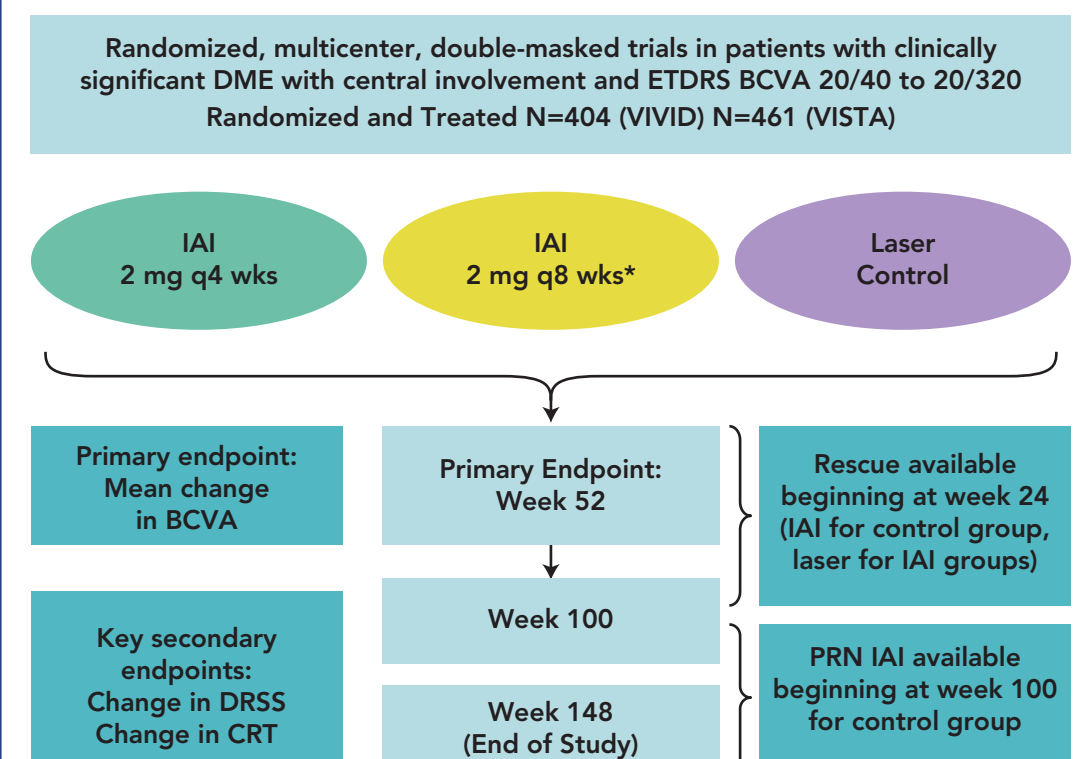


Impact of Presence or Absence of Posterior Vitreous Detachment (PVD) at Baseline on Treatment Outcomes in Patients With Diabetic Macular Edema in the VISTA and VIVID trials

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BACKGROUND

The VISTA and VIVID studies evaluated efficacy and safety of intravitreal aflibercept injection (IAI) compared with laser control for treatment of diabetic macular edema (DME)



- IAI 2 mg given q4 weeks (2q4) or q8 weeks following 5 monthly doses (2q8) significantly improved visual and anatomic outcomes over laser at week 52. These improvements were sustained through week 100 with both IAI regimens.
- In an integrated safety analysis, the most frequent serious ocular adverse event at week 100 was cataract (2.4%, 1.0%, and 0.3% for 2q4, 2q8, and control).

