Original Article

Study of *In-vivo* morphology of the injection site in eyes receiving Ozurdex implant using AS-OCT and its comparison with sutureless and sutured TSSV incision sites

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Abstract

Aim: To evaluate in-vivo the morphology of the injection site in eyes receiving Ozurdex implant with anterior segment optical coherence tomography. **Methods:** This is a prospective study of 9 consecutive patients who received Ozurdex dexamethasone drug delivery system for cystoid macular oedema associated with retinal vein occlusions. The AS-OCT of the injection site was done 3 hours after injection, on 15th day after injection and 30th day after injection. The injection site was evaluated for diameter of inner and outer openings of the injection site, injection site morphology, intra-ocular pressure and any associated complications. **Results:** All cases had uneventful post-injection period. None of the patients had any evidence of wound leak or hypotony. The average outer diameter was 214.33 microns and inner diameter was 122.66microns. On the 15th day the average outer diameter 101.67 microns and inner diameter had reduced to 48.88 microns and on 30th day the diameters had reduced to 53.33 microns and 18.33 microns for the outer and inner diameters respectively. None of the patients had low IOP during the follow up period.

Keywords: Ozurdex Implant, AS-OCT, Injection site morphology, intra-ocular pressure, hypotony.

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INTRODUCTION

Macular edema is the most common cause of visual loss in patients with central retinal vein occlusion (CRVO) and branch retinal vein occlusion (BRVO). In some cases, it can be persistent and difficult to treat[1]. Laser photocoagulation[2], intravitreal therapy with the antivascular endothelial growth factor agent ranibizumab[3,4] and the corticosteroids triamcinolone acetonide[2,5] and dexamethasone[6,7] can be of benefit in the treatment of macular edema associated with BRVO or CRVO. A sustained delivery, biodegradable dexamethasone intravitreal implant (DEX implant; Ozurdex; Allergan, Inc., Irvine, CA) has been shown in phase III, randomized, controlled trials to reduce macular edema and improve visual acuity in patients with BRVO and CRVO, with effects sustained for up to 6 months after a single injection[7]. No study has documented the wound healing characteristics of these injection sites. Our study aims at looking at the wound morphology of Ozurdex injection site and comparing it with wound morphology of sutured and sutureless TSSV sites.

MATERIALS AND METHODS

This is a prospective study of 9 consecutive patients of macular oedema due to venous occlusions who had been injected with Ozurdex.

Inclusion Criteria

1. Patients who had received Ozurdex
2. Patients who completed 1 month of follow-up

Exclusion Criteria

1. Patients in whom vitrectomy has been done earlier
2. Patients having pathological myopia
3. Patients having localised scleral pathology at the injection site

Methodology

Patients underwent anterior segment OCT scans on the 1st, 15th and 30th post-operative day with AS-OCT. All

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injections were given by a single surgeon (MPN) and all the AS OCT sequential scans were performed by a single surgeon (GP) Injections were given in a manner similar to what we use for making the ports of TSSV.(17) All injections were given in biplanar fashion. This is a two-stepped approach. Initially the applicator tip is inserted at a 30° angle and then the entry is made perpendicular to sclera. The advantage of this technique is that it prevents hypotony and the wound is more secure. The injections were given 3.5mm to 4mm posterior to limbus. The overlying conjunctiva was displaced prior to giving the injections. We use the Trocar Fixation Plate (pressure plate forceps), from ASICO (Westmont, IL), in a multifunctional manner while making the incisions. The pressure plate forceps have incorporated callipers to measure distance from the limbus and have serrations on the under surface allowing good hold of the conjunctiva for misalignment over the proposed sclera entry. The applicator was withdrawn and then the wound area was massaged with a blunt tipped applicator for 10 to 15 seconds to facilitate the stretched sclera fibres to regain their elastic memory. This technique allows better sealing of the wound and prevents any inadvertent vitreous incarceration. After the procedure, gross examination was done to assess the wound integrity. None of the injection sites showed any evidence of wound leak like (eg.continued conjunctival bleb formation) or required sutures. Detailed slit lamp assessment was carried out on the day 1, 15 and 30 to assess wound integrity and also note any inadvertent intraocular reaction as well monitor intraocular pressures. The injection sites were imaged using Spectralis HRA+OCT (Heidelberg Engineering, Germany) with Infra-red imaging using an anterior segment objective. The OCT device was used to scan across the incision site, so as to traverse the centre of the incisions, showing them in profile. The scans were evaluated for the lengths of external and internal entry wounds, presence of any wound gape and any associated complications. The length of the incisions was measured using the analysis software provided with the Spectralis HRA+OCT.

