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· 临床研究 ·

调Q激光与手术切除治疗口腔黏膜黑斑后的复发率比较:一项回顾性队列研究

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【摘要】目的 比较755 nm调Q激光与手术切除治疗口腔黏膜黑斑后的复发率。**方法** 本研究已通过单位伦理委员会审查批准，并获得患者知情同意。采用回顾性队列研究设计，纳入2019年1月—2021年8月在上海交通大学医学院附属第九人民医院口腔黏膜病科门诊接受调Q激光或手术切除治疗的口腔黏膜黑斑患者，收集患者的一般资料、临床特征和随访病史。将治疗后1年复发率作为主要结局指标，长期不良反应发生率作为安全性评价指标，采用Kaplan-Meier法分析两组间的1年无复发率。**结果** 本研究共纳入了57例患者，其中16例患者接受了手术切除治疗，41例患者接受了调Q激光治疗，两组人口统计学和临床特征基线无显著差异。手术切除组所有患者均未观察到口腔黏膜黑斑的复发(0%)，而调Q激光组有12例(29.27%)患者出现复发，平均复发时间为治疗后6.08个月，复发与吸烟($P = 1.000$)、胃肠道息肉($P = 1.000$)、纵型黑甲($P = 0.187$)、家族史($P = 0.552$)、治疗次数($P = 0.567$)或是否多发($P = 0.497$)均无相关性。与手术切除相比，调Q激光治疗口腔黏膜黑斑1年复发的比值比为4.41，95%置信区间为1.27-15.24($P = 0.020$)。手术切除组中有3例患者(18.75%)报告损害切除处出现凹陷和疤痕，而调Q激光组没有患者报告长期不良反应(0%)($P = 0.019$)。**结论** 与手术切除相比，调Q激光治疗口腔黏膜黑斑的优势在于长期不良反应率较低，但复发率相对较高，在治疗前需与患者沟通两种方法的优劣，以助临床决策。

【关键词】 口腔黏膜黑斑；调Q激光；手术切除；随访；复发；不良反应；凹陷；疤痕



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Recurrence rate of oral melanotic macule treated with Q-switched alexandrite laser versus surgical excision: a retrospective cohort study SUN Kai, SHI Linjun, SHEN Xuemin. Department of Oral Medicine, Shanghai Ninth Peoples Hospital, Shanghai Jiao Tong University School of Medicine; College of Stomatology, Shanghai Jiao Tong University; National Center for Stomatology; National Clinical Research Center for Oral Diseases; Shanghai Key Laboratory of Stomatology; Shanghai Research Institute of Stomatology, Shanghai 200011, China

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[Abstract] **Objective** To compare the recurrence rates between 755 nm Q-switched alexandrite laser (QSAL) treatment and surgical excision of oral melanotic macules (OMM). **Methods** This study was reviewed and approved by the Ethics Committee, and informed consent was obtained from the patients. A retrospective cohort study was designed to collect demographic and clinical characteristics and follow-up data from patients with OMM. Patients who received QSAL or surgical excision in the Department of Oral Medicine, Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine from January 2019 to August 2021 were included. The one-year recurrence rate was in-

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vestigated as the primary outcome. Long-term adverse reaction rates were investigated as safety indicators. Kaplan-Meier analyses were performed to analyze the recurrence-free rates between the groups. **Results** A total of 57 patients were enrolled in this study. 16 patients underwent surgical excision, and 41 underwent QSAL. The baseline demographic and clinical characteristics between the groups were not significantly different. No recurrence (0%) of OMM was observed in the surgical excision group, while in the QSAL group, the macule recurred in 12 patients (29.27%). The average duration of recurrence was 6.08 months after treatment. Recurrence was not found to be associated with smoking ($P = 1.000$), gastrointestinal polyps ($P = 1.000$), longitudinal melanonychia ($P = 0.187$), family history ($P = 0.552$), treatment sessions ($P = 0.567$) or multiple macule lesions ($P = 0.497$). Compared with treatment with surgical excision, the odds ratio of recurrence for treatment with QSAL was 4.41, with a 95% confidence interval of 1.27-15.24 ($P = 0.020$). In the surgical excision group, 3 patients (18.75%) reported depressions and scars on the lesion, while no long-term adverse reactions (0%) were reported in the QSAL group ($P = 0.019$). **Conclusion** Compared with surgical excision, the advantage of QSAL is the low long-term adverse reaction rate, while the disadvantage is the relatively high one-year recurrence rate. It is necessary to communicate the advantages and disadvantages of the two methods with OMM patients to assist in clinical decision-making.

