Pupil size influence on the intraocular performance of the multifocal AMO-Array intraocular lens in elderly patients

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PURPOSE. *To study the relationship between pupil size and AMO-Array multifocal intraocular lens (MIOL) performance in a population of elderly patients.*
METHODS. *This prospective trial included 62 patients (mean age 76 years; range 70 to 86) undergoing bilateral cataract phacoemulsification and MIOL (AMO-Array SA-40N, Allergan) implantation. Patients were divided into two groups based on preoperative pupil diameter: small pupil group (pupil size of 2.5-2.9 mm; 45 subjects) and large pupil group (pupil size of 3-5 mm; 17 subjects). The analysis included uncorrected (UC) and best-corrected (BC) near and distance visual acuity (VA), spectacle dependence, and photic phenomena complaints (postoperative follow-up 16.6±6.2 months; range 11-26 months).*
RESULTS. *Patients in the small pupil group showed postoperatively significantly higher distance UCVA and BCVA, but lower near UCVA compared to those in the large pupil group (Mann-Whitney test, p≤0.02). Patients with small pupils also tended to: be more (not statistically significant) spectacle independent for distance (73.3% versus 47.1%) and spectacle-dependent for near vision (55.6% versus 28.4%); report significantly less photic phenomena complaints (37.8% versus 93.1%, chi-square test, p<0.001); and, more satisfied with the surgery (95.5% versus 76.5%). Posterior capsular opacification (PCO) was observed in 19.4% of the patients.*
CONCLUSIONS. *Bilateral AMO-Array MIOL implantation in elderly patients seems to be an effective and safe surgical procedure that improves distance and near UCVA, providing spectacle independence in many cases. The use of these MIOLs, however, can induce photic phenomena and cause PCO. Patients with small preoperative pupils (<3 mm) presented less photic phenomena complaints and expressed a higher visual outcome satisfaction after surgery. (Eur J Ophthalmol 2007; 17: 571-8)*

KEY WORDS. *Cataract surgery, Intraocular lens, Multifocal intraocular lens, Pupil size, Visual acuity, Photic phenomena*

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INTRODUCTION

The ideal outcome after cataract surgery is good distance and near visual acuity (VA) without the use of spectacles. Multifocal intraocular lenses (MIOLs) have been designed to compensate for normal accommodation, which is usually lost after the crystalline lens is removed and replaced with an artificial monofocal IOL (1-3). The MIOL design is based on diffractive optics or zones of differing refractive power (4). Several clinical studies have reported that MIOLs provide enhanced quality of vision (3, 5, 6). The advantages that MIOLs show compared to monofocal IOLs include improved uncorrected (UC) near VA and re-

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duced spectacle dependency for near and intermediate vision (5, 7-10). There are, however, some drawbacks with MIOLs, which include worsening of both near distance corrected VA and contrast sensitivity (7, 11-13), increased subjective perceptions of photic phenomena under scotopic conditions (7, 11, 12, 14, 15), and visual outcome influenced by pupil size (7, 13).

Pupil diameter has become increasingly important in modern ocular surgery. The preoperative patient evaluation and inclusion/exclusion criteria for MIOL insertion usually include pupil size (2) because the optical performance of implanted MIOLs is theoretically dependent on the size and position of the pupil in relation to the near and distance zones of the lens (16). Previous studies have shown that VA in patients with MIOLs varies with pupil size (17, 18). Optical aberration, diffraction, and retinal luminance (19, 20) are affected by pupil size. Patients with MIOLs having large scotopic pupils are more prone to poor contrast sensitivity under mesopic light conditions (21) and frequently complain about photic phenomena such as glare, starbursts, and halos perception around light sources (7, 11, 14, 15).

The Advanced Medical Optics (AMO) Array SA-40N is a foldable five-zone refractive multifocal IOL (22, 23). Its bilateral implantation has been shown to be effective and safe in patients undergoing cataract surgery, providing good uncorrected near and distance VA outcomes (12, 24-26).

The aim of our study was to examine the relationship between pupil size and AMO MIOL performance in a population of elderly patients. Our analysis was based on a comparison of how small or large pupils affected postoperative VA, spectacle dependency, perception of photic phenomena, and subjective visual satisfaction.

