

多区正向光学离焦镜片对双眼视功能和视觉质量影响的随机双盲对照研究

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【摘要】 目的 评估配戴多区正向光学离焦(DIMS)镜片对近视儿童双眼视功能和视觉质量的影响。

方法 采用随机双盲对照研究方法,于2021年1月至2022年3月在四川大学华西医院招募6~15岁近视儿童176例352眼。采用随机数字表法将其分为DIMS组85例170眼和单光组91例182眼,分别配戴DIMS和单光镜片,最终完成随访并纳入分析者共151例302眼,其中DIMS组72例144眼,单光组79例158眼。在戴镜前和戴镜后6、12个月分别测量受试者的调节幅度、调节灵敏度、远/近水平眼位、调节性集合与调节比值(AC/A),分析2个组受试者戴镜1年的视功能变化。每次随访均测量受试者主观对比敏感度(CS),客观评估镜片对视觉质量的影响。**结果** 2个组戴镜前后不同时间点单眼调节幅度、双眼调节灵敏度总体比较差异均有统计学意义(Wald $\chi^2_{\text{时间}} = 84.435, 48.201$, 均 $P < 0.001$),其中2个组戴镜后6和12个月单眼调节幅度均较戴镜前下降,双眼调节灵敏度均较戴镜前增加,差异均有统计学意义(均 $P < 0.001$)。戴镜后12个月,DIMS组和单光组单眼调节幅度分别较戴镜前下降2.68 D(95% CI: 1.60~3.75 D)和2.82 D(95% CI: 1.81~3.84 D)。2个组戴镜前后不同时间点远水平眼位和近水平眼位总体比较差异均有统计学意义(Wald $\chi^2_{\text{时间}} = 10.398, 23.947$, 均 $P < 0.01$),其中,戴镜后12个月DIMS组远水平眼位较戴镜前向外漂移 0.68^Δ (95% CI: 0.06~1.25 $^\Delta$),差异有统计学意义($P < 0.05$);DIMS组和单光组近水平眼位分别较戴镜前向外漂移 1.67^Δ (95% CI: 0.15~3.20 $^\Delta$)和 1.73^Δ (95% CI: 0.49~2.96 $^\Delta$),差异均有统计学意义(均 $P < 0.05$)。2个组戴镜前后不同时间点梯度性AC/A值和计算性AC/A值总体比较差异均有统计学意义(Wald $\chi^2_{\text{时间}} = 22.001, 13.411$, 均 $P < 0.01$),其中2个组戴镜后12个月梯度性AC/A值均较戴镜前降低,单光组戴镜后12个月计算性AC/A值较戴镜前降低,差异均有统计学意义(均 $P < 0.05$)。2个组间调节幅度、调节灵敏度、远水平眼位、近水平眼位、梯度性AC/A值和计算性AC/A值总体比较,差异均无统计学意义(Wald $\chi^2_{\text{组别}} = 2.385, 2.266, 2.070, 0.571, 0.578, 0.053$, 均 $P > 0.05$)。2个组戴镜前后不同时间点在3、6、12、18 cpd空间频率下的CS总体比较,差异均无统计学意义(Wald $\chi^2_{\text{组别}} = 1.104, 2.263, 1.861, 3.671$, 均 $P > 0.05$; Wald $\chi^2_{\text{时间}} = 2.260, 5.382, 2.573, 1.637$, 均 $P > 0.05$)。**结论** 配戴DIMS镜片后视功能表现与配戴单光镜片表现一致,对儿童长期视觉质量无明显不利影响。

【关键词】 近视;眼调节;对比敏感度;眼位;离焦;视功能;视觉质量

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A randomized double-blind controlled study on the effects of wearing defocus incorporated multiple segments lenses on binocular visual function and visual quality

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[Abstract] Objective To evaluate the effects of wearing defocus incorporated multiple segments (DIMS) spectacle lenses on binocular visual function and visual quality in myopic children. **Methods** A randomized double-blind controlled study was conducted. A total of 176 children (352 eyes) with myopia aged 6 to 15 years were

enrolled in the West China Hospital of Sichuan University from January 2021 to March 2022. They were randomly divided into DIMS group of 85 cases (170 eyes) and single-vision group of 91 cases (182 eyes) wearing DIMS and single-vision lenses, respectively, using the random number table method. A total of 151 cases (302 eyes) who completed follow-up visits were included in the analysis, including 72 cases (144 eyes) in the DIMS group and 79 cases (158 eyes) in the single-vision group. Before and after 6 and 12 months of lens wear, accommodation amplitude, binocular accommodative sensitivity, distance/near horizontal eye position, and accommodative convergence/accommodation (AC/A) of subjects were measured. Changes in visual function over the year were compared between the two groups. In addition, subjective contrast sensitivity (CS) was assessed at each follow-up visit to evaluate the effect of the lenses on visual quality. The study adhered to the Declaration of Helsinki. The study protocol was approved by the Ethics Committee of West China Hospital of Sichuan University (No. 2020-06). Parents or legal guardians signed written informed consent before the child's participation.

