Financial Disclosure

I have no financial interests or relationships to disclose.

Web versus Paper Ophthalmic PRO Assessments

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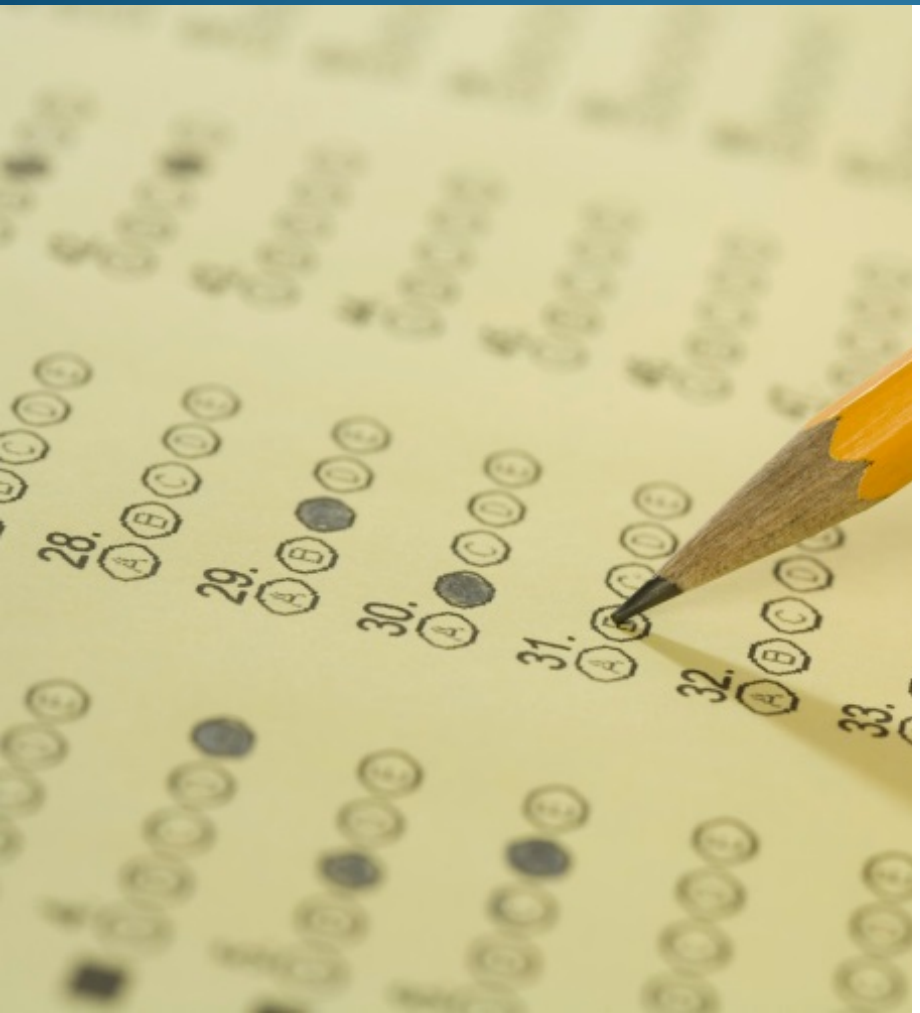
Patient-reported outcomes (PROs)

Increasingly important in clinical studies

- Assessment of safety
- Support of specific medical claims

Modes of administration

Paper



Electronic

Potential advantage of electronic PROs for conditions affecting vision

Images of visual aberrations

Adjusting display and formatting

Pilot
FDA/NEI Collaborative Study

Why?

Decrease resources (time, $) associated with administration of PRO instruments and

Facilitate use in device trials

Existing QoL instruments used

NEI-VFQ

Driving

OSDI

Symptoms

NEI-RECQ

Near vision, Far vision, Glare, Clarity of vision, Symptoms, Worry, Satisfaction with correction

