Research Article

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Evaluation of Satisfaction in Patients Submitted to the Surgery of Phacoemulsification and Implant of Multifocal Intraocular Lens

Ayrton Roberto Branco Ramos^{*}, Aline Sudoski and Débora Zanatta

*Corresponding author Ayrton Roberto Branco Ramos, Hospital Governador Celso Ramos, Brazil

Hospital Governador Celso Ramos, Brazil

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Abstract

Introduction: Cataract surgery with intraocular multifocal lens (IOML) implant allows visual recovery for different distances, regardless of the use of external correction, despiteits undesirable effects. The visual function has impact on quality of life, as on the ability to perform daily activities and on the patient satisfaction.

Objectives: Evaluate satisfaction and quality of vision in patients who underwent phacoemulsification surgery with implant of multifocal intraocular lens, even with the eyewear independence and with the presence of adverse effects.

Methods: An observational, descriptive and retrospective study was carried out with patients undergoing phacoemulsification surgery with IOML implantation at a private clinic in Florianópolis (Brazil) from January 2009 to December 2015. Objective data were collected from electronic medical records and the questionnaire "TyPEqustionnaire" was completed for subjective analysis, through telephone calls. Afterwards, the data were submitted to descriptive statistical analysis and the corresponding variables were correlated through the Pearson chi-square test, with a significance level of p < 0.05 being considered.

Results: A total of 436 cataract surgeries were performed with IOML implantation in 223 patients. Ninety-nine patients were excluded either because they did not complete the inclusion criteria list or because of the impossibility of being reached by telephone contact. Thus, 124 patients effectively participated in the study. There was a higher prevalence of women (79%), and a non-toric aspheric lens implant (65%). The average age was 64 years and all patients were residents in the Santa Catarina state. The mean score for far distance vision was 8.35; for intermediate distance vision was 8.43 and for near distance vision was 7.87; at a rate from 0 to 10, being equivalent to unsatisfactory and very satisfied visual acuity, respectively. Glare was reported in 44,30% of patients, halos during the day were verified in 20,60% of the sample and halo-related complaint at night in 35,48% of the patients.

Conclusion: In the final assessment of the questionnaire it was found that the patients were satisfied with the visual acuity after IOML implant. There was a moderate incidence of undesirable photopic effects and little dependence on glasses. IOML may be a good choice when immersed in real expectation for patients who want vision improvement without eyewear. In addition, the good relationship between surgeon and patient and the informed consent about the procedure are very important to the patient's satisfaction with the final visual result as well.

Keywords: Cataract, Multifocal intraocular lens, Presbyopia, Visual satisfaction

Introduction

Crystalline is a biconvex and transparent structure that composes one part of natural lenses of the human eye. This structure gains variable refractive ability with ciliary muscle help, being able to adjustments in its thickness according to the distance of the focused object, mechanism called accommodation. The contraction of the muscle provides increased crystalline curvature, which makes larger dioptric power of the visual system and allow near vision [1,2,3]. Age progression is inversely related to lens elasticity and contraction capacity of the ciliary muscle, progressively impairing vision up to total presbyopia [2,3].

Not only, but often associated with aging, the pathological loss of lens transparency, denominated cataract has been observed. This is the leading cause of visual impairment in Latin America, and ranks second in the world. Data from the World Health Organization (WHO) 2012 estimate that the disease represents 33% of the causes of vision deficits in the world, reaching more than 50% in less favored regions economically [4].

In Brazil it is estimated that prevalence of blindness due to cataract is approximately 350,000. It is conjectured that 120,000 new cases occur per year, with variations due to socioeconomic conditions and the repressed demand resulting from population aging [4].

The improvement of the surgical techniques, as well as the evolution of intraocular lenses, provide alternatives to correct two above mentioned diseases - cataract and presbyopia - upon the same procedure. At present, good view for different distances, without glasses dependence, can be obtained through implants of bifocal, trifocal or multifocal lenses after phacoemulsification surgery [1,2,5].

Current technology of multifocal intraocular lenses (LIOM) provides better results in optical and refractive quality. The base model of some of these lenses uses pupillary dynamics as a reference. From this concept we obtain a disposition of the lens with central design for near vision (convergence miosis) and periphery for distant vision (mydriasis). The disadvantage of this model is that the distance correction is lost when in intense illumination, consequent to the activation of the physiological reflex of pupillary sphincter contraction [3,6,7].

As an alternative, some models have lenses with far and near optical zones varying successively. This lens uses a set of circular rings to divide light into two focus, approximately 40% away (projected directly on the foveal), 40% for close (1.0mm in front of the foveal) and the remainder are lost in light diffraction. The interaction between geometric optics and optical diffraction acts on the multifocality effect.

