·临床报告·

SMILE和FS-LASIK联合monovision治疗近视合并老视的疗效比较

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引用:张婉婷,高芬. SMILE和FS-LASIK联合monovision治疗近视合并老视的疗效比较. 国际眼科杂志 2021;21(7):1288-1291

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收稿日期:2020-11-13 修回日期:2021-05-31

摘要

目的:观察用monovision原理设计治疗近视合并老视在飞秒激光小切口基质透镜取出术(SMILE)和飞秒激光辅助原位角膜磨镶术(FS-LASIK)应用后的远视力、近视力。

方法:在我院行monovision设计进行近视激光治疗的近视合并老视患者,SMILE组10例20眼,年龄45±2.83岁,屈光度-5.42±1.74D;FS-LASIK组9例18眼,年龄45±1.97岁,屈光度-5.60±1.84D。组间及组内对比手术前后单眼及双眼远、近视力。

结果:术前SMILE组:主视眼:远视力0.05±0.04,近视力0.36±0.15;客观眼:远视力0.35±0.11,近视力0.16±0.11;双眼:远视力0.05±0.05,近视力0.18±0.09。术前FS-LASIK组:主视眼:远视力0.09±0.09,近视力0.42±0.17;客观眼:远视力0.44±0.11,近视力0.19±0.10;双眼:远视力0.03±0.04,近视力0.19±0.11。两组间术前各参数均无差异(P>0.05)。术后SMILE组:主视眼:远视力为-0.01±0.06,近视力为0.32±0.14;客观眼:远视力0.16±0.18,近视力0.12±0.12;双眼:远视力-0.04±0.07,近视力0.10±0.11。术后FS-LASIK组:主视眼:远视力0.03±0.03,近视力0.45±0.13;客观眼:远视力0.20±0.15,近视力0.24±0.12;双眼:远视力0.01±0.03,近视力0.22±0.09。术后两组双眼远视力、近视力均有差异(t=-2.383,P=0.034;t=-2.424,P=0.027)。SMILE组术后主视眼远视力(t=3.914,P=0.004),客观眼远视力(t=4.894,P=0.001),双眼远视力(t=4.870,P=0.001),双眼近视力(t=2.388,P=0.041)均优于术前预计视力。FS-LASIK组术后客观眼远视力优于术前(t=4.068,P=0.004)。

结论:对近视角膜屈光手术的患者,用monovision设计治疗老视,SMILE和FS-LASIK均能达到预计效果,但SMILE术后的双眼远、近视力更优。

关键词:monovision;飞秒激光小切口基质透镜取出术;飞秒激光辅助原位角膜磨镶术
DOI:10.3980/j.issn.1672-5123.2021.7.33

Observation on the clinical efficacy of monovision therapy in SMILE and FS-LASIK

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Received:2020-11-13 Accepted:2021-05-31

Abstract

• AIM: To observe the clinical efficacy between SMILE and FS-LASIK with monovision design to treat the presbyopia.

• METHODS: According to the methods of operation, the presbyope with myopia were divided into two groups, who received the treatment with monovision design. SMILE group had 10 patients (20 eyes), the average age were 45±2.83 years old and myopia degree was -5.42±1.74D. FS-LASIK group had 9 patients (18 eyes), the average age were 45±1.97 years old and myopia degree was -5.60±1.84D. The far vision and the near vision of monocular and binocular of preoperative and postoperative between two groups were observed.

