

# Efficacy of Topical Diclofenac versus Dexamethasone after Strabismus Surgery

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**Aim:** To compare the efficacy of diclofenac and dexamethasone when administered after strabismus surgery.

**Methods:** Fifty consecutive patients requiring strabismus surgery were randomly assigned to receive either diclofenac 0.1% (group 1) or dexamethasone 0.1% (group 2) as eye drops 4 times daily for 1 month after strabismus surgery. All patients were examined 1 day and 1, 2, and 4 weeks postoperatively. The degree of patient discomfort, chemosis, and conjunctival congestion and gap were recorded and intraocular pressure was measured. Mann-Whitney U, Fisher exact, and Chi squared tests were used for analysis.

**Results:** The patients were aged between 2 and 45 years. The male to female ratios in groups 1 and 2 were 0.92:1 and 1.08:1, respectively. There were statistically significant differences between groups 1 and 2 with respect to discomfort, conjunctival congestion, chemosis, and conjunctival gap 2 weeks postoperatively in favour of dexamethasone. There was no statistically significant difference in intraocular pressure between the groups 1 day or 4 weeks after surgery.

**Conclusions:** Dexamethasone 0.1% was more effective than diclofenac 0.1% post-strabismus surgery. No serious side effects of dexamethasone treatment were noted.

**Key words:** Intraocular pressure, Non-steroidal anti-inflammatory agents, Ophthalmological surgical procedures, Steroids, Strabismus

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## Introduction

Strabismus surgery generally results in irritation and mild discomfort to the eye or peri-orbital area. Wide variations exist in recommendations for postoperative management of inflammation. Patients usually receive standard over-the-counter analgesics for minor discomfort; narcotics are seldom required for pain relief. Topical steroids are usually prescribed after surgery. However, serious side effects such as increased intraocular pressure (IOP), delayed conjunctival and scleral wound healing, herpetic keratitis, and cataract have been reported.<sup>1-7</sup> Diclofenac, a cyclooxygenase inhibitor, has been used to decrease inflammation and has been shown to have efficacy equal to or greater than that of steroidal anti-inflammatory drugs.<sup>8-11</sup>

The aim of this study was to compare the efficacy of diclofenac 0.1% and dexamethasone 0.1% eye drops in terms of improvements in postoperative comfort and reduction of signs of inflammation.

## Methods

### Patients

Fifty consecutive patients who underwent 2-muscle strabismus surgery in 1 or both eyes due to esotropia or exotropia at Khalili Hospital, Shiraz, Iran, during a 6-month period were randomly assigned to 2 groups of 25 patients. Patients with even record numbers were assigned to group 1 to receive diclofenac 0.1% (Novartis, Calgary, Canada) and patients with odd record numbers were assigned to group 2 to receive dexamethasone phosphate 0.1% (Sina Darou, Tehran, Iran). All patients or their parents signed a consent form. Patients with a history of allergic reaction to non-steroidal anti-inflammatory drugs, any systemic disorder, previous ocular surgery, or who had a family history of glaucoma were excluded from the study. Also excluded were patients who had undergone surgery involving more than 2 muscles or the oblique muscles. Each patient received a complete ocular examination prior to surgery.

### Procedure

Strabismus surgery (recession and resection) was performed according to the standard protocols by the same surgeon. Limbal conjunctival incisions with relaxing incisions were used for

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**Table 1. Symptoms present 1 day and 2 weeks postoperatively in patients treated with diclofenac (group 1) or dexamethasone (group 2).**

