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Thieme

Safety of DIMS Spectacle Lenses and Atropine as Combination Therapy for Myopia Progression

Sicherheit von Brillengläsern mit DIMS-Technologie und Atropin in der Kombinationstherapie der Myopieprogression

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ABSTRACT

Background The aim of this study was to evaluate traffic safety of Defocus Incorporated Multiple Segments (DIMS) spectacle lenses in combination therapy with atropine.

Patients and Methods 12 young adults (age: 24–45; 30,1 ± 5,7 years) were recruited to evaluate corrected distance visual acuity (CDVA), contrast sensitivity (CS; FrACT), glare sensitivity (Mesotest) under the influence of DIMS spectacle correction alone and combination therapy with 0,01 % atropine.

Results When looking through the central area of the DIMS lens, far vision does not decrease due to the influence of atropine; influence of glare and atropine leads to a reduction of CDVA by 0.10 logMAR. When forced to look through the DIMS area, far vision is reduced by 0.09 logMAR due to the influence of atropine in the absence of glare; in the presence of glare, no further loss of visual acuity can be observed under the influence of atropine. Contrast vision with DIMS glasses is not altered by the effects of atropine. Concerning glare sensitivity, DIMS lenses did not show any visual impairment that would be relevant to vision and road safety. Additional atropinization does not affect glare sensitivity.

Conclusion DIMS spectacle lenses are safe for participation in road traffic and do not relevantly impair traffic safety, neither alone nor under the acute influence of 0,01 % atropine.

ZUSAMMENFASSUNG

Hintergrund Es soll die Sicherheit im Straßenverkehr beim Tragen von Brillengläsern mit DIMS-Technologie (DIMS: Defocus Incorporated Multiple Segments) in der Kombination mit Atropin evaluiert werden.

Patienten und Methoden An 12 jungen Erwachsenen (Alter: 24–45; 30,1 ± 5,7 Jahre) wurde der Fernvisus und die Kontrastempfindlichkeit (KE), sowie Blendempfindlichkeit bei Versorgung mit DIMS-Brillengläsern allein und in der Kombination mit 0,01 % Atropin untersucht.

Ergebnisse Durch Atropineinwirkung vermindert sich der Fernvisus beim Blick durch den zentralen Bereich des DIMS-Brillenglases nicht; bei Blendung und unter Atropin kommt es zu einem Visusabfall um 0,10 logMAR. Beim erzwungenen Blick durch den DIMS-Bereich vermindert sich der Fernvisus durch Atropineinwirkung ohne Blendung um 0,09 logMAR; bei Blendung ist durch Atropin kein weiterer Visusabfall zu beobachten. Die Kontrastempfindlichkeit mit DIMS-Gläsern wird durch Atropineinwirkung nicht relevant verändert. Hinsichtlich der Blendempfindlichkeit findet sich bei DIMS-Gläsern

keine für das Sehen und die Sicherheit im Straßenverkehr relevante Sehbeeinträchtigung. Zusätzliche Atropinisierung hat keinen Einfluss auf die Blendempfindlichkeit.

Schlussfolgerung DIMS-Brillengläser sind sicher im Straßenverkehr und verursachen keine relevante Beeinträchtigung des Sehens, auch nicht unter Einfluss von 0,01 % Atropin. DIMS-Brillengläser sind daher auch bei der Behandlung von progressiven Myopien in der Kombinationstherapie mit Atropin sicher.

Introduction

Myopia (short-sightedness) results in unclear distance vision, due to an imbalance between the axial length and refractive power of the eye. This is most often caused by excessive growth of the globe of the eye during childhood and adolescence. Physiologically, children's eyes grow until they reach emmetropia. Genetic predisposition and environmental factors [1], which usually exert an influence in the pre-teen years, can cause the eyes to grow excessively long, resulting in progressive myopia. In addition to visual defects, which are generally easily correctable using optical means depending on severity, myopia can increase the risk of developing serious eye diseases such as retinal detachment, myopic maculopathy, myopic choroidal neovascularization, or glaucoma [2].

One current approach to inhibiting myopia progression is pharmacological intervention with low-dose atropine eye drops. The effect of atropine is dose-dependent, as are the associated side effects [3], especially sensitivity to light and glare caused by the mydriatic effect of atropine, as well as weakening of accommodation. In its 2019 statement, the German Ophthalmological Society (DOG) recommends treatment with 0.01 % atropine, administered regularly in the evenings before going to bed [4]. Although this dose and treatment regimen has an effect on pupil size and accommodation [3] that can still be measured the following day [5], it is nevertheless well tolerated. Unfortunately, it has been demonstrated that while atropine at this dose has few side effects, under real life conditions it does not always achieve the expected inhibition of myopia progression suggested by clinical studies [6]. For this reason, increasing the dose to 0.02 % or 0.025 % to improve the therapeutic effect is currently under discussion [7].

