MODULE 10.6
Clinical Studies and Treatment Data - CHAMPLAIN

CHAMPLAIN[1]

Study Name	Dexamethasone Intravitreal Implant for Treatment of Diabetic Macular Edema in Vitrectomized Patients
Purpose of study	To evaluate the safety and efficacy of Ozurdex 0.7-mg in patients that had undergone previous vitrectomy
Study authors	Boyer DS, Faber D, Gupta S, Patel SS, Tabandeh H, Li X-Y, Liu CC, Lou J, Whitcup SM, for the Ozurdex Champlain Study Group.
Published in	*Retina.* 2011;31:915-923.
Study also known as	CHAMPLAIN
Subsequent studies	N/A

Study Overview

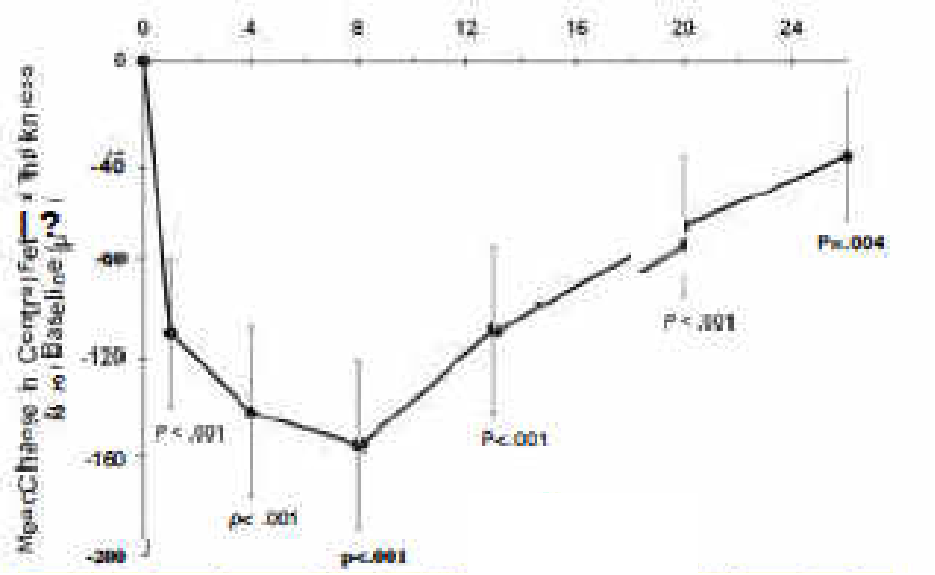
CHAMPLAIN1 was a prospective, phase 2, multicenter, open-label, 26-week study enrolling 55 patients with treatment-resistant diabetic macular edema (DME) and a history of pars plana vitrectomy in the study eye; most of the study eyes (n = 42) were pseudophakic at baseline. All eyes received a single injection of 0.7-mg dexamethasone intravitreal implant. The primary efficacy outcome was the change in central retinal thickness from baseline to week 26 as measured by optical coherence tomography (OCT). Secondary outcomes included mean change in best-correct visual acuity (BCVA) and mean change in the National Eye Institute's VFQ-25 score at 26 weeks. At the time of study enrollment, the mean BCVA was 55 Early Treatment Diabetic Retinopathy Study (ETDRS) letters (about 20/100), and patients had undergone vitrectomy an average 31 months before study enrollment. About half the patients had undergone previous anti-VEGF therapy, and two-thirds had undergone focal laser. Most (91%) patients had received at least 1 of the following: anti-VEGF therapy, corticosteroid therapy, laser, and vitrectomy); 84% had received at least 2 types of treatment, 61% had received 3 types of treatment, and 34% had received all types of treatment.

Mean central retinal thickness (CRT) was 403.4 µm at baseline, 292.8 µm at week 1, 261.1 µm at week 4, and 364.5 µm at week 261 (see Figure 1).

Statistically significant improvement in BCVA also was seen as early as 1 week after treatment and at each subsequent follow-up visit. The largest increase in BCVA from baseline was 6 letters at week 8, which had decreased to 3.0 letters by week 26. At week 13, 30% of patients had gained at least 10 letters, and 11% had gained at least 15 letters. By week 26, 21% of patients had gained at least 10 letters, 11% had gained at least 15 letters, but 11% had lost at least 10 letters, and 7% had lost at least 15 letters.[1]

Study Implications

One unintended consequence of vitrectomy is that intravitreal medications may be less effective because drug diffusion and clearance from the vitreous cavity occurs more rapidly; this has the effect of reducing drug exposure to the retina, which may affect dosing strategies. This consequence is particularly concerning with chronic disorders and the main reason this particular subset of DME patients was evaluated. Intravitreal corticosteroid treatment may be more effective in pseudophakic eyes; results in CHAMPLAIN contradicted those found in the bevacizumab anti-VEGF studies, which indicated no significant difference in mean foveal thickness or BCVA. Of interest, this is one of the only studies to evaluate CRT as the primary outcome with VA as a secondary outcome.



Figures 1: Mean changes from baseline in central retinal thickness.

Take-Home Points

- In vitrectomized eyes, dexamethasone 0.7 mg intravitreal implant can improve both CRT and BCVA.
- The results from CHAMPLAIN suggest this corticosteroid may be more effective in pseudophakic eyes with DME. These results are in contrast to those with bevacizumab, which found no change in retinal thickness or BCVA in vitrectomized eyes.
- Post-vitrectomized eyes lack a reservoir of vitreous gel to prolong the duration of typical intravitreal medication in the vitreous cavity. The dexamethasone implant allows for a sustained release implant that remains viable in the eye for 3 to 6 months.
- Recalcitrant DME has often failed multiple modalities of treatment, including focal laser, anti-VEGF injections, and vitrectomy. Dexamethasone 0.7 mg has shown further improvement in CRT, even after all previous modalities are attempted.

References

1. Boyer DS, Faber D, Gupta S, et al. Dexamethasone intravitreal implant for treatment of diabetic macular edema in vitrectomized patients. *Retina.* 2011;31:915-923.