

# Comparison of orbital floor triamcinolone acetonide and oral prednisolone for cataract surgery management in patients with non-infectious uveitis

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## Abstract

**Purpose** To compare orbital floor triamcinolone acetonide and oral prednisolone in cataract surgery in patients with chronic non-infectious uveitis with regard to visual outcome, postoperative inflammation and macular edema.

**Methods** Monocentric prospective randomized clinical trial with 40 eyes included. Patients underwent phacoemulsification with intraocular acrylic foldable lens (IOL) implantation. Patients were randomized either to intraoperative orbital floor triamcinolone acetonide (TA) (1 ml=40 mg) (group 1,  $n=20$ ), or to 4-week postoperative oral prednisolone (group 2,  $n=20$ ). Laser flare photometry (LFM), cells in the anterior chamber (AC), best-corrected visual acuity (BCVA), IOL cell deposits, cystoid macular edema (CME) by means of fluorescein angiography, and central foveal thickness (OCT), posterior capsule opacification (PCO), and intraocular pressure (IOP) were analysed during a 6-months period.

**Results** Mean BCVA postoperatively improved ( $p<0.01$ ) from logMAR 0.74 and 0.86 to 0.23 and 0.35 in groups 1 and 2 respectively. The number of AC cells, LFM and IOL cell deposits did not differ. Macular edema stayed unchanged in most cases in both groups, and mean foveal thickness (OCT) initially increased postoperatively, but after 6 months it nearly returned to baseline thickness. Differences between the groups were not significant. Up to 12% in group 1 and 28% of group 2 developed IOP elevation over 21 mmHg.

**Conclusions** A single intraoperative orbital floor injection of triamcinolone acetonide is as effective on postoperative inflammation, macular edema, and visual outcome as a 4-week course of postoperative oral prednisolone in cataract surgery with IOL implantation in uveitis patients.

**Keywords** Uveitis · Phacoemulsification · Corticosteroids · Triamcinolone · Cystoid macular edema · Immunosuppression

## Introduction

Cataract development is a very frequent complication resulting from uveitis and its treatment. Although good visual outcome is often obtained with phacoemulsification and posterior chamber intraocular lens (IOL) implantation [1, 2], the absence of inflammation before and after surgery is critical for the achievement of a good visual outcome [3–6]. Cataract extraction in patients with non-infectious uveitis requires thoughtful planning of the perioperative anti-inflammatory regimen. Otherwise, complications such as uveitis recurrence, fibrin accumulation, posterior synechiae, pupillary membrane formation, IOL capture, cell deposition on the IOL surface, IOL decentration and dislocation, epiretinal membrane formation, intraocular pressure rise, vitreous opacities, chronic hypotony and phthisis, or cystoid macular edema (CME) may occur [7].

For perioperative anti-inflammatory management, intraoperative intravenous methylprednisolone injections, oral corticosteroids (ideally continued postoperatively), and subconjunctival, posterior subtenon, orbital floor, or intravitreal steroid injections were suggested [8–14]. Intravitreal triamcinolone acetonide demonstrated better

The study is registered at [clinicaltrials.gov](http://clinicaltrials.gov), NCT00403832.

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effectiveness than orbital floor triamcinolone or oral prednisolone [13, 14].

The aim of this prospective clinical trial was to compare the effects of a single intraoperative orbital floor triamcinolone acetonide (OFTA) injection with a 4-week treatment with oral prednisolone after cataract surgery in patients with non-infectious uveitis.

## Patients and methods

This monocentric, prospective, randomized clinical trial included patients who suffered from vision-impairing lens opacification as well as from chronic non-infectious uveitis. None of the patients had shown a tendency for steroid-induced intraocular hypertension when treated topically with prednisolone acetate. Patients with previous anterior segment surgery were excluded. The study was performed in accordance with the Declaration of Helsinki. Informed consent was obtained prior to surgery, and the study was approved by the local ethics committee. Quiescence of inflammation (<1+ cells in the anterior chamber) was attempted for at least 3 months prior to surgery.

1% prednisolone acetate eye drops were administered 5 times daily for 1 week prior to surgery. Patients underwent phacoemulsification with posterior chamber lens implantation under general anesthesia. All patients underwent a standard endocapsular phacoemulsification surgery with a limbal 2.5 mm incision, curvilinear capsulorhexis (CCC) of approximately 5.0 mm, phacoemulsification, and irrigation–aspiration for complete removal of the lens cortex. Cells were polished from the central 5 mm of the posterior capsule, the incision was enlarged to 2.8 mm, and an acrylic foldable IOL was implanted into the bag using an injector. Synechiolysis (group 1 and 2=11 each), iris stretching (group 1=five, group 2=seven), and incision of pupil (group 1=two, group 2=five) were performed intraoperatively when required.