Study description

Web vs paper administration

Identical questions, same order

Participants completed both versions

Randomized crossover design

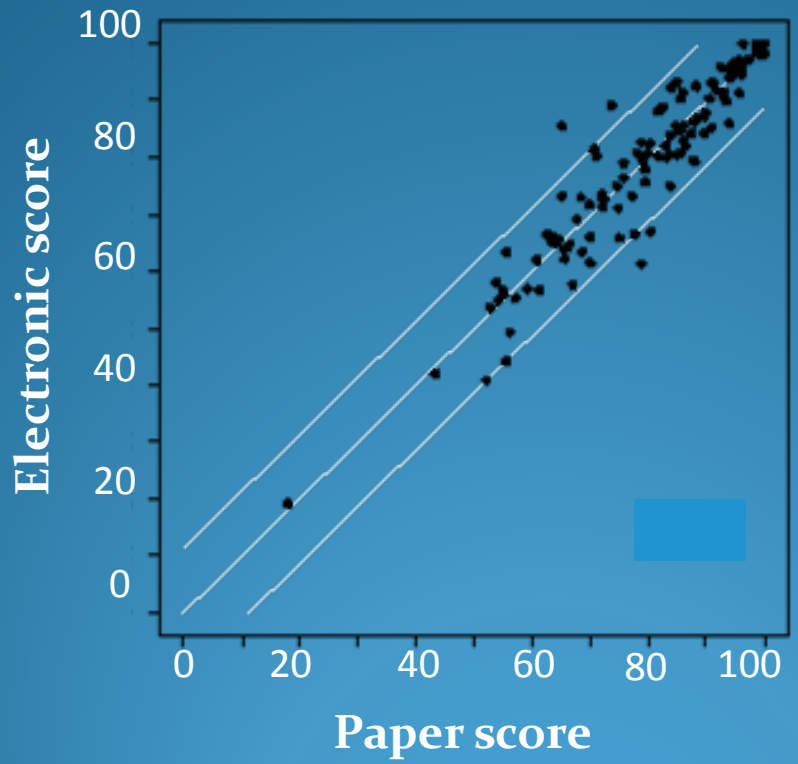
Subjects randomized to

Paper first, Web second (**P1**)

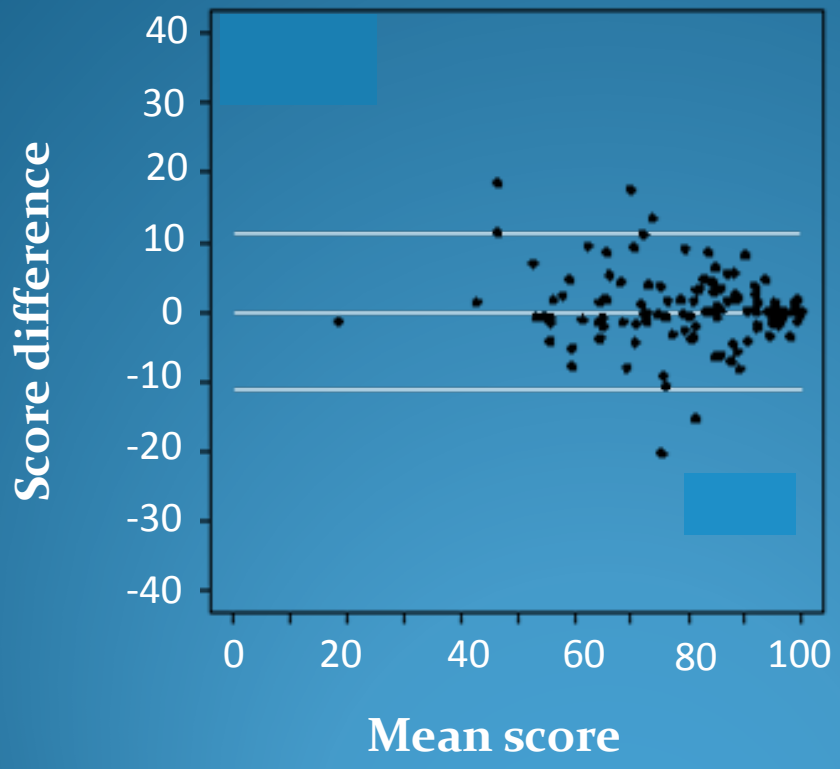
or to

Web first, Paper second (**P2**)

Analysis of agreement



Analysis of agreement



Bland-Altman approach

Analysis of agreement

Participant	Paper score	Electronic score	Difference
1	P_1	E_1	$(P_1-E_1) = D_1$
2	P_2	E_2	$(P_2-E_2) = D_2$
⋮	⋮	⋮	⋮
n	P_n	E_n	$(P_n-E_n) = D_n$
	Mean P	Mean E	Mean D

