

## Comparative study of efficacy of topical dexamethasone 0.1% with difluprednate 0.05% in post-operative small incision cataract surgery

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### Abstract

**Introduction:** Post-operative ocular inflammation is a common occurrence following cataract surgery. Corticosteroids have been used to treat ocular inflammation; however, they carry a risk of side effects, particularly an increase in intra ocular pressure (IOP). Previous studies have proved that difluprednate is more efficacious compared to dexamethasone. Hence this study was undertaken to compare the efficacy of difluprednate ophthalmic emulsion 0.05% and dexamethasone 0.1% in postoperative management after small incision cataract surgery.

**Materials and Methods:** A total 200 patients were selected as per inclusion criteria and equally divided between difluprednate and dexamethasone groups. Dexamethasone 0.1% or difluprednate 0.05% was prescribed post operatively following small incision cataract surgery. Patients were examined on post-operative day 1, 7, 15 and 30 for anterior segment by slit-lamp examination and side effects. IOP was measured in both the groups on day 30.

**Results:** In our observation both drugs were efficient in the reduction of anterior chamber cells and flare with difluprednate being more rapid. Corneal edema was reduced equally by both the drugs at all observation periods. There was no clinically significant IOP elevation in both difluprednate and dexamethasone group. Difluprednate was found to be more effective in controlling pain compared to dexamethasone.

**Conclusion:** As per present study both difluprednate ophthalmic emulsion 0.05% eye drops and dexamethasone 0.1% eye drops were equally effective in reducing post cataract surgery inflammation. Hence, difluprednate emulsion 0.05% can be used in post-operative management after cataract surgery; nonetheless, further clinical trials with long follow-up period are required.

**Keywords:** Cataract surgery, Dexamethasone, Difluprednate, Dose uniformity, Ocular inflammation, Ophthalmic emulsion.

### Introduction

The major cause of the blindness across the globe is cataract, and around 1 to 4% population of the world suffers from blindness. Cataract surgery should be performed with equal emphasis on quality and quantity of surgery.<sup>1</sup> Surgical techniques in all fields of ophthalmology has evolved considerably over the years from transition to clear corneal incisions by anterior segment surgeons to adoption of small-gauge minimally invasive pars planovitrectomies by vitreo-retinal specialists. Cataract surgery can cause ocular inflammation and it could be due to surgical trauma itself and due to various physical, chemical and biological agents introduced during the surgery. The host response to these injurious agents in the form of inflammation is a complex interaction of immuno reactive cells, their products and other chemical mediators of inflammation. More is known today about chemical mediators of inflammation; the prostaglandins, the kinins the complement system etc and their role in inflammation. It is becoming more apparent that prostaglandins help to mediate the response of eye to acute trauma. This response is marked by miosis, hyperemia of conjunctiva, disturbance of blood aqueous barrier and transient increase in intraocular pressure followed by hypotension.<sup>2</sup> In the last few years cataract surgery operative techniques have been improved tremendously and it has become least traumatic. And due to this improved cataract surgeries there is low chance of ocular

inflammation and high chance of maintenance of integrity of blood aqueous barrier. In 1950, with the arrival of cortisone in the medical field, there was major advancement in the management of inflammatory conditions.<sup>3</sup>

In the immediate post-operative period, topical corticosteroids are employed to suppress the production of inflammatory mediators, providing local treatment without any side effects. Corticosteroids prevent the release of arachidonic acid from cell membrane phospholipids there by inhibiting the genesis of prostaglandins and leukotrienes contributing to the disruption of the inflammatory cascade. These agents are continued until the anterior chamber (AC) reaction has resolved and the blood-aqueous barrier has been re-established.<sup>4</sup> Routinely topical corticosteroids are in use for the reduction of inflammation after surgery but side effects of corticosteroids are; inhibition of wound healing, high risk of infections and in some patients intraocular hypertension also seen.<sup>5</sup>

