

角膜塑形镜治疗区偏位的近视控制影响的研究进展

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【摘要】 角膜塑形镜(OK 镜)作为儿童青少年近视控制的有效手段,其治疗区偏位是临床常见现象。目前对于 OK 镜配戴后治疗区偏位的评估主要基于角膜地形图的切向曲率数据。角膜形态不对称性(角膜散光、8 mm 弦长处平均高度差及角膜不对称向量)是偏位的主要成因。临床中偏位方向常见为颞下。关于偏位对近视控制的影响,部分研究认为偏位量与眼轴增长呈负相关,治疗区偏位可能通过改变中央光学区特性、提升相对瞳孔屈光力的数值与改变其空间分布、诱导正向球面像差降低调节滞后、增强周边视网膜离焦信号的非对称性与模糊度、影响 S 型视锥细胞的激活状态等多重的光学和神经生物学途径影响近视进展;亦有研究显示偏位与眼轴增长无关联或呈正相关。虽然重度偏位可能增加角膜上皮点染风险,但安全性证据尚不一致。未来需通过多中心长期研究,结合人工智能辅助的治疗区标准化评估,明确偏位的安全阈值与主动调控价值,以优化近视控制策略。本文针对 OK 镜治疗区偏位的评价方法、偏位影响因素、近视矫治效果及可能的作用机制与并发症展开系统综述。

【关键词】 角膜塑形镜; 近视控制; 偏位; 治疗区

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Research progress on the influence of decentered orthokeratology treatment zones on myopia control

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【Abstract】 Orthokeratology (OK) lens is an effective method for myopia control in children and adolescents, and decentration of the treatment zone is a common clinical phenomenon. Currently, the assessment of treatment zone decentration following OK lens wear relies primarily on tangential curvature data derived from corneal topography. Corneal morphological asymmetry, including corneal astigmatism, the mean elevation difference at the 8 mm chord, and the corneal asymmetry vector, is identified as the main contributor to decentration. In clinical practice, inferotemporal direction is a common type of decentration. Regarding the impact of decentration on myopia control, findings are divergent. Some studies suggest a negative correlation between the magnitude of decentration and axial elongation. Proposed mechanisms include alterations in the characteristics of the central optical zone, increasing the value of relative corneal refractive power and altering its spatial distribution, inducing positive spherical aberration to reduce accommodative lag, enhancing the asymmetry and blur intensity of peripheral retinal defocus signals, and influencing the activation state of S-cones. These multiple optical and neurobiological pathways may affect myopia progression. Conversely, other research indicates no association, or even a positive correlation, between decentration and axial elongation. Although severe decentration may increase the risk of corneal epithelial staining, evidence regarding its overall safety profile remains inconsistent. Future research should employ long-term, multi-center studies combined with artificial intelligence-assisted standardized assessment of the treatment zone to define the safe threshold of decentration and explore its potential value for active modulation, thereby optimizing myopia control strategies. This

article provides a systematic review focusing on the evaluation methods, influencing factors, myopia control efficacy, potential mechanisms, and complications associated with decentered OK treatment zones.

[Key words] Orthokeratology; Myopia control; Decentration; Treatment zone

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近视作为全球高发的屈光不正性眼病,其低龄化与高度化趋势显著,眼轴过度伸长可引发近视性黄斑变性、视网膜脱离、青光眼等严重并发症,早期干预对儿童青少年近视控制至关重要^[1-4]。目前已采用的近视控制手段包括行为干预、药物治疗与光学治疗等^[5-8]。角膜塑形镜(orthokeratology, OK 镜)是以逆几何设计为主要特征的硬性角膜接触镜,通过夜间佩戴可重塑角膜形态,使角膜中央区形成平坦化治疗区以矫正视力,周边区则产生近视性离焦,是目前公认有效的近视控制手段^[7,9-13]。临床实践中,OK 镜治疗区偏位现象时常发生,偏位会改变离焦区域相对于瞳孔中心的位置及角膜的多焦性,进而影响 OK 镜的近视控制能力,其对近视的控制效果及相关机制目前仍存在争议^[14-15]。本文围绕这一核心问题,系统梳理 OK 镜偏位的定义、评价方法、影响因素、对近视控制效果的影响、作用机制及并发症,以为临床优化验配策略提供参考。