Despite the excellent technology, photopic phenomena can be generated by the overlapping of images, such as decrease image quality, lower contrast sensitivity and halo or glare perception. These are factors that can lead to dissatisfaction felt by some patients [8].

Cataract surgery with LIOM implantation is effective, resulting in almost immediate rehabilitation of vision, even without the use of optical correction. However, some studies have shown an ideal time, not precisely estimated, for adequate cortical neuroadaptation to occurs, due to the different visual information provided by LIOM. Lubinski, et al. who found no difference in the degree of overall patient satisfaction assessed at 3 and 12 months after the procedure. However, the frequency and severity of the side optical effects decreased in this same time evolution [9,10].

Objective

The objective of the present study was to analyze the level of satisfaction and quality of vision in patients who underwent phacoemulsification surgery with multifocal intraocular lens implantation.

The study also included evaluation of subjective data as judgment of the patient about quality of vision achieved at different distances (near, intermediate and far), percentage of glasses and side effects.

Methods

A cross-sectional, descriptive, retrospective and qualitative-based observational study.

The patients selected for the study were treated at a private clinic in Florianópolis (Brazil) and underwent cataract surgery using the phacoemulsification technique with multifocal intraocular lens implantation by a single surgeon from January 2009 to December 2015.

Objective data collection was done by the researchers, after patients selection through the lens identification card, and subsequent electronic records check, which included information about the preoperative ophthalmologic examination, as well as follow-up visits after the procedure.

After this first evaluation, the patients were submitted to the modified and validated "TyPEquestionnaire", developed specifically to evaluate quality of life after cataract surgery and adapted to LIOM. This questionnaire evaluates 10 functional items with 18 questions. The level of satisfaction was scored from 0 to 10 (0 unsatisfied, 5 neutral and 10 very satisfied), being the interpretation exclusive on each patient [10]. The questionnaire was filled out exclusively through telephone contact.

Results were structured in a database, using the software "Excel 2007". Qualitative variables were grouped according to the evaluation score within the own requirements, making them quantitative results in each specific segment previously established. Data were analyzed by statistical analysis. Significance tests (Qui Square de Pearson) and tests of correlations between the variables (Pearson correlation and contingency) were performed. The program used was IBM SPSS Statistics 19. All probabilities of significance (p-values) of less than 0.05 were considered statistically significant. The correlation between all the topics studied expressed the analogy between them. The strength of this association quantified how consistent these data interposed (ranging from +1: very strong to -1: very weak), while the direction showed proportionality between them or the inverse.

The lens used in all patients was Alcon AcrySof Restor[®], which is a pupil-dependent LIOM. Its anterior central surface has 3.6 mm with 12 diffractive optical zones, continued to periphery by a refractive surface. The models varied according to the addition and presence of astigmatism [7,10-12].

The established variables for analysis in this study were: sex, age, origin, occupation, schooling, LIOM model, addition, visual satisfaction at various distances and presence of unwanted photopic effect.

patients with previous ocular surgery, monocular IOL implantation, systemic alterations that could alter postoperative scarring, ocular disease that could alter visual acuity or contraindicate surgery (herpetic ocular disease, (Eg: dry eye, uveitis, glaucoma and retinal diseases), lack of collaboration to perform exams and / or surgery, intraoperative complications, reinterventions (lens exchange, refractive surgery for grade refinement or postoperative vitrectomy) were excluded.

Results

A total of 2118 eyes, whose lens cards were cataloged, underwent cataract surgery between 2009 and 2015 in the study clinic. Of these, 436 were submitted to LIOM.

Thus, 223 patients were initially selected for chart analysis. Of these, 99 patients were excluded, because 55 belonged to the previously determined exclusion criteria and 44 could not be reached by telephone contact (Table1).

riteria for the study or were not able to be reached by telephone contact									
	2009	2010	2011	2012	2013	2014	2015	Total	
Lost call	7	8	10	6	8	3	2	44	
PPV	8	5	4	10	2	4	1	34	
PRK	0	0	0	0	1	2	1	4	
Death	1	0	1	0	0	1	0	3	
Glaucoma	0	0	0	0	1	0	0	1	
Ozurdex	0	0	1	0	0	0	0	1	
Anti-VEGF	0	0	1	0	0	0	1	2	
Single eye	3	3	1	2	0	0	1	10	
Total	19	16	18	18	12	10	6	99	

Table 1: Distribution of patients submitted to phacoemulsification surgery with LIOM implantation who didn't present inclusion
criteria for the study or were not able to be reached by telephone contact

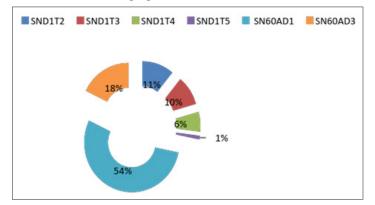
PRK: Photorefractive Keratectomy; PPV: Pars plana vitrectomy; Anti-VEGF: Anti-vascular endothelial growth factor therapy.