【Key words】 oral melanotic macule; Q-switched alexandrite laser; surgical excision; follow-up; recurrence; adverse reaction; depression; scar

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口腔黏膜黑斑(oral melanotic macule, OMM)是一种良性、无症状的口腔黏膜色素沉着性疾病,好发于下唇和牙龈^[1-2],在口腔黏膜活检的局灶性色素性疾病中,OMM最常见^[3]。OMM可以发生在任何年龄,患者平均发病年龄为40.83岁,女性发病率更高^[4-5]。OMM的病因尚不清楚,临床表现为均匀、棕色至黑色的损害,通常小于1 cm,可单发或多发,多发性OMM提示患者可能罹患系统性疾病,如Peutz-Jeghers综合征、Laugier-Hunziker综合征等^[6-11]。尽管OMM无严重不良后果,但患者通常会因美观需求来院就诊。目前,OMM的常规治疗方法包括手术切除和激光。手术切除通常不会复发,但可能会出现疤痕或畸形,部分患者不能接受,并且手术切除不适用于多发性OMM^[12]。近年来,调Q激光(Q-switched alexandrite laser, QSAL)已逐渐成为OMM治疗的另一种主要方法,其不仅可用于单发性OMM的治疗,对于多发性OMM的临床效果亦令人满意^[13-14]。然而,目前尚缺乏高质量临床研究来比较手术切除和激光治疗的优劣。本研究拟比较QSAL和手术切除治疗OMM的1年复发率和长期不良反应,为临床制定OMM治疗策略提供参考。