OBJECTIVE

- To examine the impact of posterior vitreous detachment (PVD) at baseline on visual and anatomic outcomes in patients with DME

METHODS

- Post-hoc analysis of integrated data from VISTA and VIVID
- Patients categorized as (+) PVD or (-) PVD at baseline based on physician-reported indirect ophthalmoscopy exam; investigators were asked to document the PVD status at every visit
- Analyses were conducted within each treatment group (laser, IAI 2q4, IAI 2q8)
- In patients receiving rescue treatment, data was censored from the time rescue treatment was given
- For patients with (-) PVD at baseline, data were censored at the earliest of either rescue treatment or onset of PVD after baseline
 - Onset of PVD was defined as presence of PVD at two consecutive visits

RESULTS

Figure 1. Proportion of Patients with (+) PVD at Baseline

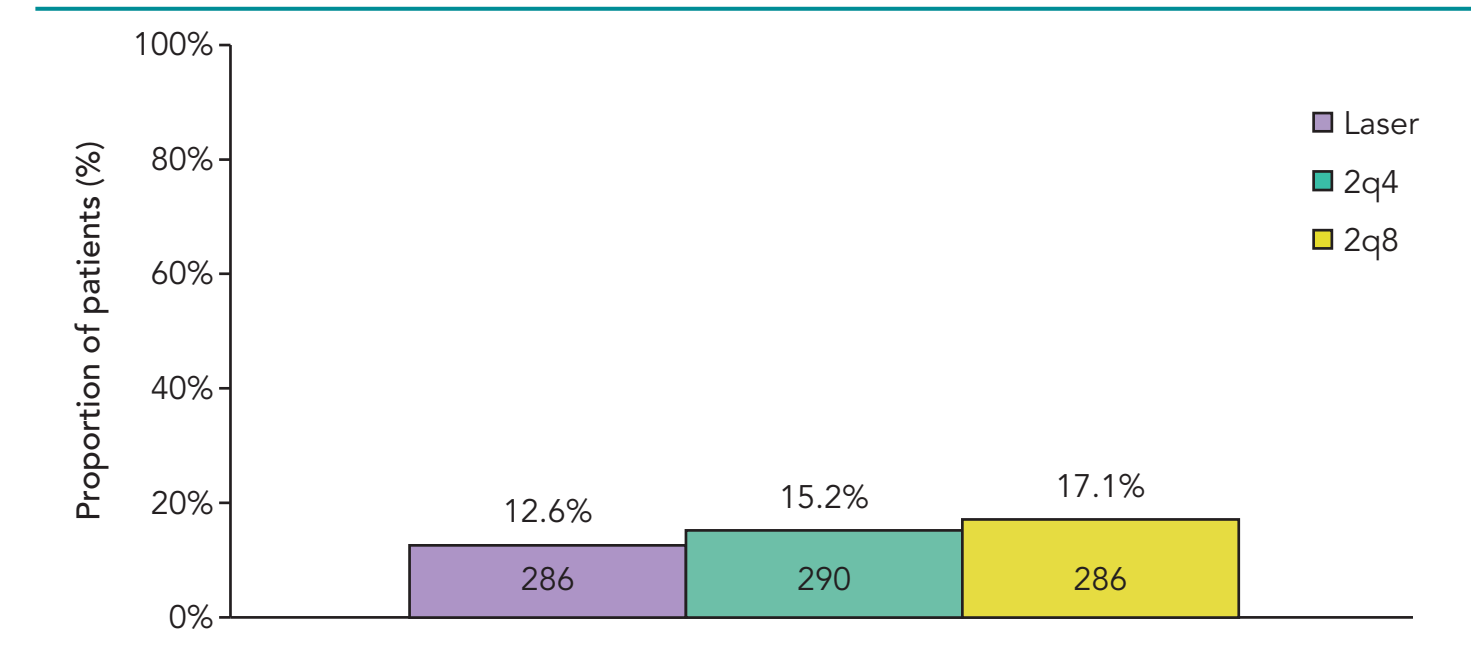


Table 1. Baseline Characteristics

	(+ Baseline PVD)			(- Baseline PVD)		
	Laser	2q4	2q8	Laser	2q4	2q8
N (full analysis set)	36	44	49	250	246	237
Mean age, years (SD)	63.9 (7.5)	66.6 (8.1)	66.5 (7.2)	62.5 (8.8)	61.5 (10.2)	63.0 (8.8)
Mean duration of diabetes, years (SD)	21.8 (10.6)	18.5 (10.9)	19.4 (11.8)	15.7 (9.5)	15.2 (9.2)	15.4 (10.1)
HbA1c >8%, n (%)	12 (33.3)	12 (27.3)	11 (22.4)	75 (30.0)	100 (40.7)	90 (38.0)
Mean BCVA, ETDRS letters (SD)	58.8 (11.2)	59.8 (11.1)	59.0 (10.9)	60.4 (10.7)	59.8 (10.7)	59.2 (11.1)
Mean CRT, μm (SD)	518.8 (157.3)	467.3 (148.7)	514.0 (154.5)	508.4 (155.0)	497.8 (150.8)	494.2 (151.5)
DRSS Score, n (%)						
Low Risk (DRSS ≤43)	16 (44.4)	19 (43.2)	23 (46.9)	92 (36.8)	77 (31.3)	74 (31.2)
Moderate Risk (DRSS =47)	11 (30.6)	7 (15.9)	12 (24.5)	39 (15.6)	37 (15.0)	47 (19.8)
High Risk (DRSS ≥53)	6 (16.7)	14 (31.8)	11 (22.4)	85 (34.0)	96 (39.0)	82 (34.6)