Results There were significant differences in monocular accommodation amplitude and binocular accommodation sensitivity at different time points between before and after lens wear in both groups (Wald $\chi^2_{\text{time}} = 84.435, 48.201$; both $P < 0.001$). In both groups, monocular accommodation amplitude was decreased and the binocular accommodation sensitivity was increased at 6 and 12 months after wearing glasses compared with baseline (all $P < 0.001$). After 12 months of lens wear, the monocular accommodation amplitude decreased by 2.68 D (95% CI: 1.60–3.75 D) in DIMS group and 2.82 D (95% CI: 1.81–3.84 D) in single-vision group. There were statistically significant differences in distance and near horizontal eye position between the two groups at different time points before and after wearing glasses (Wald $\chi^2_{\text{time}} = 10.398, 23.947$; both $P < 0.01$). In the DIMS group, after 12 months of wearing lenses, the distance horizontal eye position drifted outward by 0.68^Δ (95% CI: $0.06 - 1.25^\Delta$) compared to baseline, with a significant difference ($P < 0.05$). There was 1.67^Δ (95% CI: $0.15 - 3.20^\Delta$) outward drift at near horizontal eye position in the DIMS group and 1.73^Δ (95% CI: $0.49 - 2.96^\Delta$) outward drift in the single-vision group compared with baseline, with significant differences (both $P < 0.05$). There were statistically significant differences in gradient AC/A values and calculated AC/A values between the two groups at different time points before and after wearing glasses (Wald $\chi^2_{\text{time}} = 22.001, 13.411$; both $P < 0.01$). After 12 months of wearing glasses, the gradient AC/A values significantly decreased in both groups compared to respective baseline, and the calculated AC/A values in the single-vision group showed a significant decrease compared to baseline (all $P < 0.05$). There were no significant difference in the monocular accommodation amplitude, binocular accommodation sensitivity, distance and near horizontal eye position, gradient AC/A values and calculated AC/A values between the two groups (Wald $\chi^2_{\text{group}} = 2.385, 2.266, 2.070, 0.571, 0.578, 0.053$; all $P > 0.05$). There was no significant difference in the CS at 3, 6, 12, and 18 cpd spatial frequencies between the two groups at different time points before and after wearing lenses (Wald $\chi^2_{\text{group}} = 1.104, 2.263, 1.861, 3.671$; all $P > 0.05$. Wald $\chi^2_{\text{time}} = 2.260, 5.382, 2.573, 1.637$; all $P > 0.05$).

Conclusions Visual function performance after wearing DIMS lenses is consistent with that after wearing single-vision lenses. Wearing DIMS lenses has no obvious negative effect on the long-term visual quality in children.

[Key words] Myopia; Accommodation, ocular; Contrast sensitivity; Eye position; Defocus; Visual function; Visual quality

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近视通常是由于眼球屈光力和眼轴长度不匹配,在非调节状态下,远处物体的像在视网膜前聚焦,导致远视力下降^[1]。近年来,近视患病率不断上升,已成为全球公共卫生问题^[2]。在中国,青少年近视患病率为80%~90%,15~18岁青少年高度近视患病率也较高,为7%~20%^[3-5]。因此,临床上亟需寻找有效方法来降低近视的患病率,延缓或阻止其向高度近视发展

的趋势,以避免可能导致的视力损害,甚至盲。目前,减缓近视进展的有效措施包括每天使用低浓度(如0.01%)阿托品滴眼液、角膜塑形镜、周边离焦框架眼镜和多焦点软性角膜接触镜等^[6-8],其中,周边离焦框架眼镜在满足青少年矫正近视的同时还能控制或减缓近视的发展,是一种安全、方便、易获得的近视控制方法^[2,6]。

周边离焦框架眼镜是基于“近视离焦理论”设计的。多项研究强调了周边视网膜在影响眼生长和屈光发育方面的重要作用^[9-11]。近视患者通常表现出相对周边远视离焦,这意味着物像的焦点落在周边视网膜后面,可能是一种潜在的生长信号^[12-13]。通过在周边提供额外的正镜片,将物像聚焦在视网膜前方,以此产生的周边视网膜近视离焦被证明可以减缓眼球生长和近视度数的加深^[14-15]。多区正向光学离焦(defocus incorporated multiple segments, DIMS)镜片表面分布有 396 个屈光度为 +3.50 D 的微型透镜,用于形成周边近视离焦。一项随机对照临床试验结果显示,配戴 DIMS 镜片 2 年可使近视进展减缓 -0.44 D,眼轴增长减少 0.34 mm,具有显著的近视控制效果^[16]。

