

US010682255B2

(12) United States Patent Yan et al.

(54) ULTRASONIC NEEDLE AND APPARATUS APPLIED FOR VITRECTOMY

(71) Applicant: INNOLCON MEDICAL
TECHNOLOGY (SUZHOU) CO.
LTD, Suzhou (CN)

(72) Inventors: **Zhongyu Yan**, Suzhou (CN); **Wei Luo**, Suzhou (CN)

(73) Assignee: Innolcon Medical Technology (Suzhou) Co. Ltd, Suzhou (CN)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35

U.S.C. 154(b) by 216 days.

(21) Appl. No.: 15/573,810

(22) PCT Filed: Apr. 28, 2016

(86) PCT No.: **PCT/CN2016/080452**

§ 371 (c)(1),

(2) Date: Nov. 13, 2017

(87) PCT Pub. No.: WO2016/184300PCT Pub. Date: Nov. 24, 2016

(65) **Prior Publication Data**

US 2018/0256396 A1 Sep. 13, 2018

(30) Foreign Application Priority Data

May 15, 2015 (CN) 2015 1 0249346

(51) **Int. Cl.**A61F 9/007 (2006.01)

A61B 17/22 (2006.01)

(Continued)

(52) U.S. Cl. CPC A61F 9/00745 (2013.01); A61B 17/22004 (2013.01); A61B 17/22012 (2013.01); (Continued)

(10) Patent No.: US 10,682,255 B2

(45) **Date of Patent:** Jun. 16, 2020

(58) Field of Classification Search

CPC Y10T 29/49925; Y10T 29/49927; Y10T 29/49929; A61B 17/22004–22029; A61B 2017/00477–00486

See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS

5,222,937 A 6/1993 Kagawa 5,651,783 A 7/1997 Reynard (Continued)

FOREIGN PATENT DOCUMENTS

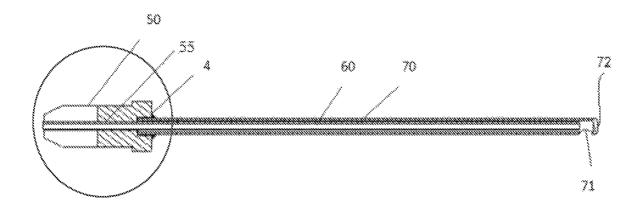
CN 102256574 A 11/2011 CN 104055620 A 9/2014 (Continued)

Primary Examiner — Nathan R Price Assistant Examiner — Anh Bui (74) Attorney, Agent, or Firm — Seed Intellectual Property Law Group LLP

(57) ABSTRACT

This disclosure disclosed an ultrasonic needle and apparatus used for removal of the vitreous body and other tissues. An ultrasonic vitrectomy needle, comprising: a connector, a connected inner needle, and an outer sheath. The length of the outer sheath at the distal end is slightly longer than that of the inner needle; the sheath distal end is of blind with smooth surface, but there is an open cut at the side of the distal end used for aspirating the vitreous body. The benefits of this disclosure: due to the difficulty if not impossible in the prior arts making a slim long center bore needle for ultrasonic surgical system, this disclosure clears the way to make the ultrasonic vitrectomy a practical reality; the ultrasonic vibration inherent advantages of the quietness, minuscule displacement, liquid repulsion and viscosity reduction improve safety of the surgery; the possibility of integrating ultrasonic vitrectomy and ultrasonic phaco emulsification procedures simplifies the complexity from prior arts, thus brings ease to the ophthalmic surgeries and reduces the cost.

