

**Impact of Baseline Vision on Subsequent Visual Outcomes and Vision-Related Functions in Eyes With Diabetic Macular Edema:
A Post Hoc Analysis of VISTA and VIVID Trials**

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on behalf of the VISTA and VIVID study investigators

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Disclosures

- Mark R Barakat reports receiving research grants from, and being a consultant and speaker bureau member for, AbbVie, Adverum Biotech, Alcon, Allegro, Allergan, Alimera, Annexon, Apellis, Arctic Vision, Biogen, Bausch & Lomb, Clearside Biomedical, EyePoint Pharma, Kodiak Sciences, Gemini Therapeutics, Genentech, Graybug, Gyroscope Therapeutics, Novartis, Ocular Therapeutix, Oculis, Opthea, Outlook Therapeutics, Oxular, Oxurion, Palatin Technologies, Regeneron, RegenxBio, ReNeuron, Ribomic, Roche, Stealth Biotherapeutics, and Unity Biotechnology; and being an equity holder in NeuBase, Oxurion and RevOpsis
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Background

Several clinical trials in DME showed that eyes with better baseline vision have smaller visual gains from treatment compared with eyes with worse baseline vision¹⁻³

However, other factors are important to patients in the real world



ETDRS CHART



DRIVING



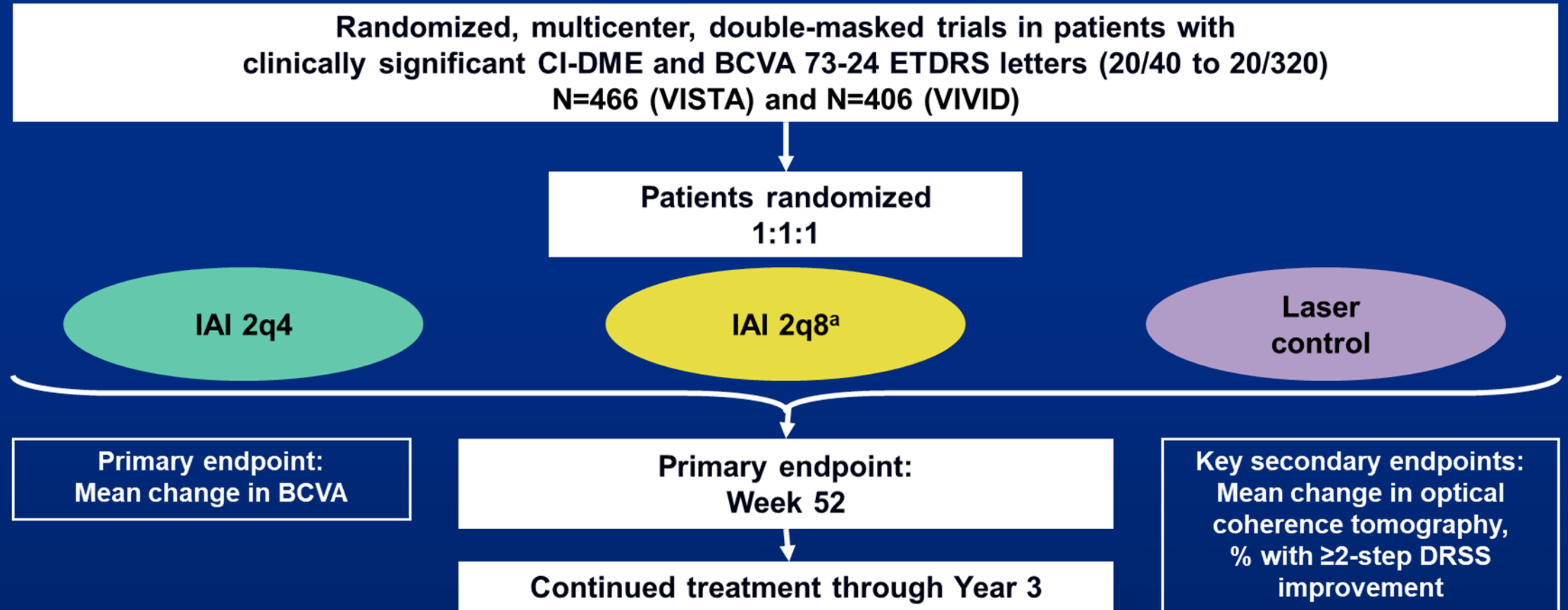
DEPENDENCY



READING

This post hoc analysis of VISTA and VIVID examined the relationship between baseline BCVA and visual outcomes and vision-related functions in patients with DME

VISTA and VIVID: Study Design



^aAfter 5 initial monthly doses.

2q4, 2 mg every 4 weeks; 2q8, 2 mg every 8 weeks; CI-DME, center-involved diabetic macular edema; DRSS, Diabetic Retinopathy Severity Scale; IAI, intravitreal aflibercept injection.
Brown DM et al. *Ophthalmology*. 2015;122:2044-2052.

