Published in final edited form as:

Retina. 2016 November ; 36(11): 2087–2092. doi:10.1097/IAE.0000000000001063.

Combined Vitrectomy and Intravitreal Dexamethasone (Ozurdex) Sustained-Release Implant

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Abstract

Purpose—To evaluate the safety and efficacy of combining intravitreal dexamethasone implantation (Ozurdex) with pars plana vitrectomy (PPV).

Methods—A retrospective review was conducted on cases where Ozurdex injection was performed in the operating room in conjunction with pars plana vitrectomy. Our primary outcome measure was the presence of surgical complications in the perioperative and three-month postoperative window. We also measured visual acuity, intraocular pressure (IOP), and macular edema at baseline, one, and three months after surgery.

Results—Fifteen eyes in 14 cases were reviewed. There were no complications intraoperatively or at 1-month postoperatively. Two patients (2 eyes) with prior retinal detachment developed proliferative vitreoretinopathy and re-detachment at 3 months. Visual acuity improved in 7 of 15 eyes, and an average improvement of 2 lines was achieved for the entire cohort. There was no overall change in IOP, although 1 patient developed an increase in IOP > 5 mmHg. Five of nine patients with baseline macular edema experienced improvement or resolution at 3 months.

Conclusions—Intraoperative Ozurdex in combination with PPV may be safe and effective in treating macular edema caused by many different underlying diseases.

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Author Contributions: Dr. Mahajan had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: All authors. Acquisition of data: All authors. Analysis and interpretation of data: All authors. Drafting of the manuscript: Zheng and Mahajan. Critical revision of the manuscript for important intellectual content: All authors. Statistical analysis: Zheng and Mahajan.

Conflict of Interest Disclosures: None.

Keywords

Vitreoretinal surgery; pars plana vitrectomy; Ozurdex; macular edema; proliferative diabetic retinopathy; retinal vein occlusion; posterior uveitis

INTRODUCTION

Pars plana vitrectomy (PPV) is an established and safe surgical approach for the treatment of many retinal and retinal vascular complications. However, the procedure is not without risks and has been known to cause postoperative inflammation, hypotony, and changes to the ciliary body, among other adverse events.^{1,2} Conventionally, intravitreal triamcinolone (IVTA) is used in PPV to help visualize the vitreous and internal limiting membrane, and it has additionally been shown to be effective in controlling a number of postsurgical complications.³ One key limit of IVTA, however, is that it relies partly on the vitreous to act as a drug depot for more sustained release. Studies suggest that clearance of triamcinolone proceeds up to six times more quickly in vitrectomized eyes.^{4,5}

Given this limitation, dexamethasone implant (Ozurdex®, Allergan Inc, Irvine, CA, USA) may be a useful alternative or adjunct to IVTA in post-vitrectomy eyes. The implant is a free-floating device consisting of a biodegradable polymer matrix that provides sustained release of corticosteroid as it hydrolyzes to carbon dioxide and water. Inserted into the vitreous cavity, Ozurdex is able to release medication for up to 6 months and has been shown to have similar pharmacokinetic profiles in vitrectomized and non-vitrectomized eyes.^{6–8} Because the implant undergoes complete dissolution within the vitreous cavity, it may also have distinct advantages over other sustained-release steroid implants using fluocinolone acetonide such as Retisert (Bausch & Lomb, Rochester, NY, USA) and Iluvien (Alimera Sciences, Alpharetta, GA, USA), which contain non-biodegradable components that remain in the eye, and may require surgical removal as in the case of Retisert.

Ozurdex is currently approved for a number of retinal conditions that may require vitrectomy as part of their treatment, including retinal vein occlusion (RVO), non-infectious posterior uveitis, and diabetic macular edema (DME).^{9,10} Generally, insertion of the implant is performed as an outpatient office procedure using a single-use applicator to make a transscleral injection. In patients scheduled for PPV, however, it may be reasonable to also consider concurrent, intra-operative Ozurdex placement for both therapeutic and postsurgical benefit. In this retrospective cohort study, we investigated the effects of intraoperative Ozurdex injection in patients undergoing pars plana vitrectomy in order to determine whether the addition of a gradual-release steroid implant at the time of surgery would be safe and of potential benefit to patients.