Patients were randomly divided into two groups. Group 1 ( $n=20$ ) received 1 ml (40 mg) orbital floor triamcinolone acetonide (Volon A<sup>®</sup>, Bristol-Myers Squibb) intraoperatively, and group 2 ( $n=20$ ) was given approximately 0.5 mg/kg body weight of oral prednisolone for 4 weeks following surgery, in addition to the preexisting immunosuppression. Within the 3 months before surgery, there were no treatment alterations or dosage modifications of the immunosuppression. In both groups there were two patients who had azathioprine and one patient who received cyclosporine A. In the orbital floor group, five patients required methotrexate, whereas in the oral prednisolone group there were eight patients with methotrexate. Azathioprine was applied in a dosage of 2 to 2.5 mg/kg body weight daily, methotrexate was given orally or subcutane-

ously once a week in a dosage from 10 mg to 25 mg. Cyclosporine A was used in a dosage of 3 mg/kg body weight daily. Laserflare photometry values before surgery were 24.6 ph/s (SD 10.7) in the orbital floor group and 25.1 ph/s (SD 14.3) in the oral prednisolone group.

For orbital floor application, TA was injected through the temporal third of the inferior lid in 1 ml using a 27-gauge needle. Oral prednisolone was either given on its own or in addition to any previously taken anti-inflammatory medication. Postoperative management always included treatment with 8 times prednisolone acetate eye drops a day, 5 times gentamycin eye drops a day, and 3 times scopolamine eye drops a day. The dosages were tapered off during the following 4 to 6 weeks according to the individual course of inflammation, while pre-existing immunosuppressive treatment was continued.

Baseline evaluations were performed 2 weeks prior to surgery, and follow-up examinations took place 1, 3, and 6 months after surgery. Best-corrected visual acuity (BCVA), intraocular pressure (IOP, Goldmann tonometry) and laserflare photometry (Kowa FM-500, Kowa Company Ltd, Electronics and Optics Division, Tokyo, Japan) were performed. Ten tests were performed. Means were calculated with omission of the highest and lowest values. In addition, a slit-lamp examination and ophthalmoscopy were performed.

Inflammation in the anterior chamber was graded, and uveitis was classified anatomically in accordance with the recently published standardization [15].

Opacification of the central 3 mm of the posterior lens capsule (PCO) was graded using the scale used by Abela-Formanek et al. (0 = no opacification observed; 1 = transparent opacification, visible in reflecting light of the slit lamp; 2 = moderate white-gray and flat opacification, easily visible in reflecting light; 3 = dense and white opacification, reducing visibility of the anterior third of the vitreous) [16].

IOL deposits (small round cells and giant cells) were analyzed and graded semiquantitatively according to Schauersberger et al. [17]. The number of small round cells was graded by density (cells/mm<sup>2</sup>), while the giant cells were graded by number (0=none; 1 = 1–9; 2 = 10–25; 3=>25).

Presence of CME was confirmed using a fluorescein angiography (FLA), performed with an HRA II device (Heidelberg Retina Angiograph 2, Heidelberg Engineering, Heidelberg, Germany). Perifoveal leakage accumulating in cystic spaces in a petaloid pattern and continuing to diffuse positive staining at the fovea in the late frames was diagnosed as CME. FLA pictures were assessed independently by two observers in masked fashion. Macular leakage noted after approximately 5 minutes was rated as improved, unchanged or worsened compared to the baseline examination. Central foveal thickness was detected

using optical coherent tomography (OCT, Stratus OCT III, Carl Zeiss Meditec, Germany) [12–14].

Data analysis was performed with MedCalc® Version 9.9.3. Normality of the data sample was confirmed using the Kolmogorov-Smirnov test. The chi-square test and Fisher's exact test for categorical data and *t*-test, Wilcoxon test and Mann-Whitney U Test were used during the statistical analysis when appropriate. A *p*-value of <0.05 was judged as significantly different.