10 Claims, 3 Drawing Sheets



US 10,682,255 B2 Page 2

(51)	Int. Cl.		5,935,09	6 A	8/1999	Barrett		
, ,	A61B 17/00	(2006.01)	5,989,20	8 A *	11/1999	Nita	A61B 17/22	
	A61M 1/00	(2006.01)					604/22	
(52)	U.S. Cl.		6,270,47	1 B1*	8/2001	Hechel	A61B 17/22012	
. /	CPC A61B 17/22	202 (2013.01); A61B 17/22022					604/22	
	(2013.01); A6	61B 17/22029 (2013.01); A61B	8,439,93			Moore, Jr.		
		7 (2013.01); <i>A61B 2017/00482</i>	2010/016085		6/2010	Moore, Jr.		
		3 2017/00486 (2013.01); A61B	2012/022100			Tada et al.		
		5 (2013.01); <i>A61B 2017/22007</i>	2012/031649		12/2012			
		3 2017/22008 (2013.01); A61B	2014/007401			Charles		
		9 (2013.01); A61B 2017/22011	2014/007401			McCary et al.		
		3 2017/22014 (2013.01); A61B	2015/019642	6 AI	7/2015	Kuebler et al.		
	2017/22015 (2013.01); A61B 2017/22017		г	EODEICNI DATENIT DOCUMENTO				
	(2013.01); A61B 2017/22018 (2013.01); A61B		FOREIGN PATENT DOCUMENTS					
		I (2013.01); A61B 2017/22024	CN	10405	5622 A	9/2014		
		3 2017/22025 (2013.01); A61B	CN CN		3622 A 8621 U	12/2014		
		7 (2013.01); A61B 2017/22028	CN		2457 U	1/2014		
		77	CN		2457 U 2458 U	1/2015		
	(20	13.01); <i>A61M 1/008</i> (2013.01)	CN		2438 U 4603 U	1/2015		
(50)	D. C	64.1	CN		0821 A	2/2016		
(56)	Reieren	ices Cited	EP		2591 A1	4/2014		
	II C DATENIT	DOCUMENTS			8550 A1	4/2014		
	U.S. PATENT	DOCUMENTS	WO	ZU14U4	ossu Al	4/2014		
	5,667,489 A 9/1997	Kraff et al.						
5,746,713 A 5/1998 Hood et al.		* cited by examiner						

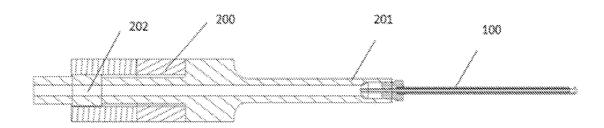


FIG.1

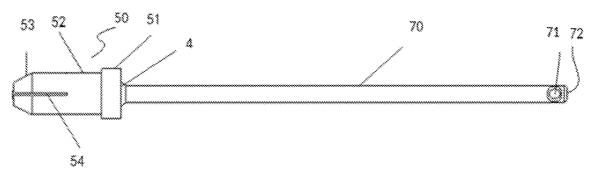


FIG. 2

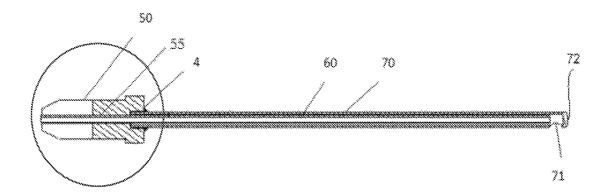
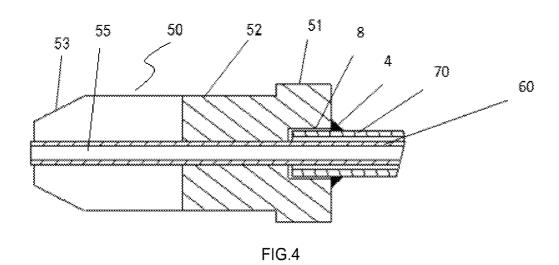


FIG. 3



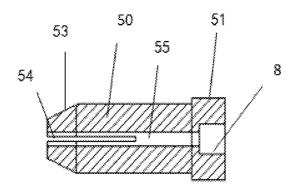


FIG. 5A

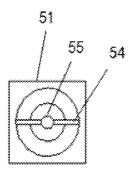


FIG. 5B

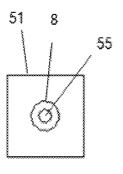


FIG. 5C

1

ULTRASONIC NEEDLE AND APPARATUS APPLIED FOR VITRECTOMY

BACKGROUND

Technical Field

This invention is related to medical device and the related method, particularly to the ultrasonic vitrectomy and its needle.

Description of the Related Art

Human eyes working principle is like this: a light beam passing through the cornea and lens to focus, then passing 15 through the vitreous body and falling on the retina to form an image. The focusing quality is affected by many factors, including the size and shape of the eye and the transparency of the cornea, lens and vitreous body.

