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Research Article

# Diabetic Retinopathy Progression and Visual Outcome after Phacoemulsification: A Prospective Study

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## Abstract

**Purpose:** To assess diabetic retinopathy (DR) progression and visual outcome following phacoemulsification in north African diabetic patients with non-proliferative diabetic retinopathy at baseline.

**Methods:** This prospective trial evaluated 60 consecutive cases of diabetic patients with non-proliferative diabetic retinopathy, undergoing monocular phacoemulsification cataract surgery by the same surgeon.

Initial evaluation included preoperative retinal findings; stage of DR and glycosylated hemoglobin (HbA1c) level. DR was assessed using the modified Early Treatment Diabetic Retinopathy Study (ETDRS) classification.

Outcomes were assessed 6 months postoperatively and included visual acuity (VA), progression of retinopathy (comparison of preoperative and 6 months post-operative retinal photographies), and incidence of macular edema (referring to optical coherence tomography). Progression of retinopathy and incidence of CSME were compared to the non-operated fellow eyes.

Main outcome measure: DR progression was defined as an increase of 1 or more ETDRS stage during the period of follow-up. Aggravation of macular edema was defined by an increase in the central macular thickness measured on OCT.

**Results:** Postoperative visual acuity increased by 2 or more lines in 50 patients (83%); it was better than 0,5 in 80%. Progression of retinopathy occurred in 25% of eyes after cataract surgery and in 18.33% of non-operated fellow eyes. The progression was associated with high levels of HbA1c in both groups. Macular edema occurred or progressed in 13.33% of operated eyes and in 10% of control eyes. There was a significant difference in the number of operated and fellow eyes whose retinopathy or maculopathy progressed postoperatively.

**Conclusion:** Uncomplicated phacoemulsification cataract surgery seems to exacerbate the progression of DR in north African patients with worse controlled diabetes. Poorer visual outcome is observed in patients developing macular edema.

***Keywords:*** *Diabetic Retinopathy; Cataract Surgery; Visual Outcomes; Phacoemulsification*

## Introduction

The prevalence of lens opacification is higher in diabetic patients. They develop cataract at an earlier age than non-diabetics [1]. Almost 20% of all cataract surgery is performed on diabetic patients [2]. Cataract surgery in diabetic patients is associated with a higher incidence of postoperative complications. Progression of diabetic retinopathy after extracapsular extraction was postulated by the royal college of ophthalmology in 1997 [3]. However, progress in surgical techniques with the vulgarization of phacoemulsification and the use of hydrophobic intra-ocular lenses may minimize post-operative inflammation and blood-ocular barrier break.

## Purpose of the Study

The purpose of this prospective study was to investigate whether uncomplicated phacoemulsification cataract surgery was responsible for an acceleration of progression of diabetic retinopathy and diabetic maculopathy. We reported the visual outcome and assessed the progression in diabetic retinopathy stage in North African's diabetic patients after phacoemulsification. We used the non-operated fellow eyes as a control group.

## Patients and Methods

We prospectively followed 120 eyes of type 2 diabetic patients, divided in two groups: 60 eyes consecutively operated for cataract by phacoemulsification between January and December 2016 in the ophthalmological department of the military hospital of Tunis, and 60 control non-operated eyes. We included in this study: north African diabetic patients who's fundus examination showed non-proliferative diabetic retinopathy, whether if a macular edema was present or not and in which the diagnosis of cataract was effectuated. Exclusion criteria were: proliferative diabetic retinopathy, bilateral cataract needing surgery in both eyes, per operative complications and the presence of other ocular diseases such as glaucoma, uveitis ocular surgery and trauma.

Preoperative data included age, sex, race, type and duration of diabetes, glycosylated hemoglobin level, ocular history, and Snellen visual acuity. Digital imaging of both fundi was performed in all patients preoperatively. Preoperative OCT is usually difficulty or is of low quality in cataract patients and consequently the CMT measurement preoperatively will not be accurate (response: concerning the OCT exam, all the eyes included in the study haven't a total cataract, it was a moderate opacification that doesn't affect the quality of the OCT images. The central macular thickness was measured by the topography program). and at 6 months post-operatively.