MATERIALS AND METHODS

A retrospective, consecutive, single-center, observational study at a tertiary care academic medical center was conducted. After obtaining University of Iowa institutional Review Board approval, we evaluated all patients undergoing pars plana vitrectomy between April

2014 and April 2015 who also received intraoperative, intravitreal Ozurdex implantation in the surgical eye. Patients were evaluated at one- and three-month follow-up time points.

The primary outcome measure was the presence or absence of complications in the intra- and post-operative periods and at subsequent follow-up evaluations. Complications were defined as anterior chamber cell or flare, subconjunctival hemorrhage, implant migration into the anterior chamber, new retinal tears or breaks, worsening of visual acuity (VA) by 2 lines of vision or more, or increases in intraocular pressure (IOP) by 5 mmHg from the pre-operative baseline. IOP was measured by Tono-Pen (Reichert Technologies, Depew, NY) at each visit. Snellen chart equivalents of counting fingers and hand motion vision were estimated at 20/2000 and 20/4000, respectively. Secondary outcome measures included indications for PPV and Ozurdex injection, history of glaucoma or ocular hypertension, history of previous steroid or anti-VEGF injections, and the need for continuation of post-operative eye drops at or beyond the 3-month follow-up time point. The degree of cystoid macular edema (CME) was also assessed by optical coherence tomography (OCT), and we noted the proportion of patients with worsening CME from baseline at the third post-operative month.

Descriptive statistics, including frequencies and proportions, were used to analyze patient characteristics and the occurrence of discrete events such as surgical complications, IOP elevations, or resolution of CME. Continuous descriptive statistics (mean, range, standard deviation) were calculated for the magnitudes and changes in VA and IOP.

Surgical Technique

Vitrectomies were performed with retrobulbar anesthesia under monitored anesthesia care. A caliper was used to mark the sclera 3.0 or 3.5 mm posterior to the limbus in pseudophakic and phakic eyes, respectively. Three triplanar wounds—in the inferotemporal, superotemporal, and superonasal quadrants—were created using a single-step 23- or 25-gauge trocar/cannula microvitrectomy system (Alcon Laboratories Inc, Fort Worth, Texas) as previously described.¹¹ A binocular indirect ophthalmomicroscope (BIOM) viewing system was used in all cases. The central core vitreous was removed, and any remaining adherent posterior hyaloid was separated from the retinal surface by suction using a silicone-tipped cannula or the vitreous cutter. Peripheral vitreous was removed with the assistance of scleral depression and paying particular attention to remove all traction from any identified retinal breaks. A partial air–fluid exchange was performed with the air infusion set to 25 mmHg, and in cases of macular hole or retinal detachment, a complete air–fluid exchange followed by air–gas exchange was performed. Prior to cannula removal, Ozurdex implant was injected 4.0mm posterior to the limbus using a beveled incision at 5:00 or 7:00 in all cases. At the conclusion of surgery, cannulas were removed, and any sclerotomy sites shown to be leaking vitreous, gas, or fluid were sutured.

RESULTS

Demographics and Clinical Indications

A total of 15 eyes in 14 patients undergoing PPV received intravitreal Ozurdex implantation at the time of surgery. The mean age among patients was 60 years, with a range of 31 – 85 years. There were 6 women and 8 men, and there were 7 right eyes and 8 left eyes. With regards to lens status, 6 eyes were phakic, 8 eyes were pseudophakic, and 1 eye was made aphakic during the treatment procedure. Clinical indications for adding Ozurdex to PPV included DME (6 eyes), non-infectious posterior segment uveitis (5 eyes), RVO with macular edema (2 eyes), as well as proliferative vitreoretinopathy with macular edema (PVR, 4 eyes), and neovascular age-related macular degeneration (AMD, 2 eyes) with concomitant epiretinal membrane and history of recalcitrant macular edema. The two cases of RVO and one case of DME had recent reductions in chronic, recurrent CME and were being treated with periodic intraocular steroid injections. Therefore they were also included in the study due to the elevated risk of post-operative recurrent CME following vitrectomy. Several eyes had more than one indication for receiving combination PPV and Ozurdex therapy. Follow-up evaluations at one and three months after surgery were available for all patients. Surgical objectives were achieved in all cases. Demographic characteristics including clinical indications for vitrectomy and Ozurdex implantation are summarized in Table 1.