RESULTS

Demography: Out of the 9 patients 6 were males and 3 were females. All patients were of Indian origin. Average age was 64.3 years. The most common indication for implant was macular oedema due to central retinal vein occlusion in 5 patients, followed by macular oedema due to branch retinal vein occlusion in 4 patients. The injection site was thoroughly examined for any evidence of wound leak (conjunctival ballooning). Slit-lamp examination revealed localised subconjuctival hemorrhage and conjunctival chemosis over the incision site. The external or entry wound was often visible under slit-lamp examination, but did not show signs of leakage in any patient. The average outer diameter was 214.44 microns and average inner diameter was 122.66 microns on the day of injection. On the 15th day the average outer diameter was 101.67 microns and the average inner was 48.88 microns. At 1 month post-operatively a faintly visible incision site was seen in all cases. The average outer diameter at one month was 53.33 microns and the average inner diameter was 18.33 microns.

Table 1

Sr No.	Diagnosis	1st Day		15th Day		30th Day	
		Outer	Inner	Outer	Inner	Outer	Inner
1	CRVO with ME	221	132	118	59	52	21
2	CRVO with ME	197	110	94	42	59	23
3	BRVO with ME	232	116	112	51	51	17
4	BRVO with ME	192	122	91	47	49	15
5	CRVO with ME	227	117	97	49	55	15
6	BRVO with ME	204	131	93	53	54	19
7	CRVO with ME	239	143	107	58	56	18
8	CRVO with ME	217	123	93	39	54	17
9	BRVO with ME	201	110	110	42	50	20

Table 2: Comparative analysis of incision sites of Ozurdex 23 gauge sutureless TSSV and conventional sutured 20 gauge TSSV

Incision with applicator tip of azurdex	Sutureless 23 Gauge TSSV	Conventional sutured 23 gauge TSSV
Not sharp	Sharp Tip	-
Post op. complications like endoph. and hypotony not seen	High incidence of endoph and hypotony	Low incidence of endoph and hypotony
Curved incision	Oblique or biplanar incisions	–
Stability of the incision better because of the momentary stretching of sclera	Longer surgical duration leads to wound leakage and less stability	-

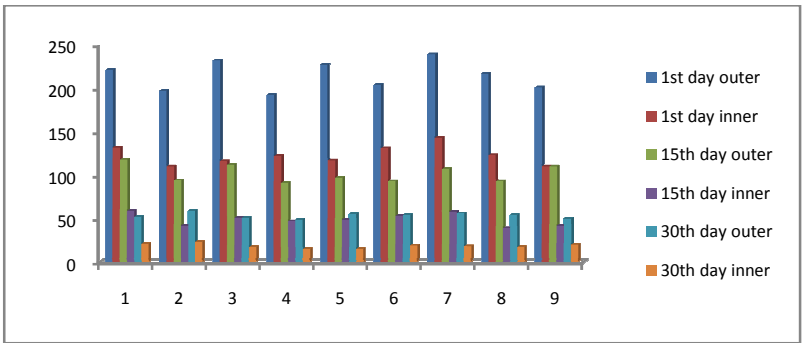

Figure 1:

