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Patent Owners' Demonstratives
MicroSurgical Technology, Inc.
The Regents of the University of California

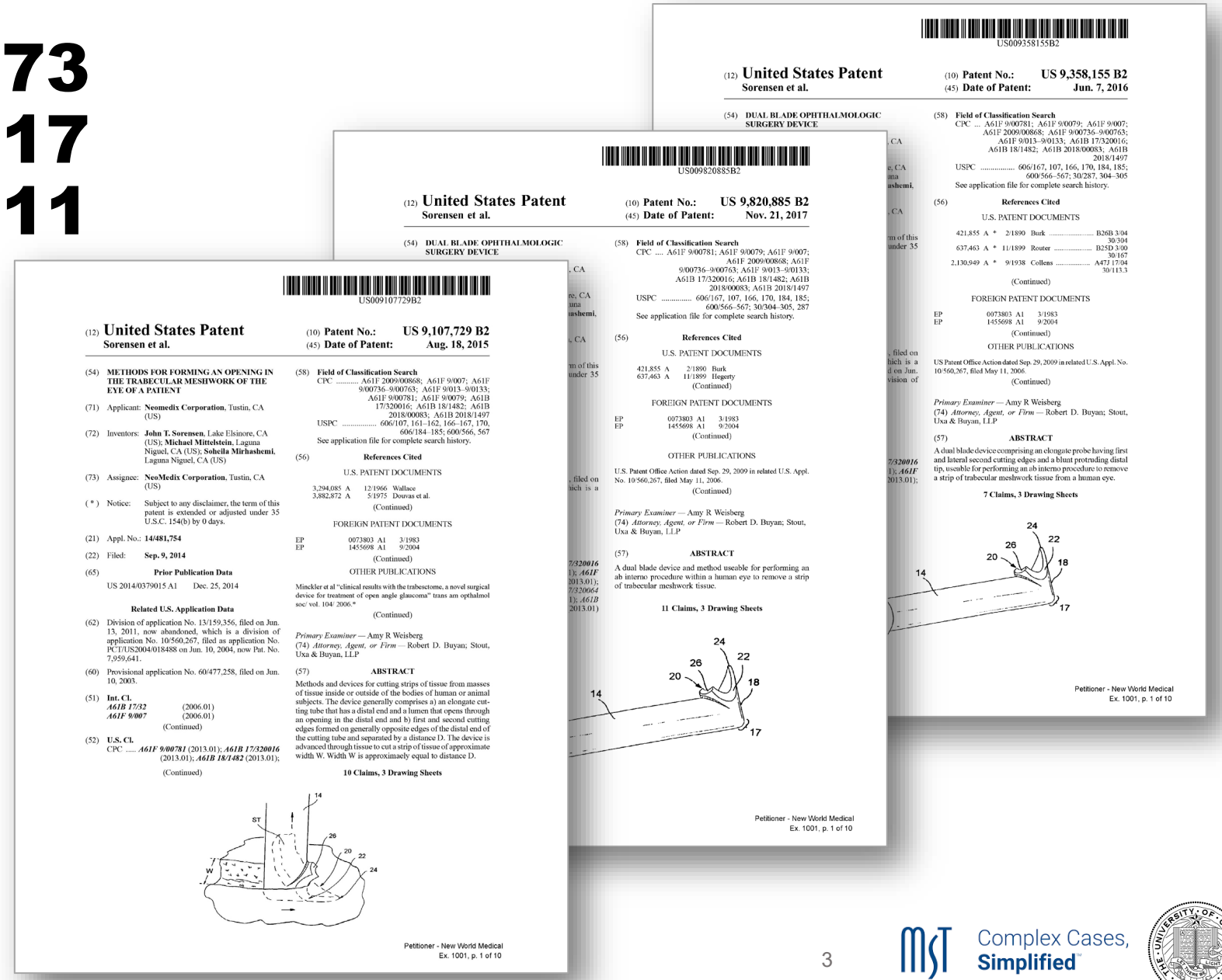
IPR Nos. 2020-01573, 2020-01711, 2021-00017, 2021-00065, 2021-00066

wiley

	01573 (’729)	00017 (’885)	01711 (’155)	00065 (’905)	00066 (’544)
Specification	same				
Claim Elements	ab interno	ab interno	ab interno		ab interno
	dual blade	dual blade	dual blade	knife blades	
	concurrently cutting				
	protruding tip	tip	blunt protruding tip	tip	tip
			blunt top edge		
				protector member (upwardly sloping incline)	foot member (angled platform)
Prior Art	Quintana	Quintana	Quintana	Quintana	Quintana
	Quintana + Lee	Jacobi	Quintana +Lee	Jacobi	Jacobi
	Jacobi		Jacobi		

’729 Patent, -01573
’885 Patent, -00017
’155 Patent, -01711

Ex. 1001



US009107729B2

(12) **United States Patent**
Sorensen et al.

(10) **Patent No.: US 9,107,729 B2**
(45) **Date of Patent: Aug. 18, 2015**

(54) **METHODS FOR FORMING AN OPENING IN THE TRABECULAR MESHWORK OF THE EYE OF A PATIENT**

(71) Applicant: **Neomedix Corporation**, Tustin, CA (US)

(72) Inventors: **John T. Sorensen**, Lake Elsinore, CA (US); **Michael Mittelstein**, Laguna Niguel, CA (US); **Soheila Mirhashemi**, Laguna Niguel, CA (US)

(73) Assignee: **NeoMedix Corporation**, Tustin, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/481,754**

(22) Filed: **Sep. 9, 2014**

(65) **Prior Publication Data**

US 2014/0379015 A1 Dec. 25, 2014

Related U.S. Application Data

(62) Division of application No. 13/159,356, filed on Jun. 13, 2011, now abandoned, which is a division of application No. 10/560,267, filed as application No. PCT/US2004/018488 on Jun. 10, 2004, now Pat. No. 7,959,641.

(60) Provisional application No. 60/477,258, filed on Jun. 10, 2003.

(51) **Int. Cl.**
A61B 17/32 (2006.01)
A61F 9/007 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61F 9/00781*** (2013.01); ***A61B 17/320016*** (2013.01); ***A61B 18/1482*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61F 2009/00868; A61F 9/007; A61F 9/00736–9/00763; A61F 9/013–9/0133; A61F 9/00781; A61F 9/0079; A61B 17/320016; A61B 18/1482; A61B 2018/00083; A61B 2018/1497
USPC 606/107, 161–162, 166–167, 170, 606/184–185; 600/566, 567
See application file for complete search history.

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Primary Examiner — Amy R Weisberg
(74) *Attorney, Agent, or Firm* — Robert D. Buyan; Stout, Uxa & Buyan, LLP

(57) **ABSTRACT**

Methods and devices for cutting strips of tissue from masses of tissue inside or outside of the bodies of human or animal subjects. The device generally comprises a) an elongate cutting tube that has a distal end and a lumen that opens through an opening in the distal end and b) first and second cutting edges formed on generally opposite edges of the distal end of the cutting tube and separated by a distance D. The device is advanced through tissue to cut a strip of tissue of approximate width W. Width W is approximaely equal to distance D.

10 Claims, 3 Drawing Sheets

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US009820885B2

(12) **United States Patent**
Sorensen et al.

(10) **Patent No.: US 9,820,885 B2**
(45) **Date of Patent: Nov. 21, 2017**

(54) **DUAL BLADE OPHTHALMOLOGIC SURGERY DEVICE**

(58) **Field of Classification Search**
CPC A61F 9/00781; A61F 9/0079; A61F 9/007; A61F 2009/00868; A61F 9/00736–9/00763; A61F 9/013–9/0133; A61B 17/320016; A61B 18/1482; A61B 2018/00083; A61B 2018/1497
USPC 606/167, 107, 166, 170, 184, 185; 600/566–567; 30/304–305, 287
See application file for complete search history.

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U.S. Patent Office Action dated Sep. 29, 2009 in related U.S. Appl. No. 10/560,267, filed May 11, 2006.
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Primary Examiner — Amy R Weisberg
(74) *Attorney, Agent, or Firm* — Robert D. Buyan; Stout, Uxa & Buyan, LLP

(57) **ABSTRACT**

A dual blade device and method useable for performing an ab interno procedure within a human eye to remove a strip of trabecular meshwork tissue.

11 Claims, 3 Drawing Sheets

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US009358155B2

(12) **United States Patent**
Sorensen et al.

(10) **Patent No.: US 9,358,155 B2**
(45) **Date of Patent: Jun. 7, 2016**

(54) **DUAL BLADE OPHTHALMOLOGIC SURGERY DEVICE**

(58) **Field of Classification Search**
CPC ... A61F 9/00781; A61F 9/0079; A61F 9/007; A61F 2009/00868; A61F 9/00736–9/00763; A61F 9/013–9/0133; A61B 17/320016; A61B 18/1482; A61B 2018/00083; A61B 2018/1497
USPC 606/167, 107, 166, 170, 184, 185; 600/566–567; 30/287, 304–305
See application file for complete search history.

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OTHER PUBLICATIONS

US Patent Office Action dated Sep. 29, 2009 in related U.S. Appl. No. 10/560,267, filed May 11, 2006.
(Continued)

Primary Examiner — Amy R Weisberg
(74) *Attorney, Agent, or Firm* — Robert D. Buyan; Stout, Uxa & Buyan, LLP

(57) **ABSTRACT**

A dual blade device comprising an elongate probe having first and lateral second cutting edges and a blunt protruding distal tip, useable for performing an ab interno procedure to remove a strip of trabecular meshwork tissue from a human eye.

7 Claims, 3 Drawing Sheets

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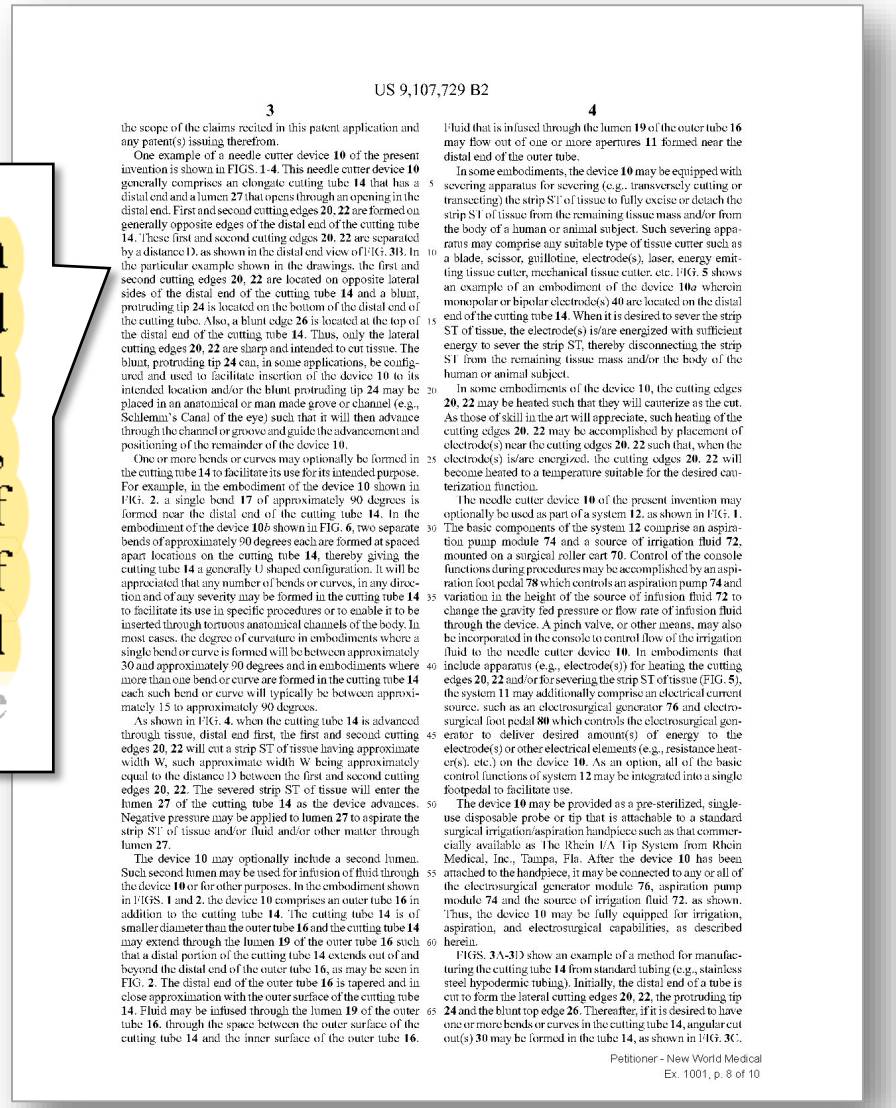
by a distance D, as shown in the distal end view of FIG. 3B. In the particular example shown in the drawings, the first and second cutting edges **20**, **22** are located on opposite lateral sides of the distal end of the cutting tube **14** and a blunt, protruding tip **24** is located on the bottom of the distal end of the cutting tube. Also, a blunt edge **26** is located at the top of the distal end of the cutting tube **14**. Thus, only the lateral cutting edges **20**, **22** are sharp and intended to cut tissue. The



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the scope of the claims recited in this patent application and any patent(s) issuing therefrom.

One example of a needle cutter device **10** of the present invention is shown in FIGS. **1-4**. This needle cutter device **10** generally comprises an elongate cutting tube **14** that has a distal end and a lumen **27** that opens through an opening in the distal end. First and second cutting edges **20**, **22** are formed on generally opposite edges of the distal end of the cutting tube **14**. These first and second cutting edges **20**, **22** are separated by a distance D, as shown in the distal end view of FIG. **3B**. In the particular example shown in the drawings, the first and second cutting edges **20**, **22** are located on opposite lateral sides of the distal end of the cutting tube **14** and a blunt, protruding tip **24** is located on the bottom of the distal end of the cutting tube. Also, a blunt edge **26** is located at the top of the distal end of the cutting tube **14**. Thus, only the lateral cutting edges **20**, **22** are sharp and intended to cut tissue. The blunt, protruding tip **24** can, in some applications, be configured and used to facilitate insertion of the device **10** to its intended location and/or the blunt protruding tip **24** may be placed in an anatomical or man made grove or channel (e.g., Schleman's Canal of the eye) such that it will then advance through the channel or groove and guide the advancement and positioning of the remainder of the device **10**.

One or more bends or curves may optionally be formed in the cutting tube **14** to facilitate its use for its intended purpose. For example, in the embodiment of the device **10** shown in FIG. **2**, a single bend **17** of approximately 90 degrees is formed near the distal end of the cutting tube **14**. In the embodiment of the device **10***b* shown in FIG. **6**, two separate bends of approximately 90 degrees each are formed at spaced apart locations on the cutting tube **14**, thereby giving the cutting tube **14** a generally U shaped configuration. It will be appreciated that any number of bends or curves, in any direction and of any severity may be formed in the cutting tube **14** to facilitate its use in specific procedures or to enable it to be inserted through tortuous anatomical channels of the body. In most cases, the degree of curvature in embodiments where a single bend or curve is formed will be between approximately 30 and approximately 90 degrees and in embodiments where more than one bend or curve are formed in the cutting tube **14** each such bend or curve will typically be between approximately 15 to approximately 90 degrees.

As shown in FIG. **4**, when the cutting tube **14** is advanced through tissue, distal end first, the first and second cutting edges **20**, **22** will cut a strip ST of tissue having approximate width W, such approximate width W being approximately equal to the distance D between the first and second cutting edges **20**, **22**. The severed strip ST of tissue will enter the lumen **27** of the cutting tube **14** as the device advances. Negative pressure may be applied to lumen **27** to aspirate the strip ST of tissue and/or fluid and/or other matter through lumen **27**.

The device **10** may optionally include a second lumen. Such second lumen may be used for infusion of fluid through the device **10** or for other purposes. In the embodiment shown in FIGS. **1** and **2**, the device **10** comprises an outer tube **16** in addition to the cutting tube **14**. The cutting tube **14** is of smaller diameter than the outer tube **16** and the cutting tube **14** may extend through the lumen **19** of the outer tube **16** such that a distal portion of the cutting tube **14** extends out of and beyond the distal end of the outer tube **16**, as may be seen in FIG. **2**. The distal end of the outer tube **16** is tapered and in close approximation with the outer surface of the cutting tube **14**. Fluid may be infused through the lumen **19** of the outer tube **16**, through the space between the outer surface of the cutting tube **14** and the inner surface of the outer tube **16**.

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Fluid that is infused through the lumen **19** of the outer tube **16** may flow out of one or more apertures **11** formed near the distal end of the outer tube.

In some embodiments, the device **10** may be equipped with severing apparatus for severing (e.g., transversely cutting or transecting) the strip ST of tissue to fully excise or detach the strip ST of tissue from the remaining tissue mass and/or from the body of a human or animal subject. Such severing apparatus may comprise any suitable type of tissue cutter such as a blade, scissor, guillotine, electrode(s), laser, energy emitting tissue cutter, mechanical tissue cutter, etc. FIG. **5** shows an example of an embodiment of the device **10***a* wherein monopolar or bipolar electrode(s) **40** are located on the distal end of the cutting tube **14**. When it is desired to sever the strip ST of tissue, the electrode(s) is/are energized with sufficient energy to sever the strip ST, thereby disconnecting the strip ST from the remaining tissue mass and/or the body of the human or animal subject.

In some embodiments of the device **10**, the cutting edges **20**, **22** may be heated such that they will cauterize as the cut. As those of skill in the art will appreciate, such heating of the cutting edges **20**, **22** may be accomplished by placement of electrode(s) near the cutting edges **20**, **22** such that, when the electrode(s) is/are energized, the cutting edges **20**, **22** will become heated to a temperature suitable for the desired cauterization function.

The needle cutter device **10** of the present invention may optionally be used as part of a system **12**, as shown in FIG. **1**. The basic components of the system **12** comprise an aspiration pump module **74** and a source of irrigation fluid **72**, mounted on a surgical roller cart **70**. Control of the console functions during procedures may be accomplished by an aspiration foot pedal **78** which controls an aspiration pump **74** and variation in the height of the source of infusion fluid **72** to change the gravity fed pressure or flow rate of infusion fluid through the device. A pinch valve, or other means, may also be incorporated in the console to control flow of the irrigation fluid to the needle cutter device **10**. In embodiments that include apparatus (e.g., electrode(s)) for heating the cutting edges **20**, **22** and/or for severing the strip ST of tissue (FIG. **5**), the system **11** may additionally comprise an electrical current source, such as an electrosurgical generator **76** and electrosurgical foot pedal **80** which controls the electrosurgical generator to deliver desired amount(s) of energy to the electrode(s) or other electrical elements (e.g., resistance heater(s), etc.) on the device **10**. As an option, all of the basic control functions of system **12** may be integrated into a single footpedal to facilitate use.

The device **10** may be provided as a pre-sterilized, single-use disposable probe or tip that is attachable to a standard surgical irrigation/aspiration handpiece such as that commercially available as The Rhein I/A Tip System from Rhein Medical, Inc., Tampa, Fla. After the device **10** has been attached to the handpiece, it may be connected to any or all of the electrosurgical generator module **76**, aspiration pump module **74** and the source of irrigation fluid **72**, as shown. Thus, the device **10** may be fully equipped for irrigation, aspiration, and electrosurgical capabilities, as described herein.

FIGS. **3A-3D** show an example of a method for manufacturing the cutting tube **14** from standard tubing (e.g., stainless steel hypodermic tubing). Initially, the distal end of a tube is cut to form the lateral cutting edges **20**, **22**, the protruding tip **24** and the blunt top edge **26**. Thereafter, if it is desired to have one or more bends or curves in the cutting tube **14**, angular cut out(s) **30** may be formed in the tube **14**, as shown in FIG. **3C**.

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As shown in FIG. **4**, when the cutting tube **14** is advanced through tissue, distal end first, the first and second cutting edges **20**, **22** will cut a strip ST of tissue having approximate width W, such approximate width W being approximately equal to the distance D between the first and second cutting edges **20**, **22**. The severed strip ST of tissue will enter the lumen **27** of the cutting tube **14** as the device advances.

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the scope of the claims recited in this patent application and any patent(s) issuing therefrom.

One example of a needle cutter device **10** of the present invention is shown in FIGS. **1-4**. This needle cutter device **10** generally comprises an elongate cutting tube **14** that has a distal end and a lumen **27** that opens through an opening in the distal end. First and second cutting edges **20**, **22** are formed on generally opposite edges of the distal end of the cutting tube **14**. These first and second cutting edges **20**, **22** are separated by a distance D, as shown in the distal end view of FIG. **3B**. In the particular example shown in the drawings, the first and second cutting edges **20**, **22** are located on opposite lateral sides of the distal end of the cutting tube **14** and a blunt, protruding tip **24** is located on the bottom of the distal end of the cutting tube. Also, a blunt edge **26** is located at the top of the distal end of the cutting tube **14**. Thus, only the lateral cutting edges **20**, **22** are sharp and intended to cut tissue. The blunt, protruding tip **24** can, in some applications, be configured and used to facilitate insertion of the device **10** to its intended location and/or the blunt protruding tip **24** may be placed in an anatomical or man made grove or channel (e.g., Schleman's Canal of the eye) such that it will then advance through the channel or groove and guide the advancement and positioning of the remainder of the device **10**.

One or more bends or curves may optionally be formed in the cutting tube **14** to facilitate its use for its intended purpose. For example, in the embodiment of the device **10** shown in FIG. **2**, a single bend **17** of approximately 90 degrees is formed near the distal end of the cutting tube **14**. In the embodiment of the device **10***b* shown in FIG. **6**, two separate bends of approximately 90 degrees each are formed at spaced apart locations on the cutting tube **14**, thereby giving the cutting tube **14** a generally U shaped configuration. It will be appreciated that any number of bends or curves, in any direction and of any severity may be formed in the cutting tube **14** to facilitate its use in specific procedures or to enable it to be inserted through tortuous anatomical channels of the body. In most cases, the degree of curvature in embodiments where a single bend or curve is formed will be between approximately 30 and approximately 90 degrees and in embodiments where more than one bend or curve are formed in the cutting tube **14** each such bend or curve will typically be between approximately 15 to approximately 90 degrees.

As shown in FIG. **4**, when the cutting tube **14** is advanced through tissue, distal end first, the first and second cutting edges **20**, **22** will cut a strip ST of tissue having approximate width W, such approximate width W being approximately equal to the distance D between the first and second cutting edges **20**, **22**. The severed strip ST of tissue will enter the lumen **27** of the cutting tube **14** as the device advances. Negative pressure may be applied to lumen **27** to aspirate the strip ST of tissue and/or fluid and/or other matter through lumen **27**.

The device **10** may optionally include a second lumen. Such second lumen may be used for infusion of fluid through the device **10** or for other purposes. In the embodiment shown in FIGS. **1** and **2**, the device **10** comprises an outer tube **16** in addition to the cutting tube **14**. The cutting tube **14** is of smaller diameter than the outer tube **16** and the cutting tube **14** may extend through the lumen **19** of the outer tube **16** such that a distal portion of the cutting tube **14** extends out of and beyond the distal end of the outer tube **16**, as may be seen in FIG. **2**. The distal end of the outer tube **16** is tapered and in close approximation with the outer surface of the cutting tube **14**. Fluid may be infused through the lumen **19** of the outer tube **16**, through the space between the outer surface of the cutting tube **14** and the inner surface of the outer tube **16**.

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Fluid that is infused through the lumen **19** of the outer tube **16** may flow out of one or more apertures **11** formed near the distal end of the outer tube.

In some embodiments, the device **10** may be equipped with severing apparatus for severing (e.g., transversely cutting or transecting) the strip ST of tissue to fully excise or detach the strip ST of tissue from the remaining tissue mass and/or from the body of a human or animal subject. Such severing apparatus may comprise any suitable type of tissue cutter such as a blade, scissor, guillotine, electrode(s), laser, energy emitting tissue cutter, mechanical tissue cutter, etc. FIG. **5** shows an example of an embodiment of the device **10***a* wherein monopolar or bipolar electrode(s) **40** are located on the distal end of the cutting tube **14**. When it is desired to sever the strip ST of tissue, the electrode(s) is/are energized with sufficient energy to sever the strip ST, thereby disconnecting the strip ST from the remaining tissue mass and/or the body of the human or animal subject.

In some embodiments of the device **10**, the cutting edges **20**, **22** may be heated such that they will cauterize as the cut. As those of skill in the art will appreciate, such heating of the cutting edges **20**, **22** may be accomplished by placement of electrode(s) near the cutting edges **20**, **22** such that, when the electrode(s) is/are energized, the cutting edges **20**, **22** will become heated to a temperature suitable for the desired cauterization function.

The needle cutter device **10** of the present invention may optionally be used as part of a system **12**, as shown in FIG. **1**. The basic components of the system **12** comprise an aspiration pump module **74** and a source of irrigation fluid **72**, mounted on a surgical roller cart **70**. Control of the console functions during procedures may be accomplished by an aspiration foot pedal **78** which controls an aspiration pump **74** and variation in the height of the source of infusion fluid **72** to change the gravity fed pressure or flow rate of infusion fluid through the device. A pinch valve, or other means, may also be incorporated in the console to control flow of the irrigation fluid to the needle cutter device **10**. In embodiments that include apparatus (e.g., electrode(s)) for heating the cutting edges **20**, **22** and/or for severing the strip ST of tissue (FIG. **5**), the system **11** may additionally comprise an electrical current source, such as an electrosurgical generator **76** and electrosurgical foot pedal **80** which controls the electrosurgical generator to deliver desired amount(s) of energy to the electrode(s) or other electrical elements (e.g., resistance heater(s), etc.) on the device **10**. As an option, all of the basic control functions of system **12** may be integrated into a single footpedal to facilitate use.

The device **10** may be provided as a pre-sterilized, single-use disposable probe or tip that is attachable to a standard surgical irrigation/aspiration handpiece such as that commercially available as The Rhein I/A Tip System from Rhein Medical, Inc., Tampa, Fla. After the device **10** has been attached to the handpiece, it may be connected to any or all of the electrosurgical generator module **76**, aspiration pump module **74** and the source of irrigation fluid **72**, as shown. Thus, the device **10** may be fully equipped for irrigation, aspiration, and electrosurgical capabilities, as described herein.

FIGS. **3A-3D** show an example of a method for manufacturing the cutting tube **14** from standard tubing (e.g., stainless steel hypodermic tubing). Initially, the distal end of a tube is cut to form the lateral cutting edges **20**, **22**, the protruding tip **24** and the blunt top edge **26**. Thereafter, if it is desired to have one or more bends or curves in the cutting tube **14**, angular cut out(s) **30** may be formed in the tube **14**, as shown in FIG. **3C**.