• RESULTS: SMILE group in preoperative: the preoperative subjective eye's far visual acuity was 0.05±0.04, the subjective eye's near vision was 0.36±0.15; the objective eye's far visual acuity was 0.35±0.11, the objective eye's near visual acuity was 0.16±0.11; the binocular far visual acuity was 0.05±0.05 and the binocular near visual acuity was 0.18±0.09. Preoperative FS-LASIK group: preoperative subjective eye's far visual acuity was 0.09±0.09, subjective eye's near vision was 0.42±0.17; the objective eye's far visual acuity was 0.44±0.11, the objective eye's near visual acuity was 0.19±0.10; the binocular far visual acuity was 0.03±0.04 and the binocular near visual acuity was 0.19±0.11. The result of before surgery between the two groups had no statistical difference (P > 0.05). Postoperative SMILE group: the far visual acuity of subjective eye was -0.01±0.06, the near vision of subjective eye was 0.32±0.14; the far visual acuity of objective eye was 0.16±0.18, the near visual acuity of objective eye was 0.12±0.12; the binocular far visual acuity was -0.04±0.07, the binocular near visual acuity was 0.10±0.11. Postoperative FS-LASIK group: the far visual acuity of subjective eye was 0.03±0.03, the near

vision of subjective eye was 0.45±0.13; the far visual acuity of objective eye was 0.20±0.15, the near visual acuity of objective eye was 0.24±0.12; the binocular far visual acuity was 0.01±0.03 and the binocular near visual acuity was 0.22±0.09. The comparisons of after surgery between the two groups were statistical differences in the binocular far vision (t = -2.383, P = 0.034), and the binocular near vision (t = -2.424, P = 0.027). The vision comparisons between preoperative and postoperative in SMILE group, there were all statistically significant in the far visual acuity of subjective eye (t=3.914, P=0.004), the far visual acuity of objective eye (t=4.894, P=0.001), the binocular far visual acuity (t=4.870, P=0.001) and the binocular near visual acuity (t=2.388, P=0.041). That means the vision of postoperative was better than the expected vision before operation. The far visual acuity of objective eye were compared between preoperative and postoperative in FS-LASIK group, the differences was statistically significant (t=4.068, P=0.004).

• CONCLUSION: To presbyope with myopia, the treatment of SMILE and FS-LASIK all can get expected results with monovision design. But the patients after SMILE would have better binocular far vision and binocular near vision than after FS-LASIK.

• KEYWORDS: monovision; small incision lenticule extraction; femtosecond laser *in situ* keratomileusis

Citation: Zhang WT, Gao F. Observation on the clinical efficacy of monovision therapy in SMILE and FS-LASIK. *Guoji Yanke Zazhi* (*Int Eye Sci*) 2021;21(7):1288-1291

0 引言

随着年龄的增加,晶状体调节功能下降,视近不清晰或不持久这种情况的发生势必会给40岁以上的人们带来困扰以及生活质量的下降[1]。据估计,到2020年将会有21亿人受到这种困扰[2-3]。目前,对老视的治疗有配戴眼镜、多焦点人工晶状体植入、角膜植入物、巩膜植入物等多种方式,但每种方式都各有利弊,其中准分子激光原位角膜磨镶术联合monovision设计治疗也成为一种治疗老视的方式,并已被证明其有效性和安全性[4]。目前,随着角膜屈光手术的发展,飞秒激光小切口基质透镜取出术(small incision lenticule extraction,SMILE)因其创伤小,安全性和有效性以及保留更好的角膜生物力学等优点被广大近视患者所接受[5-6],monovision联合SMILE用于治疗近视合并老视的报道较少,本研究就针对monovision联合SMILE和monovision联合飞秒激光辅助原位角膜磨镶术(femtosecond laser *in situ* keratomileusis,FS-LASIK)矫治近视合并老视的患者术后视远视近的视力进行分析,现报告如下。

1 对象和方法

1.1 对象 回顾性研究2015-05/2020-10在我院行近视角膜屈光手术的患者中,符合角膜屈光手术适应证,矫正视力≥0.8,愿意接受monovision设计的近视合并老视的患者。monovision联合SMILE手术的近视伴老视患者10例20眼,年龄45±2.83岁,屈光度-5.42±1.74D,monovision联合FS-LASIK手术的近视伴老视患者9例18眼,年龄45±1.97岁,屈光度-5.60±1.84D。两组一般资料比较,差异均无统计学意义(P>0.05)。本研究已得到医院伦理委员会的批准,研究过程遵循《赫尔辛基宣言》的原则并获得研究对象的知情同意。