Bias

Analysis of agreement

Multivariable logistic regression models

Outcome: **Close agreement** (difference between paper and web is <10% of paper score)

$$\frac{\text{(Paper – web)}}{\text{Paper}} \leq 10\%$$

Participants

OSD patients (n=68)

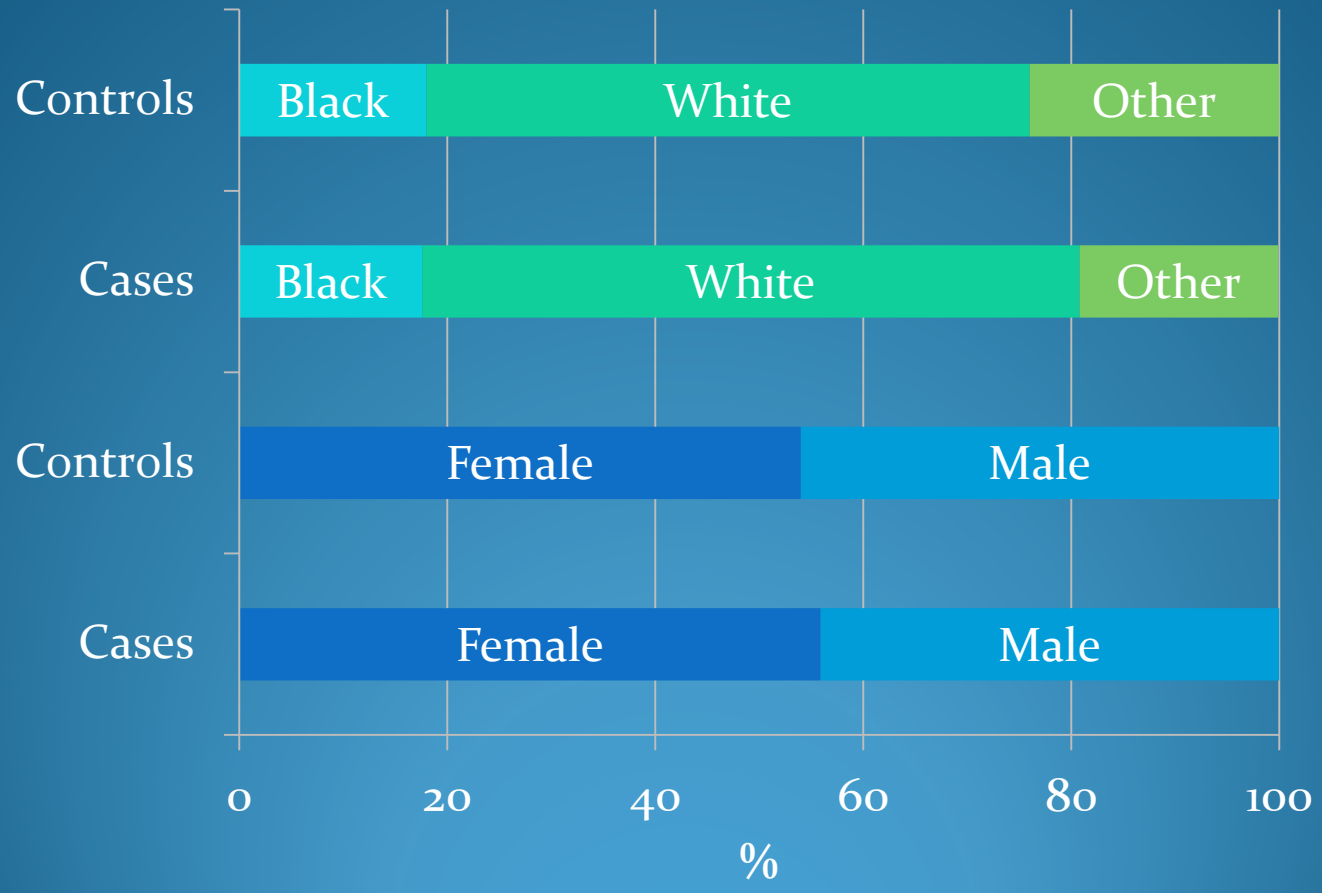
Schirmer 1 ≤ 10
or TBUT ≤ 10

Controls (n=50)

