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ORIGINAL ARTICLE

Response predictors of a topical corticosteroid-based regimen for dry eyes: A real-life study

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Abstract

Purpose: To examine the effectiveness and identify clinical response predictors of a short corticosteroid-based regimen consisting of topical preservative-free 0.1% dexamethasone (Monopex®, Théa Laboratories) in conjunction with artificial tears (AT) for dry eyes in a real-life clinical setting.

Methods: Patients were recruited from the Norwegian Dry Eye Clinic and were allowed to use ATs of their own choice in addition to the prescribed 14-day topical dexamethasone course. Ocular Surface Disease Index (OSDI), Dry Eye Questionnaire (DEQ-5), Schirmer test (ST), fluorescein tear film break-up time (FBUT), ocular surface staining (OSS), meibum expressibility (ME), meibum quality (MQ), number of expressible meibomian glands among the central eight glands in the lower lids (N_{MG}) and intraocular pressure (IOP) were measured at baseline and at 1-month follow-up. The average values of clinical parameters from both eyes were used for analyses. A paired *t*-test and a significance value of $p<0.05$ were used for statistical analyses. Associations between sex, age, baseline values and the changes after the intervention (Δ) were explored using linear regression.

Results: A total of 167 patients (124 women, mean age 54 years ±17 (standard deviation)) were included. One month after initiation of intervention, OSDI and DEQ5 scores improved from 39.5±22.1 to 31.4±21.3 ($p<0.001$) and from 12.6±4.2 to 11.0±4.6 ($p<0.001$), respectively. OSS improved from 2.2±1.4 to 1.8±1.5 ($p<0.001$), N_{MG} increased from 4.8±2.2 to 5.1±2.2 ($p<0.05$), while IOP decreased from 12.9±3.3 to 12.4±3.5 mmHg ($p<0.05$). Significant associations were found between the change in symptoms and objective measures of DED (Δ_{OSDI}, Δ_{DEQ5}, Δ_{OSS}, Δ_{FBUT}, ΔN_{MG}, Δ_{MQ}) and their respective baseline values (OSDI, DEQ5, OSS, FBUT, N_{MG}, MQ). The remaining tests did not show statistically significant changes.

Conclusion: Improvement in dry eye symptoms and signs were observed following a short course of topical, preservative-free 0.1% dexamethasone treatment in combination with AT. Individuals exhibiting more pronounced symptoms and signs witnessed the most profound improvements with the treatment regimen, suggesting that poor baseline parameters may serve as response predictors of the treatment regimen. While the real-life data presented herein are valuable, the conclusions are limited by the inherent biases of a non-controlled study.

KEYWORDS
corticosteroids, dry eyes, real-life study, response predictors, topical dexamethasone

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1 | INTRODUCTION

Dry eye disease (DED) is a common condition that affects the tear film and ocular surface (Bron et al., 2017). A variety of treatment modalities have been developed to manage the symptoms and improve the tear film stability in dry eye patients. These include the use of artificial tear supplements (AT), warm compresses, eyelid hygiene, dietary modifications, intense pulsed light (IPL) and punctal plugs. In cases of severe DED, prescription medications such as topical steroids and immunomodulatory agents may be used.

Topical steroid preparations are particularly useful in patients where a rapid anti-inflammatory control is desired, in which case a short steroid course as pretreatment before initiating long-term non-steroid immunomodulating medications (e.g., cyclosporine) can be of great value (Jones et al., 2017).

Efforts to find the most cost-effective medications for DED are highly welcomed because such medications contribute substantially to prescription costs in ophthalmic care (Nichols et al., 2016; Yu et al., 2011). In the last decade, several literature reviews have been conducted on this topic (de Paiva et al., 2019; Downie et al., 2019; Ervin et al., 2017; Pan et al., 2017; Pucker et al., 2016), including a recent systematic review by the Cochrane Collaboration that evaluated the effectiveness of topical corticosteroids (Liu et al., 2022). The review concluded that while topical corticosteroids may provide moderate symptom improvement, they do not impact tear film quality or quantity. The authors emphasized the need for further studies on the use of topical corticosteroids in treating DED. The present study aims to assess the effectiveness and clinical response predictors of a short, topical corticosteroid-based regimen for dry eyes. Rather than designing a randomized controlled trial (RCT), the present study was carried out as a real-life study where patients were allowed to use ATs of their own choosing in addition to the prescribed 0.1% dexamethasone course (Saturni et al., 2014). Although RCTs have high internal validity, the strict and controlled conditions in which they are conducted leads to low generalizability because they are performed in conditions very different from routine clinical practice. The purpose of designing the current investigation as real-life study was to examine the corticosteroid-based treatment regimen in a real-life clinical setting similar to routine clinical practice as opposed to controlled and optimal environments in RCTs.