Figure 2. Proportion of Patients Receiving Rescue Treatment by Week 100

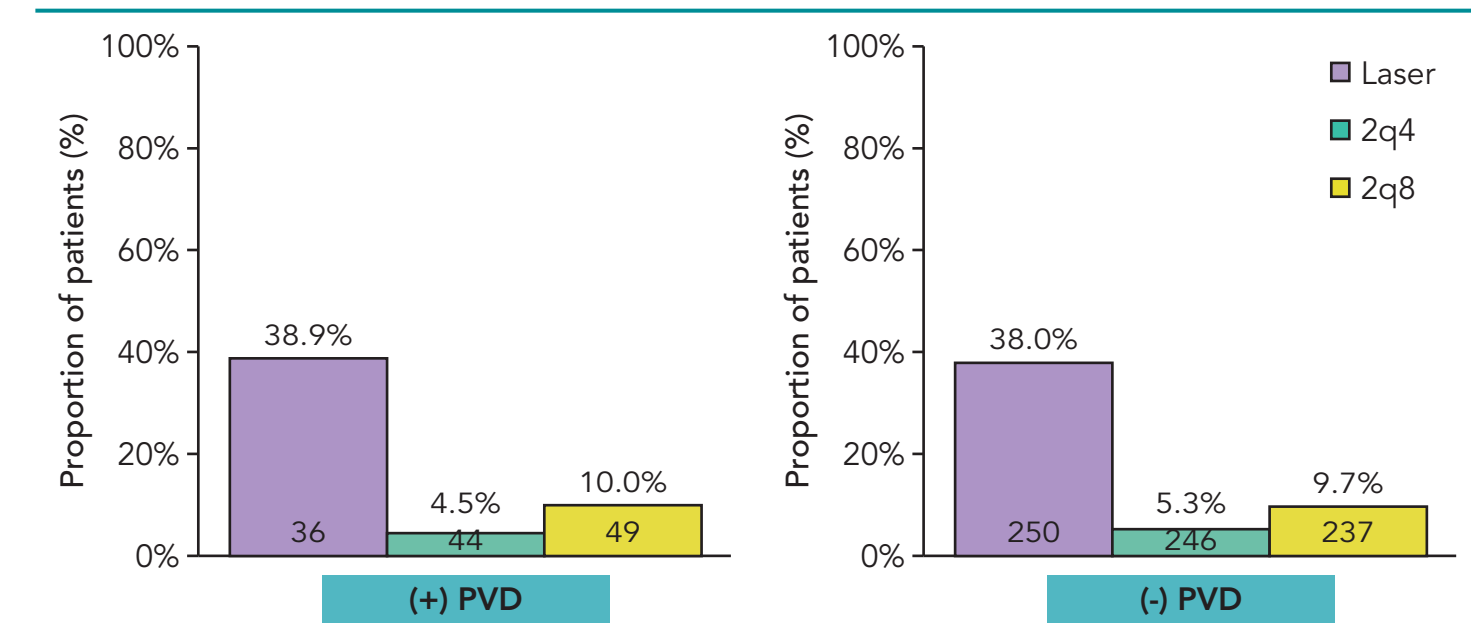


Table 2. Proportion of Patients with (-) PVD at Baseline Developing PVD by week 100

	Laser	2q4	2q8
N (full analysis set)	250	246	237
Proportion with (+) PVD after Baseline, n (%)	23 (9.2)	22 (8.9)	27 (11.4)

