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Posterior subtenon triamcinolone acetonide combined with phacoemulsification for patients with diabetic maculopathy

Acetónido de triamcinolona de subtenon posterior combinado con facoemulsificación para pacientes con maculopatía diabética

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Abstract

Background: The aim of the study was to evaluate the role of posterior subtenon triamcinolone in prevention of diabetic maculopathy progression after phacoemulsification surgery. **Patients and methods:** Forty eyes of 30 diabetic patients with cataract and diabetic maculopathy were enrolled the study. We planned for phacoemulsification surgery followed by posterior subtenon triamcinolone acetonide (PSTA). Best corrected visual acuity (BCVA), anterior chamber reaction, and intraocular pressure were assessed at baseline and follow-up visits. Optical coherence tomography was used to assess the central subfield macular thickness (CSMT), inner ring, and the outer ring thickness. **Results:** There is no statistically significant elevation of IOP during all follow-up visits. The mean BCVA is improved from 1.02 ± 0.12 Log MAR to 0.58 ± 0.01 ($p = 0.0001$), and 0.56 ± 0.02 ($p = 0.0001$), at 1 month and 3 months follow-up visits. At 6 months, BCVA is 0.42 ± 0.1 with a statistically significant difference from 1 month ($p = 0.002$) which is related to the progression of maculopathy. At 1 month and 3 months visits, there is no statistically significant difference in CSMT, inner ring, and outer ring from the baseline values. At 6 months, there is a statistically significant difference in CSMT and inner ring thickness as compared with the corresponding baseline values but there is no difference in the outer ring thickness. **Conclusions:** Combined phacoemulsification surgery with PSTA for patients with cataract and diabetic maculopathy prevents the possible progression of maculopathy in the 1st month and the results were maintained for 3 months with good control of the inflammation even if no topical steroid eye drops were prescribed.

Keywords: Triamcinolone acetonide. Phacoemulsification. Diabetic maculopathy. Intracameral moxifloxacin. Dropless cataract surgery.

Resumen

Objetivo del estudio: Evaluar el papel de la triamcinolona del subtenón posterior en la prevención de la progresión de la maculopatía diabética después de la cirugía de facoemulsificación. **Pacientes y métodos:** Cuarenta ojos de 30 pacientes diabéticos con cataratas y maculopatía diabética se inscribieron en el estudio. Planificamos cirugía de facoemulsificación seguida de ace-

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tónico de triamcinolona subtenoniano posterior (PSTA). La mejor agudeza visual corregida (MAVC), la reacción de la cámara anterior y la presión intraocular se evaluaron al inicio y en las visitas de seguimiento. Se utilizó tomografía de coherencia óptica para evaluar el grosor macular del subcampo central, el anillo interno y el grosor del anillo externo. **Resultados:** No hay una elevación estadísticamente significativa de la PIO durante todas las visitas de seguimiento. La AVMC media se mejora de 1.02 ± 0.12 Log MAR a 0.58 ± 0.01 ($p = 0.0001$) y 0.56 ± 0.02 ($p = 0.0001$), a 1 mes y 3 meses de visitas de seguimiento. A los 6 meses, la MAVC es de 0.42 ± 0.1 con una diferencia estadísticamente significativa de 1 mes ($p = 0.002$) que está relacionada con la progresión de la maculopatía. En las visitas de 1 mes y 3 meses, no hay una diferencia estadísticamente significativa en el CSMT, el anillo interior y el anillo exterior con respecto a los valores iniciales. A los 6 meses, hay una diferencia estadísticamente significativa en CSMT y el espesor del anillo interior en comparación con los valores de línea de base correspondientes, pero no hay diferencia en el espesor del anillo exterior. **Conclusiones:** La cirugía combinada de facoemulsificación con PSTA para pacientes con catarata y maculopatía diabética previene la posible progresión de la maculopatía en el primer mes y los resultados se mantienen durante 3 meses con buen control de la inflamación incluso sin prescripción de colirio esteroide tópico.

