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Visual Outcomes, Quality of Life and Satisfaction After Phacoemulsification in Patients With Type 2 Diabetes Mellitus and Patients Without Diabetes

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Abstract

Background

Diabetic retinopathy (DR) and cataract are major complications that lead to significant visual impairment of diabetic patients. This study aims to compare the changes in visual acuity, quality of life and satisfaction after phacoemulsification between type 2 diabetic and nondiabetic patients.

Methods

Fifty-seven diabetic patients (37 with no diabetic retinopathy [DR], 11 with mild/moderate nonproliferative DR and 9 with severe nonproliferative/proliferative DR) and 45 controls were submitted to first-eye cataract surgery by phacoemulsification alone or with co-adjuvant intravitreal injection of bevacizumab or triamcinolone. National Eye Institute Visual Function Questionnaire (NEI VFQ-25) was recorded preoperatively and 6 months after surgery; and satisfaction evaluated at 1-month.

Results

Corrected distance visual acuity (CDVA) of the operated eye at 1 and 6-months ($p<0.001$) was significantly higher than preoperative value in the controls and all diabetic subgroups. The final CDVA in the severe nonproliferative/proliferative DR subgroup was significantly lower compared to the controls and the remaining diabetic subgroups ($p<0.05$). The mean NEI VFQ-25 composite score significantly improved in both control (15.4±13.2 points) and diabetic (15.4±13.0 points) groups, without differences among the diabetic subgroups ($p>0.05$). Overall patient satisfaction was 93% in both control and diabetic groups.

Conclusion

This study provides vision-related patient-reported outcomes that support the benefit from phacoemulsification in all stages of DR, as long as there is adequate monitoring and treatment of retinopathy.

Introduction

Diabetic retinopathy (DR) and cataract are major complications that lead to significant visual impairment of diabetic patients. With the increasing prevalence of type 2 diabetes mellitus (DM) in the community (1), largely due to an aging population and a sedentary lifestyle, DR–related visual impairment has become a serious public health issue. In addition, diabetic patients have been shown to develop cataract earlier in life and at a higher rate compared to nondiabetic subjects, which puts them at greater risk of requiring surgery (2). Although cataract surgery provides an effective mean to restore visual acuity and function, patient satisfaction may be limited (3, 4).

An important and underexplored aspect in diabetic patients is the relative influence of cataract surgery on the quality of life (QoL). Patient-perceived outcome, which is based on the patients' interpretation of the impact of the intervention on their daily life, has become a significant factor in the evaluation of the outcome of surgical interventions (5). National Eye Institute Visual Function Questionnaire (NEI VFQ-25) (6) is probably the most widely used and researched instrument to capture the specific impact of vision loss on health-related QoL. It has been validated for use in patients with cataract, DR and diabetic macular edema (7-10).

This study proposes to investigate the relative influence of uneventful phacoemulsification cataract surgery on visual outcomes, vision-related QoL measured by the NEI VFQ-25 and satisfaction in type 2 diabetic patients with different stages of DR and nondiabetic patients. In addition, it aims to determine which factors may predict greater benefit following surgery.

Methods

This was a single-center prospective observational study conducted at the Department of Ophthalmology, Centro Hospitalar Universitário São João, Porto, Portugal, between September 2015 and March 2016. The study protocol adhered to the tenets of the Declaration of Helsinki and received Centro Hospitalar Universitário São João Institutional Review Board approval. Informed consent was obtained from each participant before inclusion in the study.

Study population

Caucasian patients with type 2 DM and controls, aged 50 or older, were included. Full selection criteria are described elsewhere (11); succinctly, DM diagnosis was confirmed by medical history and glycated hemoglobin (HbA1c) levels ≥ 6.5% . The exclusion criteria included the presence of any ocular disease, except cataract and DR (however, patients were excluded if presented white/brown cataracts and/or uncontrolled complications of proliferative DR, such as, neovascular glaucoma, vitreous hemorrhage or tractional retinal detachment); prior ocular surgery (except for intravitreal treatment ≥ 120 days or laser photocoagulation ≥ 90 days before surgery); and current treatment with glucocorticoids. All patients with a serious illness or mental problem (dementia, cognitive impairment) that could hinder the examinations required for the study were also excluded.

Sample size calculation

Based on the findings of Mangione et al. (6), for a type I error of 0.05 and type II error of 0.20 (80% power), considering a 10-point difference for the postoperative change in the mean VFQ-25 composite score to be significant between the control and diabetic groups, the minimal required sample size would be 40 subjects in each group.

Study protocol

Study assessments

Participants underwent a complete ophthalmological examination in a standardized fashion by the same ophthalmologist (JNB) preoperatively (within two weeks before surgery), 1 and 6 months after surgery. DR was graded preoperatively according to the international clinical classification system for DR (12). Diabetic macular edema and development of postoperative cystoid macular edema were evaluated clinically (12) and with spectral-domain optical coherence tomography (Spectralis HRA+OCT, Heidelberg, Germany) at each visit (13). The tomographic diagnostic criteria for postoperative cystoid macular edema were central retinal thickness increase ≥ 10% from baseline and foveal cysts. A single trained interviewer (JEL) performed all VFQ-25 interviews preoperatively and 6 months after surgery; and patient satisfaction questionnaires at 1 month follow-up.