1.2 方法

1.2.1 术前检查 术前对患者进行术前的常规检查,包括常瞳验光、角膜地形图、眼前节分析PENTACAM、角膜生物力学corvis-st、裂隙灯、眼底,主视眼用孔洞法测量3次,确定主视眼,测量单眼及双眼的调节幅度,正相对调节和负相对调节,老视附加度数,以及患者的远近视力,最后试患者的耐受度,在客观眼上下加+1.50D,测量患者远近视力,调整下加度数,直至患者有满意的双眼远视力和双眼近视力的最大下加度数,就是monovision设计的客观眼要保留的屈光度。

1.2.2 手术方法及术后处理

1.2.2.1 monovision联合SMILE组 术前局部麻醉,常规消毒铺巾,采用VisuMax飞秒激光治疗仪,负压吸引固定眼球,边吸引边引导患者注视,确定中心,中心定位良好,根据预先输入参数进行激光切削,先做透镜后表面,再做角膜帽,最后在12:00位做2mm的边切口,分离透镜,平衡液冲洗囊袋,吸血海绵平复边切口。

1.2.2.2 monovision联合FS-LASIK组 术前局部麻醉,常规消毒铺巾,用VisuMax飞秒激光治疗仪制作角膜瓣,吸引环固定眼球,根据预先设置的参数制作角膜瓣,分离角膜瓣,用准分子激光MEL 80治疗仪进行激光切削,冲洗,角膜瓣复位,配戴角膜绷带镜。

1.2.2.3 术后处理 两组患者术后均给予左氧氟沙星滴眼液4次/日,氟米龙滴眼液6次/日,每3d减少一次,溴芬酸钠滴眼液2次/日,玻璃酸钠滴眼液4次/日。

观察术前monovision设计的矫正视力以及40cm处的近视力,术后3~18mo单眼和双眼裸眼远视力(uncorrected distance visual acuity,UDVA)以及40cm处裸眼近视力(uncorrected neat visual acuity,UNVA)。远近视力以LogMAR视力记录。

统计学分析:采用统计学软件SPSS21.0进行统计学分析,计量资料数据以 $\bar{x}\pm s$ 的形式表示,相同手术方式术前术后比较用配对样本 t 检验,两组间比较先进行方差方程的Levene检验,再采用独立样本 t 检验。P<0.05为差异有统计学意义。

2 结果

2.1 monovision联合SMILE组视力 SMILE组术前主视眼远视力为0.05±0.04,客观眼远视力0.35±0.11,双眼远视力0.05±0.05,双眼近视力0.18±0.09;术后主视眼远视力为-0.01±0.06,客观眼远视力0.16±0.18,双眼远视力-0.04±0.07,双眼近视力0.10±0.11。术后主视眼的远视力、客观眼的远视力、双眼的远视力、双眼的近视力与术前比较,差异均有统计学意义(P=0.004、0.001、0.001、0.041),见表1。

2.2 monovision联合FS-LASIK组视力 FS-LASIK组术前客观眼远视力0.44±0.11,术后客观眼远视力0.20±0.15,差异有统计学意义(P=0.004),其余各项视力术前术后比较差异均无统计学意义(P>0.05),见表2。

2.3 SMILE和FS-LASIK两组各参数之间的比较 先进行方差方程的Levene检验,只有术后双眼远视力方差不

表 1　SMILE 组患者术前术后视力的比较　($\bar{x}\pm s$,LogMAR)

视力	术前	术后	t	P
主视眼远视力	0.05±0.04	−0.01±0.06	3.914	0.004
主视眼近视力	0.36±0.15	0.32±0.14	1.089	0.304
客观眼远视力	0.35±0.11	0.16±0.18	4.894	0.001
客观眼近视力	0.16±0.11	0.12±0.12	0.851	0.417
双眼远视力	0.05±0.05	−0.04±0.07	4.870	0.001
双眼近视力	0.18±0.09	0.10±0.11	2.388	0.041