Vitreous body is a transparent tissue located at the pos-20 terior chamber of the eye. When an eye has a disease, such as hemorrhage, retina tear, sometimes need to take out the vitreous body which is called vitrectomy. Commonly used vitrectomy devices include vitrectomy hand piece, illuminating tube and irrigation needle etc. In prior arts, the 25 commonly used vitrectomy equipment is driven by pneumatic source, and occasionally by electrical source; these complex apparatus require specified driven source. For the often used ophthalmic surgical equipment, the vitrectomy apparatus is usually integrated in one equipment with the 30 phaco emulsification cataract removal apparatus, so the equipment is bodily large, design complex, cost high and operation inconvenient; in addition, the pneumatic apparatus operating frequency is within the audio range, so it is noisy and has high needle tip moving displacement.

In the prior arts, there are many ultrasonic phaco emulsification apparatus, but no practically useful ultrasonic vitrectomy apparatus. There is no still appropriate ultrasonic vitrectomy needle, or related ultrasonic apparatus or hand piece to safely drive a long slim needle with a through center 40 bore, so that it is able to reach a certain ultrasonic magnitude and depth into the vitreous body for liquefying and crushing it

BRIEF SUMMARY

Provided is an ultrasonic vitrectomy needle, to make the vitreous body removal by ultrasonic technology a practical reality. By applying the advantages of ultrasonic vibration of noise-free, micro-displacement, fluid-repulsion and viscosity-reduction, a practically usable ultrasonic vitrectomy needle is provided, and the surgical safety is improved.

Provided is an ultrasonic vitrectomy needle, including: a connector and a connected inner needle, the characteristic is: outside of the inner needle there is a sheath tube; the sheath 55 tube is slightly longer at the distal end than the inner needle; the sheath distal end is blind non-sharp smooth surface, but there is an open port at the distal end side for aspirating vitreous body.

At the fastening portion distal end, surrounding the inner 60 needle, there is a counter bore; the sheath tube proximal end inserted in the counter bore, and the contacting area between the sheath and fastening portion is sealed/adhered with plastic sealant/adhesive. The distal end counter bore is used to receive, adjust and fix the sheath position.

There is gap between the sheath tube inner wall and the inner tube outer wall.

2

In the connector body there is a center bore running through the body; the center bore has the matching shape as to the inner needle, used to receiving the inner needle, and the center axis of the connector coincides with that of the 5 inner needle.

Outside sheath tube distal end is blind with a flat surface, or a convex round surface. Of course, known by the skills in this field, other non-sharp smooth end surfaces can used to instead.

The connector includes a fastening portion, a threaded portion for connecting to a hand piece, and a tapered portion at the proximal end for tightening the inner needle. The fastening portion is a feature used for wrench gripping, having matching shape and size to the wrench tool. The threaded portion is outer thread located on distal end outside of the connector body. The tapered portion is located at the proximal end of the threaded portion, and the tapered portion is adapted to the inner lumen in the ultrasonic hand piece.

On the tapered portion, there is at least one slit used for tightening the inner needle.

The vitrectomy needle by the connector is connected to the hand piece distal end, and the hand piece through an electric cable is connected to the ultrasonic emulsification apparatus.

In the distal end of the hand piece is an inner thread that matching the threaded portion on the connector.

In the proximal end of the inner thread in the distal end of the hand piece is a tapered surface that matches the taper portion on the connector, which helps tightening the slit(s) on the tapered portion, to improve the security of the inner needle.

Comparing to the prior art of pneumatic driven vitrectomy apparatus, the ultrasonic vitrectomy apparatus from this invention possesses advantages such as minimized-noise and micro-displacement, and it can be easily integrated to the currently commonly used phace emulsification system. The benefits of this invention may include:

- (1) As it is concerned as the long slim center bore needle for the ultrasonic surgical system, this invention makes the ultrasonic vitrectomy a practical reality. The ultrasonic vibration inherent advantages of minimized-noise, microdisplacement fluid-repulsion and viscosity-reduction improved the safety of the surgery.
- (2) The design of the outer sheath for the ultrasonic vitrectomy needle: the distal end is a blind non-sharp smooth surface, but at the side of the distal end where is longer than the inner needle has a side port, which is used to aspirating the vitreous body. The smooth distal end prevents the delicate retina from inner needle ultrasonic vibration or cavitation causing damage, while the side port allows the inflow of the vitreous body for ultrasonic crashing. It solved the problem with the prior art that the sharp distal tip at the ultrasonic needle easily piercing the unintended tissues, thus reduced the risk and improve the safety of the surgery.
 - (3) The integration of the ultrasonic vitrectomy and the ultrasonic cataract emulsification greatly simplified the complicity of the apparatus of prior art, thus provides ease and cuts the cost for ophthalmic surgeries.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

FIG. 1 is an illustration of an embodiment illustrates the connecting structure between the ultrasonic vitrectomy 65 needle and the hand piece distal end.

