INDEX study: To assess clinical effectiveness of Iluvein® in Diabetic Macular Oedema (DMO) with no or sub-optimal response to Dexamathasone intravitreal implant- 6 months interim results.

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Introduction:

Sustained-release steroid implants have been shown to have a role in DMO treatment as first or second line following suboptimal response to Anti-VEGF agents. Most retinal physicians believe the efficacy of Dexamethasone and Flucinolone-Acetonide implants is interchangeable and linked. Here we report interim 6-months results of Iluvien® implant in DMO patients with prior poor response to Dexamethasone.

Methods:

Exploratory prospective study with data collection over 12 months after Iluvein® implantation. 20 patients recruited. Inclusion criteria included; no response (<20% reduction in Central sub-field thickness) (CST) after 6-8 weeks or sub-optimal response (reversal of initial response in CST and recurrence of DMO by month 3); post-Dexamethasone implant. Wilcoxon signed rank test with continuity correction was used to ascertain difference between Best-corrected Visual Acuity (BCVA), CST and Intraocular pressure (IOP) at baseline and month 1,3 and 6.

Baseline Characteristics (N = 15)	Mean (Median) (Std Deviation)
Age (years)	69.27 (69.0) (6.46)
Gender (male:female)	(11) : (5)
Duration of DM (years)	17 (18) (5.9)
Duration of DME (years)	9 (10) (4.4)
Previous Anti VEGF injections	20.67 (16) (14.1)
Previous Ozurdex implants	1.8 (1.0) (1.57)
Baseline BCVA	62.27 (63.0) (9.7)
Baseline CMT	487 (516) (121.9)
Baseline IOP	14.5 (14.0) (3.9)

	Baseline	Month 3	Month 6	P value @ M3	P value @ M6
BCVA	62.27 (9.7)	68.1 (10.5)	66.7 (10.5)	P= 0.01	P= 0.03
CST	487.4 (121.9)	410.2 (90.8)	409.8 (104.2)	P= 0.006	P= 0.009
IOP	14.5 (3.9)	14.2 (3.6)	16.8 (2.5)	P = 0.9	P= 0.029

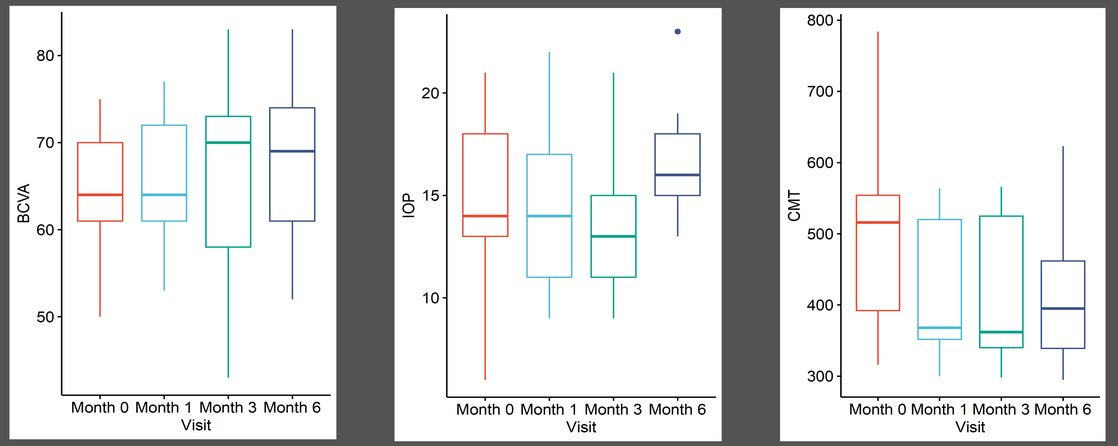


Figure 1: Box-Whisker plots showing Best-corrected Visual Acuity (BCVA), Intraocular Pressure (IOP) and Central Macular Thickness (CMT) at baseline, 1 month, 3 months and 6 months following Iluvein® injection. Central line indicating median at each interval

Results:

Fifteen patients have completed the 6-Month follow up. 13 Patients were classified as non responders and 2 patients were sub optimal responders. Baseline Demographics and Clinical characteristics are presented in (Table 1). At 6 months following Iluvein® Implant, Mean Baseline BCVA improved from 62.2 to 68.1 (SD = 10.5) and 66.7 letters (SD – 10.5) at 3 and 6 months respectively. (p= 0.01, 0.03). Similarly, the baseline CST has improved from 487 to 410.2 (SD= 91) and 408.9 microns (SD = 104) at 3 and 6 months respectively. (p = 0.006, 0.009). Mean IOP changed from 14.5 mmHg at baseline to 14.2 mmHg (SD = 3.6), and 16.8 mmHg (SD = 2.5) at 3 and 6 months respectively. (p=0.9, 0.02), yet these changes were not considered clinically significant. (Table 2

Conclusion:

Our interim results suggest a statistically significant improvement in BCVA and reduction in CST at 6 months after Iluvein® implantation. 54% achieved >5 letters VA gain. No significant increase in IOP. No adverse events were reported. Our results advocate, a new but safe paradigm shift, suggesting beneficial intervention with Iluvein® in patients with refractory DMO, despite having no or sub-optimal response to dexamethasone implant.