MATERIALS AND METHODS

A total of 124 eyes of 62 patients were included in this prospective randomized trial (mean age 76 years; range 70–86). All patients underwent bilateral cataract phacoemulsification surgery and AMO Array SA-40N MIOL (Allergan, Irvine, CA) insertion. The study abided by the principles of the Declaration of Helsinki and the Ethics Committee of our institution approved the design of the study. Patients were provided with a detailed explanation of the advantages, limitations, and complications of both monofocal and multifocal IOLs and were given considerable time to make a voluntary decision based on personal needs. Informed consent was obtained from each subject prior to surgery.

The inclusion criteria included bilateral senile cataract, refractive astigmatism ≤1.5 diopters (D), ametropia ranging from –6 to +4 D of spherical equivalent (SE), axial length ranging from 19.5 to 26 mm, absence of ocular pathologies other than cataract, and the ability to complete an Italian questionnaire and willingness to provide informed consent. Exclusion criteria included pseudophakia in the fellow eye; presence of corneal diseases, glaucoma, amblyopia, and retinal abnormalities (especially age-related macular degeneration); recurrent inflammatory eye diseases; abnormal iris, pupil deformation, or abnormal pupil function; mesopic pupil diameter greater than 5 mm and less than 2 mm; and previous intraocular surgery. Subjects with night driving professions or mental handicaps were also excluded.

The participants were recruited from August 2001 to January 2003 in the Department of Ophthalmology, S. Maria della Misericordia Hospital of Udine, Italy. All patients underwent surgery by the same ophthalmic surgeon (C.S.). Phacoemulsification was performed under peribulbar anesthesia with a non-stitch 3.2 mm posterior limbal incision, followed by AMO Array SA-40N MIOL insertion in the capsular bag. The SRK II formula, based on an adjusted A-constant of 118.0, was used for all lens implant calculations (23). Postoperative refraction was aimed at emmetropia. The AMO Array MIOL implantation was performed bilaterally. Surgery of the fellow eye was performed within a 2-month period.

The AMO Array SA-40N is a 6-mm diameter silicone foldable lens that lacks optical disc square edges. The refractive optic surface is made up of five concentric refractive zones designed for distance, intermediate, and near vision; the first, third, and fifth zones are far dominant, while the second and fourth zones are near dominant. The light distribution is arranged so that 50% is focused on distance vision, 13% on intermediate, and 37% on near vision to form a distant dominant IOL (10).

Pupil diameters were measured by the same examiner under the same conditions at an average ambient room luminance of about 15 cd/m^2. An autorefractometer (RKT 7700, Nidek Co., Ltd., Aichi, Japan) having a graduated grid scale was used, in which the subject was asked to look at the screen while the instrument light was turned off so that the pupil size could be measured with the instrument grid by the observer under the same conditions. The mean of three measurements was used in the analysis. Patients were divided into two groups based on pupil diameter: 45 subjects (90 eyes) had a pupil diameter ranging from 2.5 to 2.9 mm (small pupil group) and 17 subjects (34 eyes) had a pupil diameter from 3 to 5 mm (large pupil group). The following were determined before and after surgery:

- Refractive error in SE.
- UCVA and BCVA, near and distance.
- Spectacle dependence for distance and near vision
- Presence of postoperative double or distorted vision, glare, halos, changes in color perception, and worsening of vision.
- Satisfaction assessment of near and distance vision using a questionnaire.
- Intra- and postoperative complications.
- Presence of anterior capsular opacification (ACO) and posterior capsular opacification (PCO).

VA was in decimal units for distance and in Jaeger (J) reading card print size units for near vision. The mean follow-up was 16.6±6.2 months, ranging from 11 to 26 months. Postoperative outcomes were based on the patient's last postoperative examination. Differences between pre- and postoperative outcomes were evaluated using the Wilcoxon test. The analysis between the two groups based on different preoperative pupil diameter was assessed using the Mann-Whitney test. Percentages were compared using the chi-square test. The statistical analysis was done with SPSS 11.0 program package (SPSS Inc., Chicago, IL, USA). A p value <0.05 was taken as statistically significant.

