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RESEARCH ARTICLE

Evaluation of The Ocular Surface with and Without Preservatives in the Treatment of Patients Undergoing Cataract Surgery

Katarakt Ameliyatı Yapılan Hastaların Tedavisinde Prezervanlı ve Prezervansız İlaç Kullanımı İle Oküler Yüzeyin Değerlendirilmesi

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ABSTRACT
Objective: The present study aims to evaluate the effect of medical treatment, with and without preservatives, on the ocular surface in patients without dry eye who underwent phacoemulsification surgery.
Materials and Methods: The study comprised a total of 70 patients. Following the operation, the patient was administered moxifloxacin 8x1 for a period of one week, followed by a course of steroid treatment spanning four weeks. The initial dosage of the steroids was 8x1, which was then reduced by two drops on a weekly basis. The patients were divided into two groups according to steroid use. Dexasine SE (Group 1, preservative-free) was prescribed to 35 patients, while Dexasine (Group 2, with preservatives) was prescribed to 35 patients. Schirmer's test and the evaluation of corneal and conjunctival staining were conducted before the operation, and then at one week, one month, and three months post-surgery.
Results: The mean age of the study participants was 72.03 years (±6.29) in Group 1 and 71.43 years (±5.12) in Group 2, with no statistically significant difference between the two groups (p=0.66). A comparison between Groups 1 and 2 revealed a significant discrepancy in Schirmer I, Break Up Time scores, and corneal conjunctival staining at the conclusion of the initial week and initial month. However, no substantial difference was observed at the three-month mark.
Conclusion: In patients without dry eyes, dry eye tests may deteriorate on the ocular surface for up to the first 3 months preservatives contained in the drops used before and after surgery. Therefore, the use of medication without the concomitant use of a preservative should be the preferred option.

Keywords: Schirmer I test, BUT, corneal conjunctival staining, cataract, phacoemulsification

ÖZET
Amaç: Bu çalışma kuru göz hastalığı bulunmayan ve fakoemülsifikasyon cerrahisi geçirmiş bireylerde, prezervan içeren ve prezervan içermeyen topikal tedavilerin postoperatif dönemde oküler yüzey sağlığı üzerine etkilerini değerlendirmek amacıyla yapılmıştır.
Gereç ve Yöntemler: Çalışma toplam 70 hastayı kapsamaktadır. Ameliyattan sonra, hastalara bir hafta boyunca 8x1 moksifloksasin uygulandı, ardından dört hafta süren bir steroid tedavisi uygulandı. Steroidlerin başlangıç dozu 8x1 idi ve daha sonra haftalık olarak 2 damla azaltıldı. Hastalar steroid kullanımına göre iki gruba ayrıldı. 35 hastaya Dexasine SE (Grup 1, Prezervansız), 35 hastaya ise Dexasine (Grup 2, Prezervanlı) reçete edildi. Schirmer testi ile kornea ve konjonktiva boyanmasının değerlendirmesi ameliyattan önce, ameliyattan bir hafta, bir ay ve üç ay sonra yapıldı.
Bulgular: Çalışmaya katılan hastaların ortalama yaşı Grup 1'de 72,03 ± 6,29 yıl, Grup 2'de ise 71,43 ± 5,12 yıl olarak hesaplandı; iki grup arasında yaş açısından istatistiksel olarak anlamlı bir fark bulunmadı (p = 0,66). Grup 1 ve Grup 2 karşılaştırıldığında, postoperatif 1. hafta ve 1. ayda Schirmer I testi sonuçları, gözyaşı kırılma zamanı skorları ile kornea ve konjonktiva boyanma düzeyleri arasında her iki grupta da istatistiksel olarak anlamlı fark saptandı (p<0,05). Ancak 3. ay değerlendirmelerinde bu parametreler açısından gruplar arasında anlamlı bir fark izlenmedi (p>0,05).
Sonuç: Kuru gözü olmayan hastalarda, fakoemülsifikasyon ameliyatı öncesinde ve sonrasında kullanılan damlaların içerdiği prezervanlara bağlı olarak ilk 3 aya kadar oküler yüzeyde kuru göz testlerinde bozulma olabilmektedir. Bu nedenle prezervansiz ilaç kullanımı tercih edilmelidir.