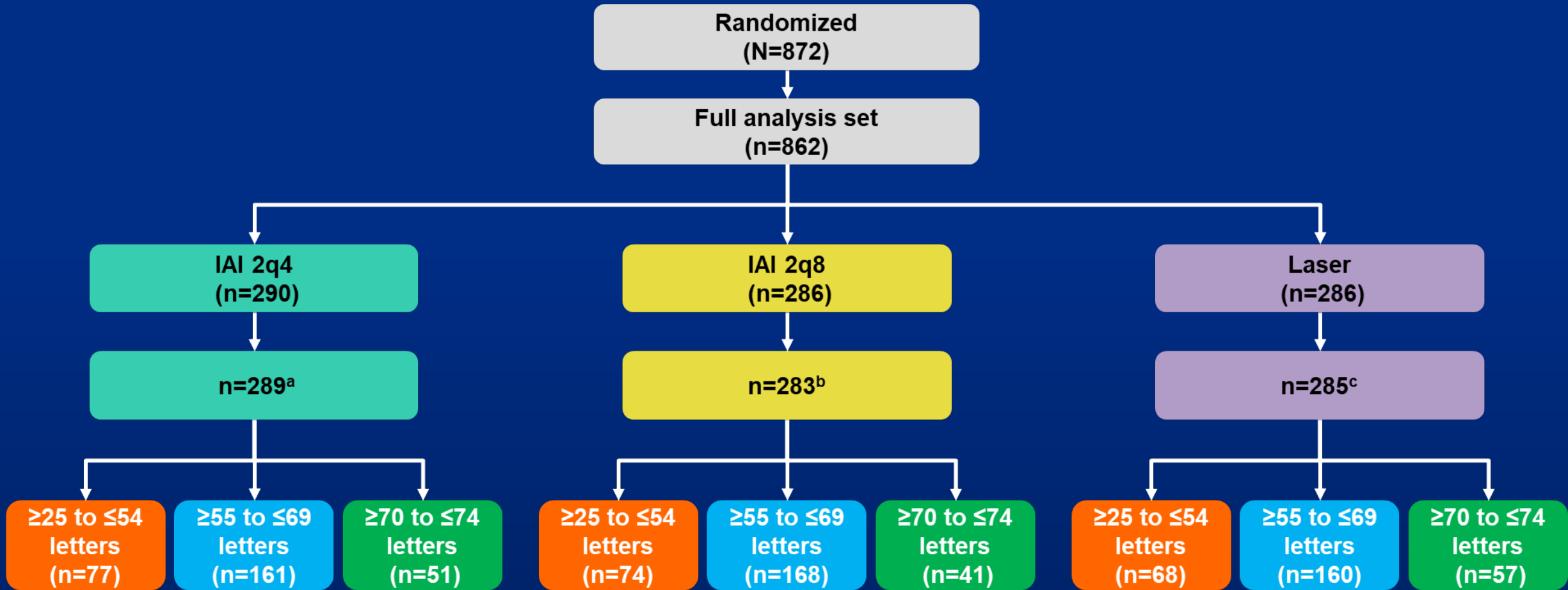
Methods

- This was an integrated analysis of VISTA and VIVID trials in patients who received laser, IAI 2q4, or IAI 2q8
- Eyes were categorized by **baseline BCVA**:

	BCVA		
ETDRS letters	≥25 to ≤54 letters	≥55 to ≤69 letters	≥70 to ≤74 letters
Snellen equivalent	20/320 to <20/80	20/80 to <20/40	20/40 to <20/32

- The full analysis set comprised observed cases; for patients who received rescue treatment (laser or 5 initial monthly doses of IAI followed by 2q8 in IAI- or laser-treated patients, respectively), data were censored from the time of rescue
- Change in BCVA, percentage of patients with BCVA ≥70 letters, change in CST, and VFQ-25 scores were analyzed by baseline BCVA category in each of the 3 treatment groups
- To compare the difference between groups, the Cochran-Mantel-Haenszel test was used for binary outcomes and analysis of covariance was used for continuous outcomes

Patient Disposition at Baseline



^aOne patient in the IAI 2q4 group had baseline BCVA of 75 letters and was excluded from this analysis.

^bThree patients in the IAI 2q8 group had baseline BCVA of 24, 76, and 80 letters, respectively, and were excluded from this analysis.

^cOne patient in the laser group had baseline BCVA of 76 letters and was excluded from this analysis.

Demographics and Baseline Characteristics by Baseline BCVA Category

	IAI 2q4 (n=289 ^a)			IAI 2q8 (n=283 ^b)			Laser (n=285 ^c)		
	≥25 to ≤54 (n=77)	≥55 to ≤69 (n=161)	≥70 to ≤74 (n=51)	≥25 to ≤54 (n=74)	≥55 to ≤69 (n=168)	≥70 to ≤74 (n=41)	≥25 to ≤54 (n=68)	≥55 to ≤69 (n=160)	≥70 to ≤74 (n=57)
Male, n (%)	43 (55.8)	91 (56.5)	35 (68.6)	42 (56.8)	100 (59.5)	22 (53.7)	32 (47.1)	2 (57.5)	39 (68.4)
White, n (%)	61 (79.2)	136 (84.5)	39 (76.5)	62 (83.8)	130 (77.4)	37 (90.2)	54 (79.4)	132 (82.5)	51 (89.5)
Hispanic or Latino, n (%)	9 (11.7)	23 (14.3)	4 (7.8)	5 (6.8)	21 (12.5)	3 (7.3)	4 (5.9)	17 (10.6)	1 (1.8)
BCVA, letters	45.5 (8.8)	62.8 (4.6)	71.3 (1.1)	44.2 (8.2)	62.7 (4.2)	71.5 (1.1)	44.4 (8.2)	62.9 (4.4)	71.4 (1.1)
CST, μm	567.6 (205.0)	480.6 (115.4)	423.5 (101.0)	579.9 (165.7)	476.3 (132.2)	422.5 (97.0)	599.5 (188.9)	492.4 (131.2)	446.3 (121.3)
VFQ-25 composite	60.5 (20.2)	72.2 (18.1)	77.9 (19.3)	66.0 (17.3)	70.9 (17.2)	76.1 (15.3)	62.2 (18.0)	69.6 (17.9)	75.0 (16.3)

At baseline, patients with better vision had lower CST values and higher VFQ-25 composite scores in each treatment group

^aOne patient in the IAI 2q4 group had baseline BCVA of 75 letters and was excluded from this analysis.