0.05% difluprednate got US food and drug administration (FDA) approval in June 2008 for post-operative management of inflammation and pain. This is the first ophthalmic steroid approved by FDA since 1973. A study conducted showed that difluprednate emulsion 0.05% safely decreased the inflammation associated with cataract surgery with no serious adverse effects compared to placebo. Thus difluprednate in the

past 35 years has proved to be high potent, safe, and effectively reduces the post-operative pain.<sup>6</sup>

The emulsion formulations of difluprednate can be credited to its dose uniformity.<sup>7</sup>

Various studies have proved that difluprednate is more efficacious compared to dexamethasone. There are few studies about the comparison of efficacy of difluprednate and dexamethasone. Hence this study was undertaken to compare the efficacy of difluprednate ophthalmic emulsion 0.05% and dexamethasone 0.1% in postoperative management after small incision cataract surgery.

## Materials and Methods

Total two hundred patients diagnosed with senile cataracts reported to HKE Society's Basaveshwara General and Teaching Hospital, Kalaburagi have been selected for the research. The study period was from December 2015 to June 2017. Before the start of the study informed consent of the patient was acquired and permission from the institutional ethical committee was procured.

A total of two hundred patients with senile cataract were divided into two groups.

Group A- 100 cases (Difluprednate ophthalmic emulsion 0.05% group)

Group B- 100 cases (Dexamethasone phosphate ophthalmic suspension 0.1% group)

**Inclusion Criteria:** Patients diagnosed with cataract aged more than 40yrs and undergoing small incision cataract surgery with PC IOL implantation.

**Exclusion Criteria:** Below years old patients, patients on long term steroids or NSAIDS, Patients sensitive to any of the study or procedural medicines, patients with preoperative inflammation in either eye, patients with H/O ocular trauma, previous intraocular surgery or wear of contact lens, patients developing intraoperative complications, patients not giving consent, and patients undergoing phacoemulsification

**Methodology:** Before surgical procedure the patients were evaluated for following; history was evaluated, slit lamp examination of the patient was done, visual acuity was assessed, Keratometry has been done, A-scan has been done, and routine pre-operative blood investigations was carried out and blood pressure was measured. Intraocular pressure measurement and lacrimal patency test was done as the part of investigations. The intraocular surgery was a conventional SICS with PCIOL implantation done by experienced surgeons. Surgery was uncomplicated in all cases. The study medications topical difluprednate ophthalmic emulsion (0.05%) or dexamethasone phosphate ophthalmic solution (0.1%) was administered in a randomized fashion.

Patients in Group A has been administered with difluprednate eye drops 4 times per day and Moxifloxacin eye drops 4 times per day for 1st week followed by tapering of difluprednate till 6<sup>th</sup> week.

Patients in Group B received dexamethasone eye drops 8 times and Moxifloxacin eye drops 4 times in a day for the 1<sup>st</sup> week followed by tapering of dexamethasone till 6<sup>th</sup> week.

On 1,7,15 and 30 days of post-operative period each patient was examined for pain, watering or any other symptom which has been experienced by the patient. For the assessment of inflammation slit lamp examination was carried out and Snellen's chart was used to assess visual acuity. With maintenance of standard conditions slit lamp examination was carried out: room was illuminated with dim light, voltage of the lamp was high, 3x1 millimeter aperture for Anterior chamber Flare and Cells (Hogan's grading). 30 degrees was used as illumination angle and magnification of 16x. Visual analogue scale (VAS) was used to determine ocular pain. Symptoms of watering and discomfort were recorded as present or absent.

At each visit the following parameters were noted and the degree of parameters are graded as 0,1,2,3, etc

As per VAS scale pain is graded as 0-absent, 1-mild, 2-moderate, 3-severe and 4-extreme.

Corneal edema grading; 0- none, 1- mild, 2 - moderate, 3 -severe

Anterior chamber flare grading; 0- absent, 1- mild, 2- moderate (iris and lense details seen), 3- severe (iris and lense details seen).

