

Effect of rozanolixizumab on ocular symptoms in generalized myasthenia gravis: Analysis of Phase 3 studies

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Introduction

- Patients with gMG may experience disabling ocular symptoms, such as diplopia and ptosis, due to ocular muscle weakness and fatigability^{1–3}
 - Such ocular symptoms impede daily activities and significantly reduce QoL⁴
- Rozanolixizumab, a humanized IgG4 mAb that targets and blocks FcRn with high affinity, is approved for the treatment of adults with anti-AChR Ab+ or anti-MuSK Ab+ gMG⁴
- In the Phase 3 MycarinG study (NCT03971422), one 6-week cycle of rozanolixizumab demonstrated greater improvements in ocular item scores across MG-specific outcomes than placebo in patients with gMG⁵
- This *post hoc* analysis investigated the effect of repeated rozanolixizumab treatment cycles on ocular symptoms in patients with gMG**

Methods

- In MycarinG, patients aged ≥18 years with MGFA Disease Class II–IVa anti-AChR Ab+ or anti-MuSK Ab+ gMG with an MG-ADL score ≥3 (for non-ocular symptoms) and a QMG score ≥11 were enrolled
- Following MycarinG, patients could enroll in OLE studies MG0004 (NCT04124965) and then MG0007 (NCT04650854), or MG0007 directly
 - MG0004: once-weekly rozanolixizumab 7 mg/kg or 10 mg/kg for ≤52 weeks
 - MG0007: an initial 6-week rozanolixizumab 7 mg/kg or 10 mg/kg cycle, with further cycles administered upon symptom worsening at the investigator’s discretion
- Final efficacy data were pooled across MycarinG, MG0004 (first 6 weeks) and MG0007 for patients with ≥2 symptom-driven rozanolixizumab cycles
- Mean item scores (weighted by sample size, per cycle) were evaluated at baseline and Day 43 across Cycles 1–13 for ocular items within the MG-ADL, QMG, MG Symptoms PRO and MG-QoL15r scales

Results

- Overall, 129 patients received ≥2 symptom-driven cycles
- Baseline demographics and disease characteristics are shown in **Table 1**
- Across 13 cycles, weighted mean ocular item-level scores improved between baseline and Day 43 for MG-ADL, QMG, MG Symptoms PRO and MG-QoL15r (**Figure 1**)
- Across Cycles 1–13 (weighted mean), the percentages of patients who improved to have no symptoms in each ocular item-level score across all four measures ranged from 17.7% (MG Symptoms PRO; Difficulty moving eyes side to side) to 31.1% (MG-ADL; eyelid droop) (**Figure 2**)
- In total, 93.1% (175/188) of patients with ≥1 treatment cycle across MycarinG and MG0007 experienced a TEAE; most were mild or moderate

Table 1 Baseline demographics and disease characteristics were indicative of a broad population of patients with gMG

	RLZ total (N=129)
Age, years, mean (SD)	50.9 (16.3)
Sex, female, n (%)	77 (59.7)
Age at initial gMG diagnosis, years, mean (SD)	43.1 (17.8)
Duration of disease from diagnosis, years, mean (SD)	8.1 (8.5)
MGFA Disease Class, n (%)	II 52 (40.3)
	III 72 (55.8)
	IV 5 (3.9)
	Anti-AChR Ab+, n (%) 117 (90.7)
	Anti-MuSK Ab+, n (%) 12 (9.3)
	MG-ADL score, mean (SD) 8.7 (3.4)
	MG-ADL ocular subdomain score, mean (SD) 2.8 (1.7)
	QMG score, mean (SD) 16.0 (3.8)
	QMG ocular subdomain score, mean (SD) 4.0 (1.9)
	CS for systemic use 80 (62.0)
Baseline gMG medication, n (%)	Immunosuppressants 66 (51.2)
	Parasympathomimetics 113 (87.6)

Summary and conclusions



This *post hoc* analysis of pooled data from the Phase 3 MycarinG study and its OLEs evaluated the effect of long-term, cyclic rozanolixizumab treatment on the ocular signs and symptoms experienced by patients with gMG