Effective sample of 124 patient, 98 women and 26 men, at a mean age of 64.65 years \pm 8.76, 47 were the youngest patient and 81 the oldest.

All of them lived in Santa Catarina (Brazilian state), the majority (60.5%) coming from Florianópolis (Brazilian city). Forty-seven (37.90%) reported being professionally active, 53 (42.74%) retired and 24 (19.4%) housewife/househusband.

Regarding the type of AcrySof Restor lens, 102 people implanted the SN6AD1 model, with additional central dioptric power of +3.00D and 22 the SN60AD3 model with addition of +4.00D (Graph 1). There was an inverse relationship between distance satisfaction and the addition chosen (Correlation -0.210 and p =0.020), and patients with a lower addition gave higher scores for distance satisfaction, showing greater satisfaction for this distance. No significant association was observed for intermediate and near distances.

In eighty-one patients (65.32%) the implant was bilateral with non-aspheric and 30 (24%) bilateral aspherical lenses. Thirteen patients (10.48%) had an implant with both options. The biometric mean was +22.00, ranging from +15.50 to + 29.50.



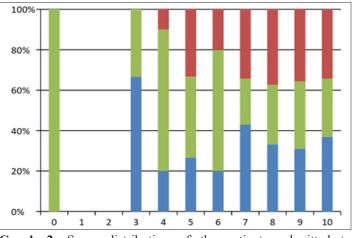
Graph 1: Percentage distribution of patients submitted to phacoemulsification surgery with LIOM implant according to the specific model of the lens used

In relation to satisfaction, an average score of 8.21 was scored for the set of distances evaluated, according to the grouping of general scores.

The distant view presented a final score of 8.35 ± 1.71 , and was stratified in 111 patients (approximately 90%) score 6 or higher, of which 41 evaluated (33%) described their visual condition as very satisfactory (Equivalence 10).

In relation to the intermediate view, they presented 8.43 ± 1.54 final points. One hundred and twelve patients (91%) reported visual satisfaction equal to or better than 6 points, of which 38 patients (30.6%) scored the highest mark (10).

A general note for near vision was 7.87 ± 2.05 , in which 95 patients (77%) determined score 6 or greater and 32 patients (25.8%) reported as very satisfied. One patient (1.24%) scored zero, defining their vision as very unsatisfactory (Graph 2, Table 2).



Graph 2: Score distribution of the patients submitted to phacoemulsification surgery with LIOM implant referring to visual quality at different distances ((far (blue line), intermediate (red line) and near (green line))

Score	Distant	Intermediate	Near View	
0	0 (0%)	0 (0%)	1(0,8%)	
1	0 (0%)	0 (0%)	0 (0%)	
2	0 (0%)	0 (0%)	0 (0%)	
3	2 (1,6%)	0 (0%)	1 (0,8%)	
4	2 (1,6%)	1 (0,8%)	7 (5,6%)	
5	8 (6,5%)	10 (8,1%)	12 (9,7%)	
6	4 (3,2%)	4 (3,2%)	12 (9,7%)	
7	15 (12,1%)	12 (9,7%)	8 (6,5%)	
8	25 (20,2%)	28 (22,6%)	22 (17,7%)	
9	27 (21,8%)	31 (25%)	29 (23,4%)	
10	41 (33,1%)	38 (30,6%)	32 (25,8%)	

Table 2: Disposition of patients underwent phacoemulsification surgery with LIOM implant and their respective percentage in relation to satisfaction score and visual distance

Ninety-eight patients (79%) reported eyewear independence from distant and near distance, 22 (17.7%) used it for reading and/or computer activities, and 4 (3.2%) reported total dependence (all activities).

