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【应用研究】

对比分析阿玛仕 1050RS 自旋补偿 FS-LASIK 与 SMILE 矫正近视散光的临床疗效[△]

肖静 李娜 张蕊 杜改萍

【摘要】目的 对比分析阿玛仕 1050RS 自旋补偿飞秒激光制瓣准分子激光原位角膜磨镶术

作者简介:肖静 (ORCID: 0000-0002-7816-0464),女,1974年9月出生,四川绵阳人,硕士,主治医师。研究方向:眼视光学及眼屈光相关研究。E-mail:juliaoph@126.com

通信作者:杜改萍 (ORCID: 0000-0003-0068-648X),山西大同人,博士后,副主任医师。研究方向:眼角膜疾病、眼屈光及眼视光相关研究。E-mail:glaucoma@163.com

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作者单位:100000 北京市,北京华德眼科医院屈光中心(肖静,李娜,张蕊);266000 山东省青岛市,解放军海军第971医院眼科(杜改萍)

(FS-LASIK)与飞秒激光小切口角膜基质透镜取出术(SMILE)矫正近视散光的临床疗效。方法 选取2021年1月至9月在我院行近视屈光手术的患者113例(203眼)作为研究对象。按手术方式不同将患者分为FS-LASIK组56例(103眼,行自旋补偿FS-LASIK)和SMILE组57例(100眼,行SMILE)。根据术前散光度将两组患者进一步分为低度散光组(散光度 < -2.0 D)和高度散光组(散光度 ≥ -2.0 D)。低度散光组:FS-LASIK组患者38例(70眼),SMILE组患者40例(70眼);高度散光组:FS-LASIK组患者18例(33眼),SMILE组患者17例(30眼)。分别于术前和术后6个月常规检查患者裸眼视力(UCVA)、最佳矫正视力(BCVA)、球镜度、柱镜度并记录与分析。

结果 两组患者术前基线资料,年龄、性别构成、球镜度、柱镜度、BCVA、角膜厚度及角膜曲率比较,差异均无统计学意义(均为 $P>0.05$)。低度散光组:术后SMILE组和FS-LASIK组患者UCVA达到或超过0.8的患眼比例均为100.0%;UCVA达到或超过1.0的患眼比例,SMILE组为90.0%,FS-LASIK组为93.2%,差异均无统计学意义(均为 $P>0.05$)。高度散光组:术后患者UCVA达到或超过0.8的患眼比例,SMILE组为83.3%,FS-LASIK组为87.9%,差异无统计学意义($P>0.05$);UCVA达到或超过1.0的患眼比例,SMILE组为80.0%,FS-LASIK组为84.9%,差异无统计学意义($P>0.05$)。低度散光组:术后SMILE组患眼柱镜度为(-0.39 ± 0.22)D,FS-LASIK组为(-0.32 ± 0.21)D,差异无统计学意义($t=1.249, P=0.147$);高度散光组:术后SMILE组患眼柱镜度为(-0.65 ± 0.33)D,FS-LASIK组为(-0.42 ± 0.28)D,SMILE组高于FS-LASIK组,差异有统计学意义($t=2.583, P=0.014$)。进一步比较柱镜度矫正的可预测性:低度散光组中FS-LASIK组患眼实际矫正柱镜度与预期矫正柱镜度差值为(-0.14 ± 0.12)D,SMILE组为(-0.18 ± 0.16)D,两组差异无统计学意义($t=0.700, P=0.472$);高度散光组中FS-LASIK组患眼实际矫正柱镜度与预期矫正柱镜度差值[(-0.31 ± 0.17)D]低于SMILE组[(-0.46 ± 0.24)D],两组差异有统计学意义($t=2.117, P=0.020$)。结论 阿玛仕1050RS自旋补偿FS-LASIK对于近视散光的矫正效果优于SMILE。 ≥ -2.0 D的高度散光患者选择自旋补偿的FS-LASIK矫治效果较好。