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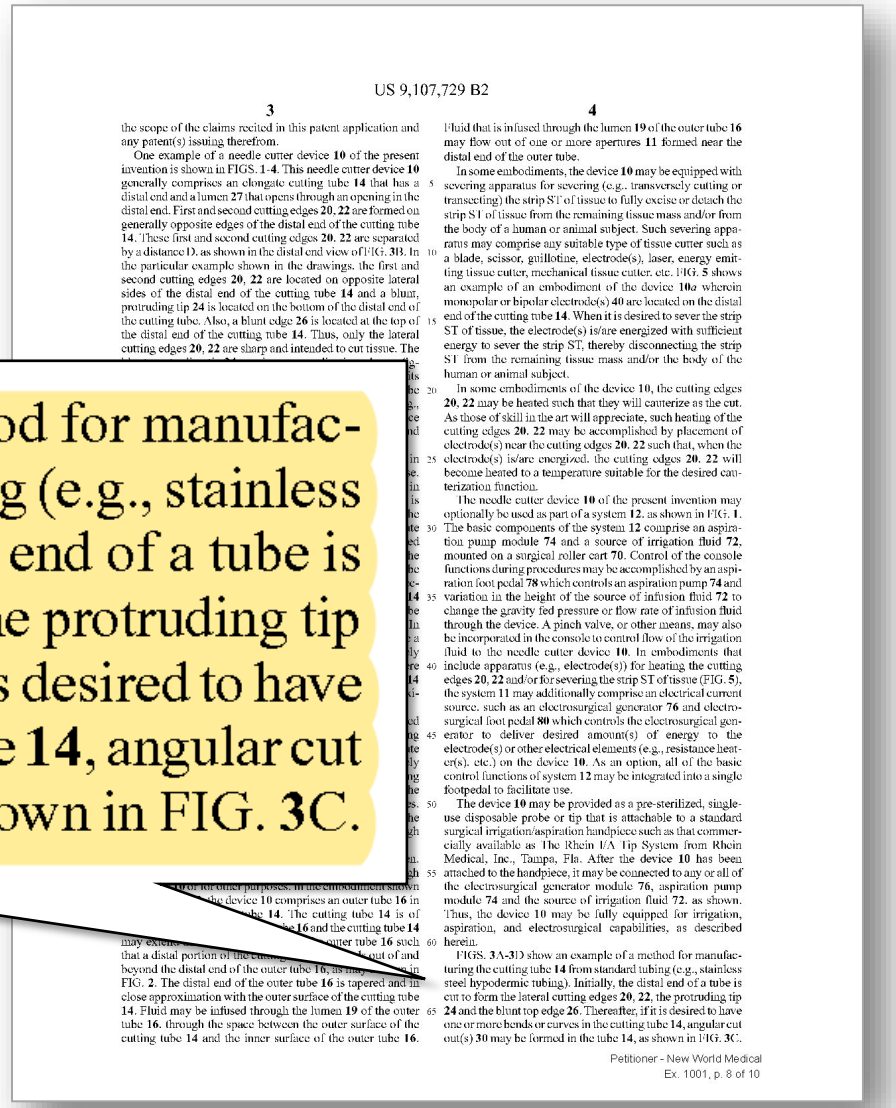

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the scope of the claims recited in this patent application and any patent(s) issuing therefrom.

One example of a needle cutter device **10** of the present invention is shown in FIGS. **1-4**. This needle cutter device **10** generally comprises an elongate cutting tube **14** that has a distal end and a lumen **27** that opens through an opening in the distal end. First and second cutting edges **20**, **22** are formed on generally opposite edges of the distal end of the cutting tube **14**. These first and second cutting edges **20**, **22** are separated by a distance D, as shown in the distal end view of FIG. **3B**. In the particular example shown in the drawings, the first and second cutting edges **20**, **22** are located on opposite lateral sides of the distal end of the cutting tube **14** and a blunt, protruding tip **24** is located on the bottom of the distal end of the cutting tube. Also, a blunt edge **26** is located at the top of the distal end of the cutting tube **14**. Thus, only the lateral cutting edges **20**, **22** are sharp and intended to cut tissue. The

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Fluid that is infused through the lumen **19** of the outer tube **16** may flow out of one or more apertures **11** formed near the distal end of the outer tube.

In some embodiments, the device **10** may be equipped with severing apparatus for severing (e.g., transversely cutting or transecting) the strip ST of tissue to fully excise or detach the strip ST of tissue from the remaining tissue mass and/or from the body of a human or animal subject. Such severing apparatus may comprise any suitable type of tissue cutter such as a blade, scissor, guillotine, electrode(s), laser, energy emitting tissue cutter, mechanical tissue cutter, etc. FIG. **5** shows an example of an embodiment of the device **10a** wherein monopolar or bipolar electrode(s) **40** are located on the distal end of the cutting tube **14**. When it is desired to sever the strip ST of tissue, the electrode(s) is/are energized with sufficient energy to sever the strip ST, thereby disconnecting the strip ST from the remaining tissue mass and/or the body of the human or animal subject.

In some embodiments of the device **10**, the cutting edges **20**, **22** may be heated such that they will cauterize as the cut. As those of skill in the art will appreciate, such heating of the cutting edges **20**, **22** may be accomplished by placement of electrode(s) near the cutting edges **20**, **22** such that, when the electrode(s) is/are energized, the cutting edges **20**, **22** will become heated to a temperature suitable for the desired cauterization function.

The needle cutter device **10** of the present invention may optionally be used as part of a system **12**, as shown in FIG. **1**. The basic components of the system **12** comprise an aspiration pump module **74** and a source of irrigation fluid **72**, mounted on a surgical roller cart **70**. Control of the console functions during procedures may be accomplished by an aspiration foot pedal **78** which controls an aspiration pump **74** and variation in the height of the source of infusion fluid **72** to change the gravity fed pressure or flow rate of infusion fluid through the device. A pinch valve, or other means, may also be incorporated in the console to control flow of the irrigation fluid to the needle cutter device **10**. In embodiments that include apparatus (e.g., electrode(s)) for heating the cutting edges **20**, **22** and/or for severing the strip ST of tissue (FIG. **5**), the system **11** may additionally comprise an electrical current source, such as an electrosurgical generator **76** and electrosurgical foot pedal **80** which controls the electrosurgical generator to deliver desired amount(s) of energy to the electrode(s) or other electrical elements (e.g., resistance heater(s), etc.) on the device **10**. As an option, all of the basic control functions of system **12** may be integrated into a single footpedal to facilitate use.

The device **10** may be provided as a pre-sterilized, single-use disposable probe or tip that is attachable to a standard surgical irrigation/aspiration handpiece such as that commercially available as The Rhein I/A Tip System from Rhein Medical, Inc., Tampa, Fla. After the device **10** has been attached to the handpiece, it may be connected to any or all of the electrosurgical generator module **76**, aspiration pump module **74** and the source of irrigation fluid **72**, as shown. Thus, the device **10** may be fully equipped for irrigation, aspiration, and electrosurgical capabilities, as described herein.

FIGS. **3A-3D** show an example of a method for manufacturing the cutting tube **14** from standard tubing (e.g., stainless steel hypodermic tubing). Initially, the distal end of a tube is cut to form the lateral cutting edges **20**, **22**, the protruding tip **24** and the blunt top edge **26**. Thereafter, if it is desired to have one or more bends or curves in the cutting tube **14**, angular cut out(s) **30** may be formed in the tube **14**, as shown in FIG. **3C**.

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FIGS. **3A-3D** show an example of a method for manufacturing the cutting tube **14** from standard tubing (e.g., stainless steel hypodermic tubing). Initially, the distal end of a tube is cut to form the lateral cutting edges **20**, **22**, the protruding tip **24** and the blunt top edge **26**. Thereafter, if it is desired to have one or more bends or curves in the cutting tube **14**, angular cut out(s) **30** may be formed in the tube **14**, as shown in FIG. **3C**.

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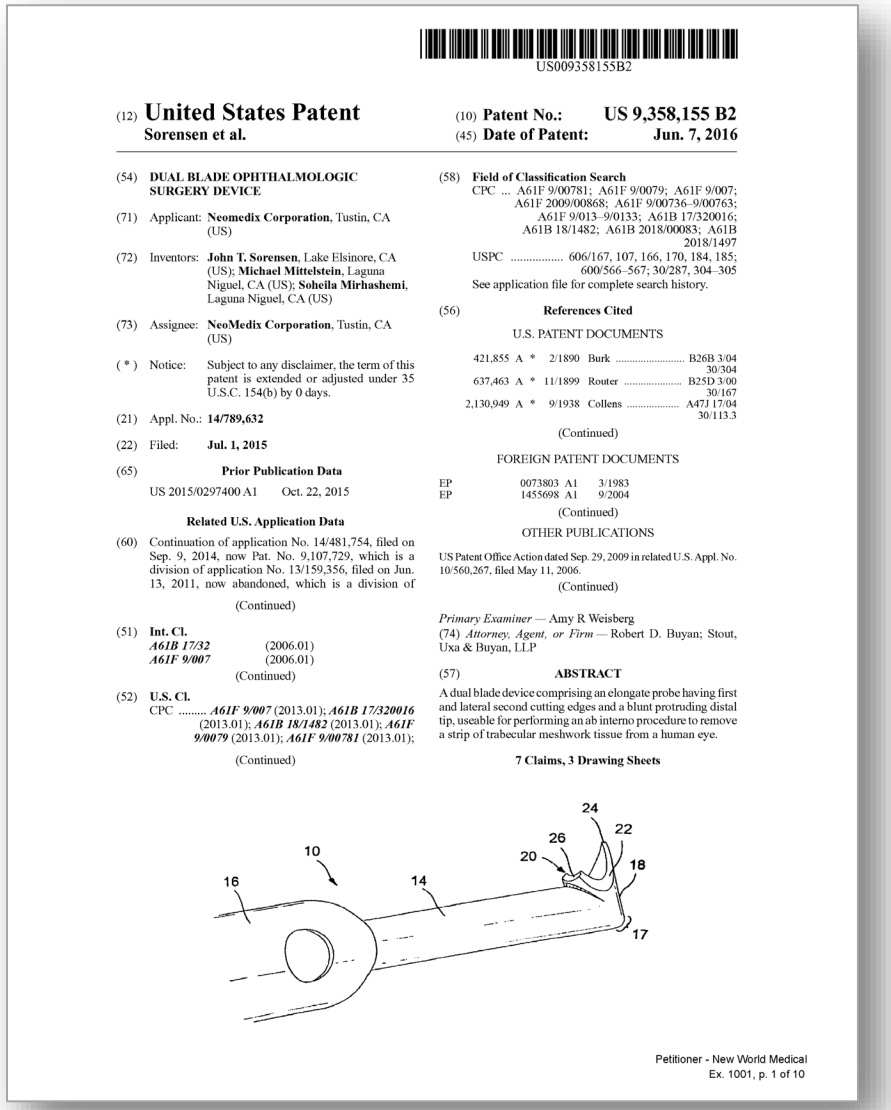

US009358155B2

(12) **United States Patent**
Sorensen et al.

(10) **Patent No.: US 9,358,155 B2**
(45) **Date of Patent: Jun. 7, 2016**

(54) **DUAL BLADE OPHTHALMOLOGIC SURGERY DEVICE**

(71) Applicant: **Neomedix Corporation**, Tustin, CA (US)

(72) Inventors: **John T. Sorensen**, Lake Elsinore, CA (US); **Michael Mittelstein**, Laguna Niguel, CA (US); **Soheila Mirhashemi**, Laguna Niguel, CA (US)

(73) Assignee: **NeoMedix Corporation**, Tustin, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/789,632**

(22) Filed: **Jul. 1, 2015**

(65) **Prior Publication Data**

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Related U.S. Application Data

(60) Continuation of application No. 14/481,754, filed on Sep. 9, 2014, now Pat. No. 9,107,729, which is a division of application No. 13/159,356, filed on Jun. 13, 2011, now abandoned, which is a division of

(Continued)

(51) **Int. Cl.**
A61B 17/32 (2006.01)
A61F 9/007 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61F 9/007*** (2013.01); ***A61B 17/320016*** (2013.01); ***A61B 18/1482*** (2013.01); ***A61F 9/0079*** (2013.01); ***A61F 9/00781*** (2013.01);

(Continued)

(58) **Field of Classification Search**
CPC ... A61F 9/00781; A61F 9/0079; A61F 9/007; A61F 2009/00868; A61F 9/00736–9/00763; A61F 9/013–9/0133; A61B 17/320016; A61B 18/1482; A61B 2018/00083; A61B 2018/1497
USPC 606/167, 107, 166, 170, 184, 185; 600/566–567; 30/287, 304–305
See application file for complete search history.

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(Continued)

Primary Examiner — Amy R Weisberg
(74) *Attorney, Agent, or Firm* — Robert D. Buyan; Stout, Uxa & Buyan, LLP

(57) **ABSTRACT**

A dual blade device comprising an elongate probe having first and lateral second cutting edges and a blunt protruding distal tip, useable for performing an ab interno procedure to remove a strip of trabecular meshwork tissue from a human eye.

7 Claims, 3 Drawing Sheets

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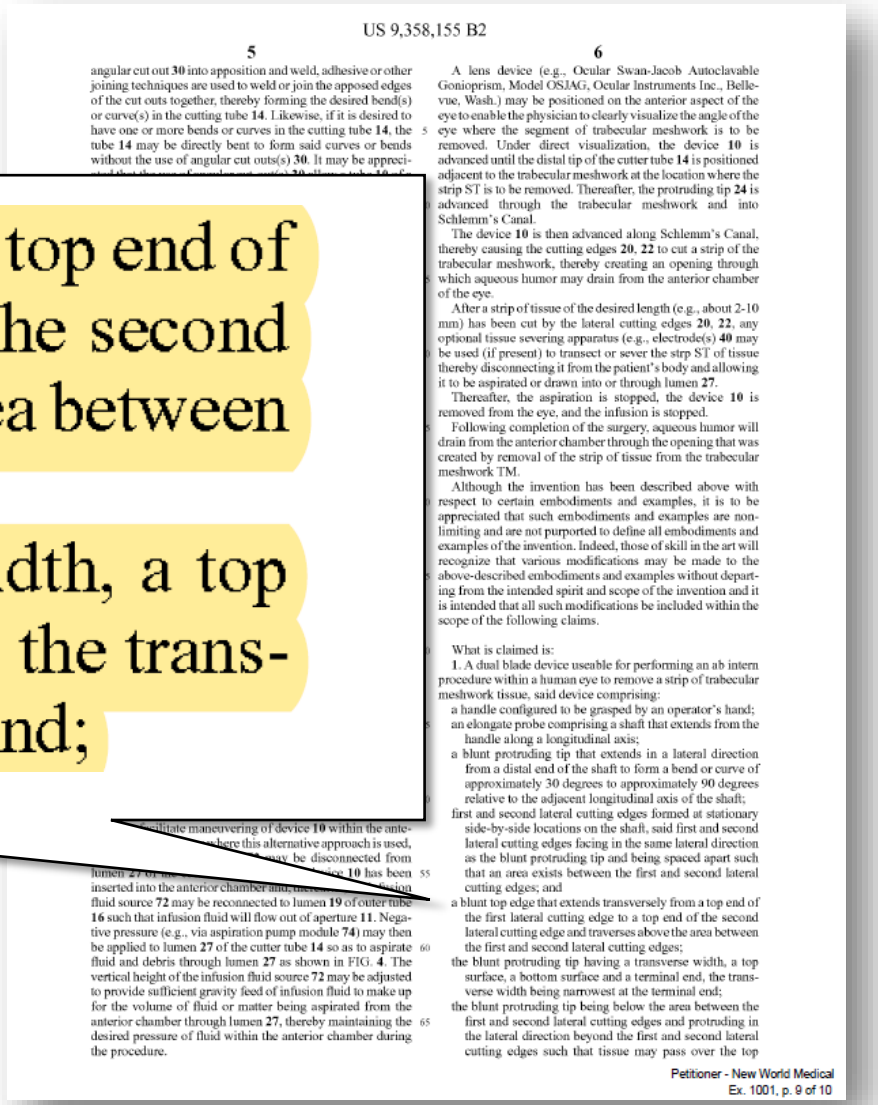
’155 Patent 6:57-63 (Claim 1)

a blunt top edge that extends transversely from a top end of the first lateral cutting edge to a top end of the second lateral cutting edge and traverses above the area between the first and second lateral cutting edges;

the blunt protruding tip having a transverse width, a top surface, a bottom surface and a terminal end, the transverse width being narrowest at the terminal end;



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angular cut out **30** into apposition and weld, adhesive or other joining techniques are used to weld or join the apposed edges of the cut outs together, thereby forming the desired bend(s) or curve(s) in the cutting tube **14**. Likewise, if it is desired to have one or more bends or curves in the cutting tube **14**, the tube **14** may be directly bent to form said curves or bends without the use of angular cut outs(s) **30**. It may be appreci-

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A lens device (e.g., Ocular Swan-Jacob Autoclavable Gonioprism, Model OSJAG, Ocular Instruments Inc., Bellevue, Wash.) may be positioned on the anterior aspect of the eye to enable the physician to clearly visualize the angle of the eye where the segment of trabecular meshwork is to be removed. Under direct visualization, the device **10** is advanced until the distal tip of the cutter tube **14** is positioned adjacent to the trabecular meshwork at the location where the strip ST is to be removed. Thereafter, the protruding tip **24** is advanced through the trabecular meshwork and into Schlemm's Canal.

The device **10** is then advanced along Schlemm's Canal, thereby causing the cutting edges **20**, **22** to cut a strip of the trabecular meshwork, thereby creating an opening through which aqueous humor may drain from the anterior chamber of the eye.

After a strip of tissue of the desired length (e.g., about 2-10 mm) has been cut by the lateral cutting edges **20**, **22**, any optional tissue severing apparatus (e.g., electrode(s) **40** may be used (if present) to transect or sever the strp ST of tissue thereby disconnecting it from the patient's body and allowing it to be aspirated or drawn into or through lumen **27**.

Thereafter, the aspiration is stopped, the device **10** is removed from the eye, and the infusion is stopped.

Following completion of the surgery, aqueous humor will drain from the anterior chamber through the opening that was created by removal of the strip of tissue from the trabecular meshwork TM.

Although the invention has been described above with respect to certain embodiments and examples, it is to be appreciated that such embodiments and examples are non-limiting and are not purported to define all embodiments and examples of the invention. Indeed, those of skill in the art will recognize that various modifications may be made to the above-described embodiments and examples without departing from the intended spirit and scope of the invention and it is intended that all such modifications be included within the scope of the following claims.

What is claimed is:

1. A dual blade device useable for performing an ab intern procedure within a human eye to remove a strip of trabecular meshwork tissue, said device comprising:

a handle configured to be grasped by an operator's hand;

an elongate probe comprising a shaft that extends from the handle along a longitudinal axis;

a blunt protruding tip that extends in a lateral direction from a distal end of the shaft to form a bend or curve of approximately 30 degrees to approximately 90 degrees relative to the adjacent longitudinal axis of the shaft;

first and second lateral cutting edges formed at stationary side-by-side locations on the shaft, said first and second lateral cutting edges facing in the same lateral direction as the blunt protruding tip and being spaced apart such that an area exists between the first and second lateral cutting edges; and

a blunt top edge that extends transversely from a top end of the first lateral cutting edge to a top end of the second lateral cutting edge and traverses above the area between the first and second lateral cutting edges;

the blunt protruding tip having a transverse width, a top surface, a bottom surface and a terminal end, the transverse width being narrowest at the terminal end;

the blunt protruding tip being below the area between the first and second lateral cutting edges and protruding in the lateral direction beyond the first and second lateral cutting edges such that tissue may pass over the top

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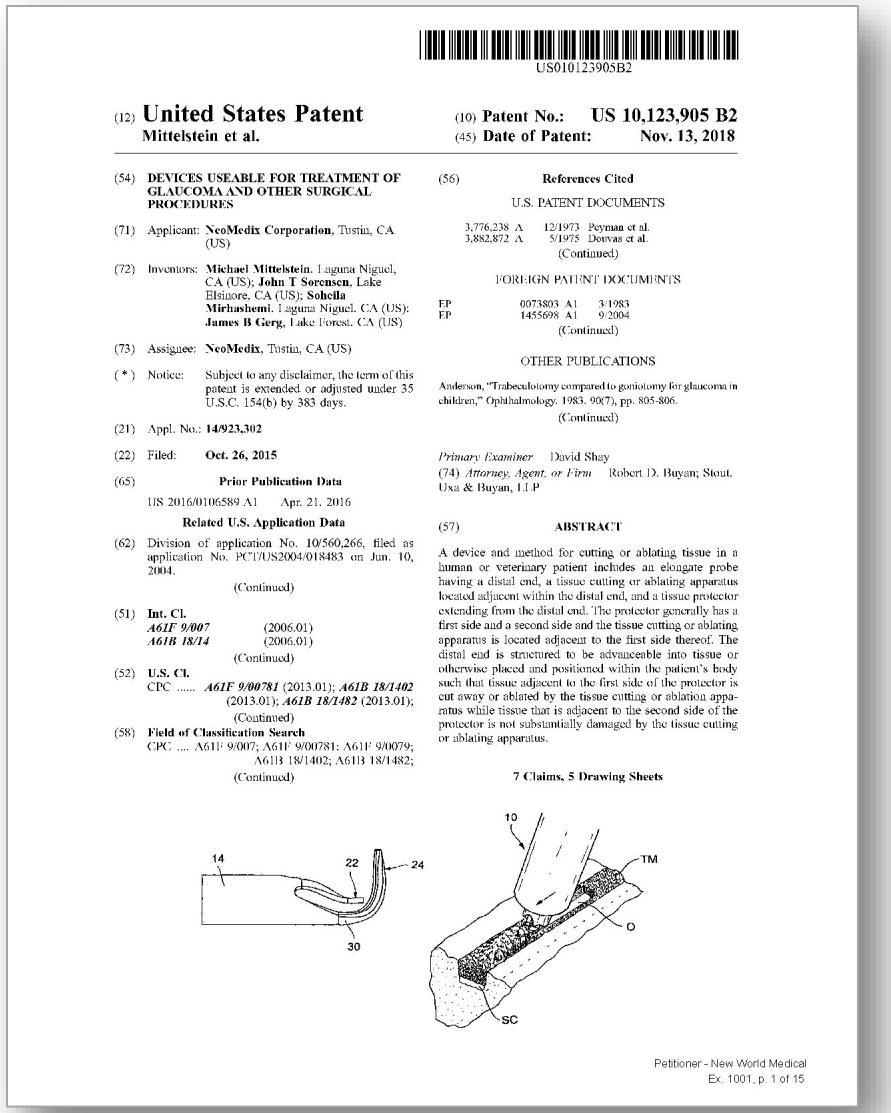
’905 Patent, -00065 Ex. 1001



US010123905B2

(12) **United States Patent**
Mittelstein et al.

(10) **Patent No.: US 10,123,905 B2**
(45) **Date of Patent: Nov. 13, 2018**

(54) **DEVICES USEABLE FOR TREATMENT OF GLAUCOMA AND OTHER SURGICAL PROCEDURES**

(71) Applicant: **NeoMedix Corporation**, Tustin, CA (US)

(72) Inventors: **Michael Mittelstein**, Laguna Niguel, CA (US); **John T Sorensen**, Lake Elsinore, CA (US); **Sohella Mirhashemi**, Laguna Niguel, CA (US); **James B Gerg**, Lake Forest, CA (US)

(73) Assignee: **NeoMedix**, Tustin, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 383 days.

(21) Appl. No.: **14/923,302**

(22) Filed: **Oct. 26, 2015**

(65) **Prior Publication Data**

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Related U.S. Application Data

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(Continued)

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A61B 18/14 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61F 9/00781*** (2013.01); ***A61B 18/1402*** (2013.01); ***A61B 18/1482*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61F 9/007; A61F 9/00781; A61F 9/0079; A61B 18/1402; A61B 18/1482;
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Primary Examiner David Shay
(74) *Attorney, Agent, or Firm* Robert D. Buyan; Stout, Uxa & Buyan, LLP

(57) **ABSTRACT**

A device and method for cutting or ablating tissue in a human or veterinary patient includes an elongate probe having a distal end, a tissue cutting or ablating apparatus located adjacent within the distal end, and a tissue protector extending from the distal end. The protector generally has a first side and a second side and the tissue cutting or ablating apparatus is located adjacent to the first side thereof. The distal end is structured to be advanceable into tissue or otherwise placed and positioned within the patient's body such that tissue adjacent to the first side of the protector is cut away or ablated by the tissue cutting or ablation apparatus while tissue that is adjacent to the second side of the protector is not substantially damaged by the tissue cutting or ablating apparatus.

7 Claims, 5 Drawing Sheets

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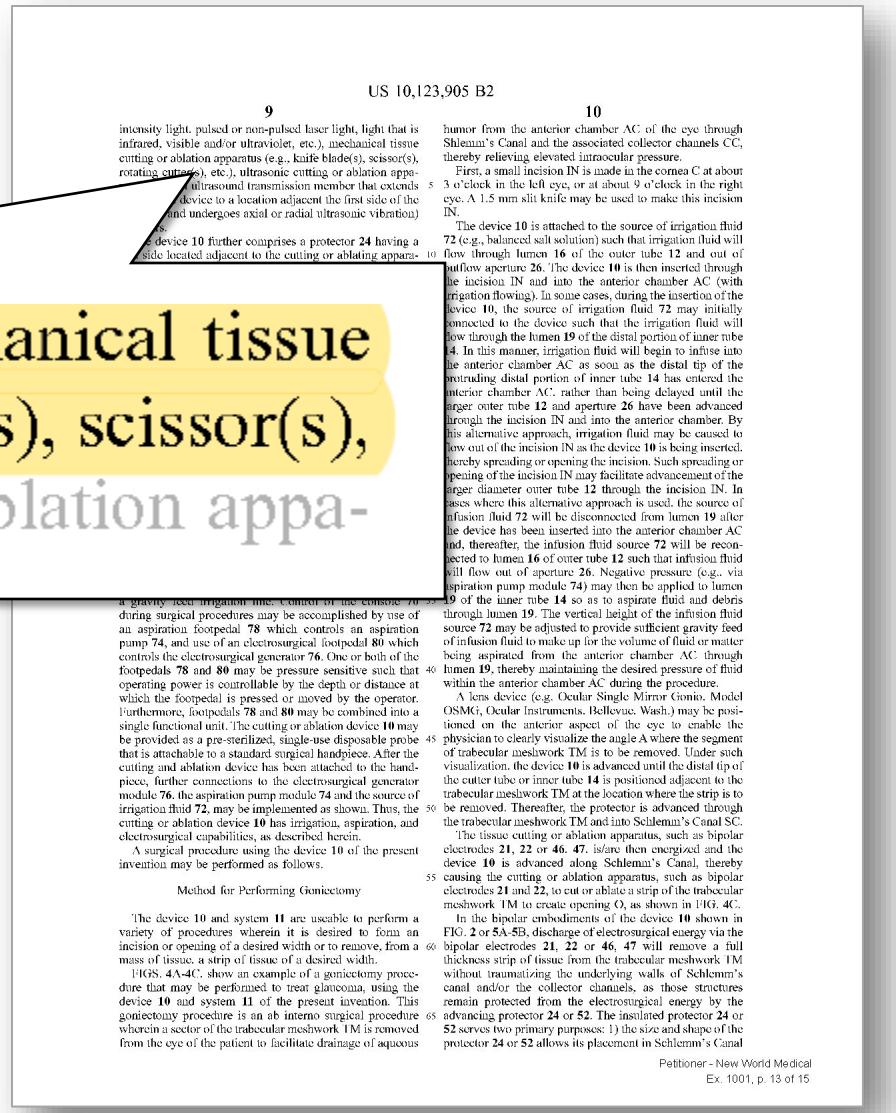
infrared, visible and/or ultraviolet, etc.), mechanical tissue cutting or ablation apparatus (e.g., knife blade(s), scissor(s), rotating cutter(s), etc.), ultrasonic cutting or ablation appa-



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intensity light, pulsed or non-pulsed laser light, light that is infrared, visible and/or ultraviolet, etc.), mechanical tissue cutting or ablation apparatus (e.g., knife blade(s), scissor(s), rotating cutter(s), etc.), ultrasonic cutting or ablation appa-
ultrasound transmission member that extends
device to a location adjacent the first side of the
and undergoes axial or radial ultrasonic vibration)
s.
e device **10** further comprises a protector **24** having a
side located adjacent to the cutting or ablating appara-

during surgical procedures may be accomplished by use of an aspiration footpedal **78** which controls an aspiration pump **74**, and use of an electrosurgical footpedal **80** which controls the electrosurgical generator **76**. One or both of the footpedals **78** and **80** may be pressure sensitive such that operating power is controllable by the depth or distance at which the footpedal is pressed or moved by the operator. Furthermore, footpedals **78** and **80** may be combined into a single functional unit. The cutting or ablation device **10** may be provided as a pre-sterilized, single-use disposable probe that is attachable to a standard surgical handpiece. After the cutting and ablation device has been attached to the handpiece, further connections to the electrosurgical generator module **76**, the aspiration pump module **74** and the source of irrigation fluid **72**, may be implemented as shown. Thus, the cutting or ablation device **10** has irrigation, aspiration, and electrosurgical capabilities, as described herein.