The grading was performed by one masked observer referring to the Early Treatment Diabetic Retinopathy Study (ETDRS) [4]. Maculopathy was graded as no maculopathy and clinically significant macular edema, according to the ETDRS criteria, and the central macular thickness on OCT exam.

All patients underwent phacoemulsification by the same surgeon, with a 2.2 incision, ozil technology and the implantation of a hydrophobic foldable intra-ocular lens into the capsular bag. The incision wasn't sutured. No complications were noted for patients included in the study.

An ophthalmological examination was performed one day, two weeks one month and 6 months after cataract surgery. A retinal photography and an OCT exam were done at 6 months.

DR progression was defined as an increase of 1 or more ETDRS stage during the period of follow-up. An increase in central macular thickness more than 100 microns on OCT was considered as a progression of the macular edema.

The comparison of data was performed with the control non-operated eyes.

## Statistical analysis

Friedman's two way analysis of variance (ANOVA), combined with comparisons with baseline (cb), was used to evaluate the change of visual acuity after surgery in diabetic and controls groups. A change in the visual acuity in the 2 groups cannot be an accurate measure for the retinal state as an eye which had cataract and became pseudophakic may have an improved vision inspite of some progression of a NPDR. Conversely the control eye may have some drop of vision with a milder change in retinopathy. Consequently the 2 groups cannot be compared by this parameter. (We noted in the results chapter that the visual acuity was improved in the first group after cataract surgery for all the operated eyes, the second group contains eyes without significant cataract, so that, the two groups can be compared and the visual acuity reflected the retinal and macular status).

The McNemar test for paired data was used to compare the number of operated and fellow eyes that had progressive retinopathy and maculopathy. Student's paired t test was used to compare the mean HbA1C and mean duration of diabetes in patients whose retinopathy or maculopathy progressed in the operated eye, with patients whose retinopathy or maculopathy did not progress in the operated eye. This calculation was performed for the group of non-operated eyes. Regression analysis was performed to study the relationship between retinopathy or maculopathy progression and the following factors: Age, duration of diabetes and HBA1C level.

## Results

Sixty eyes of 60 diabetic patients were included to the study. The mean age was 70.5 (±10) years, range 49 - 89 years. All patients had type 2 diabetes. 33 patients required insulin, while 27 patients were controlled by oral hypoglycaemic agents

Main demographic data were resumed in table 1.

| |
|---|
| Male to female ratio = 1.14 |
| Age in years (mean) 70.5 (range 49 - 89) |
| Duration of diabetes in years (mean) 19 (range 5 - 20) we are sorry it was a mistake 20 years and not 40 |
| Preoperative mean HbA1C 9.5% (range 6 - 13.5%) |

***Table 1:*** *Preoperative patient's data.*

Mean preoperative visual acuity was 0.23 (0.05 to 0.61) (Figure 1).

