

# 一种新型器械辅助的微创内路小梁切削术的临床应用

黄丽娜<sup>1,2\*#</sup>, 胡晶晶<sup>1\*</sup>, 官凡钰<sup>1</sup>, 林晨<sup>3</sup>, 马瑛娜<sup>1</sup>, 段阆阆<sup>1</sup>

<sup>1</sup>暨南大学附属深圳爱尔眼科医院, 广东 深圳

<sup>2</sup>暨南大学附属深圳眼科医院, 广东 深圳

<sup>3</sup>深圳市人民医院, 广东 深圳

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## 摘要

目的: 介绍一种新型器械辅助的微创内路小梁切削术, 并报道其手术一年结果。方法: 这种新型的微创内路小梁切削术使用自创的小梁切削刀, 微创切削小梁网和Schlemm's管内壁。所有手术均由同一位术者完成。记录的结果指标为: 眼压, 用药数量和并发症, 手术成功率定义为: 术后用药(条件成功率)或不用药(完全成功率)的情况下眼压维持在21 mmHg以下。结果: 连续入选18人(20眼), 其中男9人, 女9人, 年龄:  $52.3 \pm 20.7$ 岁, 发育性青光眼1例, 原发性开角型青光眼11例, 原发性闭角型青光眼4人, 混合性青光眼2人; 单纯性内路小梁切削术的4例, 内路小梁切削合并白内障超声乳化人工晶体植入16例, 其中4人还联合了房角分离术; 术前眼压:  $22.8 \pm 11.4$  mmHg ( $n = 20$ ), 术前用药:  $2.5 \pm 1.2$ 种, 术后1月、3月、6月及12月眼压分别为 $16.6 \pm 6.4$  mmHg ( $n = 19$ ),  $15.1 \pm 6.2$  ( $n = 20$ ),  $15.7 \pm 7.1$  ( $n = 16$ ),  $15.0 \pm 5.3$  ( $n = 19$ ), 术后1月、3月、6月及12月用药数分别为:  $1.1 \pm 1.4$ 种,  $1.2 \pm 1.2$ 种,  $1.2 \pm 1.3$ 种,  $1.2 \pm 1.3$ 种; 术后1月、3月、6月、12月眼压较术前眼压均存在统计学意义, P值分别为0.018, 0.002, 0.005, 0.001; 术后1年完全成功率为42.1%, 条件成功率为94.7%, 术中术后并发症: 12例术后出现一过性前房出血, 6例出现术后短暂眼压增高, 1例出现术后1周内一过性眼压高。结论: 该自创的微创内路小梁切削术可以有效降低眼压和减少术后使用药物, 表现出足够的安全性, 从而经济地丰富了微创青光眼手术(MIGS)方法, 使得该类手术更易于推广。

## 关键词

青光眼, 微创青光眼手术, 内路小梁削, 眼压

## Clinical Application of a New Instrument Assisted Minimally Invasive Internal Trabeculectomy

Lina Huang<sup>1,2\*#</sup>, Jingjing Hu<sup>1\*</sup>, Fanyu Guan<sup>1</sup>, Chen Lin<sup>3</sup>, Yingna Ma<sup>1</sup>, Tiantian Duan<sup>1</sup>

\*共同第一作者。

#通讯作者。

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<sup>1</sup>Shenzhen Aier Eye Hospital, Jinan University, Shenzhen Guangdong