In addition to this pharmacological intervention, there are optical devices that have been shown to be effective in the treatment of myopic progression. These include orthokeratology contact lenses and multifocal contact lenses [8, 9], as well as spectacle lenses with peripheral defocus that have been specially developed for the treatment of myopia [10 – 12]. An example of this are the spectacle lenses with DIMS technology (defocus incorporated multiple segments). Based on a single vision lens, a multitude of small plus lenses are inserted into the glass around a free central zone so as to generate additional myopic defocus in the periphery of the retina; this is intended to have an inhibiting effect on the eye's excessive axial growth, and therefore also on the progression of myopia [12]. The simple use of therapeutic spectacles lenses of this kind means there are hardly any limitations in terms of providing care to children. Despite users of these lenses occasionally noticing the defocusing elements in their peripheral vision, according to the current study data, DIMS lenses have a high rate of acceptance and tolerability [13, 14]. Another lens design for myopia-inhibiting spectacle lenses is based on incorporating highly aspherical lenses, arranged in a concentric ring, into a single vision lens [15].

In the aim of improving or enhancing the therapeutic effect, the possibility of combining optical therapies with pharmacological intervention is under discussion. For example, increased therapeutic efficacy has been observed for the combination of orthokeratology lenses with daily administration of 0.01 % atropine eye drops [16 – 18].

Nevertheless, in the context of combining atropine therapy with the use of therapeutic spectacle lenses with local defocusing optics such as the DIMS lenses, it is important to exclude all possible safety concerns, especially with regard to the road safety of children. Visual functions that have been proven to be essentially relevant to road safety are visual acuity (especially daytime visual acuity with photopic adaptation), field of vision, mesopic vision, glare sensitivity (especially under mesopic conditions), color vision, eye position, motility, and stereoscopic vision [19]. Based on the literature, it was expected that DIMS lenses, in comparison to conventional single vision lenses, would not give rise to any relevant impairment in scotopic or photopic visual acuity, or with regard to subjective impairments of the field of vision, color vision, or stereoscopic vision [9, 13, 15, 20, 21]. Although the occasional perception of the peripheral, defocusing treatment zone of DIMS lenses could not be seen as restricting the wearer's vision [13], due to the mydriatic effect of atropine there was some fear that the combination therapy with atropine could be associated with increased glare sensitivity and reduced depth of focus [5], which could reduce contrast sensitivity, and also increase glare sensitivity under mesopic conditions.

For this reason, the aim of this study was to investigate the parameters relevant to vision and road safety in combination therapy with DIMS lenses and low-dose atropine (0.01 %).

Materials and Methods

Study cohort

We used G*Power (version 3.1.9.4.) [22] to calculate the sample size. Using a two-sided Wilcoxon signed-rank test (α-error: 0.05; power: 95 %), we determined a sample size of at least 9 for an assumed mean value (MV) 0.3 logMAR for change in visual acuity, with standard deviation (SD) ± 0.2 logMAR. The study complied with the ethical principles of the Declaration of Helsinki, and the examination of the study subjects took place in the context and within the scope of the project that received a positive vote from under No. 2018124 from the Ethics Committee of the Medical Association of North Rhine. The study data were collected from

practice employees during training and professional development events, and were retrospectively analyzed and evaluated in the context of this study. For this reason, the age of the patient group is considerably higher than that of the general target group for myopia progression inhibition therapies. The twelve study subjects (age: 24–45; 30.1 ± 5.7 years) were experienced in performing psychophysical tests, and did not have any ocular pathologies. The spherical equivalent of the study subjects ranged from − 8.13 dpt to + 1.13 dpt (− 2.84 ± 2.35 dpt).

Test lenses and atropine

In all of the tests we used glasses with DIMS lenses (MiYOSMART, Hoya Lens, Thailand) that were specially adapted to the current visual acuity of the test subjects. These lenses have a central "free" single vision area, surrounded by a ring-shaped area in which a large number of small pulse lenses are incorporated into the glass ("DIMS area"); when the wearer looks normally straight ahead, the DIMS area generates a multitude of local defocuses in the periphery of the retina which are superimposed onto the image from the single vision lens. Due to the manufacturing range of DIMS lenses, the hyperopic study subject was first provided with corrective contact lenses so as to achieve emmetropia, and then received DIMS lenses without any additional vision enhancement in the basic lens. For atropine administration we used 0.01 % atropine (Berg Apotheke, Tecklenburg, Germany).

Pupillography

To assess the actual effect of the atropine in these study subjects and with the specific atropine formula used, in preliminary tests we measured the scotopic (< 3 lx) and photopic (> 100 lx) pupil size of both eyes using a MYAH device (Topcon Corp., Japan), in each case before administration of atropine ("0 hrs"), and at 60 minutes ("1 hr"), 4 hours ("4 hrs"), and 8 hours ("8 hrs") after administration. The aim here was to assess the pupil dynamic (difference between scotopic and photopic pupils), because a persisting pupil dynamic is indicative of a slight adverse sensation of glare and accommodation weakness.