【关键词】 近视;散光;屈光手术;眼球自旋补偿;飞秒激光

【中图分类号】 R779.63

飞秒激光制瓣准分子激光原位角膜磨镶术(FS-LASIK)与飞秒激光小切口角膜基质透镜取出术(SMILE)是目前两种主流的角膜屈光手术。大量研究结果显示,FS-LASIK和SMILE均具有良好的安全性、有效性和可预测性。然而,也有研究人员认为,部分屈光手术患者术后会有散光度残留,导致术后像差增加,影响手术矫正的效果。其中一个重要原因就是手术过程中患者由坐位转为卧位时,大部分人会出现眼球旋转,即眼球自旋,导致手术过程中散光轴向对准发生偏离,术后散光残留,影响术后的视觉效果。研究发现^[1],眼球自旋是影响患者屈光手术散光矫正可预测性的一个重要因素。VisuMax飞秒激光器的SMILE已经获批可用于散光的矫正,但其技术的局限性在于缺乏自旋补偿的手术模式和可定制的手术治疗方案^[2-3],导致散光欠矫。阿玛仕1050RS手术系统的七维眼球跟踪的手术模式可对患者眼球进行主动跟踪进而补偿眼位自旋^[4]。本研究比较阿玛仕1050RS自旋补偿FS-LASIK与SMILE

矫正近视散光的临床疗效,现报道如下。

1 资料与方法

1.1 一般资料 本研究为回顾性临床试验研究。选取2021年1月至9月在我院行近视屈光手术的患者113例(203眼)作为研究对象。按手术方式不同将患者分为FS-LASIK组56例(103眼)和SMILE组57例(100眼)。根据术前散光度将两组患者进一步分为低度散光组(散光度 < -2.0 D)和高度散光组(散光度 ≥ -2.0 D)。低度散光组:FS-LASIK组患者38例(70眼),SMILE组患者40例(70眼);高度散光组:FS-LASIK组患者18例(33眼),SMILE组患者17例(30眼)。本研究遵循《赫尔辛基宣言》所要求的伦理学原则,所有患者均知情并签署知情同意书。

1.2 患者纳入标准和排除标准 纳入标准:(1)年龄18~45岁;(2)近视及散光度稳定1年以上;(3)

角膜形态正常无瘢痕;(4)最佳矫正视力(BCVA) 0.8以上;(5)停戴软性角膜接触镜2周以上、硬性角膜接触镜4周以上。排除标准:(1)年龄 ≤ 18 岁;(2)角膜厚度 $\leq 480 \mu\text{m}$;(3)圆锥角膜或疑似圆锥角膜;(4)严重的干眼症;(5)无眼部活动性炎症或其他眼病,如青光眼、白内障以及眼底病等;(6)患有全身系统性及免疫性疾病。

1.3 方法

1.3.1 自旋补偿 FS-LASIK FS-LASIK 组患者所有手术设计和操作均由同一位医师完成,根据术前显然验光进行手术参数 nomogram 的设计。先用 Visu Max3.0 型全飞秒激光仪制作角膜板层瓣,角膜瓣厚度为 $110 \mu\text{m}$,蒂位于上方,直径 8.1 mm 。在角膜瓣掀开前开启阿玛仕 1050RS 准分子激光机的七维眼球跟踪系统,启动静态自旋跟踪模式,调整头位使眼球自旋度范围在 $-1.5^\circ \sim +1.5^\circ$,术中启动动态眼球自旋跟踪,采用阿玛仕 1050RS 准分子激光治疗仪完成角膜基质层切削。激光光斑直径 0.54 mm ,频率 1050 Hz ,能量 1.0 mJ ,光学区直径 6.5 mm 。

1.3.2 SMILE SMILE 组患者术前进行部分 nomogram 手术设计。患者就位后,直视正上方,适当的头位调整,启动 Visu Max3.0 型全飞秒激光仪,完成基质透镜切削,人工分离出基质透镜层次,用镊子将透镜取出。激光能量 110 mJ ,频率 500 kHz ,基质透镜直径 6.5 mm ,边切 90° ,帽厚度设为 $120 \mu\text{m}$ 。

1.4 观察指标 分别于术前和术后6个月常规检查患者裸眼视力(UCVA)、BCVA、球镜度、柱镜度并记录。

1.5 统计学方法 采用 SPSS 19.0 软件对数据进行分析。计量资料以 $\bar{x} \pm s$ 表示,两组间的比较采用独立样本 t 检验,率的比较采用卡方检验。检验水准: $\alpha = 0.05$ 。

