Original Article

Incidence and causes of negative dysphotopsia after uncomplicated cataract surgery – A randomized clinical trial

Pankaj Sharma, Sonal Kalia, Jugal Kishor Chouhan

Purpose: The purpose of this study is to find incidence of negative dysphotopsia (ND) in eyes undergoing clear corneal phacoemulsification and identify its causes including corneal wound hydration and type of intraocular lens (IOL). **Methods:** In this randomized clinical trial, consenting adult patients undergoing phacoemulsification were randomized to receive a hydrophobic (Alcon Acrysof® SN60WF) or a hydrophilic acrylic IOL (CT Asphina® 603P, Carl Zeiss Meditec) in a 1:1 ratio. At time of surgery, eyes were again randomized in 1:1 fashion to receive stromal wound hydration or not (n = 80 each in four groups). Primary outcome measure was the incidence of ND between eyes receiving stromal hydration versus no hydration. Those with ND were observed for 5 years after surgery. **Results:** Of the 320 eyes, 29 (9.06%) reported ND of which 24 (83%) were transient. Eyes with wound hydration had significantly higher proportion of ND (n = 21/160, 13%) compared to no hydration (n = 8/160, 5%) (P = 0.01). Additionally, eyes with wound hydration were three times more likely to experience ND (odds ratio = 3.29, 95% CI = 1.3–8.2, P = 0.01). Majority of eyes (20/21, 95%) with ND after hydration had it transiently while half (4/8, 50%) of those with ND without wound hydration had it persistently at 6 weeks (P < 0.001) and continued to experience ND for 5 years but did not request intervention. **Conclusion:** ND occurred in 9% cases with majority being transient. Corneal wound hydration led to significant higher likelihood of experiencing transient ND. Those with persistent ND for more than 6 weeks (1.5%) continue to experience ND for at least 5 years.

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Cataract surgery has improved tremendously over the past decade and is now considered a refractive procedure. Spectacle dependence, including for reading, has reduced due to sophisticated developments in types of intraocular lenses (IOLs), such as toric, trifocal, and extended depth of focus IOLs. Despite these developments, optical phenomenon referred to as dysphotopsias continues to be experienced by patients and is a cause for dissatisfaction. Positive and negative dysphotopsias (NDs) have been described in different studies ranging in incidence from 0.2% to 20% even in uncomplicated cataract surgeries.[1–4]

ND, typically described as a dark arc like peripheral temporal shadow,[5] is especially concerning since, even after two decades of its first description,[2] its cause remains enigmatic and hence treatment options remain unproven with variable success. Using *in vitro* optical models, Holladay *et al.* have shown that ND is likely to be more common in eyes with a small pupil, higher iris – IOL optic distance, receiving a sharp-edged IOL design with a high index of refraction optic material, and functional nasal retina that extends anterior to the shadow.[6] Other authors have postulated that the transparent nasal anterior capsule covering the IOL optic is responsible for the shadow.[7] Osher has proposed the role of the clear corneal incision in the occurrence of transient ND and reported a relative high incidence of 15% in his series of 250 patients almost a decade ago.[3] However, this theory has been questioned and refuted by many authors over the years.[8,9] However, like Osher, we believe that transient and persistent ND are two different optical phenomena with possibly different etiologies.[10,11]

In our early experience, we observed that it is not merely the temporal clear corneal incision, but the stromal hydration of the wound that might potentially lead to the transient dysphotopsia during the early postoperative period. To study this hypothesis, we performed a randomized study where patients were grouped based on the stromal hydration as well as the type of IOL implanted.

Methods

This is a randomized, double-masked, parallel assignment study conducted at the department of ophthalmology at a tertiary care government hospital in north India. Patients were recruited between January 2011 and December 2012. Informed consent was obtained from all participants before enrollment. The trial was approved by the institutional ethics committee and was conducted as per the tenets of the Declaration of Helsinki.

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Participants

All patients > 21 years of age attending the outpatient services of our institution during the study period and requiring cataract surgery in at least one eye were invited to enroll for the study. Patients with complicated cataract, poor mydriasis, cataract secondary to trauma, history of prior ocular surgery, coexistent ocular pathologies like glaucoma, macular degeneration, retinitis pigmentosa, diabetic retinopathy, uveitis that may compromise surgical safety and visual outcomes, eyes with an IOL power of ≤ 17 D or ≥ 25 D, and any history of dysphotopsia in the other eye were excluded.

