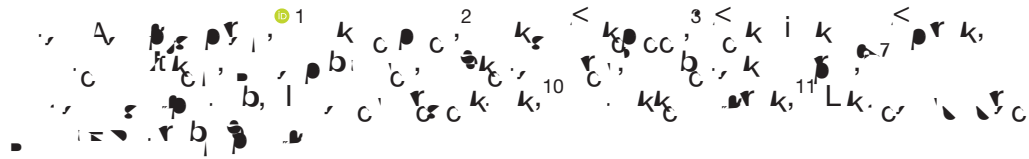


Patient-reported outcomes in the RELIGHT clinical trial of ranibizumab in diabetic macular oedema



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METHODS

RESULTS

	All N=110	Male N=78	Female N=32	Mean difference	P value	95% CI
$\Delta C_{IC} (C_{IC} - C_{IC0})$	3.7	3.0	1.0	1.3	0.1	-.1 to 2.0
$\Delta C_{IC} - \Delta C_{IC0} (C_{IC} - C_{IC0})$	2.7	3.7	0.0	3.0	0.107	1.0 to 4.7
- $\Delta C_{IC} - \Delta C_{IC0}$	1.3	1.0	0.7	1.2	0.17	-0.7 to 1.1
- $\Delta C_{IC} - \Delta C_{IC0}$	2.0	3.1	0.0	2.0	0.3	-.3 to 10.3
- $\Delta C_{IC} - \Delta C_{IC0}$	1.0	0.7	1.0	3.0	0.07	-.3 to 13.3
- $\Delta C_{IC} - \Delta C_{IC0}$	1.0	1.0	1.0	10.0	0.0	0.23 to 21.3
- $\Delta C_{IC} - \Delta C_{IC0}$	1.0	1.0	1.0	13.02	0.02	2.0 to 24.0
- $\Delta C_{IC} - \Delta C_{IC0}$	0.73	0.7	0.72	1.0	0.32	-.1 to 1.3
- $\Delta C_{IC} - \Delta C_{IC0}$	1.07	1.07	1.1	1.0	0.20	3.0 to 10.7
- $\Delta C_{IC} - \Delta C_{IC0}$	1.0	1.3	0.7	1.1	0.37	11.0 to 1.0
- $\Delta C_{IC} - \Delta C_{IC0}$	1.1	1.0	2.0	2.1	0.2	-.1 to 1.2
- $\Delta C_{IC} - \Delta C_{IC0}$	1.0	0.0	1.0	3.2	0.2	1.0 to 1.2
- $\Delta C_{IC} - \Delta C_{IC0}$	1.0	1.0	1.1	3.0	0.0	1.0 to 1.0
- $\Delta C_{IC} - \Delta C_{IC0}$	0.0	1.0	0.3	2.0	0.07	1.0 to 2.3
- $\Delta C_{IC} - \Delta C_{IC0}$	1.0	1.0	1.0	1.1	0.207	1.1 to 1.3
$\Delta C_{IC} - \Delta C_{IC0} - 1^*$	33.3	33.0	33.0	0.077	0.20	2.2 to 0.0
$\Delta C_{IC} - \Delta C_{IC0} - 2$	2.7	2.3	2.0	1.1	0.107	0.0 to 3.0

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Table 3A Change in NEI-VFQ 25 subscales at baseline and 12 months

Change in NEI-VFQ 25 subscales	N	Baseline	Month 12	Difference	95% CI	Significance
Overall		1.0	.2	1.2	2.3	0.3
Distance		2.2	.1	2.1	1.2	0.00
Low contrast	100	.1	.73	.1	0.2	0.01
High contrast	100	.7	2.2	1.5	1.2	0.013
Visual acuity	100	.1	.3	.2	2.2	0.003
Visual function		.7	.71	0.0	3.1	0.3
Visual perception	11	.0	.7	.7	2.1	0.2
Visual memory		.070	.70	.0	0.0	0.0
Visual attention		.3	.1	10.2	1.1	0.001
Visual speed	100	0.2	.2	.0	1.2	0.01
Visual accuracy	100	.1	.7	.6	0.2	0.01
Visual quality	677	.0	.2	3.2	2.2	0.0077
Visual function	100	.7	.2	.7	1.2	0.001