2 结果

2.1 两组患者术前基线资料比较 两组患者术前基线资料,年龄、性别构成、球镜度、柱镜度、BCVA、角膜厚度及角膜曲率比较差异均无统计学意义(均为 $P < 0.05$),两组资料具有可比性(表1)。

表1 两组患者术前基线资料的比较

参数	FS-LASIK 组	SMILE 组	t	P
年龄/岁	25.68 ± 5.25	25.96 ± 6.52	0.359	0.970
性别(男/女)	21/35	25/32	0.473	0.491
球镜度/D	-4.76 ± 2.02	-4.52 ± 1.46	1.037	0.301
柱镜度/D	-1.60 ± 0.69	-1.46 ± 0.56	1.614	0.108
BCVA	1.09 ± 0.21	1.02 ± 0.16	1.060	0.303
角膜厚度/ μm	555.00 ± 21.74	560.00 ± 26.29	-0.445	0.524
角膜曲率/D	43.21 ± 1.54	43.35 ± 1.24	0.149	0.883

2.2 术后两组患眼 UCVA 比较 低度散光组:术后 SMILE 组和 FS-LASIK 组患者 UCVA 达到或超过 0.8 的患眼比例均为 100.0%; UCVA 达到或超过

1.0 的患眼比例,SMILE 组为 90.0%,FS-LASIK 组为 93.2%,差异均无统计学意义(均为 $P > 0.05$)。高度散光组:术后患者 UCVA 达到或超过 0.8 的患眼比例,SMILE 组为 83.3%,FS-LASIK 组为 87.9%,差异无统计学意义($P > 0.05$); UCVA 达到或超过 1.0 的患眼比例,SMILE 组为 80.0%,FS-LASIK 组为 84.9%,差异无统计学意义($P > 0.05$)。

2.3 术后两组患眼柱镜度比较 术后 FS-LASIK 组患眼柱镜度为 $(-0.41 \pm 0.24) \text{ D}$, SMILE 组为 $(-0.47 \pm 0.27) \text{ D}$,差异无统计学意义($t = 0.916$, $P = 0.361$)。进一步按散光分级比较,低度散光组:术后 SMILE 组患眼柱镜度为 $(-0.39 \pm 0.22) \text{ D}$,FS-LASIK 组为 $(-0.32 \pm 0.21) \text{ D}$,差异无统计学意义($t = 1.249$, $P = 0.147$);高度散光组:术后 SMILE 组患眼柱镜度为 $(-0.65 \pm 0.33) \text{ D}$,FS-LASIK 组为 $(-0.42 \pm 0.28) \text{ D}$,SMILE 组高于 FS-LASIK 组,差异有统计学意义($t = 2.583$, $P = 0.014$)。

2.4 两组患眼柱镜度矫正的可预测性比较 进一步比较柱镜度矫正的可预测性:低度散光组中 FS-LASIK 组患眼实际矫正柱镜度与预期矫正柱镜度差值为 $(-0.14 \pm 0.12) \text{ D}$,SMILE 组为 $(-0.18 \pm 0.16) \text{ D}$,两组差异无统计学意义($t = 0.700$, $P = 0.472$);高度散光组中 FS-LASIK 组患眼实际矫正柱镜度与预期矫正柱镜度差值 $[(-0.31 \pm 0.17) \text{ D}]$ 低于 SMILE 组 $[(-0.46 \pm 0.24) \text{ D}]$,两组差异有统计学意义($t = 2.117$, $P = 0.020$)。

3 讨论

角膜屈光手术过程中由于体位的变化会发生眼球自旋,由站位到卧位产生的眼球自旋称为静态眼球旋转,卧位手术切削过程中患者精神紧张等产生的眼球自旋称为动态眼球旋转。研究表明^[1],在 LASIK 手术过程中的眼球静态自旋,自旋度数达 5° 以上的患者比例达 38%;而整个手术过程发生的眼球自旋(静态和动态旋转),自旋度数超过 2° 的患者比例达 68%。当眼球自旋超过 2° 而手术未采取任何自旋补偿模式,会显著影响散光的矫正效果并且可能引入新的像差,出现散光欠矫^[5-6]。散光的欠矫主要由散光轴位的旋转导致,散光轴位的旋转甚至会诱发散光或高阶像差,从而导致术后患眼视觉质量的下降。导致散光轴位旋转的原因包括眼球的静态和动态旋转,眼睑开睑器或负压吸引锥使眼球变形,Kappa 角,角膜术前曲率,术前散光轴以及 SMILE 中透镜取出操作技术等^[7-9],最主要的原因还是缺乏主动眼球自旋补偿的手术模式。