Surgical Technique

Complete surgical technique is described elsewhere.(14) All subjects underwent standard clear cornea phacoemulsification with in-the-bag 1-piece acrylic posterior chamber intraocular lens by experienced surgeons. Patients with antecedents of diabetic macular edema, severe nonproliferative diabetic retinopathy (NPDR) or previously treated proliferative diabetic retinopathy (PDR) were submitted to phacoemulsification with co-adjuvant intravitreal treatment of anti-vascular endothelial growth factor (VEGF, bevacizumab 1.25mg/0.05ml) or corticosteroids (triamcinolone acetonide 2mg/0.05 ml), which was at discretion of patient´s retinal specialist.

The same postoperative medication was prescribed to all the patients and it consisted of 1mg/ml dexamethasone, 0.3mg/ml flurbiprofen and 5mg/ml levofloxacin eye drops, five times daily 1 week and then tapered gradually over 3 weeks.

Questionnaires

National Eye Institute Visual Function Questionnaire (NEI VFQ-25)

The VFQ-25 is a vision-related QoL instrument designed to assess patients' perception of visual function and vision-related QoL. It evaluates several domains, which represent different subscales: general health and vision, ocular pain, near and distance activities, driving, color vision, peripheral vision, social functioning, mental health, role difficulties, and dependency (6). All participants answered the Portuguese validated version of VFQ-25, also including the optional items of near and distance activities subscales (15).

Patient satisfaction questionnaire

Satisfaction regarding the cataract surgery outcome was evaluated using three questions with a dichotomous answer (yes/no), adapted from a previous study by Mozaffarieh et al (3):

1. Whether the patient believed that cataract surgery had improved his/her vision;
2. Whether the patient believed that cataract surgery had improved his/her quality of life, and
3. Whether the result of the final surgical outcome corresponded to his/her expectations.

For each question, a sub-question was added to quantify to what degree the patients experienced the surgical result that corresponded to their expectations (rated 1 to 5) (16). This answer was then converted into a 100-point scale, with 100 being the optimum score (answer 5) and 0 being the worst score (answer 1). These scores were not entered into VFQ-25 scores but were analyzed separately.

Data and Statistical analysis

Statistical analysis was performed using the SPSS® statistical software (version 21.0 for Mac OS; SPSS Inc., Chicago, IL., USA). For statistical analysis, Snellen visual acuity measurements were converted to a logarithm of the minimum angle of resolution (logMAR) units. NEI VFQ-25 scores were calculated according to authors' guidelines (6, 15), which result in a continuous measure for each subscale ranging from 0 (worst) to 100 (best). The patient overall satisfaction with the final surgical outcome was defined by the positive answer to the three dichotomous questions asked; in addition, an average score of the three sub-questions answers was calculated for each patient. Internal consistency reliability of NEI VFQ-25 and satisfaction questionnaires was assessed using Cronbach's alpha.

All comparisons between the groups, as well as between pre and postoperative periods, were performed with parametric or nonparametric tests, accordingly to the normality of data. Chi2 or Fisher´s exact test were performed for categorical variables comparison. Generalized linear models were generated to assess the influence of the different clinical and demographic parameters on NEI VFQ-25 composite score change from baseline to 6-months. All tests were two-sided, and p-values <0.05 were considered statistically significant.

Results

Fitty-seven diabetic patients (37 with no apparent DR, 11 with mild to moderate NPDR and 9 with severe NPDR to PDR) and 45 controls submitted to first-eye cataract surgery were enrolled in the study. Patient demographics and vision-related preoperative characteristics were similar between the control and diabetic groups, as well as across the diabetic subgroups (Table 1); except for HbA1c levels ($p<0.001$, One-way ANOVA).

In the diabetic group, longer duration of DM was significantly associated with higher HbA1c levels ($p<0.001$, $r=0.519$, Spearman correlation rank). More advanced stages of DR were significantly associated with longer duration of DM ($p<0.001$, Kruskal-Wallis test). The HbA1c levels were significantly greater in the severe NPDR/PDR subgroup when compared to the no DR subgroup ($p=0.016$, One-way ANOVA bonferroni adjusted). All diabetic subjects exhibited symmetrical DR stage preoperatively.

Concerning previous DR treatements, one patient with moderate NPDR had received macular laser photocoagulation five years before surgery; one patient with severe NPDR received macular laser photocoagulation and multiple intravitreal anti-VEGF injections for diabetic macular edema over one year before surgery; all six patients with antecedents of PDR were treated with macular and panretinal laser

photocoagulation, and three of them received multiple intravitreal anti-VEGF injections over 1 year before surgery.

Phacoemulsification alone was performed in all patients from the control group and in diabetic patients with no DR. In the mild/moderate NPDR subgroup, seven patients (64%) underwent phacoemulsification alone and four patients (36%) with co-adjuvant intravitreal bevacizumab. In the severe NPDR/PDR, phacoemulsification was performed simultaneously with intravitreal bevacizumab in seven patients (78%) and with intravitreal triamcinolone in two patients (22%).