Table 3B Change in NEI-VFQ 25 subscales at baseline and 18 months

Change in NEI-VFQ 25 subscales	N	Month 0	Month 18	Difference	95% CI	Significance
Overall	67	0.3	.1	2.1	2.0	0.2
Distance	67	2.1	.7	1.4	1.2	0.011
Low contrast	100	.1	.70	.6	2.1	0.00
High contrast	100	.7	2.1	1.4	1.2	0.012
Visual acuity	100	.3	1.0	.7	0.3	0.01
Visual function		.77	.77	0.0	.3	0.00
Visual perception	2	.0	.3	1.3	3.1	0.03
Visual memory		.073	.370	2.7	1.1	0.13
Visual attention	67	.7	.1	.1	1.2	0.001
Visual speed	100	0.1	.7	.6	2.1	0.003
Visual accuracy	100	.1	.3	.2	0.2	0.03
Visual quality	67	0.1	.3	2.1	3.1	0.3
Visual function	100	.1	2.0	1.9	1.3	0.00

Change in NEI-VFQ 25 subscales at baseline and 18 months

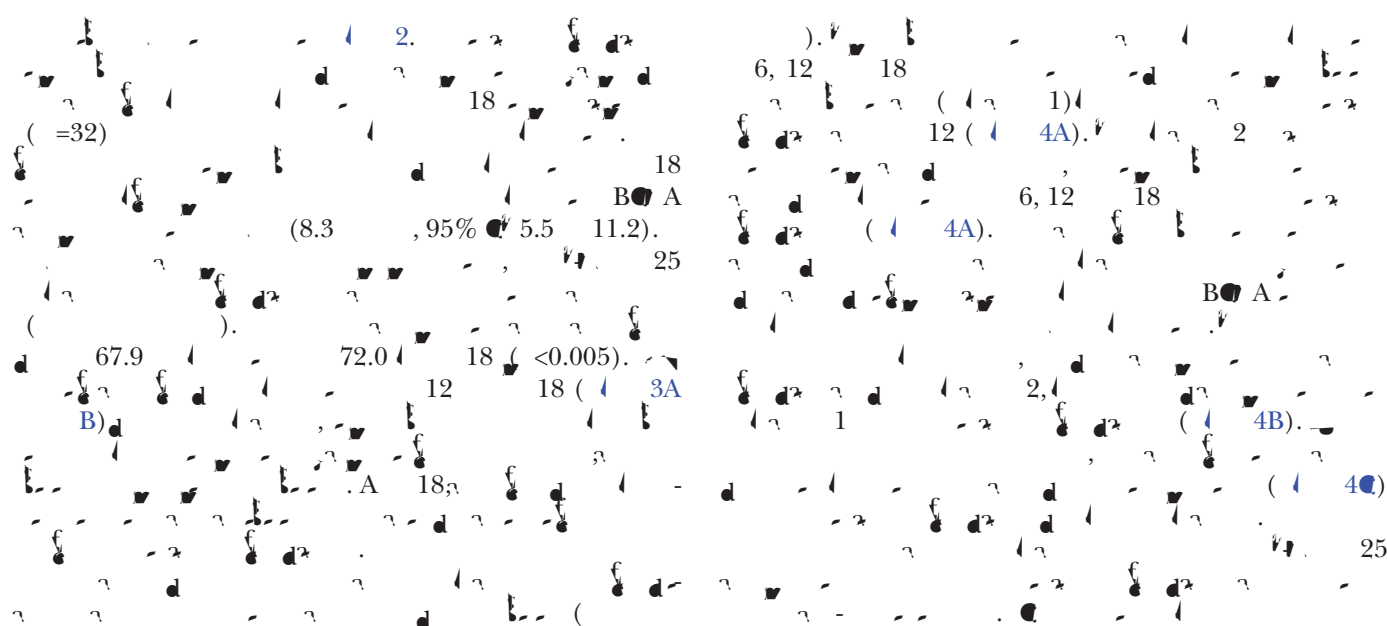


Table 4A Change in MacTSQ subscales (Mean 1, Mean 2, Difference, 95% CI, Significance)