Anahtar Kelimeler: Schirmer I testi, BUT, kornea konjonktiva boyanması, katarakt, fakoemülsifikasyon

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INTRODUCTION

Cataract surgery is among the most prevalent surgical procedures in current clinical practice, playing a pivotal role in enhancing patients' visual acuity. Postoperative complications may be observed in patients following ocular surgery despite the success of the intervention. A range of alterations to the ocular surface may be identified during this period. Contemporary advances in techniques and minimally invasive approaches in anterior segment surgery have been developed to mitigate ocular surface damage during surgery. This paper is intended to provide a comprehensive overview of the subject. Nevertheless, despite these advances, ocular surface problems, especially dry eye, are prevalent after cataract and refractive surgery. Moreover, patients suffering from dry eye syndrome often experience an exacerbation of symptoms in the postoperative period. Postoperative complaints frequently include symptoms such as stinging and burning, even though the surgical procedure itself was uneventful (1). It is therefore important to review the risk factors, determine the mechanisms that trigger dry eye, and choose appropriate treatments to reduce postoperative complaints and obtain a healthy ocular surface.

The increase in dry eye symptoms after anterior segment surgeries, such as cataract surgery, is associated with the effects of the drugs used, independent of the surgery itself. The use of topical medications in the postoperative treatment process may exacerbate dry eye symptoms by having various effects on the tear film (2). Postoperative use of topical drops is a component of the healing process, and drops are commonly used for approximately one month. The drops used contain preservative active ingredients, highlighting the potential impact of preservatives on the ocular surface. Specifically, the use of topical medications containing preservatives has been associated with toxic effects that may adversely affect the ocular surface. Prolonged use of these medications can lead to alterations in the ocular surface as well as symptoms such as tear film instability, conjunctival inflammation, subconjunctival fibrosis, epithelial apoptosis, and corneal surface disruption (3,4).

Benzalkonium chloride (BAC), a widely used preservative in ophthalmic formulations, is a quaternary ammonium compound known to exert various toxic effects on the ocular surface with prolonged use. Numerous studies have demonstrated that BAC contributes to corneal epithelial damage, goblet cell loss, and tear film instability (3-5). Additionally, it has been suggested that BAC triggers several cellular mechanisms, including oxidative stress, the release of pro-inflammatory cytokines, and apoptosis, ultimately leading to ocular surface inflammation and epithelial injury. These pathological processes compromise tear film stability, intensify conjunctival inflammation, and may induce degenerative changes in both corneal and conjunctival tissues over time (6-9).

The objective of this study is to compare the effects of preservative-containing and preservative-free ophthalmic medications on the ocular surface following cataract surgery. To achieve this aim, the study will assess their impact on tear film stability, conjunctival inflammation, corneal epithelial integrity, and overall ocular surface health. The findings are expected to inform strategies for optimizing ocular surface management in the postoperative period.

MATERIAL AND METHODS

This prospective study was conducted in a tertiary care ophthalmology center between January 2024 and July 2024. The study was approved by the independent ethics committee of our hospital, and all the patients signed the informed consent form (Decision No: 2024/11/67).

Patient Selection and Grouping

The patients included in the study were selected to ensure a homogeneous distribution in terms of age, gender, and oculomotor health. The operated eye was randomized between the two groups, and the patients were divided into two main groups according to the steroid treatment used:

Group 1: 35 patients treated with dexamethasone sodium phosphate (Dexasine SE®, preservative-free formulation, Abdi İbrahim Ilac, Türkiye).

Group 2: 35 patients treated with dexamethasone sodium phosphate (Dexasine®, preservative-containing formulation, Abdi İbrahim Ilac, Türkiye)

Surgery Protocol

The surgical procedure was conducted using the standard phacoemulsification (Phaco) technique. Preoperatively, the patients received 0.1% diclofenac sodium eye drops, administered as one drop three times daily starting one day before surgery. The operations were performed under local anesthesia. Following topical anesthetic application, the ocular surface was disinfected with 5% povidone-iodine solution. The mean duration of the surgery was approximately 15 minutes.

Postoperative Treatment Protocol

In the postoperative period, the following treatment protocols were routinely applied to the patients. First, the patients received moxifloxacin 0.5% (eight times daily) for one week as an antibiotic treatment. Steroid treatment was initiated with dexamethasone sodium phosphate (Dexasine or Dexasine SE) eight times a day for the first week and continued for a total of 4 weeks, with a gradual reduction of two drops every week.