2 | METHODS

2.1 | Ethics

The Regional Committee for Medical & Health Research Ethics, Section C, South East Norway (REK) reviewed the use of the data for the study and determined that it could be conducted without its approval. A letter of exemption by REK was provided (IRB ref.: IRB00001870 REK Sør-Øst C). The study adhered to the Declaration of Helsinki. Patient enrolment was based on informed consent. Data from questionnaires and clinical tests were anonymized.

2.2 | Patients

Following standardized clinical examination at the initial visit to the Norwegian Dry Eye Clinic, patients demonstrating signs of inflammation (Ocular Surface Staining; OSS > 0) were included in the study and prescribed a 14-day preservative-free 0.1% dexamethasone (Monopex®, Théa Laboratories) course. Dexamethasone was started with thrice-daily administration for 6 days, followed by application twice daily for 4 days, before tapering to once-daily application for a final 4 days. Additionally, the patients used ATs of their own preference. Standardized symptomatic and clinical assessments were repeated at a follow-up 1 month after the initial visit, that is, 2 weeks after completion of the dexamethasone course. All examinations were performed by the same physician. Patients who did not attend the scheduled 1-month follow-up appointment, or who simultaneously received other treatment (e.g. cyclosporine or IPL) were excluded. Thus, a total of 167 patients were included in the final analyses.

2.3 | Assessments

The patient-reported symptom questionnaires Ocular Surface Disease Index (OSDI) (Schiffman et al., 2000) and Dry Eye Questionnaire (DEQ-5) (Chalmers et al., 2010) were employed. Ocular surface assessments were performed from least to most invasive. The Schirmer test (ST) was performed without anaesthesia using sterile strips, following standard protocol (Bron, 2001). The Fluorescein Tear Film Break-Up Time (FBUT) was measured as the duration between a full blink and the appearance of the first dry area in the precorneal tear film. Ocular Surface Staining (OSS) was assessed using a biomicroscope with cobalt filtered light. A volume of 1 µL of fluorescein sodium 2% solution was instilled to the inferior fornix, and fluorescein staining of the cornea was evaluated according to the Oxford grading scheme ranging from 0 to 5. Meibomian gland expressibility (ME) was evaluated based on the number of expressible Meibomian glands among the central five glands using a four-point score (0: 5 glands expressible; 1: 3–4 glands expressible; 2: 1–2 glands expressible; 3: 0 glands expressible). Meibum quality (MQ) of each gland was assessed according to a four-point score (0: clear; 1: cloudy; 2: granular; 3: toothpaste). The number of expressible Meibomian glands among the central eight glands in the lower lids (N_{MG}) was evaluated by applying moderate pressure on the lower lid margin using a cotton swab, and viewed through biomicroscopy. Intraocular pressure (IOP) was measured with iCare tonometer. Symptom scores and clinical examinations were collected at baseline and at one-month follow-up. Given the short duration of dexamethasone use in the current study, long-term adverse effects, such as cataract formation, were not evaluated.

2.4 | Statistical analyses

The average values of clinical parameters from both eyes were used for analyses. A paired *t*-test was used

to compare the values at baseline and at the 1-month follow-up. Associations between sex, age, baseline values and the changes after the treatment (Δ) were explored using linear regression. A p-value of <0.05 was considered statistically significant (SPSS ver. 21.0).

3 | RESULTS

3.1 | Patient demographics

The study included 167 patients with an average age of 54±17 years, 74% were women.

3.2 | Effect on patient-reported symptom scores

One month after initiation of intervention, OSDI and DEQ5 scores improved from 39.5±22.1 to 31.4±21.3 ($p<0.001$) and from 12.6±4.2 to 11.0±4.6 ($p<0.001$), respectively.