1 资料和方法

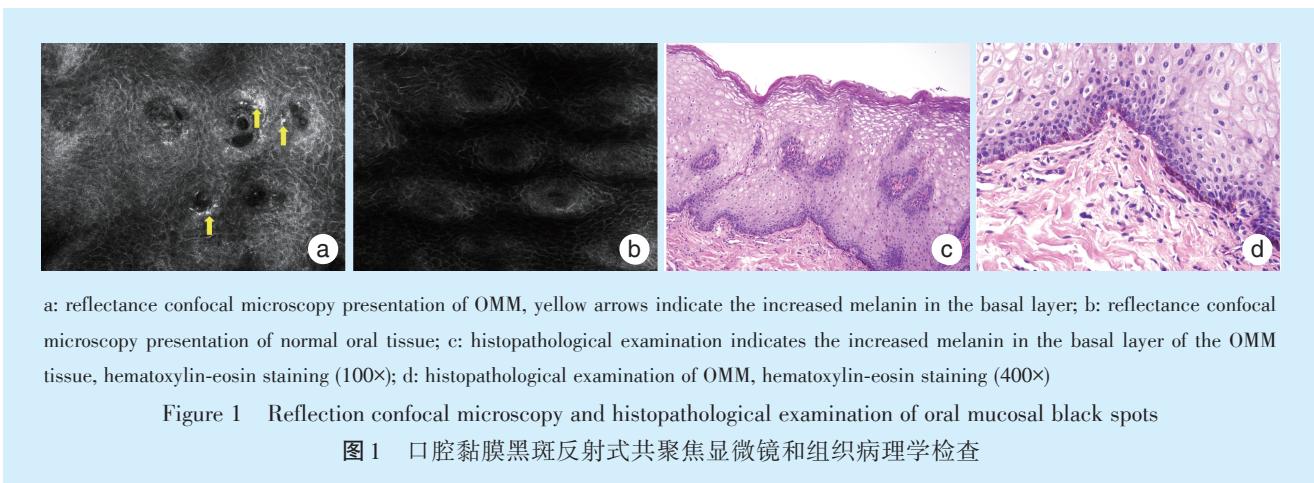
1.1 研究对象

本研究经上海交通大学医学院附属第九人民医院伦理委员会批准(批准号:SH9H-2021-T230-2),选取2019年1月-2021年8月口腔黏膜病科门诊治疗且有相关医学资料留存的OMM患者开展此回顾性队列研究。纳入标准:(1)临床表现为表面光滑、均质的OMM;(2)反射式共聚焦显微镜(Vivascope 3000, Lucid, 美国)影像显示固有层乳头周围见高度反射的细胞(图1a&1b)或组织病理学(图1c&1d)诊断为OMM;(3)OMM采用了手术切除或755 nm QSAL(Cynosure, 美国)治疗;(4)具有复发和不良反应的详细数据。排除标准:(1)患者的OMM在1年内接受过其他治疗;(2)疑似黑色素痣或黑色素瘤;(3)局部或全身存在感染。

从病史记录和临床照片中收集人口统计学和临床信息。采用可将颜色从白到黑区分为20种不同色深的灰度比色卡在自然光下人为对黑斑进行颜色深度评价,同时收集治疗后的随访病史。

1.2 分组及治疗方案

将入选的OMM患者根据所接受的不同治疗方案分为QSAL治疗组和手术切除组,所有激光治疗或



手术切除均由同一位医生完成。QSAL治疗的参数包括:(1)光斑直径,3 mm;(2)短脉冲宽度,50 ns;(3)脉冲频率,1 Hz;(4)能量密度,6.6~7.4 J/cm²;(5)手柄输出端到治疗部位组织距离,49 mm。激光治疗的范围为OMM损害周围外延1 mm,所有接受QSAL治疗的患者在治疗后即刻损害处均出现了“白霜反应”。手术切除的过程包括使用了手术刀在黑斑边缘外延1 mm进行损害切除,深度约3 mm,并进行了仔细对位缝合,行组织病理学检查。两组患者均被告知了避免抓挠治疗部位,避免日晒。

1.3 安全性与疗效评价

在本研究中,主要结局指标为治疗后一年复发率,当原治疗部位重新出现色素则定义为复发。若患者接受了多次激光治疗,一年复发率的时间起点以最后一次激光治疗时开始计算。由于OMM治疗后短期内可能出现的不良反应已较为明确,而治疗后长期不良反应尚缺乏关注,因此本研究的安全性评价指标为长期不良反应率,包括但不限于治疗区域出现疼痛、麻木、凹陷或疤痕等。

1.4 统计学分析

运用SPSS 26.0进行数据分析,运用GraphPad Prism 7统计作图。使用成组t检验或Mann-Whitney U检验对年龄、体重指数、病程、颜色深度等指标进行比较,使用 χ^2 检验或Fisher确切概率法对计数资料进行分析,Kaplan-Meier法比较两组患者的复发率,log-rank法计算复发的比值比和95%置信区间。 $P < 0.05$ 认为具有统计学意义。

2 结 果

2.1 入组病例情况

共获60例患者的临床资料,经入选标准筛选

后共纳入57例OMM患者。41例患者接受了QSAL治疗,16例患者接受了手术切除治疗。对患者的分组和治疗随访流程见图2。两组治疗比例最高的部位均为唇部(QSAL组97.56% vs. 手术切除组93.75%, $P = 0.486$)。在接受手术切除OMM的患者中,9例患者(56.25%)为单发的OMM,接受了损害的完整切除,7例患者OMM多发,在多个黑斑中选取了部位较为隐蔽的单个黑斑进行完整切除,行组织病理学检查。在QSAL治疗组中,OMM单发和多发分别为23例(56.10%)和18例(43.90%)。37例患者接受了单次激光治疗,2例患者接受了2次激光治疗,另有2例患者接受了3次激光治疗。

