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全飞秒激光与飞秒激光辅助 Lasik 治疗高度近视患者的效果 及对角膜曲率、视觉质量的影响分析 *

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摘要 目的:探究全飞秒激光与飞秒激光辅助 Lasik 治疗高度近视患者的效果,并分析治疗对患者角膜曲率、视觉质量的影响。**方法:**选择 2020 年 7 月至 2022 年 7 月在我院接受治疗的 120 例(240 眼)高度近视患者为研究对象,按照随机数字表法结合患者意愿的方式将其区分为研究组($n=60$,接受飞秒激光辅助 Lasik 治疗)与对照组($n=60$,接受全飞秒激光治疗),对比两组患者术前术后调制传递函数截止频率(MTF)值及客观散射指数(OSI)、角膜曲率变化、屈光度差异、视力情况差异,统计两组患者各类并发症发生率并进行比较。**结果:**(1)两组患者术前 MTF 值及 OSI 组间差异无统计学意义($P>0.05$),术后研究组患者的 MTF 值和 OSI 值均明显低于对照组,差异具有统计学意义($P<0.05$);(2)术前、术后 90 d 两组患者的最佳矫正视力组间差异无统计学意义($P>0.05$),但组内前后比较两组患者的最佳矫正视力均较术前有明显提高($P<0.05$);(3)术前两组患者的角膜前表面曲率以及后表面曲率组间差异均无统计学意义($P>0.05$),术后 90 d 时开展组间比较,研究组患者角膜前表面曲率中 K1、K2 以及 Km 值均明显低于对照组($P<0.05$),但后表面曲率中 K1、K2 以及 Km 值组间差异无统计学意义($P>0.05$);进一步分析显示,两组患者术前术后前表面曲率 K1、K2 以及 Km 值有明显变化($P<0.05$),后表面曲率 K1、K2 以及 Km 值前后差异无统计学意义($P>0.05$);(4)统计研究组患者共出现弥漫性层间反应 2 例,感染 1 例,角膜内生 1 例,并发症总发生率 3.33%(4/120),明显高于对照组的 0.00%(0/120)($P<0.05$)。**结论:**全飞秒激光和飞秒激光辅助 Lasik 术对高度近视均具有较好的治疗效果,相比于全飞秒激光术,飞秒激光辅助 Lasik 术在改善患者视觉质量方面明显占优,但其并发症发生率同样更高,全飞秒激光术术后视觉质量,但安全性更高,建议临床上结合患者实际情况灵活选择术式,以改善高度近视患者预后。

关键词:全飞秒激光;飞秒激光辅助 Lasik;高度近视

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Analysis of the Effect of All Femtosecond Laser and Femtosecond Laser Assisted Lasik in the Treatment of High Myopia and Its Influence on Corneal Curvature and Visual Quality*

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ABSTRACT Objective: To investigate the effect of all femtosecond laser and femtosecond laser assisted Lasik in the treatment of high myopia, and analyze the effect of treatment on corneal curvature and visual quality of patients. **Methods:** 120 patients (240 eyes) with high myopia who were treated in our hospital from July 2020 to July 2022 were selected as the study subjects. They were divided into the study group ($n=60$, receiving femtosecond laser-assisted Lasik treatment) and the control group ($n=60$, receiving full femtosecond laser treatment) according to the method of random number table combined with the wishes of the patients. The cutoff frequency (MTF) value, objective scattering index (OSI), changes in corneal curvature, refraction, and visual acuity between the two groups, and the incidence of various complications in the two groups were compared. **Results:** (1) There was no significant difference between the two groups in preoperative MTF value and OSI value ($P>0.05$). After operation, the MTF value and OSI value of patients in the study group were significantly lower than those in the control group, and the difference was statistically significant ($P<0.05$); (2) There was no statistically significant difference in the best corrected visual acuity between the two groups before and 90 days after operation ($P>0.05$), but the best corrected visual acuity of the two groups before and after operation was significantly higher than that before operation ($P<0.05$); (3) There was no statistically significant difference between the two groups in the corneal anterior surface curvature and posterior surface curvature before surgery ($P>0.05$). After 90 days of surgery, the values of K1, K2 and Km in the anterior surface curvature of the cornea