3.3 | Effect on ocular surface parameters

At the 1-month follow-up, OSS had improved from 2.2±1.4 to 1.8±1.5 ($p<0.001$). No significant change was observed in FBUT (pre-intervention: 4.7±2.8; post-intervention: 4.6±2.8; $p=0.53$) or ST (pre-intervention: 16.0; post-intervention: 16.1; $p=0.89$).

3.4 | Effect on meibomian glands

The number of expressible Meibomian glands among the central eight glands in the lower lids (N_{MG}) increased from 4.8±2.2 to 5.1±2.2 ($p<0.05$). However, ME (pre-intervention: 1.4±1.0; post-intervention: 1.3±0.9; $p=0.41$) and MQ (pre-intervention: 4.7±3.2; post-intervention: 5.1±3.7; $p=0.13$) did not show any statistically significant change.

3.5 | Effect on intraocular pressure

At the 1-month follow-up, IOP had declined from 12.9±3.3 (at baseline) to 12.4±3.5 mmHg ($p<0.05$) (Figure 1).

3.6 | Baseline disease severity was associated with greater improvement

Significant associations were found between the change in symptoms and objective measures of DED (Δ_{OSDI}, Δ_{DEQ5}, Δ_{OSS}, Δ_{FBUT}, ΔN_{MG}, Δ_{MQ}) and their respective baseline values (OSDI, DEQ5, OSS, FBUT, N_{MG},

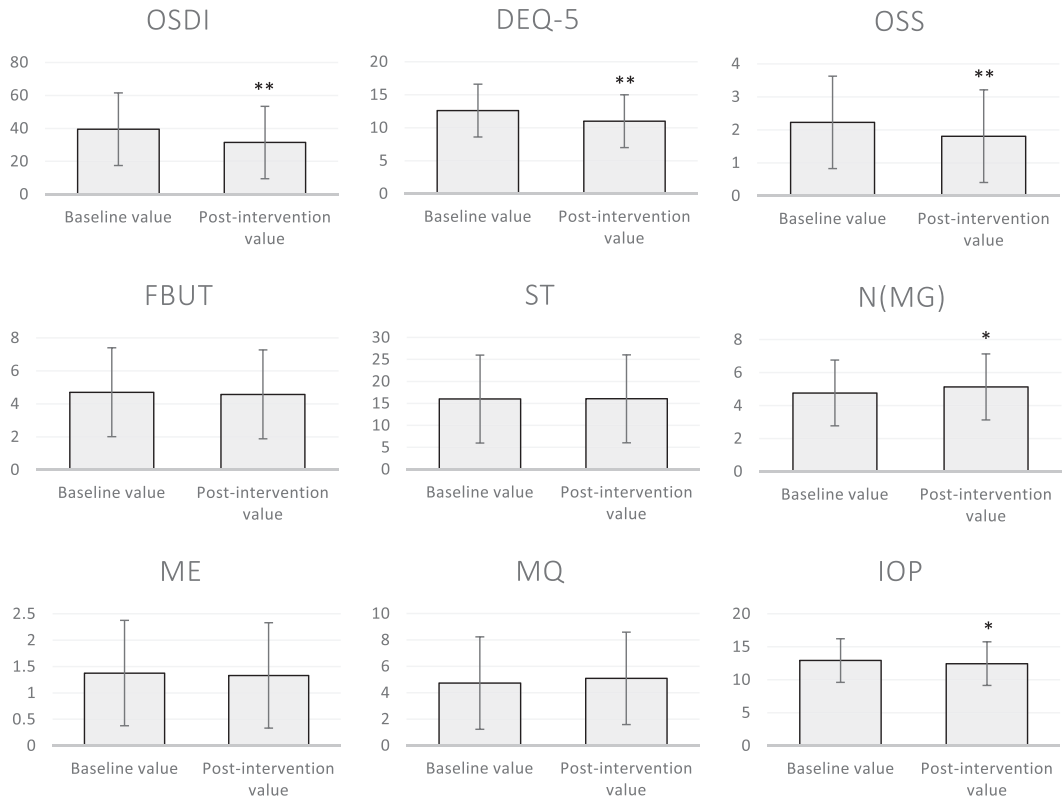

FIGURE 1 The bar charts show the baseline values and post-intervention values of the following subjective and objective dry eye parameters after a 2-week course of topical preservative-free 0.1% dexamethasone in conjunction with artificial tears: Ocular Surface Disease Index (OSDI), Dry Eye Questionnaire (DEQ-5), ocular surface staining (OSS), fluorescein tear film break-up time (FBUT), Schirmer test (ST), number of expressible Meibomian glands among the central eight glands in the lower lids (N_{MG}), meibum expressibility (ME), meibum quality (MQ) and intraocular pressure (IOP). * indicates statistical significance at $p<0.05$ while ** indicates statistical significance at $p<0.001$. Error bars represent standard deviation.