两组间的年龄、性别、体重指数、吸烟、饮酒、病程时间、每天日晒时间、是否使用唇膏、经胃肠镜检查明确的胃肠道息肉、纵型黑甲、家族史、颜色深度、伴随用药等基线数据未发现显著性差异,两组资料具有可比性,基线资料见表1。

2.2 一年复发率

在接受手术切除治疗的患者中,未出现OMM的复发(0%),而在QSAL治疗组中有12例患者(29.27%)出现了复发,治疗后复发的平均时间为(6.08±4.06)个月。复发患者的特征如表2所示,代表性病例见图3。OMM的复发与吸烟($P = 1.000$)、胃肠道息肉($P = 1.000$)、纵型黑甲($P = 0.187$)、家族史($P = 0.552$)、治疗次数($P = 0.567$)或是否多发($P = 0.497$)均无相关性。与手术切除相比,QSAL治疗后OMM复发的比值比为4.41,95%置信区间为1.27-15.24($P = 0.020$,图4)。

2.3 长期不良反应

在本研究中,3例接受手术切除OMM患者(18.75%)在随访中出现了治疗后出现局部凹陷和疤痕,而QSAL治疗组中没有患者出现长期不良反

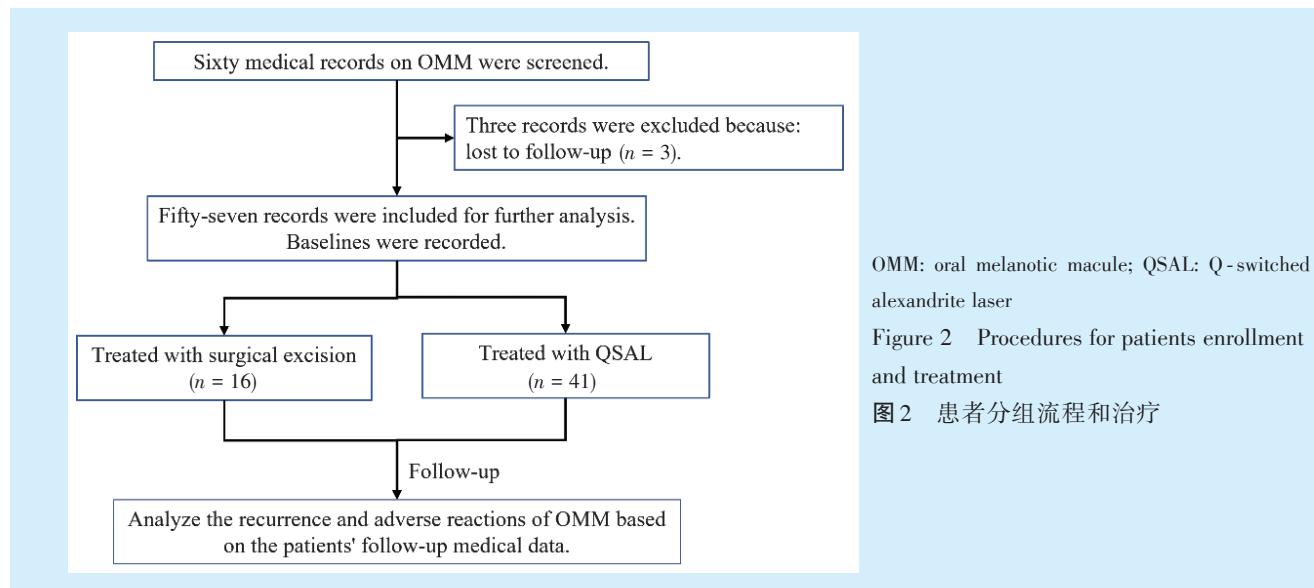


表1 纳入患者人口学和临床特征
Table 1 Demographic and clinical characteristics of the patients in this study