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in the study group were significantly lower than those in the control group ($P < 0.05$), but there was no statistically significant difference between the groups in the values of K1, K2 and Km in the posterior surface curvature ($P > 0.05$); Further analysis showed that the values of anterior surface curvature K1, K2 and Km had significant changes before and after surgery in the two groups ($P < 0.05$), while the values of posterior surface curvature K1, K2 and Km had no significant difference before and after surgery ($P > 0.05$); (4) The total incidence of complications in the study group was 3.33% (4/120), which was significantly higher than that in the control group 0.00% (0/120) ($P < 0.05$). **Conclusion:** Both femtosecond laser and femtosecond laser-assisted Lasik have good therapeutic effects on high myopia. Compared with full femtosecond laser, femtosecond laser-assisted Lasik is obviously superior in improving the visual quality of patients, but its complication rate is also higher. Although full femtosecond laser has poor effect, it is more safe. It is recommended to select the surgical method flexibly according to the actual situation of patients, To improve the prognosis of patients with high myopia.

Key words: Full femtosecond laser; Femtosecond laser assisted Lasik; High myopia

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前言

近些年随着人们生活习惯的改变、电子设备的普及,以及不良用眼习惯的出现,近视的发病率呈现逐年升高趋势,已有的研究指出,近视属于屈光不正的一种,当个体眼睛放松时,平行于视轴进入眼镜的光线未聚焦于视网膜上,而是聚焦在视网膜前,导致个体视物不清^[1,2]。流行病学研究指出,我国属于近视高发地区,年轻人近视患病率达到 80%-90%,位居全球第一,且近些年患病年龄有降低趋势^[3],有研究指出,至 2050 年,全球近视人数将突破 48 亿,约占全球人口的 50%^[4]。近视目前已成为全球性的公共卫生问题,虽然当前尚无治愈近视的方式,但近视可控、可防且可矫正,通过手术方式可有效改善高度近视患者临床症状,对提高其矫正视力具有积极意义^[5,6]。学者 McDonald 于 1987 年首次将 193 nm 的 ArF 准分子激光应用于近视的治疗中,开创了准分子激光角膜表面切削术^[7],1990 年学者 Pallikaris 则将角膜磨镶术与准分子激光角膜切削术相结合,创造了准分子激光原位角膜磨镶术(Lasik)^[8],上述术式因具有安全性高、患者术中疼痛轻微且术后视力恢复快等优势,目前已成为矫正高度近视最主要的手术方式。虽然已有较多学者证实了全飞秒激光和飞秒激光辅助 Lasik 在高度近视患者中的效果肯定^[9],但针对两种术式优劣的比较目前临床上仍然较少。本文就两种术式在高度近视治疗中的优劣进行了比较,为后续高度近视患者术式选择提供了一定理论借鉴,现详述如下。

1 资料与方法

1.1 一般资料

选择 2020 年 7 月至 2022 年 7 月在我院接受治疗的 120 例(240 眼)高度近视患者为研究对象,按照随机数字表法结合患者意愿的方式将其区分为研究组($n=60$,接受飞秒激光辅助 Lasik 治疗)与对照组($n=60$,接受全飞秒激光治疗)。研究已报医院伦理委员会批准开展。

纳入标准:(1)年龄位于 18-45 岁之间;(2)临床资料齐全完备;(3)咽部屈光度数稳定;(4)散光度数 $\leq -2.00D$;(5)术前最少 7 d 未佩戴软性角膜接触镜,最少 21 d 未佩戴硬性角膜接触镜;(6)视网膜无明显功能异常。

排除标准:(1)确诊为圆锥角膜;(2)并发精神疾病患者;(3)妊娠或哺乳期女性;(4)严重干眼或眼表异常者;(5)并发角膜

炎、虹膜炎影响手术者;(6)并发糖尿病或全身性免疫系统疾病者;(7)并发影响角膜伤口愈合疾患者;(8)纳入其他未结题临床研究。

1.2 干预方法

术前两组患者均接受常规眼部检查,使用裂隙灯显微镜对患者眼前节、裸眼视力、最佳矫正视力、眼压进行检测,散瞳后对患者眼底进行检测,排除变性区、裂孔或视网膜脱落等眼底疾病,对存在视网膜变性或裂孔者,需预选接受视网膜光凝治疗。