A surgical procedure using the device **10** of the present invention may be performed as follows.

Method for Performing Goniectomy

The device **10** and system **11** are useable to perform a variety of procedures wherein it is desired to form an incision or opening of a desired width or to remove, from a mass of tissue, a strip of tissue of a desired width.

FIGS. **4A-4C**. show an example of a goniectomy procedure that may be performed to treat glaucoma, using the device **10** and system **11** of the present invention. This goniectomy procedure is an ab interno surgical procedure wherein a sector of the trabecular meshwork TM is removed from the eye of the patient to facilitate drainage of aqueous humor from the anterior chamber AC of the eye through Schlemm's Canal and the associated collector channels CC, thereby relieving elevated intraocular pressure.

First, a small incision IN is made in the cornea C at about 3 o'clock in the left eye, or at about 9 o'clock in the right eye. A 1.5 mm slit knife may be used to make this incision IN.

The device **10** is attached to the source of irrigation fluid **72** (e.g., balanced salt solution) such that irrigation fluid will flow through lumen **16** of the outer tube **12** and out of outflow aperture **26**. The device **10** is then inserted through the incision IN and into the anterior chamber AC (with irrigation flowing). In some cases, during the insertion of the device **10**, the source of irrigation fluid **72** may initially connected to the device such that the irrigation fluid will flow through the lumen **19** of the distal portion of inner tube **14**. In this manner, irrigation fluid will begin to infuse into the anterior chamber AC as soon as the distal tip of the protruding distal portion of inner tube **14** has entered the anterior chamber AC, rather than being delayed until the larger outer tube **12** and aperture **26** have been advanced through the incision IN and into the anterior chamber. By this alternative approach, irrigation fluid may be caused to flow out of the incision IN as the device **10** is being inserted, thereby spreading or opening the incision. Such spreading or opening of the incision IN may facilitate advancement of the larger diameter outer tube **12** through the incision IN. In cases where this alternative approach is used, the source of infusion fluid **72** will be disconnected from lumen **19** after the device has been inserted into the anterior chamber AC and, thereafter, the infusion fluid source **72** will be reconnected to lumen **16** of outer tube **12** such that infusion fluid will flow out of aperture **26**. Negative pressure (e.g., via aspiration pump module **74**) may then be applied to lumen **19** of the inner tube **14** so as to aspirate fluid and debris through lumen **19**. The vertical height of the infusion fluid source **72** may be adjusted to provide sufficient gravity feed of infusion fluid to make up for the volume of fluid or matter being aspirated from the anterior chamber AC through lumen **19**, thereby maintaining the desired pressure of fluid within the anterior chamber AC during the procedure.

A lens device (e.g. Ocular Single Mirror Gonio, Model OSMG, Ocular Instruments, Bellevue, Wash.) may be positioned on the anterior aspect of the eye to enable the physician to clearly visualize the angle A where the segment of trabecular meshwork TM is to be removed. Under such visualization, the device **10** is advanced until the distal tip of the cutter tube or inner tube **14** is positioned adjacent to the trabecular meshwork TM at the location where the strip is to be removed. Thereafter, the protector is advanced through the trabecular meshwork TM and into Schlemm's Canal SC.

The tissue cutting or ablation apparatus, such as bipolar electrodes **21**, **22** or **46**, **47**. is/are then energized and the device **10** is advanced along Schlemm's Canal, thereby causing the cutting or ablation apparatus, such as bipolar electrodes **21** and **22**, to cut or ablate a strip of the trabecular meshwork TM to create opening O, as shown in FIG. 4C.

In the bipolar embodiments of the device **10** shown in FIG. **2** or **5A-5B**, discharge of electrosurgical energy via the bipolar electrodes **21**, **22** or **46**, **47** will remove a full thickness strip of tissue from the trabecular meshwork TM without traumatizing the underlying walls of Schlemm's canal and/or the collector channels, as those structures remain protected from the electrosurgical energy by the advancing protector **24** or **52**. The insulated protector **24** or **52** serves two primary purposes: 1) the size and shape of the protector **24** or **52** allows its placement in Schlemm's Canal

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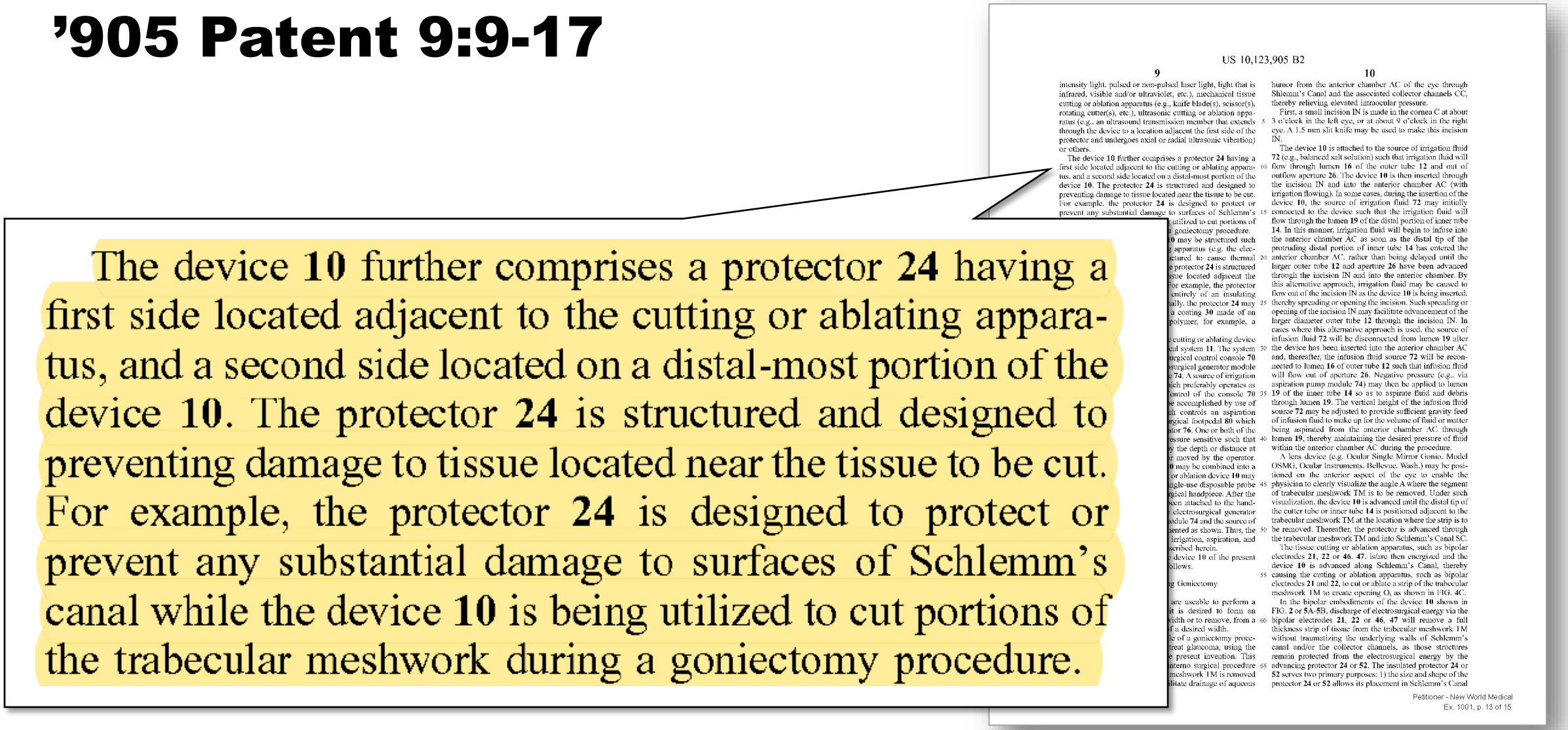
’905 Patent 9:9-17



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intensity light, pulsed or non-pulsed laser light, light that is infrared, visible and/or ultraviolet, etc.), mechanical tissue cutting or ablation apparatus (e.g., knife blade(s), scissor(s), rotating cutter(s), etc.), ultrasonic cutting or ablation apparatus (e.g., an ultrasound transmission member that extends through the device to a location adjacent the first side of the protector and undergoes axial or radial ultrasonic vibration) or others.

The device **10** further comprises a protector **24** having a first side located adjacent to the cutting or ablating apparatus, and a second side located on a distal-most portion of the device **10**. The protector **24** is structured and designed to preventing damage to tissue located near the tissue to be cut. For example, the protector **24** is designed to protect or prevent any substantial damage to surfaces of Schlemm's canal while the device **10** is being utilized to cut portions of the trabecular meshwork during a goniectomy procedure.

humor from the anterior chamber AC of the eye through Schlemm's Canal and the associated collector channels CC, thereby relieving elevated intraocular pressure.

First, a small incision IN is made in the cornea C at about 3 o'clock in the left eye, or at about 9 o'clock in the right eye. A 1.5 mm slit knife may be used to make this incision IN.

The device **10** is attached to the source of irrigation fluid **72** (e.g., balanced salt solution) such that irrigation fluid will flow through lumen **16** of the outer tube **12** and out of outflow aperture **26**. The device **10** is then inserted through the incision IN and into the anterior chamber AC (with irrigation flowing). In some cases, during the insertion of the device **10**, the source of irrigation fluid **72** may initially connected to the device such that the irrigation fluid will flow through the lumen **19** of the distal portion of inner tube **14**. In this manner, irrigation fluid will begin to infuse into the anterior chamber AC as soon as the distal tip of the protruding distal portion of inner tube **14** has entered the anterior chamber AC, rather than being delayed until the larger outer tube **12** and aperture **26** have been advanced through the incision IN and into the anterior chamber. By this alternative approach, irrigation fluid may be caused to flow out of the incision IN as the device **10** is being inserted, thereby spreading or opening the incision. Such spreading or opening of the incision IN may facilitate advancement of the larger diameter outer tube **12** through the incision IN. In cases where this alternative approach is used, the source of infusion fluid **72** will be disconnected from lumen **19** after the device has been inserted into the anterior chamber AC and, thereafter, the infusion fluid source **72** will be reconnected to lumen **16** of outer tube **12** such that infusion fluid will flow out of aperture **26**. Negative pressure (e.g., via aspiration pump module **74**) may then be applied to lumen **19** of the inner tube **14** so as to aspirate fluid and debris through lumen **19**. The vertical height of the infusion fluid source **72** may be adjusted to provide sufficient gravity feed of infusion fluid to make up for the volume of fluid or matter being aspirated from the anterior chamber AC through lumen **19**, thereby maintaining the desired pressure of fluid within the anterior chamber AC during the procedure.

A lens device (e.g. Ocular Single Mirror Gonio, Model OSMG, Ocular Instruments, Bellevue, Wash.) may be positioned on the anterior aspect of the eye to enable the physician to clearly visualize the angle A where the segment of trabecular meshwork TM is to be removed. Under such visualization, the device **10** is advanced until the distal tip of the cutter tube or inner tube **14** is positioned adjacent to the trabecular meshwork TM at the location where the strip is to be removed. Thereafter, the protector is advanced through the trabecular meshwork TM and into Schlemm's Canal SC.

The tissue cutting or ablation apparatus, such as bipolar electrodes **21**, **22** or **46**, **47**, is/are then energized and the device **10** is advanced along Schlemm's Canal, thereby causing the cutting or ablation apparatus, such as bipolar electrodes **21** and **22**, to cut or ablate a strip of the trabecular meshwork TM to create opening O, as shown in FIG. 4C.

In the bipolar embodiments of the device **10** shown in FIG. **2** or **5A-5B**, discharge of electrosurgical energy via the bipolar electrodes **21**, **22** or **46**, **47** will remove a full thickness strip of tissue from the trabecular meshwork TM without traumatizing the underlying walls of Schlemm's canal and/or the collector channels, as those structures remain protected from the electrosurgical energy by the advancing protector **24** or **52**. The insulated protector **24** or **52** serves two primary purposes: 1) the size and shape of the protector **24** or **52** allows its placement in Schlemm's Canal

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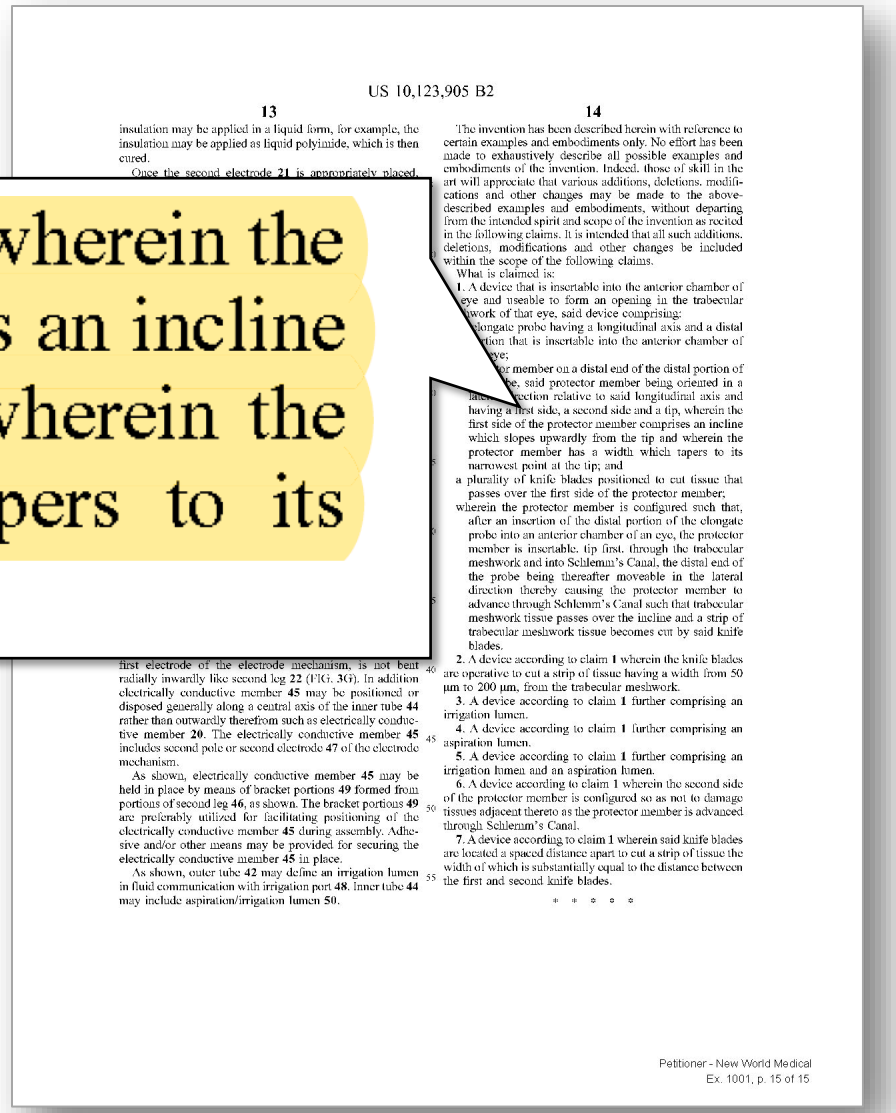
’905 Patent 14:21-25 (Claim 1)

having a first side, a second side and a tip, wherein the first side of the protector member comprises an incline which slopes upwardly from the tip and wherein the protector member has a width which tapers to its narrowest point at the tip; and



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insulation may be applied in a liquid form, for example, the insulation may be applied as liquid polyimide, which is then cured.

Once the second electrode **21** is appropriately placed, first electrode of the electrode mechanism, is not bent radially inwardly like second leg **22** (FIG. **3**G). In addition electrically conductive member **45** may be positioned or disposed generally along a central axis of the inner tube **44** rather than outwardly therefrom such as electrically conductive member **20**. The electrically conductive member **45** includes second pole or second electrode **47** of the electrode mechanism.

As shown, electrically conductive member **45** may be held in place by means of bracket portions **49** formed from portions of second leg **46**, as shown. The bracket portions **49** are preferably utilized for facilitating positioning of the electrically conductive member **45** during assembly. Adhesive and/or other means may be provided for securing the electrically conductive member **45** in place.

As shown, outer tube **42** may define an irrigation lumen in fluid communication with irrigation port **48**. Inner tube **44** may include aspiration/irrigation lumen **50**.

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The invention has been described herein with reference to certain examples and embodiments only. No effort has been made to exhaustively describe all possible examples and embodiments of the invention. Indeed, those of skill in the art will appreciate that various additions, deletions, modifications and other changes may be made to the above-described examples and embodiments, without departing from the intended spirit and scope of the invention as recited in the following claims. It is intended that all such additions, deletions, modifications and other changes be included within the scope of the following claims.

What is claimed is:

1. A device that is insertable into the anterior chamber of eye and useable to form an opening in the trabecular ...work of that eye, said device comprising:

...longate probe having a longitudinal axis and a distal ...tion that is insertable into the anterior chamber of ...eye;

...or member on a distal end of the distal portion of ...be, said protector member being oriented in a ...irection relative to said longitudinal axis and having a first side, a second side and a tip, wherein the first side of the protector member comprises an incline which slopes upwardly from the tip and wherein the protector member has a width which tapers to its narrowest point at the tip; and

a plurality of knife blades positioned to cut tissue that passes over the first side of the protector member;

wherein the protector member is configured such that, after an insertion of the distal portion of the elongate probe into an anterior chamber of an eye, the protector member is insertable, tip first, through the trabecular meshwork and into Schlemm's Canal, the distal end of the probe being thereafter moveable in the lateral direction thereby causing the protector member to advance through Schlemm's Canal such that trabecular meshwork tissue passes over the incline and a strip of trabecular meshwork tissue becomes cut by said knife blades.

2. A device according to claim **1** wherein the knife blades are operative to cut a strip of tissue having a width from 50 μm to 200 μm, from the trabecular meshwork.

3. A device according to claim **1** further comprising an irrigation lumen.

4. A device according to claim **1** further comprising an aspiration lumen.

5. A device according to claim **1** further comprising an irrigation lumen and an aspiration lumen.

6. A device according to claim **1** wherein the second side of the protector member is configured so as not to damage tissues adjacent thereto as the protector member is advanced through Schlemm's Canal.

7. A device according to claim **1** wherein said knife blades are located a spaced distance apart to cut a strip of tissue the width of which is substantially equal to the distance between the first and second knife blades.

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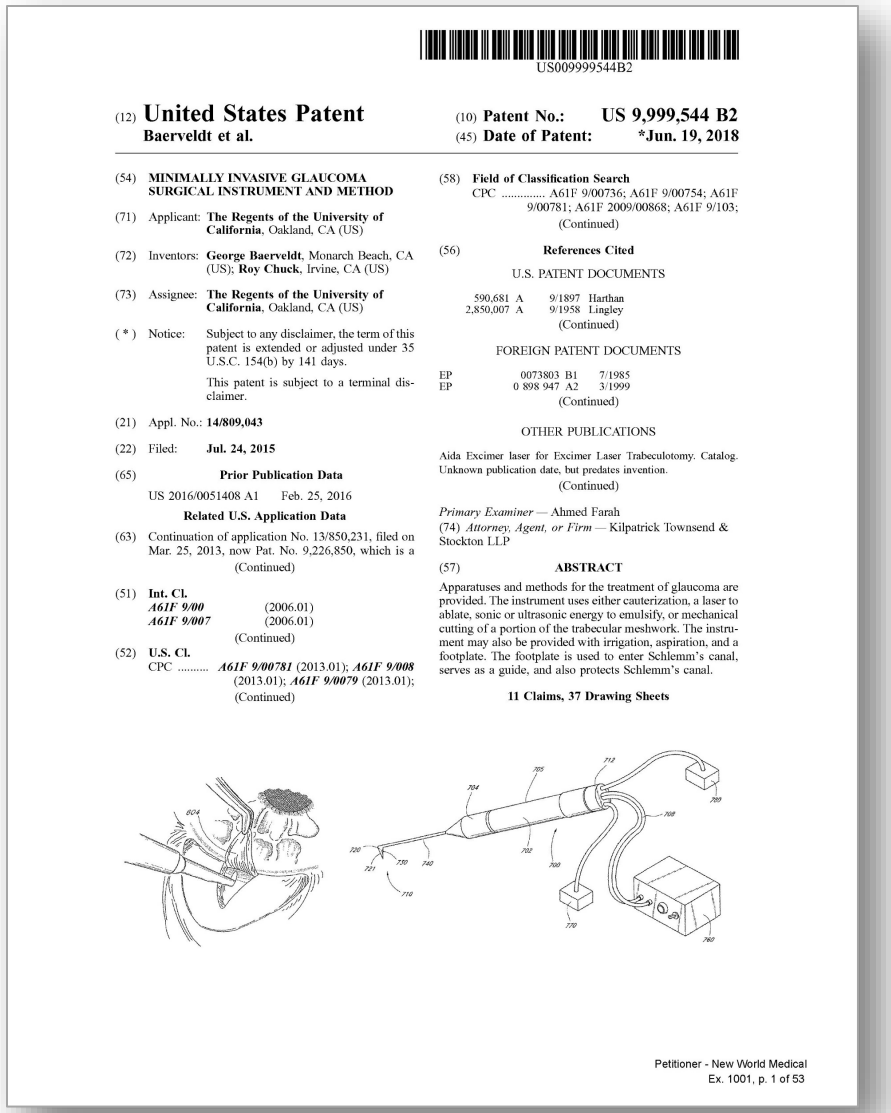
’544 Patent, -00066 Ex.1001



US009999544B2

(12) **United States Patent**
Baerveldt et al.

(10) **Patent No.: US 9,999,544 B2**
(45) **Date of Patent: *Jun. 19, 2018**

(54) **MINIMALLY INVASIVE GLAUCOMA SURGICAL INSTRUMENT AND METHOD**

(71) Applicant: **The Regents of the University of California**, Oakland, CA (US)

(72) Inventors: **George Baerveldt**, Monarch Beach, CA (US); **Roy Chuck**, Irvine, CA (US)

(73) Assignee: **The Regents of the University of California**, Oakland, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 141 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/809,043**

(22) Filed: **Jul. 24, 2015**

(65) **Prior Publication Data**

US 2016/0051408 A1 Feb. 25, 2016

Related U.S. Application Data

(63) Continuation of application No. 13/850,231, filed on Mar. 25, 2013, now Pat. No. 9,226,850, which is a (Continued)

(51) **Int. Cl.**
A61F 9/00 (2006.01)
A61F 9/007 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ..... ***A61F 9/00781*** (2013.01); ***A61F 9/008*** (2013.01); ***A61F 9/0079*** (2013.01); (Continued)

(58) **Field of Classification Search**
CPC A61F 9/00736; A61F 9/00754; A61F 9/00781; A61F 2009/00868; A61F 9/103;
(Continued)

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(Continued)

Primary Examiner — Ahmed Farah
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(57) **ABSTRACT**

Apparatuses and methods for the treatment of glaucoma are provided. The instrument uses either cauterization, a laser to ablate, sonic or ultrasonic energy to emulsify, or mechanical cutting of a portion of the trabecular meshwork. The instrument may also be provided with irrigation, aspiration, and a footplate. The footplate is used to enter Schlemm’s canal, serves as a guide, and also protects Schlemm’s canal.

11 Claims, 37 Drawing Sheets

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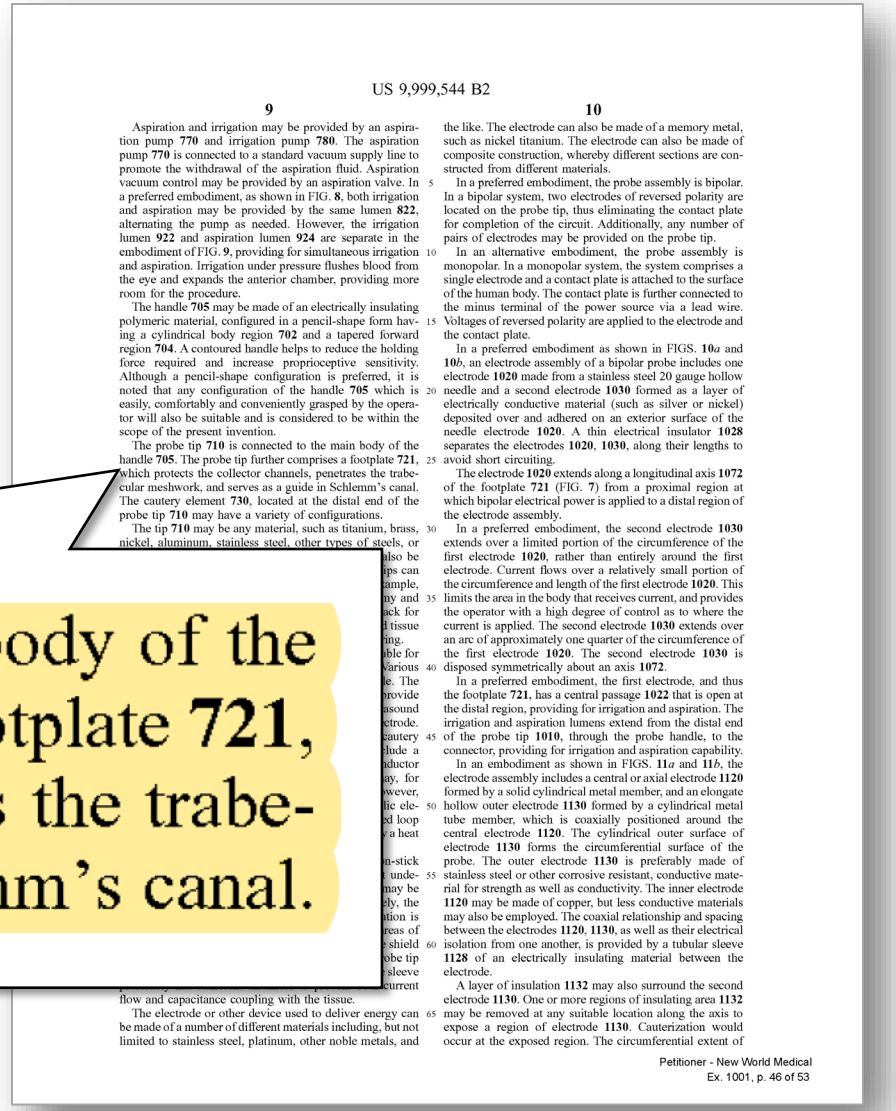
’544 Patent 9:24-27



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Aspiration and irrigation may be provided by an aspiration pump **770** and irrigation pump **780**. The aspiration pump **770** is connected to a standard vacuum supply line to promote the withdrawal of the aspiration fluid. Aspiration vacuum control may be provided by an aspiration valve. In a preferred embodiment, as shown in FIG. **8**, both irrigation and aspiration may be provided by the same lumen **822**, alternating the pump as needed. However, the irrigation lumen **922** and aspiration lumen **924** are separate in the embodiment of FIG. **9**, providing for simultaneous irrigation and aspiration. Irrigation under pressure flushes blood from the eye and expands the anterior chamber, providing more room for the procedure.