RESULTS

The mean ages of the small and large pupil groups were not significantly different (75.7±4.3 and 76.6±4.3 years, respectively; Mann-Whitney test, p=0.47). The mean follow-up was 16.8±7.2 and 14.7±5.9 months, respectively (Mann-Whitney test, p=0.23). The pre- and postoperative refractive and visual outcomes for the two groups are listed in Table I. The preoperative parameters showed no significant differences between the two groups (Mann-Whitney test, p not significant). Based on the last follow-up results for each individual subject, the following significant differences between pre- and postoperative parameters were found after surgery for both groups: reduced mean refractive error and improved mean UCVA and BCVA for near and distance (Tab. I, Wilcoxon test, p<0.01). No significant differences between pre- and postoperative astigmatism were found in the groups (Tab. I, Wilcoxon test). When comparing the parameters after surgery, no significant differences were found between the two groups for mean refractive error, mean refractive astigmatism, and mean near BCVA (Mann-Whitney test). The small pupil group showed a significantly worse near UCVA (Mann-Whitney test, p=0.01), improved distance UCVA (Mann-Whitney test, p=0.01), and improved distance BCVA (Mann-Whitney test, p=0.02). All postoperative eyes showed a distance UCVA ≥0.6 and a near UCVA of J6 or better (Tab. I).

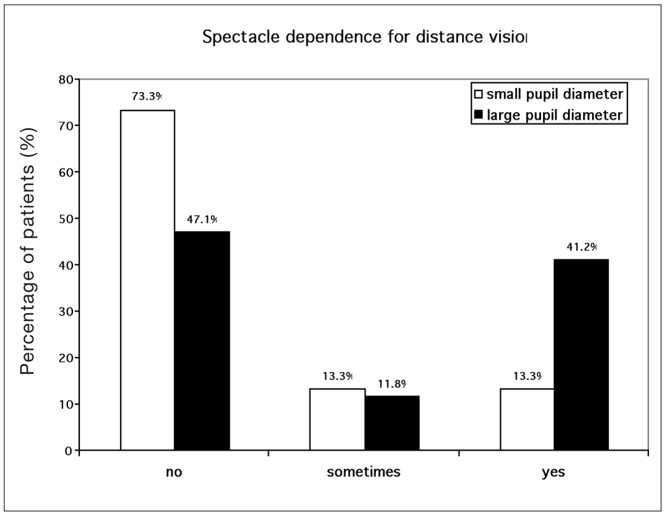

Fig. 1 - *Sample distribution based on spectacle dependence for distance vision.*

With regards to postoperative spectacle dependency for distance, 73.3% and 47.1% of the patients, respectively in the small and large pupil groups were spectacle-independent for distance (Fig. 1, chi-square test, p=0.10); 13.3% and 11.8%, respectively, claimed to need spectacles frequently (>50% of the day);

TABLE I - REFRACTIVE ERROR AND VISUAL PERFORMANCE

			Small pupil ø (45 eyes) mean ± SD (range)	**Large pupil ø (34 eyes) mean ± SD (range)**	**Groups comparison p****
Preoperative		Refractive error (SE, D)	−0.56 ± 3.9 (‘−5.50 - 4.00)	−0.75 ± 3.1 (‘−4.75 - 3.50)	NS
		Refractive astigmatism (D)	0.57 ± 0.54 (0 - 1.50)	0.54 ± 0.53 (0 - 1.25)	NS
	Near	UCVA*	5.0 ± 1.4 (7 - 3)	4.5 ± 1.9 (8 - 3)	NS
		BCVA*	4.3 ± 1.2 (6 - 3)	4.0 ± 1.0 (6 - 3)	NS
	Distance	UCVA^	0.23 ± 0.10 0.2 - 0.4	0.27 ± 0.12 0.1 - 0.4	NS
		BCVA^	0.40 ± 0.17 0.2 - 0.6	0.35 ± 0.19 0.1 - 0.6	NS
Postoperative		Refractive error (SE, diopters)	0.54 ± 0.73 § (‘-1.25 - 0.75)	0.45 ± 0.65 § (‘-1.00 - 0.75)	NS
		Refractive astigmatism (D)	0.46 ± 0.46 (0 - 1.00)	0.54 ± 0.60 (0 - 1.50)	NS
	Near	UCVA*	2.4 ± 1.2 § (6 - 1)	1.8 ± 0.8 § (4 - 1)	0.01
		BCVA*	1.6 ± 0.5 § (2 - 1)	1.3 ± 0.5 § (2 - 1)	NS
	Distance	UCVA^	0.89 ± 0.1 § (0.6 - 1)	0.81 ± 0.1 § (0.6 - 1)	0.01
		BCVA^	0.93 ± 0.1 § (0.7 - 1)	0.88 ± 0.1 § (0.7 - 1)	0.02