Sample size calculation

Given 1:1 randomization 90% power, and a precision error of 5% to detect a difference of 10% or more in proportion of patients experiencing ND in the wound hydration versus no hydration group, a required sample size of 320 eyes (160 in each group) was calculated. To account for a 10% loss to follow-up, we recruited 350 patients.

Randomization, allocation, and masking protocols

All consenting patients were first randomized at the time of enrollment into two treatment groups based on the type of IOL to be placed: a hydrophobic acrylic IOL (Alcon Acrysof® SN60WF) made of high index material (refractive index = 1.55), a 6-mm optic with a square edge optic design and C-loop haptics and a hydrophilic acrylic IOL (CT Asphina® 603P, Carl Zeiss Meditec) with a 6-mm optic, square-edged optic design, refractive index of 1.46 and plate haptics. The second randomization was done during the study, and eyes were allocated into receiving stromal hydration versus no stromal hydration for wound apposition [Supplemental Online Material 1]. In the latter, all eyes were bandaged for 24 h to prevent any wound leakage and hypotony.

Randomization codes were generated using a computer program (random number assignment protocol) and placed in serially numbered sealed envelopes for the two allocation protocols. An ophthalmologist who evaluated the patients' preoperatively was masked to the type of IOL and wound hydration status. The operating surgeon and patients were masked to the procedural details throughout the study. Due to differing "A-constants," the IOL power calculation was done preoperatively based on the IOL group allocated. The sealed envelopes for hydration were attached to the case files and opened in the operating room by the staff just prior to completion of the cataract surgery. In the groups without stromal hydration of the main wound, side ports were hydrated well and the eye was patched for 24 h to ensure there was no hypotony. The status of intraoperative hydration of the wound could not be masked in all cases due to its clear appearance on the slit lamp. However, the type of IOL used (hydrophobic vs. hydrophilic) was masked by an undilated slit-lamp examination in the postop visits.

All patients were administered a questionnaire (modified from Osher[3] – online Supplementary File 2) on postoperative day 1 and 6 weeks after surgery which, apart from specific questions, also asked patients with dysphotopsia to draw the extent of the temporal shadow in the form of clock hours. The person asking about the dysphotopsia was kept masked of the methods of surgery.

Preoperative clinical assessment

All participants underwent a comprehensive ophthalmic examination in the preoperative period including uncorrected (UCDVA) and best-corrected distance visual acuity (BCDVA), biometry for IOL power calculation, a dilated slit-lamp and fundus evaluation to assess eligibility. All visual acuity values were converted to a logarithm of the minimum angle of resolution scale for analysis.

Surgical technique

Participants underwent phacoemulsification as previously described.[12] Briefly, all surgeries were performed under topical anesthesia by one experienced surgeon. Phacoemulsification was performed using a 2.2-mm clear corneal temporal incision; the nucleus disassembly was performed by phaco-chop techniques using the Sovereign Compact phacoemulsification system (WhiteStar Signature System Abbott Medical Optics, Inc.) and the allocated IOL type as per first randomization was implanted in the bag. All intraoperative complications, if any, were recorded. The surgeon attempted a capsulorhexis size of 5.5 mm in all eyes such that the IOL optic was covered by the rhexis margin over 360 degrees in all cases.

Postoperative evaluation

An independent, masked ophthalmologist performed examinations on postoperative days 1 and 7 and 6 weeks postoperatively. Snellen UCDVA and BCDVA were recorded at all visits and a complete ophthalmic examination, including IOP measurement, slit-lamp evaluation, fundus evaluation, and refraction were performed at 6 weeks. Those experiencing ND also underwent anterior segment optical coherence tomography (ASOCT) at 7th-day and 6th-week follow-up visit to measure the distance between the center of iris and the anterior surface of the IOL without pupillary dilatation, in a semi-dark room. The eye was also examined under full mydriasis to visualize the overlap of the anterior capsule margin over the IOL optic. The flow plan shows processes followed during enrollment, intervention, follow-up, and analysis.