The handle **705** may be made of an electrically insulating polymeric material, configured in a pencil-shape form having a cylindrical body region **702** and a tapered forward region **704**. A contoured handle helps to reduce the holding force required and increase proprioceptive sensitivity. Although a pencil-shape configuration is preferred, it is noted that any configuration of the handle **705** which is easily, comfortably and conveniently grasped by the operator will also be suitable and is considered to be within the scope of the present invention.

The probe tip **710** is connected to the main body of the handle **705**. The probe tip further comprises a footplate **721**, which protects the collector channels, penetrates the trabecular meshwork, and serves as a guide in Schlemm’s canal. The cautery element **730**, located at the distal end of the probe tip **710** may have a variety of configurations.

The tip **710** may be any material, such as titanium, brass, nickel, aluminum, stainless steel, other types of steels, or

flow and capacitance coupling with the tissue.

The electrode or other device used to deliver energy can be made of a number of different materials including, but not limited to stainless steel, platinum, other noble metals, and

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the like. The electrode can also be made of a memory metal, such as nickel titanium. The electrode can also be made of composite construction, whereby different sections are constructed from different materials.

In a preferred embodiment, the probe assembly is bipolar. In a bipolar system, two electrodes of reversed polarity are located on the probe tip, thus eliminating the contact plate for completion of the circuit. Additionally, any number of pairs of electrodes may be provided on the probe tip.

In an alternative embodiment, the probe assembly is monopolar. In a monopolar system, the system comprises a single electrode and a contact plate is attached to the surface of the human body. The contact plate is further connected to the minus terminal of the power source via a lead wire. Voltages of reversed polarity are applied to the electrode and the contact plate.

In a preferred embodiment as shown in FIGS. **10***a* and **10***b*, an electrode assembly of a bipolar probe includes one electrode **1020** made from a stainless steel 20 gauge hollow needle and a second electrode **1030** formed as a layer of electrically conductive material (such as silver or nickel) deposited over and adhered on an exterior surface of the needle electrode **1020**. A thin electrical insulator **1028** separates the electrodes **1020**, **1030**, along their lengths to avoid short circuiting.

The electrode **1020** extends along a longitudinal axis **1072** of the footplate **721** (FIG. **7**) from a proximal region at which bipolar electrical power is applied to a distal region of the electrode assembly.

In a preferred embodiment, the second electrode **1030** extends over a limited portion of the circumference of the first electrode **1020**, rather than entirely around the first electrode. Current flows over a relatively small portion of the circumference and length of the first electrode **1020**. This limits the area in the body that receives current, and provides the operator with a high degree of control as to where the current is applied. The second electrode **1030** extends over an arc of approximately one quarter of the circumference of the first electrode **1020**. The second electrode **1030** is disposed symmetrically about an axis **1072**.

In a preferred embodiment, the first electrode, and thus the footplate **721**, has a central passage **1022** that is open at the distal region, providing for irrigation and aspiration. The irrigation and aspiration lumens extend from the distal end of the probe tip **1010**, through the probe handle, to the connector, providing for irrigation and aspiration capability.

In an embodiment as shown in FIGS. **11***a* and **11***b*, the electrode assembly includes a central or axial electrode **1120** formed by a solid cylindrical metal member, and an elongate hollow outer electrode **1130** formed by a cylindrical metal tube member, which is coaxially positioned around the central electrode **1120**. The cylindrical outer surface of electrode **1130** forms the circumferential surface of the probe. The outer electrode **1130** is preferably made of stainless steel or other corrosive resistant, conductive material for strength as well as conductivity. The inner electrode **1120** may be made of copper, but less conductive materials may also be employed. The coaxial relationship and spacing between the electrodes **1120**, **1130**, as well as their electrical isolation from one another, is provided by a tubular sleeve **1128** of an electrically insulating material between the electrode.

A layer of insulation **1132** may also surround the second electrode **1130**. One or more regions of insulating area **1132** may be removed at any suitable location along the axis to expose a region of electrode **1130**. Cauterization would occur at the exposed region. The circumferential extent of

The probe tip **710** is connected to the main body of the handle **705**. The probe tip further comprises a footplate **721**, which protects the collector channels, penetrates the trabecular meshwork, and serves as a guide in Schlemm’s canal.

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Goniectomy Cutting Probe. Another preferred embodiment of a goniectomy cutting probe, used to cut and remove trabecular meshwork, is shown in FIG. **18**. The probe

anesthetized the eye. A knife, preferably 20 gauge, is used to make a clear corneal temporal incision. The goniectomy instrument is inserted into the anterior chamber up to the infusion sleeve to maintain the intraocular pressure and deepen the anterior chamber. The surgeon positions the gonio lens, preferably a Schwann-Jacobs lens or a modified Barkan goniotomy lens, on the cornea. The goniectomy probe is advanced to the trabecular meshwork. The sharp end point of the footplate incises the middle one third of the trabecular meshwork, which is known as the pigmented portion of the trabecular meshwork. The footplate **721** (FIG. **7**) is further inserted into Schlemm’s canal. The cautery element is activated, preferably by a footplate, which may also be used to activate irrigation and aspiration. The current provided to the cautery element heats the tissue. The instru-

[illegible] knife, the tissue is ablated with the probe. Similarly, [illegible] embodiment, a substantial portion, preferably at least half, of the trabecular meshwork is removed.

Goniectomy Cutting Probe. Another preferred embodiment of a goniectomy cutting probe, used to cut and remove trabecular meshwork, is shown in FIG. **18**. The probe comprises a handle **1805** and a probe tip **1810**. Preferably, the handle is 20 gauge and the probe tip is approximately 25 gauge. The handle **2405** is sized and configured to fit completely and comfortably within a hand. The handle **2405** may be formed of a variety of materials, including plastics, and may be designed in a variety of shapes. Generally, it will be preferred that a convenient shape for gripping, such as a cylindrical shape, be provided. The probe tip **1810** further comprises a footplate **1820**, protecting endothelial cells and collector channels lining the scleral wall of Schlemm’s canal. The footplate **1820** also serves as a guide in Schlemm’s canal. The sharpened end of the footplate is used to penetrate the trabecular meshwork.

FIGS. **19-20** show sectional views of different embodiments of the internal components and construction of the probe **1800**. The probe is configured to define therewithin a hollow inner chamber. A drive member, coupled to a rotatable drive cable within a drive cable assembly, extend into the hollow inner chamber, as shown. A rotatable drive shaft **1944**, **2044** is rotatably connected or engaged to the drive member, such that the shaft may be rotatably driven at speeds required for the trabecular meshwork removal. The rotatable drive shaft is inserted into a bore formed in the distal face of the drive member.

The elongate rotatable drive shaft **1944**, **2044** passes longitudinally through the probe and terminates, at its distal end, in a cutting head **1945**, **2045**. A protective tubular sheath may be disposed about the rotatable shaft. The rotatable shaft and/or sheath are axially movable so as to allow the cutting head to be alternately deployed in a) a first non-operative position wherein the cutting head is fully located within the inner bore of the tubular sheath so as to be shielded during insertion and retraction of the instrument or b) a second operative position wherein the cutting head is advanced out of the distal end of the sheath so as to contact and remove the trabecular meshwork. The cutting head **1945**, **2045** may be configured such that rotation of the head will create and sustain a forced circulation of fluid within the meshwork. Such forced circulation causes the trabecular meshwork to be pulled or drawn into contact with the rotating. cutting head, without the need for significant axial movement or manipulation of the probe while the cutting head is rotating.

A control pedal may be connected to the motor-drive system to induce actuation/deactuation, and speed control of the rotatable drive cable within the drive cable assembly by the operator. Additional switches or control pedals may be provided for triggering and actuating irrigation and/or aspiration of fluid and/or debris through the probe.

The probe of FIG. **19**, shows the probe **1900** having two separate lumens, **1922**, **1924**, for irrigation and aspiration. The hollow passageway **2022** extending longitudinally through the probe of FIG. **20**, containing the rotatable drive shaft, is in fluid communication with an irrigation pump (not shown). By such arrangement, a flow of irrigation fluid may be infused through the tube. A separate lumen **2024** is also provided for aspiration.

The independent processes of irrigation and aspiration may be performed simultaneously with the rotation of the head or while the head is in a non-rotating, stationary mode. It will also be appreciated that the infusion and aspiration pathways may be reversed or interchanged by alternately connecting the aspiration pump to the irrigation tubing and irrigation pump to the aspiration tubing.

In an alternative embodiment, as shown in FIGS. **21-23**, the probe cuts tissue in a guillotine fashion. As shown in FIG. **21**, the probe **2100** may include an inner sleeve **2144** that moves relative to an outer sleeve **2146**. The sleeves are coupled to the handle. The inner sleeve **2144** may be coupled to a vacuum system which pulls tissue into the port **2125** when the inner sleeve **2144** moves away from the port. The inner sleeve **2144** then moves in a reverse direction past the outer port to sever tissue in a guillotine fashion. The vacuum system draws the severed tissue away from the port, so the process may be repeated. The inner sleeve may be connected to a diaphragm and a spring, rigidly attached to the handle. The diaphragm is adjacent to a pneumatic drive chamber that is in fluid communication with a source of pressurized air (not shown). The drive chamber is pressurized, expanding the diaphragm. Expansion of the diaphragm moves the inner sleeve so that the tissue within the port is severed by the sleeve. Alternatively, the inner sleeve **2144** is driven by a motor located within the handle. The inner sleeve **2144** is coupled to the motor by a rotating lever mechanism or wobble plate, inducing an oscillating translational movement of the sleeve in response to a rotation of the output shaft. The motor is preferably an electrical device coupled to an external power source by wires that are attached to a control system at the handle.

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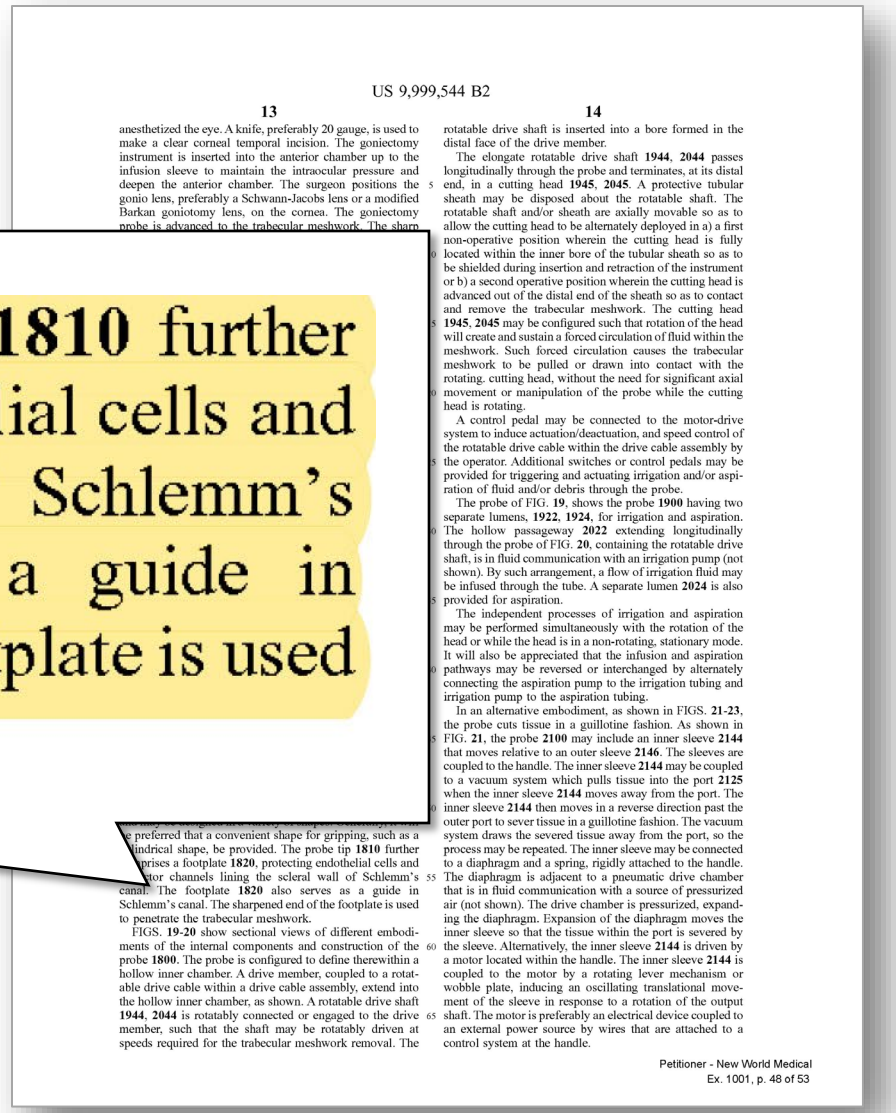

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A control pedal may be connected to the motor-drive system to induce actuation/deactuation, and speed control of the rotatable drive cable within the drive cable assembly by the operator. Additional switches or control pedals may be provided for triggering and actuating irrigation and/or aspiration of fluid and/or debris through the probe.

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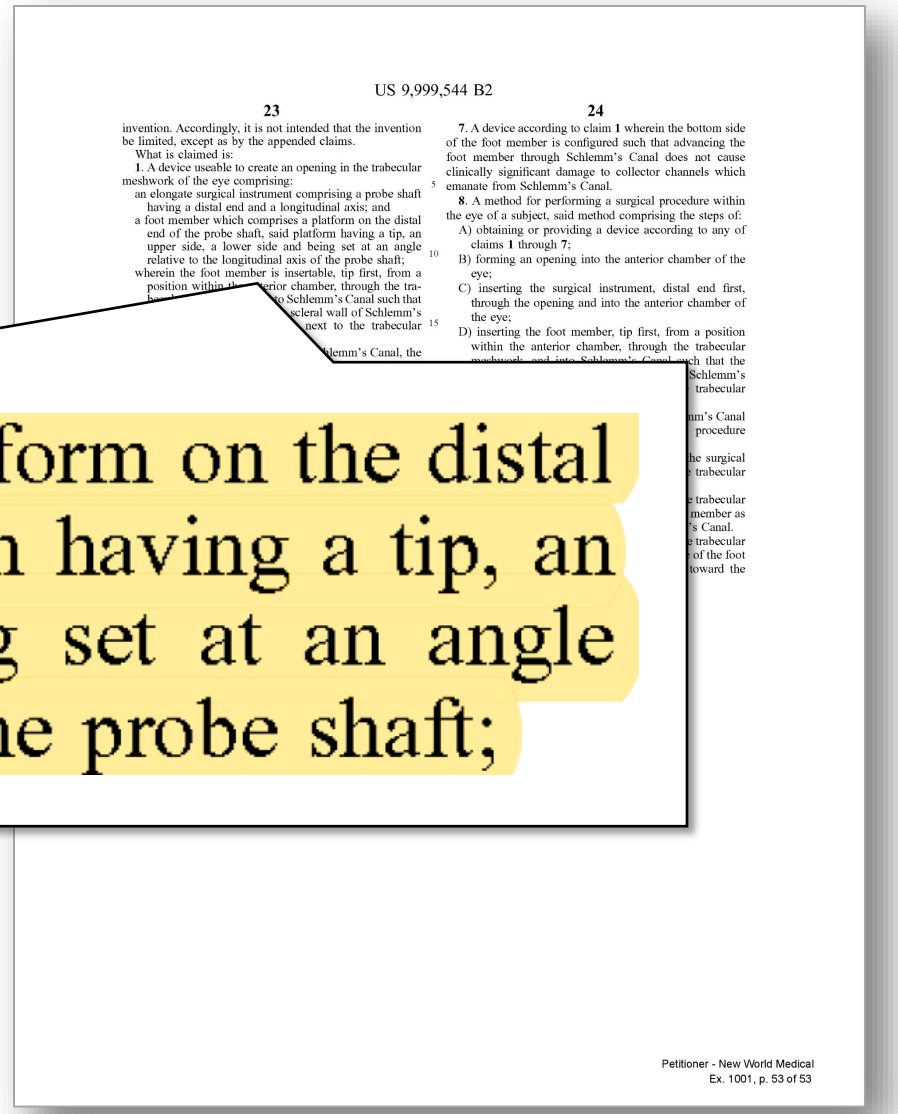
’544 Patent 23:8-11 (Claim 1)



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invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

What is claimed is:

1. A device useable to create an opening in the trabecular meshwork of the eye comprising:

an elongate surgical instrument comprising a probe shaft having a distal end and a longitudinal axis; and

a foot member which comprises a platform on the distal end of the probe shaft, said platform having a tip, an upper side, a lower side and being set at an angle relative to the longitudinal axis of the probe shaft;

wherein the foot member is insertable, tip first, from a position within the anterior chamber, through the tra-

to Schlemm’s Canal such that

scleral wall of Schlemm’s

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lemm’s Canal, the

24

7. A device according to claim 1 wherein the bottom side of the foot member is configured such that advancing the foot member through Schlemm’s Canal does not cause clinically significant damage to collector channels which emanate from Schlemm’s Canal.

8. A method for performing a surgical procedure within the eye of a subject, said method comprising the steps of:

A) obtaining or providing a device according to any of claims 1 through 7;

B) forming an opening into the anterior chamber of the eye;

C) inserting the surgical instrument, distal end first, through the opening and into the anterior chamber of the eye;

D) inserting the foot member, tip first, from a position within the anterior chamber, through the trabecular

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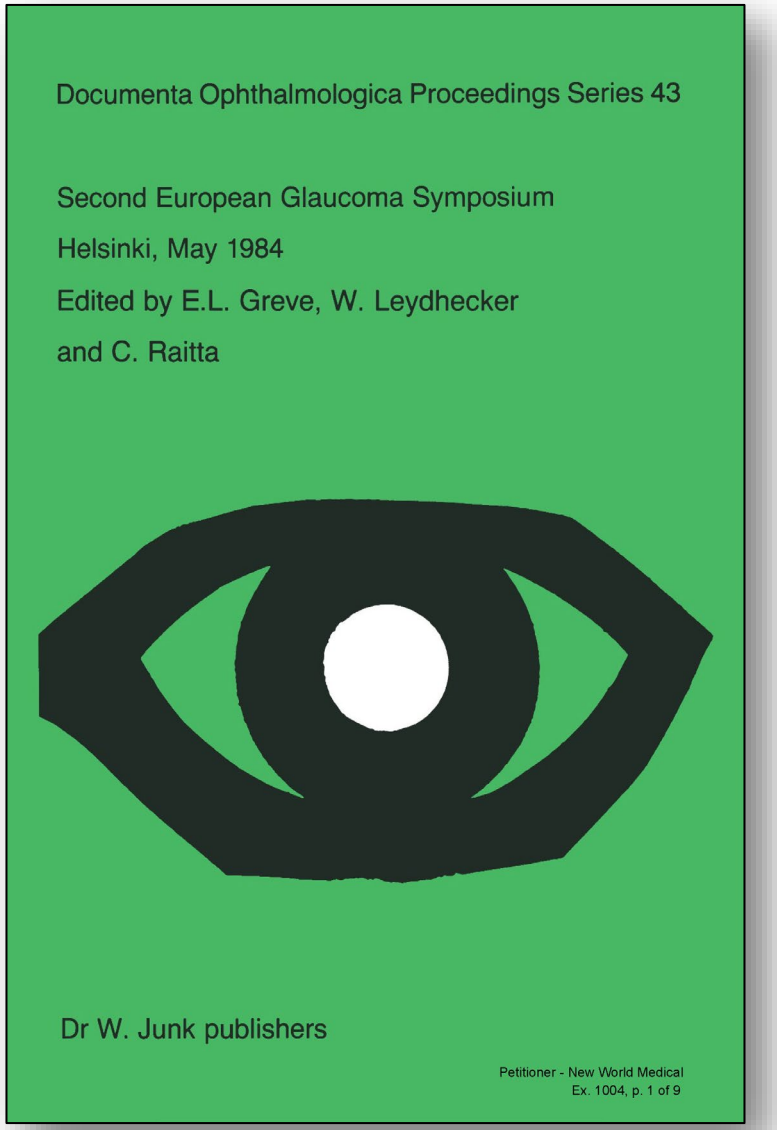
a foot member which comprises a platform on the distal end of the probe shaft, said platform having a tip, an upper side, a lower side and being set at an angle relative to the longitudinal axis of the probe shaft;

Ex. 1004 (Quintana)



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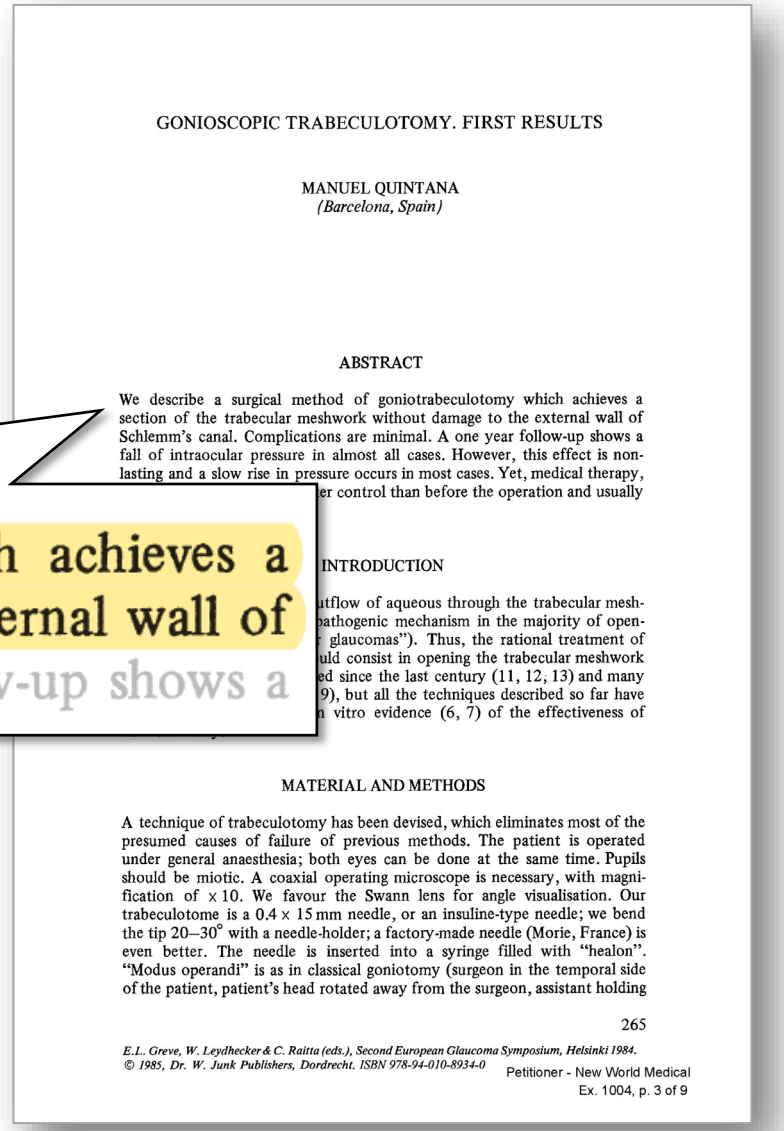

GONIOSCOPIC TRABECULOTOMY. FIRST RESULTS

MANUEL QUINTANA
(Barcelona, Spain)

ABSTRACT

We describe a surgical method of goniotrabeculotomy which achieves a section of the trabecular meshwork without damage to the external wall of Schlemm's canal. Complications are minimal. A one year follow-up shows a fall of intraocular pressure in almost all cases. However, this effect is non-lasting and a slow rise in pressure occurs in most cases. Yet, medical therapy, ...er control than before the operation and usually

INTRODUCTION

...utflow of aqueous through the trabecular mesh-...pathogenic mechanism in the majority of open-... glaucomas"). Thus, the rational treatment of ...uld consist in opening the trabecular meshwork ...ed since the last century (11, 12, 13) and many ...9), but all the techniques described so far have ...n vitro evidence (6, 7) of the effectiveness of

MATERIAL AND METHODS

A technique of trabeculotomy has been devised, which eliminates most of the presumed causes of failure of previous methods. The patient is operated under general anaesthesia; both eyes can be done at the same time. Pupils should be miotic. A coaxial operating microscope is necessary, with magnification of × 10. We favour the Swann lens for angle visualisation. Our trabeculotome is a 0.4 × 15 mm needle, or an insuline-type needle; we bend the tip 20–30° with a needle-holder; a factory-made needle (Morie, France) is even better. The needle is inserted into a syringe filled with "healon". "Modus operandi" is as in classical goniotomy (surgeon in the temporal side of the patient, patient's head rotated away from the surgeon, assistant holding

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E.L. Greve, W. Leydhecker & C. Raitta (eds.), Second European Glaucoma Symposium, Helsinki 1984.
 ISBN 978-94-010-8934-0

We describe a surgical method of goniotrabeculotomy which achieves a section of the trabecular meshwork without damage to the external wall of Schlemm's canal. Complications are minimal. A one year follow-up shows a

IPR2020-01573 Paper 29 at 1-6, 12-22, 24-39, 42- 45, 48, 54-55; 2020-01711 Paper 17 at 1-7, 20-44, 47-50, 54, 57; 2021-00017 Paper 17 at 1-5, 10-34, 38; 2021-00065 Paper 18 at 1-4, 11-31; 2021-00066, Paper 17 at 1-3, 5, 12-46.