在关注近视控制效果的基础上,考虑 DIMS 镜片对视功能和视觉质量的影响同样重要。有研究表明,相较于未近视人群,近视人群的视功能和视力会发生变化^[17-18]。目前,周边离焦镜片对视功能影响的报道较少,且结果不一致。Lam 等^[19]研究发现,配戴 DIMS 镜片后,调节幅度下降,调节滞后显著降低,远、近眼位均无明显改变,远距高对比度视力提高,低对比度视力无明显变化。Huang 等^[20]研究显示,配戴非球面微透镜镜片会增加调节幅度,并且与配戴单光镜片相比,高对比度视力和低对比度视力均较低,调节滞后量会随戴镜时间的延长而降低。对比敏感度(contrast sensitivity, CS)是衡量视觉质量较灵敏的指标,目前长期配戴周边离焦镜片对 CS 的影响尚不清楚。既往研究显示,配戴多焦点角膜接触镜会降低近视患者的短期 CS^[21-22]。配戴带有微透镜的周边离焦镜片可能面临与多焦点角膜接触镜类似的视觉质量问题。

本研究评估并比较配戴 DIMS 镜片与单光镜片在视功能,包括调节幅度、调节灵敏度、调节性集合与调节比值(accommodation convergence/accommodation, AC/A)、远和近水平眼位,以及 CS 方面的变化,旨在探讨周边离焦镜片对视功能和视觉质量的影响,为临床医师选择更合适的儿童近视控制方法提供参考依据。

1 资料与方法

1.1 一般资料

采用随机双盲对照研究方法,于 2021 年 1 月至 2022 年 3 月在四川大学华西医院眼科门诊招募近视儿童 176 例 352 眼,包括初诊近视或既往已诊断近视儿童。纳入标准:年龄 6~15 岁;任一眼球镜度数为 -8.00~0.00 D,任一圆柱镜度数 ≤ 1.50 D,双眼屈光

参差 ≤ 2.00 D,任一眼最佳远矫正视力 ≤ 0.0 LogMAR。排除标准:双眼视功能异常儿童,包括远水平眼位 $>1^\Delta$ 或 $<-3^\Delta$ 、近水平眼位 $>2^\Delta$ 或 $<-8^\Delta$ 、任一调节幅度低于儿童年龄最低调节幅度值(15-0.25×年龄)、双眼调节灵敏度 <6 cpm、AC/A 值 $>6^\Delta/D$ 或 $<2^\Delta/D$ 、集合近点 >5 cm;既往有眼部或全身性疾病,或既往有眼部手术史者;试验期间使用/更换其他近视控制方法者,如其他特殊设计的框架眼镜、角膜塑形镜、多焦点软性角膜接触镜、低浓度阿托品滴眼液等。采用随机数字表法将受试者随机分为 DIMS 组 85 例 170 眼和单光组 91 例 182 眼,分别配戴 DIMS 和单光镜片,2 个组中分别有 13 和 11 例受试者因 COVID-19 流行以及其他个人原因未按时到医院完成随访,单光组 1 例受试者因中途配戴角膜塑形镜而选择退组,共计 151 例 302 眼受试者完成了全部随访,其中 DIMS 组 72 例 144 眼,单光组 79 例 158 眼。2 个组受试者戴镜前年龄、性别构成比、等效球镜度和眼轴长度比较,差异均无统计学意义(均 $P>0.05$) (表 1)。在研究期间,为了保持双盲,在发放镜片之前撕掉所有镜片标签,使受试者和检查人员难以区分镜片类型。本研究遵循《赫尔辛基宣言》原则,研究方案经四川大学华西医院伦理委员会批准[批文号:2020 年审(6)号]。在儿童参与研究前,均已获得儿童父母或法定监护人的书面知情同意。

表 1 2 个组完成全部随访的受试者基线资料比较
Table 1 Comparison of baseline demographics between two groups of subjects with complete follow-up visits

组别	例数/眼数	年龄 ($\bar{x}\pm s$, 岁) ^a	性别构成比 (男/女, n) ^b	等效球镜度 ($\bar{x}\pm s$, D) ^a	眼轴长度 ($\bar{x}\pm s$, mm) ^a
DIMS 组	72/72	10.69±1.56	42/30	-3.16±1.62	24.82±0.87
单光组	79/79	10.38±1.68	44/35	-3.13±1.61	25.02±1.04
t/χ^2 值		-1.188	0.107	0.113	1.275
P 值		0.237	0.744	0.910	0.204

注:(a:独立样本 t 检验; b: χ^2 检验) DIMS:多区正向光学离焦
Note: (a: Independent samples t -test; b: χ^2 test) DIMS: defocus incorporated multiple segments

1.2 方法

2 个组患者分别在戴镜前和戴镜后 6、12 个月进行视功能和 CS 检查。

1.2.1 视功能测量 所有受试者均进行睫状肌麻痹验光,并配戴完全矫正的试镜架(单光镜片)在非睫状肌麻痹条件下进行视功能测量,包括调节幅度、调节灵敏度、眼位和 AC/A。(1)调节幅度 采用移近、移远