对照组患者接受全飞秒激光术治疗,常规眼部消毒后,患者取平卧位,使用表面麻醉剂滴眼后开眼睑,负压吸引环吸附眼球后,使用飞秒激光器对角膜进行切削,设置频率为 500 kHz,设置能量为 110-150 nJ,光学区为 6.5 mm,角膜帽直径为 7.5 mm,厚度为 120 μm ,记录切削比,扫描透镜后、前表面、周边小切口,分离角膜透镜,对角膜基质囊袋进行冲洗后恢复平整。术后第 1 d 患者使用妥布霉素地塞米松滴眼液滴眼,4 次/d,而后间隔 3 d 每日频次减少 1 次,连续使用 10 d,左氧氟沙星滴眼液和玻璃酸钠滴眼液每日 4 次,连续使用 14 d。

研究组患者则接受飞秒激光辅助 Lasik 术治疗,常规眼部消毒后,患者取平卧位,使用表面麻醉剂滴眼后开眼睑,负压吸引环吸附眼球后,使用飞秒激光机进行角膜瓣制作,角膜瓣参数设置如下:厚度 95-110 μm ,直径 9.0 mm,蒂角度 45°,蒂方向 12 点,瓣边切角 70°,制瓣 10 min 后,使用准分子激光机进行切削,设置直径为 6.5 mm,切削后使用生理盐水冲洗角膜瓣和基质层间,复位角膜瓣并再次冲洗,取开睑器,术后使用裂隙灯检查角膜瓣对合良好后,使用妥布霉素地塞米松滴眼液滴眼,频次与对照组一致。

1.3 观察指标及评测标准

对比两组患者术前、术后 7 d 时的调制传递函数截止频率 (Modulation transfer function, MTF) 值及客观散射指数 (Objective scatter index, OSI)值^[10],对比两组患者术前、术后 90 d 时的最佳矫正视力^[11],对比两组患者术前、术后 90 d 时的前后角膜曲率变化,统计两组患者术后 90 d 内各类不良反应^[12]发生率并进行组间比较。

1.4 统计学方法

采用 SPSS 24.0 软件进行统计学分析,对于服从正态分布且方差齐性的计量资料比较采用 t 检验,以(均数 $\pm$ 标准差)描述,计量资料比较采用卡方检验,以例(%)表示, $P < 0.05$ 为差异

具有统计学意义。

2 结果

2.1 两组患者一般临床资料比较

表 1 两组患者一般临床资料比较

Table 1 Comparison of general clinical data of two groups of patients

General clinical data		Research group(n=60)	Control group(n=60)	t/ χ^2	P
Gender	male [n(%)]	37(61.67)	38(63.33)	0.132	0.716
	female [n(%)]	23(38.33)	22(36.67)		
Average age($\bar{x} \pm s$, year)		26.29 $\pm$ 3.11	26.34 $\pm$ 3.18	1.549	0.125
Average body weight($\bar{x} \pm s$, kg)		67.01 $\pm$ 10.39	66.98 $\pm$ 10.21	0.44	0.661
Mean eye axis($\bar{x} \pm s$, mm)		23.61 $\pm$ 0.62	23.58 $\pm$ 0.59	0.326	0.698

2.2 两组患者治疗前后 MTF 及 OSI 变化

两组患者术前 MTF 值及 OSI 组间差异无统计学意义

纳入两组患者的一般临床资料如性别、平均年龄、平均体重、平均眼轴等并实施组间差异性比较,结果显示两组患者上述资料组间差异无统计学意义($P>0.05$),见表 1。

($P>0.05$), 术后研究组患者的 MTF 值和 OSI 值均明显低于对照组,差异具有统计学意义($P<0.05$),见表 2。

表 2 两组患者治疗前后 MTF 及 OSI 变化($\bar{x} \pm s$)

Table 2 Changes of MTF and OSI in two groups of patients before and after treatment($\bar{x} \pm s$)