Study procedure

The following measurements were performed before atropine administration ("0 hrs") and 1 hour after additional installation of atropine ("1 hr"):

- Distance visual acuity using the Freiburg Visual Acuity an Contrast Test (FrACT, software version 3.10.5) [23], with and without glare, with the study subject looking straight ahead through the defocus-free central area of the lenses, as well as with forced gaze looking explicitly through the defocusing DIMS zone. This measurement was performed on the right eye.
- Contrast sensitivity (CS) using the Freiburg Visual Acuity and Contrast Test (FrACT, software version 3.10.5) under the same conditions as described above.
- Contrast sensitivity (CS) using Visual Function Analyzer (Stereo Optical, USA) following the F. A. C.T protocol (Functional Acuity Contrast Test) under photopic and mesopic conditions, in each case with and without glare (135 lx under photopic conditions, 28 lx under mesopic conditions). This measurement was performed on both eyes.
- Mesopic vision and glare sensitivity with a Mesotest device (Oculus Optikgeräte, Wetzlar), which uses a glare source that directs 0.3 lx light beam at the eye at the level of the pupil. This measurement was performed on both eyes.

In addition, using a calibrated color LCD screen with a diagonal measurement of 58 cm (ColorEdge CS230, Eizo, Japan), Landolt rings, as an opotype, were displayed at a distance of 2 m to measure distance visual acuity, and for CS, sinusoidal patches were displayed in differing orientations, with 3 and 6 cycles per degree.

The point glare source used (38 lx at the pupil level, 3 mm LED, 10,000 mcd) was located on the upper edge of the LCD screen. To determine distance visual acuity and CS looking exclusively through the DIMS area of the lenses, we then used chin rests to immobilize the heads of the study subjects during these measurements. By shifting the LCD screen sideways by 21° (i. e., 78 cm to the left of the given viewing distance), the gaze was forced to look through the nasal peripheral DIMS area [21]. If the gaze deviation was accompanied by a head movement on the part of the study subject, this was always corrected by the investigator.

All measurements took place in a darkened room (ambient light < 15 lx), with no sources of interfering light.

For the statistical analysis of the study results we used by the Kolmogorov-Smirnov test as well as a multifactorial ANOVA test with Matlab (Mathworks Inc., USA, version: R2021b).

Results

Effect of atropine on the pupils

The pupil sizes under scotopic and photopic conditions and resulting pupil dynamics, determined in the preliminary tests, are illustrated in ▶ **Fig. 1**. The pupil dynamic was 2.59 ± 0.52 mm prior to atropine administration, and it was 1.97 ± 1.08 mm ($p < 0.05$) 1 hour after administration of atropine 0.01 %, 1.35 ± 0.83 mm ($p < 0.001$) 4 hours after administration, and 1.81 ± 0.69 mm ($p < 0.01$) 8 hours after administration.

Mesopic vision and glare sensitivity

The results from the tests performed on the Mesotest device are set out in ▶ **Fig. 2**.

Without glare, all of the study subjects were able to confidently recognize the optotypes up to a contrast of 1 : 2.7, which corresponds to a logarithmic CS (logCS) of 0.2. In addition, 11 of the study subjects (92 %) recognized the optoptypes at the weakest contrast of 1 : 2 (0.3 logCS); 1 study subject (8 %) did not recognize the optotypes at this contrast.

With glare, all of the study subjects were still able to recognize the optotypes up to a contrast of 1 : 2.7. Furthermore, 9 of the study subjects (75 %) recognized the optoptypes at the weakest contrast of 1 : 2; 3 study subjects (25 %) did not recognize the optotypes at this contrast.

With additional atropinization but without glare, all of the study subjects were still able to recognize the optotypes up to a contrast of 1 : 2.7/Eleven subjects (92 %) could also correctly recognize the optotypes up to the lowest contrast of 1 : 2; one subject (8 %) could not recognize the optotypes at this contrast level.

With atropinization and glare, all of the study subjects could still recognize the optotypes up to a contrast of 1:2.7. Nine subjects (75%) could also recognize the optotypes at a contrast of 1:2; 3 subjects (25%) could not recognize the optotypes at this contrast.

Distance visual acuity (FrACT)

The mean visual acuity (logMAR) with SD looking through the "central area" and through the "DIMS area" are set out in ▸ **Table 1** und **Table 2**; in each case measurements are shown with and without atropine administration, and with and without the influence of glare.

Without glare, there was a significant reduction in distance visual acuity of 0.24 logMAR ($p < 0.001$) looking through the DIMS area compared to looking straight ahead through the central area; with atropine, there was a significant reduction in distance visual acuity of 0.27 logMAR ($p < 0.001$; ▸ **Table 1**).

With the subject looking straight ahead, administration of atropine did not significantly reduce the distance visual acuity; with the subject looking through the DIMS area, administration of atropine reduced the distance visual acuity by 0.09 logMAR ($p < 0.05$).

With additional glare, there was a significant reduction in distance visual acuity of 0.25 logMAR ($p < 0.001$) looking through the DIMS area compared to looking straight ahead through the central area of the lens; with atropine, there was a significant reduction in distance visual acuity of 0.17 logMAR ($p < 0.001$; ▸ **Table 2**).