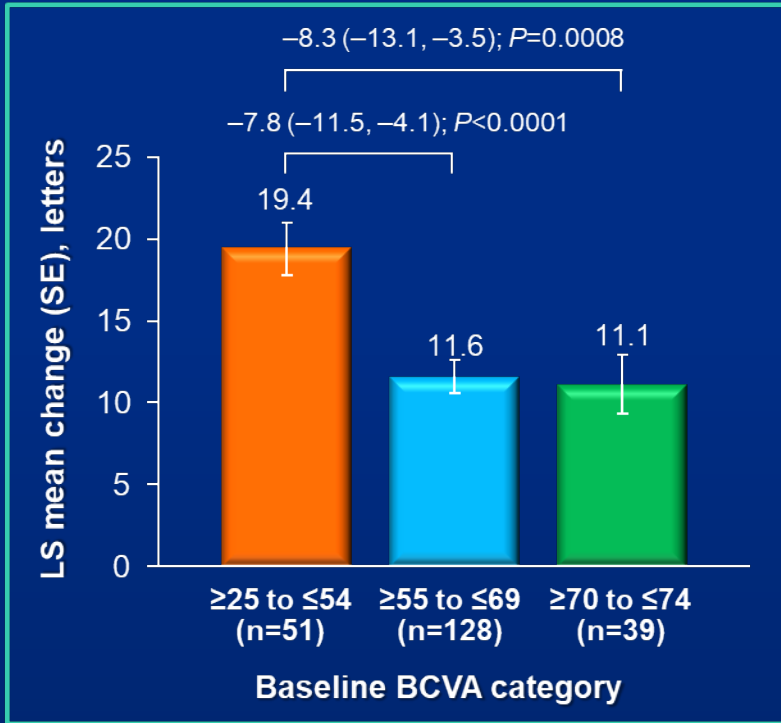
^bThree patients in the IAI 2q8 group had baseline BCVA of 24, 76, and 80 letters, respectively, and were excluded from this analysis.

^cOne patient in the laser group had baseline BCVA of 76 letters and was excluded from this analysis.

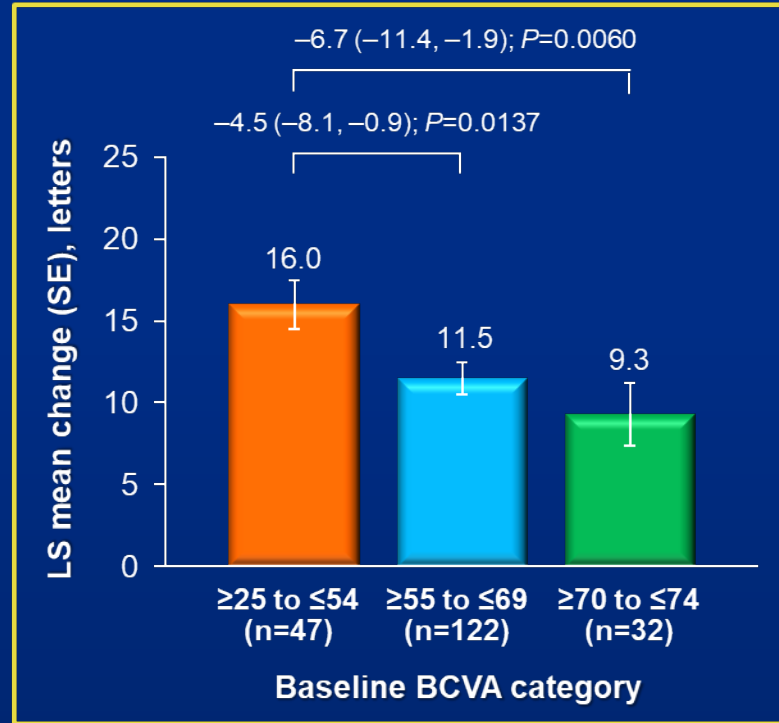
Data are mean (SD) unless specified otherwise.
SD, standard deviation.