Palabras clave: Acetónido de triamcinolona. Facoemulsificación. Maculopatía diabética. Moxifloxacino intracameral. Cirugía de cataratas sin gotas.

Introduction

Macular edema is an important cause of reduced post-operative visual outcome after cataract surgery¹⁻³. Diabetic patients having preexisting retinopathy are more susceptible for developing macular edema after cataract surgery than normal subjects or diabetic patients with no retinopathy before the surgery^{1,4,5}.

Outcome of cataract surgeries is directly correlated to the severity of maculopathy before the surgery^{6,7}.

For the clinically significant macular edema, the macular photocoagulation has shown to be effective according to early treatment diabetic retinopathy study^{8,9}; however, laser photocoagulation is aimed to prevent further moderate vision loss. Nevertheless, it is unable to restore the already lost vision before the treatment¹⁰.

According to this limitation, other treatment modalities became more popular such as intravitreal anti-vascular endothelial growth factors (VEGF) which proved to be effective for the treatment of neovascular and exudative diabetic retinopathy since 2005; however, its use during the surgery needs long-term studies¹¹.

Intravitreal steroid injection has anti-inflammatory role and mediates downregulation of VEGF and can improve refractory macular edema but it associated with serious vision threatening complication such as cataract, glaucoma, and endophthalmitis^{12,13}.

Posterior subtenon triamcinolone acetate (PSTA) is less invasive alternate to intravitreal route and proved to be effective for posterior uveitis with associated macular edema¹⁴.

Some studies reported that PSTA when combined with macular laser-photocoagulation as a treatment for diabetic macular edema has better visual outcome if compared with laser alone¹⁵.

Macular thickness changes in response to the combined treatment also has been reported by optical coherence tomography (OCT)¹⁶.

The aim of current study is to show the effect of PSTA at the conclusion of phacoemulsification surgeries in patients with preexisting macular edema before the surgery and to evaluate the macular thickness map changes after this combined approach.

Patients and methods

This is a case and control study that was conducted with approval of the scientific committee of Al-Kindy College of Medicine and was adherent to principles of the Declaration of Helsinki.

A 30 diabetic patients presented with visually significant cataract who were planned for their cataract surgeries at Eye-Specialty-Private Hospital in the period between January-2020 and January-2021 have enrolled in the study.

The patients having maculopathy and their demographic characteristics are shown in [table 1](#).

Exclusion criteria

The following criteria were excluded from the study:

1. Previous intraocular surgeries, or inflammation.
2. History of glaucoma or steroid therapy.
3. Patients with proliferative retinopathy.
4. Patients with poor macular perfusion by OCT-Angio.
5. Intraoperative complications including posterior capsule rapture, iris injury, sulcus placement of intraocular lens.

Before the candidates were enrolled in the research, the diagnosis, prognosis, available therapeutic alternatives,

Table 1. Pre-operative patients characteristics

Demographic	Data
Eye/patient	40/30
Sex Male/female	16/14
Age (year)	60.2 ± 54
Preoperative BCVA Log MAR	1.02 ± 0.12
Baseline Central subfield thickness μm	296.4 ± 80.9
Base line inner-ring thickness μm	350.1 ± 75.5
Baseline outer-ring thickness μm	315.6 ± 80.5
Baseline IOP (mmHg)	17.4 ± 2.8
History of photo-coagulation	no
History of anti-VEGF injection during the last 3 months	28/47

BCVA: best corrected visual acuity, IOP: intraocular pressure.

and their potential benefits and drawbacks were outlined to them, and their formal informed consent was obtained.

Pre-operative assessments

All patients were examined by slit lamp for complete anterior and posterior segment examinations, intraocular pressure (IOP) by applanation tonometry (AT900, Haag-Streit Diagnostics, Switzerland), best corrected visual acuity (BCVA), OCT, and OCT-Angio and specular microscopy.