1 OK 镜治疗区偏位的定义与评价方法

1.1 治疗区与偏位的核心定义

配戴 OK 镜后,角膜前表面被重塑为中心平坦、周边相对陡峭的非球面形态,角膜变为多焦角膜,自角膜顶点向周边延伸依次为治疗区与离焦区^[16]。治疗区负责提供清晰的中心视力,离焦区则产生一定的周边视网膜近视性离焦,对延缓近视进展具有重要意义^[15,17-18]。治疗区偏位指治疗区中心与角膜顶点(或瞳孔中心)的偏离距离,是评估 OK 镜配适状态的关键指标。目前主流的治疗区确定方法为:角膜屈光力较基线降低 >0.00 D 的区域,其边界为曲率差值 0.00 D 等值线(± 0.10 D 或 ± 0.25 D,部分研究为 ± 1.00 D)。精准、客观地评估治疗区位置、大小以及偏位量对于研究 OK 镜的光学设计、配适状态、近视控制效果影响因素分析及疗效预测具有重要意义。

1.2 基于角膜曲率差异数据的传统测量方法

本方法通过角膜地形测量仪获取佩戴 OK 镜前后的角膜地形图,将术后地形图与术前地形图曲率数据相减得到角膜屈光力变化的切向曲率差异图,基于该图进行治疗区边界确定与中心定位。具体方法为:标记各径线 0.00 D 等值线作为治疗区边界,将其导入 MATLAB 或 Python 软件拟合为圆或椭圆,圆心即为治疗区中心,其与角膜顶点(0,0)或瞳孔中心的直线距离为偏位量;治疗区大小以治疗区横径(水平线上两边界点间的距离)或拟合圆面积表示^[15,19-22]。该方法可直接反映 OK 镜的塑形效果,且操作简便、可重复性好,是临床与科研中常用的基础评价方法。

1.3 基于治疗后单一时间点的角膜曲率数据的测量方法

本方法仅选取治疗后稳定期的角膜地形图切向曲率图进行分析,无需依赖治疗前基线数据。已有研究证实,治疗区在佩戴 1 个月后相对稳定,多数研究选择治疗后 1 个月作为评估时间点^[20,23]。Sun 等^[23]和 Song 等^[24]采用均值滤波去除噪点,并采用 K-means 聚类算法识别屈光力降低区域^[23-24]。Chen 等^[25]对 10 mm 直径的角膜前表面进行泽尼克多项式拟合,计算各测量点散光值,提出散光值为 0.00 D 的点围成的区域则为治疗区。该方法适用于回顾性研究中基线数据缺失的场景。

1.4 基于深度学习的治疗区识别与参数评估

随着人工智能(artificial intelligence, AI)技术的发展,基于深度学习的治疗区自动化评估方法逐渐成为研究热点。以专家标注的治疗区边界与中心为金标准,采用全卷积网络、Segformer 架构、U-Net 系列神经网络等深度学习方法,基于大量曲率图进行训练后,部分模型治疗区边界识别交并比可高达 0.9808 ,中心点定位与人工标注的偏差仅为 (0.22 ± 0.22) mm,且可同步输出多参数^[26-28]。基于深度学习方法的核心优势为精准、高效、可重复性强,但需注意的是,其训练数据多来自单一中心,且对异常角膜形态(如中央岛、不规则散光)的识别能力尚有不足。

2 OK 镜治疗区偏位的相关影响因素

2.1 角膜形态学因素

多项研究均指出,治疗区偏位以颞下方向最为常见^[17,29-31]。角膜形态的不对称性是导致偏位的主要因素。角膜 8 mm 弦长处对应 OK 镜的定位弧区域,而该区域对 OK 镜的稳定具有重要影响,故研究 8 mm 弦长处的角膜形态意义显著。Li 等^[32]发现角膜散光的 2 条主子午线上 8 mm 弦长处的平均高度差与偏位量呈正相关(标准化 $\beta = 0.599, P < 0.01$)。Ding 等^[33]的研究表明,鼻侧 8 mm 弦长处的角膜曲率与偏位量呈显著负相关($r = -0.154, P = 0.012$),进一步进行亚组分析发现,该结论在鼻侧 8 mm 弦长处的角膜曲率低于 41.00 D 的患者中更为明显。Li 等^[34]的研究表明,偏位组中 8 mm 处鼻颞象限与上下象限之间的 Q 值差异更大,这也解释了临床中 OK 镜偏位方向多为颞下的原因。Chen 等^[29]的团队对角膜不对称向量定义如下:角膜 8 mm 弦长处的高度差为向量的大小,向量的方向为高处指向低处,在角膜散光的 2 条主子午线上分别计算 2 个向量后取其合并向量,该合并向量即为角膜不对称向量,该研究证实,角膜不对称向量的方向与偏位方向显著相关($r =$