Symptom and severity*	Discomfort				Conjunctival congestion				Chemosis			
	Number of patients (%)				Number of patients (%)				Number of patients (%)			
	0	I	II	III	0	I	II	III	0	I	II	III
Day 1												
Group 1	4 (16)	9 (36)	9 (36)	3 (12)	3 (12)	5 (20)	10 (40)	7 (28)	2 (8)	11 (44)	7 (28)	5 (20)
Group 2	0 (0)	13 (52)	12 (48)	0 (0)	0 (0)	15 (60)	10 (40)	0 (0)	6 (24)	17 (68)	2 (8)	0 (0)
Week 2												
Group 1	17 (68)	8 (32)	0 (0)	0 (0)	15 (60)	10 (40)	0 (0)	0 (0)	19 (76)	6 (24)	0 (0)	0 (0)
Group 2	25 (100)	0 (0)	0 (0)	0 (0)	25 (100)	0 (0)	0 (0)	0 (0)	25 (100)	0 (0)	0 (0)	0 (0)

\* Grading system: 0 = none, I = mild, II = moderate, III = severe.

all patients. In 4 patients in group 1 and 6 patients in group 2, a recession-resection procedure was performed on 1 eye and 1 other patient in each group required recession of 1 muscle, either medial rectus or lateral rectus muscle recession, in both eyes. The muscles were re-attached with 6-0 vicryl sutures and the conjunctiva was closed with 7-0 silk sutures. At completion of surgery, 1 drop of chloramphenicol 0.5% was applied and patients were discharged from the recovery room without a dressing.

Postoperatively, groups 1 and 2 were prescribed diclofenac or dexamethasone eye drops, respectively, 4 times daily for 4 weeks commencing 4 hours after surgery. In addition, all patients were prescribed chloramphenicol eye drops every 6 hours for 1 week. Similar containers labelled 'anti-inflammatory agent' were used for both dexamethasone and diclofenac eye drops so that the patients were unaware of which drug they were receiving.

All patients were examined 1 day and 1, 2, and 4 weeks after surgery. Data were collected by an ophthalmologist who was unaware of the drug used according to a specially designed form. Patient discomfort, conjunctival congestion, and chemosis were assessed and grades were assigned as follows:

- discomfort and chemosis were graded as none (0), mild (I), moderate (II), or severe (III)
- conjunctival congestion was graded as none (0), pre-limbal congestion (I), bulbar congestion (II), or bulbar with palpebral congestion (III).

Reference images were used for grading chemosis. At each visit, IOP was measured using a Goldmann applanation tonometer or a Tonopen for children younger than 6 years. Conjunctival gap was measured by slit-lamp examination. At each visit all patients were advised to use the eye drops exactly as recommended to maximise compliance.

### Statistical Analysis

The Mann-Whitney *U* test was used to assess the statistical significance of differences between mean values for conjunctival gap and IOP. The Fisher exact test and Chi squared test were used to assess differences in patient discomfort, conjunctival congestion,

and chemosis. A *p* value of less than 0.05 was considered statistically significant.

### Results

The patients were aged between 2 and 45 years, with a mean of 18.5 years (SD, 12.4 years) for patients in group 1 and 20.7 years (SD, 14.2 years) for patients in group 2. The male to female ratios in groups 1 and 2 were 0.92:1 and 1.08:1, respectively. There were no statistically significant differences between the 2 groups with respect to age or sex. Preoperatively, visual acuity varied widely between patients, from 20/400 in amblyopic eyes to 20/20 in normal emmetropic eyes. Values for cycloplegic refraction also varied between patients, with sphere equivalents ranging from -2.50 D to +7.25 D. Four weeks after surgery, the values for these parameters ranged from 20/400 to 20/20 and -2.00 D to +6.50 D, respectively. The results of subjective and objective observations on day 1 and at week 2 are given in Table 1 and the results of corresponding statistical analyses in Table 2. Results for conjunctival gap and IOP measurements are given in Tables 3 and 4. In group 1, only 76% of patients had no conjunctival gap at 4 weeks (Table 3). In contrast, all patients in group 2 showed no conjunctival gap at weeks 2 and 4. This difference between treatments was statistically significant (*p* = 0.01; Table 3). There was no significant difference in mean

**Table 2. Comparison of symptoms present 1 day and 2 weeks postoperatively in patients treated with diclofenac or dexamethasone.**

Symptom	p Value*	
	Day 1	Week 2
Discomfort	0.78	0.002
Congestion	0.01	<0.0001
Chemosis	0.002	0.02

\* Indicates the significance of the difference between the 2 treatments based on data in Table 1.