法测量单眼调节幅度。对于移近法,将近用 Snellen 视力表沿着标尺慢慢移向儿童眼,直到儿童报告 20/30 行视标持续模糊为止。对于移远法,将近用 Snellen 视力表从眼镜平面慢慢推离、移远,直到儿童刚好能读出第 20/30 行视标。根据既往研究选择 20/30 行视标,以便受试者更好地配合进行标准化测量^[23-24]。调节幅度为近用 Snellen 视力表与眼镜平面之间距离的倒数,以屈光度(D)表示。将 2 次测量的平均值记为受试者的调节幅度,仅纳入右眼调节幅度进行分析。(2)调节灵敏度 使用±2.00 D 翻转拍和视标大小为 20/30 的近用 Snellen 视力表测量双眼调节灵敏度。将视力表放置在眼前 40 cm 处,告知儿童每当翻转后能看清字标时,立即报告“看清”,并翻转另一面镜片继续看视标。每分钟循环周数(cpm)记录为调节灵敏度。(3)眼位和 AC/A 使用综合验光仪(日本 Nidek 株式会社)和 Risley 旋转棱镜(日本 Nidek 株式会社),采用 von Graefe 方法测量远、近水平眼位。使用单个 20/30 视标在远距离(5 m)和近距离(40 cm)处测量。将 6[△]底向上分离棱镜放置在右眼前方,将 12[△]底向内测量棱镜放置在左眼前方,使儿童看到分离的左上、右下 2 个视标。缓慢减少底向内的 Risley 旋转棱镜度数,当儿童报告看到分离的 2 个视标上下对齐,排成 1 条竖线时,记录此时的水平眼位值。使用梯度法和计算法测量 AC/A 比值,梯度法 AC/A 是在看近时(40 cm)在双眼±1.00 D 条件下测量近眼位后计算获得,计算法 AC/A 根据公式 AC/A = 瞳距 + 近视距离 × (近隐斜值 - 远隐斜值)进行计算。

1.2.2 CS 检查 测试在暗室中进行,受试者根据分组情况配戴 DIMS 镜片或单光镜片。测试灯箱自动校准照明光线强度至 85 cd/m²,检查距离为 2.5 m。使用 CSV-1000E(美国 Vector Vision 公司)灯箱对受试者进行 CS 测试,评估并记录右眼 3、6、12、18 cpd 空间频率下的对比度阈值。

1.3 统计学方法

采用 SPSS 27.0 统计学软件进行统计分析。计量资料数据采用 Kolmogorov-Smirnov 检验进行正态性检验,采用 Levene 检验进行方差齐性检验。正态分布数据以 $\bar{x} \pm s$ 表示,组间比较采用独立样本 *t* 检验。非正态分布数据以 $M(Q_1, Q_3)$ 表示。计数资料数据以频数表示,2 个组性别构成比的比较采用 χ^2 检验。采用广义

估计方程对 2 个组视功能和视觉质量数据的差异进行组间和组内比较,随访缺失数据不填补,模型选择非结构化矩阵,采用最大似然估算值。采用双侧检验, $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 2 个组戴镜前后视功能相关指标比较

2 个组戴镜前后不同时间点单眼调节幅度总体比较差异有统计学意义(Wald $\chi^2_{\text{时间}} = 84.435, P < 0.001$),其中 2 个组戴镜后 6 和 12 个月单眼调节幅度均较戴镜前下降,差异均有统计学意义(均 $P < 0.001$);戴镜后 6 个月与 12 个月比较差异均无统计学意义(均 $P > 0.05$)。DIMS 组和单光组戴镜后 12 个月单眼调节幅度分别下降 2.68 D (95%CI: 1.60 ~ 3.75 D) 和 2.82 D (95%CI: 1.81 ~ 3.84 D)。2 个组间调节幅度比较,差异无统计学意义(Wald $\chi^2_{\text{组别}} = 2.385, P = 0.123$) (表 2)。

2 个组戴镜前后不同时间点双眼调节灵敏度总体比较差异有统计学意义(Wald $\chi^2_{\text{时间}} = 48.201, P < 0.001$),其中 2 个组戴镜后 6 和 12 个月调节灵敏度均较戴镜前增加,差异均有统计学意义(均 $P < 0.05$);戴镜后 6 个月与 12 个月比较差异均无统计学意义(均 $P > 0.05$)。2 个组间调节灵敏度比较,差异无统计学意义(Wald $\chi^2_{\text{组别}} = 2.266, P = 0.132$) (表 3)。

2 个组戴镜前后不同时间点远水平眼位和近水平眼位总体比较差异均有统计学意义(Wald $\chi^2_{\text{时间}} = 10.398, 23.947$, 均 $P < 0.01$),其中 DIMS 组戴镜后 12 个月远水平眼位较戴镜前向外漂移 0.68[△] (95%CI: 0.06 ~ 1.25[△]),差异有统计学意义($P < 0.05$);单光组随时间延长变化不大,戴镜后 12 个月与戴镜前相比向外漂移 0.16[△] (95%CI: -0.42 ~ 0.74[△]),差异无统计学意义($P > 0.05$);2 个组近水平眼位随戴镜时间延长向外