<sup>2</sup>Shenzhen Eye Hospital, Jinan University, Shenzhen Guangdong

<sup>3</sup>Shenzhen People's Hospital, Shenzhen Guangdong

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## Abstract

**Objective:** To introduce a novel instrument-assisted minimally invasive internal trabeculectomy and report its one-year results. **Methods:** This novel minimally invasive internal trabeculectomy technique uses a self-created trabecular cutter to minimally cut the trabecular meshwork and the inner wall of Schlemm's canal. All operations were performed by the same surgeon. The recorded outcome measures were Intraocular pressure, numbers of the drugs of anti-glaucoma, and surgical and postoperative complications. Success was defined as maintaining IOP below 21 mmHg with (qualified success) or without (complete success) medication. **Results:** A total of 20 eyes from 18 patients (9 males and 9 females, aged  $52.3 \pm 20.7$  years) were enrolled, including 1 case with developmental glaucoma, 11 cases with primary open-angle glaucoma, 4 cases with primary angle-closure glaucoma, and 2 cases with mixed glaucoma. 4 cases were treated with standalone instrument-assisted ab intern trabeculectomy. 16 cases were treated with instrument-assisted ab intern trabeculectomy combined phacoemulsification and intra-ocular lens implantation, four of which also combined goniosynechialysis. Preoperative intraocular pressure:  $22.8 \pm 11.4$  mmHg ( $n=20$ ), preoperative medication:  $2.5 \pm 1.2$  kinds. The mean IOP at 1 month, 3 months, 6 months and 12 months after the surgery was  $16.6 \pm 6.4$  ( $n=19$ ),  $15.1 \pm 6.2$  ( $n=20$ ),  $15.7 \pm 7.1$  ( $n=16$ ),  $15.0 \pm 5.3$  ( $n=19$ ), and the number of medications at 1 month, 3 months, 6 months and 12 months after surgery were:  $1.1 \pm 1.4$ ,  $1.2 \pm 1.2$ ,  $1.2 \pm 1.3$ , and  $1.2 \pm 1.3$ . The intraocular pressure at 1 month, 3 months, 6 months, and 12 months after the operation was statistically significant compared with the preoperative intraocular pressure, with P values of 0.018, 0.002, 0.005, and 0.001, respectively; the complete success rate 1 year after the operation was 42.1% and the qualified success rate was 94.7%. **Intraoperative and postoperative complications:** 12 cases had transient hyphema after operation, 6 cases had transient intraocular pressure increase, and 1 case had transient intraocular pressure within 1 week after operation. **Conclusions:** This novel instrument-assisted ab intern trabeculectomy can effectively reduce intraocular pressure and postoperative using of anti-glaucoma medication use, showing sufficient safety, thus economically enriching the strategy of minimally invasive glaucoma surgery (MIGS) and making this kind of surgery more available.

## Keywords

Glaucoma, Minimally Invasive Glaucoma Surgery (MIGS), Ab Interno Trabeculectomy, Intraocular Pressure

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## 1. 前言

随着青光眼手术进入微创手术时代, 涌现出一系列针对早中期青光眼的非滤过泡依赖的内引流手术[1]。内路小梁切削术通过微创切除小梁网和 Schlemm's 管降低房水外流阻力, 恢复房水生理性引流途径, 从而避免了滤过手术依赖滤过泡而产生的各种严重并发症[2]。该手术可以通过内入路和外入路, 其中内

入路可通过消融[3]、KDB [4]、Fugo 刀[5]及微创刀[6] [7]等方法完成。但是这些手术需要昂贵的手术设备或者相关一次性耗材,这无疑增加了病人的经济负担,尤其在发展中国家。基于该现状,本文作者自主设计了一种专门用于切削小梁网的手术刀(专利号:ZL.2018 2 2078577.0),切削范围大概 120°,可重复使用。本文报道了该器械辅助的 120 度内路小梁切削术的一年疗效。

## 2. 对象与方法

这是一项前瞻性、干预性、非对照的病例系列研究,连续收集自 2019 年 1 月 1 日到 2020 年 12 月 31 日在暨南大学附属深圳爱尔眼科医院行内路小梁切削术以及该术式联合白内障超声乳化人工晶体植入术的病例 18 人(20 眼),所有研究对象均同意参加该研究并于术前签署手术知情同意书,该研究符合《赫尔辛基宣言》和医院伦理审查。

### 2.1. 对象

入选标准:① 诊断为青光眼;② 药物控制眼压不良或不能耐受药物或依从性差;③ 房角镜下可观察到小梁网结构;④ 联合白内障超声乳化人工晶体植入的患者均符合白内障的手术指征。排除标准:① 不能签署手术同意书;② 不能配合完成手术;③ 不能配合完成随访或随访时间 < 1 年;④ 角膜明显混浊,影响观察房角结构;⑤ 前房角可见新生血管;⑥ 严重心肺功能疾病和晚期癌症。所有患者术前均进行完整的基线眼科检查,包括青光眼史、用药情况、眼压、最佳矫正视力(BCVA)、房角镜检查、裂隙灯及眼底评估,条件允许者行视野、眼底照相及 OCT 检查。

### 2.2. 手术

#### 2.2.1. 手术器械

内路小梁切削刀是由本文第一作者研发的专用于切削小梁网的可重复使用的手术刀(专利号:ZL.2018 2 2078577.0)。

#### 2.2.2. 手术方法

术前准备:单纯小梁切削术者术前半小时内使用 1%毛果芸香碱 10 min × 4 次缩瞳,联合白内障超声乳化 + 人工晶体植入术者,先行白内障超声乳化人工晶体植入术再使用卡巴胆碱缩瞳。