表 2　FS-LASIK 组患者术前术后视力的比较　($\bar{x}\pm s$,LogMAR)

视力	术前	术后	t	P
主视眼远视力	0.09±0.09	0.03±0.03	1.606	0.147
主视眼近视力	0.42±0.17	0.45±0.13	−0.623	0.551
客观眼远视力	0.44±0.11	0.20±0.15	4.068	0.004
客观眼近视力	0.19±0.10	0.24±0.12	−2.308	0.051
双眼远视力	0.03±0.04	0.01±0.03	1.810	0.108
双眼近视力	0.19±0.11	0.22±0.09	−1.500	0.172

表 3　SMILE 组与 FS-LASIK 组术前术后各参数之间的比较　$\bar{x}\pm s$

参数	SMILE 组	FS-LASIK 组	t	P
年龄(岁)	45±2.83	45±1.97	−0.174	0.864
术前屈光度(D)	−5.42±1.74	−5.60±1.84	−0.328	0.747
术前主视眼远视力(LogMAR)	0.05±0.04	0.09±0.09	−1.063	0.303
术前主视眼近视力(LogMAR)	0.36±0.15	0.42±0.17	−0.835	0.415
术前客观眼远视力(LogMAR)	0.35±0.11	0.44±0.11	−1.718	0.104
术前客观眼近视力(LogMAR)	0.16±0.11	0.19±0.10	−0.648	0.526
术前双眼远视力(LogMAR)	0.05±0.05	0.03±0.04	0.804	0.432
术前双眼近视力(LogMAR)	0.18±0.09	0.19±0.11	−0.285	0.779
术后主视眼远视力(LogMAR)	−0.01±0.06	0.03±0.03	−1.858	0.081
术后主视眼近视力(LogMAR)	0.32±0.14	0.45±0.13	−2.085	0.052
术后客观眼远视力(LogMAR)	0.16±0.18	0.20±0.15	−0.618	0.545
术后客观眼近视力(LogMAR)	0.12±0.12	0.24±0.12	−2.011	0.060
术后双眼远视力(LogMAR)	−0.04±0.07	0.01±0.03	−2.383	0.034
术后双眼近视力(LogMAR)	0.10±0.11	0.22±0.09	−2.424	0.027

齐($F=6.816$,$P=0.018$),其余各参数方差齐性检验均 $P>0.05$。术前 SMILE 组和 FS-LASIK 组各参数比较,差异均无统计学意义($P>0.05$)。术后两组双眼远视力、近视力比较,差异均有统计学意义($t=-2.383$,$P=0.034$;$t=-2.424$,$P=0.027$),见表 3。

3 讨论

随着电子设备的普及,网络办公已成为大部分人们的工作模式,40 岁以后,随着调节能力的下降,视近开始出现视疲劳、不持久、看不清等症状。为了帮助这部分人解除苦恼,一种可能的治疗选择是 monovision 激光治疗,该技术可以校正优势眼的看远距离和非优势眼的视近。以前曾报道 monovision 联合 LASIK 治疗近视患者中的老视[7-8],但其满意度各有不同[9-10]。随着 SMILE 以微创、无瓣等优势被广大患者接受,有少量报道 monovision 联合 SMILE 矫治近视患者中的老视,但是 SMILE 和 FS-LASIK 之间到底有没有差异未见有报道。