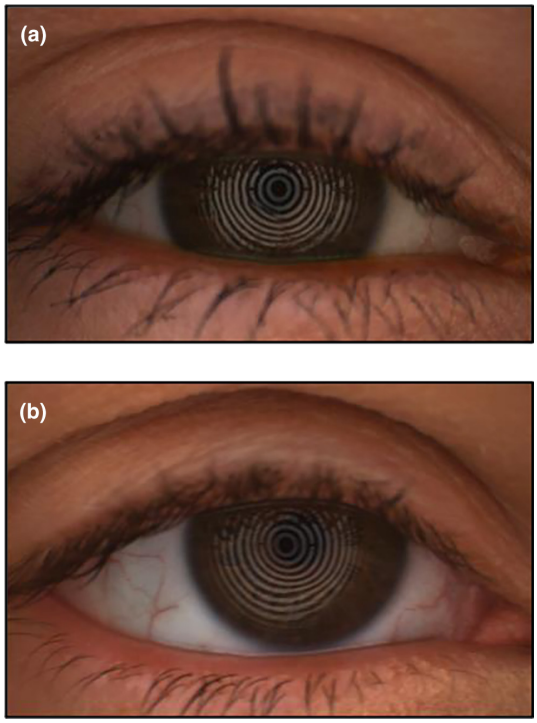

FIGURE 2 Representative clinical photographs before (a) and after (b) intervention show increased palpebral fissure height and reduction in palpebral oedema as an indirect sign of symptom relief. Images reproduced upon consent from the patient.

MQ). Specifically, Δ_{OSDI} was associated with baseline OSDI ($b=-0.645$, $p<0.001$), Δ_{DEQ5} was associated with baseline DEQ5 ($b=-0.297$, $p<0.05$), Δ_{OSS} with baseline OSS ($b=-0.326$, $p<0.001$), Δ_{FBUT} with baseline FBUT ($b=-0.53$, $p<0.001$) and ST ($b=0.08$, $p<0.001$), ΔN_{MG} with baseline N_{MG} ($b=-0.449$, $p<0.001$), and Δ_{MQ} with baseline MQ ($b=-0.456$, $p<0.001$). The results suggest that poor baseline values in subjective and objective measures of DED are associated with more pronounced improvements post-intervention (Figure 2).

4 | DISCUSSION

The aim of the current investigation was to examine the effectiveness and clinical response predictors of a short term, topical corticosteroid-based regimen for dry eyes in a real-life clinical setting similar to routine clinical practice as opposed to a controlled RCT-like environment. The patients were allowed to use ATs of their own choice in addition to the prescribed 0.1% preservative-free dexamethasone course. We found an alleviation of dry eye symptoms, decreased ocular surface staining, decreased IOP, and improvement in Meibomian gland secretions that persisted beyond the duration of the intervention. Patients exhibiting more pronounced symptoms and signs at baseline witnessed the most profound improvements with the treatment protocol. This observation holds particular significance as DED is characterized by a lack of correlation between symptom severity and ocular findings. Although the improvement in DED signs and symptoms reported herein are in line with previous reports (Akhlaq et al., 2019; Korenfeld et al., 2021; Lee et al., 2014; Pflugfelder et al., 2004), our findings that poor baseline values in subjective and objective measures of DED were associated with more pronounced improvements post-intervention have not, to the best of our knowledge, been published to date. These observations are promising news for patients and care providers.