With the subject looking straight ahead, additional atropine reduced the distance visual acuity by 0.10 logMAR ($p < 0.01$); with the subject looking through the DIMS area, the additional atropine did not significantly reduce the distance visual acuity.

Contrast sensitivity (FrACT)

▸ **Table 3** and **Table 4** show the contrast sensitivities (logCS) for the four conditions investigated, for the spatial frequencies 3 and 6 cpd.

With a spatial frequency of 3 cpd, there was no noticeable difference in CS with the subject looking through the DIMS area compared to looking straight ahead (without atropine); with atropine, this comparison showed that the CS was reduced by 0.16 logCS ($p < 0.01$).

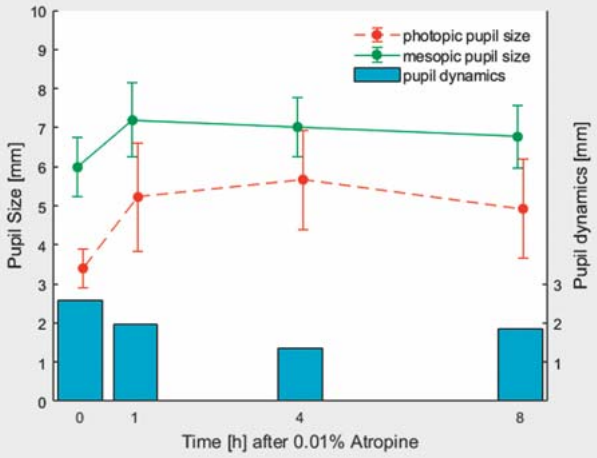
CS when looking straight ahead was not significantly reduced by the effect of the atropine; the CS looking through the DIMS area was reduced by 0.22 logCS ($p < 0.001$).

With a spatial frequency of 6 cpd, the CS looking through the DIMS area compared with looking straight ahead, both with and without atropine, was reduced significantly by 0.09 logCS (without atropine: reduction by 0.35 logCS, $p < 0.001$; with atropine: reduction by 0.38 logCS, $p < 0.001$).

The atropine did not have any noticeable effect on CS, either looking straight ahead or looking through the DIMS area.

Contrast sensitivity (Visual Function Analyzer)

On determining contrast sensitivity using the Visual Function Analyzer following the F. A. C. T. protocol, administration of atropine was not observed to have any statistically significant effect on CS with DIMS lenses, even when subjected to glare (▸ **Fig. 3**). With atropine there is a tendency for contrast sensitivity to increase under mesopic conditions, with and without glare.



▸ **Fig. 1** Influence of acute atropinization with 0.01% atropine on pupil dynamic (bar graph) and pupil size (error bars) over time (before atropine administration [0 hrs] and 45–60 mins [1 hr], 4 hours and 8 hours after atropine administration).

Mesotest				
Kontrast	1:23	1:5	1:2,7	1:2
DIMS only				
Without glare	100%	100%	100%	92%
With glare	100%	100%	100%	75%
DIMS + 0.01% Atropine				
Without glare	100%	100%	100%	92%
With glare	100%	100%	100%	75%

▸ **Fig. 2** Percentage of test subjects who were able to see the contrast levels using the Mesotest instrument with DIMS lenses, in each case with and without glare and with and without atropine; 1:23 corresponds to the highest contrast setting, and 1:2 the lowest contrast. (Being able to see a contrast of 1:23 is the requirement for a Class B driver license.)

Discussion

This study serves to evaluate different visual functions when wearing DIMS spectacle lenses to inhibit myopia progression, especially in combination with low-dose atropine (0.01%).

▶ **Table 1** Distance visual acuity (reported in logMAR as mean value ± SD) with subject looking through the central part of the lens and through the DIMS area, in each case with and without atropine and with and without glare; ns = not significant. Example for interpretation: a difference of + 0.1 logMAR between „central“ and „DIMS area“ corresponds to a drop in visual acuity of 1 level.

Without glare	Distance visual acuity [logMAR] (MV ± SD)			
	Without atropine		With atropine	
	Central	DIMS area	Central	DIMS area
	− 0.06 ± 0.15	0.18 ± 0.12	0.00 ± 0.13	0.27 ± 0.05
	P < 0.001		P < 0.001	
	ns			
		p < 0.05		

▶ **Table 2** Distance visual acuity (reported in logMAR as mean value ± SD) with subject looking through the central part of the lens and through the DIMS area, in each case with and without atropine and with and without glare; ns = not significant. Example for interpretation: a difference of + 0.1 logMAR between „central“ and „DIMS area“ corresponds to a drop in visual acuity of 1 level.

With glare	Distance visual acuity [logMAR] (MV ± SD)			
	Without atropine		With atropine	
	Central	DIMS area	Central	DIMS area
	− 0.01 ± 0.16	0.24 ± 0.17	0.09 ± 0.18	0.26 ± 0.16
	P < 0.001		P < 0.001	
	P < 0.01			
		ns		

▶ **Table 3** Mean value ± SD of contrast sensitivity (logCS) with subject looking straight ahead through the central area of the lens and looking through the DIMS area, in each case with and without atropine, for the spatial frequency 3 cpd; ns = not significant.