No progression of retinopathy was observed in the operated and nonoperated eyes during the course of the study. At 1-month visit, only three diabetic patients had an increase in the central retinal thickness of more than 10% in the operated eye (incidence: 5%): one from the no DR subgroup (wihtout intraretinal cysts) and one from the mild/moderate NPDR subgroup (with intraretinal cysts) - both had phacoemulsification alone and edema resolved with 1mg/ml nepafenac topical eye drops three times daily for two months; another one from the PDR subgroup who had preoperative diabetic macular edema and received phacoemulsification with co-adjuvant intravitreal bevacizumab – edema did not respond to topical nepafenac but improved with triamcinolone injection at 4 months.

Preoperative diabetic macular edema in the operated eye was present in three patients with moderate NPDR, one with severe NPDR and four with PDR (prevalence: 14%). After surgery, the edema remained stable or improved in all patients up to 6 months; except for three patients with PDR who needed intravitreal injections (the one who got worse 1-month after the surgery and two others that got worse during the follow-up). The fellow nonoperated eyes of two patients with moderated NPDR and two patients with PDR showed progression of diabetic macular edema during the follow-up and were treated with intravitreal injections.

Visual outcomes

Visual Acuity

No statistically significant differences were observed in the preoperative mean corrected distance visual acuity (CDVA) of the operated and nonoperated eyes between the control group and diabetic subgroups ($p=0.762$ and $p=0.054$, respectively; One-way ANOVA) (Table 1).

Regarding the nonoperated eyes, there were no statistically significant differences across the groups for the mean CDVA change from baseline to 6 months (Fig. 1) and the mean CDVA at 6-month visit ($p=0.607$ and $p=0.128$, One-way ANOVA).

The mean CDVA of the operated eyes was observed to be significantly higher than preoperative value in all groups at 1- and 6-month follow-up ($p<0.05$, paired t-test) (Fig. 1). The mean CDVA change from baseline to 6-month visit of the operated eyes did not differ between the control group and diabetic subgroups ($p=0.687$, One-way ANOVA); however, the mean CDVA at 6-months in the severe NPDR/PRD subgroup (0.20 [95% CI, 0.03 to 0.37]) was significantly lower compared to the control group (0.01 [95%

CI, 0.00 to 0.02]) and the remaining diabetic subgroups (no DR, 0.02 [95% CI, 0.01 to 0.04]; mild/moderate NPDR, 0.00 [95% CI, 0.00 to 0.00]) ($p<0.001$, One-way ANOVA bonferroni adjusted) (Table 1).

Final CDVA was 20/32 or greater in 100% of the eyes in the control group and in 95% of the eyes in the diabetic group (100% in those with no DR and mild/moderate NPDR; 67% in those with severe NPDR/PRD). The operated eye became the better eye or had a visual acuity equal to that in the fellow eye in 98% of cases in the control group and severe NPDR/PRD subgroup; and 100% in the two-remaining diabetic subgroups. None of the patients in our study lost vision after cataract surgery. Overall, 98% of control subjects had at least a 2-lines of improvement in CDVA compared with 86% of patients with diabetes (89% with no DR, 100% of those with mild/moderate NPDR and 67% of those with severe NPDR/PDR).

NEI VFQ-25 Composite and Subscale results

The internal consistency reliability of the questionnaire in this sample was high. The overall Cronbach's α statistic was 0.850 and 0.855 at baseline and 6-month visits, respectively. Driving subscale obtained a small number of responses (n=29); Cronbach's α statistic was from 0.733 and 0.712 to baseline and 6-month visits, respectively.

The preoperative NEI VFQ-25 composite and subscale scores were comparable across the groups (Table 2). No correlation was observed between the preoperative NEI VFQ-25 composite score and the preoperative CDVA of the operated and nonoperated eyes ($p>0.05$, Spearman correlation). There were no differences between groups for the postoperative change of each of the questionnaire variables; however, at 6-months evaluation, there were significant differences between groups for the color vision, social functioning and ocular pain subscales (Table 2).

The mean composite score change from baseline to 6-month visit were 15.4 points (95% CI, 11.4 to 19.4), 15.5 points (95% CI, 11.4 to 19.9), 13.0 points (95% CI, 3.1 to 22.9) and 18.3 points (95% CI, 7.3 to 29.2) for the control group, no DR subgroup, mild/moderate NPDR subgroup and severe NPDR/PDR, respectively ($p=0.849$, one-way ANOVA) (Fig. 2). No group differences were observed regarding the categorical analysis of the NEI VFQ-25 composite score variation ($p=0.280$, Fisher´s exact test) (Fig. 3).

Regarding the NEI VFQ-25 subscales scores, statistically significant increases were observed in all groups for the variables general vision, near activities, distance activities and peripheral vision (Fig. 2). The general health subscale was the only item for which there was no significant improvement in any of the groups. Color vision was found to significantly improve in the control group; social functioning score increased in the control group and severe NPDR/PDR subgroup; driving, dependency and role difficulties were significantly better in the control group and no DR subgroup; ocular pain and mental health were improved in the control, no DR and severe NPDR/PDR subgroups.

Multivariate linear regression showed that age, preoperative CVDA of the operated eye, preoperative NEI VFQ-25 composite score and CDVA change from baseline to 6 months were significantly associated with

NEI VFQ-25 changes at 6 months postoperatively (Table 3). In a “fixed model”, the NEI VFQ-25 composite score was found to significantly increase on average 0.31 points for each year of increase in age; to decrease on average 3.93 points for each line of increase in preoperative CDVA (logMAR); to decrease on average 0.67 points for each unit of increase in preoperative NEI VFQ-25 composite score; to increase on average 4.19 points for each line of improvement in CDVA from baseline to 6 months.