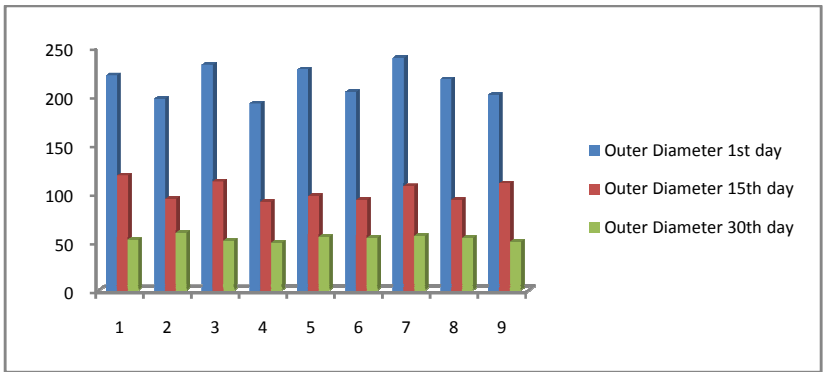

Figure 2: Outer Diameters

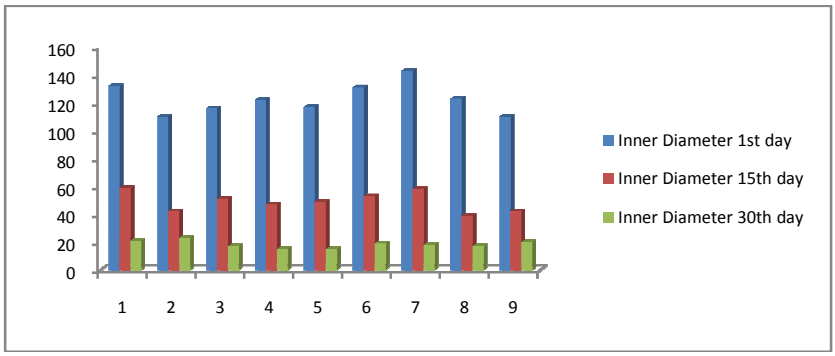

Figure 3: Inner Diameters

AS-OCT Photographs to be added

DISCUSSION

Ozurdex has been accepted as a modality of treatment of macular oedema secondary to retinal venous occlusions. A single treatment with DEX implant 0.7 or 0.35 mg has been shown to significantly improve the visual acuity than did a sham procedure in eyes with vision loss due to ME associated with BRVO or CRVO.[8] Haller *et al* reported the dexamethasone drug delivery system applicator system which allowed safe, effective, and sutureless intravitreal placement of 700 µg dexamethasone drug delivery.[8] The device is implanted into the vitreous cavity using an applicator which is provided with the device. The size of the applicator tip which is inserted inside the eye to inject the implant is of 22gauge[8]. The outer diameter of the Ozurdex implant tip which pierces the sclera to enter in vitreous cavity is of 22-gauge (0.72mm) which is almost of same size of the outer diameter of 23 gauge trocar-cannula system (0.73mm-Edge Plus Trocar Cannula system) used for vitrectomy. The Edge Plus trocars are sharp and they have a hump perpendicular to the horizontal plane of the blade, which stretches the tissue in the direction perpendicular to the horizontal plane of the blade and thus ensures a slit-like incision. A slitlike incision is always better, as it is stable and not patulous. Studies have shown that the 23-gauge sclerotomies and even the smaller 25-gauge sclerotomies are associated with increased

incidences of hypotony and endophthalmitis if the incision making is not proper.[12-15] Ozurdex applicator tip is not as sharp as the trocar and also it doesn't have a characteristic hump to make the incision stable. So there can be some doubts regarding the stability of the incisions. In one of our previous study we have noted that the average outer and inner diameter if the 23 gauge ports are 232.6 and 146 microns respectively (on the first post-operative day).[16] These findings show that even though the outer diameter of the Ozurdex tip is of almost same size of 23 gauge trocar, the incison size on OCT is smaller than the 23 gauge ports. This may be because of the tissue fatigue with the 23 gauge vitrectomy ports. In case of vitrectomy the duration could range from 15 minutes to 30 minutes or even more depending on the type of pathology and circumstances and throughout this period the sclera remains stretched while in case of Ozurdex injection the sclera is stretched just momentarily which is less than 30 seconds. With longer surgical duration, more fatigue would set in the stretched sclera fibres. This would lead to corresponding decreased elasticity and increased rigidity of the scleral fibres leading to increased latency of regaining its pre surgical allignment. In fact Albert L. Lin *et al* have noted that, increased surgical duration may lead to wound leakage in 23 gauge sclerotomies. This might be the reason of the Ozurdex ports being of smaller size and more stable than the 23 gauge vitrectomy ports.

CONCLUSION

Ozurdex has become an accepted modality of treatment for macular oedema associated with retinal venous occlusions. The applicator tip of the injector, even though not sharp enough as that of the vitrectomy trocars, do provide us with a stable injection site.

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