Items	Surgical excision (n = 16)	Q-switched alexandrite laser (n = 41)	$\bar{x} \pm s$
Age/years	42.88 ± 11.85	39.05 ± 13.31	0.320
Gender (female/male)	12/4	36/5	0.250
Body mass index /(kg/m^2)	21.67 ± 2.56	21.45 ± 3.16	0.162
Duration of occurrence period/months*	12 (6, 24)	18 (6, 60)	0.809
Sun exposure/h	1.84 ± 1.62	1.38 ± 1.67	0.350
Usage of lipstick	4	21	0.085
Smoking	2	3	0.613
Alcohol	0	4	0.568
Gastrointestinal polyps	1	2	1.000
Longitudinal melanonychia	2	1	0.187
Family history	0	3	0.552
Degree of color	15.88 ± 1.26	15.17 ± 1.91	0.179
Medication for systemic diseases	Anti-hypertensive drugs Vitamins Other	1 1 2	4 1 7
Patients with multiple lesions (%)	7 (43.75)	18 (43.90)	1.000
Treated area/ mm^2 **	12 (9, 13.5)	12 (6, 20)	0.555

*: the data are presented as the median (25% quartile, 75% quartile).

应, QSAL治疗OMM的长期不良反应发生率较手术切除相比显著降低($P = 0.019$)。

3 讨 论

本研究比较了QSAL和手术切除两种方式治疗OMM的复发率和长期不良反应率。研究结果表明,与手术切除相比,调Q激光治疗OMM的优势在于长期不良反应率较低,劣势在于复发率相对较高。本研究为OMM治疗的临床决策提供了高

质量的循证医学证据。

目前,二极管激光、掺钕钇铝石榴石激光、掺铒铬钇钪镓石榴石激光、铒钇铝石榴石激光、二氧化碳激光和冷冻手术等方法已被广泛用于治疗口腔色素沉着^[15-20]。QSAL利用755 nm波长处氧合血红蛋白的低吸收系数和黑色素的高吸收系数,将黑色素破坏成黑素小体,并排出体外,因此,与上述治疗方式相比,QSAL对正常细胞或组织结构的损伤很小,术后不出血,因此在保证良好疗效的同

表2 调Q激光治疗后口腔黏膜黑斑复发患者的特征

Table 2 Characteristics of patients with recurrence of oral melanotic macule treat with Q-switched alexandrite laser

Case	Age/years	Gender	Gastrointestinal polyps	Longitudinal melanonychia	Family history	Treatment sessions	Solitary or multiple	Site of lesion	Recurrence interval/months
1	45	Male	No	No	No	1	Solitary	Labial mucosa	6
2	28	Female	No	No	No	1	Multiple	Labial mucosa, gingiva	3
3	43	Female	No	No	No	1	Solitary	Vermillion	3
4	40	Female	No	No	No	1	Multiple	Labial mucosa, vermillion, buccal mucosa	2
5	27	Male	No	No	No	1	Solitary	Labial mucosa	5
6	64	Female	No	Yes	Yes	1	Multiple	Labial mucosa, vermillion, palate, gingiva, tongue	12
7	43	Male	NA	No	No	1	Solitary	Labial mucosa	8
8	43	Female	No	No	No	1	Solitary	Vermillion	12
9	31	Female	No	No	No	3	Multiple	Vermillion, gingiva	6
10	31	Female	No	No	No	2	Solitary	Vermillion	12
11	31	Female	NA	No	No	1	Solitary	Vermillion	3
12	34	Female	No	No	No	1	Solitary	Labial mucosa	1

NA: not applicable



a: multiple oral melanotic macule on the lower labial mucosa before treatment with QSAL, yellow arrow indicates typical oral melanotic macule; b: a significant reduction of oral melanotic macule at six months after treatment, yellow arrow indicates the disappearance of oral melanotic macule; c: partial recurrence of oral melanotic macule at twelve months after treatment, yellow arrow indicates the recurrence of oral melanotic macule. QSAL: Q-switched alexandrite laser

Figure 3 Representative case with partial recurrence of oral melanotic macule treated with QSAL