Outcome measures

The incidence of ND between the different hydration and IOL groups was the primary outcome measure. The duration of ND was noted and patients whose symptoms disappeared within 6 weeks of surgery were labeled as *transient* while those with symptoms at 6 weeks and beyond were categorized as having *persistent* ND. Those with persistent dysphotopsia were observed for at least 5 years after surgery to determine whether the dysphotopsia persisted or disappeared over time and whether they had any additional surgical intervention in the interim period.

Statistical analysis

All continuous variables were expressed as means with standard deviation or median with interquartile range while categorical variables were expressed as proportions (*n*, %). The Kolmogorov–Smrinov test was used to test normalcy of distribution of continuous variables. When normally distributed, group differences between continuous variables were analyzed using the Student *t* test when two groups were involved and analysis of variance was used when there were more than two groups. The Wilcoxon rank-sum test or the Kruskall–Wallis test was used when data distribution was nonparametric. Differences in categorical variables between groups were assessed using the

Chi-square or Fischer's exact test. Univariate and multivariable logistic regression analysis were used to assess factors associated with occurrence of the ND and outputs were presented as odds ratios with 95% confidence intervals.

All data were entered in Microsoft Excel and analyzed using STATA (12.1 I/c, STATA Corp, Fort Worth, Texas, USA). All P values < 0.05 were considered statistically significant.

Results

We enrolled 350 patients, of which 30 were lost to follow-up leading to 320 eyes of 320 consenting patients during the study period. None of the patients experienced any surgical or postoperative complications. Of those enrolled, 160 eyes (50%), each received a hydrophobic and hydrophilic IOL as part of the first randomized allocation. Similarly, 160 eyes did and did not receive corneal stromal wound hydration at the end of surgery, as per the second randomized allocation protocol. A total of 29 (9.06%) patients were found to have ND on first postoperative day. No patients complained of delayed onset of dysphotopsia after day 1.

Table 1 shows a comparison of demographics and clinical characteristics between eyes with and without ND. Patients with dysphotopsia were significantly younger, with more having undergone surgery in their left eye compared to those without dysphotopsia. There was no difference in the type of IOL implanted; however, eyes with wound hydration had significantly higher proportion of ND (13%) compared to those that did not have hydration (5%) (P = 0.01). Of those with dysphotopsia, 5 (17%, 5 out of total 29) complained of persistent dysphotopsia at the 6 weeks' time point, while the remaining experienced resolution.

Comparing between the two types of IOLs implanted [Table 2], we found no significant differences between groups, including in rates of ND (11% in hydrophobic vs. 7% in hydrophilic groups, P = 0.17), except that there were more men in the hydrophobic group. In contrast, ND occurred significantly more commonly in eyes that had wound hydration (13%) compared to those that did not (5%) (P = 0.01) [Table 2]. Additionally, we also found that if dysphotopsia occurred without wound hydration, then it was persistent in half the eyes [Table 2] as opposed to only 5% eyes with wound hydration. There were no other differences in eyes that did and did not receive wound hydration. Comparing across four groups (n = 80 in each group) with a combination of IOL type and wound hydration [Table 3], we found significantly higher ND in the hydrophobic IOL group with wound hydration (n = 13/80, 16%). However, persistent dysphotopsia was commonest in the hydrophobic IOL group without wound hydration (n = 4/5, 80% eyes). All the five patients with persistent dysphotopsia (1.5% of total study population) continued to experience it at 5-year follow-up. However, none of them had undergone secondary surgery to correct it or even request for this. Characteristics of the five (1.5%) persistent ND (using Supplemental online material 2) patients are shown in Table 4. There was no significant difference in the iris–optic distance measured at 6 weeks between those that had persistent (529 ± 190 μm) versus transient dysphotopsia (560 ± 79 μm) (P = 0.45)

Table 1: Comparison of demographic and clinical characteristics of eyes with and without negative dysphotopsia

Variable	No dysphotopsia (n=291)	Negative dysphotopsia (n=29)	P
Age (years)	63.7±10.5	55.2±9.9	<0.001
Gender (% men)	155 (53%)	20 (69%)	0.12
Operated eye (% RE)	172 (59%)	10 (34%)	0.01
IOL type:Hydrophobic	142 (49%)	18 (62%)	0.17
Hydrophilic	149 (51%)	11 (38%)	
Wound: Hydration	152 (52%)	8 (28%)	0.01
No hydration	139 (48%)	21 (72%)	

A multivariable logistic regression analysis [Table 5] showed that after adjusting for covariates, older individuals (P < 0.001) were at a 30% reduced risk of developing ND. Those getting operated for the left eye cataract had a three times higher likelihood of dysphotopsia (P = 0.01) while those getting wound hydration had nearly three and half time higher likelihood of dysphotopsia (P = 0.01), irrespective of the type of IOL implanted.