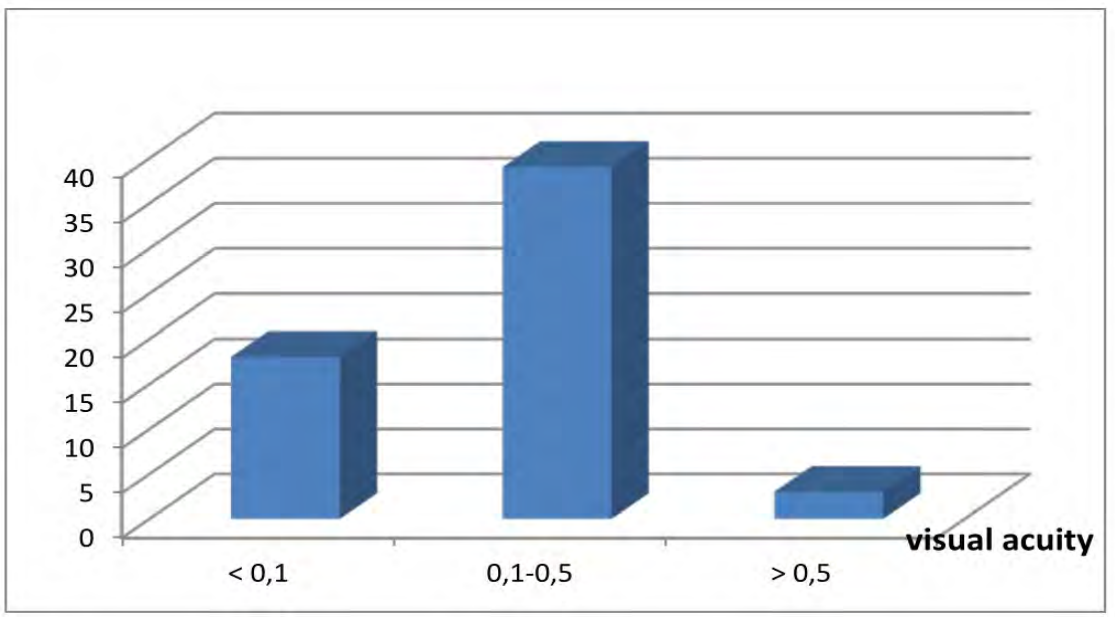


***Figure 1:*** *Preoperative visual acuity.*

The preoperative fundus status (DR stage and macular thickness) in both operated and control eyes was resumed in the table 2.

| Stage of DR | Mild NPDR | Moderate NPDR | Severe NPDR | Total |
|---|---|---|---|---|
| Operated eyes | 17 | 29 | 14 | 60 |
| Control eyes | 16 | 30 | 14 | 60 |

***Table 2:*** *Preoperative status of diabetic retinopathy.*

A clinically significant macular edema was diagnosed on fundus photography and OCT for 22 operated eyes and 18 non-operated eyes. Preoperative central macular thickness in the two groups is resumed in figure 2.

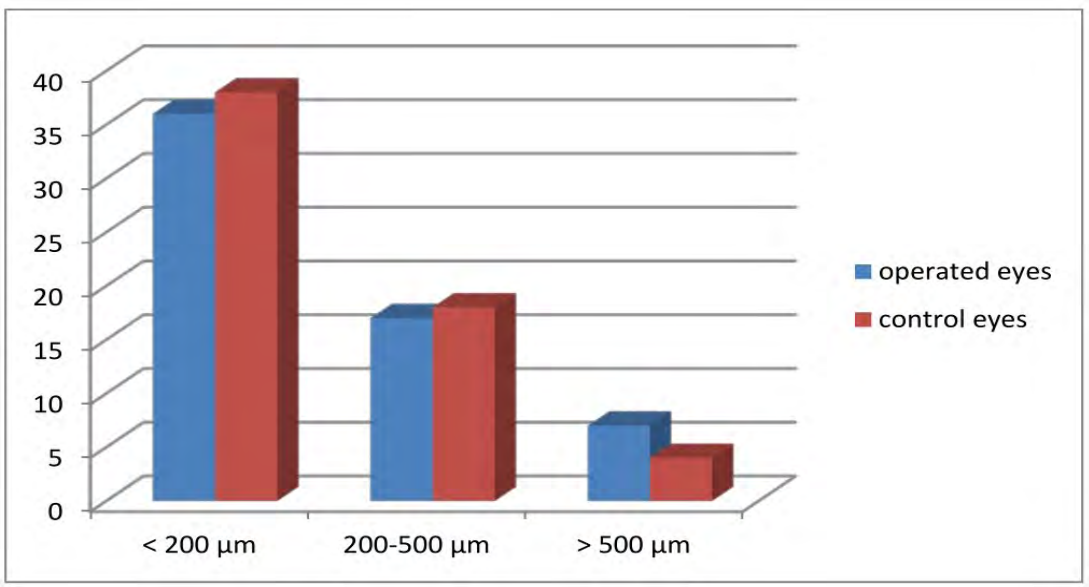


***Figure 2:*** *Preoperative central macular thickness.*

A standard phacoemulsification technique was performed for all eyes. It was an ozil procedure with?? 2.2 mm incision, a stop and shop nuclear extraction and an implantation of a hydrophobic preloaded foldable intraocular lens. A preventive antibiotic prophylaxis was prescribed for all diabetic patients (Levofloxacin 500 mg 12 hours and 2 hours before surgery). The mean of total dissipated energy was 15.69. No per operative complication was noted for this cohort of patients.