Seventy-one patients (57.2%) reported that they would not perform surgery only as a refractive method, without associated cataract, and 17 of them (13.7%) would not suggest their friends this lens model as a good option. An inversely proportional association was observed between the patient's age and his propensity to recommend LIOM. In the same way, when older, the smaller the acceptance of LIOM implant as correction only for refractive purposes. Regarding the undesired optical effects, the most prevalent was the glare with 55 patients (44.3%) complaining. Interpreted as visual glare due to high intensity lights, it was classified as little (without difficulty) in 14 patients (25.45%), moderate (adapted) in 30 patients (54.54%) and severe (with damage) in 9 patients (16.36%). The second adverse effect observed in frequency was halos at night, an optical phenomenon consisting of the formation of rings around the lights, reported by 44 patients (35.48%) questioned. It was defined as little (without difficulty) by 15 patients (34.09%), moderate (adapted) by 20 patients (45.45%) and severe (with impairment) by 9 patients (20.45%). The least incident complaint was halos during the day, with only 25 patients scoring (20.16%) such symptom. Eleven operated (44%) inferred the adverse effect as mild (without difficulty), 10 patients (40%) as moderate and 4 patients (16%) as severe (with impairment).

Referring to the above-mentioned reports, when the undesirable effects were moderate 3 patients (2.41%) would accept the change LIOM to monofocal lens even if they re-depended on eyewear, as well as 3 patients (2.41%) who reported having severe symptoms and 2 patients (1.61%) who reported dissatisfaction with the lens because of poor overall quality of vision. The other patients reported that they became accustomed to the symptoms or considered that the lack of eyeglasses exceeded the adverse effects dysphotopia.

It was also observed that, the greater the patient satisfaction operated on his or her vision condition, the less unwanted effects were reported. Glare was the only undesirable symptom that interfered significantly (p = 0.01) in satisfaction, so patients who reported the presence of such symptom were more likely not to report positive effects with LIOM.

Discussion

Visual quality can be defined as the measure of the functional capacity of the individual in a multidimensional aspect with their physical, emotional, functional and social ability, taking into consideration their subjective opinion regarding the concept of quality and satisfaction [10].

This work demonstrates in an objective way that the average satisfaction punctuated by the patients was 8.21 points (maximum of 10), which suggests a positive evaluation regarding the use of multifocal lenses. Concordant and slightly higher than that observed in the study by Hida et al., in which the mean was 7.8 (\pm 0.79). Different from the Hida et al work, which showed a greater variation between the different distances measured; score for far vision of 9.10 (\pm 0.69), near vision 8.70 (\pm 0.63) and intermediate vision 5.60 (\pm 1.05); the present study observed a smaller disparity between the notes, 8.35 \pm 1.71, 8.43 \pm 1.54 and 7.87 \pm 2.05 respectively [10].

Twenty-one patients (16.93%) considered the visual acuity very satisfactory at any distance (maximum score in the question), excluding those who complained of any undesirable effects, 16 (12.90%) patients from the general sample studied, reported visual excellence with the LIOM model.

The predominance of women was expected, due to the profile of the female to be more compatible with the lens model, being therefore more frequently recommended for this population sample. This natural behavior by the feminine sex can be justified by better acceptance due to aesthetic purpose and organic mechanisms inherent in the gender.

A negative correlation was observed between eyeglasses dependence and visual quality, that is, the greater the visual content referred to by the patient, the lower the need for external correction as an adjunct to quality of vision; with a greater impact, although a weak association (-0.381), in activities at a short distance (p = 0.0001). In most studies found in the literature, spectacles dependents particularly for intermediate distance, such as the use of computers and / or the like, a characteristic not mentioned in the sample of this study, in which the external correction dependence was more evident in the patients dissatisfied with the near vision [13]. In a multi-center study conducted in London and published in 2013, which compare the evaluation of patients who were LIOM implanted (Tecnis ZM900 diffractive multifocal lenses model) with those who underwent monovision (Acreos Bausch & Lomb), users of LIOM reported glasses independence approximately 2.66 times lower than the control group. In the objective analysis of that study, VA distance did not differ significantly, where as intermediate vision had a worse multifocal outcome and near vision was unsatisfactory in the monovision group [13,14]. Unlike the present study, in witch inferior performance was found from near vision, even with reports of extreme dissatisfaction and greater reliance oneyeglasses.

AcrySof Restor SN60AD3, which has an optical addition of +4.00 D (diopters) in the central area (equivalent to + 3.40D in the glasses plane), with effective performance at 40 cm distance, were less used. Only 22 patients were submitted to this LIOM model. While AcrySof Restor SN6AD1 with +3.00 D (+2.40D glasses equivalence) were implanted in 102 patients [11].

Reduced addition (+3.00D) like AcrySof Restor SN6AD1 represents a significant functional improvement in the issue of intermediate visual acuity. As shown by Afonso et al., 75% (AD +3.00) versus 1% (AD +4.00) of the analyzed patients could read line 2 or better of the Jagger table (J2 at 60cm distance) [15]. It is important to individualize the addition choice with the activities of the patient, because the satisfaction interpretation is relative to the distance measured as preferential to the patient. Within the present population, a valid association was found only in relation to long-distance vision, and the best satisfaction is present in the patients with the lowest diopter (AD +3.00).