Groups	Number of eyes	MTF cut off(c/deg)		OSI	
		Preoperative	7 day after operation	Preoperative	7 day after operation
Research group	120	34.26 $\pm$ 10.21	27.15 $\pm$ 10.21	0.86 $\pm$ 0.41	1.81 $\pm$ 1.10
Control group	120	33.98 $\pm$ 11.21	30.98 $\pm$ 11.14	0.91 $\pm$ 0.39	2.31 $\pm$ 1.68
t	-	0.202	2.741	0.963	2.728
P	-	0.840	0.007	0.337	0.007

2.3 两组患者治疗前后最佳矫正视力比较

术前、术后 90 d 两组患者的最佳矫正视力组间差异无统

计学意义($P>0.05$),但组内前后比较两组患者的最佳矫正视力均较术前有明显提高($P<0.05$),见表 3。

表 3 两组患者治疗前后最佳矫正视力比较($\bar{x} \pm s$)

Table 3 Comparison of the best corrected vision between the two groups before and after treatment($\bar{x} \pm s$)

Groups	Number of eyes	Preoperative	90 d after operation	t	P
Research group	120	0.04 $\pm$ 0.05	-0.02 $\pm$ 0.03	3.757	<0.001
Control group	120	0.05 $\pm$ 0.04	-0.02 $\pm$ 0.01	7.971	<0.001
t	-	1.711	0.000	-	-
P	-	0.088	1.000	-	-

2.4 两组患者治疗前后角膜曲率变化

术前两组患者的角膜前表面曲率以及后表面曲率组间差异均无统计学意义($P>0.05$),术后 90 d 时开展组间比较,研究组患者角膜前表面曲率中 K1、K2 以及 Km 值均明显低于对照组($P<0.05$),但后表面曲率中 K1、K2 以及 Km 值组间差异无统计学意义($P>0.05$);进一步分析显示,两组患者术前术后前表面曲率 K1、K2 以及 Km 值有明显变化($P<0.05$),后表面曲率 K1、K2 以及 Km 值前后差异无统计学意义($P>0.05$),见表 4、表 5。

2.5 两组患者并发症发生率统计

统计研究组患者共出现弥漫性层间反应 2 例,感染 1 例,

角膜内生 1 例,并发症总发生率 3.33%(4/120),明显高于对照组的 0.00%(0/120)($P<0.05$),见表 6。

3 讨论

高度近视是引起视力损害的重要原因之一,甚至有致人失明的危险,虽然近些年各国近视患病率有多差异,但整体看全球近视患病率持续维持升高态势^[14,15]。临床实践指出,近视在人群中普遍易感,无特殊易感性,在东亚国家,近视已达到流行程度,其中中国学生群体近视发病率远超其他所有种族群体,对国内人群生活质量造成了明显影响^[16,17]。近视的定义为眼镜眼轴长度高于正常水平,或眼镜整体光学系统折射力过大,依据

患者屈光组成差异,可区分为轴性近视和屈光性近视^[18]。当前近视的主要矫正措施仍依赖手术治疗,而不同矫正手术在治疗效果上也存在较大差异,如何根据患者情况选择最佳术式成为眼科医师研究热点方向^[19]。

表 4 两组患者治疗前后角膜前表面曲率变化($\bar{x} \pm s, D$)

Table 4 Changes of corneal anterior surface curvature before and after treatment in two groups of patients($\bar{x} \pm s, D$)

Observation indicators	Preoperative				90 d after operation			
	Research group	Control group	t	P	Research group	Control group	t	P
K1	42.88± 3.26	42.86± 3.05	0.236	0.659	36.32± 1.56 ^a	38.98± 2.15 ^a	5.326	<0.001
K2	44.36± 1.32	44.41± 1.29	0.665	0.514	37.59± 1.62 ^a	39.21± 2.01 ^a	4.559	<0.001
Km	43.82± 1.23	43.79± 1.36	1.023	0.098	37.56± 1.26 ^a	39.65± 1.32 ^a	6.325	<0.001

Note: compared with the same group was performed before surgery, ^aP<0.05.