Discussion

We found a 9% incidence of ND in our cohort of north Indian patients undergoing uncomplicated cataract surgery. Of these, more than 80% experienced transient dysphotopsia while the remaining had persistent dysphotopsia even at 6 weeks postoperatively. Wound hydration increased the risk of ND by three times, even after adjusting for other covariates. We also found that dysphotopsia that occurs in the absence of wound hydration is more often of the persistent variety and lasts for at least 5 years in the majority. Additionally, increasing age was associated with lower incidence of dysphotopsia while left eyes were more prone to it. The type of IOL did not influence the occurrence of dysphotopsia in our study.

The incidence of ND varies from 0.2% to 20% in different studies,[1,3,4] and thankfully, most cases are transient in nature.[5,13] Since it has been postulated that facial bone structure and depth of the orbit may influence incidence rates, there may be racial differences in this across different populations. To the best of our knowledge, there are no studies from the Indian subcontinent on incidence of transient and persistent ND from a randomized study design. Our incidence of 9% out of more than 300 surgeries, with most being transient, agrees well with previously published incidence rates.

As postulated before by Osher,[3,10,11] the causes for transient and persistent ND may be different. We noted that all but one out of the 21 patients in our series, who had ND after wound hydration, experienced it transiently, whereas half (4 out of 8) who had dysphotopsia without wound hydration experienced it persistently even at 6 weeks. The regression analysis also showed this causality association with significantly higher odds of dysphotopsia when wound hydration was performed, even after adjusting for potential confounders. These findings make a strong case for stromal wound hydration as the most important cause for transient ND. This is also strengthened by the fact that this is the only prospective study reporting on dysphotopsia after temporal 2.2-mm phacoemulsification in all participating eyes, thereby was robust enough to comment on corneal hydration as the possible underlying etiology.

Table 2: Comparison in clinical characteristics between two types of IOL and in between eyes that had and did not have wound hydration

Variable	Hydrophobic IOL (*n*=160)	Hydrophilic IOL (*n*=160)	*P*	No wound hydration (*n*=160)	Wound hydration (*n*=160)	*P*
Age	63.1±11.9	62.8±9.4	0.36	53±10.6	56±9.8	0.76
Gender (% men)	98 (61%)	77 (48%)	0.02	84 (52%)	91 (57%)	0.43
Operated eye (% RE)	89 (55%)	93 (58%)	0.65	97 (61%)	85 (53%)	0.18
Preop. BCVA	0.91±0.43	1.14±0.73	0.28	0.8±0.2	1.1±0.6	0.42
Average K value (D)	43.2±1.5	43.6±1.6	0.48	43.2±1.5	43.5±1.6	0.65
Axial length (mm)	23.1±0.6	23.3±0.7	0.55	23.4±0.5	23.1±0.6	0.33
IOL power (D)	21.3±1.5	20.7±1.8	0.29	20.5±1.6	21.3±1.6	0.20
Postop BCVA (logMAR)	0.05±0.07	0.09±0.08	0.17	0.08±0.08	0.06±0.07	0.33
Negative dysphotopsia	18 (11%)	11 (7%)	0.17	8 (5%)	21 (13%)	0.01
% Wound hydration in ND	13 (72%)	8 (73%)	0.97	-	-	-
% Hydrophobic in ND	-	-	-	5 (62%)	13 (62%)	0.97
Dysphotopsia: Transient	14 (78%)	10 (91%)	0.36	4 (50%)	20 (95%)	0.013
Dysphotopsia:Persistent	4 (22%)	1 (9%)		4 (50%)	1 (5%)	
Iris-optic distance	535±78	588±82	0.10	558±79	588±82	0.77

Table 3: Comparison in clinical characteristics between four groups with combinations of IOL type and hydration