ø = Diameter; SD = Standard deviation; ** = Mann-Whitney test; SE = Spherical-equivalent; D = Diopters; NS = Not significant; UC = Uncorrected; BC = Best corrected; VA = Visual acuity; * = Jaeger notation; ^ = Decimal notation; § = Significantly different from pre-op value

and 13.3% and 41.2% seldom required them (<50% of the day). With regards to postoperative spectacle dependency for near vision, 44.4% and 70.6% of the patients, respectively in the small and large pupil groups, did not need glasses for near vision (Fig. 2, chi-square test, p=0.12); 33.3% and 11.8%, respectively, required spectacles frequently; and 22.2% and 17.6% seldom needed glasses. All of the patients claimed not to have spectacle dependency for either distance or near vision on a full-time basis after surgery.

Postoperative photic phenomena were reported in a total of 33 patients (53.2%). The most frequently reported complaints were starbursts and halos, which occurred significantly more frequently in the large pupil group than in the small one (Fig. 3, 93.1% and 37.8%, respectively; chi-square, p<0.001). A total of 57 patients (91.9%) claimed to be satisfied with their overall postoperative visual outcome. Patient satisfaction after surgery tended to be higher (not statistically significantly different) in the small pupil group compared to the large one (95.5% versus 76.5%; chi-square test, p=0.07). All of the postoperative patients, with the exception of two and three, respectively, were satisfied with their distance and near UCVA. When asked whether they would undergo the same type of surgery given their general outcome, 95.5% and 82.4% of the patients said yes in the small and large pupil group, respectively (chi-square test, p=0.24). No patients showed signs of intra- or postoperative complications (including iris prolapse, iris atrophy, persistent corneal edema, pupillary block, retinal detachment, endophthalmitis, and reactive fibrosis) up to their last follow-up examination. Capsular rupture and IOL decentration were not observed in any of the postoperative eyes. A slight ACO (4 eyes, 6.45%) and mild PCO (12 eyes, 19.4%) developed within a mean follow-up of 16.6±6.2 months, showing no significant differences between the two groups (chi-square test, p=0.26 and p=0.18, respectively).

DISCUSSION

The influences of advanced age and pupil size on postoperative visual outcomes with MIOLs are of increasing interest in modern day ophthalmic surgery. It is well known that pupil size affects various visual functions in pseudophakic patients with MIOLs, including glare disability (27, 28), binocular vision, contrast sensitivity (21), and far and near VA (13, 17, 18, 29). In addition, age seems to have a negative influence on MIOL visual outcomes considering that older patients tend to have lower near UCVA and contrast sensitivity (30). Previous studies have shown that pupil size decreases as age increases in a linear fashion at all luminance levels (17, 31). Our aim was to study visual outcomes with AMO Array MIOLs in a population of elderly subjects (70 years and older) in relation to preoperative pupil size. Our results are indicative of long-term visual outcomes, considering the long follow-up period (mean 16.6±6.2 months, range of 11 to 26 months). Previous studies with long follow-ups reported increased contrast sensitivity 1 year after surgery (15). The AMO Array IOL is currently no longer available and thus our study may be of limited future clinical interest. The AMO ReZoom is a modified version of the Array, which aims at addressing the problems encountered with the previous MIOL. It is also made up of concentric focusing surfaces on the front (having posterior square edges), but the zones are spaced further apart and have smoother intermediate transitional zones between the distance and near vision focusing surfaces, permitting about up to 50% of light energy to be used for near vision at a pupil aperture of 3 mm (AMO ReZoom package insert). Although the AMO Array is seldomly currently used, our study adds to literature by emphasizing the importance and MIOL visual outcomes related to pupil size