OCT and OCT-angio: (Optovue Inc, Fremont, California, USA)

Topical tropicamide 1% eye drops were used to dilate the pupils, and the imaging study was performed 3 times per patient on the same day by the same professional technician who had been qualified to use the Optovue-OCT device.

Every scan were taken as close to the fovea as possible with sufficient image clarity, and the thinnest point of the macula was imaged to prevent inaccuracies in thickness measurements due to minor positioning variations. Only if the entire extent and depth of the retina could be easily discerned, and there were no eye changes or blinking artifacts during image processing, were the photographs considered suitable.

The central subfield (circular area represents the central 1mm diameter located around the center) was calculated using OCT. The thickness of the nine early

treatments of diabetic retinopathy analysis inner and outer rings, as well as overall macular thickness, was all measured.

Cataract surgery

Phacoemulsification surgeries were done by the single experienced surgeon; clear corneal incision by 2.8 mm keratome was done, continuous curvilinear anterior capsulorhexis was performed then phaco-surgery was done by (INFINITI Vision System (Alcon Laboratories, Inc) stop and chop technique then after cortical aspiration an Sensar monofocal one piece IOL (Johnson and Johnson) in the bag was implanted, stromal hydration of the main incision by balanced salt solution till insured that it was sealed, 200 Mg in 0.2 cc of Auromox (is a preservative free, Auromox vial contains 1 cc Moxifloxacin hydrochloride 5.45 mg equivalent to 5 mg of moxifloxacin Aurolab, India) solution had been administered in the anterior chamber through the side port, its efficacy for prevention of endophthalmitis was proven by our previous cohort study¹⁷, and at the completion of the surgery 1 cc of 40 mg triamcinolone acetonide (Aurocort, Aurolab company, India, is a preservative-free 40 mg/1 cc) was injected in posterior subtenon at inferotemporal approach.

Post-operative assessments

Follow up visit after 1 day, 1 week, 1, 3, and 6 months. Anterior segment examination for AC reaction by slit lamp was done at all visits. BCVA assessment at 1, 3, and 6 months, OCT was done at 3 and 6 months. IOP was done at 1 week, 1, 3, and 6 months by applanation tonometry.

Pre-operative systemic assessments: Fasting blood sugar, HBA1C, serum lipid profile, and any patient with deranged systemic parameters have referred to physician for better glycemic control before taking the appointment for surgery.

The principal investigators at pre-operative/post-operative evaluation were ophthalmologist and optometrist who did not enroll in the study.

Statistical analysis

Minitab 16 software was used for data analysis, which was expressed in mean ± SD. Pre-operative baseline versus the corresponding postoperative data were compared by paired-sample t-test, while comparison of more than 2 means was done by one-way

ANOVA. Results were considered statistically significant if $p < 0.05$.

Results

Forty eyes of 30 patients, mean age 60 ± 4.5 , 16 were males and 14 were females. During follow-up:

Anterior segment examination

Moderate anterior segment inflammation (+2) in five eyes at 1 week follow-up visit, the condition resolved with the prescription of topical Ketorolac-tromethamine 0.5% 4 times a day and tropicamide 1% prescribed 3 times a day for 2 weeks.

BCVA changes: Mean BCVA is improved from 1.02 ± 0.12 Log MAR at base line to 0.58 ± 0.01 ($p = 0.0001$), and 0.56 ± 0.02 ($p = 0.0001$), at 1 month and 3 months follow-up visits. And at 6 months 0.42 ± 0.1 ($p = 0.002$)

IOP changes: No statistical significant elevation of IOP from the baseline values ($p = 0.62$), two patients develop significant IOP elevation (> 10 mmHg). One of them, the fellow eye has complicated cataract surgery with secondary open angle glaucoma. The other patient had no history of IOP elevation in both eyes. Both patients IOP controlled by topical IOP lowering eye drops.