麻醉:利多卡因 2~3 ml 行下方球结膜局部浸润麻醉,同时辅助丙美卡因表面麻醉。

手术方式:① 内路小梁切削术:手术由同一位青光眼专家(本文第一作者)完成。麻醉后,于 10 点位用 2.2 穿刺刀行 2.2 mm 角巩膜缘切口,2 点位角巩膜缘用 15°刀行侧切口,前房内注入粘弹剂,使患者头部向远离手术者的方向倾斜 30°~45°,调整显微镜位置,使其向术者倾斜 30°~45°,角膜上放置可固定于眼球的房角镜(图 1),指导患者眼球转动,配合调整显微镜,使得房角镜下清晰的观察到鼻侧,下方及颞侧房角结构,使用小梁切削刀行鼻侧、下方、颞侧约 120 度小梁切削,可见前房少许出血,使用 I/A 手柄吸除前房内粘弹剂及出血,水密切口,妥布霉素地塞米松眼膏涂眼,术闭。② 内路小梁切削术联合白内障超声乳化人工晶体植入术:先行常规白内障超声乳化联合人工晶体植入术,缩瞳后经主切口(10 点位)行后续内路小梁切削术。③ 白内障超声乳化人工晶体植入联合房角分离术及内路小梁切削术:先行常规白内障超声乳化联合人工晶体植入术,缩瞳后于房角镜辅助直视下房角分离术,分离房角后,暴露全部小梁网,接着行内路小梁切削术。

术后并发症观察指标:前房出血、一过性眼压高。

#### 2.2.3. 术后护理

术后使用左氧氟沙星滴眼液,每日 4 次,妥布霉素地塞米松滴眼液,每日 4 次,妥布霉素地塞米松

眼膏，睡前 1 次，普拉洛芬滴眼液，每日 4 次，均使用至术后 1 月，使用硝酸毛果芸香碱滴眼液，每日 4 次，连续至术后 2 月。术后使用的毛果芸香碱不计为降眼压药物。术后 1 天、1 周、两周、1 月、3 月、6 月及 1 年对患者进行规律随访。



**Figure 1.** Intraoperative gonioscopy  
**图 1.** 术中房角镜

### 2.3. 统计学方法

前瞻性系列病例研究。使用 IBM SPSS Statistics Veision20 进行统计学分析。描述性统计使用平均值和标准差(SD)来描述定量数据。采用 Kolmogorov Smirnov 正态性检验对参数数据和非参数数据进行区分。分析统计学方面，术前、术后两项相关参数比较采用 Wilcoxon 秩和检验。p 值小于 0.05 被认为有统计学意义。

## 3. 结果

### 3.1. 基本资料

连续入选 18 人(20 眼)，其中男 9 人，女 9 人，年龄： $52.3 \pm 20.7$  岁，发育性青光眼 1 例，原发性开角型青光眼 11 例，原发性闭角型青光眼 4 人，混合性青光眼 2 人。单纯性内路小梁切削术的 4 例，内路小梁切削合并白内障超声乳化人工晶体植入 16 例。

### 3.2. 术前术后眼压及成功率

术前眼压： $22.8 \pm 11.4$  mmHg (n = 20)，术前用药： $2.5 \pm 1.2$  种，术后 1 月眼压： $16.6 \pm 6.4$  mmHg (n = 19)，术后用药数： $1.1 \pm 1.4$  种，术后 3 月眼压： $15.1 \pm 6.2$  mmHg (n = 20)，用药： $1.2 \pm 1.2$  种；术后 6 月眼压： $15.7 \pm 7.1$  mmHg (n = 16)，用药： $1.2 \pm 1.3$ ，术后 1 年眼压： $15.0 \pm 5.3$  mmHg (n = 19)，用药： $1.2 \pm 1.3$  种(见图 2、图 3)。术后 1 月、3 月、6 月、12 月眼压较术前眼压均存在统计学意义，P 值分别为 0.018、0.002、0.005、0.001(见表 1)；术后 1 年完全成功率为 42.1%，条件成功率为 94.7%。图 4、图 5 分别为小梁切削术前、术后 UBM 图。

**Table 1.** Intraocular pressure and medication before and after operation

**表 1.** 术前、术后眼压及用药数

	术前	术后 1 月	术后 3 月	术后 6 月	术后 1 年
眼压(mmHg)	$22.8 \pm 11.4$	$16.6 \pm 6.4$	$15.1 \pm 6.2$	$15.7 \pm 7.1$	$15.0 \pm 5.3$
用药(数量)	$2.5 \pm 1.2$	$1.1 \pm 1.4$	$1.2 \pm 1.2$	$1.2 \pm 1.3$	$1.2 \pm 1.3$
(与术前眼压比较)	P	0.018	0.002	0.005	0.001