Variable	Hydrophobic IOL + no wound hydration	Hydrophobic IOL + wound hydration	Hydrophilic IOL + no wound hydration	Hydrophilic IOL + wound hydration	*P*
Sample size	80 (25%)	80 (25%)	80 (25%)	80 (25%)	-
Age	63.3±12.5	62.9±11.3	62.2±9.2	63.4±9.6	0.57
Gender (% men)	47 (59%)	51 (64%)	37 (46%)	40 (50%)	0.10
Operated eye (% RE)	48 (60%)	41 (51%)	49 (61%)	44 (55%)	0.55
Preop BCVA	0.68±0.2	1.0±0.4	1.0±0.1	1.2±0.8	0.27
Average K value (D)	43.3±1.8	43.2±1.5	43.0±1.0	43.9±1.8	0.74
Axial length (mm)	23.4±0.6	23.1±0.5	23.4±0.2	23.2±0.8	0.71
IOL power (D)	20.4±1.5	21.7±1.8	20.6±1.6	20.3±1.6	0.31
Postop BCVA (logMAR)	0.04±0.05	0.06±0.07	0.16±0.05	0.06±0.07	0.10
Negative dysphotopsia	5 (6%)	13 (16%)	3 (4%)	8 (10%)	0.03
Dysphotopsia: Transient	1 (20%)	13 (100%)	2 (100%)	7 (88%)	0.001
Dysphotopsia: Persistent	4 (80%)	0	0	1 (12%)	
Iris-optic distance	499±89	549±73	629±31	572±92	0.16

Table 4: Characteristics of persistent negative dysphotopsia in five patients

			Subjective questionnaire findings							
Patient	Eye	Description	Clock hours	First noticed	When seen?	Effect of light background	Gaze direction	Effect of fatigue	Peripheral vision beyond shadow	Does shadow interfere?
No. 1	OD	Thin dark semicircular shadow peripherally	1-5	PO day 1	All the time	Yes	Worse left gaze gone right gaze	Worse	No	Very little
No. 2	OS	Crescent-shaped shadow	7-11	PO day 1	All the time	No	Worse right gaze	None	Yes	Yes
No. 3	OD	Thin dark semicircular shadow peripherally	2-5	PO day 1	In driving, distance work	Yes	Unable to tell much difference	None	No	No
No. 4	OS	Crescent-shaped darkness on side	7-11	PO day 1	Mostly in day	Yes	More distinct in upgaze	None	Yes	No
No. 5	OS	Black side cover of crescent shape	8-11	PO day 1	All the time	Yes	Worse right gaze	None	No	Very little

Table 5: Univariate and multivariable logistic regression analysis for factors associated with occurrence of negative dysphotopsia in our cohort (*n*=29 eyes)

Variable	Interval	Univariate analysis		Univariate analysis	
		OR	95% CI	OR	95% CI
Age	5-year increment	0.71**	0.59-0.84	0.69**	0.57-0.82
Gender	Men vs. women	0.51	0.2-1.1	-	-
Operated eye	RE vs. LE	2.74**	1.2-6.1	3.1**	1.2-7.0
IOL type	Hydrophobic vs. hydrophilic	0.58*	0.2-1.2	0.59	0.2-1.3
Wound hydration	Hydration vs. no hydration	2.87**	1.2-6.7	3.29**	1.3-8.2

*denotes $P < 0.1$ ** denotes $P < 0.05$

Fortunately, persistent ND was seen in only 1.5% of patients in our study. The causes for persistent ND may be different and related to the IOL material, shape, size, design, and patient-related anatomic variables such as pupil size, orbital depth, angle kappa and alpha, distance between the iris and IOL,[14] and extent of anterior extent of the nasal retina.[6,13] Since we had very few patients with persistent dysphotopsia, we are unable to comment further on the underlying etiologies in these patients. Following up those with persistent dysphotopsia periodically for at least 5 years, we found that all of them continued to experience the dysphotopsia. In some, who were unable to physically follow up, a telephonic conversation was used to document presence or the dysphotopsia. However, all of these patients were able to manage daily activities and were not troubled by the symptoms, and hence none requested surgical interventions such as IOL exchange or piggyback IOL.