## Results

The two groups ( $n=20$ , each) did not differ with respect to age, sex, cataract score, anatomic classification of uveitis or associated diseases. Furthermore, no significant difference was noted between the groups with regards to the preoperative BCVA (LogMAR), the treatment with systemic corticosteroids or other immunosuppressive drugs, and the occurrence of vision-threatening complications, such as vitreous opacities, cystoid macular edema, epiretinal membrane, macular atrophy, mean foveal thickness (OCT) and the presence of CME (FLA) prior to surgery (Table 1).

The BCVA at baseline and after treatment is summarized in Table 2. Mean BCVA compared to baseline improved significantly ( $p<0.01$ ) in both groups (group 1: 0.74 LogMAR up to 0.23; group 2: 0.86 LogMAR up to 0.31). Percentage of patients who improved about 2 or more lines after surgery was up to 100% for both groups. Differences between the OFTA and oral group were not significant. No patient decreased in BCVA about 2 or more lines.

The number of patients with active uveitis, as detected by the presence of  $\geq 1+$  anterior chamber cells, and the laserflare photometric values which were noted after the operation, are listed in Table 3. Cells in the anterior chamber were found in up to 26% in group 1 and 44% in group 2. Differences between the groups did not reach the level of significance. Laserflare values were higher in the oral group over the follow-up; however, this was without significance. Only one patient in the prednisolone group developed posterior synechiae. The two treatment groups did not differ with respect to number and degree of giant cell depositions on the IOL surface. In up to 25% in the OFTA group and up to 36% in the oral group giant cells were observed. Seventy-one percent in group 1 and 77% in group 2 developed a posterior capsule opacification, and 18% in group 1 and 13% in group 2 underwent neodymium YAG capsulotomy. Number and degree of PCO and ND: YAG rate were similar in the two groups.

Central foveal thickness and presence of macular edema over the follow up are listed in Table 4. After surgery, the course of macular thickness in the two treatment groups was similar: In the early postoperative period mean foveal

thickness raised (345.5  $\mu$  group 1 and 287.3  $\mu$  group 2). Later, the mean thickness decreased (276.7  $\mu$  group 1 and 262.9  $\mu$  group 2 after 6 months). Differences between the groups were not significant.

Macular edema before injection was present in 60% in group 1, and in 65% in the oral prednisolone group. Over the follow-up period, percentages of patients with macular edema varied around 60% in both groups (group 1: 55%–63% and group 2: 56%–69%). Significant differences between the groups were not detectable.

The complications that occurred after surgery are listed in Table 3. Percentage rates of ocular hypertension ( $\geq 22$  mmHg) were higher in patients, who received oral prednisolone. But in this group, the number of patients with ocular hypertension was already higher before phacoemulsification. Differences were not significant. After oral prednisolone, glaucoma surgery was required in three patients. In the OFTA group, glaucoma surgery was not necessary. No further complications occurred in any of the patients in this study. In particular, none of the patients developed endophthalmitis, retinal detachment, ocular perforation or bleeding.

## Discussion

This study prospectively compared the effect of a single intraoperative orbital floor triamcinolone acetonide injection with a 4-week postoperative course of oral prednisolone after phacoemulsification in uveitic eyes. Our observations suggest that the visual outcome and the effect on inflammation and macular edema are comparable.

Suppression of postoperative inflammation and prevention of the respective sequelae appears to be crucial for a good visual outcome. In this study, there were no differences in number or degree with regard to AC cell inflammation, laserflare values, posterior synechias, giant cell deposition and PCO formation detectable between patients treated with a single intraoperative orbital floor injection or a 4-week course of oral prednisolone (0.5 mg/kg body weight daily). In a comparative study by Dada et al., the authors did not observe significant differences in AC cells and flare between intravitreal TA (IVTA) and oral steroids given at 1 mg/kg daily after phacoemulsification in uveitic eyes. In Dada's study, recurrence of inflammation occurred in 20% in the IVTA group and in 25% of the oral group [8]. Relapse rates in the literature vary profoundly, ranging from 5% to 53% [1, 7, 12, 18, 19]. Synechias developed in 6.1% to 8.0% of patients [1, 19]. The lowest rate of inflammation relapse was reported by Okhravi et al. (5%) following phacoemulsification with intravitreal TA [12].