Spatial frequency 3 cpd	Contrast Sensitivity [logCS] (MV ± SD)			
	Without atropine		With atropine	
	Central	DIMS area	Central	DIMS area
	2.23 ± 0.11	2.19 ± 0.17	2.13 ± 0.20	1.97 ± 0.24
	ns		P < 0.01	
	ns			
		P < 0.001		

In a previous study of young adults, it was shown that looking through the central, defocus-free area of DIMS lenses, which is equivalent to single vision correction, does not result in any impairment of visual acuity [21]; however, this requires correct centering of the spectacle lenses. When looking through the treatment area of the DIMS lenses, a reduction in visual acuity by 0.3 logMAR was observed [21]; this corresponds approximately to a spherical defocus of 0.5 to 0.75 dpt. The decrease in visual acuity described above was also precisely confirmed in our study. This reduction in visual acuity, which is small for a defocus of + 3.50 dpt, can be explained by the configuration of the DIMS lenses. The plus lenses arranged on the front surface of the DIMS spectacle lenses are on average significantly smaller in diameter (1 mm) than the eye's pupil size, which means the light ray bundle shining on the eye is always a combination of light rays that on the one hand can only be refracted by the single vision lens, and on the other hand are always refracted by more than one lens [20]. In a study of 20 children, a smaller reduction in visual acuity was measured looking through the treatment area of the DIMS lenses (0.06 logMAR) [13]. This prompts us to suspect that children, in

▶ **Table 4** Mean value ± SD of contrast sensitivity (logCS) with subject looking straight ahead through the central area of the lens and looking through the DIMS area, in each case with and without atropine, for the spatial frequency 6 cpd; ns = not significant.

Spatial frequency 6 cpd	Contrast Sensitivity [logCS] (MV ± SD)			
	Without atropine		With atropine	
	Central	DIMS area	Central	DIMS area
	1.94 ± 0.22	1.59 ± 0.27	1.84 ± 0.37	1.46 ± 0.33
	P < 0.001		P < 0.001	
	ns			
		ns		

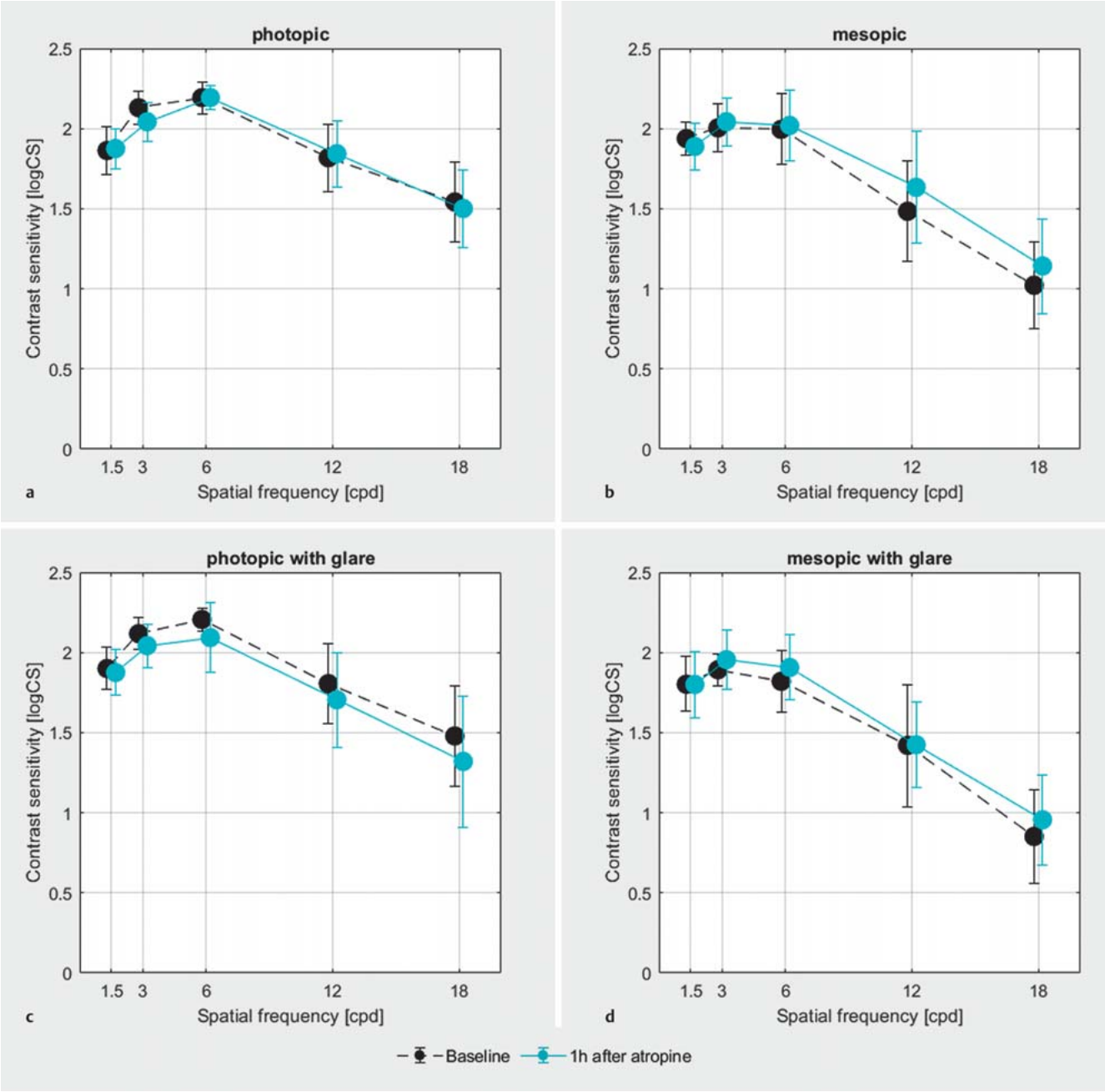
contrast to the adult volunteers, are quicker to adapt and are less susceptible to interference from the defocus. Lam et al. were able to show that visual functions are not impaired using DIMS spectacle lenses compared to single-vision lenses, and that visual function improves over the course of two years, both with DIMS lenses and with single-vision lenses [10]. In practice, this reduction in visual acuity at the periphery of the lenses has been found to be not clinically relevant: in an as yet unpublished survey in which the authors of this article systematically surveyed 54 children being treated with DIMS spectacle lenses, after a maximum adjustment period of 14 days, there were no further reports of subjective impairment of visual acuity, while the vision problems originally reported related solely to reading close up; there were no reports of impaired distance vision or impairment in the context of road safety. It should be mentioned here that randomized studies with DIMS spectacle lenses have yet to be performed in European.