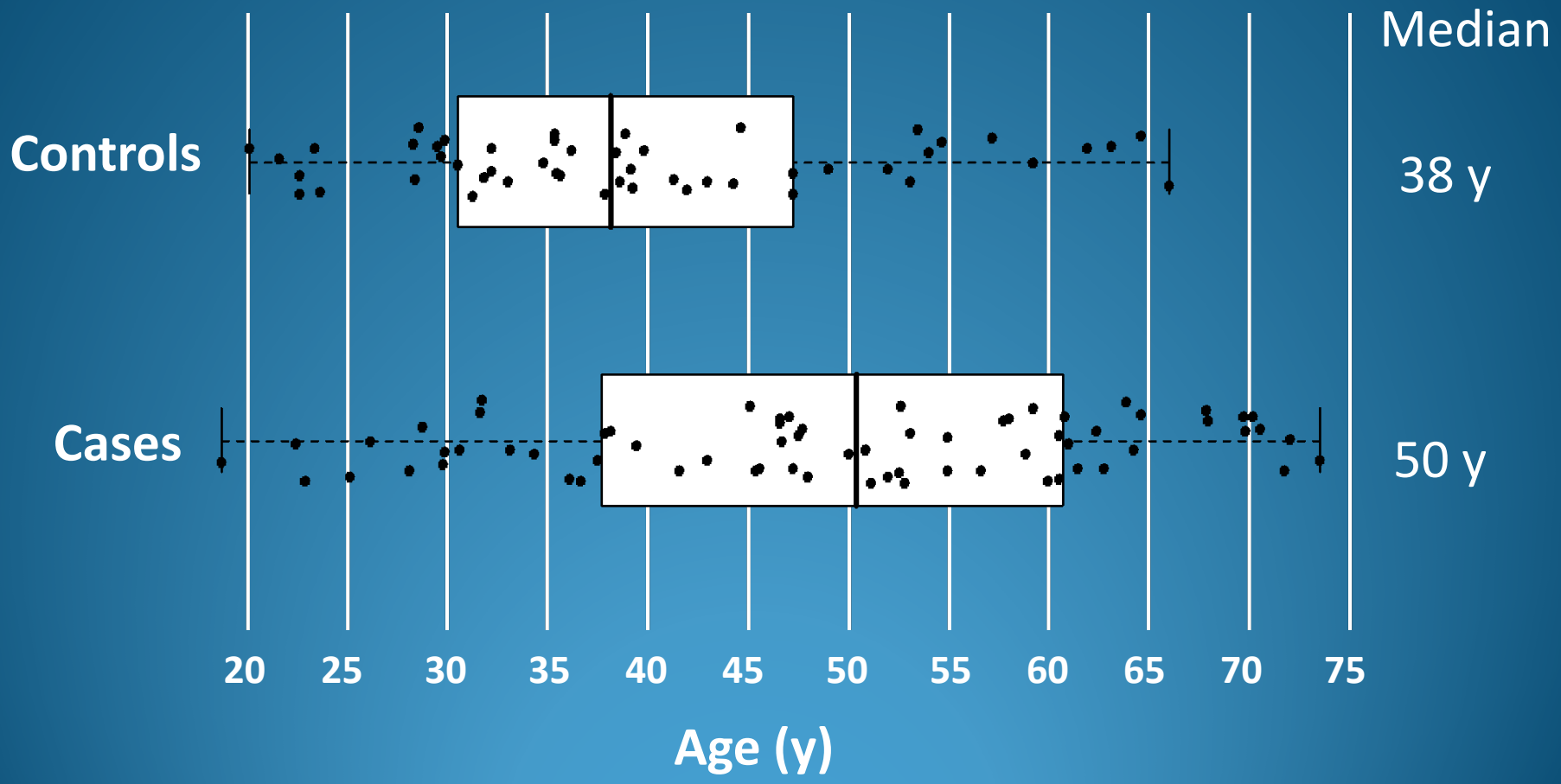
Sex-matched

Age >=18 y, near VA 20/40 or better

Study population

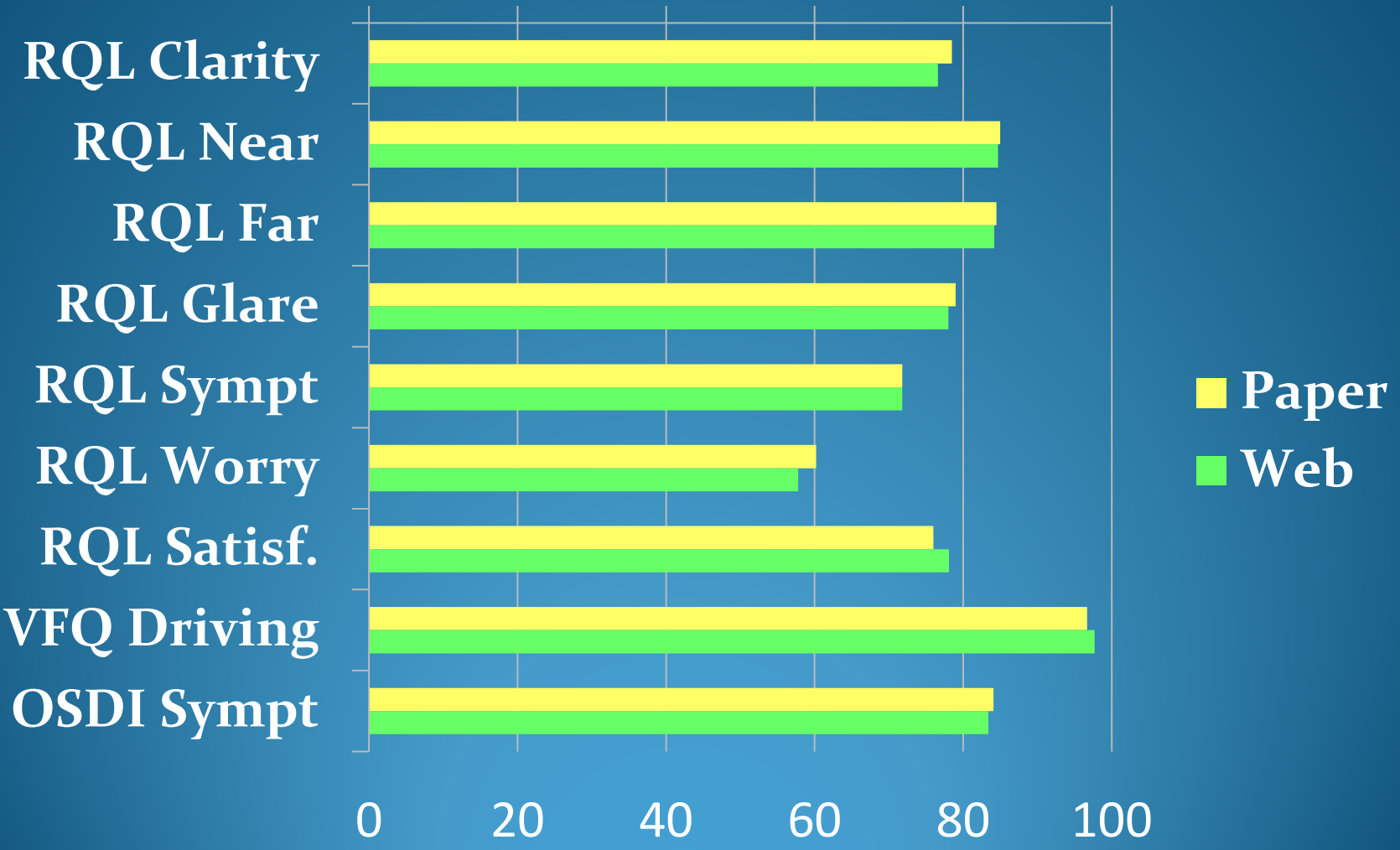


Study population



Cases were significantly older than controls