Patient satisfaction questionnaire

The internal consistency reliability of the questionnaire in this sample was high. The overall Cronbach’s α statistic was 0.891.

Overall patient´s satisfaction at 1-month visit was 93%, 89%, 100% and 100% for the control group, no DR subgroup, mild/moderate NPDR subgroup and severe NPDR/PDR, respectively (p=0.968, Fisher´s exact test).

The mean patient satisfaction score was comparable between groups with composite scores of 64.2 (95% CI, 57.7 to 70.8), 71.4 (95% CI, 63.9 to 78.8), 63.6 (95% CI, 49.6 to 77.6), and 73.1 (95% CI, 59.6 to 86.6) for the control group, no DR subgroup, mild/moderate NPDR subgroup and severe NPDR/PDR, respectively (p=0.420, one-way ANOVA). No group differences were observed with respect to patient´s self-reported improvement in vision, quality of life or surgery expectations (p=0.426, p=283 and p=0.346, respectively; one-way ANOVA).

Discussion

We conducted a prospective observational study to evaluate the visual outcomes, vision-related QoL and patient satisfaction after first-eye cataract surgery in type 2 diabetic patients with different stages of DR and nondiabetic patients. Overall, our results support that phacoemulsification cataract surgery is safe and effective in diabetic patients; demonstrating that good visual outcomes, significant improvement in QoL and high levels of satisfaction are possible in all stages of DR, provided that adequate treatment of retinopathy is ensured.

Cataract surgery is important at several levels in the management of diabetic patients, not only for the visual rehabilitation purpose, but also, because it improves the accuracy of the diagnosis and treatment of the underlying retinopathy (17). Formerly considered a high-risk procedure due to the possibility of increasing the risk of retinopathy progression and the development or worsening of macular edema, it is currently considered safe due to the modern surgical techniques (17-20) and effective pharmacological approaches (21, 22). In our study, the incidence of postoperative cystoid macular edema or worsening of diabetic macular edema was low and progression of the retinopathy was not observed in any of the operated and nonoperated eyes; however, some of the eyes with the more advanced stages of retinopathy, both operated and nonoperated, required diabetic macular edema treatment during the follow-up. These results emphasize the importance of an integrated approach to cataracts and DR, as well as, the need for careful monitoring over time.

Cataract extraction is expected to improve vision, both in the short and long term, in the majority of diabetic patients with all levels of DR; but, the benefits may be reduced in the more advanced stages of retinopathy (3, 4, 23-25), presence of preoperative clinically significant macular edema (23) and past laser therapy (17, 26).

The magnitude of visual acuity improvement in our study corresponded well to the results of previous studies in diabetic patients (17, 18, 20, 23, 24); conversely, the proportion of diabetic subjects attaining a final visual acuity equal or greater than 20/32 was rather higher (visual acuity equal or greater than 20/40 in Zaczek et al. (23) 79%, Mittra et al. (24) 62% and Somaya et al. (25) 82%). Several reasons may explain these findings. Firstly, the exclusion of patients with any ocular diseases other than cataract and DR, the low prevalence of preoperative diabetic macular edema and the relatively small sample size of subjects with DR could largely justify this result. In addition, all participants had stabilized retinopathy, without any treatment in the months preceding the surgery. Lastly, the standard postoperative use of topical steroids in combination with nonsteroidal anti-inflammatory drugs in all patients associated to the use of co-adjuvant intraoperative intravitreal injection of bevacizumab or triamcinolone in selected cases (preexistent diabetic macula edema, severe NPDR or PDR) may have contributed to achieve better anatomical and, consequently, functional results (21, 22).

The relevance of ocular surgery for diabetic patients´ eyes is not completely established. While visual and anatomic outcomes following cataract surgery have been extensively studied in those patients, limited attention has been paid to patients' perspective on the results of this specific surgical intervention (3, 4, 19, 27, 28). Previous researches addressing patient´s subjective interpretation of the surgical outcome have faced its complexity, but also highlighted the validity and reliability of their measurement capabilities (3, 16).

NEI-VFQ-25 has been proven to be an efficient method to capture QoL changes related to medical conditions or interventions (19, 29); and visual acuity has been found to be the most important determinant associated with those changes, rather than other demographic or clinical factors (29-31). Our results are consistent with those of previous studies; as demonstrated by the low preoperative NEI VFQ-25 composite and subscales scores (due to the advanced age of the study population with decreased visual acuity secondary to senile cataracts and/or DR), the absence of preoperative differences between control group and diabetic subgroups (due to comparable visual acuity in the operated and nonoperated eyes across all groups), and the marked improvement in the postoperative scores coinciding with the significant improvement in visual acuity of the operated eyes (a 10-point increase in NEI VFQ-25 scores has been estimated to be associated with a clinically meaningful change in QoL (32)).