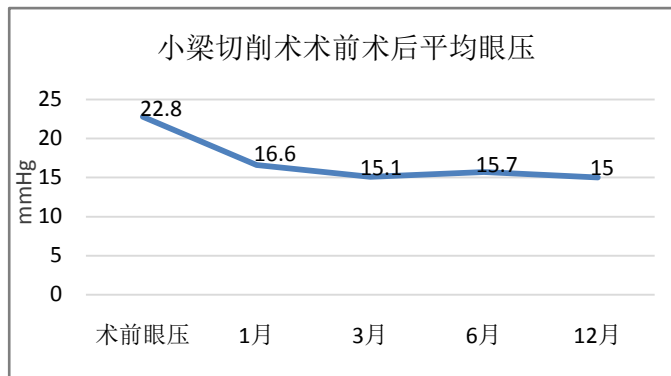


Figure 2. Mean intraocular pressure before and after trabeculectomy (mmHg)

图 2. 小梁切削术术前术后平均眼压(mmHg)

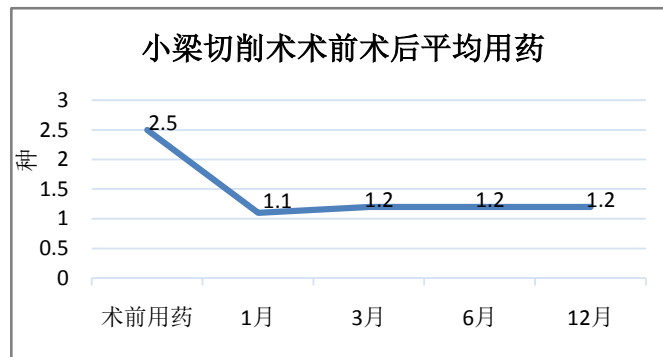


Figure 3. Average number of drugs used before and after trabeculectomy

图 3. 小梁切削术术前术后平均用药数目

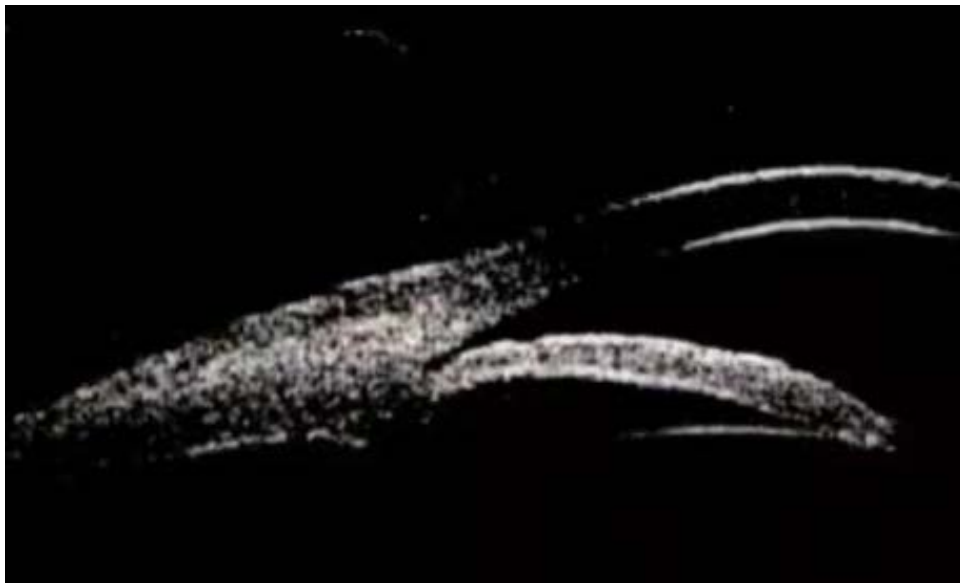


Figure 4. Preoperative UBM image

图 4. 术前 UBM 图像



**Figure 5.** In the postoperative UBM image (the yellow arrow indicates that the trabecular meshwork was cut after operation)