It was observed in the first patients submitted to LIOM implantation, that those who used the lenses with greater addition (AcrySof Restor SN60AD3), since it was the model available at the time. The availability on the market of lenses with minor addition enabled the choice and preference for this second LIOM model, as demonstrated in this study, in which the most recent surgeries predominated the use of the AcrySof Restor SN6AD1 lens.

In 42 patients (33.9%) the AcrySof Restor Toric model was implanted, lens which consists of 9 optical steps in its central zone and gives a +3.00 D addition for the short distance. Toric component is part of the posterior surface of the lens and presents four cylinder options, model SND1T2 (lens plane - LP +1,00 D corresponding to +0,68D of the corneal plane - CP), SND1T3 (+1,50D LP and +1,03D CP), SND1T4 (+2.25D LP and +1.55D CP) and SND1T5 (3.00D LP and 2.06D CP) [16,17].

Corneal astigmatism equal to or greater than 1.50D is generally found in 15 to 29% of patients with cataract, coinciding with the population of this study which 17.33% of toric lenses (21 units) were used with this cylinder degree. Residual astigmatism of 1.50 to 3.00D may lead to a decrease in visual acuity and interfere with the desired independence of eyeglasses, justifying their concomitant correction [18]. Interestingly, patients who opted for the use of this lens model, presented a smaller propensity to perform the surgery only as a refractive method (association -0.207 p = 0.022), perhaps because they were already accustomed to the use of some long-term external correction or because of a predominance of low power astigmatism (<1,5 D), which causes less interference in the daily

life of the patient.

A positive trend (+0,179) was observed in the regression of symptoms of halos perceived at night with the evolution time of the surgery, that is, the longer the procedure had passed, the lower complaints about halos, as well as their severity decreased. The others photopic effects did not have this same temporal relation in a significant way. In the spontaneous report and not as part of the questionnaire; a considerable percentage of patients when they were approached for adverse effects, reported that this kind of symptom was present more intensely early, but over the months they subsided or disappeared. Cochener and collaborators described a reciprocity of visual comfort with neuroadaptation and cerebral plasticity, associated with pupil learning in recognize and interpreting different foci, thus minimizing distortions or translating them as less intense [19].

An apodization arrangement, that is, modification in the curvature of the lens through the progressive reduction in the height of the diffractive grooves, initiated from the center $(1.3 \ \mu\text{m})$ to the periphery $(0.2 \ \mu\text{m})$, soften undesirable dysphotopic affectation in mesopic conditions and assists a better adaptation to them [7,10-12].

There was a positive (+0,451 to +0,557) and significant (p = 0.0001) association between three different distances evaluated and a confidence in performing a multifocal lens implant surgery, as well as recommending this lens model. Therefore, the more satisfied the patient, the greater tendency to rely on the lens LIOM.

An impersonal conversation during the calls revealed clearly that the most unhappy patients were those who generated false preoperative prospects. Those who understood the limitation of the procedure, exposed to all during the surgical planning, were more satisfied with the choice.

The success of the therapy is based, among other factors, on the good doctor-patient relationship, where attention is fundamental beyond the organic problems. The ability to decrease anguishes and fantasies of the patient, as well as avoid semantic mismatch and know how to direct the reality of the facts in relation to surgery, are values that add satisfaction and content to patient recovery.

Conclusion

The applied questionnaire was able to identify a good adaptation of the patients who opted for the multifocal intraocular lens implantation, with above average scores in the 3 distances examined, leaving a final satisfactory evaluation. The intermediate distance view had a higher score (8.43), followed by the distant view (8.35) and finally a near view (7.87).

Use of external correction, as an aid in the improvement of vision, was reported as not necessary in 79% of the interviewees, which characterizes a low dependence on eyeglasses. Unwanted visual symptoms were reported in 52.41% patients. When stratified data, glare predominance was observed in 44.3%, halos at night in 35.48% and halos during the day in 20.16% of the sample. Configuring a moderate prevalence of photopic phenomena, but with positive and regressive adaptation with temporal evolution. Based on the results of this study we inferred that the a spherical and non-toric a spherical Restor multifocal intraocular lens were a good option when adequately recommended and when the patient was aware

of the limitations as well as was aware of the undesirable effects inherent in the implant of this lens model. No lens can be defined as ideal for everyone, that is, the treatment should be performed in a personalized way and always based on the individual's lifestyle and personality, as well as respecting the anatomy and physiology of each eye [20-23].

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