On the other hand, there is widespread recognition that changes in visual function after cataract surgery may differ in important ways from visual acuity alone (16, 19). Lundqvist et al.(27) in population-based study of 57 diabetic patients, with DR stage distribution similar to our sample, and 473 controls found comparable significant visual acuity and functional (evaluated by the visual function questionnaire, VF-14) improvements between the diabetic and control groups at 4-months follow-up; without any

statistically significant difference between the scores of the diabetic subgroups in the pre and postoperative periods. However, as occurred in our study, PDR subgroup was able to significantly improve vision-related QoL despite obtaining a lower postoperative visual acuity. The main reason for this may be related to the patient´s subjective perception of an increased ability to perform visually demanding daily tasks, which naturally leads to an increase in QoL (19).

Remarkably, “general health” subscale was the only item where no significant postoperative improvements were observed in any of the groups. That lack of changes were likely because it is an additional-single item, not directly related to vision, that has been included in the questionnaire to act as a predictor of future health and mortality (6).

The inclusion of degree of satisfaction with the surgical outcome represents a significant contribution to our knowledge on the topic. We used an adapted version from a previous questionnaire designed by Mozaffarieh et al. (3) with additional sub-questions in order to quantify to what extent patients' expectations were met (16). Overall, patient satisfaction was 93% in both control and diabetic groups and no differences were found in patient´s self-reported improvement in vision, quality of life or surgery expectations. These results contrast with those of Mozaffarieh et al. (3) who stated that the degree of satisfaction decreased as the baseline level of retinopathy increased. However, both reports agree that there is a consistent correlation between the improvement in visual acuity and function and the degree of satisfaction. When interpreting satisfaction and QoL scores, one must bear in mind that those are subjective measures that can be influenced in several ways. Thereby, patient´s education and counseling prior to surgery are essential to set realistic expectations and minimize the proportion of dissatisfied patients (3, 4, 16).

The main strengths of this study include the use of objective (16) and subjective (3, 6) measures to accurately characterize the benefit of phacoemulsification in a cohort of diabetic patients with different stages of DR. In addition, the use of a control group and the study´s design with multiple surgeons performing cataract surgeries can provide information that may be generalizable to a larger group of patients, which is of utmost importance for daily clinical practice.

The main limitation of this study is the inclusion of a low number of patients with more advanced stages of DR, as discussed previously. Although the visual outcomes in those groups were so unmistakable, the authors still recognize that stronger evidence could be obtained from a larger cohort. Additionally, only participants submitted to first-eye cataract surgery were included, despite some of them already had some degree of cataract in the nonoperated fellow eye. The authors believe that this had little influence on the visual results obtained since the operated eye was always the one with the worst visual acuity. Lastly, the decision to perform phacoemulsification with co-adjuvant intravitreal injection of bevacizumab or triamcinolone was based exclusively in the judgement of patient´s retinal specialist.

Conclusion

In conclusion, this study provides vision-related patient-reported outcomes that support the benefit from phacoemulsification in all stages of DR, as long as there is adequate management of the retinopathy. Moreover, it highlights that the more advanced stages of DR, in particular severe NPDR and PDR, might be able to obtain comparable QoL improvement and satisfaction scores, despite obtaining a lower absolute postoperative visual acuity. Finally, the universal postoperative use of topical steroids and nonsteroidal anti-inflammatory drugs combined with the use of intraoperative co-adjuvant intravitreal injection (anti-VEGF or corticosteroids) in selected patients, may improve anatomical and functional outcomes in diabetic patients.

Abbreviations

CDVA: corrected distance visual acuity; DM: Diabetes mellitus; DR: Diabetic retinopathy; HbA1c: glycated hemoglobin; logMAR: Logarithm of the minimum angle of resolution; NEI VFQ-25: National Eye Institute Visual Function Questionnaire; NPDR: Non-proliferative diabetic retinopathy; PDR: Proliferative diabetic retinopathy; QoL: quality of life; SD-OCT: spectral-domain optical coherence tomography; VEGF: vascular endothelial growth factor; VF-14: visual function questionnaire.

Declarations

Ethics approval: Project number CES 285-15, approved by the Research Ethics Committee of Hospital São João.

Disclosures: None of the authors have any financial/conflicting interests to disclose.

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Author contributions: All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content; gave final approval of the version to be published; and agree to be accountable for all aspects of the work

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Data Availability: The data used to support the findings of this study are available from the corresponding author upon request.

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Tables

Table 1. Demographic, clinical characteristics and intraoperative data of the study population.