Special lenses for inhibiting myopia progression are not the only type of lenses that incorporate more than one vision strength into the same lens: older people often wear glasses with progressive lenses, which are classed as safe in the context of road safety [24]. However, compared to progressive lenses, DIMS spectacle lenses have a fundamentally different optical design. Because the plus lenses incorporated into a single-vision lens have a cover ratio of less than approx. 50%, the magnification is the same over the whole surface of the lens, even when looking through the peripheral DIMS area. In contrast, depending on their design, progressive lenses have more or less prominent undesired optical effects that change over the surface of the lens and have an effect on visual functions [25, 26]. Relating this to the optical design of DIMS spectacle lenses, these lenses can consequently be classed as safe in the context of road safety.

Combination therapy with atropine eye drops is used to improve the therapeutic effect of DIMS lenses in individual cases. However, parents and ophthalmologists may still fear that the special optical characteristics of the myopia-inhibiting lens design will be amplified through the pupil dilation and reduction in pupil dynamic caused by the atropine. This might cause the wearer of the DIMS glasses to be more strongly aware of the defocusing treatment area ("DIMS area") of the DIMS lenses, leading to a reduction in visual function in this area, especially under the influence of glare. In this study we have shown that even given acute atropinization with impairment of pupil function, as can occur in myopia therapy with low-dose atropine, there is no clinically relevant impairment to visual function using DIMS glasses. With the subject looking straight ahead (through the central area of the DIMS lenses), we did not observe any statistically significant or clinically relevant change in visual acuity following administration of atropine. While visual acuity is generally reduced when looking through the DIMS area, there is no impairment to contrast sensitivity at spatial frequencies of 3 and 6 cpd. These spatial frequencies are necessary in order to roughly recognize objects and for safety-relevant vision, especially with regard to road safety [27]. Even with higher spatial frequencies, in our testing using the Visual Function Analyzer we did not observe any reduction in contrast sensitivity using DIMS glasses in combination with atropine. Our study even showed a tendency towards improved CS under mesopic conditions after administration of atropine, presumably due to the enlarged pupil [28]. Our results regarding contrast sensitivity under the influence of atropine are consistent with findings from earlier research: in a study that investigated the short-term and long-term effects of 0.01% atropine on CS, no significant reduction in CS was observed [18].

Our results with the Mesotest instrument for mesopic vision and glare sensitivity do not lead us to expect any impairment of road safety under the influence of atropine with glare. This cohort of study subjects did not at any point fall below the minimum requirements for a Class B driver license stipulated by the German Ophthalmological Society (DOG) [29]. None of the vision conditions investigated in this study showed a clinically relevant reduction in visual acuity, and on average the visual acuity scores did not fall below 0.3 logMAR. From this we conclude that glasses with DIMS technology do not give rise to any relevant impairment of road safety, even in combination with atropine.

It must be noted, in any case, that the paradigm used in this study reflected an extremely artificial and contrived adverse situation: in practical reality, it would never happen that the wearer's gaze would be forced to look through the peripheral DIMS area of the spectacle lenses, as was contrived in our study for the visual function test. In a real-life situation the wearer would move their head in the direction of the object so as to be looking through the free central single-vision area of the DIMS lenses. Conversely, the resolution in the peripheral field of vision is so low [13] that the superimposed defocus created by the optics of the DIMS area is not even noticeable when the wearer is looking straight ahead.



