Patient Tolerability of Intracanalicular Dexamethasone Insert Compared to Topical Loteprednol Etabonate Ophthalmic Gel

Authors: Jennifer S. Harthan, OD, FAAO, FSLS; Chelsea Bradley, OD, FAAO, FSLS; Elyse Nylin • Affiliations: Illinois College of Optometry, Chicago, IL

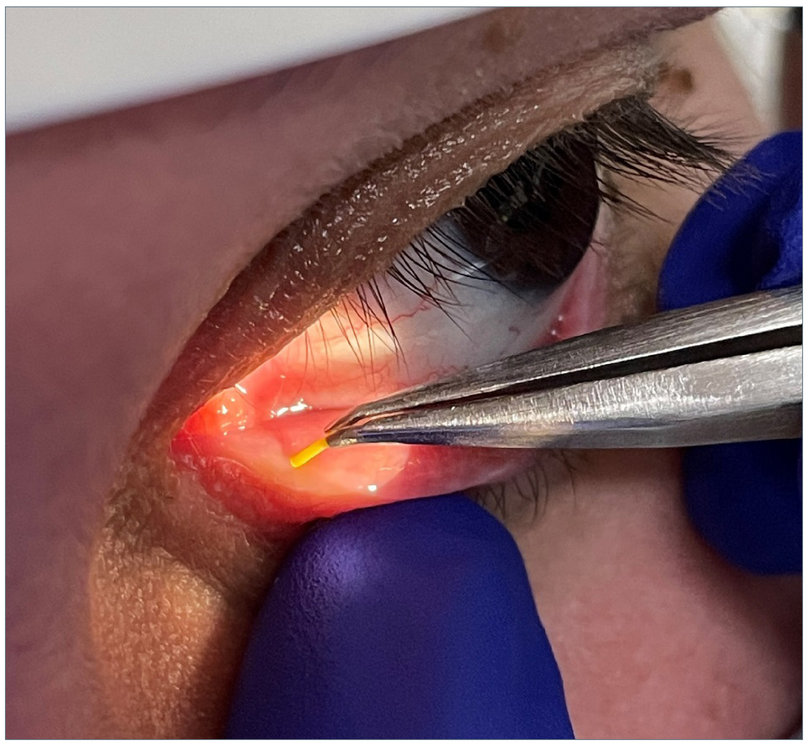
INTRODUCTION

- Keratoconus (KC) is a bilateral, asymmetric, non-inflammatory corneal ectasia and is associated with not only decreased visual acuity, but also reduced tear film quality [1].
- The TFOS DEWS II Report has included allergic conjunctivitis as a risk factor for dry eye disease [2].
- Topical steroids play an important role in the treatment of both allergic conjunctivitis and dry eye disease.
- Drug delivery platforms may allow patients to eliminate topical medications which are generally associated with lack of compliance and difficulty of use, particularly for those patients who wear contact lenses.

PURPOSE

The purpose of this study was to look at patient tolerability of intracanalicular dexamethasone insert compared to traditional topical steroid use for patients with keratoconus wearing rigid contact lenses also diagnosed with allergic conjunctivitis and dry eye disease.

FIGURE 1
Intracanalicular dexamethasone being inserted



METHODS

- Patients ≥ 18 years of age with bilateral keratoconus, wearing rigid contact lenses (corneal and sclerals), who had been diagnosed with allergic conjunctivitis and dry eye disease were invited to participate in a prospective randomized study which was reviewed and approved by the Illinois College of Optometry's IRB.
- After screening and informed consent was obtained, per participant, one eye was randomized to receive:
  - Intracanalicular dexamethasone insert at the baseline visit (study eye) (Figure 1)
  - The other eye was assigned to receive topical loteprednol etabonate ophthalmic gel 0.38% (control eye) and tapered over one month (4,3,2,1 weekly taper)
- Subjects were evaluated for a screening/ baseline evaluation, day 0, day 7, day 30 and day 90 evaluations.
  - Subjects completed the OSDI at each visit.
- At the 90 day follow up, patients completed the Comparison of Ophthalmic Medications for Tolerability (COMTOL) questionnaire.
- Descriptive statistics are presented.

RESULTS

- 18 individuals (10 females and 8 males) with keratoconus (36 eyes) wearing bilateral gas permeable contact lenses completed the study.
- The average age of subjects at the time of the study was 48.4 ± 14.8 (range: 24-74 years).
- Mean overall OSDI score at baseline screening exam was 48.6 ± 15.9 and at the final visit was 33.7 ± 12.7.
- Clinical signs were similar between treatment arms at baseline and final visit (Table 1).

TABLE 1
Summary of clinical signs at baseline and final visits (mean ± SD) for intracanalicular insert (study eye) and topical loteprednol (control eye) treatments.

Clinical Signs	Baseline Visit Study Eye (mean ± SD)	Final Visit Study Eye (mean ± SD)	Baseline Visit Control Eye (mean ± SD)	Final Visit Control Eye (mean ± SD)
Conjunctival Papillary Grade	1.8 ± 0.7	1.1 ± 0.3	1.8 ± 0.7	1.2 ± 0.4
Osmolarity	320 ± 20.1	297.8 ± 31.6	321.8 ± 17.0	304.5 ± 21.6
Tear Break-Up-Time	3.3 ± 1.8	3.4 ± 1.7	3.4 ± 1.9	3.6 ± 1.8
Corneal Stain	7.3 ± 2.7	5.0 ± 2.2	7.7 ± 2.9	5.2 ± 2.1
IOP	14.6 ± 3.1	14.7 ± 3.1	14.9 ± 3.2	15.1 ± 3.1

- At the 90-day visit, subjects were asked which treatment regimen they preferred (COMTOL questionnaire).
  - 88.9% (16) preferred the intracanalicular insert and 11.1% (2) preferred the topical loteprednol administration.
  - 33.3% (6) of subjects who received the intracanalicular insert reported ocular itching and dryness rarely but when asked how bothered they were by these symptoms, 33.3% (2) stated some, and 66.7% (4) stated a little.
  - 44.4% (8) who received the topical loteprednol reported redness and dryness, 38.9% (7) tearing and itching, and 22.2% (4) reported problems with reading. 25% (2) were bothered quite a bit by these symptoms, 37.5% (3) a little, and 37.5% (3) were not at all.
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DISCUSSION

It has been reported that patients with keratoconus have a history of dry eye syndrome and allergies [3]. Topical steroids play an important role in the treatment of inflammation and have traditionally been available in vials or bottles as a suspension. Adherence to using eye drops is generally poor, with the literature suggesting about 30% rate of nonadherence [4]. Patients wearing contact lenses generally must remove their lenses to instill medicated eye drops, increasing their burden of care.

CONCLUSION

Both intracanalicular dexamethasone insert and topical loteprednol improved signs and symptoms of dry eye and allergy in patients with keratoconus. However, the intracanalicular dexamethasone insert was the preferred treatment of choice by patients. This may enhance comfort and compliance for this cohort due to not having to remove contact lenses during treatment. Further studies are needed to compare larger study cohorts regarding additional subjective and objective measures.

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CONTACT: Jennifer S. Harthan, OD, FAAO, FSLS • JHarthan@ICO.edu