

APPENDIX

Assessment of masking in Ophthalmic Literature

To assess reporting of masking in ophthalmic clinical trials, we conducted a PubMed literature search using the following key search terms “eye disease”, “single- or double-blind” and “clinical trial phase III” published in English between 01/01/2014 and 12/31/2018. Of the 116 articles identified, 47 were excluded because they were post-hoc studies, not ophthalmic, not phase III, or not masked. Of the remaining 69 articles, four reported effectiveness of masking. Of these four articles, two reported methods for assessing masking, and either the number/percentage of participants and/or clinicians who correctly guessed treatment allocation.^{14,15} The other two articles reported that, “no subjects (Tauber)/participants (Donnerfeld) were unmasked during the study,” but neither article provided any details on methods of masking or its measurement.^{16,17}

Justification for Using the Modified Blinding Index

In the original Bang Blinding Index, unsure guesses are not pooled with either incorrect or correct guesses. For our study, we pooled “unsure” guesses with incorrect guesses to dichotomize whether bias was in the direction of “correct” vs. “incorrect” and “unsure”, because correct guesses inflate the assessment of therapeutic efficacy which was a concern of the investigators. We therefore pooled ‘unsure’ guesses with incorrect guesses and distinguish our analyses a modified Bang Blinding Index.

Appendix Table A1 compares the original Bang Blinding Index and the Modified Bang Blinding Index. The original and Modified Bang Blinding Index are generally in agreement. One exception is on day 0 among participants in the artificial tears group in Table 1, the original Bang Index is 0.15 indicating good masking whereas the modified BI is -0.38 reflecting the high proportion (18/26) of participants in the artificial tears group were incorrect (4/26) or were unsure (14/26) of their treatment.

Appendix Table A1. Comparison of Original Bang and Modified Bang Blinding Index Participants Guess of Treatment Assignment in Povidone-Iodine (PVP-I) group and Artificial Tears (AT) group at Day 0 and Day 4.

Study Visit	Treatment Group	Correct Guess (n, percent)	Incorrect Guess (n)	Unsure Guess (n)	Incorrect+ Unsure	Original Bang Blinding Index (95% CI)	Modified Bang Blinding Index (95% CI)
Day 0	PVP-I (n=29)	19 (66%)	2	8	10 (34%)	0.59 (0.39 to 0.77)	0.31 (0.02 to 0.60)
	AT (n=26)	8 (31%)	4	14	18 (69%)	0.15 (-0.06 to 0.37)	-0.38 (-0.68 to -0.09)
Day 4	PVP-I (n=21)	13 (62%)	3	5	8 (38%)	0.48 (0.21 to 0.74)	0.24 (-0.11 to +0.59)
	AT (n=21)	10 (48%)	4	7	11 (52%)	0.29 (0.01 to 0.56)	-0.05 (-0.41 to +0.31)