表 2 2 个组近视儿童戴镜前后不同时间点调节幅度比较 [M(Q₁, Q₃), D]
Table 2 Comparison of accommodation amplitude between two groups at different time points before and after lens wear in myopic children [M(Q₁, Q₃), D]

组别	眼数	戴镜前	戴镜 6 个月	戴镜 12 个月
DIMS 组	72	18.14(15.38, 20.00)	14.81(13.33, 16.67) ^a	14.29(13.33, 16.67) ^a
单光组	79	18.18(16.45, 20.00)	15.38(13.33, 18.18) ^a	15.38(14.28, 16.67) ^a

注:Wald $\chi^2_{\text{组别}} = 2.385, P = 0.123$; Wald $\chi^2_{\text{时间}} = 84.435, P < 0.001$; Wald $\chi^2_{\text{交互作用}} = 0.079, P = 0.961$ 。与各组内戴镜前比较,^a $P < 0.05$ (广义估计方程) DIMS:多区正向光学离焦
 Note:Wald $\chi^2_{\text{group}} = 2.385, P = 0.123$; Wald $\chi^2_{\text{time}} = 84.435, P < 0.001$; Wald $\chi^2_{\text{interaction}} = 0.079, P = 0.961$ 。Compared with respective baseline,^a $P < 0.05$ (Generalized estimating equation) DIMS: defocus incorporated multiple segments

表 3 2 个组近视儿童戴镜前后不同时间点调节灵敏度比较 [M(Q₁, Q₃), cpm]
Table 3 Comparison of accommodative sensitivity between two groups at different time points before and after lens wear in myopic children [M(Q₁, Q₃), cpm]

组别	眼数	戴镜前	戴镜 6 个月	戴镜 12 个月
DIMS 组	144	10.00(9.00,12.00)	12.00(10.00,14.00) ^a	13.00(10.25,14.00) ^a
单光组	158	10.00(9.00,13.00)	12.00(9.00,14.00) ^a	12.00(9.75,14.00) ^a

注:Wald $\chi^2_{\text{组别}} = 2.266, P = 0.132$; Wald $\chi^2_{\text{时间}} = 48.201, P < 0.001$; Wald $\chi^2_{\text{交互作用}} = 4.452, P = 0.108$ 。与
 各组内戴镜前比较, ^a $P < 0.05$ (广义估计方程) DIMS:多区正向光学离焦
 Note:Wald $\chi^2_{\text{group}} = 2.266, P = 0.132$; Wald $\chi^2_{\text{time}} = 48.201, P < 0.001$; Wald $\chi^2_{\text{interaction}} = 4.452, P = 0.108$ 。
 Compared with respective baseline, ^a $P < 0.05$ (Generalized estimating equation) DIMS: defocus
 incorporated multiple segments

漂移,戴镜后 12 个月 DIMS 组和单光组近水平眼位分
 别较戴镜前向外漂移 1.67[△](95%CI:0.15~3.20[△])和
 1.73[△](95%CI:0.49~2.96[△]),差异均有统计学意义
 (均 $P < 0.05$)。2 个组间远水平眼位和近水平眼位总
 体比较,差异均无统计学意义(Wald $\chi^2_{\text{组别}} = 2.070$ 、
 0.571,均 $P > 0.05$)(表 4)。

2 个组戴镜前后不同时间点梯度性 AC/A 值和计

$\chi^2_{\text{组别}} = 0.578, 0.053$,均 $P > 0.05$)(表 5)。

2.2 2 个组不同空间频率下 CS 比较

2 个组戴镜前后不同时间点在 3、6、12、18 cpd 空间
 频率下的 CS 总体比较,差异均无统计学意义(Wald
 $\chi^2_{\text{组别}} = 1.104, 2.263, 1.861, 3.671$,均 $P > 0.05$;Wald $\chi^2_{\text{时间}} =$
 2.260、5.382、2.573、1.637,均 $P > 0.05$)。CS 在各空间频
 率保持相对稳定,不随戴镜时间的延长发生变化(表 6)。

表 4 2 个组近视儿童戴镜前后不同时间点远水平眼位和近水平眼位比较 ($\bar{x} \pm s, \Delta$)
**Table 4 Comparison of distance and near horizontal eye position between two groups
 at different time points before and after lens wear in myopic children ($\bar{x} \pm s, \Delta$)**

组别	眼数	远水平眼位			近水平眼位		
		戴镜前	戴镜后 6 个月	戴镜后 12 个月	戴镜前	戴镜后 6 个月	戴镜后 12 个月
DIMS 组	144	-1.34±3.33	-1.38±2.47	-2.02±2.43 ^a	-1.92±5.78	-2.60±4.29	-3.60±4.61 ^a
单光组	158	-1.06±2.87	-0.85±2.20	-1.22±2.55	-1.61±4.86	-1.65±4.58	-3.34±4.94 ^a