In this study, we were interested by the 6 months postoperative evaluation.

Postoperative visual acuity: At 6 months after cataract surgery, best corrected visual acuity was significantly improved compared with preoperative VA whatever the stage of DR (Table 3). The visual acuity improved by 2 or more lines in 50 patients (83%); it was better than 0,5 in 80%. For the 10 eyes which visual acuity didn't increase, an ischemic maculopathy or a persistent macular edema were found.

| | **Preoperative VA** | **Postoperative VA 6 months** |
|---|---|---|
| Mild NPDR | 0.4 (0.2 - 0.6) | 0.8 (0.6 - 1) |
| Moderate NPDR | 0.3(0.1 - 0.5) | 0.7 (0.4 - 0.9) |
| Severe NPDR | 0.15 (0.05 - 0.4) | 0.3 (0.1 - 0.7) |

***Table 3:*** *VA at 6 months postoperatively compared to preoperative VA..*

Postoperative visual acuity: At 6 months after cataract surgery, best corrected visual acuity was significantly improved compared with preoperative VA whatever the stage of DR (Table 3). The visual acuity improved by 2 or more lines in 50 patients (83%); it was better than 0,5 in 80%. For the 10 eyes which visual acuity didn't increase, an ischemic maculopathy or a persistent macular edema were found.