Change in BCVA at Week 100 by Baseline BCVA

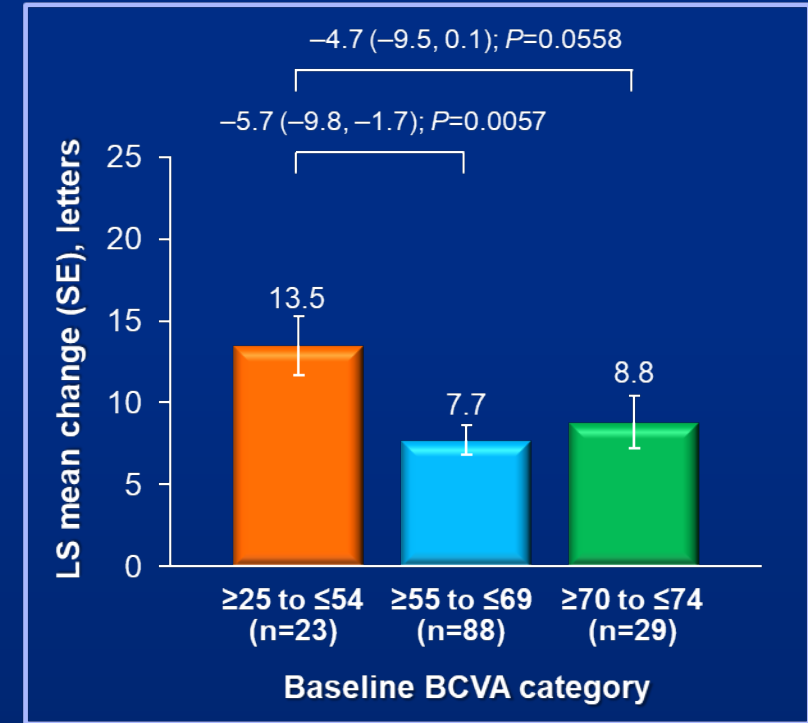
IAI 2q4



IAI 2q8



Laser

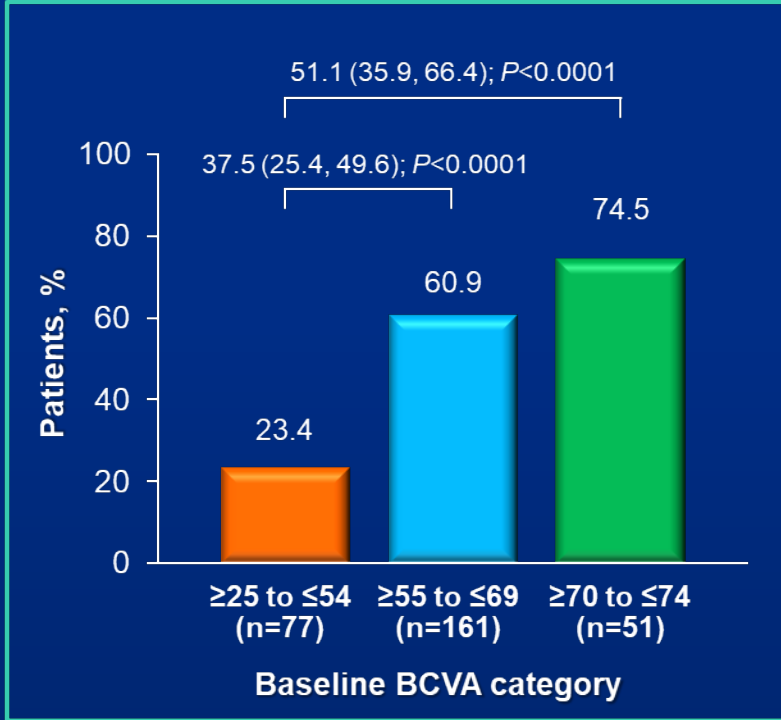


Patients with worse vision at baseline gained more letters at Week 100

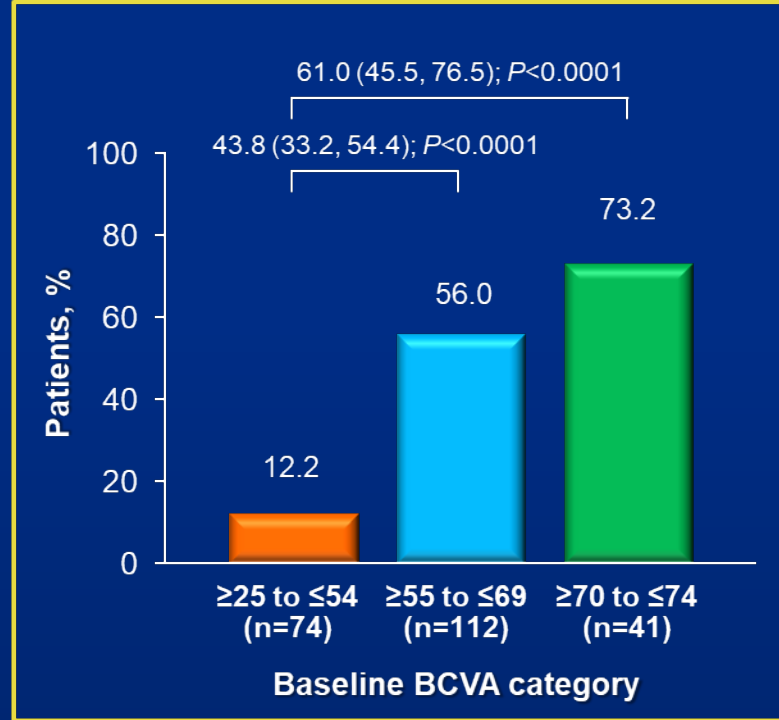
Values above the square brackets represent the difference between LS mean change (95% CI).
 Full analysis set, observed cases.
 CI, confidence interval; LS, least squares; SE, standard error.