Change in MacTSQ subscales	Mean 1	Mean 2	Difference	95% CI	Significance
12kpi r kps k kb kc kc kc	33.0	33.	0.	0.02 r 1.11	0.007
1 (k ₁)	33.1	33.22	0.12	0.32 r 1.31	0.002
1 (k ₁)	33.37	33.02	0.35	0.0 r 1.31	0.0
22i r kb ri kc ri kc ri kc	31.2	31.2	0.	1. r 3.2	0.001
1 (k ₁)	32.	32.	0.	2.1 r .22	0.001
1 (k ₁)	32.7	32.0	0.7	2.2 r .	0.001

Table 4B Change in MacTSQ subscales (Mean 1, Mean 2, Difference, 95% CI, Significance)

Change in MacTSQ subscales	Mean 1	Mean 2	Difference	95% CI	Significance
12kpi r kps k kb kc kc kc	33.3	33.3	0.20	1.1 r 0.	0.
1 (k ₁)	33.	33.2	0.	0.33 r 1.1	0.107
1 (k ₁)	33.0	33.	0.2	1.2 r 1.	0.2
22i r kb ri kc ri kc ri kc	31.3	31.3	0.	0.1 r 3.	0.00
1 (k ₁)	32.7	32.7	0.	1. r .	0.001
1 (k ₁)	32.3	32.3	0.	1.33 r .0	0.001

Table 4C Change in MacTSQ subscales (Mean 1, Mean 2, Difference, 95% CI, Significance)

Change in MacTSQ subscales	Mean 1	Mean 2	Difference	95% CI	Significance
12kpi r kps k kb kc kc kc	32.7	33.2	0.5	0.107 r 1.	0.01
1 (k ₁)	33.31	33.20	0.11	0.2 r 1.07	0.00
1 (k ₁)	33.2	33.0	0.2	0.007 r 1.	0.031
22i r kb ri kc ri kc ri kc	31.20	31.20	0.	1. r 3.2	0.001
1 (k ₁)	32.3	32.3	0.	2. r .07	0.001
1 (k ₁)	32.3	32.	0.3	2.17 r .10	0.001

Change in MacTSQ subscales (Mean 1, Mean 2, Difference, 95% CI, Significance)

$\frac{1}{k} \rightarrow 0$	$\frac{1}{k} \rightarrow 0$	$\frac{1}{k} \rightarrow 0$
$\frac{1}{k} \rightarrow 0$	$\frac{1}{k} \rightarrow 0$	$\frac{1}{k} \rightarrow 0$

[illegible]

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Patient consent for publication Not required.

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REFERENCES

1. Kibb A, Kibb K, et al. *Health Qual Life Outcomes* 2010;8:7.
2. Kibb A, Kibb K, et al. *Br J Ophthalmol* 2001;85:31.
3. Kibb A, Kibb K, et al. *Ann Intern Med* 2001;135:31.
4. Kibb A, Kibb K, et al. *Vision Res* 2001;41:72.
5. Kibb A, Kibb K, et al. *Pharmacoeconomics* 2002;20:1012.
6. Kibb A, Kibb K, et al. *Presse Med* 2002;31:12.
7. Kibb A, Kibb K, et al. *JAMA* 2001;285:37.
8. Kibb A, Kibb K, et al. *BMJ* 2001;323:3.
9. Kibb A, Kibb K, et al. *Lancet* 2001;357:203.
10. Kibb A, Kibb K, et al. *Arch Ophthalmol* 2001;119:330.
11. Kibb A, Kibb K, et al. *Drugs* 2012;72:23.
12. Kibb A, Kibb K, et al. *Ophthalmology* 2012;122:17.
13. Kibb A, Kibb K, et al. *Arch Ophthalmol* 2001;119:7.
14. Kibb A, Kibb K, et al. *J Patient Rep Outcomes* 2010;2.
15. Kibb A, Kibb K, et al. *Ophthalmology* 2011;119:2.
16. Kibb A, Kibb K, et al. *JAMA Ophthalmol* 2013;131:12.
17. Kibb A, Kibb K, et al. *Ophthalmology* 2011;119:7.
18. Kibb A, Kibb K, et al. *Res Nurs Health* 2000;27:31.
19. Kibb A, Kibb K, et al. *Diabetes Care* 2010;33:7.
20. Kibb A, Kibb K, et al. *Diabetes Care* 2010;33:7.