Effect of Desonide 0.25% Ophthalmic Solution on Central Corneal Thickness and Intraocular Pressure of Patients with Allergic Conjunctivitis

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Aim: *To evaluate whether a significant difference exists between the initial and final mean central corneal thickness that might affect Goldmann applanation tonometer recordings of patients with allergic conjunctivitis treated with desonide 0.25% ophthalmic solution, and to determine the effect of desonide on intraocular pressure by using adjusted intraocular pressure values.*
Methods: *This double-blind randomised placebo-controlled trial enrolled 30 patients (60 eyes) with allergic conjunctivitis. Patients were randomly assigned to receive desonide to 1 eye (study eye) and preservative-free tear supplement (Tears Naturale Free®) to the other eye (control eye) 3 times daily for 3 weeks. Goldmann applanation tonometry and central corneal thickness of both eyes were recorded on the day of presentation and 3 weeks later.*
Results: *Regression of itching, tearing, conjunctival hyperaemia, and tarsal conjunctival papillary reaction were noted in the study eyes after 3 weeks of treatment. The control eyes showed mild regression of pruritis, tearing, conjunctival hyperaemia, and tarsal conjunctival papillary reaction after 3 weeks. There was a significant difference between the initial and final mean central corneal thickness values for the study eyes ($p = 0.003$). There were no statistically significant differences between the initial and final mean values of Goldmann applanation tonometry and adjusted intraocular pressure for the study eyes. No statistically significant differences were found between the initial and final mean values of any of the parameters for the control eyes.*
Conclusion: *Inflammation-induced increase in central corneal thickness of patients with allergic conjunctivitis treated with desonide showed statistically significant regression. However, this regression did not significantly affect Goldmann applanation tonometry and adjusted intraocular pressure values of the treated eyes.*

Key words: *Conjunctivitis, allergic, Corneal topography, Desonide, Intraocular pressure*

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Introduction

Desonide 0.25% ophthalmic solution (desonide) is a non-fluorinated topical steroid that has been shown to be effective and safe for the treatment of ocular allergic disorders.[1,2] No significant side effects of desonide on Goldmann applanation tonometer (GAT) recordings have been reported.[2] However, inflammation-induced increase in central corneal thickness (CCT) might cause false GAT recordings initially, and regression of CCT to baseline during treatment with desonide might also cause false low GAT recordings compared with the initial GAT values.

The purpose of this study was to evaluate whether a significant difference exists between the initial and final mean CCT values that might affect GAT recordings of patients with allergic conjunctivitis treated with desonide, and to determine the real effect of desonide on intraocular pressure (IOP) by using adjusted IOP (AIOP) values.

Methods

This study was a double-masked randomised placebo-controlled clinical trial involving 30 patients (60 eyes) with allergic conjunctivitis diagnosed clinically according to the signs and criteria for

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allergic conjunctivitis, including itching, tearing, and conjunctival hyperaemia for 10 to 14 days associated with moderate to severe papillary reaction in the tarsal conjunctiva.[3] The patients were enrolled in the study according to the principles outlined in the Declaration of Helsinki. Ethics approval was given, and all patients provided written informed consent. Patients were excluded if they had a history of eye surgery and recent use of anti-allergic medications or drops.

Each eye of the patients underwent visual acuity testing, slit-lamp biomicroscopy for signs of allergic conjunctivitis, and dilated fundus examination to rule out ocular pathologies other than allergic conjunctivitis. The patients with allergic conjunctivitis (n = 30) were randomly assigned to receive desonide to 1 eye (study eye), and preservative-free tear supplement (Tears Naturale Free®) to the other eye (control eye) 3 times daily for 3 weeks. The study medication (desonide) was masked to the patients and examiner. IOP measurements were done by using the GAT (Nikon, Tokyo, Japan), and CCT measurements were done by using the ultrasonic OP-1000 pachymeter (Nidek Tech America Inc, Greensboro, USA) on the day of presentation and 3 weeks later by the same physician who was masked to the randomisation. IOP measurements were taken once at each visit by using the same GAT for the entire study. AIOP values were used to document the real effect of desonide on IOP.

GAT measurements were adjusted by CCT using the correction Formula:

$$6.\ P = A + (550 - T)/18e^{-0.005A} + 0.8\ (675 / (K1 + K2) - 7.848837)$$

where P = AIOP (mm Hg), A = applanation reading of IOP (mm Hg), T = CCT (μm), and K1 and K2 = keratometric values in D.[4]

Statistical analysis was done by using paired *t* test to compare the initial and final mean values of CCT, GAT, and AIOP measurements of the control and study eyes using the Statistical Package for the Social Sciences version 15.0 (SSPS Inc, Chicago, USA). A p value of ≤0.05 was considered to be statistically significant.

Results

There were 15 men and 15 women. The age range was 14 to 48 years (median, 24 years). All patients had best-corrected visual acuity of 20/20 with refractive errors between –6.00 and +0.50 D. None of the patients was lost to follow-up.

Regression of itching, tearing, conjunctival hyperaemia, and tarsal conjunctival papillary reaction was noted in the eyes that received desonide after 3 weeks of treatment. The control eyes showed mild regression of pruritis, tearing, conjunctival hyperaemia, and tarsal conjunctival papillary reaction after 3 weeks. No medication was used to control IOP higher than 21 mm Hg.