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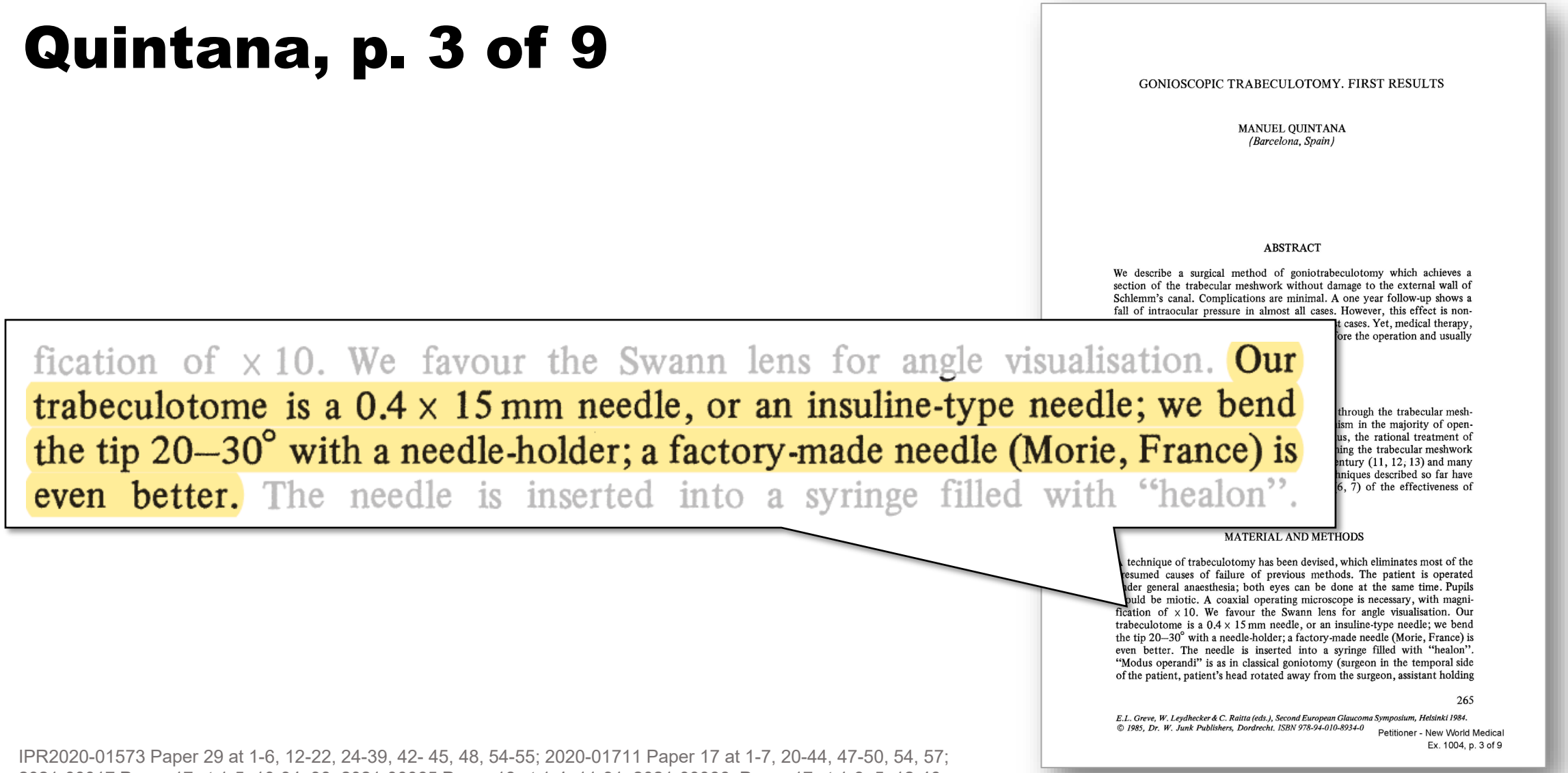

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E.L. Greve, W. Leydhecker & C. Raitta (eds.), Second European Glaucoma Symposium, Helsinki 1984.
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IPR2020-01573 Paper 29 at 1-6, 12-22, 24-39, 42- 45, 48, 54-55; 2020-01711 Paper 17 at 1-7, 20-44, 47-50, 54, 57; 2021-00017 Paper 17 at 1-5, 10-34, 38; 2021-00065 Paper 18 at 1-4, 11-31; 2021-00066, Paper 17 at 1-3, 5, 12-46.

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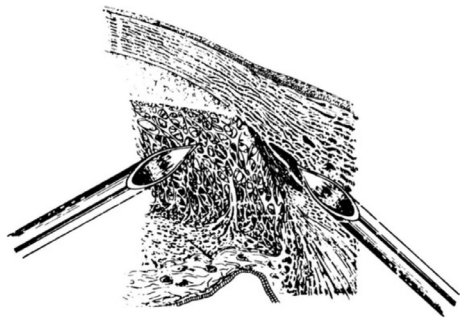

Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

the vertical recti). The needle penetrates the anterior chamber at 6 hours (right eye) or 12 hours (left eye) through the *scleral* side of the limbus; this is in order to run parallel to Schlemm's canal. Penetration at 6 or 12 hours allows a *tangential* approach (Fig. 1) to the angle; this avoids the pupillary field and the convexity of the lens. Penetration is carried on under direct control, to avoid the prismatic effect of the goniolens. Once the needle is in
inserted, held with the surgeon's left
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ed slowly, gently and easily from the
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l rotate the globe clockwise as the
ne counter-clockwise. A 100–120°
can be injected at will at any time if
There is usually no chamber loss, but
if this is the case, healon is injected.

Once trabeculotomy is completed, the trabeculotome is withdrawn, taking care of injecting some healon before leaving the anterior chamber (internal "tamponnade"); this avoids any loss of aqueous and the chamber remains full. The goniolens and rectus forceps are also withdrawn. A steroid-antibiotic ointment is applied, as well as a mild mydriatic. The eyes are patched for 24 hours.

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IPR2020-01573 Paper 29 at 1-6, 12-22, 24-39, 42- 45, 48, 54-55; 2020-01711 Paper 17 at 1-7, 20-44, 47-50, 54, 57; 2021-00017 Paper 17 at 1-5, 10-34, 38; 2021-00065 Paper 18 at 1-4, 11-31; 2021-00066, Paper 17 at 1-3, 5, 12-46.

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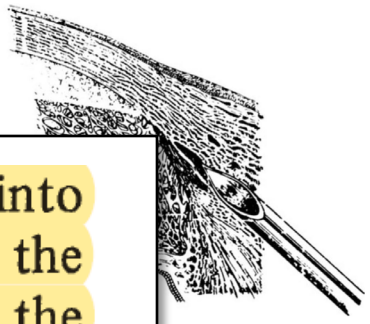
introduced in the angle. Only the tip of the instrument is introduced into Schlemm's canal, and the TM is stripped slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses in the angle (Fig. 2). Since the convexity of the tip is facing the external wall of the canal, this structure is not damaged. This is why we bend the tip and we point it towards the anterior chamber.



…e tangential approach to the perpendicular …rabeculotomy.

…trates the anterior chamber at 6 hours …ough the *scleral* side of the limbus; this is …'s canal. Penetration at 6 or 12 hours …) to the angle; this avoids the pupillary … Penetration is carried on under direct … of the goniolens. Once the needle is in … is inserted, held with the surgeon's left …wetting agent between cornea and gonio- …lens. The TM is incised with the tip of the needle. From now on, and with the concavity of the tip *towards* the surgeon, the trabeculotome is progressively introduced in the angle. Only the tip of the instrument is introduced into Schlemm's canal, and the TM is stripped slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses in the angle (Fig. 2). Since the convexity of the tip is facing the external wall of the canal, this structure is not damaged. This is why we bend the tip and we point it towards the anterior chamber.

As in goniotomy, the assistant will rotate the globe clockwise as the surgeon introduces the trabeculotome counter-clockwise. A 100–120° trabeculotomy can be achieved. Healon can be injected at will at any time if the surgeon wants to deepen the angle. There is usually no chamber loss, but if this is the case, healon is injected.

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IPR2020-01573 Paper 29 at 1-6, 12-22, 24-39, 42- 45, 48, 54-55; 2020-01711 Paper 17 at 1-7, 20-44, 47-50, 54, 57; 2021-00017 Paper 17 at 1-5, 10-34, 38; 2021-00065 Paper 18 at 1-4, 11-31; 2021-00066, Paper 17 at 1-3, 5, 12-46.

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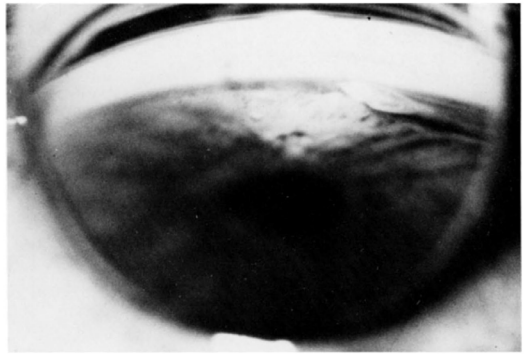

Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

patients have been operated with this technique,
ne year (mean). There are 13 eyes with chronic
igmentary glaucoma, 4 disgenetic and 1 steroid-
in Table 1.

steroids and we dilate the pupils (see discussion).

Clinical results

The behaviour of the ocular pressures over one year is represented in Table 1 and Fig. 3. They can be summarized as follows: fall of pressure below 20 mm Hg in almost all cases in the first postoperative weeks, followed by a progressive rise in the second month (mean). From the second month, medical therapy must be reinstituted in most cases, although less intensively in regard to the preoperative treatment. At one year, most cases are controlled,

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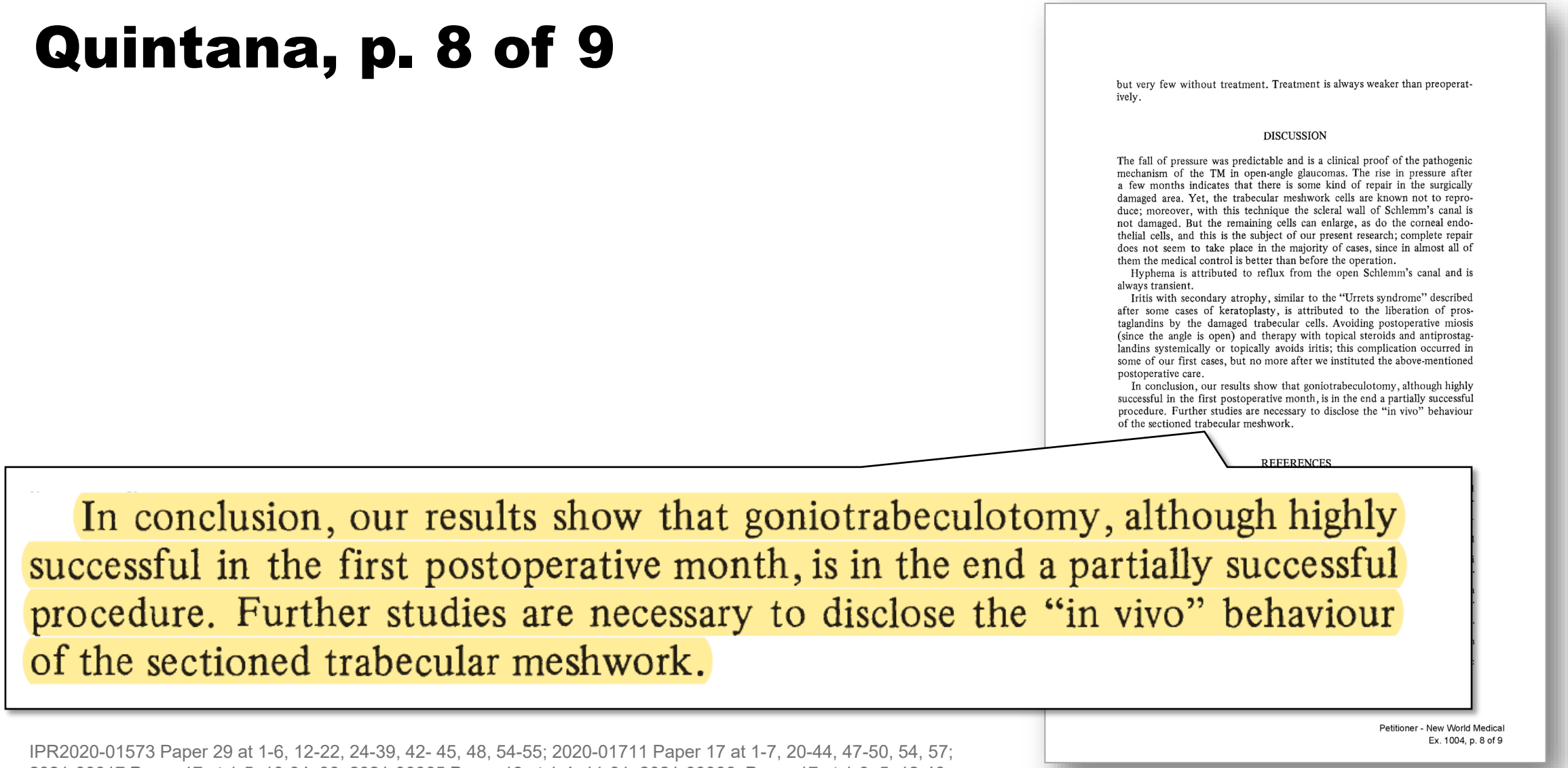
Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

IPR2020-01573 Paper 29 at 1-6, 12-22, 24-39, 42- 45, 48, 54-55; 2020-01711 Paper 17 at 1-7, 20-44, 47-50, 54, 57; 2021-00017 Paper 17 at 1-5, 10-34, 38; 2021-00065 Paper 18 at 1-4, 11-31; 2021-00066, Paper 17 at 1-3, 5, 12-46.

Quintana, p. 8 of 9



but very few without treatment. Treatment is always weaker than preoperatively.

DISCUSSION

The fall of pressure was predictable and is a clinical proof of the pathogenic mechanism of the TM in open-angle glaucomas. The rise in pressure after a few months indicates that there is some kind of repair in the surgically damaged area. Yet, the trabecular meshwork cells are known not to reproduce; moreover, with this technique the scleral wall of Schlemm's canal is not damaged. But the remaining cells can enlarge, as do the corneal endothelial cells, and this is the subject of our present research; complete repair does not seem to take place in the majority of cases, since in almost all of them the medical control is better than before the operation.

Hyphema is attributed to reflux from the open Schlemm's canal and is always transient.

Iritis with secondary atrophy, similar to the "Urrets syndrome" described after some cases of keratoplasty, is attributed to the liberation of prostaglandins by the damaged trabecular cells. Avoiding postoperative miosis (since the angle is open) and therapy with topical steroids and antiprostaglandins systemically or topically avoids iritis; this complication occurred in some of our first cases, but no more after we instituted the above-mentioned postoperative care.

In conclusion, our results show that goniotrabeculotomy, although highly successful in the first postoperative month, is in the end a partially successful procedure. Further studies are necessary to disclose the "in vivo" behaviour of the sectioned trabecular meshwork.

REFERENCES

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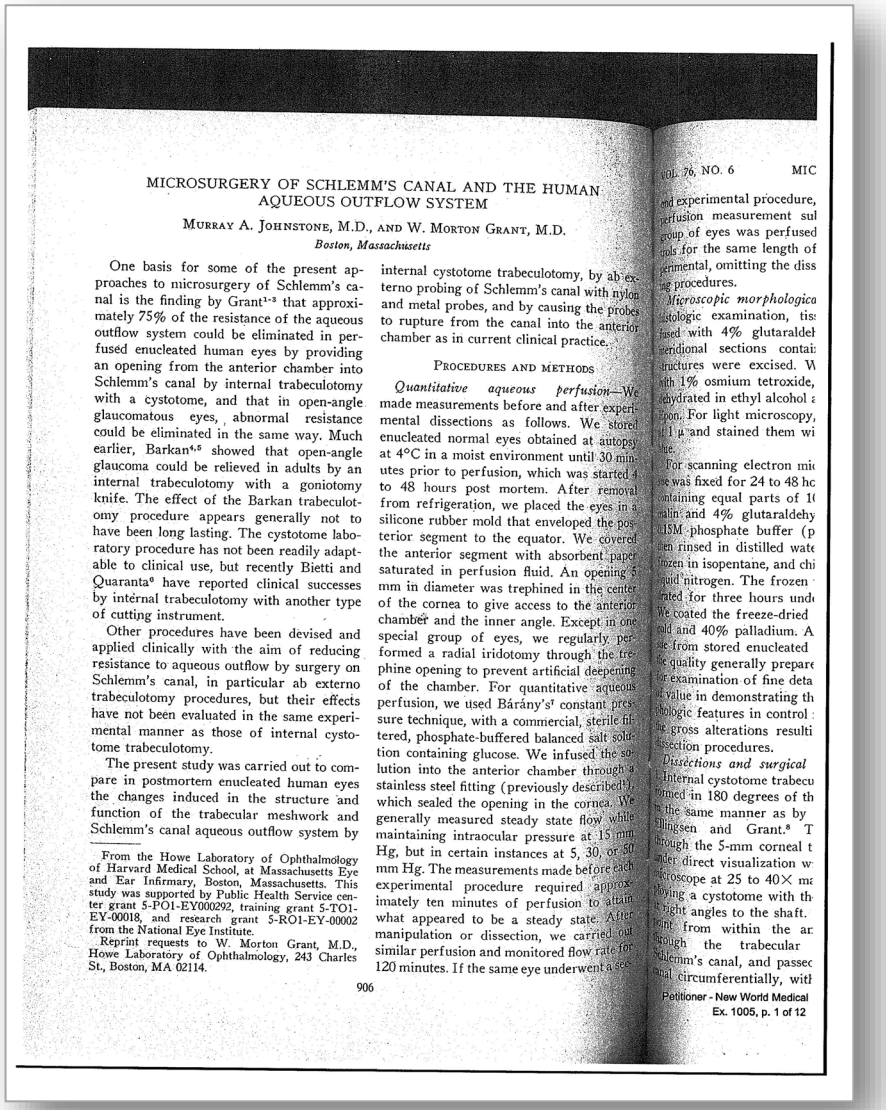
IPR2020-01573 Paper 29 at 1-6, 12-22, 24-39, 42- 45, 48, 54-55; 2020-01711 Paper 17 at 1-7, 20-44, 47-50, 54, 57; 2021-00017 Paper 17 at 1-5, 10-34, 38; 2021-00065 Paper 18 at 1-4, 11-31; 2021-00066, Paper 17 at 1-3, 5, 12-46.

Ex. 1005 (Johnstone)



MICROSURGERY OF SCHLEMM'S CANAL AND THE HUMAN AQUEOUS OUTFLOW SYSTEM

MURRAY A. JOHNSTONE, M.D., AND W. MORTON GRANT, M.D.
Boston, Massachusetts

One basis for some of the present approaches to microsurgery of Schlemm's canal is the finding by Grant[1-3] that approximately 75% of the resistance of the aqueous outflow system could be eliminated in perfused enucleated human eyes by providing an opening from the anterior chamber into Schlemm's canal by internal trabeculotomy with a cystotome, and that in open-angle glaucomatous eyes, abnormal resistance could be eliminated in the same way. Much earlier, Barkan[4,5] showed that open-angle glaucoma could be relieved in adults by an internal trabeculotomy with a goniotomy knife. The effect of the Barkan trabeculotomy procedure appears generally not to have been long lasting. The cystotome laboratory procedure has not been readily adaptable to clinical use, but recently Bietti and Quaranta[6] have reported clinical successes by internal trabeculotomy with another type of cutting instrument.

Other procedures have been devised and applied clinically with the aim of reducing resistance to aqueous outflow by surgery on Schlemm's canal, in particular ab externo trabeculotomy procedures, but their effects have not been evaluated in the same experimental manner as those of internal cystotome trabeculotomy.

The present study was carried out to compare in postmortem enucleated human eyes the changes induced in the structure and function of the trabecular meshwork and Schlemm's canal aqueous outflow system by internal cystotome trabeculotomy, by ab externo probing of Schlemm's canal with nylon and metal probes, and by causing the probes to rupture from the canal into the anterior chamber as in current clinical practice.

From the Howe Laboratory of Ophthalmology of Harvard Medical School, at Massachusetts Eye and Ear Infirmary, Boston, Massachusetts. This study was supported by Public Health Service center grant 5-PO1-EY000292, training grant 5-TO1-EY-00018, and research grant 5-RO1-EY-00002 from the National Eye Institute.

Reprint requests to W. Morton Grant, M.D., Howe Laboratory of Ophthalmology, 243 Charles St., Boston, MA 02114.

PROCEDURES AND METHODS

Quantitative aqueous perfusion—We made measurements before and after experimental dissections as follows. We stored enucleated normal eyes obtained at autopsy at 4°C in a moist environment until 30 minutes prior to perfusion, which was started 4 to 48 hours post mortem. After removal from refrigeration, we placed the eyes in a silicone rubber mold that enveloped the posterior segment to the equator. We covered the anterior segment with absorbent paper saturated in perfusion fluid. An opening 5 mm in diameter was trephined in the center of the cornea to give access to the anterior chamber and the inner angle. Except in one special group of eyes, we regularly performed a radial iridotomy through the trephine opening to prevent artificial deepening of the chamber. For quantitative aqueous perfusion, we used Bárány's[7] constant pressure technique, with a commercial, sterile filtered, phosphate-buffered balanced salt solution containing glucose. We infused the solution into the anterior chamber through a stainless steel fitting (previously described[1]), which sealed the opening in the cornea. We generally measured steady state flow while maintaining intraocular pressure at 15 mm Hg, but in certain instances at 5, 30, or 50 mm Hg. The measurements made before each experimental procedure required approximately ten minutes of perfusion to attain what appeared to be a steady state. After manipulation or dissection, we carried out similar perfusion and monitored flow rate for 120 minutes. If the same eye underwent a sec-

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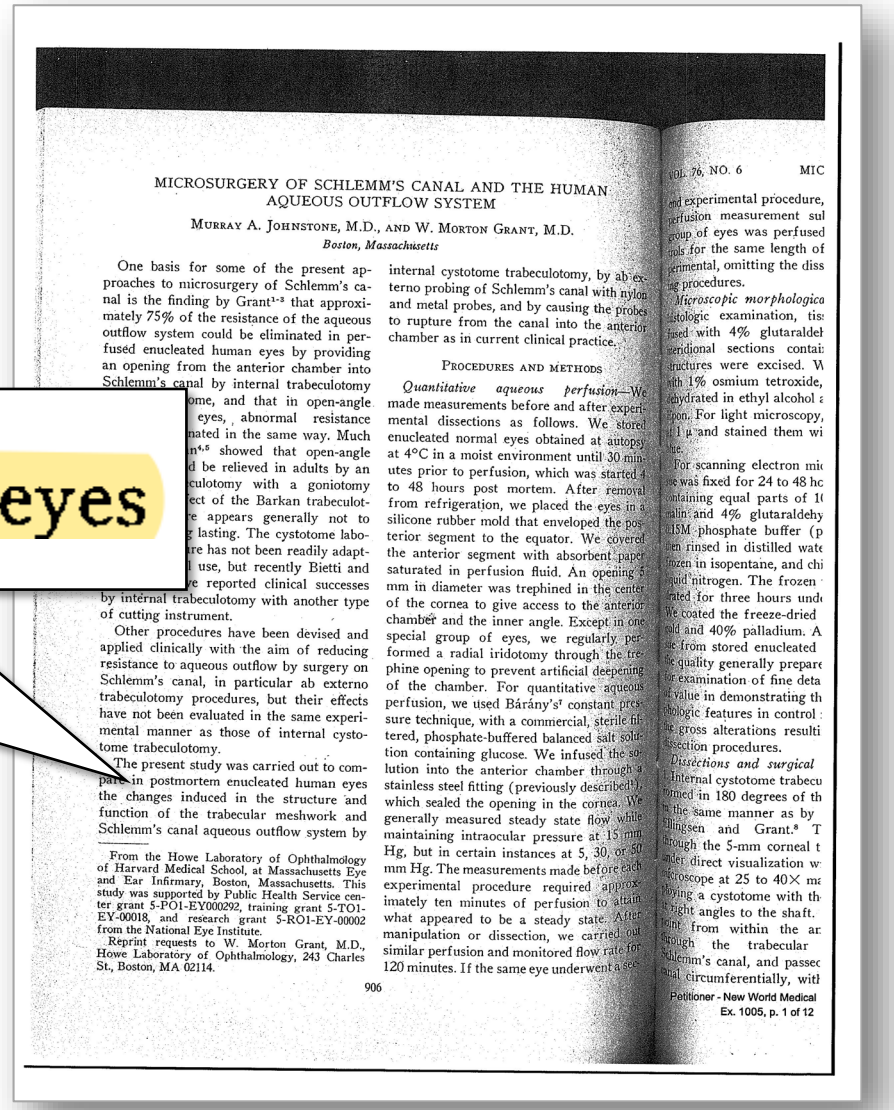
pare in postmortem enucleated human eyes



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...and experimental procedure, ...erfusion measurement sul... ...roup of eyes was perfused ...rols for the same length of ...erimental, omitting the diss... ...ng procedures.

...Microscopic morphologica... ...istologic examination, tis... ...ixed with 4% glutaralde... ...eridional sections contai... ...ructures were excised. W... ...ith 1% osmium tetroxide, ...ehydrated in ethyl alcohol ... ...pon. For light microscopy, ...1 μ and stained them wi... ...ue.

For scanning electron mi... ...ue was fixed for 24 to 48 hc... ...ntaining equal parts of 1... ...alin and 4% glutaraldehy... ...1SM phosphate buffer (p... ...en rinsed in distilled wate... ...ozen in isopentane, and chi... ...quid nitrogen. The frozen ... ...ated for three hours und... ...We coated the freeze-dried ...old and 40% palladium. A... ...ue from stored enucleated ...he quality generally prepare... ...or examination of fine deta... ...t value in demonstrating th... ...istologic features in control ... ...ne gross alterations resulti... ...ssection procedures.

...Dissections and surgical ... ...Internal cystotome trabecu... ...rmed in 180 degrees of th... ...the same manner as by ...Ellingsen and Grant.[8] T... ...through the 5-mm corneal t... ...nder direct visualization w... ...roscope at 25 to 40× ma... ...ying a cystotome with th... ...right angles to the shaft. ...oint from within the an... ...through the trabecular ...Schlemm's canal, and passec ...anal circumferentially, with

IPR2020-01573 Paper 29 at 37, 45, 55; 2020-01711 Paper 17 at 41-42, 50; 2021-00017 Paper 17 at 31.

