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CASE SERIES

Case Series Investigating the Efficacy and Safety of Bilateral Fluocinolone Acetonide (ILUVIEN®) in Patients with Diabetic Macular Edema: 10 Eyes with 12 Months Follow-up

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ABSTRACT

Introduction: This short case series presents the results from 5 patients with bilateral chronic diabetic macular edema (DME), 12 months after they were initially treated with ILUVIEN® [0.2 μg/day fluocinolone acetonide (FAc)].

Methods: Ten eyes from five patients with pseudophakic lenses were investigated. Patients had bilateral, chronic DME and had received prior laser and anti-VEGF therapy. Visual and anatomic outcomes were investigated 12 months post-FAc implant in both eyes.

Results: At baseline, central retinal thickness (CRT) was 645.3 ± 176.1 microns (mean ± standard deviation), intraocular pressure (IOP) was 13.7 ± 3.6 mmHg and visual acuity (VA) was 44.5 ± 18.6 Early Treatment Diabetic Retinopathy Study (ETDRS) letters. Mean CRT improved at 6 months (341.7 ± 169.7 microns) and 12 months (287.4 ± 103.1 microns) and there were concurrent improvements in VA (ETDRS letters were 56 ± 16 and 55 ± 16 at 6 and 12 months, respectively). Mean IOP was stable throughout and ≤21 mmHg. Left and right eyes were compared in the 5 patients by plotting changes in CFT, IOP and VA at 12 months, from baseline levels.

Conclusion: This bilateral case series demonstrates the effectiveness of a sustained, controlled low dose of FAc in the management of bilateral DME over a 12-month period. The FAc implant has shown to work well in treatment of bilateral DME, although longer follow-up of these patients is still needed.

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Keywords: Bilateral diabetic macular edema; Central retinal thickness; Fluocinolone acetonide implant; Intraocular pressure; Visual acuity

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Table 1 Patient demographics and baseline values

Patient number	Gender	Age	Diabetes type	Eye number	Left or right eye	IOP-lowering drops	Prior medical treatment for DME			Date of 0.2 µg/day FAc implant
							Laser	RBZ	IVTA	
1	Male	70	II	1	LE	N	1× Grid	9×	1×	July 29, 2014
				2	RE	N	1× Grid	9×	1×	September 9, 2014
2	Female	58	II	3	RE	Lumigan/azarga	1× Focal	19×	1×	June 10, 2014
				4	LE	Lumigan/azarga	2× Focal	19×	1×	September 23, 2014
3	Male	44	I	5	RE	Latanoprost/timolol	1× Grid	6×	3×	July 25, 2014
				6	LE	Latanoprost/timolol	1× Grid	6×	2×	October 30, 2014
4	Male	82	II	7	RE	N	1× Grid	3×	2×	April 10, 2014
				8	LE	N	1× Grid	3×	1×	July 11, 2014
5	Male	63	I	9	LE	N	1× Grid	6×	0	July 18, 2014
				10	RE	N	1× Grid	9×	0	October 21, 2014

DME diabetic macular edema, *FAc* fluocinolone acetonide, *IOP* intraocular pressure, *IVTA* intravitreal triamcinolone, *LE* left eye, *RE* right eye, *RBZ* ranibizumab

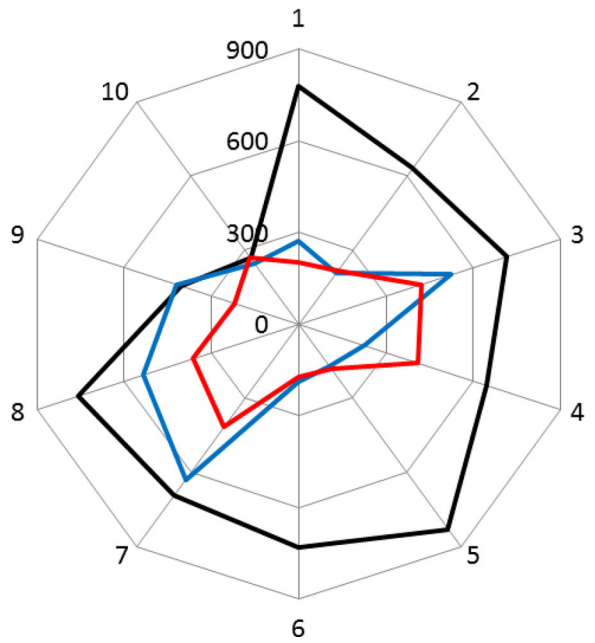

Fig. 1 Individual patient (eyes *1–10*) plots of central retinal thickness (microns) at baseline (*black line*) and 6 months (*blue line*) and 12 months (*red line*) after intravitreal injection of the fluocinolone acetonide implant

CASE SERIES

In everyday clinical practice, patients frequently present with bilateral diabetic macular edema (DME), yet there is a paucity of reported data on the bilateral use of DME therapies [1]. ILUVIEN® [fluocinolone acetonide (FAc) implant] is indicated for the treatment of vision impairment associated with chronic DME, considered insufficiently responsive to available therapies [2]. A single implant in the affected eye is recommended, with the fellow eye being available for therapy but not at the same time or visit as the first eye [2]. This inevitably means that treatment of the fellow eye is delayed; however, early intervention is important in the management of DME as prolonged edema can lead to irreversible damage and permanent vision loss [3].