目前对于自旋补偿模式的 FS-LASIK 矫正近视的疗效报道较多,患者术后均获得良好的视觉质量^[10]。Fahd 等^[11]研究发现,自旋补偿模式的 FS-LASIK 不但对于 1.0 D 以上的散光矫治具有优势,对于 -2.0 D 以上的散光矫治,也取得显著的临床疗

效和良好的视觉质量。Arbelaez 等^[12]报道 -2.0 D 以下的散光患者行无眼球跟踪模式的 FS-LASIK, 术后均取得良好的视觉效果, 术后散光度数降到亚临床值范围, 且没有手术源性角膜像差的引入。本研究中, 我们采用阿玛仕 1050RS 准分子激光治疗仪进行 FS-LASIK 矫治近视散光的治疗效果优于上述结果。研究显示, SMILE 术后散光呈欠矫的趋势, 且散光度数越大欠矫度数越大^[13-14]。Pedersen 等^[15]关于 SMILE 矫正散光的研究中, 术前散光度范围在 0.5 ~ 1.0 D 和 3.0 ~ 4.0 D 的患者术后散光低于 0.5 D 的比例分别为 94% 和 63%。本研究, SMILE 组中低度散光组和高度散光组患者术后柱镜度优于上述结果。

目前, 自旋补偿 FS-LASIK 和 SMILE 的研究方向主要集中在术后视力方面。Karaoka 等^[16]对 FS-LASIK 和 SMILE 矫正中度近视合并散光患者的回顾性研究结果显示, 两组患者术后 UCVA 和 BCVA 均取得良好效果。Khalifa 等^[18]对波前像差引导 LASIK 和 SMILE 治疗近视和散光效果进行比较发现, 波前像差引导 LASIK 组患者视觉质量的各项观察指标均优于 SMILE 组, 且术后视觉质量和术前散光度呈正相关。但是对于自旋补偿 FS-LASIK 和 SMILE 两种术式矫治近视散光的比较研究相对较少。Ganesh 等^[19]的一项关于两种手术矫治低至中度近视的研究(30 眼)结果显示, LASIK 组患者术源性散光为 (1.21 ± 0.85) D 与 SMILE 组 (1.02 ± 0.43) D 差异无统计学意义。而在 Pietila 等^[20]的调查中, 高度近视患者 SMILE 组术源性散光显著高于 FS-LASIK 组。Chan 等^[21]比较了眼球旋转补偿模式 FS-LASIK 和 SMILE 矫正散光的效果, 发现 FS-LASIK 组患眼的 UCVA 优于 SMILE 组, 且 SMILE 组患眼术后的残留散光高于 FS-LASIK 组, 尤其是中高度散光组患眼的残留散光(平均 1.58 D)显著高于低度散光组的残留散光(平均 0.54 D)。

本研究结果中, 低度散光组: FS-LASIK 组和 SMILE 组患眼的术后散光差异不明显; 高度散光组: FS-LASIK 组患眼术后散光显著低于 SMILE 组, 与上述研究基本一致。分析可能原因是当眼球自旋度小的患者行 SMILE, 即使术后散光欠矫, 但是残留散光度数较低时不足以影响术后散光矫正; 高度散光患者, 即使术中发生仅仅几度的眼球自旋, 散光轴向对准的微小误差也会导致较大的散光残留。同时我们在 SMILE 过程中, 通过观察患者眼球自旋度, 并进行适当的头位调整和 10% 的 nomogram 手术设计, 虽然术后散光的矫正效果优于其他学者针对不进行眼球自旋补偿 SMILE 的结果, 但是对于 ≥ -2.0 D 的高度散光患者, 其散光矫正效果仍然低于自旋补偿 FS-LASIK 的患者。

本研究具有一定的局限性, 样本量偏少, 术后随访时间短, 对于眼球自旋度与散光矫正效果的关系

以及角膜像差和散光欠矫的关系未做相关性研究, 在以后的研究中我们将进一步补充完善这方面的数据。

综上所述, 阿玛仕 1050RS 自旋补偿 FS-LASIK 对于近视散光的矫正效果优于 SMILE。 ≥ -2.0 D 的高度散光患者选择自旋补偿的 FS-LASIK 矫治效果较好。