Anterior chamber cells grading; grade 0 -absent, grade 1- 5 to 10 cells, grade 2 -11 to 20 cells, grade 3- 20 to 50 cells.

(If 50 cells and hypopyon was graded as 4 than Pupils were examined for any synechiae or any other abnormalities). The details of the fundus were also noted especially in the macula for the presence of cystoid macular edema by direct ophthalmoscopy.

After 1 month, intraocular pressure was measured with the help of applanation Tonometer and best corrected visual acuity was got after doing refraction. All the above details were recorded in the clinical proforma at each visit.

Statistical analysis was done using Chi-square test with Yate's correction and Wilcoxon Signed Ranks test.

Statistical analysis using descriptive statistics and inferential statistics has been done for this study. The results were analysed by using SPSS version 18 (IBM Corporation, SPSS Inc., and Chicago, IL, USA). Microsoft word and Excel was used to generate graphs, tables etc. Mean  $\pm$ SD (min-max) has been presented for the continuous measurements and number (%) has been presented for the categorical measurements. The level of significance was determined at 5%. To find the difference between groups, Chi square test with Yates correction and Wilcoxon signed ranked test was performed.

## Results

64.14 years is the mean age found in difluprednate group and 65.55 years was the mean age observed in dexamethasone group.

38 male patients were found in difluprednate group whereas dexamethasone group had 44 patients. There were 62 females in difluprednate group and 56 patients in dexamethasone group. Immature cataract was observed in 74 in patients in difluprednate group whereas in dexamethasone group there were 67 patients with immature cataract. Mature cataract was found in 17 patients in difluprednate group and 15 patients in dexamethasone group. Hypermature cataract has been diagnosed in 9 patients in difluprednate group and in 18 patients under dexamethasone group.

**Intra Ocular Pressure:** At base line the number of patients in the range of 12.2 to 13.4 mmHg was 19 patients (19%) in difluprednate group and 21 patients (21%) in dexamethasone group. 51 patients (51%) in difluprednate group and 46 patients (46%) in dexamethasone group were in the range of 14.6 to 15.9mmHg. 30 patients (30%) were in range of 17.3 to 18.9 mmHg in difluprednate group as compared with 33 patients (33%) of dexamethasone group. At the end of 1 month, 12 Patients (12%) each in difluprednate and 4 patients (4%) in dexamethasone group had IOP of 14mmHg. 40 patients (40%) in difluprednate group and 46 patients (46%) in dexamethasone group had IOP 16 mmHg. An IOP of 18 mmHg was seen in 40 patients (40%) in difluprednate group and in 38 patients (38%) in dexamethasone group. Eight patients (8%) in difluprednate group and 12 patients (12%) in dexamethasone group had IOP of 20mmHg. (Table 1)

The changes obtained in the parameters are as follows:

**Pain:** 86 patients of dexamethasone group and 90 patients of difluprednate group experienced grade 1 pain on 1<sup>st</sup> post-operative day. No pain (0 grade) was found in 69 patients of dexamethasone group and 75 patients of difluprednate group on 7<sup>th</sup> post-operative day. Grade 1 pain was experienced by 31 patients of dexamethasone group and 25 patients of difluprednate group. (Table 2)

**Corneal edema:** There was no corneal edema in 16 patients of dexamethasone group and 26 difluprednate group on 1<sup>st</sup> post-operative day. Grade 1 corneal edema was observed in 59 patients of difluprednate group and

56 patients of dexamethasone group during 1<sup>st</sup> post-operative day. Grade 2 corneal edema was found in 28 patients of dexamethasone group and 15 patients of difluprednate group on 1<sup>st</sup> post-operative day. Grade 1 corneal edema was seen in 12 patients of dexamethasone group and 8 patients of difluprednate group on 7<sup>th</sup> post-operative day. On 15<sup>th</sup> post-operative day, grade 1 corneal edema was noticed in 10 patients of dexamethasone group and 6 patients of difluprednate group. (Table 3)