Comparing subscale scores

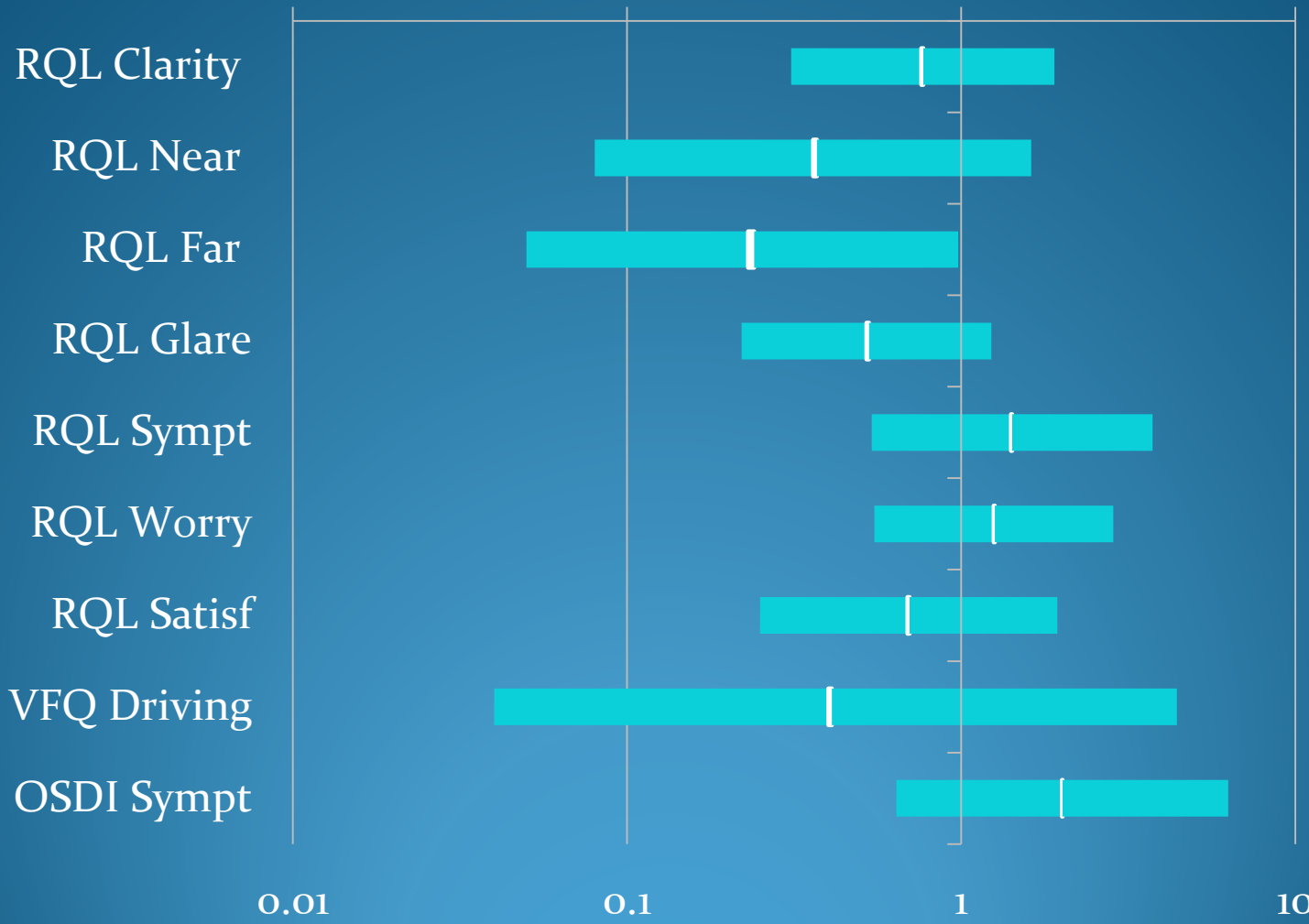


Comparing agreement between subgroups

Subscale	Age ≥40 vs <40 yrs	Male vs female sex	OSD vs controls	Paper 1st vs web 1st
Clarity	0.22	**0.03**	**0.006**	0.89
Near Vision	0.49	0.94	0.35	0.58
Far Vision	0.47	0.44	0.49	0.26
Glare	0.29	0.48	0.70	0.20
Symptoms	0.05	0.09	0.78	0.11
Worry	0.14	0.62	0.26	0.54
Satisfaction	0.78	0.89	0.73	0.49
Driving	0.20	**0.04**	0.37	0.49
OSDI	**0.04**	0.72	0.56	0.98