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Comparison of clinical efficacy between AMARIS 1050RS cyclotorsion-compensation femtosecond laser-assisted in situ keratomileusis and small incision lenticule extraction for myopic astigmatism

XIAO Jing¹, LI Na¹, ZHANG Rui¹, DU Gaiping²

1. Department of Ophthalmology, Refractive Centers of Beijing Huade Ophthalmic Hospital, Beijing 100000, China

2. Department of Ophthalmology, the PLA No. 971 Hospital of Navy, Qingdao 266000, Shandong Province, China

Corresponding author: DU Gaiping; E-mail: glaucoma@163.com

[Abstract] Objective To compare the clinical effect of AMARIS 1050RS cyclotorsion-compensation femtosecond laser-assisted in situ keratomileusis (FS-LASIK) and small incision lenticule extraction (SMILE) for myopic astigmatism.

Methods A total of 113 patients (203 eyes) who underwent refractive surgery in our hospital from January to September 2021 were enrolled in this study. According to the surgical method, these patients were divided into the FS-LASIK group (56 patients, 103 eyes, with cyclotorsion-compensation FS-LASIK) and the SMILE group (57 patients, 100 eyes, with SMILE). According to the preoperative astigmatism, these patients were further divided into the low astigmatism group (astigmatism < -2.0 D) and the high astigmatism group (astigmatism ≥ -2.0 D). The low astigmatism group included 38 patients (70 eyes) from the FS-LASIK group and 40 patients (70 eyes) from the SMILE group. The high astigmatism group included 18 patients (33 eyes) from the FS-LASIK group and 17 patients (30 eyes) from the SMILE group. The uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), sphere, and cylinder were checked and analyzed before and 6 months after operation. **Results** There were no significant differences in preoperative baseline data such as age, gender composition, sphere, cylinder, BCVA, corneal thickness, and corneal curvature between the FS-LASIK group and the SMILE group (all $P > 0.05$). In the low astigmatism group, 100.0% of eyes had the UCVA better than or equal to 0.8 after operation, and the percentage of eyes with postoperative UCVA ≥ 1.0 was 90.0% in the SMILE group and 93.2% in the FS-LASIK group ($P > 0.05$). In the high astigmatism group, the percentage of eyes with postoperative UCVA ≥ 0.8 was 83.3% in the SMILE group and 87.9% in the FS-LASIK group, and there was no significant difference between the two groups ($P > 0.05$); the percentage of eyes with postoperative UCVA ≥ 1.0 was 80.0% in the SMILE group and 84.9% in the FS-LASIK group, and there was no significant difference between the two groups ($P > 0.05$). Among the patients with preoperative astigmatism < -2.0 D, the postoperative cylinder was (-0.39 ± 0.22) D in the SMILE group and (-0.32 ± 0.21) D in the FS-LASIK group, and there was no significant difference between the two groups ($t = 1.249, P = 0.147$). Among the patients with preoperative astigmatism ≥ -2.0 D, the postoperative cylinder was (-0.65 ± 0.33) D in the SMILE group and (-0.42 ± 0.28) D in the FS-LASIK group, and the difference between the two groups was statistically significant ($t = 2.583, P = 0.014$). Among the patients with preoperative astigmatism < -2.0 D, the mean deviation of the actual and expected cylinder correction was (-0.14 ± 0.12) D in the FS-LASIK group and (-0.18 ± 0.16) D in the SMILE group, and there was no significant difference between the two groups ($t = 0.700, P = 0.472$). Among the patients with preoperative astigmatism ≥ -2.0 D, the mean deviation of the actual and expected cylinder correction was significantly higher in the SMILE group [(-0.46 ± 0.24) D] than that in the FS-LASIK group [(-0.31 ± 0.17) D] ($t = 2.117, P = 0.020$). **Conclusion** AMARIS 1050RS cyclotorsion-compensation FS-LASIK is better than SMILE in astigmatism correction. The patients with astigmatism ≥ -2.0 D improve better after the cyclotorsion-compensation FS-LASIK.

[Key words] myopia; astigmatism; refractive surgery; cyclotorsion-compensation; femtosecond laser