**Anterior chamber flare:** on the 1<sup>st</sup> post-operative day, grade 1 anterior chamber flare was observed in 43 patients of dexamethasone group and 59 patients of difluprednate group, grade 2 anterior chamber flare was noticed in 47 patients under dexamethasone group and 31 patients under difluprednate group. On the 7<sup>th</sup> post-operative day, grade 1 flare was seen 50 patients of dexamethasone group and 32 patients of difluprednate group, 12 patients in each group had been noticed with grade 2 flare. On the 15<sup>th</sup> post-operative day, grade 1 flare was observed in 10 patients of each group. (Table 4)

**Anterior chamber cells:** on 1<sup>st</sup> post-operative day grade 1 cells in the anterior chamber was found in 51 patients of dexamethasone group and 59 patients of difluprednate group, grade 2 cells was observed in 35 patients of dexamethasone group and 34 patients of difluprednate group, grade 3 cells was noticed in 8 patients of dexamethasone group. On 7<sup>th</sup> post-operative day, 58 patients of dexamethasone group and 40 patients of difluprednate group had grade 1 cells. On 15<sup>th</sup> post-operative day, grade 1 cells was noticed in 8 patients of dexamethasone group and 4 patients of difluprednate group. (Table 5)

**Best corrected visual acuity** after 1 month of post-operative period; There were 8 patients with best corrected visual acuity of 6/12(p)- 6/12 in the difluprednate group and dexamethasone group had 10 patient with best corrected visual acuity of 6/12(p)- 6/12, 70 patients in dexamethasone group and 66 patients in difluprednate group was found with best visual acuity of 6/9(p)-6/9, best visual acuity of 6/6(p)-6/6 was found in 20 patients of dexamethasone group and 26 patients of difluprednate group (Table 6).

**Table 1: Baseline intraocular pressure, and intraocular pressure at the end of 30 days**

1. Baseline intraocular pressure, and intraocular pressure at the end of 30 days						
IOP		Difluprednate		Dexamethasone		p value
		Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)	
Baseline						0.816
12.2-13.4	19	19	21	21		
14.6-15.9	51	51	46	46		
17.3-18.9	30	30	33	33		
Total	100	100	100	100		
Mean±SD	15.65±1.96		15.57±1.96			
Day 30						

14	12	12	04	04	0.153
16	40	40	46	46	
18	40	40	38	38	
20	08	08	12	12	
<b>Total</b>	100	100	100	100	
<b>Mean±SD</b>	16.98±1.58		17.06±1.53		

Table 2: Pain

Pain	Difluprednate		Dexamethasone	
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)
<b>Day 1</b>				
Grade 0 (None)	10	10	14	14
Grade 1 (Mild)	90	90	86	86
Grade 2 (Moderate)	0	0	0	0
Grade 3 (Severe)	0	0	0	0
<b>Total</b>	100	100	100	100
<b>Day 7</b>				
Grade 0 (None)	75	75	69	69
Grade 1 (Mild)	25	25	31	31
Grade 2 (Moderate)	0	0	0	0
Grade 3 (Severe)	0	0	0	0
<b>Total</b>	100	100	100	100
<b>Day 15</b>				
Grade 0 (None)	100	100	100	100
Grade 1 (Mild)	0	0	0	0
Grade 2 (Moderate)	0	0	0	0
Grade 3 (Severe)	0	0	0	0
<b>Total</b>	100	100	100	100