Variable	Control group (n= 45)	No DR (n=37)	Mild / moderate NPDR (n=11)	Severe NPDR / PDR (n=9)	*P*
Age, years	70.8 ± 6.3	73.2 ± 5.6	72.4 ± 4.8	71.3 ± 6.1	0.329†
Female, n (%)	27 (60)	23 (62)	7 (64)	6 (67)	1.000‡
Professionally inactive, n (%)	35 (78)	37 (100)	11 (100)	9 (100)	0.003*‡
Right eyes, n (%)	29 (64)	19 (51)	4 (36)	6 (67)	0.292‡
HbA1c, %	5.5 ± 0.3	6.8 ± 1.0	7.0 ± 1.1	8.0 ± 1.3	<0.001*†
Diabetes duration, years	n/a	7 (4, 12)	13 (8, 18)	20 (15, 30)	<0.001*§
Oral hypoglycemic agents, n (%)	n/a	35 (94)	11 (100)	9 (100)	1.000‡
Insulin, n (%)	n/a	5 (13)	3 (27)	5 (56)	0.019*‡
Intraoperative data					
Cataract grade	1.9 ± 0.6	1.7 ± 0.7	1.7 ± 0.5	1.9 ± 0.6	0.512†
CDE [a]	9.7 ± 6.5	8.8 ± 7.2	11.2 ± 7.2	16.7 ± 15.4	0.073†
IOL power, Diopters	22.2 ± 1.8	22.1 ± 1.6	22.4 ± 1.8	22.6 ± 2.4	0.931†
Acrysof® / Akreos®	39/6	30/7	10/1	8/1	0.885‡
CDVA, logMAR			-	-	
Operated eye					
Preop	0.50 ± 0.39	0.43 ± 0.37	0.54 ± 0.37	0.58 ± 0.58	0.762†
Postop 6-month	0.01 ± 0.03	0.02 ± 0.05	0.00 ± 0.00	0.20 ± 0.22	<0.001*†
Non-operated eye					
Preop	0.20 ± 0.19	0.16 ± 0.12	0.26 ± 0.18	0.31 ± 0.18	0.054†
Postop 6-month	0.25 ± 0.25	0.16 ± 0.15	0.26 ± 0.16	0.32 ± 0.30	0.128†

Data were derived from one-way ANOVA†, Fisher´s exact test‡ and Kruskal-Wallis test§. Continuous

variables with normal distribution are reported as mean ± standard deviation and non-normal distribution as median (first and third quartiles). Categorical variables are presented as absolute frequency (proportion). *P <0.05, statistical significance. DR, diabetic retinopathy; NPDR, non-proliferative DR; Preop, preoperative; Postop, postoperative; n/a, not applicable. [a] n = 39, 34, 9 and 9 for the control, no DR, mild/moderate NPDR and severe NPDR/PDR groups, respectively.

Table 2. Preoperative and 6-month postoperative vision-related quality of life evaluated by the NEI VFQ-25 of the study population.

Variable	Control group (n= 45)	No DR (n=37)	Mild / moderate NPDR (n=11)	Severe NPDR / PDR (n=9)	*P*
NEI VFQ-25 Composite score[a]					
Preop	71.9 ± 12.4	72.1 ± 14.8	67.5 ± 14.3	63.0 ± 15.1	0.250[†]
Postop	87.3 ± 10.4	87.6 ± 9.6	80.5 ± 11.6	81.2 ± 15.3	0.108[†]
NEI VFQ-25 Subscale score					
General health					
Preop	30.6 ± 19.9	31.8 ± 24.8	18.2 ± 16.2	36.1 ± 18.2	0.230[†]
Postop	33.9 ± 20.8	29.1 ± 18.2	22.7 ± 10.5	33.3 ± 21.6	0.336[†]
General vision					
Preop	48.9 ± 16.8	49.7 ± 15.4	45.4 ± 15.7	48.9 ± 14.5	0.895[†]
Postop	72.4 ± 13.0	70.3 ± 14.6	61.8 ± 10.8	66.7 ± 17.3	0.129[†]
Mental health					
Preop	69.0 ± 18.9	69.4 ± 21.0	68.8 ± 13.4	58.3 ± 23.6	0.478[†]
Postop	82.2 ± 17.0	85.0 ± 13.6	76.1 ± 9.2	79.9 ± 16.2	0.634[†]
Near activities					
Preop	66.7 (52.1, 79.2)	66.7 (50.0, 87.5)	50.0 (45.8, 75.0)	62.5 (47.1, 64.6)	0.320[‡]
Postop	91.7 (87.5, 100)	91.7 (83.3, 100)	91.7 (66.6, 95.8)	75.0 (64.6, 95.8)	0.141[‡]
Distance activities					
Preop	70.0 (52.5, 85.0)	68.8 (55.6, 91.7)	55.0 (37.5, 81.2)	50.0 (37.5, 75.0)	0.246[‡]
Postop	95.8 (86.2, 100)	95.8 (88.8, 100)	95.8 (68.8, 100)	75.0 (60.6, 100)	0.480[‡]

Peripheral vision					
Preop	75.0 (50.0, 87.5)	75.0 (50.0, 100)	50.0 (50.0, 75.0)	50.0 (50.0, 100)	0.226‡
Postop	100 (75.0, 100)	100 (100, 100)	100 (75.0, 100)	100 (87.5, 100)	0.421‡
Color vision					
Preop	100 (100, 100)	100 (100, 100)	100 (100, 100)	100 (62.5, 100)	0.167‡
Postop	100 (100, 100)	100 (100, 100)	100 (100, 100)	100 (87.5, 100)	0.031*‡
Ocular pain					
Preop	62.5 (43.8, 100)	62.5 (50.0, 75.0)	50.0 (25.0, 62.5)	50.0 (37.5, 62.5)	0.118‡
Postop	75.0 (62.5, 100)	75.0 (56.2, 81.2)	50.0 (25.0, 75.0)	75 (56.2, 100)	0.026*‡
Social Functioning					
Preop	100 (75.0, 100)	87.5 (75.0, 100)	87.5 (62.5, 100)	62.5 (50.0, 100)	0.178‡
Postop	100 (100, 100)	100 (100, 100)	100 (87.5, 100)	87.5 (68.8, 100)	0.007*‡
Role difficulties					
Preop	75.0 (50.0, 87.5)	62.5 (43.8, 100)	87.5 (62.5, 100)	62.5 (43.8, 93.8)	0.366‡
Postop	100 (75.0, 100)	100 (87.5, 100)	100 (50.0, 100)	100 (62.5, 100)	0.899‡
Dependency					
Preop	100 (91.7, 100)	100 (83.3, 100)	91.7 (75.0, 100)	91.7 (62.5, 91.7)	0.115‡
Postop	100 (100, 100)	100 (100, 100)	100 (75.0, 100)	100 (75.0, 100)	0.135‡
Driving[b]					
Preop	66.7 (50.0, 87.5)	66.7 (56.2, 85.4)	83.3 (50.0, 83.3)	66.7 (33.3, 66.7)	0.605‡
Postop	83.3 (66.7, 100)	91.7 (66.7, 100)	100 (52.1, 100)	75.0 (58.3, 75.0)	0.833‡