Macular OCT changes

Central subfield thickness: The mean preoperative Central subfield macular thickness (CSMT) was 296.4 ± 80.9 which improved to 287.8 ± 91.3 at 1 month despite the fact that result is not a statistically significant ($p = 0.06$) but is of clinical importance. At 3 months, it was 285.6 ± 76.2 ($p = 0.62$) again no statistically significant difference from the baseline result ($p = 0.178$). At 6 months was 320.7 ± 74.5 with a significant difference from base line value ($p = 0.001$) [Figure 1](#).

Inner ring thickness: The mean base line inner ring thickness was 350.1 ± 75.5 , at 1-month visit it was 342.1 ± 85.9 . At 3 months, it was 340.7 ± 65.9 . If we compared the post-operative results with the base line inner ring thickness by one-way ANOVA, there is no statistically significant improvement ($p = 0.09$). While at 6 months, it was 364.7 ± 78.35 with significant deterioration detected ($p = 0.008$) [Figure 2](#).

Outer ring thickness: The mean base line thickness was 315.6 ± 80.5 . At 1 month, it was 320.2 ± 83.4 , 324.3 ± 65.7 at 3 months, and 322.7 ± 119.7 at 6 months.

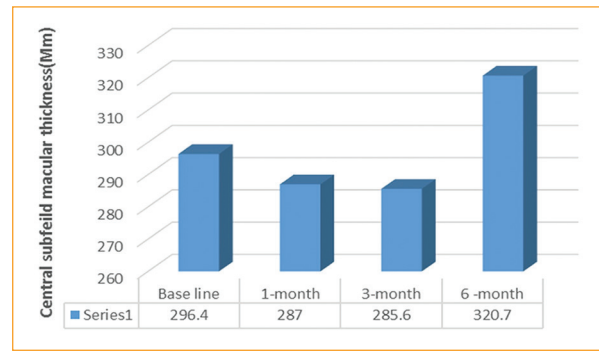


Figure 1. Central subfield macular thickness changes.

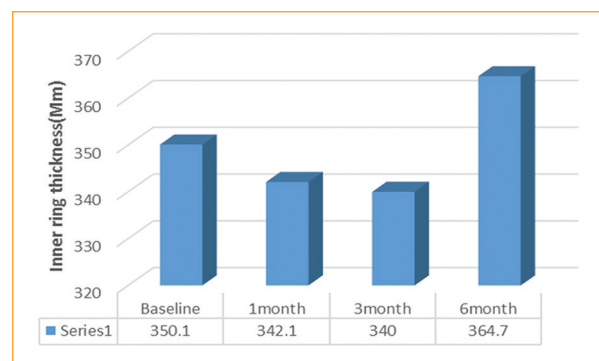


Figure 2. Inner ring thickness change.

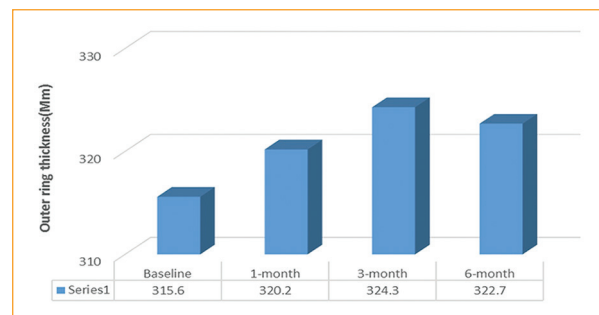


Figure 3. Outer ring thickness change.

There is no statistically significant difference by one-way ANOVA ($p = 0.74$) [Figure 3](#).

Discussion

Macular edema is the most common cause of reduced vision acuity in diabetic patients. When it comes to the matter of no retinopathy, whether cataract surgery accelerates the progression of retinopathy or not is still a point of contention¹⁷⁻²¹.

Some authors reported no significant changes of retinopathy^{18,21}, while others reported significant worsening of macular edema in eye with preexisting pre-operative macular edema^{1,4,5}. The difference in their findings may be related to difference in criteria of progression of retinopathy, confounders like blood glucose control, and the type of the surgery whether its complicated or not.