Surgical complications and safety issues

None of the 15 eyes in this study experienced unexpected intraoperative or postoperative surgical complications. At one month post-surgery, 4 of 15 eyes (27%) were noted to have mild but resolving subconjunctival hemorrhage at the injection site. There were no findings of intraocular inflammation and no instances of implant migration. At 3 months post-surgery, 12 of 14 patients had no sequelae or complications associated with PPV or Ozurdex injection; however in two patients (eyes #8 and #14), evaluation at 3 months found recurrent retinal detachment with grade-C PVR requiring subsequent surgical repair (Table 1). Each of these cases had previous repair of retinal detachment. In the case of eye #8, PPV was performed a year prior for a macula-off rhegmatogenous retinal detachment. At the time, the eye had grade-C PVR and remained attached for one year. In the case of eye #14, the fellow eye underwent PPV and scleral buckling for a diabetic tractional retinal detachment. Thus, each of the study eyes was at higher risk of recurrent retinal detachment.

Visual acuity improvement

At the pre-operative baseline, mean visual acuity ranged from 20/30 to hand-motion vision. The average change in VA at the first post-operative month was a gain of 12.5 letters, or almost three lines of vision. At one month, 3 of 15 eyes (20%) had a worse VA than at baseline, while 6 of 15 eyes (40%) experienced an improvement in VA. The mean difference in VA between baseline and three-month follow-up evaluations was similarly 12 letters of improvement, and 7 eyes maintained or continued to improve on previous gains in VA (Table 2). There were also 2 eyes in 2 patients with vision that was worse at 3-month follow-up than at baseline; one patient with severe proliferative diabetic retinopathy and prior

retinal detachment developed a new retinal detachment, and one patient developed subretinal hemorrhage shortly before surgery that progressed during the postoperative course.

Intraocular pressure changes

Baseline IOP ranged from 7 – 22 mmHg, with a mean IOP of 15 mmHg (Table 2). Four patients had a prior history of glaucoma or ocular hypertension and used pressure-lowering medications. The average change in IOP from baseline among all study eyes was 1 and 0 mmHg at one- and three-month follow-up visits, respectively. At the one month time-point, 4 eyes had increased IOP that was at least 5 mmHg higher than at baseline, of which 1 eye had an increase in IOP of 10 mmHg. All 4 eyes had improvement in IOP at 3 months, each decreasing by 2– 4 mmHg, although one eye remained significantly elevated above baseline. Among the four patients with a glaucoma or glaucoma suspect history, the average IOP was 15 and 17 mmHg at 1 and 3 months, respectively, and no eyes had significant IOP elevations at either time point.

Macular edema and other outcomes

Ten eyes in nine patients received previous or ongoing steroid or anti-VEGF injections (Table 2). At baseline, CME was noted in 9 of 15 eyes. All 14 patients had an OCT of the macula performed at the 3-month post-surgical evaluation. Of the 9 eyes with CME at baseline, 4 were noted to have edema remaining at 3 months, while 5 eyes had resolution of CME. Additionally, all 15 eyes had either discontinued or were tapering post-operative steroid and IOP-lowering eye drops by month 3.

DISCUSSION

Ozurdex has been shown to be safe for a number of underlying conditions that cause macular edema, including diabetic retinopathy, retinal vein occlusion, and uveitis. Previous studies have found that in previously vitrectomized eyes, subsequent injection of Ozurdex is not associated with increased risk of adverse events or diminished therapeutic benefit, as compared to Ozurdex implantation in non-vitrectomized eyes.⁸ In this retrospective chart review of 15 eyes, we found that addition of intraoperative Ozurdex injection to PPV did not result in unexpected peri-operative surgical complications, and overall, appears to stabilize retinal conditions during the post-surgical clinical course. However, two patients with significant histories of retinal detachment were not protected from re-detachment events at 3 months post-surgery, suggesting that even sustained release of a potent, intraocular corticosteroid may not be helpful in proliferative vitreoretinal disease. In particular, one patient with a prior history of PVR experienced re-detachment in the same eye after surgery. Although only an isolated case (among four patients with PVR), this outcome raises an additional concern that, in eyes with PVR, a co-injected steroid implant after PPV may impede healing or promote retinal thinning and in turn contribute to retinal detachment.