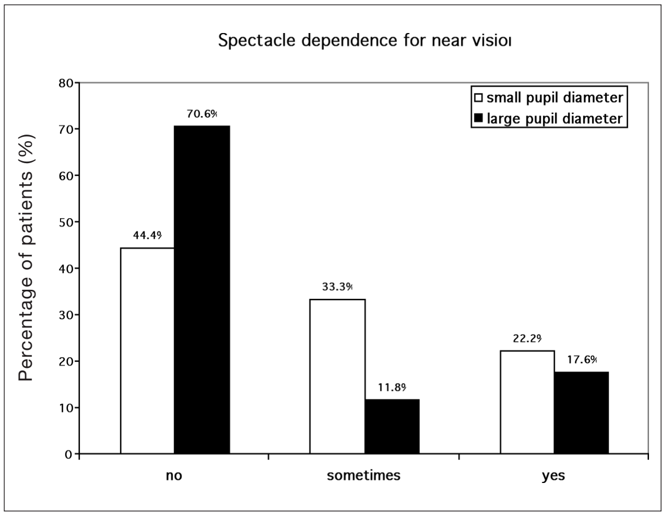

Fig. 2 - *Sample distribution based on spectacle dependence for near vision.*

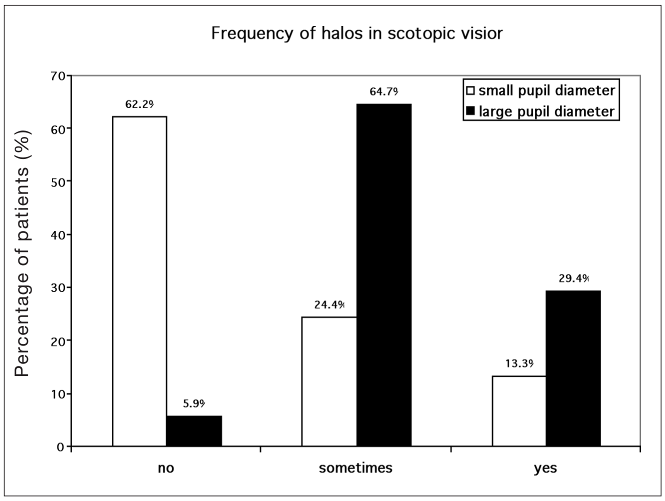

Fig. 3 - *Sample distribution based on the presence of photic phenomena in scotopic conditions.*

in the elderly, which may aid in the design of future MIOL prototypes and studies.

In agreement with other studies (5-7, 9, 12, 24-26, 32, 33), bilateral implantation of AMO Array IOLs provided good distance (≥0.6) and near UCVA (J6 or better) (Tab. I) and was effective in obtaining spectacle independence in most eyes (72.6% for distance and 54.8% for near; Figs. 1 and 2). The postoperative refractive astigmatism appeared very low (Tab. I), which was to be expected with a foldable MIOL that requires a small (3.2 mm) corneal incision (34). Some of the postoperative mean outcomes (refractive error, refractive astigmatism, and near BCVA; Tab. I) were not significantly different between the two groups, while others were (higher distance UCVA and BCVA and lower near UCVA in the small pupil group; Tab. I, p=0.02). Although not statistically significant (p=0.10), it is interesting to note that a higher percentage of patients in the small pupil group (73.3% versus 47.1%) were spectacle-independent for distance (Fig. 1), while more patients in the large pupil group (70.6% versus 44.4%) were spectacle-independent for near vision (Fig. 2).

The differences in visual outcomes and spectacle dependency between the two groups (Tab. I, Figs. 1 and 2) are not surprising. The concentric focusing zones are found at different diameter locations of this MIOL, thus the percent of light energy being used at any one particular focusing surface will obviously depend on the portion of the lens exposed from under the pupil (16). Laboratory studies showed that a minimum pupil diameter of 3.4 mm (optimally ≥3.8 mm) is needed for good near vision with the AMO Array (35). Previous clinical studies demonstrated that a preoperative pupil diameter less than 4.5 mm could not provide useful near VA with this MIOL (13). The near focus zones in the AMO Array are located on the anterior surface at a diameter of 4.6 mm, which theoretically implies that the pupil should have a diameter greater than 4.6 mm in order for this area of the MIOL to be exposed to provide near VA. This did not seem to be the case in the MIOL clinical study by Ravalico et al (29), which reported that pupillary diameter did not influence distance or near VA. Our results show that although larger pupil sizes were associated with better near UCVA, subjects with pupils ≤3 mm were also able to obtain considerable uncorrected near vision with this MIOL (Tab. I, Fig. 2). In contrast to previous reports (30), the postoperative near UCVA found in our patients seems to be more related to pupil size than to the patient's age, considering that the two groups of patients were perfectly age-matched (see Results).