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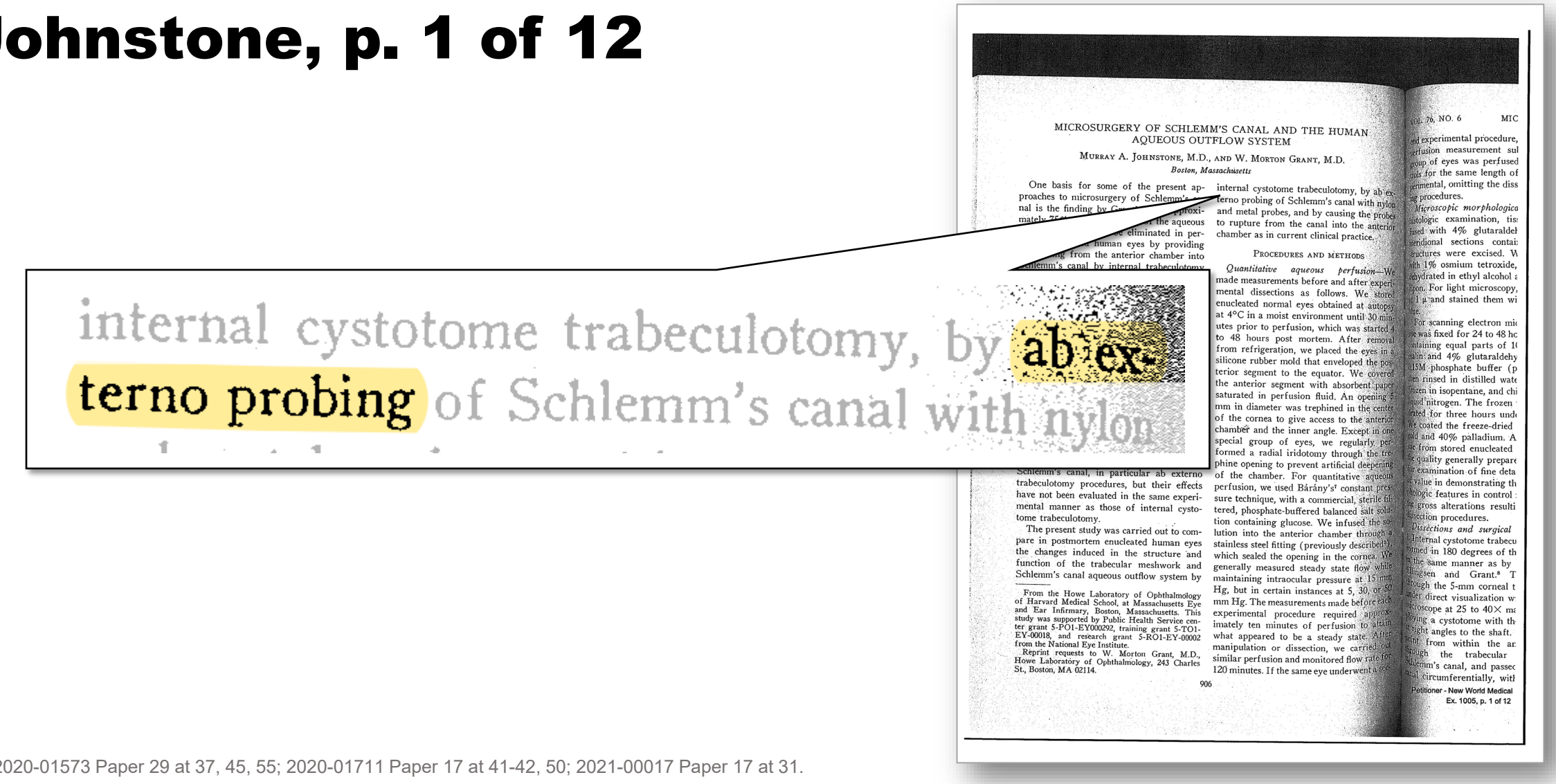

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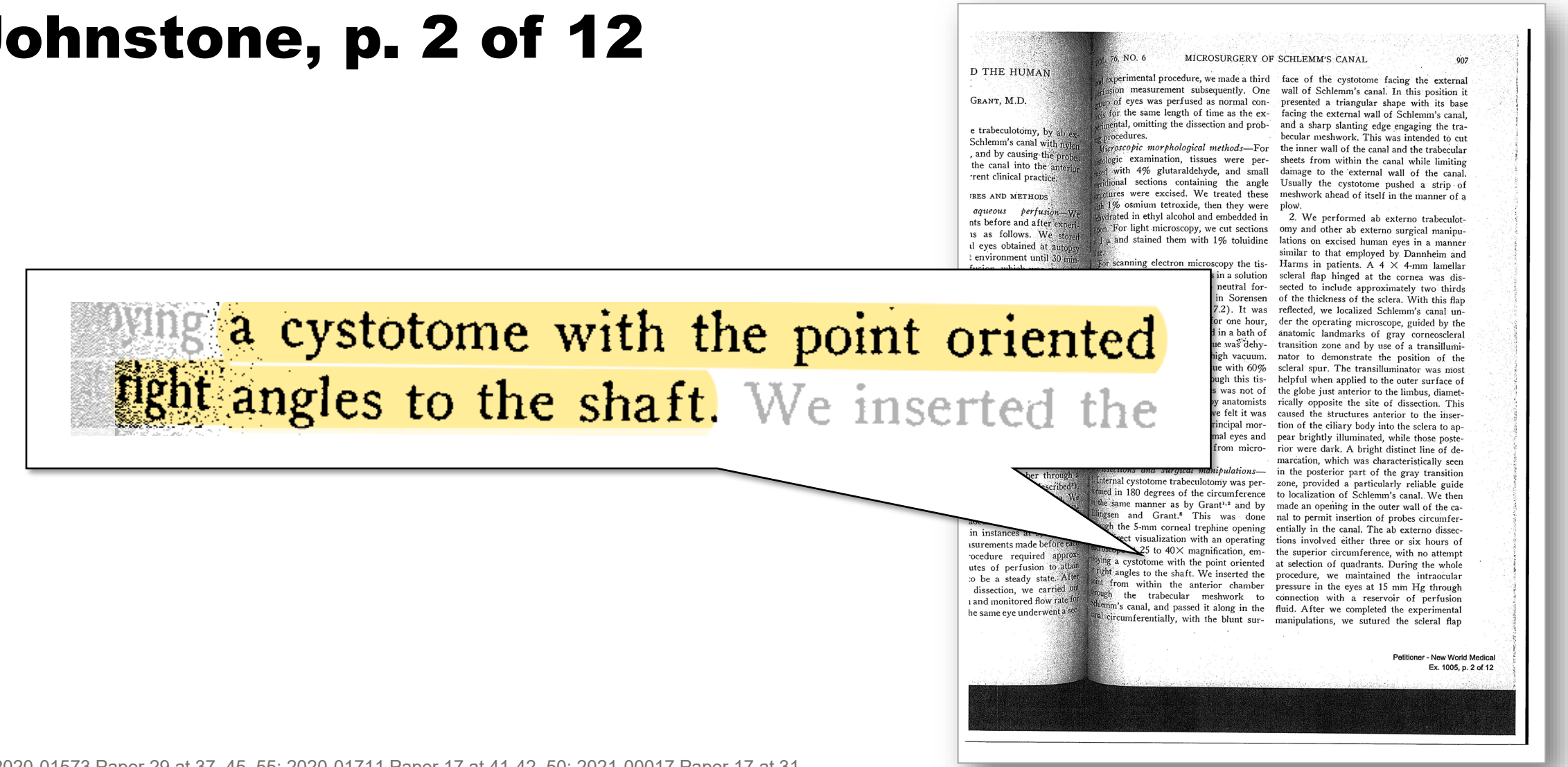
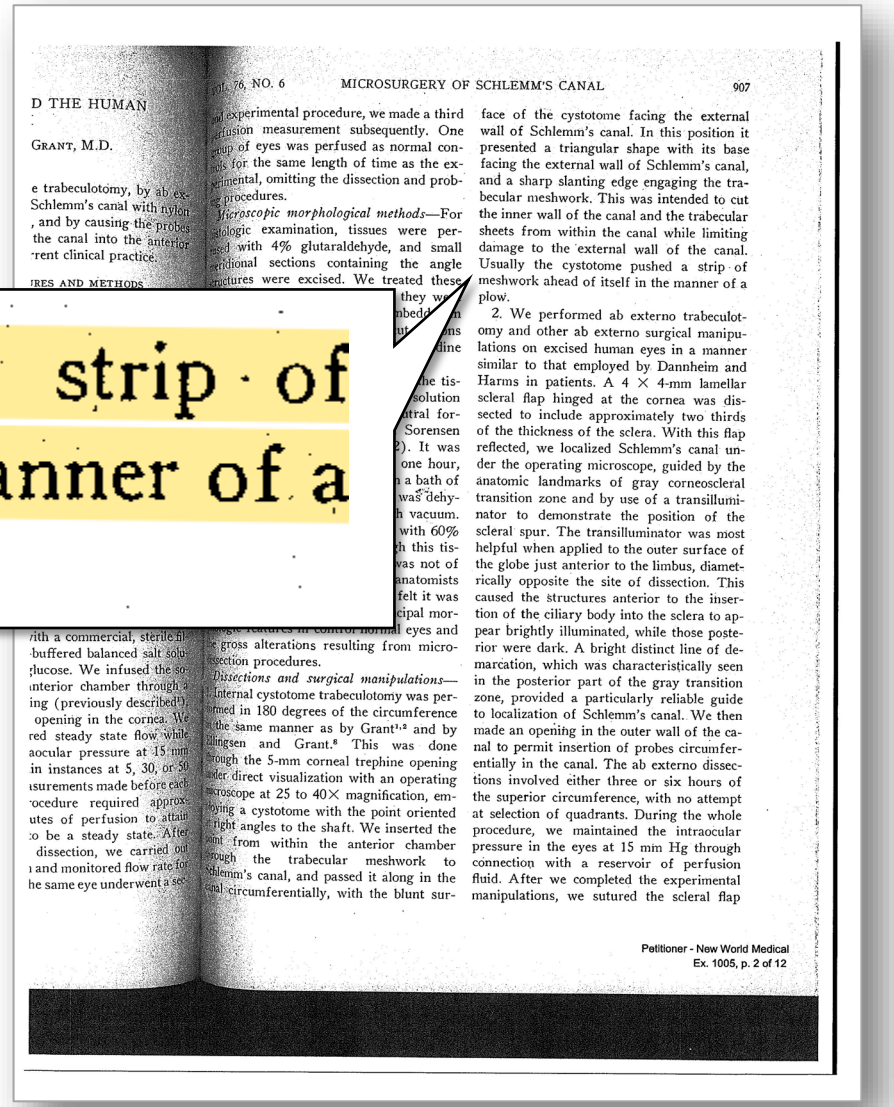


IPR2020-01573 Paper 29 at 37, 45, 55; 2020-01711 Paper 17 at 41-42, 50; 2021-00017 Paper 17 at 31.

Johnstone, p. 2 of 12

Usually the cystotome pushed a strip of meshwork ahead of itself in the manner of a plow.



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face of the cystotome facing the external wall of Schlemm's canal. In this position it presented a triangular shape with its base facing the external wall of Schlemm's canal, and a sharp slanting edge engaging the trabecular meshwork. This was intended to cut the inner wall of the canal and the trabecular sheets from within the canal while limiting damage to the external wall of the canal. Usually the cystotome pushed a strip of meshwork ahead of itself in the manner of a plow.

2. We performed ab externo trabeculotomy and other ab externo surgical manipulations on excised human eyes in a manner similar to that employed by Dannheim and Harms in patients. A 4 × 4-mm lamellar scleral flap hinged at the cornea was dissected to include approximately two thirds of the thickness of the sclera. With this flap reflected, we localized Schlemm's canal under the operating microscope, guided by the anatomic landmarks of gray corneoscleral transition zone and by use of a transilluminator to demonstrate the position of the scleral spur. The transilluminator was most helpful when applied to the outer surface of the globe just anterior to the limbus, diametrically opposite the site of dissection. This caused the structures anterior to the insertion of the ciliary body into the sclera to appear brightly illuminated, while those posterior were dark. A bright distinct line of demarcation, which was characteristically seen in the posterior part of the gray transition zone, provided a particularly reliable guide to localization of Schlemm's canal. We then made an opening in the outer wall of the canal to permit insertion of probes circumferentially in the canal. The ab externo dissections involved either three or six hours of the superior circumference, with no attempt at selection of quadrants. During the whole procedure, we maintained the intraocular pressure in the eyes at 15 mm Hg through connection with a reservoir of perfusion fluid. After we completed the experimental manipulations, we sutured the scleral flap

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IPR2020-01573 Paper 29 at 37, 45, 55; 2020-01711 Paper 17 at 41-42, 50; 2021-00017 Paper 17 at 31.

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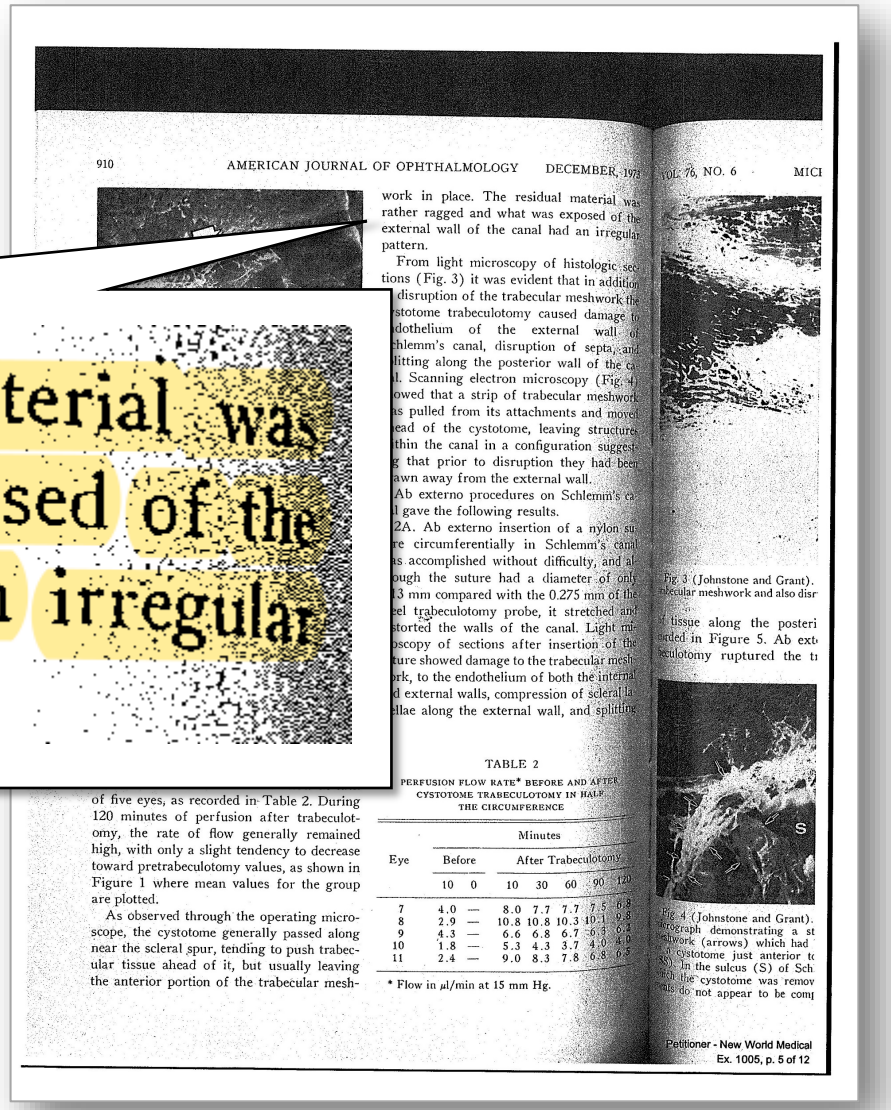
work in place. The residual material was rather ragged and what was exposed of the external wall of the canal had an irregular pattern.



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work in place. The residual material was rather ragged and what was exposed of the external wall of the canal had an irregular pattern.

From light microscopy of histologic sections (Fig. 3) it was evident that in addition to disruption of the trabecular meshwork the cystotome trabeculotomy caused damage to the endothelium of the external wall of Schlemm's canal, disruption of septa, and slitting along the posterior wall of the canal. Scanning electron microscopy (Fig. 4) showed that a strip of trabecular meshwork was pulled from its attachments and moved ahead of the cystotome, leaving structures within the canal in a configuration suggesting that prior to disruption they had been drawn away from the external wall.

Ab externo procedures on Schlemm's canal gave the following results.

2A. Ab externo insertion of a nylon suture circumferentially in Schlemm's canal was accomplished without difficulty, and although the suture had a diameter of only 0.3 mm compared with the 0.275 mm of the steel trabeculotomy probe, it stretched and distorted the walls of the canal. Light microscopy of sections after insertion of the suture showed damage to the trabecular meshwork, to the endothelium of both the internal and external walls, compression of scleral lamellae along the external wall, and splitting

of five eyes, as recorded in Table 2. During 120 minutes of perfusion after trabeculotomy, the rate of flow generally remained high, with only a slight tendency to decrease toward pretrabeculotomy values, as shown in Figure 1 where mean values for the group are plotted.

As observed through the operating microscope, the cystotome generally passed along near the scleral spur, tending to push trabecular tissue ahead of it, but usually leaving the anterior portion of the trabecular mesh-

TABLE 2

PERFUSION FLOW RATE* BEFORE AND AFTER CYSTOTOME TRABECULOTOMY IN HALF THE CIRCUMFERENCE

Eye	Minutes Before		After Trabeculotomy				
	10	0	10	30	60	90	120
7	4.0	—	8.0	7.7	7.7	7.5	6.8
8	2.9	—	10.8	10.8	10.3	10.1	9.8
9	4.3	—	6.6	6.8	6.7	6.3	6.1
10	1.8	—	5.3	4.3	3.7	4.0	4.0
11	2.4	—	9.0	8.3	7.8	6.8	6.5

* Flow in μl/min at 15 mm Hg.

Fig. 3 (Johnstone and Grant). ...ecular meshwork and also disr... ...tissue along the posteri... ...uded in Figure 5. Ab ext... ...culotomy ruptured the t...

Fig. 4 (Johnstone and Grant). ...rograph demonstrating a st... ...eshwork (arrows) which had ... ...cystotome just anterior t... ...). In the sulcus (S) of Sch... ...ugh the cystotome was remov... ...gs do not appear to be comp...

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IPR2020-01573 Paper 29 at 37, 45, 55; 2020-01711 Paper 17 at 41-42, 50; 2021-00017 Paper 17 at 31.

Johnstone, p. 11 of 12

These experiments have provided some surprises and have caused us to reconsider some of our concepts of the workings of antiglaucoma microsurgical procedures on Schlemm's canal. While we again obtained a

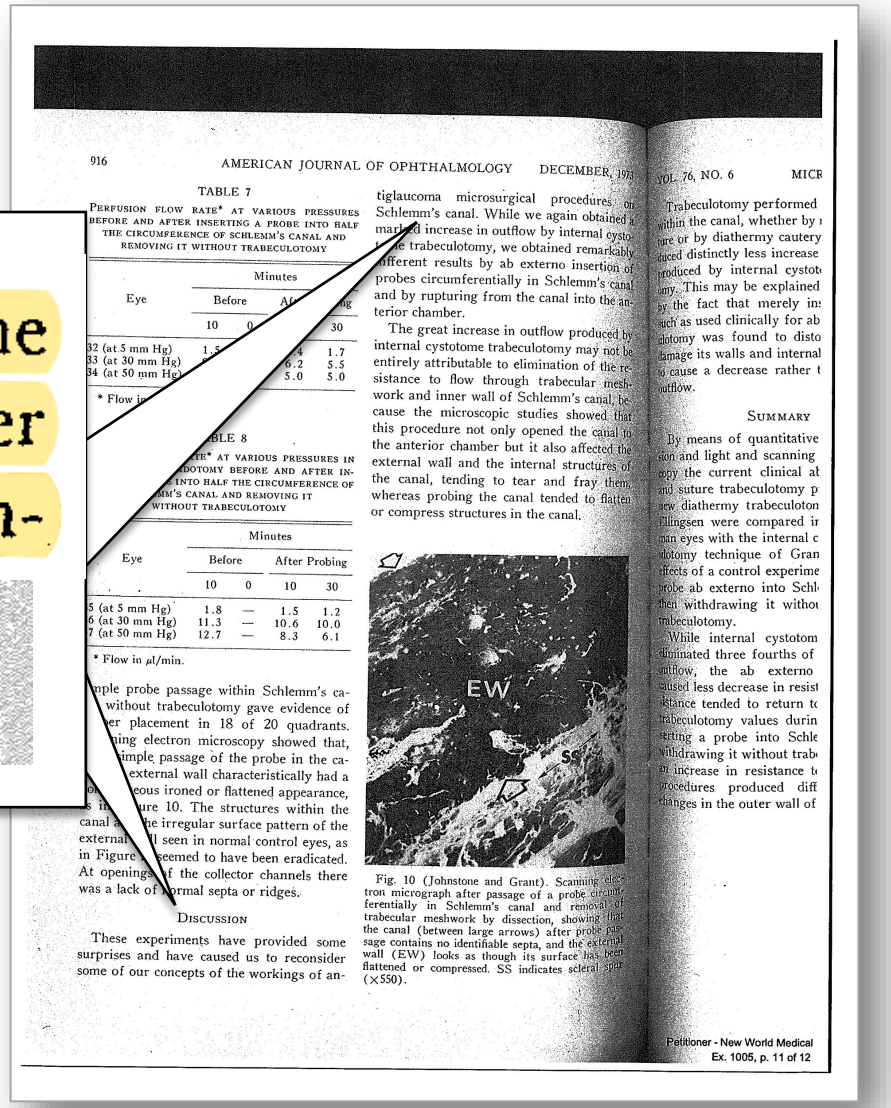

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TABLE 7

PERFUSION FLOW RATE* AT VARIOUS PRESSURES BEFORE AND AFTER INSERTING A PROBE INTO HALF THE CIRCUMFERENCE OF SCHLEMM'S CANAL AND REMOVING IT WITHOUT TRABECULOTOMY

Eye	Minutes			
	Before		After Probing	
	10	0	10	30
32 (at 5 mm Hg)	1.5		1.4	1.7
33 (at 30 mm Hg)			6.2	5.5
34 (at 50 mm Hg)			5.0	5.0

* Flow in

TABLE 8

...E* AT VARIOUS PRESSURES IN ...DOTOMY BEFORE AND AFTER IN... INTO HALF THE CIRCUMFERENCE OF ...M'S CANAL AND REMOVING IT WITHOUT TRABECULOTOMY

Eye	Minutes			
	Before		After Probing	
	10	0	10	30
5 (at 5 mm Hg)	1.8	—	1.5	1.2
6 (at 30 mm Hg)	11.3	—	10.6	10.0
7 (at 50 mm Hg)	12.7	—	8.3	6.1

* Flow in μl/min.

...mple probe passage within Schlemm's ca... without trabeculotomy gave evidence of ...er placement in 18 of 20 quadrants. ...ning electron microscopy showed that, ...imple passage of the probe in the ca... external wall characteristically had a ...eous ironed or flattened appearance, ...ure 10. The structures within the canal ...he irregular surface pattern of the external ...l seen in normal control eyes, as in Figure ... seemed to have been eradicated. At openings ...f the collector channels there was a lack of ...rmal septa or ridges.

DISCUSSION

These experiments have provided some surprises and have caused us to reconsider some of our concepts of the workings of antiglaucoma microsurgical procedures on Schlemm's canal. While we again obtained a marked increase in outflow by internal cysto... trabeculotomy, we obtained remarkably different results by ab externo insertion of probes circumferentially in Schlemm's canal and by rupturing from the canal into the anterior chamber.

The great increase in outflow produced by internal cystotome trabeculotomy may not be entirely attributable to elimination of the resistance to flow through trabecular meshwork and inner wall of Schlemm's canal, because the microscopic studies showed that this procedure not only opened the canal to the anterior chamber but it also affected the external wall and the internal structures of the canal, tending to tear and fray them, whereas probing the canal tended to flatten or compress structures in the canal.

Fig. 10 (Johnstone and Grant). Scanning electron micrograph after passage of a probe circumferentially in Schlemm's canal and removal of trabecular meshwork by dissection, showing that the canal (between large arrows) after probe passage contains no identifiable septa, and the external wall (EW) looks as though its surface has been flattened or compressed. SS indicates scleral spur (×550).

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...Trabeculotomy performed ...within the canal, whether by ... ...ure or by diathermy cautery ...uced distinctly less increase ...roduced by internal cystot... ...my. This may be explained ...by the fact that merely in... ...such as used clinically for ab... ...otomy was found to disto... ...damage its walls and internal ...to cause a decrease rather t... ...outflow.

SUMMARY

...By means of quantitative ...sion and light and scanning ...opy the current clinical at... ...and suture trabeculotomy p... ...new diathermy trabeculoton... ...Ellingsen were compared ir... ...man eyes with the internal c... ...otomy technique of Gran... ...effects of a control experime... ...probe ab externo into Schl... ...then withdrawing it witho... ...trabeculotomy.

...While internal cystotom... ...eliminated three fourths of ...outflow, the ab externo ...caused less decrease in resist... ...istance tended to return t... ...trabeculotomy values durin... ...serting a probe into Schle... ...withdrawing it without trab... ...an increase in resistance t... ...procedures produced diff... ...changes in the outer wall of...

IPR2020-01573 Paper 29 at 37, 45, 55; 2020-01711 Paper 17 at 41-42, 50; 2021-00017 Paper 17 at 31.

Ex. 1006 (Lee)

United States Patent [19]
Lee

[11] **Patent Number: 4,900,300**
[45] **Date of Patent: Feb. 13, 1990**

[54] **SURGICAL INSTRUMENT**

[76] Inventor: **David A. Lee**, 2868 Nicada Dr., #48, Los Angeles, Calif. 90077

[21] Appl. No.: **315,190**

[22] Filed: **Feb. 24, 1989**

Related U.S. Application Data

[63] Continuation of Ser. No. 70,325, Jul. 6, 1987, abandoned.

[51] **Int. Cl.**[4] **A61B 17/20**

[52] **U.S. Cl.** **604/22**; 606/162; 606/166

[58] **Field of Search** 604/22, 27, 28; 128/304, 305, 321, 757–758

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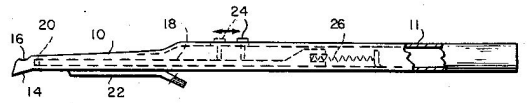
Primary Examiner—C. Fred Rosenbaum
Assistant Examiner—kathleen A. Daley
Attorney, Agent, or Firm—David Silverstein

[57] **ABSTRACT**

This invention relates to the design and application of a goniectomy instrument for the purpose of diagnostically and therapeutically removing tissue from the anterior chamber angle of the eye and for retrieving this tissue for further examination. The surgical instrument of this invention comprises in combination: a hollow, tapered shaft having a cutting edge at one end as an integral part thereof; a retractable stylet contained within the hollow interior of the tapered shaft; and an irrigation port running along the outside of the tapered shaft. This instrument is useful for excising tissue to relieve an obstruction blocking the outflow of aqueous humor from the eye as well as for providing specimens of the excised tissue for histopathological examination.