Figure 3. Mean Change in BCVA

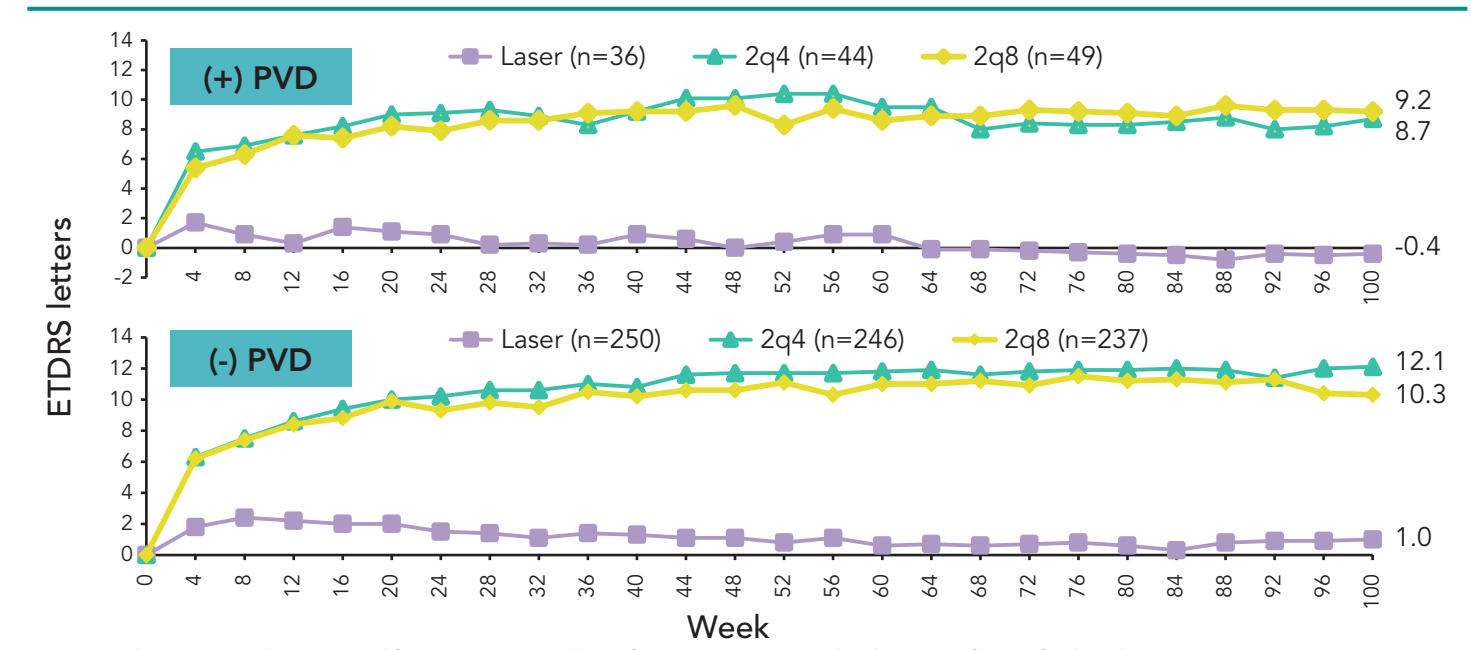


Figure 4. Difference in Mean Change in BCVA from Baseline