Data were derived from One-way ANOVA† and Kruskal-Wallis test.‡ Continuous variables with normal distribution are reported as mean ± standard deviation and non-normal distribution as median (first and third quartiles). P <0.05, statistical significance. [a] NEI VFQ-25 composite score without general

health subscale; [b] n= 13, 14, 3 and 2 for the control, no DR, mild/moderate NPDR and severe NPDR/PDR groups, respectively. *Pairwise comparisons with Mann-Whitney test: color vision: severe NPDR/PDR vs. control group (p=0.017); severe NPDR/PDR vs. no DR subgroup (p=0.038); ocular pain: mild/moderate NPDR subgroup vs. control group (p=0.004), mild/moderate NPDR subgroup vs. no DR subgroup (p=0.009); mild/moderate NPDR subgroup vs. severe NPDR/PDR subgroup (p=0.040). [±]social functioning: severe NPDR/PDR subgroup vs. control group (p=0.002), severe NPDR/PDR subgroup vs. no DR subgroup (p=0.005).

Table 3. Multivariate regression analysis of the relative effects of clinical and demographic characteristics on the change of NEI VFQ-25 composite score from baseline to 6 months postoperatively.

Variable	Δ NEI VFQ-25 composite score	
	B (95% CI)	*P*
Age, years	+0.31 (+0.01 to +0.62)	0.045*
Gender (Female)	+0.46 (-3.19 to +4.12)	0.803
DR stage		
Control group		
No DR subgroup	+0.30 (-4.77 to +5.37)	0.907
Mild/Moderate NPDR subgroup	-5.78 (-13.58 to +2.03)	0.147
Severe NPDR/PDR subgroup	+5.13 (-6.14 to +16.40)	0.373
HbA1c levels, %	+0.63 (-1.86 to +3.12)	0.618
Duration of diabetes Mellitus, years	-0.10 (-0.50 to +0.29)	0.614
Preoperative CDVA, logMAR	-3.93 (-6.46 to -1.40)	0.002* [†]
Preoperative NEI VFQ-25 composite score	-0.67 (-0.80 to -0.53)	<0.001*
Δ CDVA, logMAR	+4.19 (+1.63 to +6.74)	0.001*[‡]

Data were derived from generalized linear models. * <0.05, statistical significance. CDVA, corrected distance visual acuity; NEI VFQ-25, National Eye Institute Visual Function Questionnaire; logMAR, logarithm of the minimum angle of resolution; Δ variation. [†] CDVA of the operated eye; [‡] Δ CDVA calculated as CDVA preop – CDVA at 6 months.

Figures

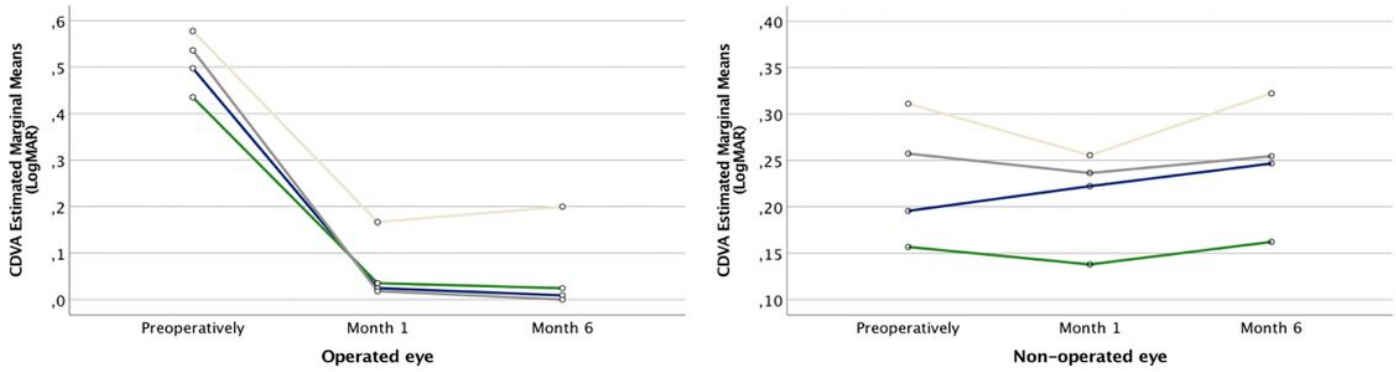

Figure 1

Estimated marginal means of corrected distance visual acuity (CDVA) in LogMAR from baseline to 6 Months in the operated and non-operated eyes. Control group, blue; No DR, green; Mild/Moderate NPDR, dark grey; Severe NPDR /PDR, light grey.