Proportion of Patients With BCVA ≥ 70 Letters ($\geq 20/40$) at Week 100 by Baseline BCVA Category

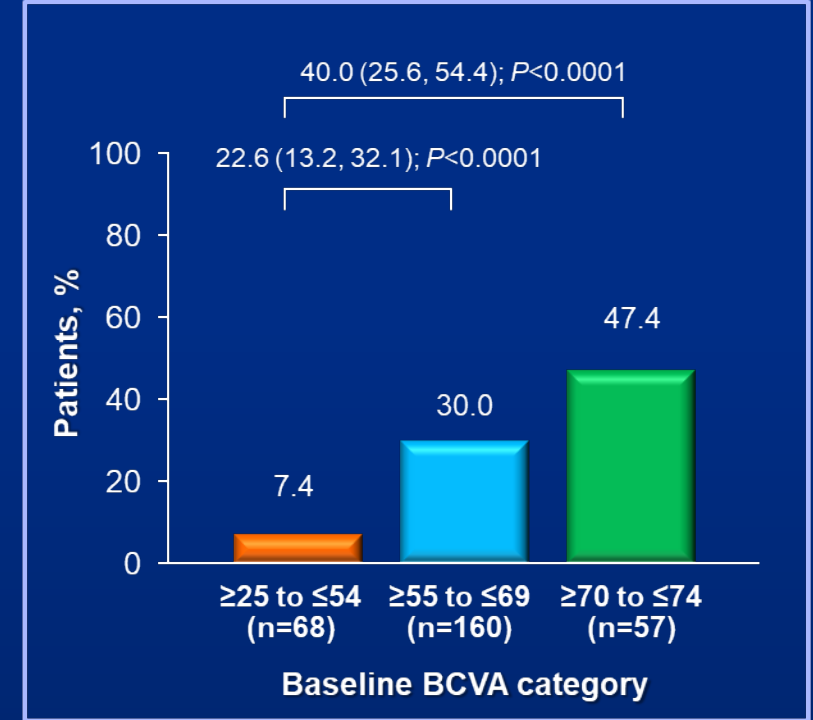
IAI 2q4



IAI 2q8



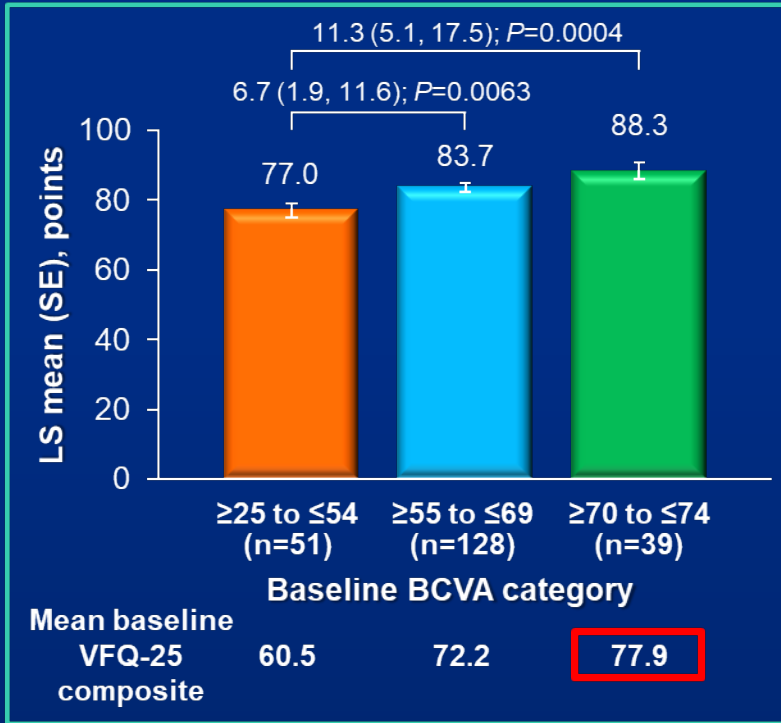
Laser



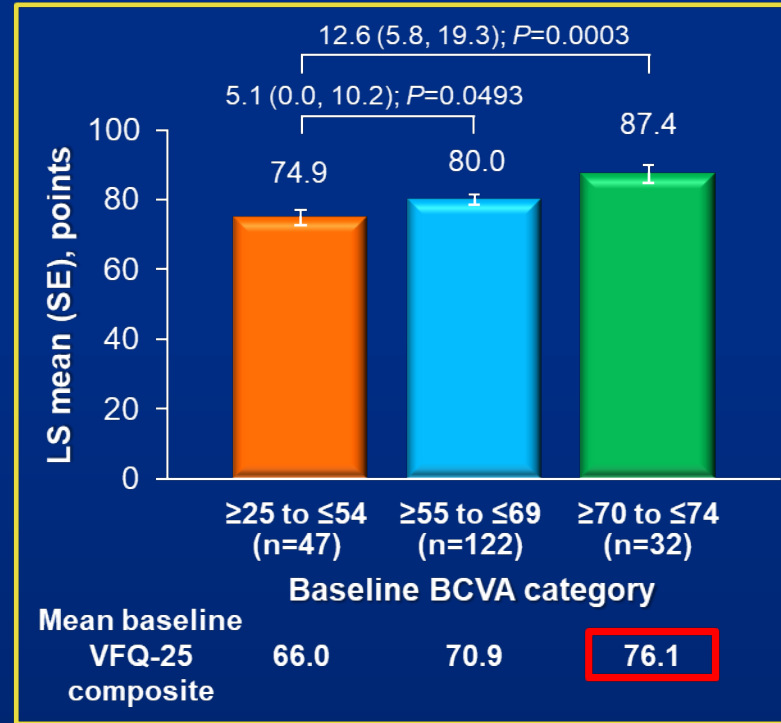
Greater proportion of patients with better vision at baseline had BCVA ≥ 70 letters at Week 100 compared with those with worse vision at baseline