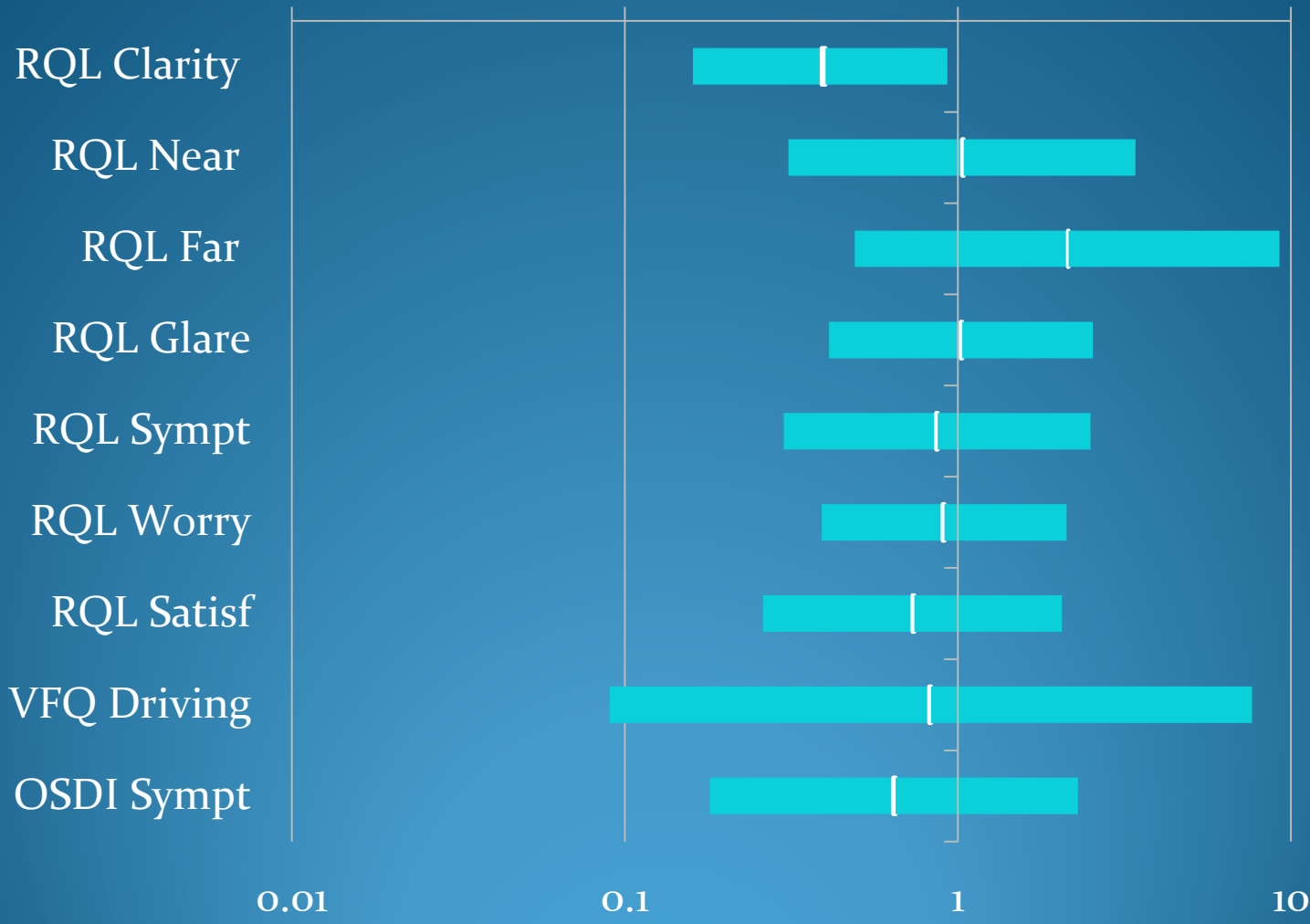
P values testing whether bias differed between groups