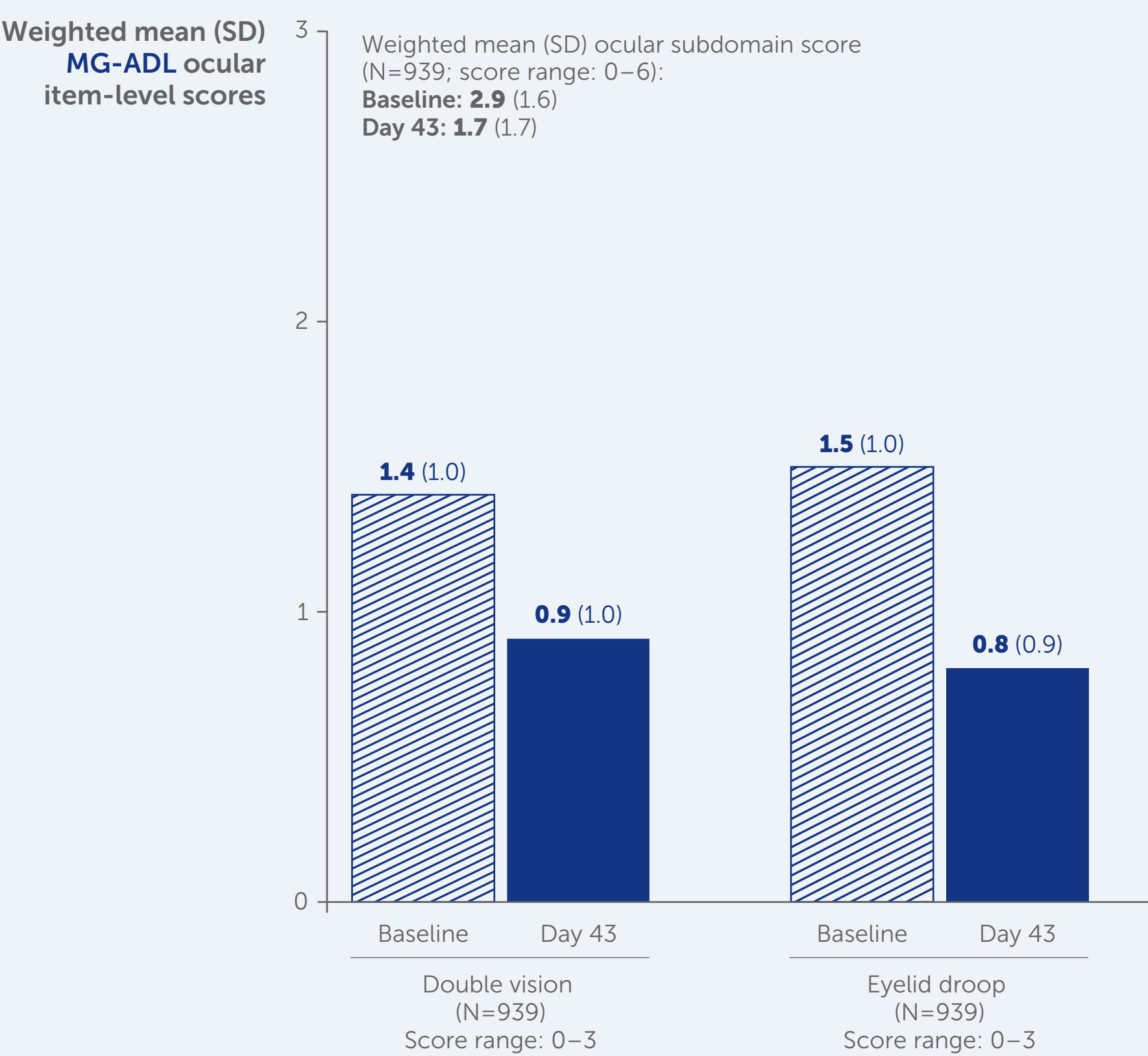
Long-term rozanolixizumab treatment cycles led to improvements across ocular items in MG-specific outcome measures, suggesting a benefit for patients with gMG experiencing ocular signs and symptoms