▶ **Fig. 3** Contrast sensitivity at 1,5, 3, 6, 12, and 18 cpd, determined in 12 trial subjects before atropinization (0 hrs) and approx. 60 minutes after atropinization (1 hr). **a** Under photopic conditions. **b** Under mesopic conditions. **c**, **d** As for **a** and **b**, but with glare.

The paradigm used in our study would only apply in the particularly unfortunate situation in which an object of relevance for safety was first roughly noticed in the periphery of a person's field of vision, so that for a brief moment it appeared only in the DIMS area of the lens, resulting in a slight delay before the reflex-like head motion followed the gaze so that the person was once again looking through the central, defocus-free, single-vision area of the DIMS lens. In contrast to progressive lenses which have changing magnification, due to the constant magnification of the base single-vision lens described above, the wearer is not expected to experience any vision impairment on "glancing sideways", triggering a "head follows gaze" reflex cascade [30].

Conclusion

According to current knowledge, DIMS glasses to not represent any risk to road safety. The safety-relevant visual functions are not adversely changed, even in combination therapy with atropine. Although the wearer's visual acuity is reduced when looking through the treatment area of DIMS lenses, there is no impair-

ment to the contrast sensitivity at safety-relevant spatial frequencies. It should also be mentioned that constraining the study subjects to gaze fixedly through the treatment area of the lens constitutes a highly artificial visual situation; in a real-life scenario, any gaze through this area would tend to be brief, and would be compensated by head movement.

CONCLUSION BOX

Already known:

- Low-dose atropine and special eyeglasses are an established method for inhibiting myopia progression.
- If therapy is insufficiently effective, a combined therapeutic approach may be helpful.
- Possible optical and sensory physiological effects of the combination therapy and their influence on road safety have yet to be clarified.

New findings:

- The combination of DIMS glasses with 0.01% atropine does not result in any clinically relevant impairment to the central visual functions.
- Optical effects that are briefly noticeable in the peripheral field of vision do not have any impact on rough recognition of objects.
- Combination therapy with DIMS and 0.01% atropine can be seen as without risk in terms of road safety.

Conflict of Interest

Hakan Kaymak works as a consultant for HOYA Lens Deutschland GmbH.

References

[1] Morgan IG, Wu P-C, Ostrin LA et al. IMI Risk Factors for Myopia. Invest Ophthalmol Vis Sci 2021; 62: 3. doi:10.1167/iovs.62.5.3

[2] Saw S-M, Gazzard G, Shih-Yen EC et al. Myopia and associated pathological complications. Ophthalmic Physiol Opt 2005; 25: 381–391. doi:10.1111/j.1475-1313.2005.00298.x

[3] Yam JC, Jiang Y, Tang SM et al. Low-Concentration Atropine for Myopia Progression (LAMP) Study: A Randomized, Double-Blinded, Placebo-Controlled Trial of 0.05%, 0.025%, and 0.01% Atropine Eye Drops in Myopia Control. Ophthalmology 2019; 126: 113–124. doi:10.1016/j.ophtha.2018.05.029

[4] Berufsverband der Augenärzte Deutschlands e.V., Deutsche Ophthalmologische Gesellschaft. Empfehlungen bei progredienter Myopie im Kindes- und Jugendalter: Stellungnahme von DOG und BVA. Stand Dezember 2018. Ophthalmologe 2019; 116: 340–345. doi:10.1007/s00347-019-0874-6

[5] Kaymak H, Fricke A, Mauritz Y et al. Short-term effects of low-concentration atropine eye drops on pupil size and accommodation in young adult subjects. Graefes Arch Clin Exp Ophthalmol 2018; 256: 2211–2217. doi:10.1007/s00417-018-4112-8

[6] Kaymak H, Graff B, Schaeffel F et al. A retrospective analysis of the therapeutic effects of 0.01% atropine on axial length growth in children in a real-life clinical setting. Graefes Arch Clin Exp Ophthalmol 2021: 1–10. doi:10.1007/s00417-021-05254-5

[7] Yam JC, Zhang XJ, Zhang Y et al. Three-Year Clinical Trial of Low-Concentration Atropine for Myopia Progression (LAMP) Study: Continued Versus Washout: Phase 3 Report. Ophthalmology 2022; 129: 308–321. doi:10.1016/j.ophtha.2021.10.002

[8] Cho P, Cheung SW. Retardation of myopia in Orthokeratology (ROMIO) study: a 2-year randomized clinical trial. Invest Ophthalmol Vis Sci 2012; 53: 7077–7085. doi:10.1167/iovs.12-10565

[9] Li SM, Kang MT, Wu SS et al. Studies using concentric ring bifocal and peripheral add multifocal contact lenses to slow myopia progression in school-aged children: a meta-analysis. Ophthalmic Physiol Opt 2017; 37: 51–59. doi:10.1111/opo.12332