Prediction of close agreement - associations with age > 40



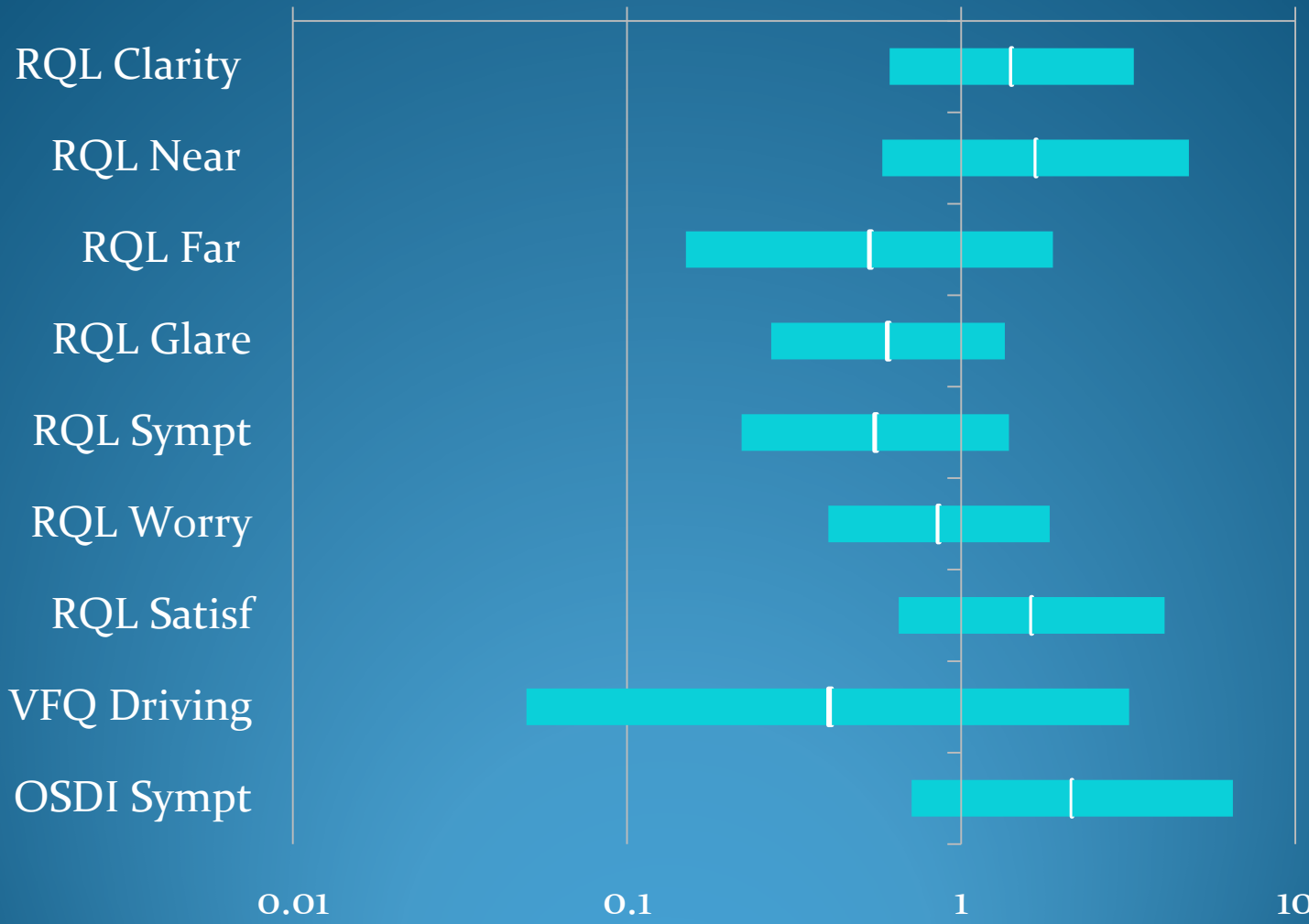
Multivariable–adjusted analyses

Prediction of close agreement - associations with OSD (vs control)



Multivariable-adjusted analyses

Prediction of close agreement - associations with sex (male vs female)



Multivariable-adjusted analyses

Conclusion

No evidence that agreement was affected by sex

Less agreement if over age 40 (RQL Far Vision) or if had OSD (RQL Clarity of Vision) – but trends were not consistent over other subscales

Conclusion

Average score differences between paper and web versions were **between 0.2 and 2.3 points** – not clinically significant

No evidence of clinically significant difference between paper and web scores for any subscales examined

Summary

One of the first to compare web-based and paper-based versions of previously psychometrically evaluated questionnaires used in ophthalmology

Summary

Validates computer administration of ophthalmic PRO instruments

Adds to the body of knowledge in the field of PROs

Reference

Clayton JA et al. Web-based versus paper administration of common ophthalmic questionnaires: comparison of subscale scores. *Ophthalmology* **2013**:120:2151-2159