Ocular Surface Assessments

A primary objective of this study was to investigate changes in the ocular surface throughout the postoperative treatment period. To this end, ocular surface parameters were assessed preoperatively and at the end of the first week, first month, and third month following surgery. The evaluations were conducted using the following clinical parameters:

1. Schirmer I Test (Sch.I): This test, which evaluates tear production, was performed in each patient at three different times before and after surgery. A Sch.I test value of ≤10 mm was considered to indicate the presence of dry eye disease (10).

2. Break Up Time (BUT) Score: This test, performed to determine tear film stability, measures the time the tear film

remains intact. A BUT of ≤10 seconds was considered indicative of tear film instability (11).

3. Corneal and Conjunctival Staining (CCS): CCS involves the staining of the cornea and conjunctiva with fluorescein dye to assess epithelial damage on the ocular surface. The extent of damage was determined by analyzing the images obtained after staining. CCS was graded using the Oxford grading scheme, with a score of 0 considered normal (12).

Statistical Analysis

The data from this study were analyzed using SPSS (Statistical Package for the Social Sciences, version 22.0; IBM Corp., Armonk, NY, USA) software. Continuous variables were reported as mean ± standard deviation (SD). Categorical variables were analyzed using either the Chi-square test or Fisher's Exact Test, as appropriate. Changes over time were assessed using a repeated measures analysis of variance (ANOVA) for normally distributed data to assess changes related to the three study periods before and after surgery (postoperative one week, one month, and three months). We considered a p-value of less than 0.05 to be statistically significant.

RESULTS

The mean age of the study participants was 72.03±6.29 years in Group 1 and 71.43±5.12 years in Group 2, and there was no statistically significant difference between the two groups (p=0.66). Similarly, there was no significant difference in the duration of surgery between Group 1 (7.28±1.19 minutes) and Group 2 (7.24±1.30 minutes) (p=0.87). In Group 1, the Sch.I and BUT values showed a significant decrease at the end of the first week (p<0.05). However, these parameters began to improve by the end of the fourth week and approached preoperative levels by the third month (p=0.59, p=0.08) (Table 1). In Group 2, significant changes in the Sch.I and BUT values were observed at both the first week and first month (p<0.05). Nevertheless, by the third month, these parameters had returned to preoperative values (p>0.05). Specifically, the BUT value had completely normalized by the third month with no statistically significant difference from baseline (p=1.0) (Table 2).

Comparative analysis demonstrated significant differences between Groups 1 and 2 across time points in both Sch.I test values and BUT (p<0.01). In Group 1, both the Sch.I test values and the BUT showed a more pronounced decrease in the early period, followed by partial recovery during follow-up; in contrast, Group 2 maintained higher Sch.I and BUT values at all the time points, demonstrating a significant advantage over Group 1 in terms of tear secretion and tear film stability (p<0.01) (Figures 1 and 2).

Table 1. Changes in Ocular Surface Parameters Over Time in Group 1 and Group 2

Group	Timepoint	Schirmer I (mm)	p (Sch.I)	BUT (s)	p (BUT) Conjunctival Staining	Corneal	p (CCS)
Group 1	Preoperative	16.2 ± 3.3	–	14.4 ± 1.7	–	0.00	–
	1 Week	13.6 ± 3.1	<0.001	13.0 ± 2.0	<0.001	0.08	0.83
	1 Month	15.2 ± 3.0	<0.001	14.0 ± 1.7	<0.001	0.02	0.32
	3 Months	16.0 ± 2.9	0.59	14.4 ± 1.5	0.08	0.00	1.0
Group 2	Preoperative	17.9 ± 3.6	–	14.4 ± 0.3	–	0.00	–
	1 Week	14.9 ± 3.4	<0.001	12.7 ± 0.3	<0.001	0.37	0.03
	1 Month	16.7 ± 3.2	<0.001	13.8 ± 0.3	0.04	0.28	0.006
	3 Months	17.4 ± 3.2	0.12	14.6 ± 0.3	1.0	0.02	0.32