VFQ-25 Composite Score at Week 100 by Baseline BCVA Category

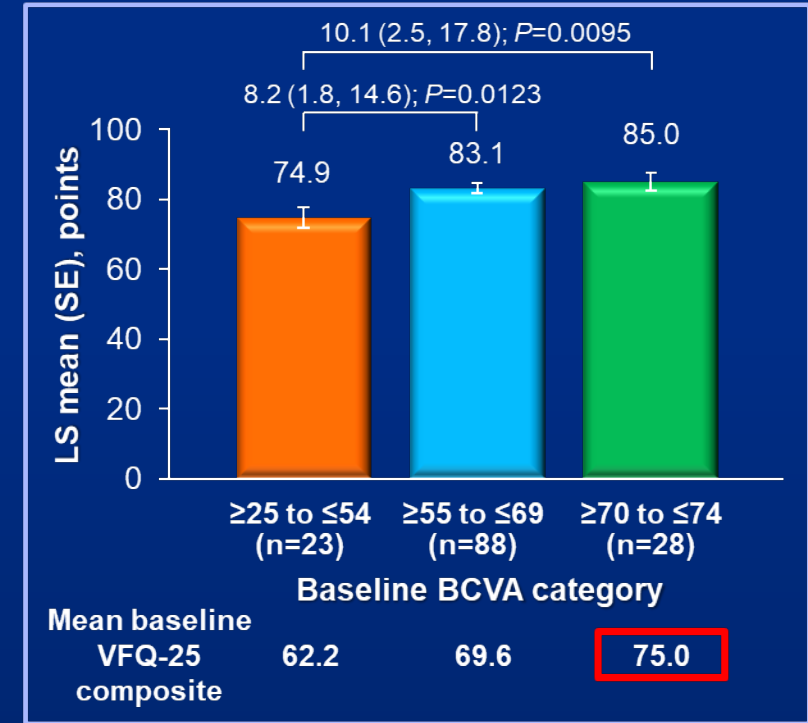
IAI 2q4



IAI 2q8

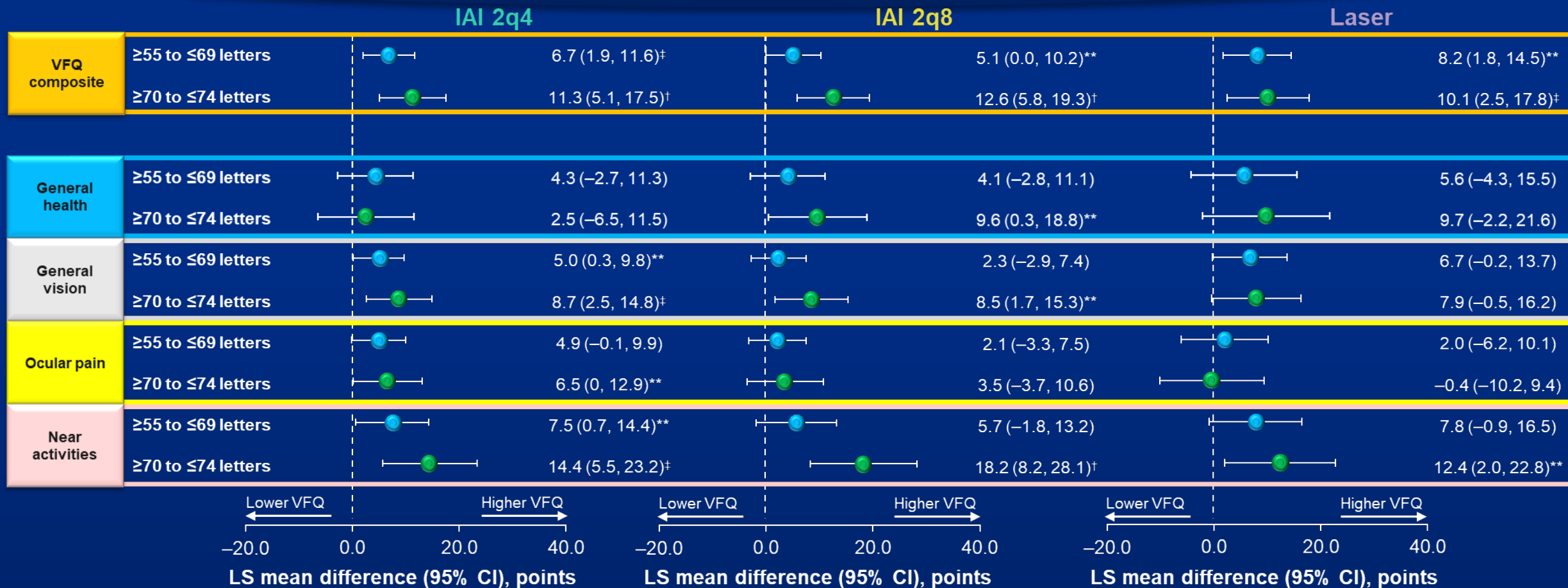


Laser



At Week 100, patients with higher baseline BCVA had significantly higher VFQ-25 composite scores in all treatment groups