**Table 3. Conjunctival gap in patients treated with diclofenac or dexamethasone.**

Treatment	Conjunctival gap (SD) [mm]	
	Day 1	Week 4
Diclofenac	1.06 (0.81)	0.20 (0.38)
Dexamethasone	0.66 (0.31)	0
p Value	0.06	0.01

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Table 4. Intraocular pressure in patients treated with diclofenac or dexamethasone.

Treatment	Intraocular pressure (SD) [mm Hg]	
	Day 1	Week 4
Diclofenac	13.7 (2.2)	14.2 (3.5)
Dexamethasone	13.0 (2.7)	16.1 (3.9)
p Value	0.16	0.09

IOP between treatments 1 day or 4 weeks after surgery (Table 4). However, there was a slight but statistically significant elevation of IOP in group 2 between 1 day and 4 weeks ( $p = 0.001$ ; Table 4), although individual values remained within normal limits. Three patients who received diclofenac developed corneal dellen in the first week after surgery. One of these patients, for whom the affected area was 2.0 x 1.5 mm, discontinued therapy. Smaller regions were affected in the other 2 patients and topical lubricants were applied. In all 3 patients, the dellen healed after 6 to 8 days.

### Discussion

Previous studies have been performed to compare the efficacy of diclofenac and dexamethasone when administered as eye drops following strabismus surgery, in an effort to replace steroids with other anti-inflammatory agents and thus avoid undesirable side effects. These have shown favourable results for diclofenac. Apt et al showed that diclofenac was at least as effective as prednisolone for controlling inflammation and relieving discomfort 1 week after strabismus surgery.<sup>9</sup> Wright et al compared betamethasone and diclofenac and obtained a similar result.<sup>11</sup> Snir et al<sup>12</sup> and Dadeya and Kamlesh<sup>13</sup> compared dexamethasone with diclofenac after strabismus surgery for children and concluded that diclofenac may be superior to dexamethasone because of a lower rate of complications. These researchers found no statistically significant differences between the 2 drugs in terms of the rate of resolution of inflammation, conjunctival healing, and IOP except for an increased IOP 4 weeks after surgery in patients who received dexamethasone.<sup>12,13</sup> Newer steroidal eye drops such as fluorometholone are less likely than prednisolone acetate to cause complications such as IOP elevation and show comparable efficacy for decreasing inflammation following cataract surgery.<sup>14</sup> However, no data has been published to indicate their efficacy following strabismus surgery and further investigation is required.

The design of the present study differs from previous studies of patients undergoing strabismus surgery<sup>9,11-13</sup> in only minor respects. However, the results differ from those reported previously in that dexamethasone seems to have been more effective than diclofenac in decreasing the postoperative signs and symptoms assessed in this study. Previous studies have noted IOP elevation associated with steroid treatment.<sup>5-7</sup> However, these studies

involved children, who tend to experience ocular hypertensive responses more frequently than adults.<sup>5</sup> In contrast, the present study had no age limit and included patients aged from 2 to 45 years. In addition, the extent of IOP elevation observed in such studies may be influenced by differences in the frequency of application of dexamethasone, as the response tends to be dose-dependent.<sup>6,7</sup> Other factors that may contribute to between-study differences, at least to some extent, include differences in race or other specific regional factors.

There is a cost benefit associated with using dexamethasone instead of diclofenac in Iran. Dexamethasone costs US\$0.20 compared with US\$2.00 for diclofenac. Moreover, dexamethasone showed no adverse effects in the present study. Thus, using diclofenac instead of dexamethasone to control inflammation associated with strabismus surgery seems to offer neither clinical nor commercial benefits.

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