注:远水平眼位:Wald $\chi^2_{\text{组别}} = 2.070, P = 0.150$; Wald $\chi^2_{\text{时间}} = 10.398, P = 0.006$; Wald $\chi^2_{\text{交互作用}} = 1.632, P = 0.442$ 。近水平眼位:Wald $\chi^2_{\text{组别}} = 0.571, P =$
 0.450;Wald $\chi^2_{\text{时间}} = 23.947, P < 0.001$;Wald $\chi^2_{\text{交互作用}} = 1.724, P = 0.422$ 。与各组内戴镜前比较, ^a $P < 0.05$ (广义估计方程) DIMS:多区正向光学离焦
 Note:Distance horizontal eye position:Wald $\chi^2_{\text{group}} = 2.070, P = 0.150$;Wald $\chi^2_{\text{time}} = 10.398, P = 0.006$;Wald $\chi^2_{\text{interaction}} = 1.632, P = 0.442$ 。Near horizontal eye
 position:Wald $\chi^2_{\text{group}} = 0.571, P = 0.450$;Wald $\chi^2_{\text{time}} = 23.947, P < 0.001$;Wald $\chi^2_{\text{interaction}} = 1.724, P = 0.422$ 。Compared with respective baseline, ^a $P < 0.05$
 (Generalized estimating equation) DIMS: defocus incorporated multiple segments

表 5 2 个组近视儿童戴镜前后不同时间点梯度性 AC/A 和计算性 AC/A 比较
**Table 5 Comparison of gradient AC/A and calculated AC/A between two groups at different time points
 before and after lens wear in myopic children**

组别	眼数	梯度性 AC/A [M(Q ₁ , Q ₃), [△] /D]			计算性 AC/A ($\bar{x} \pm s, \Delta$ /D)		
		戴镜前	戴镜后 6 个月	戴镜后 12 个月	戴镜前	戴镜后 6 个月	戴镜后 12 个月
DIMS 组	144	4.00(2.81,5.88)	3.38(2.50,4.94)	3.00(2.06,4.00) ^a	5.67±2.03	5.41±1.44	5.30±1.60
单光组	158	4.00(2.75,5.00)	3.50(2.50,5.00)	3.25(2.25,4.50) ^a	5.65±1.66	5.55±1.53	5.03±1.57 ^a

注:梯度性 AC/A:Wald $\chi^2_{\text{组别}} = 0.578, P = 0.447$; Wald $\chi^2_{\text{时间}} = 22.001, P < 0.001$; Wald $\chi^2_{\text{交互作用}} = 0.732, P = 0.697$ 。计算性 AC/A:Wald $\chi^2_{\text{组别}} = 0.053, P =$
 0.819;Wald $\chi^2_{\text{时间}} = 13.411, P = 0.001$;Wald $\chi^2_{\text{交互作用}} = 3.045, P = 0.218$ 。与各组内戴镜前比较, ^a $P < 0.05$ (广义估计方程) AC/A:调节性集合与调节比
 值;DIMS:多区正向光学离焦
 Note:Gradient AC/A:Wald $\chi^2_{\text{group}} = 0.578, P = 0.447$; Wald $\chi^2_{\text{time}} = 22.001, P < 0.001$; Wald $\chi^2_{\text{interaction}} = 0.732, P = 0.697$ 。Calculated AC/A:Wald $\chi^2_{\text{group}} =$
 0.053, $P = 0.819$;Wald $\chi^2_{\text{time}} = 13.411, P = 0.001$;Wald $\chi^2_{\text{interaction}} = 3.045, P = 0.218$ 。Compared with respective baseline, ^a $P < 0.05$ (Generalized estimating
 equation) AC/A: accommodation convergence/accommodation; DIMS: defocus incorporated multiple segments

算性 AC/A 值总体比较差异均有
 统计学意义(Wald $\chi^2_{\text{时间}} = 22.001$ 、
 13.411,均 $P < 0.01$),其中 2 个组
 戴镜后 12 个月梯度性 AC/A 值
 均较戴镜前降低,差异均有统计
 学意义(均 $P < 0.05$);单光组戴
 镜后 12 个月计算性 AC/A 值较
 戴镜前降低,差异有统计学意义
 ($P < 0.01$)。2 个组间梯度性 AC/
 A 值和计算性 AC/A 值总体比较
 差异均无统计学意义(Wald

表 6 2 个组近视儿童戴镜前后不同时间点各空间频率下 CS 比较 [M(Q₁, Q₃)]
Table 6 Comparison of CS at different spatial frequencies between two groups at different time points before and after lens wear in myopic children [M(Q₁, Q₃)]