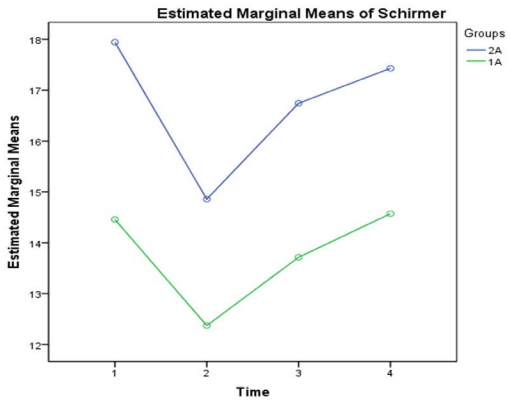

Figure 1. Changes in Schirmer I Test Values Over Time in Group 1 and Group 2

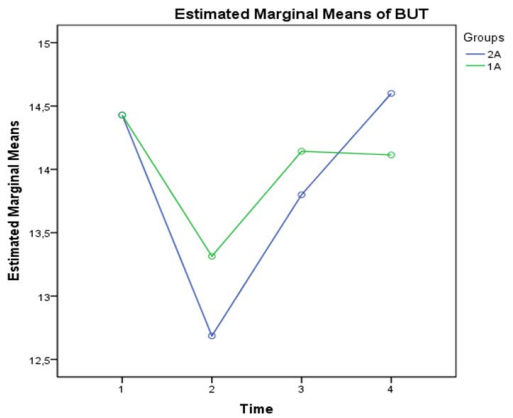

Figure 2. Changes in Tear Film Break-Up Time (BUT) Over Time in Group 1 and Group 2

DISCUSSION

The present study demonstrated that the use of eye drops containing protective agents after cataract surgery can significantly influence ocular surface health in patients without pre-existing dry eye syndrome. The findings indicate that the surgical process impacts tear film stability and the ocular surface not only through mechanical interventions but also via the pharmacological agents administered. A marked deterioration in tear film stability was observed, particularly during the first postoperative month, and this effect was noted to persist up to the third month. These results highlight the clinical relevance of using preservative-free eye drops to promote and maintain ocular surface integrity in the postoperative period. In the present study, particular emphasis was placed on the impact of detergent-type preservatives, such as BAC, on the ocular surface. BAC has been shown to disrupt the lipid layer of the tear film, leading to tear film instability, goblet cell loss, and conjunctival squamous metaplasia (13,14). These findings provide strong evidence in favor of using preservative-free eye drops to maintain optimal ocular surface health. This conclusion is further supported by similar studies in the existing literature, which have reported that both clinical and laboratory outcomes are more favorable with preservative-free formulations, particularly in patients diagnosed with dry eye disease (15,16).

In another study, the patients in the preservative-free group demonstrated superior outcomes in ocular surface tests and impression cytology findings among individuals with dry eye disease (17). Furthermore, other studies in the literature, such as that by Akçay et al., emphasize that dry eye symptoms may worsen following surgery, highlighting the importance of addressing this issue in patient counseling and postoperative treatment planning (18). These observations underscore the need for caution regarding the prolonged and intensive use of preservatives in ophthalmic treatments. The findings of our study suggest that the tear film instability and ocular surface alterations observed after cataract surgery are attributable not only to the surgical procedure itself but also to the pharmacological components of the medications administered postoperatively. Current guidelines recommend the preferential use of preservative-free ophthalmic formulations after cataract surgery, particularly in patients at risk of dry eye disease or ocular surface dysfunction. However, in daily clinical practice, preservative-containing eye drops are still commonly prescribed due to factors such as cost, availability, and established prescribing habits. Our findings indicate that postoperative tear film instability and ocular surface alterations are influenced not only by surgical trauma but also by the pharmacological properties of postoperative medications, thereby supporting a more selective and risk-based use of preservative-free treatments.

Study Limitations

This study has several limitations. First, the relatively small sample size may limit the generalizability of the findings. Future research involving larger patient cohorts is needed to validate and strengthen these results. Second, the study did not include a detailed comparison of different preservative types, which could have helped to further elucidate the specific effects of various postoperative eye drops. Lastly, the follow-up period was relatively short; longer-term studies may provide a more comprehensive understanding of ocular surface recovery and the sustained impact of postoperative treatments.

CONCLUSION

In conclusion, preservative-containing eye drops used during the postoperative period may transiently disrupt tear film stability and exert adverse effects on ocular surface health. These effects are most prominent during the first postoperative month but generally tend to resolve and return to baseline by the third month. A preference for preservative-free eye drops may represent an important strategy for preserving ocular surface health following surgery. Moreover, in clinical practice, patients should be informed about the potential adverse effects of preservative-containing agents, and the ocular surface should be carefully monitored for signs of dry eye. Future large-scale, long-term studies are warranted to further elucidate these findings and to support the development of evidence-based postoperative management protocols.

DECLARATIONS
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