Initial mean CCT values for the control and study eyes were 568.07 and 573.27 μm, respectively (Table 1). Final mean CCT values of the control and study eyes were 564.93 and 564.10 μm, respectively (Table 1). The difference between the initial and final mean CCT values for the control eyes was not statistically significant (t = 0.782; p = 0.441) [Table 2]. However, the difference between the initial and final mean CCT values for the study eyes was statistically significant (t = 3.217; p = 0.003) [Table 2]. Initial mean GAT values for the control and study eyes were 15.25 and 15.11 mm Hg, respectively (Table 1). Final mean GAT values for the control and study eyes were 14.97 and 14.83 mm Hg, respectively (Table 1). There were no statistically significant differences between initial and final mean GAT values for the control and study eyes (t = 0.851; p = 0.402 and t = 1.108; p = 0.277, respectively) [Table 2]. Initial mean AIOP values for the control and study eyes were 15.25 and 15.11 mm Hg, respectively (Table 1). Final mean AIOP values for the control and study eyes were 14.97 and 14.83, respectively (Table 1). There were no statistically significant differences between the initial and final mean AIOP values for the control

Table 1. The range and mean (standard error) of initial and final central corneal thickness, Goldmann applanation tonometer, and adjusted intraocular pressure values of eyes receiving desonide or Tears Naturale Free.

	Desonide		Tears Naturale Free	
	Mean (SE)	Range	Mean (SE)	Range
Central corneal thickness (μm)				
Initial	573.27 (4.80)	525-624	568.07 (5.24)	528-626
Final	564.10 (5.01)	524-615	564.93 (5.44)	526-618
Goldmann applanation tonometry (mm Hg)				
Initial	15.11 (0.44)	11-23	15.25 (0.55)	11-24
Final	14.83 (0.60)	11-24	14.97 (0.71)	10-26
Adjusted intraocular pressure (mm Hg)				
Initial	15.11 (2.39)	11.03-18.88	15.25 (0.55)	10.32-22.57
Final	14.83 (3.31)	7.15-23.48	14.97 (3.02)	8.96-26.85

Table 2. Difference between the initial and final mean values for central corneal thickness, Goldmann applanation tonometry, and adjusted intraocular pressure for eyes receiving desonide or Tears Naturale Free.

Paired samples	95% confidence interval	*t* Value	p Value
Central corneal thickness			
Initial versus final desonide	3.327 - 15.013	3.217	0.003
Initial versus final Tears Naturale Free	-5.067 - 11.332	0.782	0.441
Goldmann applanation tonometry			
Initial versus final desonide	-0.479 - 1.612	1.108	0.277
Initial versus final Tears Naturale Free	-0.608 - 1.474	0.851	0.402
Adjusted intraocular pressure			
Initial versus final desonide	-0.897 - 1.455	0.485	0.632
Initial versus final Tears Naturale Free	-0.979 - 1.539	0.455	0.653

and study eyes (t = 0.455; p = 0.653 and t = 0.485; p = 0.632, respectively) [Table 2].

Discussion

Ocular surface inflammation at the cellular level of the conjunctiva and the cornea has been shown in patients with allergic conjunctivitis.[5,6] Direct signs of conjunctival inflammation such as hyperaemia, papillary reaction, and oedema in ocular allergies were correlated with the severity of corneal complications.[6] The initial mean values of CCT for the control and the study eyes of the patients with allergic conjunctivitis in this study was approximately 568 and 573 μm, respectively. The mean CCT of Caucasians in the same age group was reported to be approximately 550 μm.[7] However, it is possible that inflammation-induced increase in CCT occurs in patients with allergic conjunctivitis. The effect of topical steroids, including dexamethasone sodium phosphate 0.1%, fluorometholone 0.1%, loteprednol etabonate 0.5%, prednisolone acetate 1%, and generic prednisolone acetate 1%, on corneal thickness and IOP after 24 hours or 72 hours of administration has been studied in New Zealand white rabbits with endotoxin-induced uveitis, and none of the steroids has been found to be effective at promoting the return to baseline of inflammation-induced corneal thickness and IOP.[8] It has been proposed that a longer observation period might be required to document the return of IOP and corneal thickness to baseline values.[8]

Desonide has been shown to be effective versus placebo in reducing itching, tearing, and conjunctival hyperaemia within 3 weeks for patients with allergic conjunctivitis.[2] This study also found regression of itching, tearing, and conjunctival hyperaemia within 3 weeks in the eyes receiving desonide compared with the control eyes.

No effects of desonide on GAT were reported in the previous study.[2] However, GAT was not adjusted for the variations in CCT during the treatment period. It is possible that inflammation-induced increase in CCT might affect evaluation of the effect of desonide on GAT. Therefore, this study evaluated AIOP values to ascertain the real effect of desonide on IOP. The results showed that inflammation induced increase in CCT in both the control and study eyes. The regression of inflammation-induced increase in CCT for the study eyes receiving desonide was statistically significant (p= 0.003, 2-tailed), while the regression of inflammation-induced increase in CCT for the control eyes receiving Tears Naturale Free was not statistically significant (p = 0.441, 2-tailed).

One limitation is that Tears Naturale Free might not be a placebo, although the composition of ingredients is totally different from desonide. The ideal placebo for this study would be the same composition of eye drop solution without the desonide component.

Inflammation-induced increase of CCT in patients with allergic conjunctivitis treated with desonide showed a statistically significant regression. However, this regression in CCT did not significantly affect the GAT and AIOP values of the treated eyes.

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