FIG. 2 is an illustration of an embodiment, side view of the ultrasonic vitrectomy needle.

3

FIG. 3 is an illustration of an embodiment, cross section view of the ultrasonic vitrectomy needle.

FIG. 4 is a detailed view of FIG. 3 at the connecting area.FIG. 5A is the cross section view of the connector. FIG. 5B is the side view of FIG. 4.

FIG. **5**C is the side view of the connector from the fastening portion side.

DETAILED DESCRIPTION

Based on the illustrative Figures and the embodiments, this invention is described in detail below.

As illustrated in FIG. 2-FIG. 4, FIGS. 5A, 5B, and 5C, the ultrasonic vitrectomy needle comprises the connector 50 and with which the connected inner needle tube 60. In the 15 connector 50 there is along the center axis a running through center bore 55, which has the shape matching the inner tube 60 for accommodating the inner tube 60. Part of the inner tube 60 is inserted in the center bore 55, and the axis of the inner tube 60 coincides with the axis of the center bore 55; 20 the other part of the inner tube 60 is outside of the connector body 50 and extends to the distal end; outside the connector body 50, the extended portion of the inner tube 60 is covered by an outer sheath 70; the length of the sheath is slightly longer at the distal end than the inner tube 60, and the distal 25 end 72 is a blind non-sharp smooth surface, while there is a port 71 at the side of the distal end where is the longer portion than the inner tube 60. The side port 71 is used for aspirating the vitreous body.

In a preferable embodiment, the distal end **72** of the outer 30 sheath **70** is a convex round surface. Of course it can be other no-sharp smooth surfaces known to the skills in the field.

In a preferable embodiment, the size of the center bore 55 is lightly bigger than the size of the inner needle 60 for 35 receiving the needle 60; the shape of the center bore 55, matches the shape of the inner needle 60, such as can be polygons, and the axis of the inner needle coincides with the axis of the connector.

Illustrated in FIG. 4 and FIG. 5A is an embodiment of the 40 connector 50, including the fastening portion 51, the nearby threaded portion 52 for connecting to the ultrasonic hand piece, and the tapered portion 53 at the proximal end for tightening the inner needle. The fastening portion 51 is gripping surfaces for a wrench tool with the adapting shape 45 and size; the threaded portion 52 is the outer thread located on the outside surface of the connector 50; the tapered portion 53 is located at the proximal end of the threaded portion 52, and it has the tapered shape adapting to the ultrasonic hand piece inner lumen; there is at least one 50 evenly distributed slit 54 on the tapered portion 53 for tightening the inner needle 60.

At the distal end face of the fastening portion 51, surrounding the inner needle 60, is a counter bore 8 (FIG. 4,5); the proximal end of the sheath tube 70 is inserted in the 55 counter bore 8, and the contacting area between the sheath 70 and the fastening portion 51 is sealed/adhered by plastic sealant/adhesive 4. The counter bore 8 on the fastening portion 51 distal end is used for receiving, adjusting and poisoning the center position of the sheath 70. There is a gap 60 between the sheath 70 and the inner needle 60, so during working, only the inner needle 60 has ultrasonic vibration, while the outer sheath 70 does not vibrate, nor reduce the output of the ultrasonic vibration.

When applying the ultrasonic vitrectomy needle, the 65 threaded portion 52 of the connector 50 is mated to the inner thread at the distal end of the hand piece, i.e., through the

4

thread mating, the connector **50** is screwed into the ultrasonic hand piece distal end, the guiding tapered portion **53** is adapted to the tapered surface in the hand piece. Meanwhile, the slit **54** is partially closed due to the squeezing, and the tapered surfaces of the tapered portion closely touched the inner surface of the hand piece. Due to the deformation of the slit **54**, the diameter of the center bore **55** is also changed, so the inner needle is rigidly coupled to the connector **50**, and then to the hand piece distal end, thus the ultrasonic vibration is effectively propagated to the ultrasonic surgical tool distal tip.