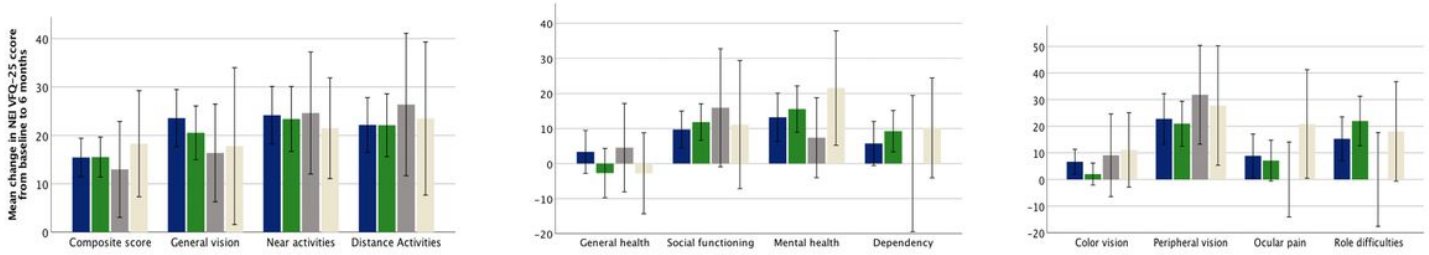

Figure 2

Mean change from baseline to 6 Months in National Eye Institute Visual Functioning Questionnaire 25 (NEI VFQ-25) composite and subscale scores. The driving subscale was not included due to the small number of responses. Control group, blue; No DR, green; Mild/Moderate NPDR, dark grey; Severe NPDR /PDR, light grey. Error bars indicate upper 95% confidence.

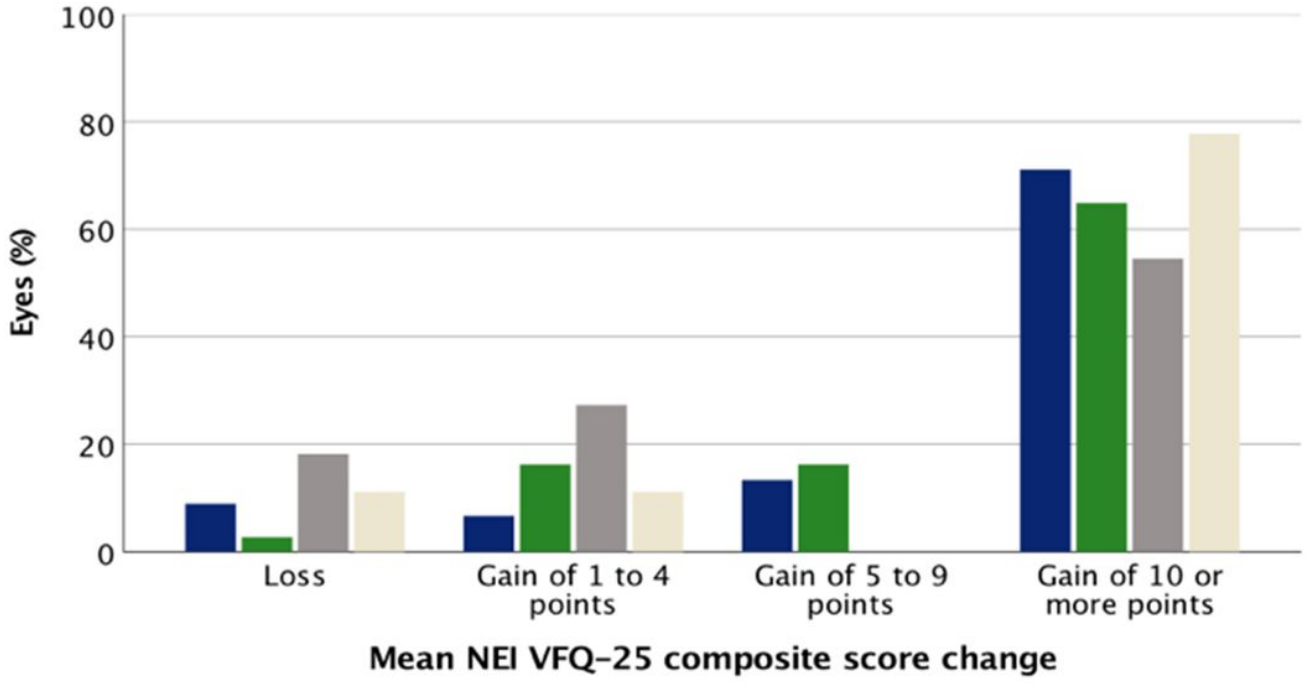

Figure 3

Mean National Eye Institute Visual Functioning Questionnaire 25 (NEI VFQ-25) composite score change from baseline to 6 months. Control group, blue; No DR, green; Mild/Moderate NPDR, dark grey; Severe NPDR /PDR, light grey.