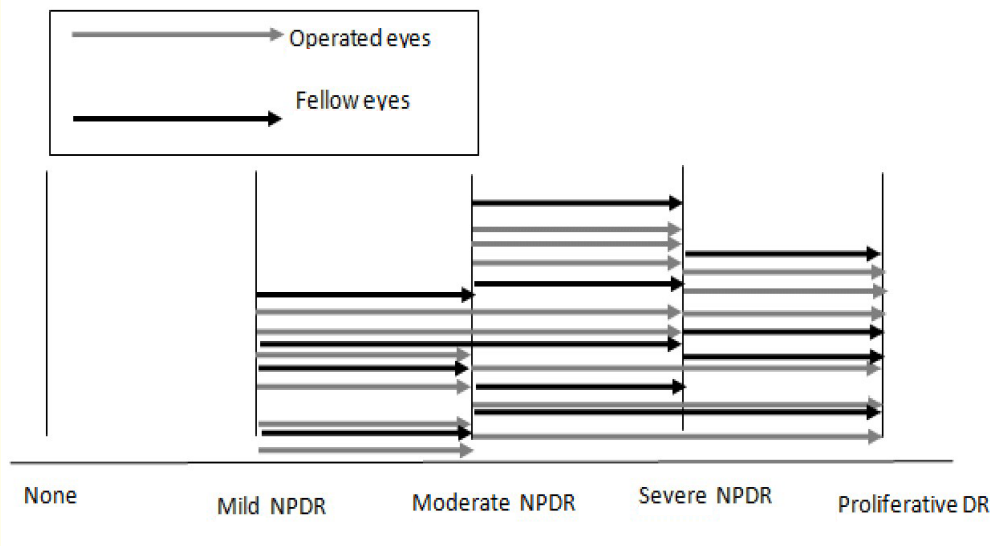


***Figure 3:*** *Graphic representation of patients whose diabetic retinopathy progressed.*

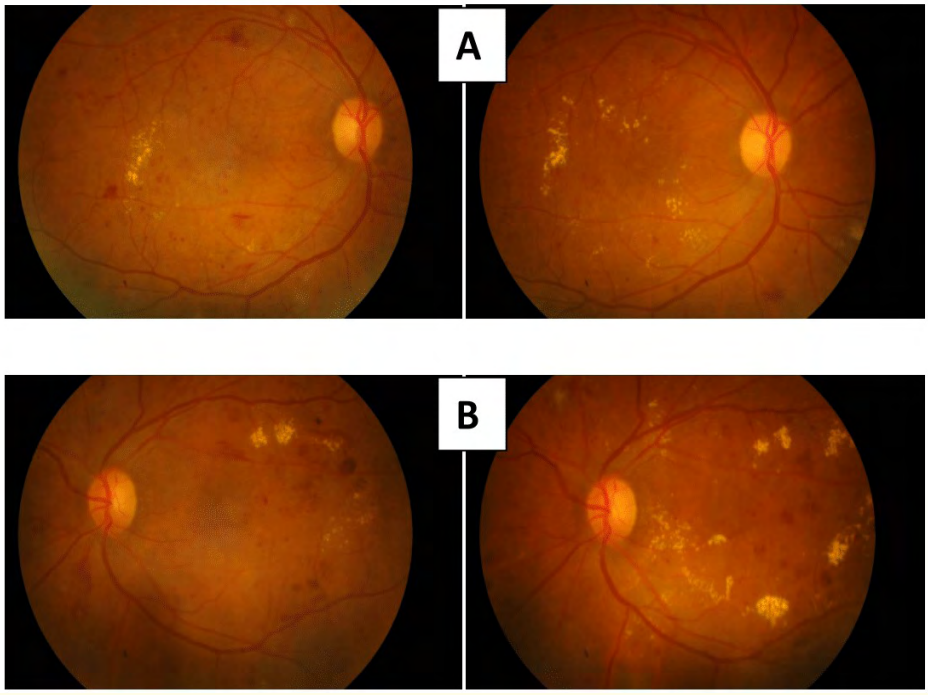


***Figure 4:*** *Bilateral asymmetric progression of DR on fundus photography 6 months after cataract surgery (A: Fellow right eye; B: operated left eye).*

There was a significant difference in the number of operated and fellow eyes that had evidence of progressive retinopathy (p = 0.04) I doubt that this p value is correct because a difference of four eyes in 60 patients is not that highly significant (after reviewing the statistical test, we find an error in the p value).

In the operate eyes group, 5 eyes (33%) had progressed their DR by 2 stages, while in the control group 2 eyes (18.18%) showed 2 stages progression (p = 0.0006).

Overall, the retinopathy progressed in 15 patients after monocular cataract surgery and in five patients the diabetic retinopathy progressed equally in both the operated and fellow eye.

In 4 patients the retinopathy progressed more rapidly in the operated eye (within 3 months in the operated eye and 6 months in the fellow eye).

In both the operated and non-operated cohorts, Student's paired t test revealed a higher mean HbA1C in those patients whose retinopathy progressed compared to those patients whose retinopathy did not progress (p = 0.004 for operated eyes, p = 0.007 for non-operated eyes).

The progression was associated with high levels of HbA1c in both groups (Table 4). The duration of diabetes was significantly associated to DR progression in both groups (p = 0.001 and p= 0.004 for operated and non-operated eyes respectively) (Table 4).

| | **Operated eyes** | | **Non-operated eye** | |
|---|---|---|---|---|
| Variable | Odds ratio (95% CI) | P | Odds ratio (95% CI) | P |
| HBA1C level | 4.56 | 0.02* | 6.3 | 0.01* |
| Age > 60 years | 3.04 | 0.41 | 2.9 | 0.1 |
| Duration of diabetes | 5.24 | 0.001* | 2.71 | 0.004* |

***Table 4:*** *Logistic regression analysis for retinopathy progression.*
**Denotes statistical significance.*

A thickening of the central macula after cataract surgery occurred in 8 eyes (13.33%) of the operated group (Figure 5) and 6 (10%) of the control group. Of these 8 eyes, two had no preoperative diabetic maculopathy. There was a significant difference in the number of operated and fellow eyes that had evidence of progressive maculopathy (p = 0.0006).

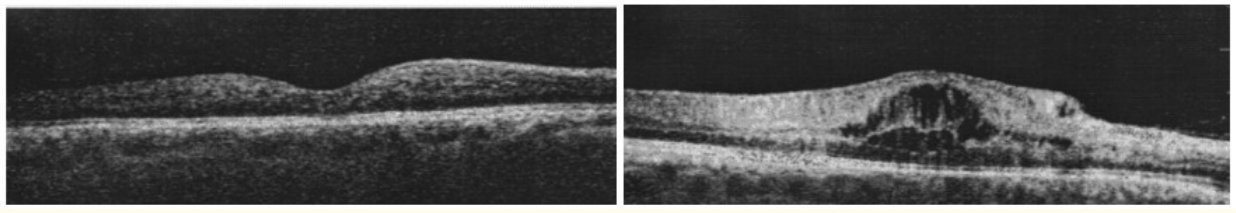

***Figure 5:*** *BThickening of the macula after cataract surgery.*

## Discussion

Overall, the final visual outcome was improved in the majority of diabetic eyes in our study. Postoperative visual acuity increased by 2 or more lines in 50 patients (83%); it was better than 0,5 in 80% at 6 months after phacoemulsification.