It is also important to note that preoperative pupil diameter alone does not resolve the issues regarding MIOL visual outcomes. Studies have shown that postoperative pupil size cannot always be predicted from the preoperative diameter because the pupil can be substantially impaired by cataract surgery (18, 36); however, newer phacoemulsification surgical techniques have shown unchanged pupils after surgery (37). In addition, several reports have demonstrated that pupil size decreases linearly with age at all luminance levels (17, 31, 38), which implies that more stringent characteristics need to be considered in the design of an ideal MIOL for the elderly. The MIOL concentric design may benefit from a central zone that is smaller than the pupil diameter (under photopic conditions) to allow both distance and near focusing surfaces of the lens to be used to provide a clearer image on the retina (17).

Preoperative pupil size is an important criterion in selecting patients for bilateral MIOL implants. A pupil that is too small may not totally benefit from near uncorrected VA; however, pupils that are too large can also prove to be problematic. Patients with large scotopic pupils often report adverse subjective photic phenomena after surgery, such as glare and halos around lights (7, 11, 14, 15), or poor contrast sensitivity under mesopic light conditions (30). The pupil size (under mesopic light conditions) must be determined prior to surgery in order to minimize subjective postoperative side effects (39). The most frequent postoperative photic phenomena reported by our patients were starbursts and halos. About half (53.2%) of the patients reported such phenomena, which occurred more frequently in the large pupil group (Fig. 3, 93.1% versus 37.8%; chi-square test, p<0.001).

The majority of the patients (91.9%) stated that they were satisfied with their overall quality of vision after surgery, which tended to be greater (but not significantly) in the small pupil group (95.5% versus 76.5%, chi-square test, p=0.07). Although our patient group may be small, it still may be indicative of the general elderly population. Considering the high percent expressing overall satisfaction, it appears as if the elderly are willing to pay the price of occasional photic phenomena in order to achieve unaided vision and spectacle independence with MIOLs. The results of our study suggest that the best candidates for AMO Array bilateral implantation are patients with preoperative mesopic pupil diameter less than 3 mm, so that halos are limited in scotopic conditions, even if near UCVA is not optimal (Tab. I, Fig. 3). The high incidence of postoperative halos suggests that a careful selection of the patients should be made, especially in subjects with a large pupil size. There was also a relatively high percentage of PCO (19.4%) observed in our study, which could partially be due to the IOL optical disc not having square edges (currently used in the new ReZoom), which has shown to help prevent PCO (40).

Our study has some limitations. Patients with preoperative astigmatism >1.5 D were excluded from our study, which may have introduced some bias in the analysis of the satisfaction score and spectacle independence. This exclusion criterion was used based on the manufacturer's recommendations for optimal visual outcome with these MIOLs (2). Moreover, it is difficult to have accurate measurements of pupil diameter because the pupil is dynamic; it varies with illumination, accommodation, emotional status, and systemic medications; and pupils are often asymmetric (31). In order to obtain precise and accurate pupil measurements, sophisticated instruments such as infrared digital pupillometers are needed (41). The method used in our study to measure pupil diameter is advantageous in that it is easy and readily available in a day-to-day clinical practice; however, the precision and intrasubject variability are probably not optimal (42).

In conclusion, AMO Array MIOL implantation in elderly patients seems to be effective and safe, providing improved unaided distance and near VA and spectacle independence in more than half of the cases. Patients with preoperative pupil size less than 3 mm showed higher distance UCVA and BCVA, lower near UCVA, perceived less photic phenomena, and expressed greater visual outcome satisfaction after surgery. Further laboratory studies are needed in designing new MIOLs to address the issues of decreasing the incidence of PCO and the photic phenomena, and providing near uncorrected vision even for patients with small pupils. MIOLs thus seem to be a good alternative in elderly patients undergoing bilateral surgery who are motivated in obtaining spectacle independence, especially in subjects with small pupils providing that they do not drive frequently at night.

The authors have no financial interest in any products or devices used in the study.

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