Vision also improved and IOP remained stable for at least 3 months after surgery. Furthermore, a majority of patients had resolution of macular edema by the 3-month follow-up time-point, which is not worse than the rates of improvement found in previous studies showing reduced fluorescein leakage in a third of patients after Ozurdex placement.¹² This

suggests that concurrent PPV in turn also does not significantly impact the therapeutic effects of the implanted steroid. These findings concur with other complementary studies that show Ozurdex implantation to be safe in combination with anterior segment surgeries such as cataract extraction or intraocular lens removal.^{13,14} However, posterior segment surgeries, and specifically vitrectomy, alter the architecture and environment of the vitreous cavity where Ozurdex is placed and may therefore affect its safety and efficacy profile. Our results are significant because they suggest that the concurrent, intraoperative use of Ozurdex implant in pars plana vitrectomy is also safe and effective for a number of conditions that cause macular edema.

Use of a sustained corticosteroid implant may be especially helpful in post-surgical recovery vitrectomy patients, where the efficacy of conventional intra-operative IVTA injection may be attenuated. In these cases that we report here, the implant can serve as a source of drug not only for the underlying disease, but also to counteract normal inflammatory and reactive changes after surgery. In many cases, including recalcitrant diabetic macular edema and uveitic macular edema, chronic corticosteroid dosing is required; however, post-vitrectomized eyes pose a challenge in that the pharmacokinetics of triamcinolone - as Triesence or Kenalog - are altered leading to rapid clearance from the eye. With Ozurdex, there is the ability for sustained release which allows for optimal prolonged dosing. The latter allows twofold efficacy at improving the primary etiology (e.g., macular edema) as well as improving postoperative inflammation as is clear from our data.

Addition of Ozurdex injection to a planned posterior segment procedure may have some benefits in selected cases over conventional microsurgical implantation of Ozurdex in the clinic. One recent case, for example, reported using non-absorbable sutures to anchor the implant to the sclera after introducing it into the vitreal cavity, to prevent anterior chamber migration in a patient with an ACIOL.¹⁵ Having ready access to the vitreal cavity also allows for action to be taken in the event of rare complications, such desegmentation of the implant or exacerbation of vitreomacular traction leading to macular hole.^{16,17}

Intraoperative combination of Ozurdex with PPV is of benefit from a patient perspective as well, as it obviates the need for a separate, albeit minor, procedure. Many patients also require periodic re-injection of Ozurdex—as its clinical efficacy in some cases has been shown to wane by the fourth month post-injection—¹⁸ and intraoperative implantation reduces the chance of a treatment lapse that might otherwise occur during the first weeks and months of the post-operative period.

This study has limitations inherent to its uncontrolled and retrospective nature. Selection biases may exist as a result of the clinical decisions that determined which patients received combined intraoperative treatment. A significant percentage of patients also received either previous or ongoing treatment with injected steroids or anti-VEGF agents, which further confounds understanding of the therapeutic benefit attributable to Ozurdex. Long-term follow-up data was also not available at the time of this study so the risk of late surgical sequelae related to intraoperative Ozurdex is not known. However, major late complications would be unexpected given that the implant dissolves entirely over the course of several months. Nevertheless, both the limitations of this study and our findings highlight the need

for future investigation of Ozurdex use in posterior segment surgery, with larger sample sizes, longer follow-up periods, and appropriate controls.

In summary, our study adds to the current clinical understanding of the use of Ozurdex in the treatment of macular edema. We show that concurrent, intra-operative use of the device during posterior segment surgery contributes to alleviation of macular edema and postoperative inflammation. Over a period of 3 months, we found that intraoperative application of the implant was safe, was not associated with any major complications, and caused only minor IOP elevations that can occur after intraocular corticosteroid use. The combination of Ozurdex therapy with PPV might be considered for select surgical patients who also have an established indication for intraocular corticosteroid therapy.

Acknowledgments

Funding/Support: VBM is supported by NIH Grants K08EY020530, R01EY016822, the Doris Duke Charitable Foundation Grant #2013103, and Research to Prevent Blindness (New York, NY)

Obtained funding: Mahajan. Administrative, technical, and material support: Mahajan. Study supervision: Mahajan.