The progression's rate of diabetic retinopathy after phacoemulsification in the diabetic patients varies from 20 to 38% [5,6]. In Our current study, progression of retinopathy occurred in 25% of eyes after cataract surgery and in 18.33% of non-operated fellow eyes at six months after phacoemulsification. The difference between the two groups was statistically significant. This results are similar to those of Mittra., et al. in a retrospective review of 150 eyes of 119 diabetic patients undergoing phacoemulsification which reported retinopathy progression in 25% of eyes after 6 - 10 months postoperative follow-up [6]. The rate of DR progression after cataract surgery seems to be influenced by numerous variables including the severity of the preoperative DR, the HBA1C level, the arterial tension and the duration of diabetes [7,8]. The progression was associated with high levels of HbA1c in both groups of our study. The duration of diabetes was significantly associated to DR progression in both groups ($p = 0.001$ and $p= 0.004$ for operated and non-operated eyes respectively). A higher mean HbA1C in those patients whose retinopathy progressed compared to those patients whose retinopathy did not progress ($p = 0.004$ for operated eyes, $p = 0.007$ for non-operated eyes) was found. The UKPDS demonstrated that the severity and progression of DR in patients with type 2 diabetes was directly affected by glycaemic control [9].

We observed that the DR progressed in 11 non-operated eyes. This can be explained by the natural disease progression. Nevertheless, the DR progression was more frequent in the group of operated eyes. Then the cataract surgery seems to accelerate DR and macular edema progression. It's known that cataract surgery leads to blood-retinal barrier breakdown and so to liquid leakage in both retina and macula. These phenomena seem to be more frequent in diabetic patients whose eyes are vulnerable [10]. Phacoemulsification with small incision expose to a less risk of retinal damage. Surgical techniques surely affect the risk of DR progression. Extracapsular extraction may logically lead to more DR progression than phacoemulsification. However, a recent prospective controlled study reported similar rates of retinopathy progression after both surgical techniques [11].

Henricsson., *et al*. prospectively followed the diabetic retinopathy of both the operated and non-operated eyes of 35 patients who underwent monocular cataract surgery. They reported a similar rate of DR progression in both groups, and also observed that patients whose DR progressed had a significantly higher mean HbA1C than those patients whose DR did not progress [7]. The activity of diabetic retinopathy at the time of surgery appears to be a major factor causing the progression of retinopathy after cataract surgery [5].

Bijun Z had recently concluded that both visual acuity and quality of life of diabetic patients improved after cataract surgery. Cataract surgery is an effective intervention for patients with stabilized DR [12].

Concerning diabetic macular edema, Macular edema occurred in 13.33% of operated eyes and in 10% of control eyes in our study. Some previous clinical studies showed that patients with maculopathy at the time of surgery had the worst postoperative prognosis relative to visual acuity [7].

## Conclusion

Our findings suggest that cataract surgery, even by uncomplicated phacoemulsification can accelerate DR and macular edema progression in north African diabetic patients. The uncontrolled diabetes seems to be a crucial risk factor for DR progression in our patients. However, it's difficult to confirm that the DR progression is due to surgery only, the natural history of the disease can play a major role in this progression.

## Compliance with Ethical Standards

This study has no funder.

## Conflict of Interest

Author Maalej Afef declares that she has no conflict of interest. Author Khallouli Asma declares that she has no conflict of interest. Author Daldoul Nedia declares that she has no conflict of interest. Author wathek Cheima declares that she has no conflict of interest. Author Rannen Riadh declares that he has no conflict of interest.

## Ethical Approval

All procedures performed in this study were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

## Informed Consent

Informed consent was obtained from all individual participants included in the study.

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