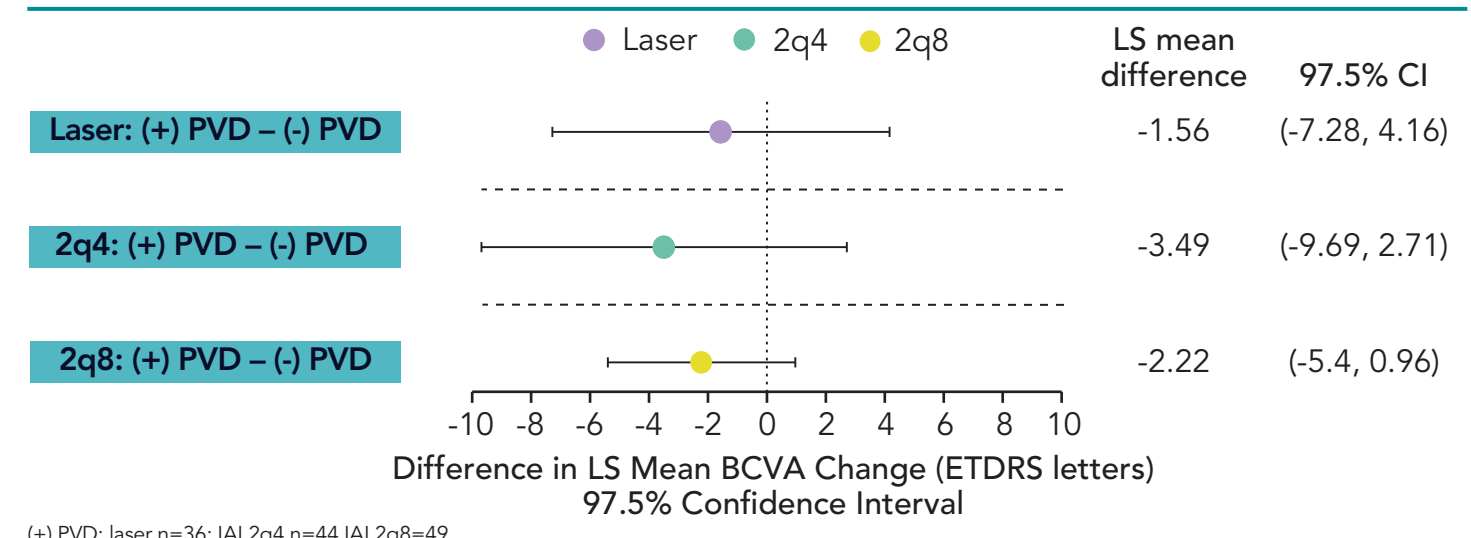


Figure 5. Mean Change in CRT

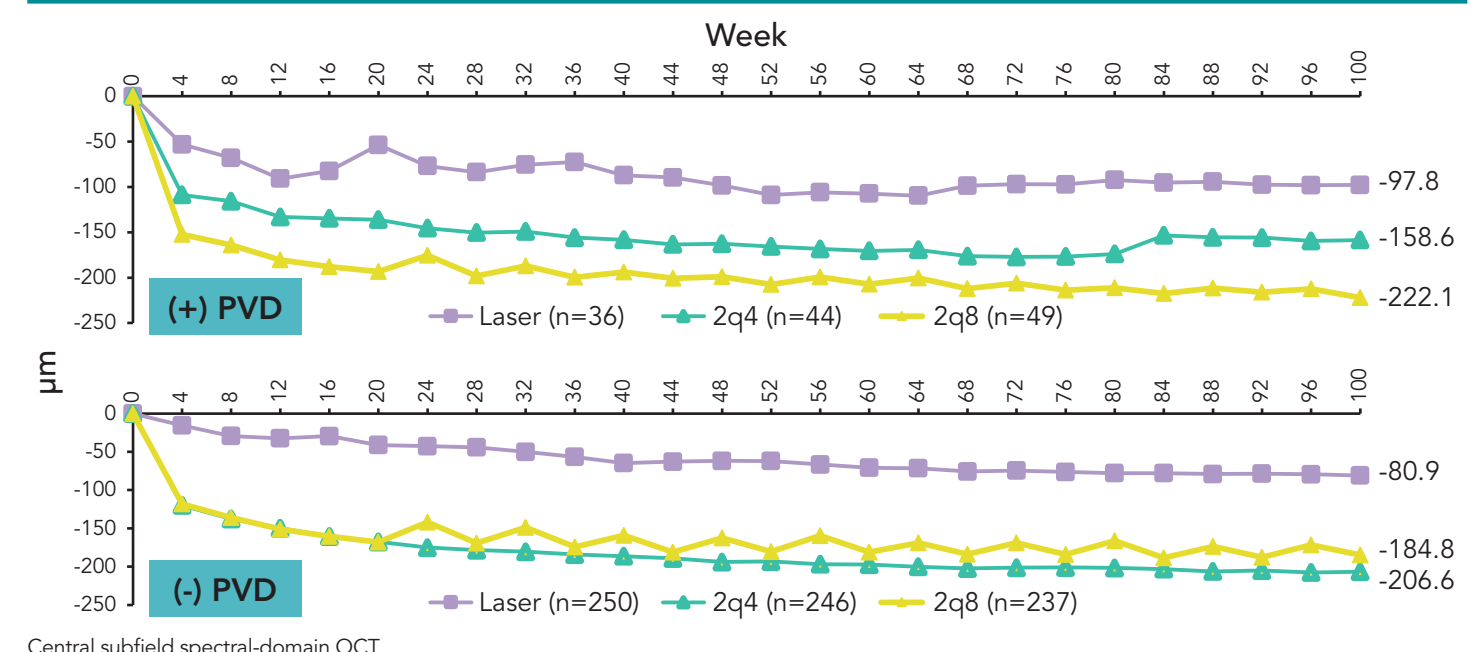


Figure 6. Difference in Mean Change in CRT from Baseline