When applying the ultrasonic vitrectomy apparatus, as shown in FIG. 1, through the connector 50, the ultrasonic vitrectomy needle 100 is connected to the ultrasonic hand piece 200 distal end, the inner needle 60 is tightened, and the ultrasonic hand piece is connected to the ultrasonic phaco emulsification equipment through the electric cable. When power is turned on, the ultrasonic vibration can be effectively propagated from the hand piece front rod 201 to the inner needle 60 distal tip. There is a gap between the outer sheath inner wall and the inner needle 60 outer wall, thus, when working, only the inner needle has ultrasonic vibration, while the outer sheath kept still from ultrasonic vibration. When the vitreous body resulted from the vacuum and the inner ocular pressure, through the outer sheath 70 side port 71 flows into the sheath, by the effects of the ultrasonic fragmenting, liquefying and viscosity reducing from the inner needle 60 distal tip, the vitreous body can be aspirated out through the inner needle 60 lumen and the hand piece center aspiration lumen 202, even under a lower aspiration pressure.

It should be understood, although the above description is based on the embodiments, each embodiment is not limited to one independent technical solution, for example, the inner needle $60\,$ may be made of medial grade metals, or of medical grade plastics; the length of the inner needle $60\,$ should be designed in a certain range not to reduce the ultrasonic vibration. In addition, due to the desire of small incision for the vitrectomy procedure, the inner needle is required within a small diameter range, usually is smaller than $500\,\mu m$, preferably $200\text{-}500\,\mu m$. The inner needle can be made of metal, plastic or resin etc. preferably of metal.

Disclosed is an ultrasonic vitrectomy apparatus, which includes the integrated ultrasonic emulsification apparatus, the ultrasonic hand piece and afore described ultrasonic vitrectomy needle. Through the outer threaded portion 51 on the connector 50 mating to the inner thread of the hand piece distal end, the ultrasonic vitrectomy needle is connected to the hand piece; at the proximal end of the inner thread on the hand piece is a tapered surface, which matches the tapered portion of the connector, in order to further closing the slit and tightening the inner needle; the ultrasonic hand piece is connected to the ultrasonic phace emulsification apparatus.

The above illustrated and described the basic principle, major characteristics and the benefits of this invention. It should be understood by the skills in this field, this invention is not limited by the above mentioned embodiments. The above embodiments and the descriptions were only used to illustrate the principle of the invention. Not apart from the spirit and the protection of the invention, there are still other alternatives and improvements, all of which shall fall in the protection of the invention. The protection range are determined by the claims and equivalent objects.

5

The invention claimed is:

- 1. An ultrasonic vitrectomy needle, comprising:
- a connector having a distal end and a proximal end; and an inner needle, the inner needle located in an outer sheath, the inner needle and the outer sheath including 5 distal ends and proximal ends;
- wherein the inner needle and the outer sheath are received by the connector at the distal end of the connector, wherein the proximal end of the inner needle extends to the proximal end of the connector and is received by at least one slit at the proximal end of the connector; and wherein the distal end of the outer sheath extends beyond the distal end of the inner needle;
- wherein the distal end of the outer sheath is blind, the outer sheath including an opening at a side near the 15 distal end for aspirating a vitreous body.
- 2. The ultrasonic vitrectomy needle according to claim 1, wherein the distal end of the connector has a counter bore, wherein the proximal end of the outer sheath is inserted in the counter bore, and wherein a sealing material is provided 20 at a contacting area between the distal end of the connector and the proximal end of the outer sheath.
- 3. The ultrasonic vitrectomy needle according to claim 1, wherein there is a gap between an inner surface of the outer sheath and an outer surface of the inner needle.
- **4**. The ultrasonic vitrectomy needle according to claim **1**, wherein the connector includes a central bore having a central axis and extending through the connector, wherein a shape of the central bore corresponds to a shape of the inner needle and is configured to receive the inner needle, wherein 30 the center axis of the connector coincides with a central axis of the inner needle.