**图 5.** 术后 UBM 图像(黄色箭头处指示术后小梁网处被切割)

### 3.3. 术中术后并发症

12 眼术后出现一过性前房出血, 6 眼出现术后短暂的眼压增高, 1 眼出现术后 1 周内一过性眼压高。

## 4. 讨论

在我们的 18 例(20 眼)的病例系列中, 一年随访结束时眼压由术前 22.8 mmHg 下降至 15.0 mmHg, 术后眼压较术前眼压下降 34.2%, 使用青光眼药物从术前的 2.5 种到术后的 1.2 种, 完全不用药的有 8 眼。报道的小梁消融术在原发性开角型青光眼中的应用, 术后一年的眼压在 15.1~16.3 mmHg, 眼压下降幅度 28%~51% [3] [8] [9], 术后两年[10], 三年[11]也能维持类似的结果。日本 Masaki Tanito [6]等报道的一项微钩辅助的内路小梁切开术, 术中使用与我们的手术器械类似的微钩, 内路切除约 7.3 个钟点的小梁网, 术后半年时眼压由术前的 25.9 mmHg 到术后的 14.7 mmHg, 用药由术前的 3.3 种到术后的 2.8 种。一项多中心的 KDB [12]在难治性青光眼应用的病例系列中, 随访半年, 眼压由术前 18.4 mmHg 到术后 13.9 mmHg, Phaco-KDB [13]手术在开角型青光眼中随访 1 年时, 平均眼压从(16.8 ± 0.6) mmHg 下降至(12.4 ± 0.3) mmHg, 所用降压药物减少。Phaco-KDB 手术在各类型青光眼中使用[14], 随访两年, 开角型青光眼眼压由术前的 21.1 mmHg 到术后下降了 6.4~7.7 mmHg (24.6%~32.1%), 闭角型青光眼联合行房角分离后, 眼压由术前的 20.8 mmHg 到术后下降了 6.1~8.7 mmHg, (23.4%~39%)。Meta [15]分析显示小梁消融术降压幅度为 24.0%, KDB 小梁切除术降压幅度为 25.1%。我们的一年随访数据与文献报道的类似手术方法显示了相似的结果。

在我们的 20 眼中有 4 眼为闭角型青光眼, 均在术中行白内障超声乳化人工晶体植入联合房角分离及内路小梁切削术, 末次随访时术后眼压在 12.3 mmHg~15 mmHg, 术后均无需使用抗青光眼药物。我们知道在闭角型青光眼中, 白内障超声乳化摘除人工晶体植入联合房角分离术有明显的降压作用, 手术成功率在 71%~92.3% [16] [17] [18] [19] [20] [21]。我们认为在术中联合内路小梁切削术, 去除小梁网的阻力, 可能进一步降低眼压, 对于部分术后预期需要更低靶眼压的患者可能获得更大收益, 特别是房角粘连超过二分之一的患者加做内路小梁切削术, 避免做外引流滤过手术, 也许是个更好的选择。但这仍需要进一步的研究证实。在白内障超声乳化摘除人工晶体植入联合房角分离及小梁消融术和白内障超

声乳化摘除人工晶体植入联合房角分离及 KDB 手术应用于闭角型青光眼中已经有类似的报道[22]。

对于术后并发症, 20 眼中 12 眼术后出现一过性前房出血, 都在术后一周内吸收, 6 眼出现术后一过性眼压增高, 使用降眼压药物后均在 1~2 周内眼压恢复至正常。在小梁消融[3] [8] [9]、微创刀[6] [7]及 KDB [23] [24] [25]手术中报道的手术并发症包括: 术后前房出血、一过性高眼压、周边房角前粘连及睫状体脱离等。术后前房出血为此类手术无法避免的手术并发症, 为术中集液管内血液返流所致, 术后当时及术后短期内的眼压一过性增高可能与术后前房出血及前房内残留粘弹剂有关。

不同的方法行内路小梁网切削术, 都能达到一定的降眼压作用。但是不同方法对周围组织的损伤不同[26], 同时不同术式的性价比也不同, 该自创的手术器械辅助的内路小梁切削术在经济有效的降低眼压的同时, 表现出足够的安全性。因为经由内路完成, 不损伤结膜组织, 不破坏眼表结构, 从而避免了外引流手术所导致的滤过泡相关的各种并发症, 同时避免了破坏眼表结构及干眼症等种种问题。

本研究存在小样本、非随机、非对照的问题。只报道了术后一年的结果, 长期的有效性仍需要长时间的观察研究。

## 5. 结论

该自创的内路小梁切削术可以有效降低眼压和减少术后抗青光眼药物的使用, 表现出足够的安全性, 从而经济地丰富了微创青光眼手术(MIGS)方法, 使得该类手术更易于推广。

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