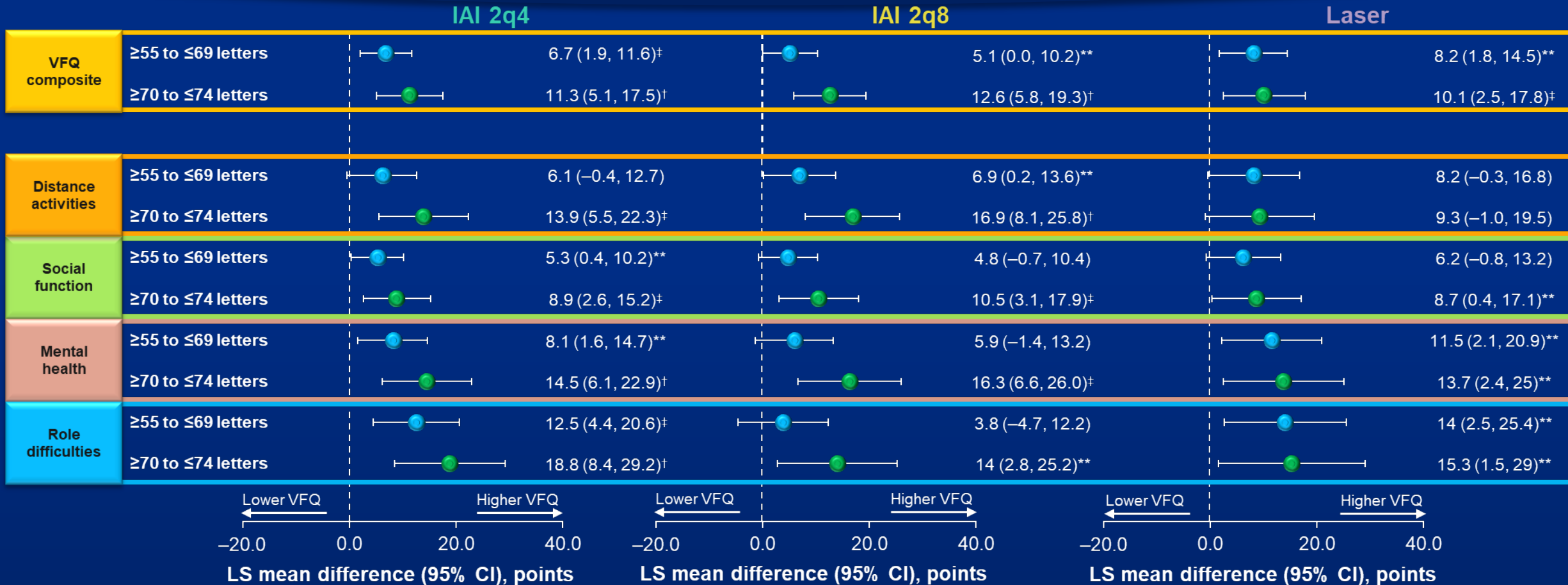
Difference in VFQ-25 Composite and Subscale Scores at Week 100 From Patients With Worse Baseline Vision



VFQ-25 composite and 9 of 12 subscale scores showed significant improvement in patients with baseline BCVA ≥25 to ≤54 letters

✓ denotes clinically significant improvement in both IAI groups in ≥1 BCVA subcategory over the subcategory with the worse vision. *P≤0.0001; †P<0.001; ‡P<0.01; **P<0.05 vs ≥25 to ≤54 letters.

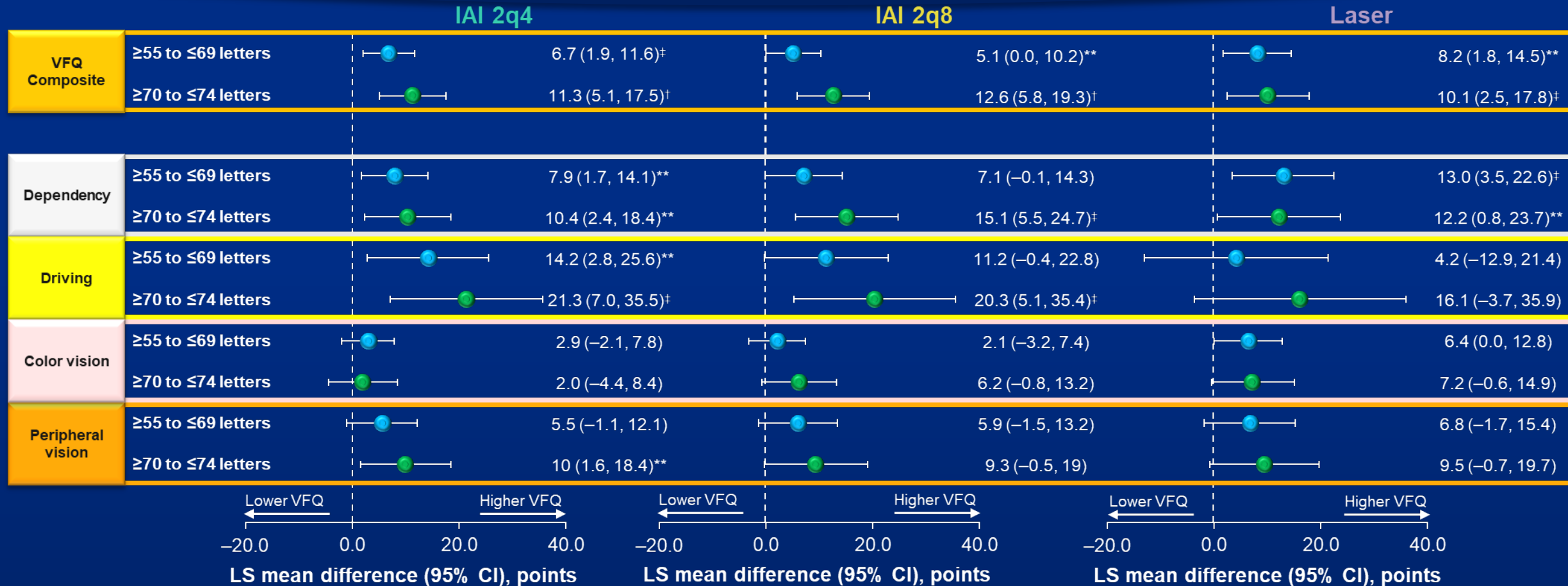
Difference in VFQ-25 Composite and Subscale Scores at Week 100 From Patients With Worse Baseline Vision