[10] Lam CSY, Tang WC, Tse DYY et al. Defocus Incorporated Multiple Segments (DIMS) spectacle lenses slow myopia progression: a 2-year randomised clinical trial. Br J Ophthalmol 2020; 104: 363–368. doi:10.1136/bjophthalmol-2018-313739

[11] Bao J, Yang A, Huang Y et al. One-year myopia control efficacy of spectacle lenses with aspherical lenslets. Br J Ophthalmol 2022; 106: 1171–1176. doi:10.1136/bjophthalmol-2020-318367

[12] Kaymak H, Graff B, Neller K et al. Myopietherapie und Prophylaxe mit "Defocus Incorporated Multiple Segments"-Brillengläsern. Ophthalmologe 2021; 118: 1280–1286. doi:10.1007/s00347-021-01452-y

[13] Lu Y, Lin Z, Wen L et al. The Adaptation and Acceptance of Defocus Incorporated Multiple Segment Lens for Chinese Children. Am J Ophthalmol 2020; 211: 207–216. doi:10.1016/j.ajo.2019.12.002

[14] Lam CSY, Tang WC, Qi H et al. Effect of Defocus Incorporated Multiple Segments Spectacle Lens Wear on Visual Function in Myopic Chinese Children. Trans Vis Sci Tech 2020; 9: 11. doi:10.1167/tvst.9.9.11

[15] Li X, Ding C, Li Y et al. Influence of Lenslet Configuration on Short-Term Visual Performance in Myopia Control Spectacle Lenses. Front Neurosci 2021; 15: 667329. doi:10.3389/fnins.2021.667329

[16] Kinoshita N, Konno Y, Hamada N et al. Efficacy of combined orthokeratology and 0.01% atropine solution for slowing axial elongation in children with myopia: a 2-year randomised trial. Sci Rep 2020; 10: 12750. doi:10.1038/s41598-020-69710-8

[17] Wan L, Wei C-C, Chen CS et al. The Synergistic Effects of Orthokeratology and Atropine in Slowing the Progression of Myopia. J Clin Med 2018; 7: 259. doi:10.3390/jcm7090259

[18] Cheng Z, Mei J, Cao S et al. The Effects of 0.01% Atropine on Adult Myopes' Contrast Sensitivity. Front Neurosci 2021; 15: 624472. doi:10.3389/fnins.2021.624472

[19] Lachenmayr B. Verkehrsophthalmologie. Fahreignungsbegutachtung im Straßenverkehr. Ophthalmologe 2006; 103: 425–443; quiz 444–445. doi:10.1007/s00347-006-1330-y

[20] Jaskulski M, Singh NK, Bradley A et al. Optical and imaging properties of a novel multi-segment spectacle lens designed to slow myopia progression. Ophthalmic Physiol Opt 2020; 40: 549–556. doi:10.1111/opo.12725

[21] Kaymak H, Neller K, Schütz S et al. Vision tests on spectacle lenses and contact lenses for optical myopia correction: a pilot study. BMJ Open Ophthalmology 2022; 7: e000971. doi:10.1136/bmjophth-2022-000971

[22] Faul F, Erdfelder E, Lang A-G et al. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behav Res Methods 2007; 39: 175–191. doi:10.3758/BF03193146

[23] Bach M. The Freiburg Visual Acuity Test-variability unchanged by post-hoc re-analysis. Graefes Arch Clin Exp Ophthalmol 2007; 245: 965–971. doi:10.1007/s00417-006-0474-4

[24] Chu BS, Wood JM, Collins MJ. The effect of presbyopic vision corrections on nighttime driving performance. Invest Ophthalmol Vis Sci 2010; 51: 4861–4866. doi:10.1167/iovs.10-5154

[25] Schilling T, Ohlendorf A, Varnas SR et al. Peripheral Design of Progressive Addition Lenses and the Lag of Accommodation in Myopes. Invest Ophthalmol Vis Sci 2017; 58: 3319–3324. doi:10.1167/iovs.17-21589

[26] Villegas EA, Artal P. Visual acuity and optical parameters in progressive-power lenses. Optom Vis Sci 2006; 83: 672–681. doi:10.1097/01.opx.0000232818.37832.ee

[27] Collin CA, McMullen PA. Subordinate-level categorization relies on high spatial frequencies to a greater degree than basic-level categorization. Percept Psychophys 2005; 67: 354–364. doi:10.3758/BF03206498

[28] Karatepe AS, Köse S, Eğrilmez S. Factors Affecting Contrast Sensitivity in Healthy Individuals: A Pilot Study. Turk J Ophthalmol 2017; 47: 80–84. doi:10.4274/tjo.93763

[29] Deutsche Ophthalmologische Gesellschaft. Prüfung des Kontrast- oder Dämmerungssehens. Ophthalmologe 2011; 108: 1195–1198. doi:10.1007/s00347-011-2488-5

[30] Zangemeister WH, Stark L. Gaze latency: Variable interactions of head and eye latency. Exp Neurol 1982; 75: 389–406. doi:10.1016/0014-4886(82)90169-8