0.76, $P < 0.001$); 逐步多因素线性回归证实, 角膜不对称向量的大小显著影响偏位程度(标准化 $\beta = 0.448$, $P = 0.002$)。角膜不对称向量为理解角膜的不对称性提供了更全面的视角。Gu 等^[35]的研究发现, 除角膜形态参数外, 角膜直径本身亦与偏位量相关($\beta = 0.205$, $P < 0.01$)。机器学习广泛应用于临床模型的建立。Xiao 等^[36]采用逻辑回归与 Lasso 回归对可能影响 OK 镜定位的自变量进行深度筛选, 发现年龄、角膜 5 mm 弦长处 $K \times 1$ 、8 mm 弦长处的平均高度差和 7 mm 弦长处 $K \times 2$ 是有效的预测变量。角膜作为一个有机整体, 其形态特征是多参数相互关联、共同作用的结果。临床应综合多参数行建模分析, 以对患者的偏位风险进行精准预判。

2.2 镜片设计与其他因素

Jiang 等^[37]的研究表明, 在戴镜 1 个月后, 对于散光 ≥ 1.50 D 的患者, 佩戴 Toric-OK 镜组治疗区偏位量小于佩戴常规镜片组。另有研究也得到类似的结论^[38-39], 提示环曲设计的 OK 镜可部分补偿角膜散光带来的偏位趋势, 但无法完全避免。Li 等^[20]的研究发现, 在戴镜 1 个月后, 佩戴 VST 设计 OK 镜患者的偏位量大于佩戴 CRT 设计 OK 镜患者 [(0.68 ± 0.30) mm vs. (0.56 ± 0.21) mm], 表明 OK 镜的不同设计类型亦会对其远期定位产生影响。多项研究发现, 对于 CRT 设计的 OK 镜基弧区直径 6 mm 组患者治疗区偏位量显著大于基弧区直径 5 mm 组^[40-41]。大基弧直径镜片可能增加偏位风险, 需通过优化定位弧设计以提升镜片稳定性。除上述因素外, 动态因素如睡眠时的眼睑压力、睡眠姿势、配适状态等也可能显著影响镜片稳定性^[42]。例如, 配适过松易导致镜片滑动偏位, 配适过紧则限制 OK 镜在角膜上正常的滑动范围(1 mm), 二者均可能诱发偏位, 但罕有对此动态因素的量化评估。目前多数结论停留在单因素关联分析, 难以直接指导个性化验配方案制定, 因此这些因素的定量研究方法及其对偏位的影响仍需更深入的探索。

3 OK 镜治疗区偏位对近视控制效果的影响

3.1 有利于减缓眼轴增长的证据

治疗区偏位是否影响眼轴增长尚存争议。Yu 等^[15]和 Guo 等^[43]发现, 偏位 < 0.5 mm 组的眼轴年增长量分别为 0.12 mm 和 (0.36 ± 0.24) mm, 均显著高于偏位 ≥ 0.5 mm 组的 0.08 mm 和 (0.25 ± 0.20) mm^[15, 43]。一项自身左右眼对照研究显示, 中心定位眼(偏位 < 0.5 mm)的眼轴年增长量显著大于偏位眼(0.5 mm \leq 偏位 < 1.5 mm)^[30]。一项 1 年随访研究证实, 轻度偏位组(偏位 < 0.5 mm)、中度偏位组(0.5 mm \leq 偏位 < 1 mm)和重度偏位组(偏位 ≥ 1 mm)的眼轴增长量分别为 (0.26 ± 0.19)、(0.14 ± 0.17) 和 (0.09 ± 0.19) mm^[22]。一项大样本研究亦发现, OK 镜偏位量与戴镜后 12 个月的眼轴增长量呈负相关^[33]。24 个月的长期随访研究进一步证实, 眼轴增长与治疗区偏位量呈负相关, 提示偏位对于眼轴增长的抑制作用具有持续性^[44-45]。此外, 部分研究也证实治疗区偏位可增强 OK 镜的眼轴抑制效果^[30, 40, 46-47]。以上研究支持 OK 镜偏位有利于减缓眼轴增长。