VFQ-25 composite and 9 of 12 subscale scores showed significant improvement in patients with baseline BCVA ≥70 to ≤74 letters versus ≥25 to ≤54 letters

✓ denotes clinically significant improvement in both IAI groups in ≥1 BCVA subcategory over the subcategory with the worse vision. * $P \leq 0.0001$; † $P < 0.001$; ‡ $P < 0.01$; ** $P < 0.05$ vs ≥25 to ≤54 letters.

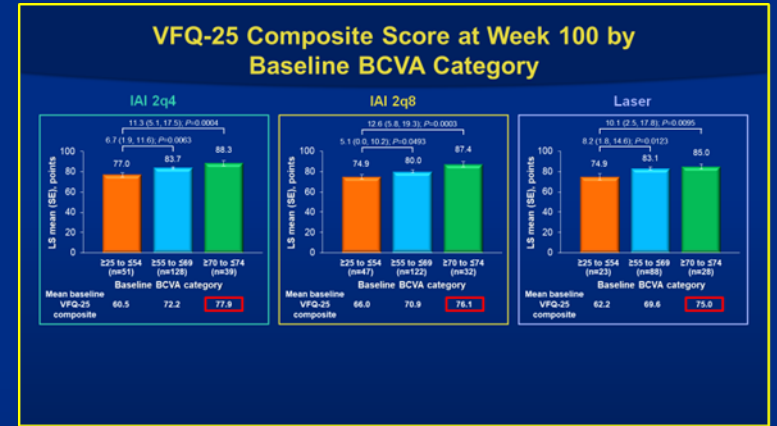
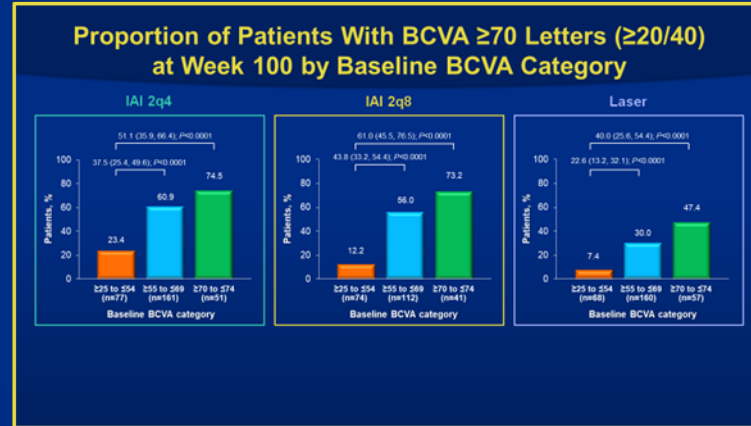
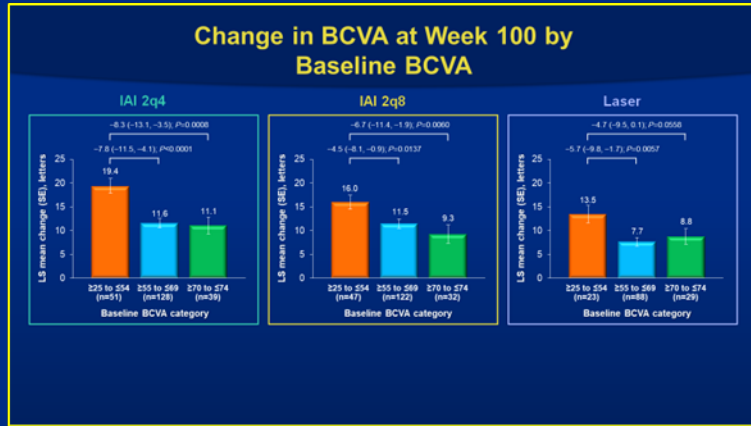
Difference in VFQ-25 Composite and Subscale Scores at Week 100 From Patients With Worse Baseline Vision



VFQ-25 composite and 9 of 12 subscale scores showed significant improvement in patients with baseline BCVA ≥70 to ≤74 letters versus ≥25 to ≤54 letters

✓ denotes clinically significant improvement in both IAI groups in ≥1 BCVA subcategory over the subcategory with the worse vision. * $P \leq 0.0001$; [†] $P < 0.001$; [‡] $P < 0.01$; ^{**} $P < 0.05$ vs ≥25 to ≤54 letters.

Conclusions



- Patients with CI-DME and worse baseline BCVA gained more letters at Week 100 than patients with better baseline BCVA; a higher proportion of patients with better baseline BCVA had BCVA ≥ 70 letters ($\geq 20/40$) at Week 100
- Patients with better baseline BCVA had higher VFQ-25 scores at Week 100
- Patients with better baseline BCVA may achieve improved visual outcomes and vision-related function through optimal treatment