Table 3: Corneal edema

Corneal Oedema	Difluprednate		Dexamethasone		p value
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)	
<b>Day 1</b>					0.094
Grade 0 (None)	26	26	16	16	
Grade 1 (Mild)	59	59	56	56	
Grade 2 (Moderate)	15	15	28	28	
Grade 3 (Severe)	0	0	0	0	
<b>Total</b>	100	100	100	100	0.346
<b>Day 7</b>					
Grade 0 (None)	92	92	88	88	
Grade 1 (Mild)	08	08	12	12	
Grade 2 (Moderate)	0	0	0	0	
Grade 3 (Severe)	0	0	0	0	
<b>Total</b>	100	100	100	100	0.297
<b>Day 15</b>					
Grade 0 (None)	94	94	90	90	
Grade 1 (Mild)	06	06	10	10	
Grade 2 (Moderate)	0	0	0	0	
Grade 3 (Severe)	0	0	0	0	
<b>Total</b>	100	100	100	100	0.943
<b>Day 30</b>					
Grade 0 (None)	100	100	100	100	
Grade 1 (Mild)	0	0	0	0	
Grade 2 (Moderate)	0	0	0	0	
Grade 3 (Severe)	0	0	0	0	
<b>Total</b>	100	100	100	100	

**Table 4: Anterior chamber flare**

Anterior chamber flare	Difluprednate		Dexamethasone		p value
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)	
Day 1					0.055
Grade 0 Absent	10	10	10	10	
Grade 1 Mild (Barely detected)	59	59	43	43	
Grade 2 Moderate (Iris & lens details seen)	31	31	47	47	
Grade 3 Severe (Iris & lens details not seen)	0	0	0	0	
Total	100	100	100	100	
Day 7					0.025*
Grade 0 Absent	56	56	38	38	
Grade 1 Mild (Barely detected)	32	32	50	50	
Grade 2 Moderate (Iris & lens details seen)	12	12	12	12	
Grade 3 Severe (Iris & lens details not seen)	0	0	0	0	
Total	100	100	100	100	
Day 15					0.99
Grade 0 Absent	90	90	90	90	
Grade 1 Mild (Barely detected)	10	10	10	10	
Grade 2 Moderate (Iris & lens details seen)	0	0	0	0	
Grade 3 Severe (Iris & lens details not seen)	0	0	0	0	
	100	100	100	100	
Day 30					0.943
Grade 0 Absent	100	100	100	100	
Grade 1 Mild (Barely detected)	0	0	0	0	
Grade 2 Moderate (Iris & lens details seen)	0	0	0	0	
Grade 3 Severe (Iris & lens details not seen)	0	0	0	0	
Total	100	100	100	100	

**Table 5: Anterior chamber cells**

Anterior Chamber Cells	Difluprednate		Dexamethasone		p value
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)	
Day 1					0.086
Grade 0 (Absent)	07	07	06	06	
Grade 1 (5-10 cells)	59	59	51	51	
Grade 2 (11-20 cells)	34	34	35	35	
Grade 3 (21-50 cells)	0	0	08	08	
Total	100	100	100	100	
Day 7					0.011*
Grade 0 (Absent)	60	60	42	42	
Grade 1 (5-10 cells)	40	40	58	58	
Grade 2 (11-20 cells)	0	0	0	0	
Grade 3 (21-50 cells)	0	0	0	0	
Total	100	100	100	100	
Day 15					0.234
Grade 0 (Absent)	96	96	92	92	

Grade 1 (5-10 cells)	04	04	08	08	
Grade 2 (11-20 cells)	0	0	0	0	
Grade 3 (21-50 cells)	0	0	0	0	
<b>Total</b>	100	100	100	100	
<b>Day 30</b>					0.943
Grade 0 (Absent)	100	100	100	100	
Grade 1 (5-10 cells)	0	0	0	0	
Grade 2 (11-20 cells)	0	0	0	0	
Grade 3 (21-50 cells)	0	0	0	0	
<b>Total</b>	100	100	100	100	

**Table 6: Best corrected visual activity**

Vision	Difluprednate		Dexamethasone		p value
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)	
6/12 (p) - 6/12	08	08	10	10	0.464
6/9 (p) - 6/9	66	66	70	70	
6/6 (p) - 6/6	26	26	20	20	
<b>Total</b>	100	100	100	100	

## Discussion

Several steroids have been introduced over the last few decades; still dexamethasone has been considered the “gold standard” and indeed has enjoyed a status as the “go-to” steroid for many inflammatory conditions. All ophthalmic corticosteroids, both topical and systemic, have the potential to provoke a rise in intraocular pressure (IOP).