3.2 不利于减缓眼轴增长的证据或二者间“无显著相关性”的证据

Zhang 等^[38]的研究观察到, 在 1 年的随访中, 配戴环曲镜片组患者相较于配戴常规球面镜片组患者的中心定位效果更优、眼轴年增长量更少(0.04 ± 0.13 mm vs. 0.09 ± 0.13 mm, $P = 0.001$); Chen 等^[48]的研究中亦发现重度偏位组(偏位 ≥ 1 mm)的眼轴增长量为 (0.23 ± 0.08) mm, 显著高于轻度偏位组(偏位 < 0.5 mm)的 (0.11 ± 0.07) mm 及中度偏位组(0.5 mm \leq 偏位 < 1 mm)的 (0.11 ± 0.06) mm。另有部分研究发现不同偏位程度组间眼轴增长差异不显著^[23, 37, 49]。

现有结论存在矛盾的本质可能源于治疗区评估方法缺乏统一标准及人群异质性的综合作用。不同研究对于治疗区的确定方法存在差异。治疗区拟合图形的选择(椭圆形或正圆形)与偏位量基准点的设定尚未统一(角膜顶点或瞳孔中心)^[20-22]。尽管主流以差异图 0.00 D 等值线为治疗区边界, 但受边界点容差影响, 不同研究的容差范围不一致(± 0.10 D 或 ± 0.25 D, 部分研究为 ± 1.00 D), 容差的细微差异会导致边界点选择产生系统误差^[16, 21-22, 34]。现有多数研究未按年龄分层分析, 年龄会影响角膜生物力学特性, 进而改变 OK 镜对于角膜的重塑能力^[50-51]。此外, 基线等效球镜度数与基线眼轴长度对于远期眼轴增长的意义显著^[52-54]。综上, 治疗区评估方法的核心参数(拟合图形、基准点、容差)缺乏统一标准, 且人群年龄段、基线等效球镜度数与基线眼轴长度的差异, 可能是导致偏位与近视控制效果相关结论出现分歧的关键原因, 也凸显了建立标准化评估体系的必要性。

4 偏位对于 OK 镜的近视控制效果的影响机制

治疗区偏位影响眼轴增长的机制尚未完全阐明。现有研究提出多种可能的假说以解释偏位可能带来的额外近视控制效益。

4.1 基于现有临床证据

不同研究表明, 瞳孔直径 4 mm 范围内的正屈光力面积和角膜顶点直径 2 mm 内的泽尼克加权离焦均与眼轴增长相关, 偏位会缩小 OK 镜离焦环距角膜中央的距离, 进而减小瞳孔直径 4 mm 范围内的正屈光力面积与增大角膜顶点直径 2 mm 内的泽尼克加权离焦, 最终达到抑制眼轴增长的效果, 其机制尚不明确, 可能由于更多的近视性离焦光线进入眼内所致^[14, 40]。

相对瞳孔屈光力(relative corneal refractive power, RCRP)与眼轴增长呈负相关, 而偏位可显著提升中央角膜(1~2 mm 半径弦长)内的 RCRP, 因此偏位可能通过增加 RCRP 的方式抑制眼轴增长^[22, 31, 55]。此外, RCRP 的空间分布亦会影响眼轴增长, 偏位会改变 RCRP 的对称分布模式, 同时缩短 X50(即 RCRP 曲线达到半峰的半径), 而后者已被证实与眼轴增长显著相关^[56-57]。故可推测偏位通过增加 RCRP 总量与改变其分布模式共同调控眼轴增长信号。

4.2 其他假说

调节滞后会增加周边视网膜远视性离焦, 进而促进眼轴增

长,而正向球面像差可降低调节滞后。增加治疗区偏位与减小治疗区面积均可增加球差,偏位亦可能通过增加正向球差的方式降低调节滞后以减缓眼轴增长,部分研究已证实了偏位量与像差间的相关性^[58-61]。

既往研究表明,高度非球面镜片与多段式离焦镜片均可以抑制近视进展,二者产生的非同轴周边离焦可在周边视网膜上形成模糊像^[62-63]。Su 等^[64]的研究进一步证实,对于非同轴的周边离焦,无论是正向或负向离焦均可以产生相同的近视控制效果。此外,诱导周边高阶像差的镜片与降低周边对比敏感度的漫射镜片亦可抑制眼轴增长,提示眼轴增长抑制信号具有多元化特征^[65-66]。偏位可能通过增加高阶像差、降低周边视网膜的清晰度与对比敏感度的方式进而对眼轴增长实现控制。