Varying dosages of perioperative oral prednisolone are recommended in the literature. In 1989, Foster et al. advocated

**Table 1** Epidemiological data of patients who underwent phacoemulsification with orbital floor triamcinolone acetonide (OFTA) or oral prednisolone

	Orbital floor TA ( <i>n</i> =20)	Oral prednisolone ( <i>n</i> =20)
Age (mean ± SD)	54.8±16.8	48.0±19.6
Visual acuity (LogMAR, mean ± SD)	0.74±0.43	0.86±0.38
Second-line systemic immunosuppressive drugs	40%	55%
Dosage of oral corticosteroids (mg, mean ± SD)	4.5±5.2	3.4±3.7
Macular edema (FLA)	60%	68%
Mean foveal thickness (μ, mean ± SD) (OCT)	263.5±139.3	238.7±77.7
Anatomic classification of uveitis		
Anterior ( <i>n</i> , %)	11 (55%)	6 (30%)
Intermediate ( <i>n</i> , %)	3 (15%)	10 (50%)
Posterior ( <i>n</i> , %)	3 (15%)	1 (5%)
Panuveitis ( <i>n</i> , %)	3 (15%)	3 (15%)
Associated systemic immune mediated diseases ( <i>n</i> , %)		
Sarcoidosis ( <i>n</i> )	5	4
Spondylarthritis ( <i>n</i> )	4	2
Chronic inflammatory bowel disease ( <i>n</i> )	2	0
Complications with visual impairment prior to surgery		
Vitrous opacities	0 (0%)	1 (5%)
Cystoid macular edema (FLA)	12 (60%)	13 (68%)
Macular pathology (epiretinal membrane or macular atrophy)	4 (20%)	5 (26%)

1 mg/kg body weight daily [20], whereas Meacock et al. used 0.5 mg/kg body weight daily [21]. In Meacock's study, the steroids were reduced by 5 mg/day every week, until the preoperative dosage was reached [21]. Moschos et al. reduced or increased oral prednisolone according to inflammatory activity [22]. Alio et al. used 1 mg/kg body weight daily starting 1 week prior to surgery, continuing for 2 weeks and then gradually tapering off over a course of 15 days [23]. As the patients are usually already suffering from the side effects of long-term systemic steroid therapy, the higher postoperative dosages may not be suitable. The oral

prednisolone dosage that was applied in our study corresponds to the preferred practice pattern suggested by the German uveitis study group based on recent evaluations. The single orbital floor TA injection appears to be a valid alternative approach.

In this study, visual acuity after phacoemulsification and intraocular lens implantation in uveitic patients improved in all of the patients. This is in close agreement with other authors: Akova et al. reported a BCVA of 20/20 in nearly 60% of patients after phacoemulsification with IOL implantation [24]. Elgohary et al. found the BCVA to have improved by 2

**Table 2** Best-corrected visual acuity (LogMAR) before and after phacoemulsification with orbital floor triamcinolone acetonide (OFTA) or oral prednisolone

(LogMAR) ± SD	Months after injection			
	Pre injection	1 month	3 months	6 months
OFTA				
Mean LogMAR	0.74±0.43	0.32±0.22*	0.25±0.20*	0.23±0.24*
≥ 2 lines improvement		90%	90%	100%
Oral prednisolone				
Mean LogMAR	0.86±0.38	0.32±0.29*	0.31±0.35*	0.35±0.31*
≥ 2 lines improvement		79%	100%	87%
Difference between the groups (LogMAR)	<i>p</i> =0.55	<i>p</i> =0.94	<i>p</i> =0.56	<i>p</i> =0.26
Difference between the groups concerning patients with ≥ 2 lines improvement		<i>p</i> =0.61	<i>p</i> =0.54	<i>p</i> =0.41

\**p*<0.01 as compared to baseline.

**Table 3** Inflammation and complications before and after phacoemulsification with intraoperative orbital floor triamcinolone acetonide ( $n=20$ ) or postoperative 4-week oral prednisolone ( $n=20$ ) in patients with chronic uveitis