The role of corticosteroids in reducing post-operative inflammation following cataract surgery is very important for the successful outcome of cataract surgery. Dexamethasone was the corticosteroid mostly used since 5 decades but recently difluprednate has assumed greater importance because recent studies proved it as safe and efficacious. Difluprednate has been approved by FDA in 2008.

We have done comparison of difluprednate and dexamethasone for their efficacy in decreasing inflammation associated with cataract surgery.

In our research at base line; 22.2 to 13.4 mm hg of IOP was observed in 19% of patients in difluprednate group and 21% of patients in dexamethasone group. There were 46 patients in dexamethasone group and 51 patients in difluprednate group who had IOP in the range of 14.6mm hg to 15.9mm hg. 33 patients in dexamethasone group and 30 patients in difluprednate group had exhibited IOP in the range of 17.3mmhg to 18.9 mmhg.

On 30<sup>th</sup> post-operative day; it has been observed that 12 patients in dexamethasone group had 14mm hg of IOP whereas only 4 patients in difluprednate group had 14mmhg of IOP, in difluprednate group 40 patients had 16mmhg of iop and 46 patients in dexamethasone group had 16mm hg of IOP, 38 patients in dexamethasone group and 40 patients in difluprednate group exhibited 18mmhg of IOP, 12 patients in dexamethasone group and 8 patients in difluprednate group showed 20mmhg

of IOP. This in in agreement with the study carried out by Tijunelis et al studied who have administered prednisolone acetate 4 times in a day for 30 days on 224 eyes and difluprednate 2 times in a days for 30 days on 225 eyes and they have found that there is no significant rise in mean IOP in both groups.<sup>8</sup>

In our observation on 1<sup>st</sup> post-operative day; grade 1 corneal edema was found in 56 patients of dexamethasone group and 59 patients in difluprednate group had exhibited grade 1 corneal edema. Grade 2 corneal edema has been observed in 15 patients in difluprednate group and 28 patients in dexamethasone group had grade 1 corneal edema (p=0.094). Statistical significance was not observed between 2 groups on 1<sup>st</sup> post-operative day. On 7<sup>th</sup> post-operative day; grade 1 corneal edema was observed in 12 patients in dexamethasone group and 8 patients of difluprednate group had grade 1 corneal edema (p=0.346). There was no statistical difference between the 2 groups. On the 15<sup>th</sup> post-operative day grade 1 corneal edema was observed in 10 patients of dexamethasone group and 6 patients of difluprednate group had grade 1 corneal edema and there was no statistical difference between the 2 groups(p=0.297).

In our investigation, on day; 1 post-operative day 59 patients in difluprednate group and 43 patients in dexamethasone group had grade 1 anterior chamber flare, 47 patients in dexamethasone group and 31 patients in difluprednate group had grade 2 flare(p=0.055). Statistically no significance was found between 2 groups on 1<sup>st</sup> post-operative day. On 7<sup>th</sup> post-operative day; grade 1 flare was decreased to 32 patients and grade 1 flare was increased to 50 patients in dexamethasone group, grade 2 flare was found in 12 patients of difluprednate and dexamethasone group (p=0.025). There was statistically no significance was found in 2 groups on 7<sup>th</sup> post-operative day. On 15<sup>th</sup> post-

operative day it's been observed that both groups had 10 patients with grade 1 flare.