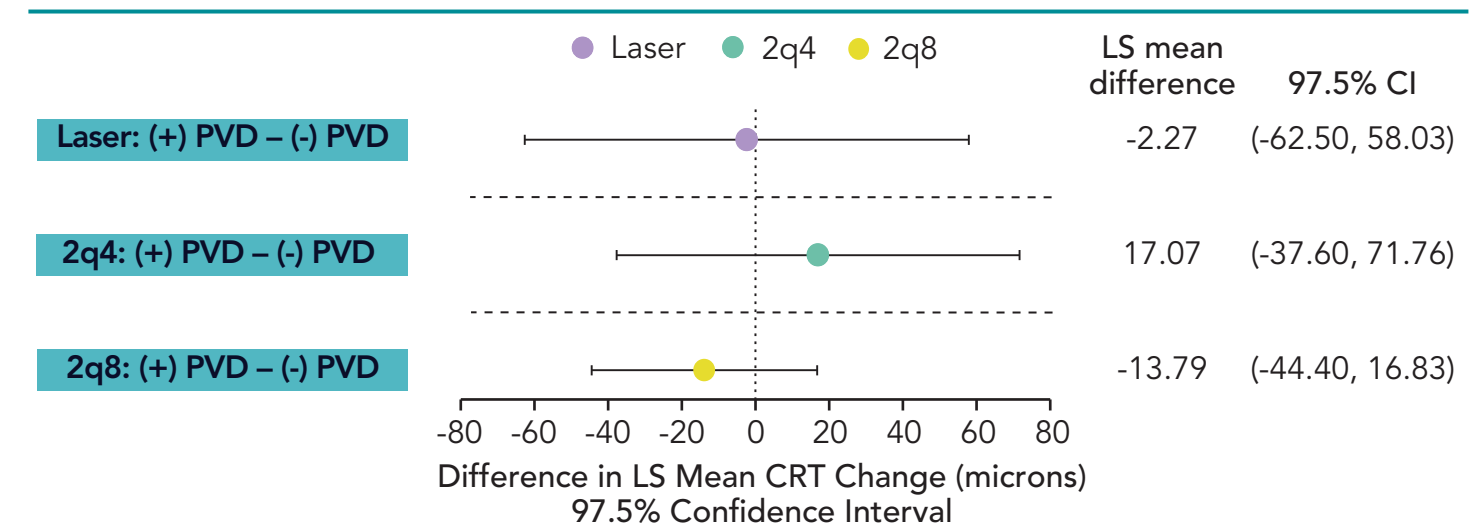


Figure 7. Proportion of Patients with ≥2 Step Improvement in DRSS Score at Week 100