DED is a chronic disease and a short dexamethasone course as described herein does not cure it. However, such treatment courses of shorter durations are employed for temporary relief or while initiating treatment with topical immunomodulators such as cyclosporine A. Repeated pulses of dexamethasone expose patients to the usual side effects of topical steroids. Given the short duration of dexamethasone use in the current study, long-term adverse effects, such as cataract formation, were not evaluated. Moreover, long-term follow-up was not possible because withholding other treatment options (e.g. IPL or non-glucocorticoid topical immunomodulators) for patients without adequate symptom relief from the corticosteroid-based treatment regimen was considered problematic from an ethics and safety point-of-view. While cataract formation and long-term IOP (known side-effects of topical corticosteroid use) were not examined in this study, a significant reduction in IOP was observed at the 1-month follow-up. The reduction in IOP, although small, was somewhat unexpected because the association between steroid use and elevated IOP is well established (Roberti et al., 2020). This finding could possibly be explained by a reduction of ocular surface inflammation and a general improvement in the ocular surface health following the corticosteroid-based treatment regimen. In fact, treating ocular surface disease has been shown to reduce IOP in glaucoma patients (Dubrulle et al., 2018; Mylla Boso et al., 2020). However, further elaboration on this hypothesis was outside the scope of this investigation, as was examination of the long-term efficacy, safety and side-effect profile of the intervention.

Previous investigations have reported improved FBUT and increased ST with the use of topical steroids in DED (Yang et al., 2006). Therefore, we expected similar results in our dataset as well. However, contrary to our expectations, no significant change was observed in FBUT, ST, ME or MQ. The difference in dosing, steroid formulation, DED severity and time from completion of steroid course to final examination could provide possible explanations for the discrepancies between the cited study and our dataset. Nevertheless, further research is needed to fully understand the impact of topical steroid use on these parameters and to determine the cause of these findings.

Osmolarity, which measures the total solute concentration in tears, has been widely used in studies assessing DED (Wolffsohn et al., 2017). It is also a part of the diagnostic criteria for DED as defined by the Tear Film and Ocular Surface Society (TFOS) in the Dry Eye Workshop (DEWS) II Diagnostic Methodology report (Wolffsohn et al., 2017). However, it has been criticized for its low precision and potential to be easily affected by external factors such as tear evaporation rate, temperature and humidity (Tashbayev et al., 2020). Thus, in the present analyses, we opted out of measuring osmolarity, however, we employed a healthy combination of

corroborating clinical parameters that taken together – in our view – adequately describe the disease state at the time of each assessment.

The present study has two important limitations. First, the absence of a control group receiving a placebo or alternative treatment limits the ability to attribute the observed improvements solely to the dexamethasone-based treatment regimen. Recruiting patients for a control group proved to be difficult as most patients visiting the Norwegian Dry Eye Clinic are in need of anti-inflammatory therapies to break the vicious cycle of DED pathophysiology. Second, the lack of blinding raises the possibility of bias, as both patients and researchers were aware of the intervention being administered. This could influence the subjective measures reported by patients and potentially affect the interpretation of objective measures. While the real-life data presented herein are valuable, the conclusions are limited by the inherent biases of a non-controlled study. A future randomized double-blind study could further expand on the findings of the current study.

5 | CONCLUSION

In conclusion, we herein report improvement in dry eye symptoms and signs following a short course of topical, preservative-free 0.1% dexamethasone in combination with AT. Individuals exhibiting more pronounced symptoms and signs at baseline witnessed the most profound improvements with the treatment regimen, suggesting that poor baseline parameters may serve as response predictors of the treatment regimen.

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CONFLICT OF INTEREST STATEMENT

TPU, FF, TS and AZK are co-owners of The Norwegian dry eye clinic and the Clinic of eye health, Oslo, Norway, The clinics deliver talks for and/or receive financial support from the following: ABIGO, Alcon, Allergan, AMWO, Bausch&Lomb, Bayer, European school for advanced studies in ophthalmology, InnZ Medical, Medilens Nordic, Medistim, Novartis, Santen, Specsavers, Shire Pharmaceuticals and Thea Laboratories. TPU has served on the global scientific advisory board for Novartis and Alcon as well as the European advisory board for Shire Pharmaceuticals. HE is the Norwegian Global Ambassador for Tear Film and Ocular Surface Society (TFOS), a Board Member of the International Ocular Surface Society, a Consultant at the Norwegian Association for the Blind and Partially Sighted, and the Editor-in-Chief of Oftalmolog, an eye journal distributed to all eye doctors in the Nordic region since 1980.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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