本研究结果显示,monovision 联合 SMILE 治疗组术后各项指标均优于术前预计视力,所有远视力(主视眼、客观眼、双眼)和双眼近视力差异有统计学意义。SMILE 手术治疗近视的有效性和安全性已有很多报道[6,10]。monovision 联合 SMILE 矫正近视中的老视是安全有效的。国外的学者报道结果[11],对 72 例 144 眼近视伴老视患者进行 monovision 联合 SMILE 的屈光手术治疗,术后 6mo 时双眼远视力达到或超过预测视力的达 98%,双眼近视力达到或超过预测视力达到 94%,使用 SMILE 的 micro-monovision 屈光手术可增强老视患者的视近功能,在 83% 患者中观察到 UDVA 为 0.0LogMAR(20/20)或更高。国内学者周行涛等研究结果,所有患者术后的近视力均大于预期的达 100%,近视力大于等于 20/25 的占 83.3%[12]。本研究结果较周行涛团队视力稍差,可能是因为患者年龄与入组人数有差异造成的。

Monovision 联合 FS-LASIK 组研究结果显示:只有客观眼远视力术后优于术前预测,其余各观察参数比较无明显差异。FS-LASIK 联合 monovision 的治疗未见有报道,但以前对 LASIK 联合 monovision 曾有报道[10],术后眩光和对比敏感度显著降低,屈光度大约在-1.74±0.59D;与此同时 Garcia-Gonzalez 等[13]研究 LASIK 单眼视矫正术后双眼对比敏感度稍有下降。

两组比较,所有双眼近视力及双眼远视力 SMILE 组更优。原因:非球面切削,球差引入小,景深增加。虽然老视会增加,但容忍度较 FS-LASIK 高。术前 SMILE 组和 FS-LASIK 组之间各种视力差异均无统计学意义,术后两组双眼远视力差异有统计学意义($t=-2.383$,$P=0.034$),术后双眼近视力差异有统计学意义($t=-2.424$,$P=0.027$)。所以,两组患者术后均能获得很好的视觉质量。SMILE 组术后双眼的远视力和近视力均比 FS-LASIK 组好,可能原因有:(1)干眼方面。因为角膜神经损伤的差别,FS-LASIK 术后干眼更加明显[14],与之相比,SMILE 手术后角膜敏感性几乎没有变化。许多研究报告了 SMILE 相对于 FS-LASIK 在泪膜破裂时间、眼表疾病指数评分、角膜敏感性和角膜基底膜下神经密度方面的优势[15-17]。而老视常发生在 43~45 岁以后,干眼也随年龄增长发病率随之增加。泪膜的不稳定势必造成视力和视觉质量上的差异。(2)屈光度矫正的准确性和稳定性方面。虽然

有观点认为[18-19]SMILE 组和 FS-LASIK 组的术后平均屈光度结果无显著差异。但还有学者研究表明:术后 3a 的等效球镜在±0.50D 以内的比例,SMILE 和 FS-LASIK 分别为 80%、65%[20]。而另一个 3a 的观察显示[21]:SMILE 组的术后屈光结果比 FS-LASIK 组更稳定,SMILE 组的平均等效球镜从+0.13±0.79D 变为-0.01±0.76D,FS-LASIK 组从+0.46±0.95D 变为-0.43±0.82D。SMILE 治疗组的平均等效球镜为 0.14D(SMILE 治疗前后平均等效球镜的配对样本 t 检验,$t=0.546$,$P=0.59$),在 FS-LASIK 处理的眼睛中为 0.89D(FS-LASIK 治疗前后平均等效球镜的配对样本 t 检验,$t=5.765$,$P=0.00$)。两者矫正近视的精确性和稳定性的差异也引起 SMILE 组效果更好。(3)高阶像差方面。诸多学者均有报道 SMILE 术后球差和总高阶像差变化小[22-25],相比 FS-LASIK,前表面球差和整个角膜的球差 SMILE 组变化较小,而角膜后表面的球差 SMILE 和 FS-LASIK未见明显差异,视觉质量更好。所以术后双眼远视力 SMILE 组更好。

对近视及正视患者的老视治疗仍然需要大家不断地努力和探索,单眼视的角膜激光矫正虽然在矫正范围、双眼视功能等方面有局限,但是它方法简单,易操作,方便开展。本研究的不足之处是入选病例数量较少,缺少对比敏感度和立体视方面的观察,还有待长时间的研究。

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