6

- **5**. The ultrasonic vitrectomy needle according to claim **1**, wherein the distal end of the outer sheath is blind with a flat smooth surface or with a convex smooth surface.
- 6. The ultrasonic vitrectomy needle according to claim 1, wherein the distal end of the connector includes a fastening portion, and the proximal end of the connector includes a tapered portion, wherein the connector includes a threaded portion between the fastening portion and the tapered portion.
- 7. The ultrasonic vitrectomy needle according to claim 1, wherein the at least one slit secures the proximal end of the inner needle to the connector.
- 8. An ultrasonic vitrectomy apparatus, comprising: integrated ultrasonic phaco emulsification equipment, a phaco hand piece, and an ultrasonic vitrectomy needle according to claim 1, wherein the connector of the ultrasonic vitrectomy needle is coupled to a distal end of the phaco hand piece, and the phaco hand piece is plugged to the ultrasonic phaco emulsification equipment.
- 9. The ultrasonic vitrectomy apparatus according to claim 8, wherein the distal end of the phaco hand piece includes inner threads that mate with outer threads of the connector, wherein a proximal end of the inner threads of the phaco hand piece has a tapered surface that corresponds to a tapered portion of the connector.
- 10. The ultrasonic vitrectomy needle according to claim 1, wherein the distal end of the connector has a counter bore, wherein the proximal end of the outer sheath is in the counter bore.

* * * * *



超声针和用于玻璃体切割的设备						
<u>US10682255</u>	公开(公告)日	2020-06-16				
US15/573810	申请日	2016-04-28				
以诺康医疗科技(苏州)有限公司						
YAN ZHONGYU LUO WEI						
YAN, ZHONGYU LUO, WEI						
A61F9/007 A61B17/22 A61M1/00 A61B17/00						
A61F9/00745 A61B17/22012 A61B17/22004 A61B2017/22028 A61B2017/22027 A61B2017/22009 A61B2017/22008 A61B2017/00486 A61B2017/00482 A61B2017/22025 A61B2017/22014 A61B2017 /22011 A61B2017/22015 A61B17/22029 A61B2017/22017 A61B2017/22007 A61B2017/22024 A61B17 /2202 A61B2017/22018 A61B17/22022 A61B2017/00477 A61M1/008 A61B2017/22005 A61B2017 /22021						
BUI , ANH						
201510249346.X 2015-05-15 CN						
US20180256396A1						
<u>Espacenet</u>						
	US10682255 US15/573810 以诺康医疗科技(苏州)有限公司 YAN ZHONGYU LUO WEI YAN, ZHONGYU LUO, WEI A61F9/007 A61B17/22 A61M1/00 A61B2017/22008 A61B2017/00486/22011 A61B2017/22015 A61B17/2/2202 A61B2017/22018 A61B17/2/22021 BUI, ANH 201510249346.X 2015-05-15 CN US20180256396A1	US10682255 US15/573810 申请日 以诺康医疗科技(苏州)有限公司 YAN ZHONGYU LUO WEI YAN, ZHONGYU LUO, WEI A61F9/007 A61B17/22 A61M1/00 A61B17/00 A61F9/00745 A61B17/22012 A61B17/22004 A61B2017/22028 A61 A61B2017/22008 A61B2017/00486 A61B2017/00482 A61B2017/22011 A61B2017/22015 A61B17/22029 A61B2017/22017 A61B20 /2202 A61B2017/22018 A61B17/22022 A61B2017/00477 A61M1/0 /22021 BUI, ANH 201510249346.X 2015-05-15 CN US20180256396A1				

摘要(译)

本公开公开了一种用于去除玻璃体和其他组织的超声针和设备。 一种超声玻璃体切除术针,包括:连接器,连接的内部针和外部护套。 外护套在远端的长度比内针的长度稍长。 护套远端是盲孔,表面光滑,但在远端侧有一个用于抽吸玻璃体的开口切口。 本公开的优点:由于现有技术中即使不是不可能的,也难以制造用于超声外科系统的细长的长中心孔针,因此本公开清除了使超声玻璃体切除术成为现实的方法。 超声波振动的固有优点是安静,微小位移,排斥液体和降低粘度,从而提高了手术的安全性; 结合超声玻璃体切除术和超声超声乳化乳化程序的可能性简化了现有技术的复杂性,从而使眼科手术变得容易并且降低了成本。