24 Claims, 1 Drawing Sheet



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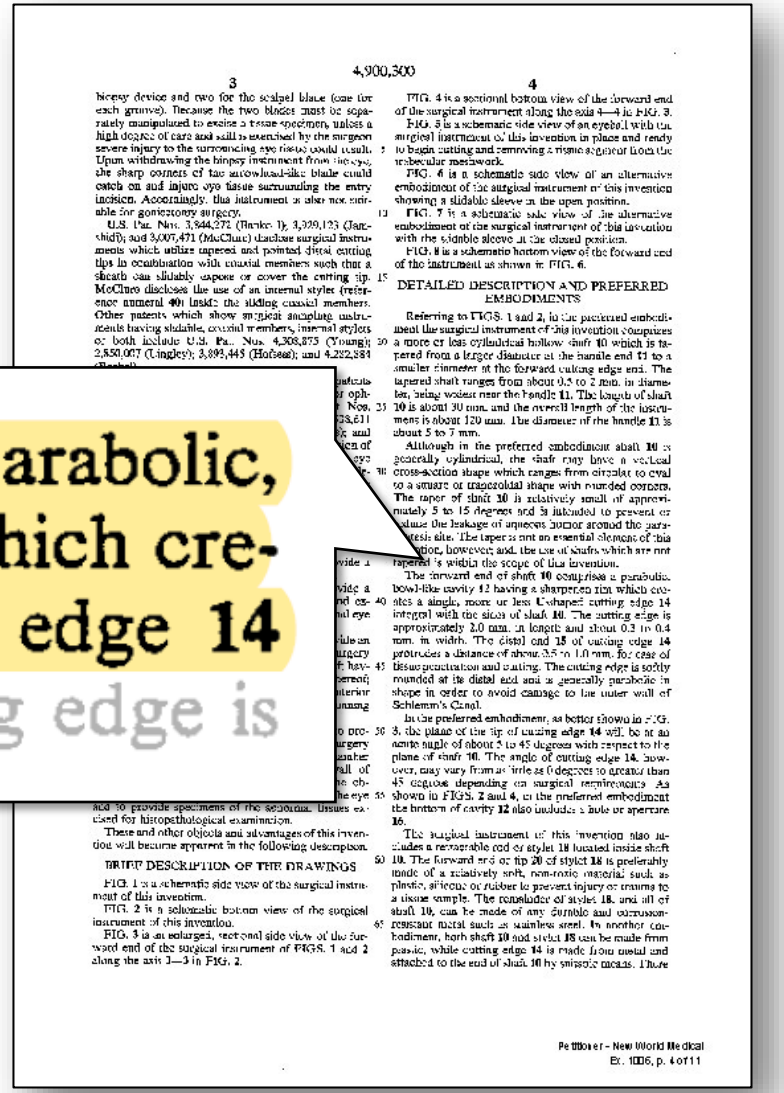

The forward end of shaft **10** comprises a parabolic, bowl-like cavity **12** having a sharpened rim which creates a single, more or less U-shaped cutting edge **14** integral with the sides of shaft **10**. The cutting edge is

IPR2020-01573 Paper 29 at 3-4, 38-44; 2020-01711 Paper 17 at 3-4, 44-50; 2021-00017 Paper 17 at 31, 41; 2021-00065 Paper 18 at 3, 18, 36, 38; 2021-00066, Paper 17 at 4, 25-26, 37, 47-48.

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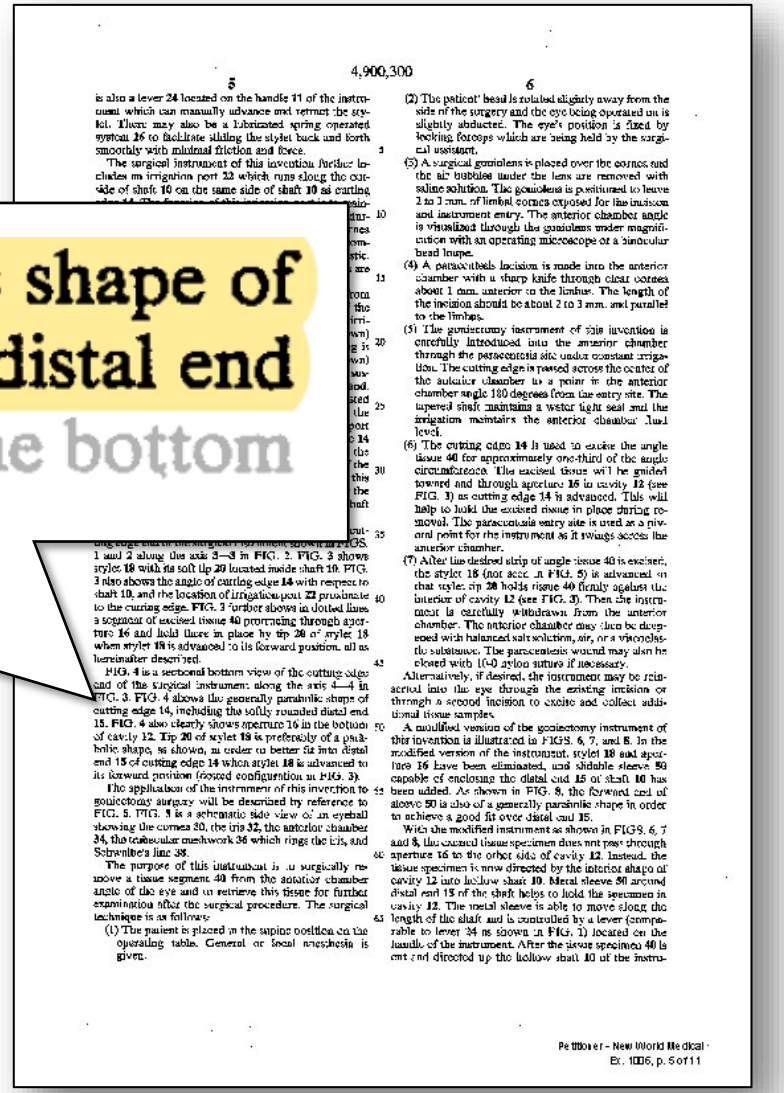
FIG. 3. FIG. 4 shows the generally parabolic shape of cutting edge 14, including the softly rounded distal end 15. FIG. 4 also clearly shows aperture 16 in the bottom



IPR2020-01573 Paper 29 at 3-4, 38-44; 2020-01711 Paper 17 at 3-4, 44-50; 2021-00017 Paper 17 at 31, 41; 2021-00065 Paper 18 at 3, 18, 36, 38; 2021-00066, Paper 17 at 4, 25-26, 37, 47-48.

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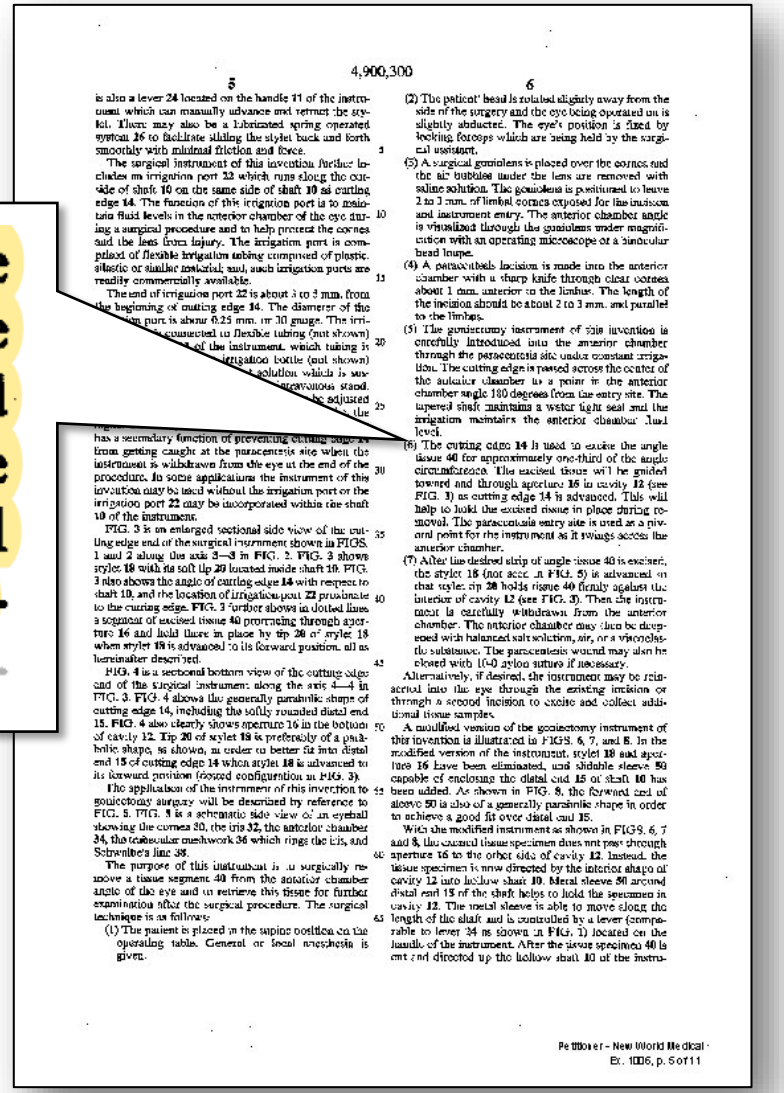
(6) The cutting edge **14** is used to excise the angle tissue **40** for approximately one-third of the angle circumference. The excised tissue will be guided toward and through aperture **16** in cavity **12** (see FIG. 3) as cutting edge **14** is advanced. This will help to hold the excised tissue in place during removal. The paracentesis entry site is used as a piv-



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is also a lever **24** located on the handle **11** of the instrument which can manually advance and retract the stylet. There may also be a lubricated spring operated system **26** to facilitate sliding the stylet back and forth smoothly with minimal friction and force.

The surgical instrument of this invention further includes an irrigation port **22** which runs along the outside of shaft **10** on the same side of shaft **10** as cutting edge **14**. The function of this irrigation port is to maintain fluid levels in the anterior chamber of the eye during a surgical procedure and to help protect the cornea and the lens from injury. The irrigation port is comprised of flexible irrigation tubing comprised of plastic, silastic or similar material, and such irrigation ports are readily commercially available.

The end of irrigation port **22** is about 3 to 5 mm. from the beginning of cutting edge **14**. The diameter of the ... port is about 0.25 mm. or 30 gauge. The irri... connected to flexible tubing (not shown) ... of the instrument, which tubing is ... irrigation bottle (not shown) ... solution which is sus... precautions stand. ... be adjusted ... the ... has a secondary function of preventing cutting edge ... from getting caught at the paracentesis site when the instrument is withdrawn from the eye at the end of the procedure. In some applications the instrument of this invention may be used without the irrigation port or the irrigation port **22** may be incorporated within the shaft **10** of the instrument.

FIG. 3 is an enlarged sectional side view of the cutting edge end of the surgical instrument shown in FIGS. 1 and 2 along the axis 3—3 in FIG. 2. FIG. 3 shows stylet **18** with its soft tip **20** located inside shaft **10**. FIG. 3 also shows the angle of cutting edge **14** with respect to shaft **10**, and the location of irrigation port **22** proximate to the cutting edge. FIG. 3 further shows in dotted lines a segment of excised tissue **40** protruding through aperture **16** and held there in place by tip **20** of stylet **18** when stylet **18** is advanced to its forward position, all as hereinafter described.

FIG. 4 is a sectional bottom view of the cutting edge end of the surgical instrument along the axis 4—4 in FIG. 3. FIG. 4 shows the generally parabolic shape of cutting edge **14**, including the softly rounded distal end **15**. FIG. 4 also clearly shows aperture **16** in the bottom of cavity **12**. Tip **20** of stylet **18** is preferably of a parabolic shape, as shown, in order to better fit into distal end **15** of cutting edge **14** when stylet **18** is advanced to its forward position (closed configuration in FIG. 3).

The application of the instrument of this invention to goniectomy surgery will be described by reference to FIG. 5. FIG. 5 is a schematic side view of an eyeball showing the cornea **30**, the iris **32**, the anterior chamber **34**, the trabecular meshwork **36** which rings the iris, and Schwalbe's line **38**.

The purpose of this instrument is to surgically remove a tissue segment **40** from the anterior chamber angle of the eye and to retrieve this tissue for further examination after the surgical procedure. The surgical technique is as follows:

(1) The patient is placed in the supine position on the operating table. General or local anesthesia is given.

(2) The patient' head is rotated slightly away from the side of the surgery and the eye being operated on is slightly abducted. The eye's position is fixed by locking forceps which are being held by the surgical assistant.

(3) A surgical goniolens is placed over the cornea and the air bubbles under the lens are removed with saline solution. The goniolens is positioned to leave 2 to 3 mm. of limbal cornea exposed for the incision and instrument entry. The anterior chamber angle is visualized through the goniolens under magnification with an operating microscope or a binocular head loupe.

(4) A paracentesis incision is made into the anterior chamber with a sharp knife through clear cornea about 1 mm. anterior to the limbus. The length of the incision should be about 2 to 3 mm. and parallel to the limbus.

(5) The goniectomy instrument of this invention is carefully introduced into the anterior chamber through the paracentesis site under constant irrigation. The cutting edge is passed across the center of the anterior chamber to a point in the anterior chamber angle 180 degrees from the entry site. The tapered shaft maintains a water tight seal and the irrigation maintains the anterior chamber fluid level.

(6) The cutting edge **14** is used to excise the angle tissue **40** for approximately one-third of the angle circumference. The excised tissue will be guided toward and through aperture **16** in cavity **12** (see FIG. 3) as cutting edge **14** is advanced. This will help to hold the excised tissue in place during removal. The paracentesis entry site is used as a pivot point for the instrument as it swings across the anterior chamber.

(7) After the desired strip of angle tissue **40** is excised, the stylet **18** (not seen in FIG. 5) is advanced so that stylet tip **20** holds tissue **40** firmly against the interior of cavity **12** (see FIG. 3). Then the instrument is carefully withdrawn from the anterior chamber. The anterior chamber may then be deepened with balanced salt solution, air, or a viscoelastic substance. The paracentesis wound may also be closed with 10-0 nylon sutures if necessary.

Alternatively, if desired, the instrument may be reinserted into the eye through the existing incision or through a second incision to excise and collect additional tissue samples.

A modified version of the goniectomy instrument of this invention is illustrated in FIGS. 6, 7, and 8. In the modified version of the instrument, stylet **18** and aperture **16** have been eliminated, and slidable sleeve **50** capable of enclosing the distal end **15** of shaft **10** has been added. As shown in FIG. 8, the forward end of sleeve **50** is also of a generally parabolic shape in order to achieve a good fit over distal end **15**.

With the modified instrument as shown in FIGS. 6, 7 and 8, the excised tissue specimen does not pass through aperture **16** to the other side of cavity **12**. Instead, the tissue specimen is now directed by the interior shape of cavity **12** into hollow shaft **10**. Metal sleeve **50** around distal end **15** of the shaft helps to hold the specimen in cavity **12**. The metal sleeve is able to move along the length of the shaft and is controlled by a lever (comparable to lever **24** as shown in FIG. 1) located on the handle of the instrument. After the tissue specimen **40** is sent and directed up the hollow shaft **10** of the instru-

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Ex. 1007 (Jacobi 1997)

British Journal of Ophthalmology 1997;81:302–307

Technique of goniocurettage: a potential treatment for advanced chronic open angle glaucoma

Philipp C Jacobi, Thomas S Dietlein, Günter K Krieglstein

Abstract

Aims—To introduce a new concept of anterior chamber angle microsurgery, designed to scrape pathologically altered trabecular meshwork from the scleral sulcus as a potential treatment in primary open angle glaucoma.

Methods—Gonioscopically controlled ab interno abrasion of the trabecular meshwork was performed on six human eyes banking eyes for morphological analysis. Thereafter, four eyes suffering from terminal glaucomatous optic nerve atrophy as a result of medically uncontrolled intraocular pressure were also treated by 'goniocurettage'. The newly designed instrument resembles a modified cyclodialysis spatula with a bowl-shaped tip, 300 µm in diameter, and with its edges sharpened. The treatment zone comprised 4–5 clock hours of the chamber angle circumference.

Results—Microscopic examination of the treatment zone revealed that in addition to a complete disruption of the trabecular meshwork and internal wall of Schlemm's canal goniocurettage also caused damage to intraocular septa. A splitting along the posterior wall of Schlemm's canal was also noted in one specimen. The clinical data of goniocurettage also showed some promising results. Mean pretreatment IOP averaged 40.7 (SD 8.8) mm Hg (range 32–51 mm Hg) and was significantly ($p<0.04$) reduced to 18.0 (4.2) mm Hg (12–22 mm Hg) after 6 months, representing an absolute decrease in IOP of 22.7 mm Hg and a mean decrease in IOP of 56%. Clinically significant hyphaema occurred in one eye, caused by iatrogenic trauma to a prominent chamber angle vessel. In three eyes a minor reflux of blood occurred at the treatment site. However, no hypotony, choroidal effusion, flattened anterior chamber, or cyclodialysis were observed in these patients.

Conclusion—Morphological analysis of treated postmortem eyes confirmed that goniocurettage completely removed the trabecular meshwork and opened Schlemm's canal, ensuring direct access into the anterior chamber. In a small number of patients over a limited period of time this new surgical procedure resulted in a clinically significant pressure reduction. However, longer term follow up and a greater number of patients are warranted before this experimental procedure is applicable to eyes that would do well with conventional surgery.

(*Br J Ophthalmol* 1997;81:302–307)

Conventional glaucoma filtering surgery is the mainstay of surgical treatment to control intraocular pressure (IOP) in primary open angle glaucoma.[1–5] There is a growing trend to perform surgery earlier in the course of glaucoma management.[1] However, despite increasing success rates, especially with the use of adjunct antimetabolites, several problems remain, such as hyphaema, flat anterior chamber, and variable wound healing response to conjunctival manipulation. In order to avoid the latter, various techniques have been investigated that minimise conjunctival dissection to improve the success rate of filtration surgery. Laser sclerotomy has recently become a viable alternative to conventional glaucoma filtration surgery.[2] However, varying success rates have been reported using different laser systems and techniques.[3–5] Based on the concept of abnormal resistance to outflow of aqueous humour as a result of maldevelopment of the trabecular meshwork,[6] goniotomy,[7,8] ab externo trabeculotomy,[9] and trabeculopuncture[10] have each been recommended as surgical procedures of choice in juvenile open angle glaucoma. In recent years, trabeculotomy has again received increasing interest among some glaucoma surgeons as a first choice surgical treatment of chronic open angle glaucoma,[11] including combined glaucoma and cataract surgery.[12]

Based on transmission and scanning electron microscopy of trabeculectomy specimens various authors have suggested that in most cases of chronic open angle glaucoma the primary increase of outflow resistance lies in the cribriform layer of the trabecular meshwork adjacent to the inner wall endothelium of Schlemm's canal.[13–15] Presuming that the outer layer of the trabecular meshwork play the key role in the pathology of primary open angle glaucoma, incisional surgery (goniotomy) or mechanical disruption (trabeculotomy) of the trabecular meshwork could then be a valid surgical approach to medically uncontrolled open angle glaucoma. Unfortunately, simple disruption of the trabecular meshwork with the trabeculotomy approach or punching small holes with the Q switched Nd:YAG laser

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Figure 1 The tip of the 'gonioscraper'. The bowl is 300 μm in diameter with its edges sharpened.

(trabeculopuncture) removes little tissue and allows filling in and scarring to occur with subsequent closure of the trabecular opening.[22 23]

The present study was carried out to introduce a new approach in glaucoma surgery aiming to scrape pathologically altered trabecular meshwork off the scleral sulcus in six patients suffering from uncontrolled IOP due to glaucoma absolutum. The aim of the surgical procedure was to abrade rather than incise uveal meshwork; this novel method, therefore, is termed goniocurettage. A description of instrumentation, surgical technique, and preliminary clinical results are given.

Materials and methods

INSTRUMENTATION AND SURGICAL TECHNIQUE

In order to shell the trabecular meshwork out of its scleral sulcus a new surgical instrument was designed. The 'gonioscraper' consists of a small handle and a slightly convex-shaped arm for intraocular use and very much resembles a cyclodialysis spatula. However, the tip of the instrument is shaped as a tiny bowl with 300 μm diameter and with its edges sharpened (Fig 1). In order to abrade clockwise and anticlockwise the scoop is angulated vertically at 90 degrees to the left and right, respectively.

The experimental part of the surgical procedure was carried out on six human eye bank globes, classified unsuitable for keratoplasty. Death had occurred no more than 12 hours before surgery. Gonioabrasion was performed under direct visualisation of the anterior chamber angle with an operating microscope and a surgical gonioscopy lens. Following injection of viscoelastic, the 'gonioscraper' was inserted into the anterior chamber through a clear corneal incision at the temporal limbus and directed against the trabecular meshwork at the opposite side. In order to peel off trabecular meshwork the 'scraper' was lightly passed over 2–3 clock hours to either side at the nasal circumference of the anterior chamber angle in sweeping movements (Fig 2). Great care was taken to selectively pare uveal meshwork and not to traumatise adjacent intraocular structures, such as the corneal endothelium or the base of the iris. Gonioscopically, strings of trabecular tissue could be observed intraoperatively to be removed by goniocurettage, leaving a 'denuded' grey-white scleral sulcus. At the end of surgery the viscoelastic along with abraded trabecular debris were removed by means of an irrigation-aspiration probe.

HISTOLOGICAL PREPARATION

Following surgery three eye banking eyes were processed for scanning electron microscopy as follows: within 5 minutes after treatment, the eyes were immersed in a fixative of 2% glutaraldehyde and 2% paraformaldehyde in 0.1 M phosphate buffer at a pH of 7.4. After 2 hours, the eyes were rinsed in phosphate buffer, and the treated area was dissected out. Specimens for scanning electron microscopy were postfixed with 1% osmium tetroxide in 0.1 M phosphate buffer at a pH of 7.4. After 2 hours in osmium tetroxide, the scanning specimens were dehydrated in graded alcohols, critical point dried in carbon dioxide, and sputter coated with gold. The specimens were then examined with the scanning electron microscope. Those samples designated for light microscopy were fixed in a 10% formalin solution. After 2 hours dissected samples were dehydrated, embedded in paraffin, sectioned by a microkeratome, and stained with haematoxylin and eosin for light microscopy.

PATIENTS

Six patients were included in this study all suffering from medically uncontrolled IOP, terminal optic nerve atrophy, and no light perception consequent on chronic open angle glaucoma. Exclusion criteria were: reduced (≥20/40) or threatened vision in the unoperated eye, a history of uveitis, anterior segment media opacity, ocular trauma, and neovascular or angle closure glaucoma. Preoperative evaluation included measurement of visual acuity, quantitative visual field testing if possible, measurement of IOP, gonioscopy, anterior and posterior segment slit-lamp biomicroscopy, indirect ophthalmoscopy of the retina, and ultrasonography when required. Informed consent was obtained from all the patients, following the tenets of the Declaration of Helsinki, after they had been fully informed about the experimental nature of the procedure. Surgery was performed in the above manner using retrobulbar anaesthesia. Treatment in the immediate preoperative period

Figure 2 With the aid of an operating microscope and under gonioscopic control ab interno goniocurettage is performed. Following abrasion an irregular pattern of a glistening white band corresponding to the 'denuded' grey-white sulcus scleralis can be seen (black arrows).

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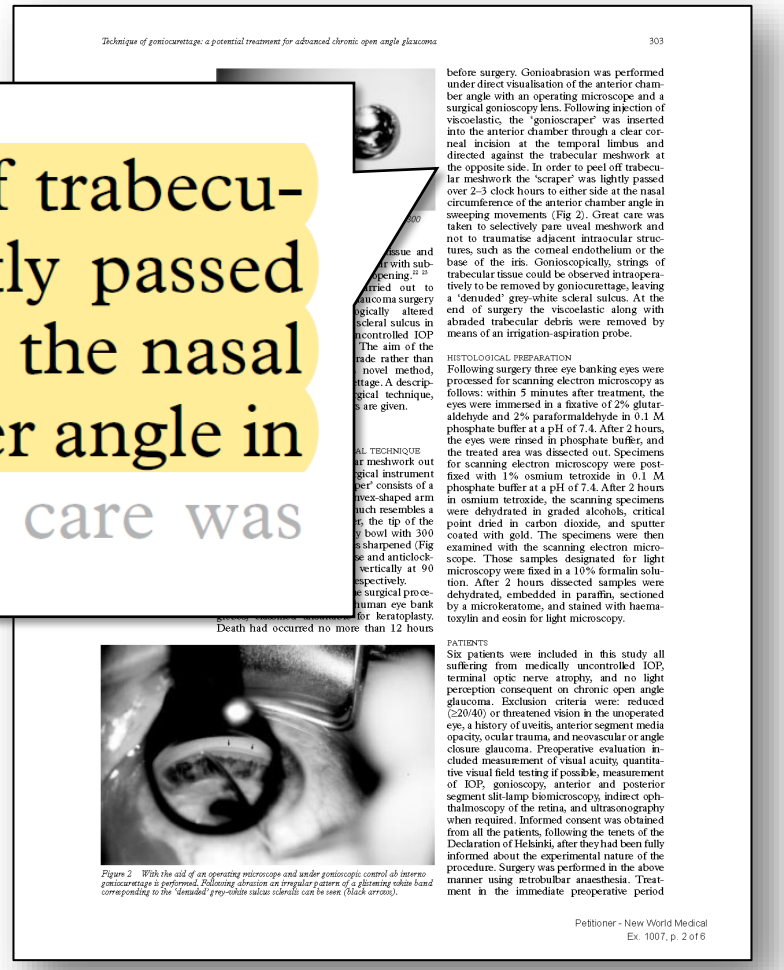

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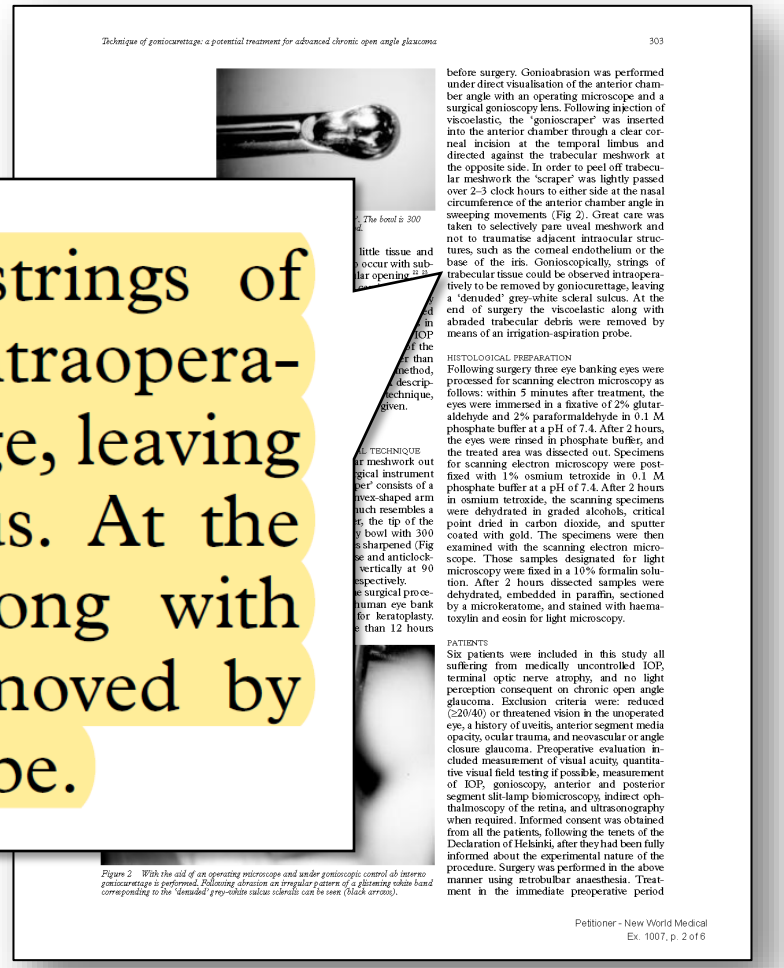

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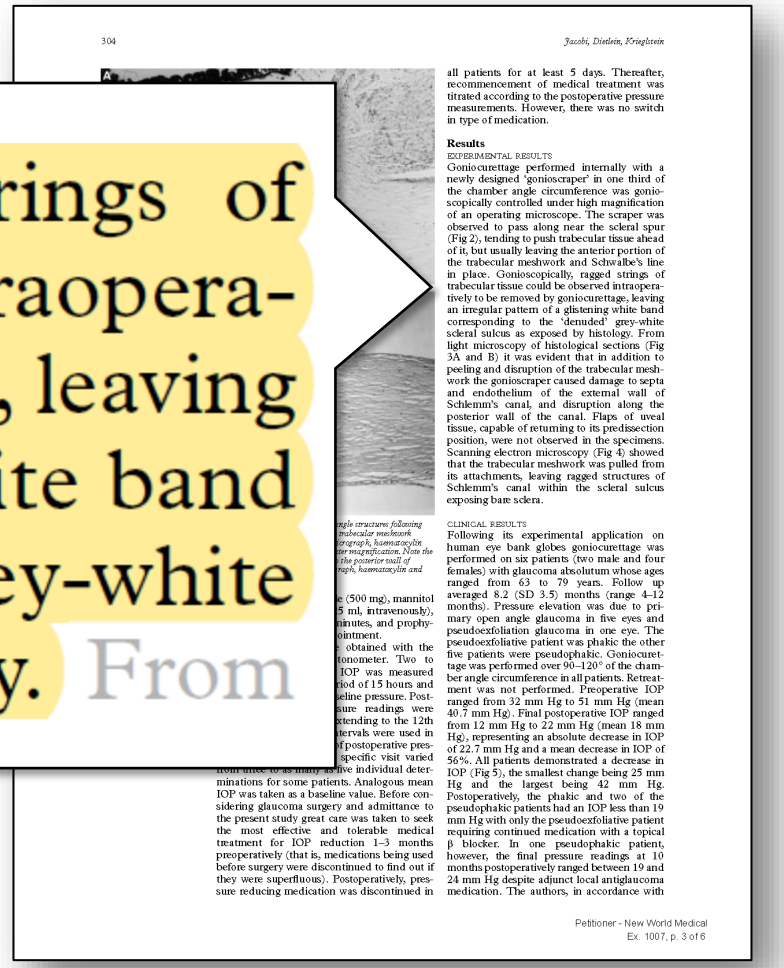

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all patients for at least 5 days. Thereafter, recommencement of medical treatment was titrated according to the postoperative pressure measurements. However, there was no switch in type of medication.