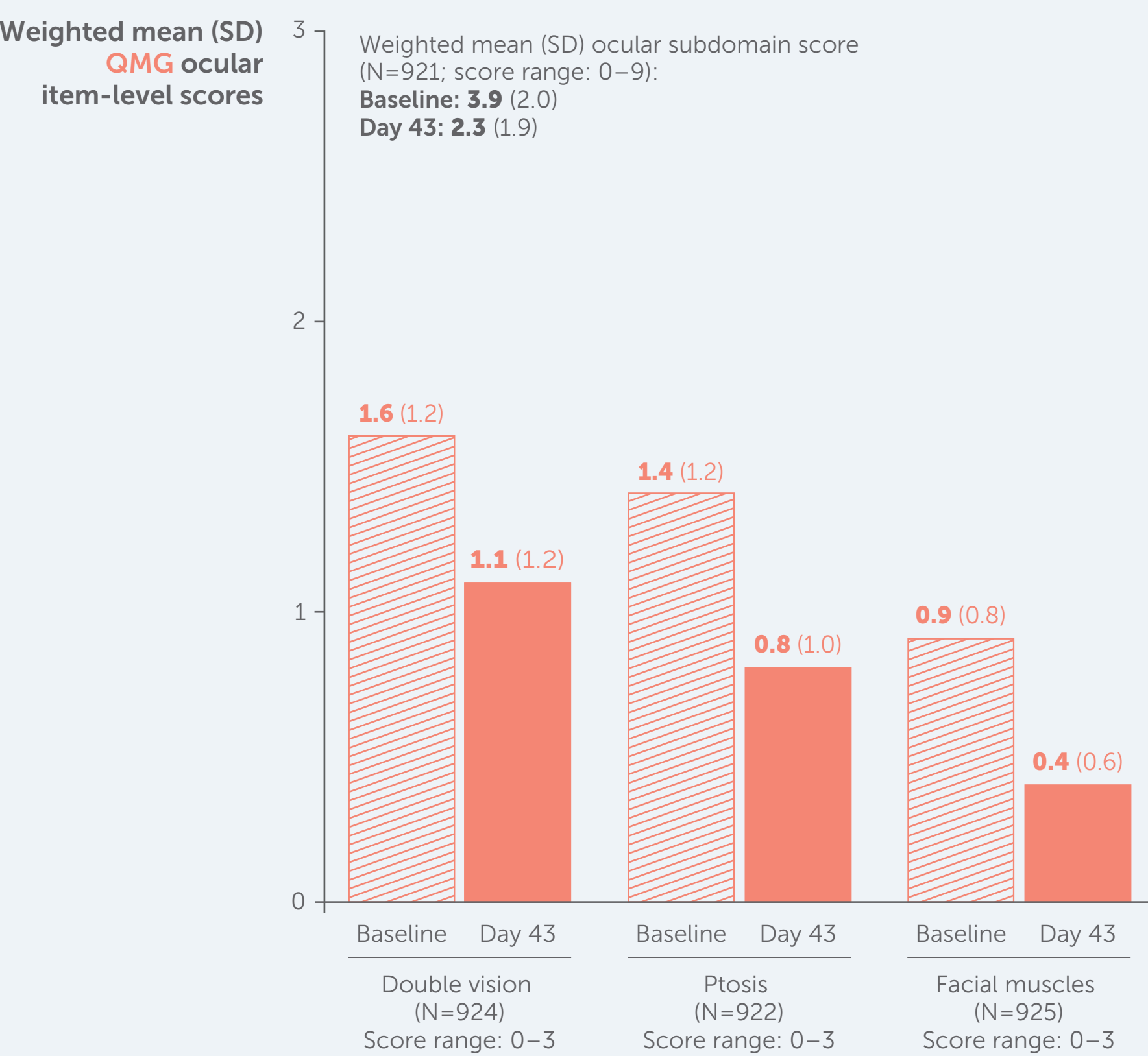
Following these results, rozanolixizumab is being investigated in the MyVision study (NCT07463521) in patients with ocular MG

Figure 1 Across 13 cycles, weighted mean ocular item-level scores improved between baseline and Day 43 for (a) MG-ADL, (b) QMG, (c) MG Symptoms PRO and (d) MG-QoL15r measures