We also found that the incidence of dysphotopsia was higher in younger individuals and was also higher when the left eye underwent surgery. It is difficult to postulate reasons for these observations but it is possible that younger individuals are more observant and are more likely to report dysphotopsia. It is also possible that younger patients likely have more active lifestyles leading to exposure of different light sources at different angulations and experience dysphotopsia more frequently. Older adults may have slightly more droopy eyelids leading to lesser dysphotopsia. Minimal variations with temporal incisions leading to left eye incisions being slightly more (by 20 degrees) toward the superotemporal axis while right eye incisions being slightly more inferotemporal may also explain why left eyes are more prone to dysphotopsia. As yet, scarcely studied anatomic factors may also explain why dysphotopsia is experienced more by younger individuals and those having surgery in the left eye more than the right eye. Lastly, the role of iris color and translucency has yet to be elucidated in the occurrence of ND.

All patients with persistent ND in Osher's series had dark-colored iris.[3] Most studies have been Caucasian populations thus far, ours being to the best of our knowledge the first Indian study on the subject and all our subjects had brown or dark iris. More data are essential from racially diverse populations to explore this relationship thoroughly.

The drawbacks of this study are the relatively smaller number of cases of dysphotopsia that occurred overall that did not allow for robust regression and causality association between corneal wound hydration and transient ND. The even lower numbers of persistent dysphotopsia (1.5%) meant that we were unable to test causality in this vexing condition. Additionally, the lack of documentation of pupillary size and the iris–IOL distance in all patients meant that these confounders could not be adjusted for. Differences in the IOL refractive index and haptic design also limit generalizability of these results. The advantages of the study are the prospective randomized and masking protocols adopted and long-term observation of patients with dysphotopsia to see the status at 5-year follow-up.

Conclusion

In conclusion, corneal wound hydration led to significant higher likelihood of experiencing ND in individuals undergoing cataract surgery, especially in younger patients. Majority of cases are transient and can be managed conservatively. Causes for transient and persistent ND appear to be different with the former related to the corneal wound and its hydration and likely multifactorial in the latter. We also observed that those with persistent dysphotopsia at 6 weeks continued to experience it for at least 5 years, though this appears not to interfere with routine activities warranting resurgery in the majority. More studies are required to elicit causes of persistent ND, which can then be used to develop treatment algorithms and improve outcomes.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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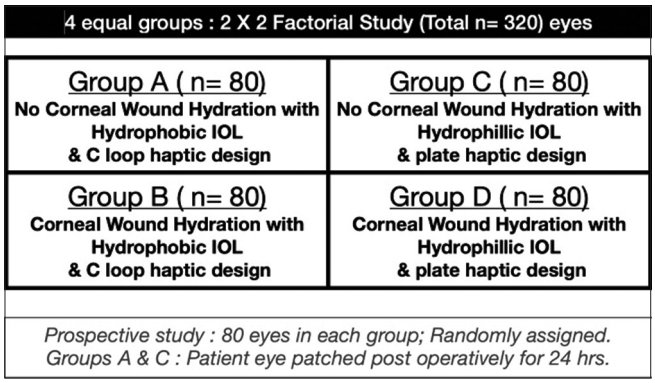


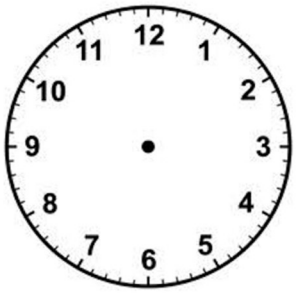
Supplemental Online Material 1: Figure showing details of study groups

SUPPLEMENTAL MATERIAL

SUBJECTIVE QUESTIONNAIRE FOR NEGATIVE DYSPHOTOPSIA

(MODIFIED FROM OSHER [3])

- Description.....
- Clock Hours?.....
- 1st Noticed?.....
- When Seen?.....
- Light Background. Worse?.....
- Gaze Direction?.....
- Effect of Fatigue?.....
- Peripheral Vision beyond shadow?.....
- Does Shadow Interfere?.....
- PLEASE DRAW WHAT YOU SEE AS DISTURBING YOUR VISION (IN TERMS OF CLOCK HOURS)



Supplemental Online Material 2: Subjective questionnaire for negative dysphotopsia (modified from Osher[3])