组别	眼数	3 cpd			6 cpd		
		戴镜前	戴镜后 6 个月	戴镜后 12 个月	戴镜前	戴镜后 6 个月	戴镜后 12 个月
DIMS 组	72	1.63(1.49, 1.78)	1.63(1.63, 1.78)	1.63(1.63, 1.78)	1.77(1.70, 1.95)	1.84(1.70, 1.99)	1.70(1.70, 1.84)
单光组	79	1.63(1.45, 1.78)	1.63(1.63, 1.78)	1.63(1.63, 1.78)	1.70(1.55, 1.84)	1.70(1.55, 1.84)	1.70(1.66, 1.84)
组别	眼数	12 cpd			18 cpd		
		戴镜前	戴镜后 6 个月	戴镜后 12 个月	戴镜前	戴镜后 6 个月	戴镜后 12 个月
DIMS 组	72	1.40(1.25, 1.54)	1.40(1.25, 1.54)	1.40(1.25, 1.54)	0.96(0.81, 1.10)	0.96(0.81, 1.10)	0.96(0.68, 1.10)
单光组	79	1.40(1.25, 1.54)	1.40(1.25, 1.44)	1.40(1.25, 1.40)	0.96(0.81, 1.00)	0.96(0.81, 1.00)	0.89(0.64, 1.10)

注: 3 cpd: Wald $\chi^2_{\text{组别}} = 1.104, P = 0.293$; Wald $\chi^2_{\text{时间}} = 2.260, P = 0.323$; Wald $\chi^2_{\text{交互作用}} = 1.707, P = 0.426$. 6 cpd: Wald $\chi^2_{\text{组别}} = 2.263, P = 0.132$; Wald $\chi^2_{\text{时间}} = 5.382, P = 0.068$; Wald $\chi^2_{\text{交互作用}} = 1.504, P = 0.471$. 12 cpd: Wald $\chi^2_{\text{组别}} = 1.861, P = 0.173$; Wald $\chi^2_{\text{时间}} = 2.573, P = 0.276$; Wald $\chi^2_{\text{交互作用}} = 4.767, P = 0.092$. 18 cpd: Wald $\chi^2_{\text{组别}} = 3.671, P = 0.055$; Wald $\chi^2_{\text{时间}} = 1.637, P = 0.441$; Wald $\chi^2_{\text{交互作用}} = 0.094, P = 0.954$ (广义估计方程) CS: 对比敏感度; DIMS: 多区正向光学离焦

Note: 3 cpd: Wald $\chi^2_{\text{group}} = 1.104, P = 0.293$; Wald $\chi^2_{\text{time}} = 2.260, P = 0.323$; Wald $\chi^2_{\text{interaction}} = 1.707, P = 0.426$. 6 cpd: Wald $\chi^2_{\text{group}} = 2.263, P = 0.132$; Wald $\chi^2_{\text{time}} = 5.382, P = 0.068$; Wald $\chi^2_{\text{interaction}} = 1.504, P = 0.471$. 12 cpd: Wald $\chi^2_{\text{group}} = 1.861, P = 0.173$; Wald $\chi^2_{\text{time}} = 2.573, P = 0.276$; Wald $\chi^2_{\text{interaction}} = 4.767, P = 0.092$. 18 cpd: Wald $\chi^2_{\text{group}} = 3.671, P = 0.055$; Wald $\chi^2_{\text{time}} = 1.637, P = 0.441$; Wald $\chi^2_{\text{interaction}} = 0.094, P = 0.954$ (Generalized estimating equation) CS: contrast sensitivity; DIMS: defocus incorporated multiple segments

3 讨论

本研究结果表明配戴 DIMS 镜片对调节幅度、调节灵敏度、近水平眼位、AC/A 以及 CS 均无不利影响; 无论是配戴 DIMS 镜片还是单光镜片, 以上视功能检测指标均随戴镜时间延长表现出一致的趋势。

既往研究表明, 调节幅度受年龄影响, 随年龄增长逐渐下降^[25-26]。但也有研究者提出对于 10 岁以下的儿童, 年龄对调节幅度的影响尚不能确定, 且各项研究测量的不同结果也表明儿童的调节幅度存在较大异质性^[27-28]。本研究结果表明, 无论是配戴 DIMS 镜片还是单光镜片, 调节幅度均随时间延长而逐渐下降, 这与 Lam 等^[19]的研究结果类似。Song 等^[29]在采用角膜塑形镜进行近视控制的研究中, 也发现调节幅度随时间延长而逐渐下降。Ruiz-Pomeda 等^[30]研究发现, 虽然配戴多焦点软性角膜接触镜后调节幅度无显著改变(其认为这可能是多焦点软性角膜接触镜配戴者需付出更多的调节), 但配戴单光镜片的儿童表现出调节幅度下降。因此, 调节幅度的下降更多地被认为是随年龄增长而发生的正常变化。

