errors in keratometric readings, axial length and value of selected lenses.[14] Recently, other authors found a myopic tendency in the group undergoing combined PHACO-TRAB surgery, but with only 27.6% of patients achieving final subjective refraction within ±0.5D. [15] Differences in the surgery technique may be responsible for this difference.

The described surgery seeks to avoid excessive loosening of the sutures, which would cause an increase in corneal curvature in the meridian of TRAB and cylindrical axis, or excessive strain leading to the opposite, flattening and against-the-rule astigmatism. Apparently, tighter stitches could lead to increased IOP, and hence would be removed. On the other hand, sutures too loose would lead to hypotonia and consequent exclusion from the study, a fact that was not noted. Thus, it is possible to assume that this "ideal strain" apparently does not alter the astigmatism values which could be induced in surgery.

Another factor of potential cylindrical induction is conjunctival stitches, which can alter the symmetry of the eye, especially if pinching the cornea, or even with increased tension. However, a small variation of the final cylinder axis was found in relation to the preoperative corneal astigmatism axis, for both control group and study group, as well as a slight variation in the average location of the cylindrical end shaft, and the K2-K1 difference.

El-Saied et al.[13] found a prevalence of with-the-rule astigmatism in TRAB only. However, some differences in the surgical technique used by them compared to the current study may explain this difference, such as the change of TRAB location (at 110º in right eye and 70º in left eye), leading to force vectors at different locations within the eye, creating a bias for comparison when both eyes are evaluated. In this study, regardless of the eye included, TRAB was always performed on the same meridian, about 90° from the phacoemulsification incision, which was always performed at the 140° axis. Furthermore, as previously mentioned, induction of against-the-rule astigmatism is generally expected in these combined procedures.[13-16]

IOP variation after surgery was not correlated with the spherical or cylindrical differences found. Law et al. obtained a statistically significant relationship between change in the axial length of eyes that underwent combined surgeries (PHACO-TRAB) and IOP postoperatively.[11] On the other hand, reduction of the axial length was not correlated with reduction of IOP. Thus, despite a large IOP reduction in patients with glaucoma, a slight decrease of the axial diameter occurred, culminating in a spherical error of about -0.25D compared to what was expected. In addition, as noted by a small standard deviation, the final IOP was similar, which apparently homogenized the patients in terms of axial length variation, reducing or even avoiding a bias if patients had been evaluated with different levels of IOP reduction. However, a larger number of patients, evaluation of results with different surgeons to check the "surgeon factor", and longer patient follow-up are still needed.

The biometric predictability in phacoemulsification surgery and the expected final refraction are significant, and not influenced by trabeculectomy in the combined surgeries. These findings suggest a compensation of -0.25D in the IOL used when calculated by IOL Master in patients undergoing combined surgeries of PHACO-TRAB to get to postoperative spherical emmetropia.

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