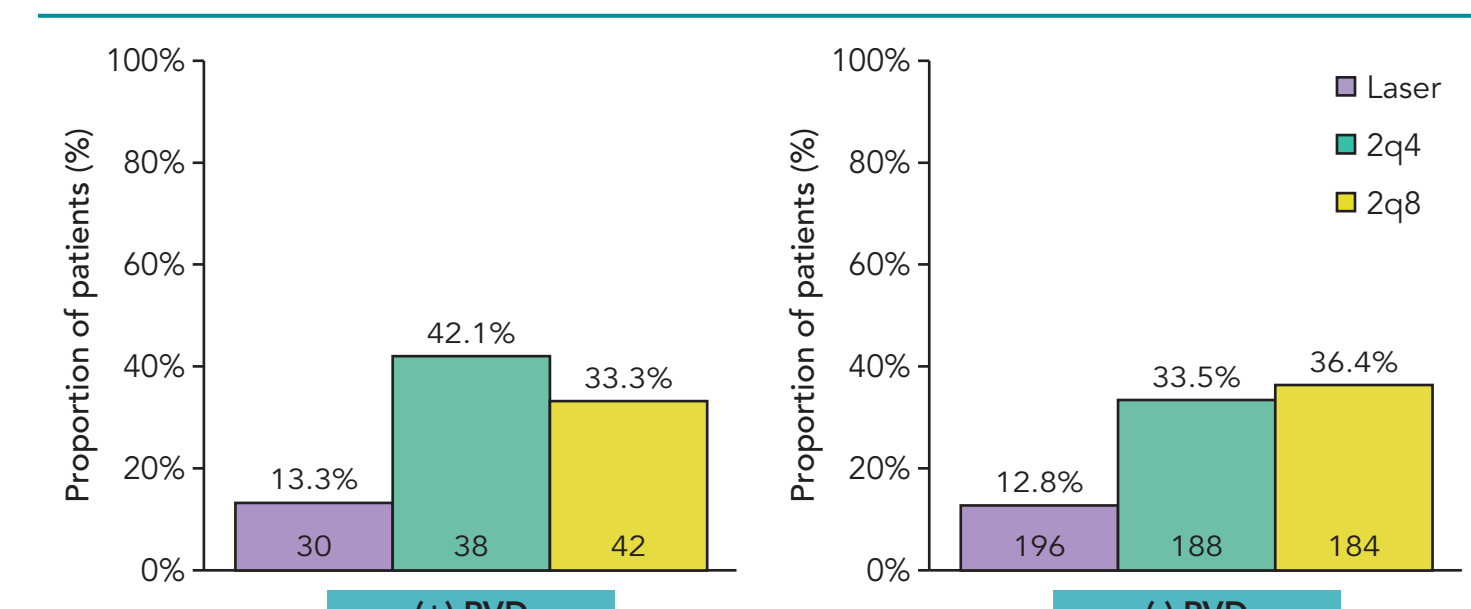
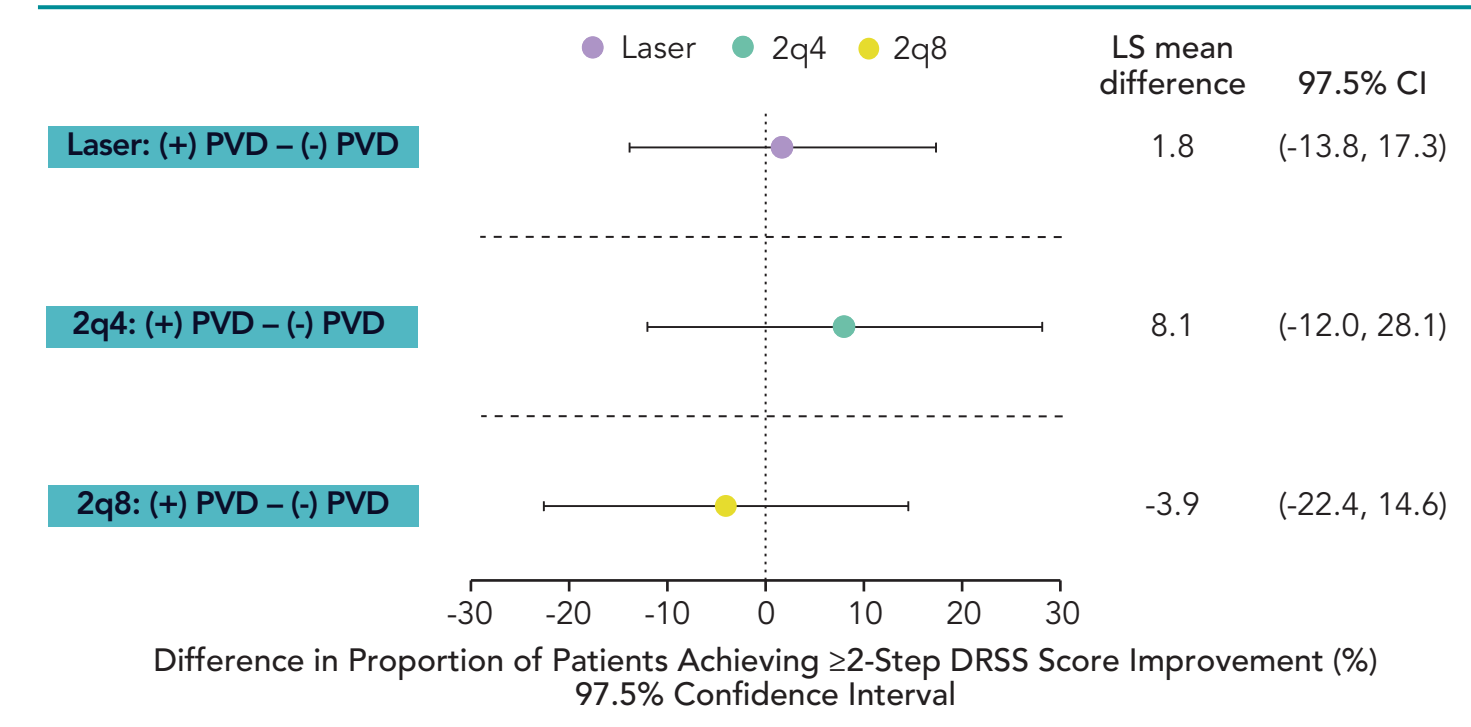


Figure 8. Difference in ≥2-Step DRSS Score Improvement from Baseline



CONCLUSIONS

- Few patients in VIVID/VISTA had PVD present at baseline as determined by the investigator
 - PVD developed in 23 (9.2%), 22 (8.9%), and 27 (11.4%) of patients in the laser, IAI 2q4, and IAI 2q8 groups with (-) PVD at baseline, respectively
- On average, within each treatment group, in patients with DME, PVD status at baseline did not appear to influence
 - need for rescue treatment
 - visual outcomes
 - anatomic outcomes