表 5 两组患者治疗前后角膜后表面曲率变化($\bar{x} \pm s, D$)

Table 5 Changes of corneal posterior surface curvature before and after treatment in two groups($\bar{x} \pm s, D$)

Observation indicators	Preoperative				90 d after operation			
	Research group	Control group	t	P	Research group	Control group	t	P
K1	-6.13± 0.27	-6.21± 0.31	0.659	0.465	-6.11± 0.26	-6.15± 0.31	0.223	0.985
K2	-6.49± 0.28	-6.51± 0.31	0.558	0.521	-6.46± 0.26	-6.50± 0.31	0.551	0.512
Km	-6.28± 0.28	-6.26± 0.31	0.469	0.645	-6.26± 0.27	-6.25± 0.31	0.326	0.668

表 6 两组患者并发症发生率统计[n(%)]

Table 6 Statistics of complication rate of patients in two groups

Groups	Number of eyes	Diffuse interlayer reaction	Infected	Corneal endogenesis	Total incidence
Research group	120	2(1.67)	1(0.83)	1(0.83)	4(3.33)
Control group	120	0(0.00)	0(0.00)	0(0.00)	0(0.00)
χ^2	-	-	-	-	4.068
P	-	-	-	-	0.044

研究通过设立对照分组的方式发现,相较于全飞秒激光手术治疗的对照组患者,接受飞秒激光辅助 Lasik 治疗的研究组患者术后 MTF 值和 OSI 值均明显低于对照组,两组患者的最佳矫正视力均较术前提高。这提示飞秒辅助激光 Lasik 治疗高度近视具有更好的效果,患者术后视觉质量改善更为明显。本文作者分析认为,当前高度近视矫正手术较为多样,矫正后的眼球周边视力和视觉质量无法与正常眼球相比,术后高度近视患者即使裸眼视力达到 1.0 甚至 1.0 以上,仍有部分患者存在视物模糊、光晕、夜间视力降低等情况,分析出现上述现象的原因为手术增加了患者的像差,导致视网膜成像质量降低,进而降低了患者视觉质量^[20,21]。文中的全飞秒激光虽然能够通过切削角膜达到改善高度近视患者视觉质量的目的,但手术过程中会对角膜表面及角膜基质进行重塑,导致其力学结构出现变化,术后角膜后表面会出现一定程度的前凸,影响患者视觉质量,而飞秒激光辅助 Lasik 则能够通过制作角膜瓣有效避免该现象,分析这也是研究组患者术后视觉质量优于对照组的重要原因^[22-24]。

文中进一步就两组患者术后角膜曲率变化进行了分析,结

果显示,术后研究组患者角膜前表面曲率中 K1、K2 以及 Km 值均明显低于对照组,而后表面曲率中 K1、K2 以及 Km 值组间差异无统计学意义。本文作者分析认为,Lasik 手术具有安全、有效、可预测高、稳定性强等优势,因更符合角膜的解剖及生理状态因而应用效果较好,但因为手术是通过切削角膜发挥作用,故患者的角膜前表面形态会发生变化,而飞秒激光与 Lasik 的联合应用使得手术的有效性进一步提高^[25,26]。已有的研究指出,飞秒激光具有作用时间短但功率高的特点,运用到 Lasik 角膜瓣切割中,能够保留更多的角膜基质床,这为后续最大程度保留角膜生物力学结构奠定了基础,因而相较单纯全飞秒激光,飞秒激光辅助 Lasik 术在改变患者角膜曲率中明显更低^[27,28]。

但飞秒激光辅助 Lasik 手术并非没有缺陷,文中最后并发症发生率的统计比较显示,研究组患者术后并发症发生率明显高于对照组,本文作者分析认为,之所以出现该结果,其原因多与 Lasik 术会较飞秒激光造成更明显的创伤有关。已有的研究指出,Lasik 手术因会对角膜前表面形态产生影响,患者在术后有出现角膜膨隆的风险,而全飞秒手术对角膜造成的损伤较

小,并无上述风险^[29]。一项针对139眼开展的对照研究也证实了该结论^[30],指出Lasik手术会对患者角膜造成一定损伤,飞秒激光的加入虽然有助于改善患者术后视觉质量,但患者角膜损伤仍大于全飞秒激光,建议予以重视。

综上所述,全飞秒激光和飞秒激光辅助Lasik术对高度近视均具有较好的治疗效果,相比于全飞秒激光术,飞秒激光辅助Lasik术在改善患者视觉质量方面明显占优,但其并发症发生率同样更高,全飞秒激光术虽然效果欠佳,但安全性更高,建议临床上结合患者实际情况灵活选择术式,以改善高度近视患者预后。

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