Smith et al carried out a study at fluoride in USA, in which they did comparison of difluprednate to a placebo and observed that reduction of inflammation which is absence of AC cells and flare has been achieved in more number of patients who have been managed using difluprednate in comparison with placebo (74.7% vs 42.5%  $p=0.0006$ ). The patients managed with difluprednate had significantly lesser ocular discomfort/pain in comparison to patients managed with placebo on 14<sup>th</sup> post-operative day (64.6% vs 30.0%  $p=0.0004$ ).<sup>9</sup>

In difluprednate group grade 1 cells were reduced from 59 patients to 40 patients on 7<sup>th</sup> post-operative day in comparison to 1<sup>st</sup> post-operative day where as in dexamethasone group grade 1 cells increased from 51 patients to 58 patients on 7<sup>th</sup> post-operative day in comparison to 1 post-operative day (statistically significant;  $p=0.011$ ). On 15<sup>th</sup> post-operative day in the anterior chamber grade 1 cells was found only in 4 patients in difluprednate group and in 8 patients in dexamethasone group ( $p=0.234$ ). On 1<sup>st</sup> post-operative day grade 2 cells was observed in 34 patients in difluprednate group and 35 patients in dexamethasone group grade 3 cells was found in 8 patients in dexamethasone group ( $p=0.086$ ).

Sood et al, did an investigation to find out the efficacy of 0.05% difluprednate and 0.1% dexamethasone eye drops in the reduction of post-operative inflammation after small incision cataract surgery. 120 patients were enrolled in the study who had undergone small incision cataract surgery. The study participants have been examined with slit lamp for IOP, anterior chamber cells and flare on 1,7,14 and 28<sup>th</sup> days of post-operative period. They observed that difluprednate was more effective in decreasing the pain in 62% patients on 3<sup>rd</sup> post operate day in comparison to dexamethasone group on 7<sup>th</sup> post-operative day. Both drugs had not produced significant effect on intraocular pressure. Their research proved that difluprednate was more efficient in comparison to dexamethasone.<sup>10</sup>

Chaudhary et al did a comparison of 0.1% dexamethasone and 0.05% difluprednate ophthalmic solution in terms of its efficacy and safety in treatment of inflammation associated with phacoemulsification. 50 patients participated in the study they were divided into 2 groups of 25 patients each. And after surgery each group received either 0.055 difluprednate ophthalmic solution or 0.1% dexamethasone eye drops. Patients were examined and compared on postoperative day 1,7,14, and 28 for anterior segment, intraocular pressure and side effects. Anterior chamber cell loss on day 7 was more in difluprednate group. Both drugs showed equal efficacy in decreasing anterior chamber flare. No significant increase in intraocular pressure in both groups and no serious adverse effects have been reported. This study reported that difluprednate is more

effective compare to dexamethsone in reducing postoperative inflammation after surgery.<sup>11</sup>

Garg et al investigated that both prednisolone acetate and 0.05% difluprednate ophthalmic solution are coequally effective in the management of inflammation associated with cataract surgery. Further they stated that difluprednate has an additional advantage due to its drug dosage uniformity and lack of harmful preservative.<sup>12</sup>

In our observation there is no rise in IOP in both groups from baseline to till 6 weeks. Dexamethasone group responded slower in comparison to difluprednate group in relation to reduction of inflammation. (i.e anterior chamber cells and flare).

Donnenfeld et al, did a review on difluprednate and identified that difluprednate was shown to be efficacious in treatment of post-operative inflammation in different clinical settings including a novel post-operative regimen.<sup>13</sup>

Our research and other previous studies proved that 0.05% difluprednate ophthalmic solution is efficacious in the treatment of inflammation after cataract surgery.

## Conclusion

As per our findings and previous results, difluprednate emulsion 0.05% appears to be a suitable medicament to manage inflammatory conditions and pain after cataract surgery. Hence, difluprednate emulsion 0.05% can be used in post-operative management after cataract surgery; nonetheless, further clinical trials with long follow-up period are required.

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