调节灵敏度可用于评估当调节刺激位于 2 个不同水平时视觉系统快速、准确地改变调节的能力。双眼调节灵敏度反映了视觉系统调节-聚散的相互作用^[31]。在本研究中, DIMS 组和单光组的基线调节灵

敏度分别为 10.00 (9.00, 12.00) 和 10.00 (9.00, 13.00) cpm, 表现出良好的调节-聚散能力。同时, 本研究发现 2 个组的调节灵敏度随戴镜时间的延长而提高, 且 DIMS 组提高更多。既往研究表明, 调节灵敏度会随年龄的增长而提高^[32-33]。学龄期儿童面临着逐年增加的看远(黑板)-看近(教科书)任务, 需要调节和聚散的快速变化^[32]。本研究推测调节灵敏度的提高可能是由于反复地练习远-近调节, 以及多次测量导致对任务做出更快速反应的学习效应。在配戴角膜塑形镜的儿童中, 也发现了类似的趋势^[29]。落在周边视网膜上的刺激可以引起调节反应^[17], 配戴周边离焦镜片减少了周边远视离焦, 并且表现出更对称的周边屈光改变^[34], 这可能会提高调节的准确性。

本研究发现, 戴镜后 12 个月 2 个组间远水平眼位总体比较差异无统计学意义。2 个组近水平眼位表现出一致的向外漂移趋势, 组间差异亦无统计学意义。Lam 等^[19]和 Huang 等^[20]的研究也发现, 配戴周边离焦镜片的儿童与配戴单光镜片的儿童在近水平眼位方面无显著差异。虽然 Lam 等^[19]和 Huang 等^[20]的研究均观察到配戴镜片后的水平眼位向外漂移, 但时间趋势差异无统计学意义。既往纵向研究表明, 随着时间推移, 学龄期儿童的远、近正融合聚散范围均减小, 近水平眼位表现得更加向外^[35]。且由于镜片的棱镜效应, 用框架眼镜矫正的近视儿童在看近时对调节和会

聚的需求更少^[36]。这或许解释了为何在本研究发现了近水平眼位向外漂移。同样,本研究发现 2 个组 AC/A 值均随时间延长显著降低,这可能是近水平眼位更向外,正融合聚散范围减少导致的。但本研究未测量戴镜前后的融合聚散范围,仍需进一步研究。

本研究结果表明,戴镜后 6 和 12 个月,2 个组 CS 水平相较于戴镜前均保持相对稳定。既往研究表明,通过 DIMS 镜片周边离焦区域的视力显著下降,而中心视力不受影响^[37]。Kaymak 等^[38]测试了 8 例成年近视患者配戴 DIMS 和单光镜片后 1 h 通过镜片中央和周边区域的 CS 水平,结果表明中央 CS 不受镜片类型的影响,与单光镜片相比,DIMS 镜片的周边区域 CS 水平下降。Li 等^[39]比较了 50 例近视儿童配戴不同类型离焦镜片后即刻的视觉表现,发现当配戴 DIMS 镜片并从周边区域视物时,在 6~18 cpd 的中高空间频率下,CS 水平显著下降。通常在正常注视状态下,儿童通过镜片中央视物,但由于眼球运动和框架可能的位置移动使得儿童可能通过周边区域视物,长期可能会对儿童的视觉质量产生一定影响。本研究评估了儿童戴镜后 12 个月的 CS 水平,结果表明正常配戴 DIMS 镜片对儿童长期视觉质量无明显不利影响。

本研究仍存在一定局限性:(1)本研究未测量戴镜前后的融合聚散范围和调节反应,这些指标可能有助于解释其他视功能变化的原因以及更全面地了解 DIMS 镜片对视功能的影响。(2)本研究在测量 CS 功能时,要求受试者按照日常戴镜习惯配戴 DIMS 镜片或单光镜片,由于可能存在的近视度数增加,导致在随访测量时视力并不是最佳矫正视力,影响高空间频率 CS 水平。(3)虽然本研究使用的 2 种镜片在外观上难以区分,但不排除有更细心的受试者可能发现所配戴镜片的类型。但本研究分析这种可能性较小,且本研究没有因此退出的受试者,对研究结果无明显影响。(4)本研究在招募受试者时未排除既往使用过近视防控手段的儿童,但从筛选期开始,所有受试者均被要求不得使用其他近视防控手段。目前尚不清楚既往使用过近视防控手段是否在停用之后对视功能和视觉质量仍存在长期影响,有待进一步研究。

综上,本研究结果表明配戴 DIMS 镜片的儿童在视功能方面与配戴单光镜片的儿童表现一致,包括调节幅度、调节灵敏度、远/近水平眼位、AC/A 值和 CS 水平。总体而言,配戴 DIMS 镜片不会对儿童的长期视觉质量产生不利影响。

利益冲突 所有作者均声明不存在利益冲突

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选题及研究设计、研究实施、数据审核;宋雨桐:研究实施、数据审核、论文修改;刘陇黔:研究设计、试验指导、论文修改及定稿

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