In the current study, the mean central subfield and mean inner ring thicknesses at 1 month after phacoemulsification and PSTA kept stable and showed no deterioration of thickness with nine eyes showing statistical improvement from base-line central subfield thickness. The macular thickness was maintained for 3 months after the surgery while the effect of triamcinolone in preventing deterioration after 3 months has subsided when 20 eyes required AVEGF (AVASTIN), for 10 eyes, we used focal laser photocoagulation under OCT-A guide since they refused the intravitreal injections (among them were the steroid responders). Five eyes remained stable while the other five eyes we used another dose of PSTA and topical Ketorolac tromethamine 0.5% 4 times a day for 1 month.

Our results are comparable to Lodhi et al.²², regarding the effect of PSTA injection in their controlled trial which enrolled 18 eyes with diabetic retinopathy who received PSTA, but their sample size is small and they prescribed topical steroid eye drops for 6 weeks post operatively while in our patients we implemented dropless approach to remove all confounders that may affect results of our study. Moreover, we used the OCT to better analyze the changes in the central subfield, inner ring, and outer ring.

Kim et al.²³ reported that the mean change in CMT at 1 month is higher in control group than PSTA group. This reflects the possible causes of deterioration of maculopathy at 1 month post cataract surgery which are the breakdown of blood ocular barrier and the enhanced inflammation in diabetic patients after cataract operation. Following the uneventful phacoemulsification, there is an elevation of the level of VEGF, hepatocyte growth factor, IL1, pigment epithelium derived factors that take up to 1 month to return to its baseline level²⁴ and this may explain the worsening of retinopathy at 1 month post cataract surgery.

Ahmadabadi et al.²⁵ reported that intravitreal injection of triamcinolone acetonide after phacoemulsification in diabetic patient reduced the amount of central point thickness and reduced the occurrence of cystoid macular edema. Intravitreal approaches carry the risk of cataract, glaucoma, and endophthalmitis. Our approach

is safe less invasive and effective in preventing deterioration for 3 months after the surgery. In spite of the mentioned side effects such as globe perforation (rare), scleritis, central retinal artery occlusion, blepharoptosis and infection, none of these complications were documented.

Chew et al.²⁶ reported that anterior peribulbar TA were associated with higher risk of IOP elevation and development of cataract as compared to PSTA. This is in agreement with our findings showing no statistically significant elevation in IOP at 1 month after PSTA.

Regarding the changes in BCVA: Improvement in BCVA after successful phacoemulsification and PSTA is significant and related to cataract extraction and the effect of triamcinolone that prevents progression of retinopathy which mostly occurs 1 month after cataract surgery. The improvement was maintained for 3 months while the significant reduction at 6 months was related mainly to the progression of retinopathy. The current results is in agreement with visual outcomes reported by Hegazy et al.²⁷ and Lodhi et al.²²

Regarding the anti-inflammatory effect of PSTA, anterior chamber reaction was comparable to topical steroid treated patients. This supports the dropless approach after phacoemulsification and here we extend the limit of our previous cohort study¹⁷, when we excluded diabetic patients with retinopathy from dropless approaches. Thus, we report the efficacy for prevention of postoperative inflammation and the safety of PSTA regarding the chance of IOP elevation.

Limitations of study

- Lack of a control group.
- Small number of patients enrolled in study.
- Lack of a sample size calculation.
- Surgical parameters are not included (e.g., cumulative dissipated energy).

Conclusion

Phacoemulsification surgery combined with subtenon triamcinolone improves the BCVA, prevents the expected deterioration of CSMT and progression of retinopathy in diabetic patients.

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Conflicts of interest

The authors declare that there is no conflict of interest.

Ethical disclosures

Protection of people and animals. The authors declare that the procedures followed were in accordance with the ethical standards of the responsible human experimentation committee and in accordance with the World Medical Association and the Declaration of Helsinki.

Data confidentiality. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is in the possession of the corresponding author.

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