The structural and functional responses following bilateral intravitreal injections of the FAc implant have been reported previously [4]. The objective of this case series is to report the structural and functional responses 12 months after intravitreal injection of the FAc implant.

Data are presented from 10 eyes. The demographics for the group and prior therapies are presented in Table 1. Prior to intravitreal injection of the FAc implant, all patients had received at least one macular laser therapy for DME. Patients had also received an average of 8.9 (range 3–19) intravitreal injections of an anti-VEGF and 1.2 (range 0–3) intravitreal injections of triamcinolone acetonide. This article does not contain any new studies with human or animal subjects performed by any of the authors.

Figure 1 plots central retinal thickness (CRT) for each patient and Table 2 shows the mean changes from baseline. There was a decrease in

Table 2 Mean visual acuity, central retinal thickness and intraocular pressure at baseline and 6 and 12 months after intravitreal injection of the fluocinolone acetonide implant

Measure	Baseline	6 months	12 months
Visual acuity, ETDRS letters	44.5 ± 18.6	+11.0 ± 13.1	+10.5 ± 13.0
Central retinal thickness, μm	645.3 ± 176.1	−303.6 ± 238.7	−357.9 ± 200.3
Intraocular pressure, mmHg	13.7 ± 3.6	+1.8 ± 4.5	+2.3 ± 4.0

Data are presented as mean ± standard deviation
ETDRS Early Treatment Diabetic Retinopathy Study

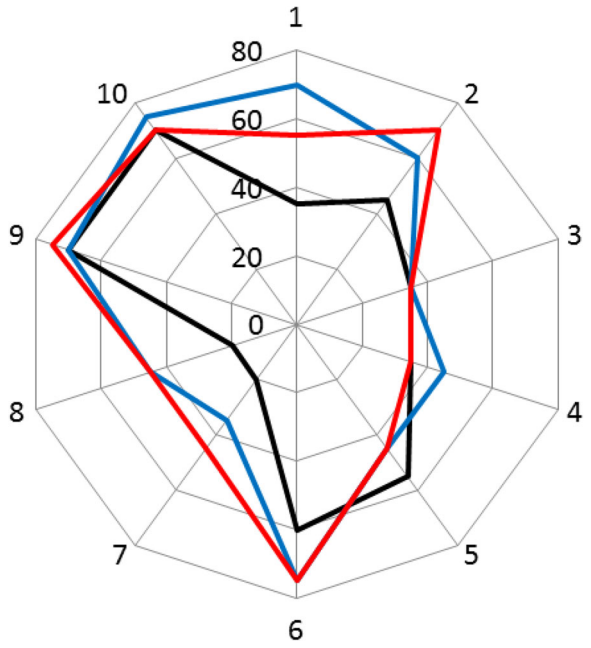

Fig. 2 Visual acuity in Early Treatment Diabetic Retinopathy Study ETDRS letters for each patient (numbered *1–10*) at baseline (*black line*), 6 months (*blue line*) and 12 months (*red line*) after intravitreal injection of the fluocinolone acetonide implant

CRT for 9 of the 10 patients at month 6 or month 12. A single patient (patient 9) initially showed a small (+16 microns) increase in CRT at 6 months but a much greater reduction (−182 microns) at 12 months indicating a delayed response, whereas for patient 10 the changes at months 6 and 12 were comparatively smaller (−22 microns at month 6 and +2 microns at months 12). Overall, mean CRT decreased by -303.6 ± 238.7 microns ($-42.1 \pm 31.5\%$) and -357.9 ± 200.3 microns ($-50.9 \pm 24.2\%$) at 6 and 12 months, respectively, from a baseline of 645.3 ± 176.1 microns.

Figure 2 plots visual acuity (VA) in Early Treatment Diabetic Retinopathy Study (ETDRS) letters for each patient and Table 2 shows the mean changes from baseline. At 6 and 12 months, VA was sustained or improved in 9 out of 10 patients with letter gains from baseline ranging between 0 and 35 ETDRS letters. Overall, mean VA increased by 11.0 ± 13.1 and 10.5 ± 13.0 ETDRS letters after 6 and 12 months, respectively, from a baseline of 44.5 ± 18.6 ETDRS letters.

Intraocular pressure (IOP) was also measured at baseline (mean of 13.7 ± 3.6 mmHg), 6 months (mean 15.5 ± 4.0 mmHg) and 12 months (mean 16.0 ± 3.3 mmHg). Table 2 shows the mean changes from baseline. In all cases, IOP remained $\leq$21 mmHg.

CONCLUSION

The patients followed up in our bilateral case series show clinical improvement up to 12 months after intravitreal FAc implantation. Over 12 months, nine out of ten patients had sustained and improved VA with mean improvements of 10.5 letters, and a mean reduction of −357.9 microns in CRT from baseline with no patients experiencing a rise of IOP above 21 mmHg.

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Compliance with ethics guidelines. This article does not contain any new studies with human or animal subjects performed by any of the authors.

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