纵向色差在近视的发展中具有重要作用^[67]。Taylor 等^[68]的研究表明,位于黄斑中央凹轴位的 S 型视锥细胞可接受短波长光的刺激,并产生抑制眼轴增长的信号,近视患者的 S 型视锥细胞阈值升高。偏位 OK 镜所产生的特殊周边离焦模式可能改变了到达视网膜不同区域的光谱构成,特别是刺激 S 型视锥细胞的短波长光的分布,进而可能影响 S 型视锥细胞的激活状态,这为偏位 OK 镜的近视控制效应提供了一种可能的神经生物学解释,但尚需直接证据。

综上,治疗区偏位可能通过改变中央光学区特性、提升 RCRP 的数值与改变其空间分布、诱导正向球面像差降低调节滞后、增强周边视网膜离焦信号的非对称性与模糊度影响 S 型视锥细胞的激活状态等多重光学和神经生物学途径影响近视进展,而非单一机制。

5 OK 镜治疗区偏位的并发症

5.1 角膜上皮损伤与感染风险

Li 等^[34]的研究报道,重度偏位组(偏位 ≥ 1 mm)角膜上皮点染的发生率高于中心定位组。Guo 等^[69]亦报道了 1 例由于配戴偏位 OK 镜出现角膜上皮水肿的患者。有研究发现偏位与角膜上皮点染间无明显相关性^[70]。此外,多数研究在随访期间未观察到严重的上皮点染及其他并发症。OK 镜佩戴过程中的并发症包括感染性角膜炎、角膜浸润、角膜染色、结膜炎、内皮细胞数量减少等^[71-73]。护理不当、配适不良、个体眼部状况以及环境因素或许是以上并发症发生的主要风险因素,而非治疗区偏位所致。

5.2 视觉质量与主观症状

Takahiro 等^[74]的研究表明,偏位量与高阶像差的均方根值、对数对比敏感度曲线下面积显著相关,与 Xue 等^[17]的研究结论一致。尽管治疗区偏位会增加角膜像差,可能对视觉质量产生潜在影响,但目前尚未有偏位严重影响患者日间视力与生活质量的报道^[75]。

综上,虽然治疗区偏位是 OK 镜临床应用中的常见现象,但明确的“安全”偏位范围尚未建立。目前普遍认为:视力良好、日间视力稳定、角膜健康且患者无不适,一定程度的偏位是可接受的。偏位对角膜生物力学、内皮细胞的影响以及更严重并发症发生率的影响尚不明确,仍需大样本的长期研究来评估其安全性。

6 未来研究方向与临床启示

未来应构建标准化评估体系,基于多中心数据训练 AI 模型,统一治疗区边界定义与偏位参考点,解决研究方法学异质性问题。同时开展大样本多中心的长期随访研究,按年龄、等效球镜度数、角膜参数等进行分层分析,以进一步明确偏位对近视控制效果的影响,并明确不同人群偏位量的允许范围。结合影像学技术(光学相干断层扫描、眼底自发荧光)与神经电生理方法,验证纵向色差、周边视网膜信号调控等机制的因果关系。整合角膜静态因素与动态因素(如眼张力、睡眠习惯等),构建临床实用的偏位风险预测模型,提升 OK 镜验配精准度。

临床中,应优先评估角膜形态,对高偏位风险人群,例如角膜 2 条主子午线上 8 mm 弦长处的平均高度差较大者,可选择环曲 OK 镜片或特殊设计的镜片^[32]。同时,应于每次复查中通过角膜地形图结合 AI 工具监测偏位状态,若出现重度偏位(偏位 ≥ 1 mm)且伴随上皮损伤或视觉质量下降,应及时调整镜片参数。同时对于患者管理,1 mm 以下的偏位可能不影响甚至有利于近视控制,应与患者及家属进行充分沟通,避免过度焦虑,但需强调规范护理的重要性,以降低间接并发症风险。

7 总结

OK 镜目前广泛应用于儿童与青少年的近视控制。临床实践中,治疗区偏位普遍存在。现有研究表明,角膜形态学因素是导致偏位的主要静态因素。关于偏位 OK 镜对近视控制的影响结论尚不统一,尽管有部分研究证明其可能有助于抑制眼轴增长,但仍需补充长期随访的循证医学证据。治疗区偏位可能通过多种途径影响近视进展,而非单一机制。对于偏位 OK 镜的安全性,部分研究提示重度偏位可能增加角膜上皮点染与水肿的风险,因此需加强 OK 镜佩戴期间的规范护理和定期随访。未来应进一步开展多中心研究以评估偏位 OK 镜的近视控制能力,同时建立统一的 OK 镜偏位诊断标准与治疗区评价体系。

利益冲突 所有作者均声明不存在利益冲突

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