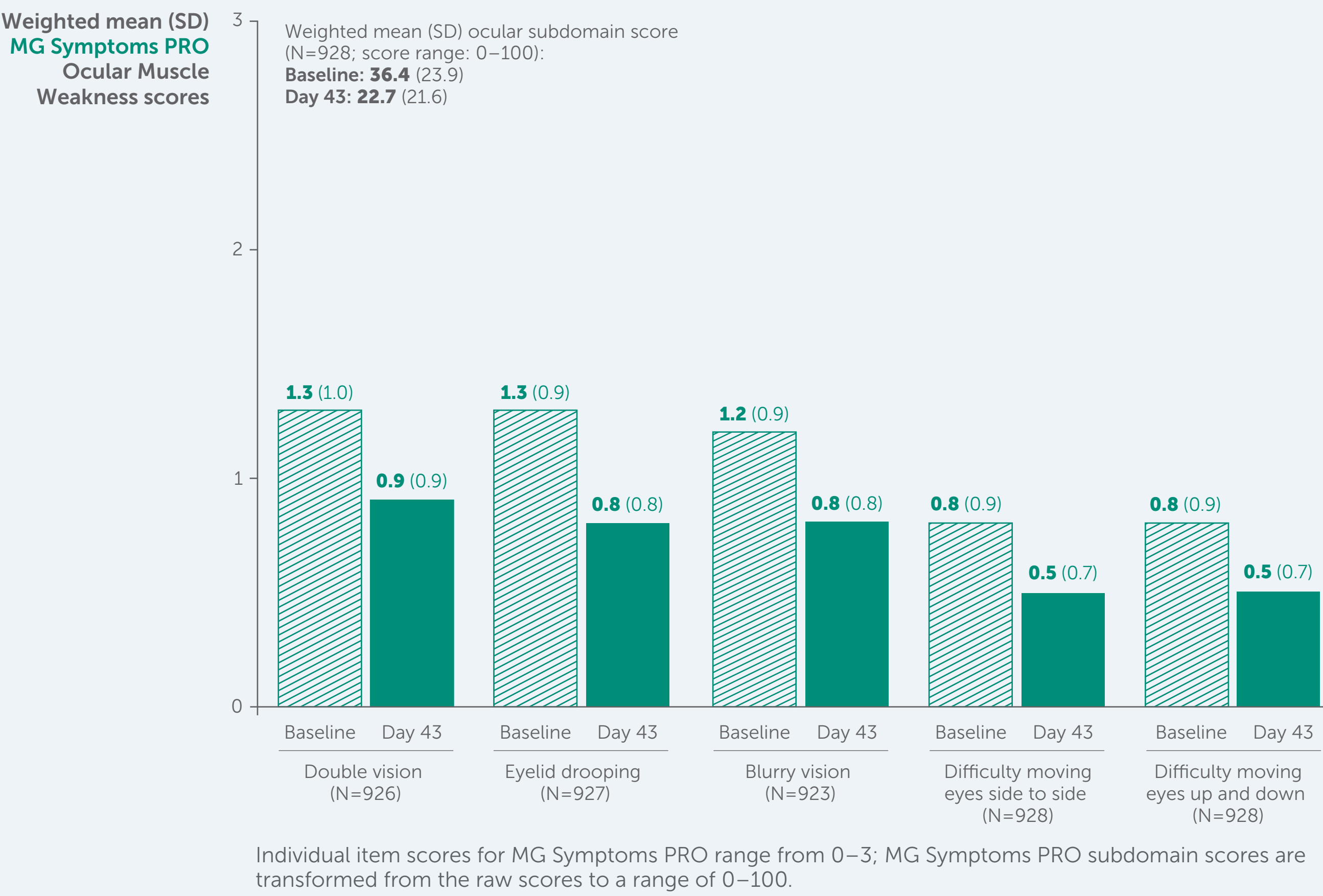
(a) MG-ADL



(b) QMG



(c) MG Symptoms PRO



(d) MG-QoL15r

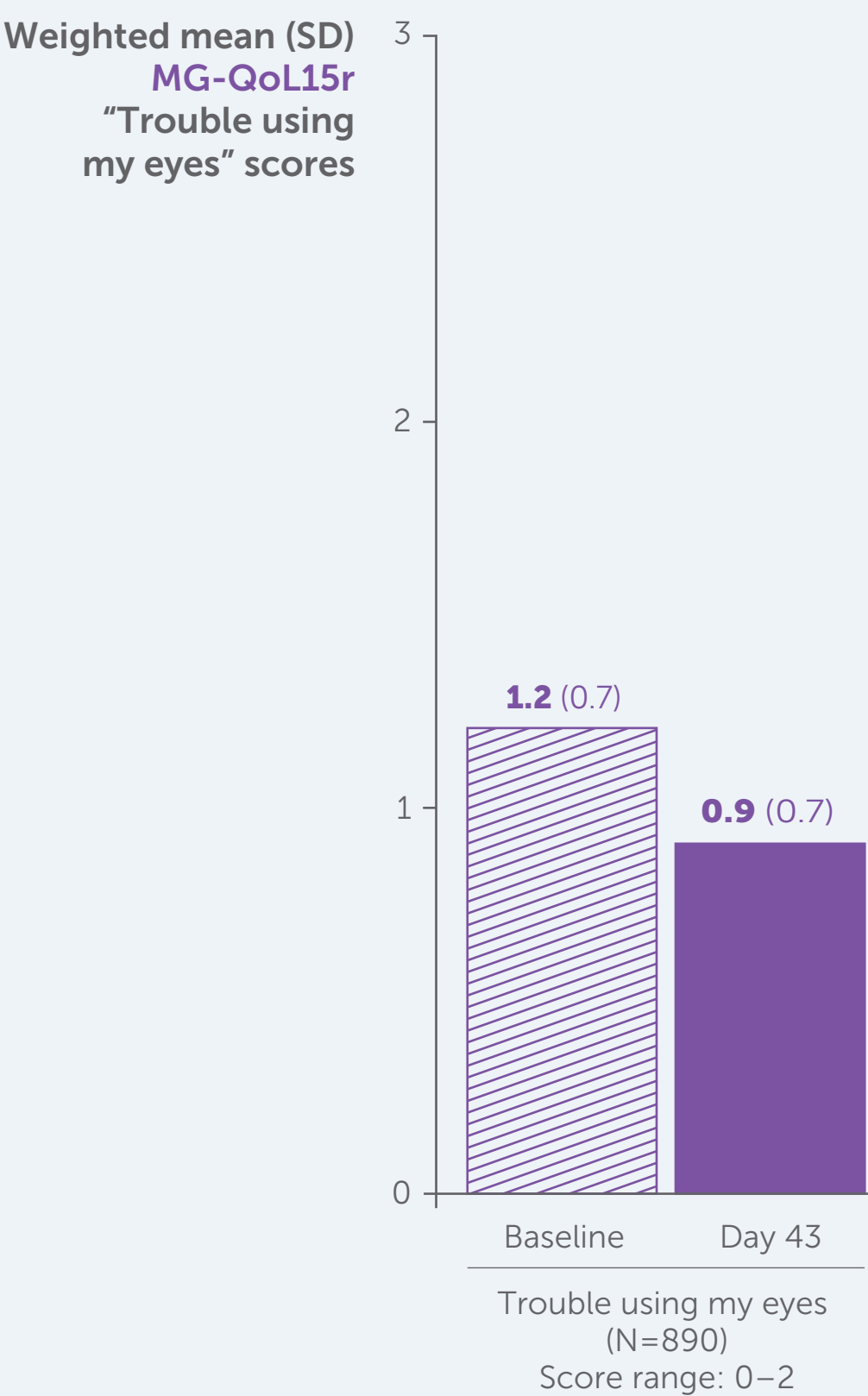
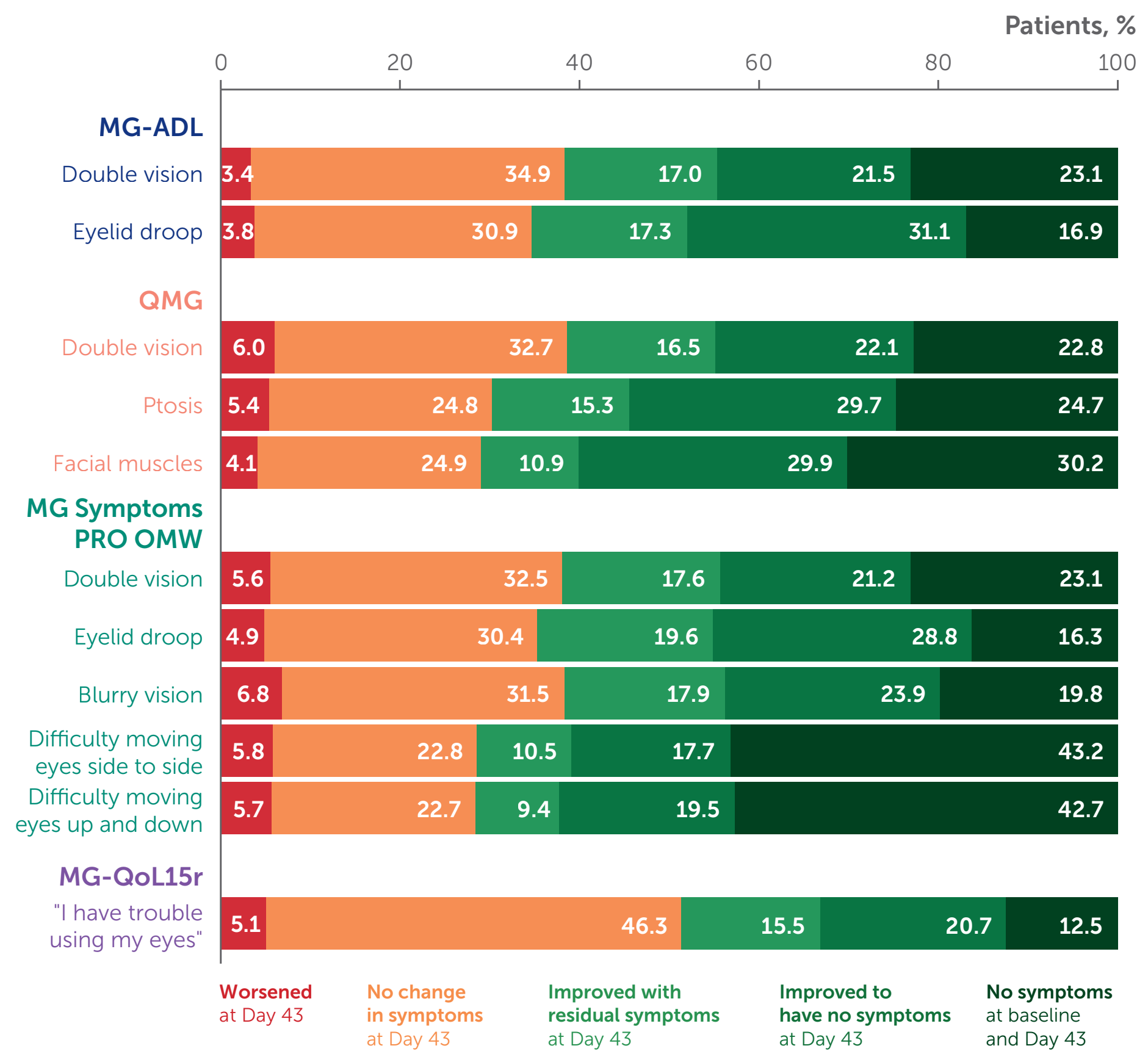


Figure 2 Most patients’ ocular item-level scores improved across Cycles 1–13



Abbreviations: Ab+, antibody positive; AChR, acetylcholine receptor; CS, corticosteroid; FcRn, neonatal fragment crystallizable receptor; (g)MG, (generalized) myasthenia gravis; IgG4, immunoglobulin G4; mAb, monoclonal antibody; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; MG-QoL15r, Myasthenia Gravis Quality of Life 15-item revised; MuSK, muscle-specific tyrosine kinase; OLE, open-label extension; OMW, Ocular Muscle Weakness; PRO, patient-reported outcome; QMG, Quantitative Myasthenia Gravis; QoL, quality of life; RLZ, rozanolixizumab; SD, standard deviation; TEAE, treatment-emergent adverse event.

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