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Summary

Dexamethasone implant (Ozurdex) may be indicated for several different conditions in patients who also require pars plana vitrectomy to improve corticosteroid efficacy in vitrectomized eyes. In this retrospective review of 15 cases, we found that concurrent, intraoperative Ozurdex combined with vitrectomy was safe and effective in treating macular edema due to diabetic retinopathy, retinal vein occlusion, and posterior uveitis.

Table 1

Summary of patient characteristics and postoperative clinical course up to 3 months after pars plana vitrectomy with intraoperative Ozurdex implantation.

Eye No.	Age	Sex	Eye	Lens status	Indication	Significant clinical events		
						Peri-op	1 month	3 months
1	79	F	OS	Phakic	PVR	None	None	None
2	65	F	OS	Pseudophakic	Uveitis	None	None	None
3	54	M	OD	Phakic	DME, Uveitis	None	SC Heme	None
4	55	M	OS	Pseudophakic	DME	None	None	None
5	35	M	OS	Phakic	DME, Uveitis	None	SC Heme	None
6	31	F	OS	Aphakic	Uveitis	None	None	None
7	85	M	OD	Pseudophakic	CRVO	None	None	None
8	80	F	OD	Pseudophakic	PVR	None	None	RD
9	50	M	OS	Pseudophakic	PVR, Uveitis	None	None	None
10	49	M	OD	Phakic	PVR	None	SC Heme	None
11	69	M	OD	Pseudophakic	DME	None	None	None
12	68	M	OD	Phakic	AMD	None	SC Heme	None
13	54	F	OS	Pseudophakic	DME	None	None	None
14	46	F	OD	Phakic	DME	None	None	RD
15	78	M	OS	Pseudophakic	HRVO, AMD	None	None	None

PVR = proliferative vitreoretinopathy, DME = diabetic macular edema, CRVO = central retinal vein occlusion, HRVO = hemiretinal vein occlusion, AMD = age-related macular degeneration, SC heme = subconjunctival hemorrhage, RD = retinal detachment

Table 2

Visual acuity, intraocular pressure, and macular edema before and after surgery

Eye No.	Visual acuity (Snellen)				Glaucoma hx	Intraocular pressure (mmHg)				Steroid/anti-VEGF injection history	CME or SRF	
	Baseline	1 mo.	3 mo.	Change		Baseline	1 mo.	3 mo.	Change		Baseline	3 mo.
1	20/250	20/250	20/250	0 lines	POAG	15	17	15	+0	STK	CME	CME
2	20/40	20/20	20/20	+3 lines	----	7	11	10	+3	Retisert	CME	None
3	20/60	20/100	20/60	0 lines	----	16	10	15	-1	BZB	None	None
4	20/100	20/40	20/30	+5 lines	----	18	18	17	-1	BZB	None	None
5	20/200	20/60	20/125	+2 lines	----	22	18	8	-14		CME	CME
6	20/80	20/125	20/100	-1 line	----	8	13	9	+1		CME	None
7	HM	20/30	20/25	+22 lines	----	14	15	13	-1		None	None
8	20/200	20/50	20/60	+5 lines	----	12	19	16	+4		CME	None
9	20/30	20/25	20/25	+1 line	----	20	17	18	-2	IVK	CME	None
10	20/400	20/100	20/60	+8 lines	OHT	12	14	12	+0	STK	SRF	None
11	20/60	20/50	20/40	+2 lines	----	15	14	14	-1	BZB, RZB, IVT, OZ	CME	CME
12	20/80	20/200	20/150	-3 lines	----	14	24	20	+6	BZB, RZB, AFL	SRF	None
13	20/30	20/30	20/40	-1 line	----	15	20	18	+3		CME	None
14	20/50	20/60	20/300	-8 lines	POAG	16	17	19	+3	BZB	CME	CME
15	20/60	20/60	20/60	0 lines	OHT	19	12	22	+3	BZB	None	None

POAG = primary open-angle glaucoma, OHT = ocular hypertension, STK = sub-Tenon Kenalog injection, IVK = intravitreal Kenalog injection, BZB = bevacizumab, RZB = ranibizumab, AFL = aflibercept, IVT = intravitreal triamcinolone, CME = cystoid macular edema, SRF = subretinal fluid, HM = hand motions visual acuity