图3 调Q激光治疗口腔黏膜黑斑复发病例

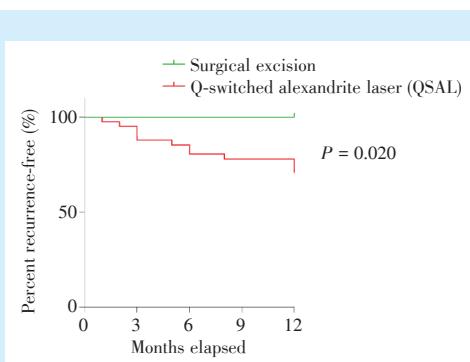


Figure 4 Comparison of the recurrence-free rates of the surgical excision and QSAL groups for patients with oral melanotic macule using Kaplan-Meier analysis

图4 Kaplan-Meier法比较手术切除法和调Q激光治疗口腔黏膜黑斑无复发率

时,不良反应也较少^[14, 21]。研究显示,激光治疗后口腔色素沉着的复发率为20%~45%^[22]。在本研究中,接受QSAL治疗的OMM患者的1年复发率为29.27%,符合此前的研究结果。此外,黑斑单发的患者与综合征相关的多发性的黑斑患者的1年复发率未发现存在显著差异,提示从治疗后复发的角度看,QSAL对单发或是多发的OMM具有相似的临床效应。

本研究中有12例接受QSAL治疗的OMM患者在1年内出现了复发,其复发的原因尚不清楚。Li等^[23]采用QSAL治疗了43例Peutz-Jeghers综合征患者的唇部黑斑,发现增加激光的治疗次数可以提升临床疗效,减少复发,推测可能是由于治疗1次不足以破坏所有色素颗粒。然而,本研究有2例患



者曾接受了多次QSAL治疗,但仍有复发。此外,也有研究显示口腔黏膜色素沉着的复发与紫外线暴露、吸烟、遗传、种族和激素水平有关,然而,本研究尚未发现OMM的复发与日晒时间或吸烟具有相关性。在后续的研究中,需收集患者的相关信息,探索OMM复发的可能因素。

除复发率外,接受QSAL治疗的OMM患者未出现不良反应,而手术切除组中有3例患者报告了术后凹陷和疤痕,提示手术切除治疗OMM具有更高的不良反应率,这也是本研究中手术切除组的患者数量明显少于QSAL组的可能原因。除了OMM外,在牙龈色素沉着治疗的相关研究中也有相似的结论。Gholami等^[24]研究发现与激光治疗相比,常规手术剥离治疗的牙龈色素沉着患者会出现疼痛程度更高和更多的出血量等不良反应。然而,在该研究中并未提到牙龈的术后凹陷或疤痕这一不良反应,可能与手术部位和手术方式不同有关。

目前,对于OMM的诊断通常是基于临床表现。如果不能通过临床表现进行诊断,则建议进行组织病理学检查。在本研究中,为了提高不愿意进行活检的OMM患者诊断的准确性,采用了无创的反射式共聚焦显微镜检查。作为组织病理学检查的一种补充方法,近十年来反射式共聚焦显微镜已被广泛用于诊断许多色素沉着病变^[25-34],在诊断唇部黑斑方面比临床和皮肤镜评估具有更好的准确性。有学者对51例唇部色素斑块的研究发现,使用临床表现结合皮肤镜图像诊断的特异性为53.2%,而在此基础上加用反射式共聚焦显微镜后,特异性提升至62.7%^[35]。以上结果提示,尽管本研究中接受QSAL治疗的患者未进行组织病理学检查,但反射式共聚焦显微镜的使用有助于提升OMM诊断的准确性。

本研究仍存在一定的局限性。本研究为单中心回顾性研究,可能存在信息偏倚,另外,接受QSAL治疗的患者的OMM诊断并非通过病理活检准确确诊的,患者OMM的诊断不能完全排除误诊的可能。

本研究发现与手术切除相比,调Q激光治疗OMM的优势在于长期不良反应率较低,劣势在于复发率相对较高,建议在治疗前与患者充分沟通,以尽可能达到满意的治疗效果。

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ticle. Shen X designed the study and revised the article. All authors read and approved the final manuscript as submitted.

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