	before	After 1month	After 3months	After 6months
Anterior chamber cells <sup>a</sup>		$p=0.99$	$p=0.16$	$p=0.66$
Orbital floor	0%	26%	20%	24%
Oral prednisolone(%)	0%	32%	44%	13%
Laserflare Photometry				
(Ph/s), SD	$p=0.93$	$p=0.39$	$p=0.50$	$p=0.20$
Orbital floor	24.6±10.7	31.9±15.8	27.5±13.9	26.5±12.6
Oral prednisolone	25.1±14.3	26.9±17.3	32.2±23.0	36.5±25.2
Synechias	$p=0.99$		$p=0.49$	
Orbital floor ( $n$ )	11	0	0	0
Oral prednisolone ( $n$ )	10	0	1	0
Giant cells		$p=0.40$	$p=0.44$	$p=0.68$
Orbital floor (%)	nd	25%	21%	18%
Oral prednisolone (%)	nd	12%	36%	27%
PCO		$p=0.48$	$p=0.99$	$p=0.99$
Orbital floor (%)	-	60%	68%	71%
Oral prednisolone (%)	-	41%	69%	77%
ND:YAG				$p=0.99$
Orbital floor (%)	-	-	-	18%
Oral prednisolone (%)	-	-	-	13%
IOP≥22 mmHg	$p=0.39$	$p=0.08$	$p=0.17$	$p=0.40$
Orbital floor	10%	5%	6%	12%
Oral prednisolone	26%	28%	29%	25%
Glaucoma surgery ( $n$ )				$p=0.11$
Orbital floor ( $n$ )				0
Oral Prednisolone ( $n$ )				3

<sup>a</sup> active uveitis= $\geq 1+$  cells in  $1\times 1$  mm in the anterior chamber as detected by slit-lamp.

$P$ -values refer to the difference between the two groups at a certain point of time.

PCO = posterior capsule opacification; IOP = intraocular pressure.

or more lines in up to 71.3% of cases [18]. Estafanous et al. observed BCVA improvement in 95% of patients [1]. Foster et al., Kawaguchi et al., and Okhravi et al. found a visual acuity of 20/40 or better in 74–90% of patients [12, 19, 25]. In a retrospective case series, Suresh et al. observed a VA of 6/9 or better in 72% of cases [5]. Moschos et al. prospectively followed 32 eyes after phacoemulsification, and reported an increase in the mean BCVA from 0.3 to 0.8 [22].

The presence of cystoid macular edema before phacoemulsification is of utmost importance for the final outcome.

The frequency of macular edema as measured by FLA did not differ between the two study groups preoperatively or after surgery. As the structural changes in the retina, which are caused by CME, are one of the major risk factors for poor visual outcome after cataract surgery in uveitis patients [26], attention to CME after surgery is mandatory.

Concerning foveal thickness measured by OCT, Dada et al. did not observe significant differences between an IVTA injection and an oral group after phacoemulsification in

**Table 4** Cystoid macular edema and central foveal thickness before and after phacoemulsification with intraoperative orbital floor triamcinolone acetonide ( $n=20$ ) or postoperative 4-week oral prednisolone ( $n=20$ ) in patients with chronic uveitis

	before	After 1month	After 3months	After 6months
Central foveal thickness (OCT) $\mu \pm$ SD	$p=0.72$	$p=0.31$	$P=0.55$	$p=0.77$
Orbital floor	263.5±139.3	345.5±192.5	302.2±186.9	276.7±151.2
Oral prednisolone	238.71±77.7	287.3±137.8	270.7±90.0	262.9±107.2
Presence of CME (FLA)	$p=0.99$	$p=0.99$	$p=0.99$	$p=0.99$
Orbital floor	60%	63%	60%	55%
Oral prednisolone	65%	69%	64%	56%

OCT: optical coherence tomography

FLA: fluorescein angiography

uveitic eyes [8]. Results in the literature with regard to macular edema vary from 3% up to 35% after phacoemulsification in uveitic eyes [1, 18, 21, 22]. In a prospective trial, Okhravi et al. did not find macula edema within the first 4 months following phacoemulsification with intravitreal triamcinolone acetonide [12]. Most studies, however, did not analyze the presence of preoperative CME. Our study indicates that the effect on macular edema of a single intraoperative orbital floor TA injection is comparable to a 4-week course of oral prednisolone.

Ocular hypertension is a common complication after treatment with corticosteroids, especially if higher systemic, intra- or periocular dosages are used. Data in literature vary between 30% and 77% after orbital floor TA [27, 28]. In this study, only 12% after OFTA and 28% of the orally treated group had ocular hypertension over 21 mmHg. One has to consider that before treatment 10% of group 1 and 22% of group 2 already had IOP elevation. Three patients of group 2 needed surgical intervention to control IOP.

This prospective randomized clinical trial indicates that the effect of a single intraoperative orbital floor triamcinolone acetonide injection to obtain a good visual outcome, to prevent inflammation, and to control CME is comparable to a 4-week course of oral prednisolone. Patients must be selected carefully, especially to prevent IOP decompensation in steroid responders. OFTA may be particularly suitable for patients who are already suffering from long-term systemic steroid use.

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