Results

EXPERIMENTAL RESULTS

Goniocurettage performed internally with a newly designed 'gonioscraper' in one third of the chamber angle circumference was gonioscopically controlled under high magnification of an operating microscope. The scraper was observed to pass along near the scleral spur (Fig 2), tending to push trabecular tissue ahead of it, but usually leaving the anterior portion of the trabecular meshwork and Schwalbe's line in place. Gonioscopically, ragged strings of trabecular tissue could be observed intraoperatively to be removed by goniocurettage, leaving an irregular pattern of a glistening white band corresponding to the 'denuded' grey-white scleral sulcus as exposed by histology. From light microscopy of histological sections (Fig 3A and B) it was evident that in addition to peeling and disruption of the trabecular meshwork the gonioscraper caused damage to septa and endothelium of the external wall of Schlemm's canal, and disruption along the posterior wall of the canal. Flaps of uveal tissue, capable of returning to its predissection position, were not observed in the specimens. Scanning electron microscopy (Fig 4) showed that the trabecular meshwork was pulled from its attachments, leaving ragged structures of Schlemm's canal within the scleral sulcus exposing bare sclera.

CLINICAL RESULTS

Following its experimental application on human eye bank globes goniocurettage was performed on six patients (two male and four females) with glaucoma absolutum whose ages ranged from 63 to 79 years. Follow up averaged 8.2 (SD 3.5) months (range 4–12 months). Pressure elevation was due to primary open angle glaucoma in five eyes and pseudoexfoliation glaucoma in one eye. The pseudoexfoliative patient was phakic the other five patients were pseudophakic. Goniocurettage was performed over 90–120° of the chamber angle circumference in all patients. Retreatment was not performed. Preoperative IOP ranged from 32 mm Hg to 51 mm Hg (mean 40.7 mm Hg). Final postoperative IOP ranged from 12 mm Hg to 22 mm Hg (mean 18 mm Hg), representing an absolute decrease in IOP of 22.7 mm Hg and a mean decrease in IOP of 56%. All patients demonstrated a decrease in IOP (Fig 5), the smallest change being 25 mm Hg and the largest being 42 mm Hg. Postoperatively, the phakic and two of the pseudophakic patients had an IOP less than 19 mm Hg with only the pseudoexfoliative patient requiring continued medication with a topical β blocker. In one pseudophakic patient, however, the final pressure readings at 10 months postoperatively ranged between 19 and 24 mm Hg despite adjunct local antiglaucoma medication. The authors, in accordance with

IPR2020-01573 Paper 29 at 4-6, 45-55; 2020-01711 Paper 17 at 4-6, 50-60; 2021-00017 Paper 17 at 3-5, 31-43; 2021-00065 Paper 18 at 3-4, 31-38; 2021-00066, Paper 17 at 4-5, 37, 39-48.

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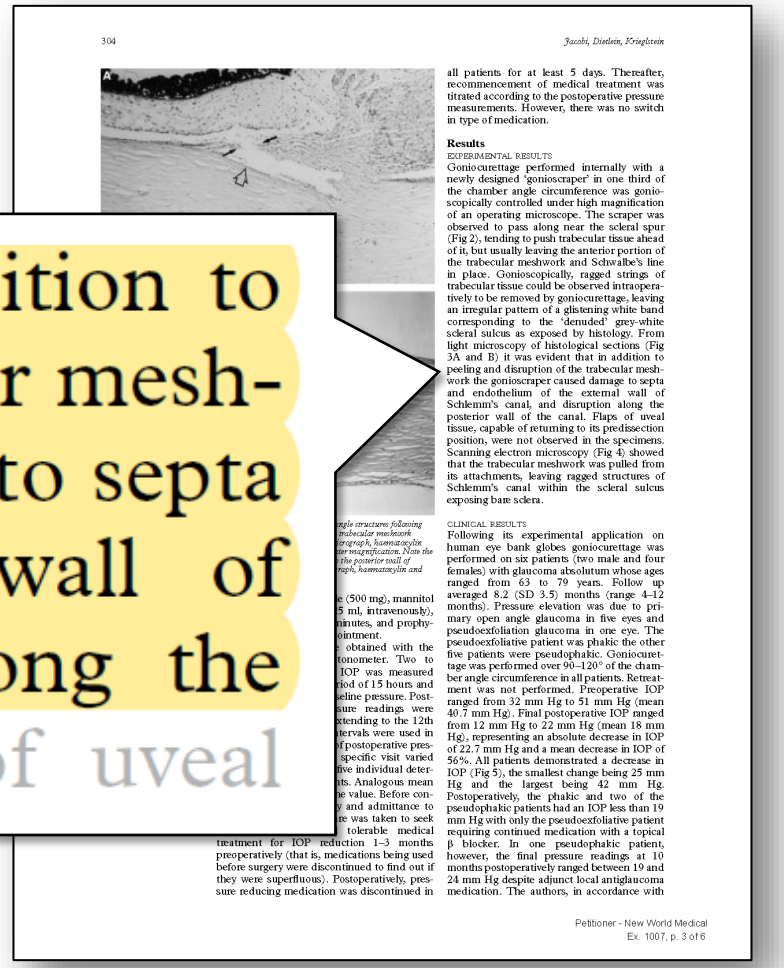
3A and B) it was evident that in addition to peeling and disruption of the trabecular meshwork the gonioscraper caused damage to septa and endothelium of the external wall of Schlemm's canal, and disruption along the posterior wall of the canal. Flaps of uveal



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all patients for at least 5 days. Thereafter, recommencement of medical treatment was titrated according to the postoperative pressure measurements. However, there was no switch in type of medication.

Results

EXPERIMENTAL RESULTS

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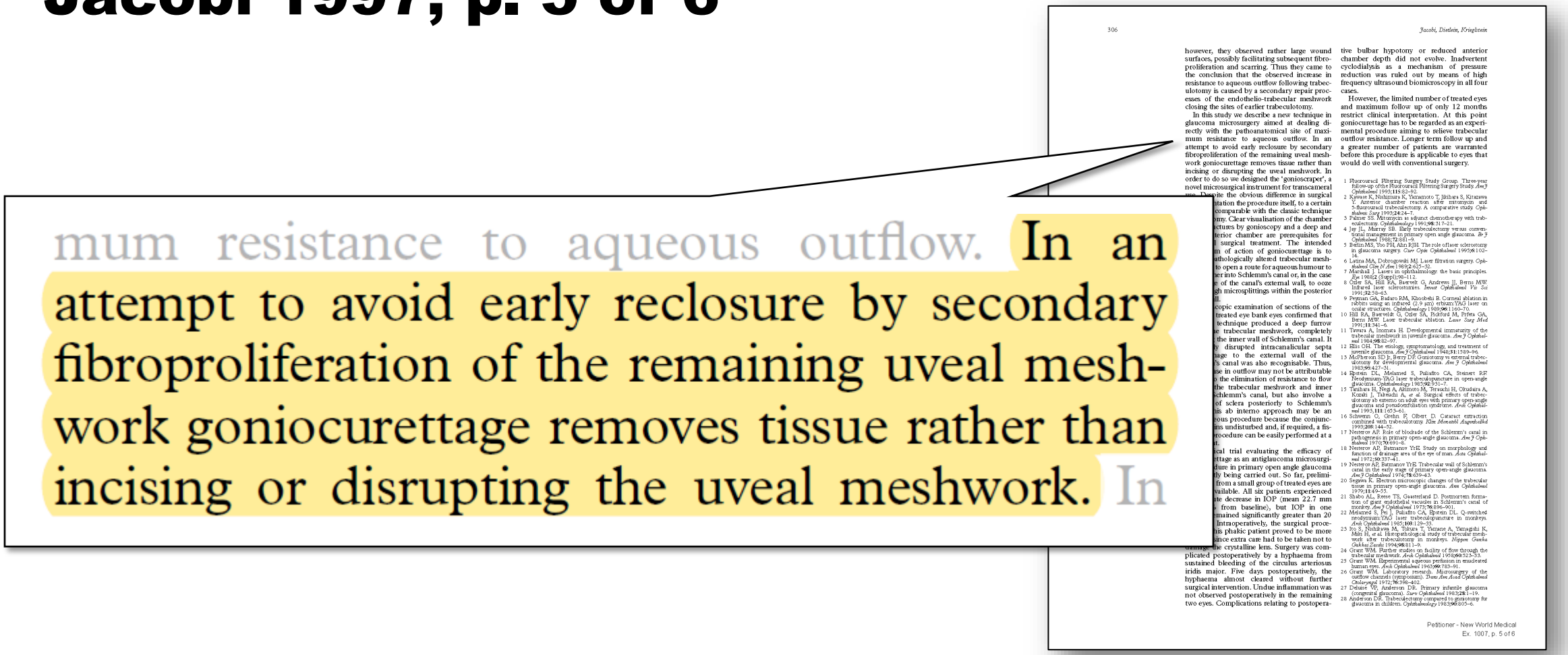

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however, they observed rather large wound surfaces, possibly facilitating subsequent fibroproliferation and scarring. Thus they came to the conclusion that the observed increase in resistance to aqueous outflow following trabeculotomy is caused by a secondary repair processes of the endothelio-trabecular meshwork closing the sites of earlier trabeculotomy.

In this study we describe a new technique in glaucoma microsurgery aimed at dealing directly with the pathoanatomical site of maximum resistance to aqueous outflow. In an attempt to avoid early reclosure by secondary fibroproliferation of the remaining uveal meshwork goniocurettage removes tissue rather than incising or disrupting the uveal meshwork. In order to do so we designed the 'gonioscraper', a novel microsurgical instrument for transcameral use. Despite the obvious difference in surgical ...tation the procedure itself, to a certain ...comparable with the classic technique ...ury. Clear visualisation of the chamber ...ctures by gonioscopy and a deep and ...terior chamber are prerequisites for ... surgical treatment. The intended ...m of action of goniocurettage is to ...athologically altered trabecular mesh... to open a route for aqueous humour to ...ber into Schlemm's canal or, in the case ...e of the canal's external wall, to ooze ...gh microsplittings within the posterior ...ll.

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However, the limited number of treated eyes and maximum follow up of only 12 months restrict clinical interpretation. At this point goniocurettage has to be regarded as an experimental procedure aiming to relieve trabecular outflow resistance. Longer term follow up and a greater number of patients are warranted before this procedure is applicable to eyes that would do well with conventional surgery.

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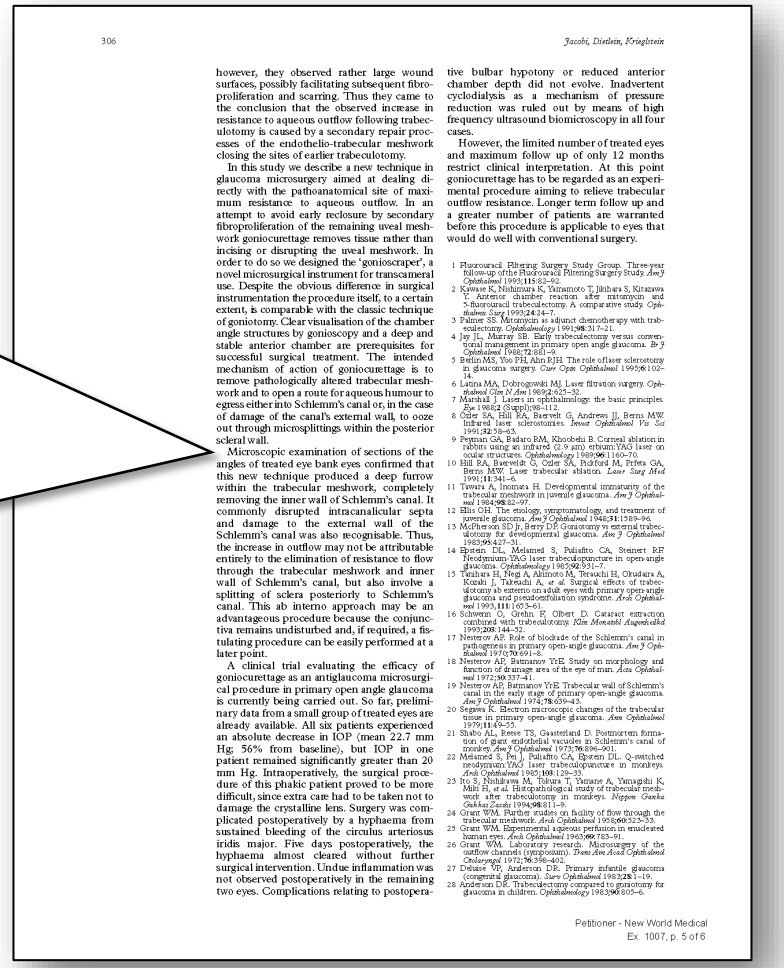
Microscopic examination of sections of the angles of treated eye bank eyes confirmed that this new technique produced a deep furrow within the trabecular meshwork, completely removing the inner wall of Schlemm's canal. It commonly disrupted intracanalicular septa and damage to the external wall of the Schlemm's canal was also recognisable. Thus,



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A clinical trial evaluating the efficacy of goniocurettage as an antiglaucoma microsurgical procedure in primary open angle glaucoma is currently being carried out. So far, preliminary data from a small group of treated eyes are already available. All six patients experienced an absolute decrease in IOP (mean 22.7 mm Hg; 56% from baseline), but IOP in one patient remained significantly greater than 20 mm Hg. Intraoperatively, the surgical procedure of this phakic patient proved to be more difficult, since extra care had to be taken not to damage the crystalline lens. Surgery was complicated postoperatively by a hyphaema from sustained bleeding of the circulus arteriosus iridis major. Five days postoperatively, the hyphaema almost cleared without further surgical intervention. Undue inflammation was not observed postoperatively in the remaining two eyes. Complications relating to postoperative bulbar hypotony or reduced anterior chamber depth did not evolve. Inadvertent cyclodialysis as a mechanism of pressure reduction was ruled out by means of high frequency ultrasound biomicroscopy in all four cases.

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Ex. 1013 (Jacobi 2000)

Perspectives in trabecular surgery

PHILIPP C. JACOBI, THOMAS S. DIETLEIN, GÜNTER K. KRIEGLSTEIN

ARTICLE

Abstract

The aim of trabecular surgery is to selectively combat the diseased structure central to the pathogenesis of chronic open-angle glaucoma, thereby reducing potential hazards during and after conventional filtering procedures. This overview considers new techniques in *ab interno* trabecular surgery. Special emphasis is placed on the description of each novel technique, its instrumentation, presumed mechanism of action and clinical results. Trabecular aspiration is evaluated as a method of clearing intertrabecular spaces of extracellular debris in pseudoexfoliation glaucoma with or without simultaneous cataract surgery or goniocurettage, while laser trabecular ablation is discussed for the treatment of absolute glaucomas. Where corneal haze has formed visualisation of the anterior chamber angle structures and trabecular surgery is performed with the aid of a microendoscope. Although the results are very promising it should be understood that some of these procedures are still in the experimental phase and are undergoing careful clinical evaluation, leaving plenty of room for refinements and further developments.

Key words Goniocurettage, Microendoscopy, Trabecular aspiration, Trabecular photoablation

Enormous progress has been made in understanding the complexity of the underlying causes of chronic open-angle glaucoma. However, indisputable concepts for effective treatment are still rare. To date, conventional filtering surgery remains the mainstay of surgical therapy in the management of glaucoma not controlled by medication.[1] Unfortunately, treatments involving full-thickness filtration are scarcely selective since healthy structures not primarily involved in the disease process are subject to surgical intervention. The application of adjunctive antimetabolites for inhibition of undesired episcleral fibroblastic proliferation dramatically increased the success rates for filtering procedures, but had the disadvantage of exacerbating serious side-effects, such as flat anterior chambers, prolonged post-operative hypotony and late endophthalmitis from infected filtering blebs.[2,3]

Mircosurgery on Schlemm's canal and the human aqueous outflow system for controlling intraocular pressure (IOP) in chronic open-angle glaucoma has been evolving over the past few decades. Theoretical considerations indicate that production of approximately 10 to 15 fistulae, each 10 μm in diameter, between the anterior chamber and Schlemm's canal should restore normal outflow facility in open-angle glaucoma.[4] The basis for most of the current approaches to microsurgery of Schlemm's canal is the finding by Grant[5] that the largest proportion of resistance to outflow is located within the trabecular meshwork, namely the cribriform layer, and can be eliminated by incising the trabecular meshwork and entering Schlemm's canal. If one agrees that the site of the pathological resistance to aqueous humour outflow is this tissue, its partial removal, taking the utmost possible care not to damage the surrounding chamber angle structures, could be a new alternative in antiglaucomatous surgery. This sort of selective non-penetrating trabecular surgery would be equivalent to internal filtration surgery without transscleral drainage of aqueous humour into the subconjunctival space, and would thereby reduce the incidence of post-operative complications typically associated with filtering procedures.

This review discusses different *ab interno* trabecular microsurgical techniques that are designed to facilitate outflow along its natural pathway. Each new technique is described in detail, newly developed instrumentation is discussed, and the presumed mechanisms of action are outlined. However, the reader must understand that none of these new microsurgical procedures threatens to replace conventional filtering approaches, since they are still in the experimental phase and under careful clinical evaluation, and there is plenty of room left for further refinements and developments. We hope this article will give impetus to the search for alternative strategies in antiglaucomatous surgery, and focus attention more closely on the diseased target structure in chronic open-angle glaucoma: the trabecular meshwork.

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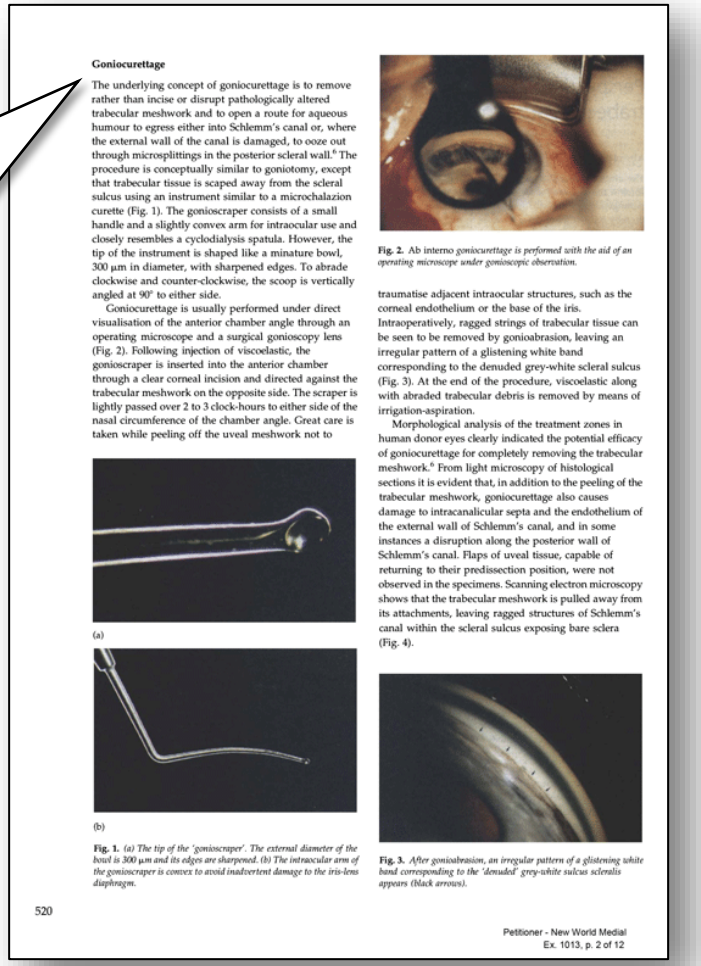
The underlying concept of goniocurettage is to remove rather than incise or disrupt pathologically altered trabecular meshwork and to open a route for aqueous humour to egress either into Schlemm's canal or, where the external wall of the canal is damaged, to ooze out through microsplittings in the posterior scleral wall.[6] The



Goniocurettage

The underlying concept of goniocurettage is to remove rather than incise or disrupt pathologically altered trabecular meshwork and to open a route for aqueous humour to egress either into Schlemm's canal or, where the external wall of the canal is damaged, to ooze out through microsplittings in the posterior scleral wall.[6] The procedure is conceptually similar to goniotomy, except that trabecular tissue is scaped away from the scleral sulcus using an instrument similar to a microchalazion curette (Fig. 1). The gonioscraper consists of a small handle and a slightly convex arm for intraocular use and closely resembles a cyclodialysis spatula. However, the tip of the instrument is shaped like a minature bowl, 300 μm in diameter, with sharpened edges. To abrade clockwise and counter-clockwise, the scoop is vertically angled at 90° to either side.

Goniocurettage is usually performed under direct visualisation of the anterior chamber angle through an operating microscope and a surgical gonioscopy lens (Fig. 2). Following injection of viscoelastic, the gonioscraper is inserted into the anterior chamber through a clear corneal incision and directed against the trabecular meshwork on the opposite side. The scraper is lightly passed over 2 to 3 clock-hours to either side of the nasal circumference of the chamber angle. Great care is taken while peeling off the uveal meshwork not to traumatise adjacent intraocular structures, such as the corneal endothelium or the base of the iris. Intraoperatively, ragged strings of trabecular tissue can be seen to be removed by gonioabrasion, leaving an irregular pattern of a glistening white band corresponding to the denuded grey-white scleral sulcus (Fig. 3). At the end of the procedure, viscoelastic along with abraded trabecular debris is removed by means of irrigation-aspiration.

Morphological analysis of the treatment zones in human donor eyes clearly indicated the potential efficacy of goniocurettage for completely removing the trabecular meshwork.[6] From light microscopy of histological sections it is evident that, in addition to the peeling of the trabecular meshwork, goniocurettage also causes damage to intracanalicular septa and the endothelium of the external wall of Schlemm's canal, and in some instances a disruption along the posterior wall of Schlemm's canal. Flaps of uveal tissue, capable of returning to their predissection position, were not observed in the specimens. Scanning electron microscopy shows that the trabecular meshwork is pulled away from its attachments, leaving ragged structures of Schlemm's canal within the scleral sulcus exposing bare sclera (Fig. 4).

(a)

(b)

Fig. 1. (a) The tip of the 'gonioscraper'. The external diameter of the bowl is 300 μm and its edges are sharpened. (b) The intraocular arm of the gonioscraper is convex to avoid inadvertent damage to the iris-lens diaphragm.

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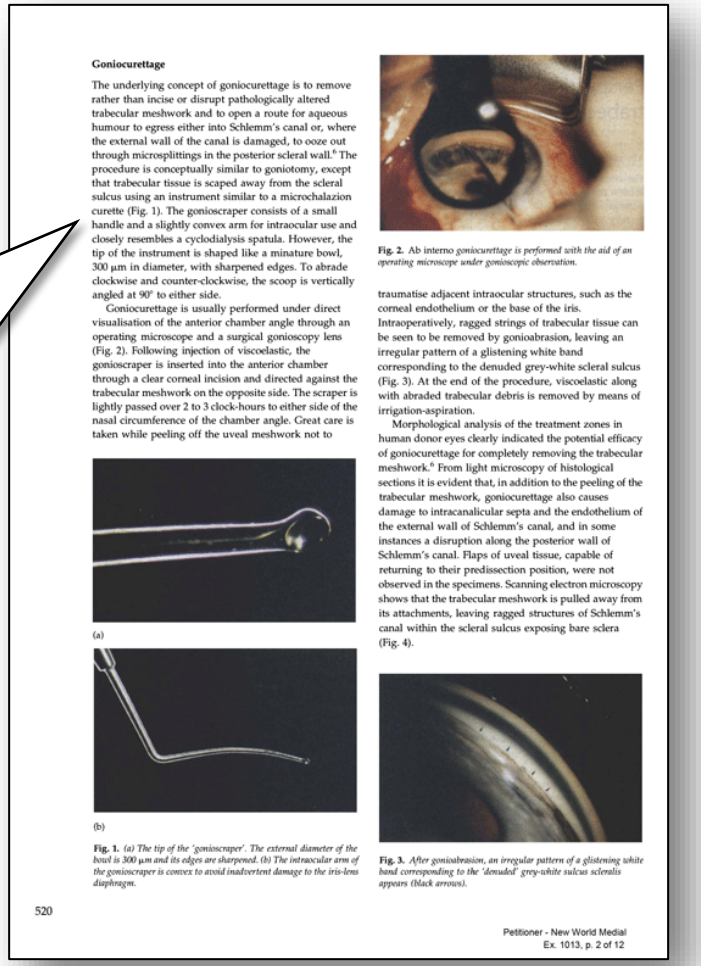

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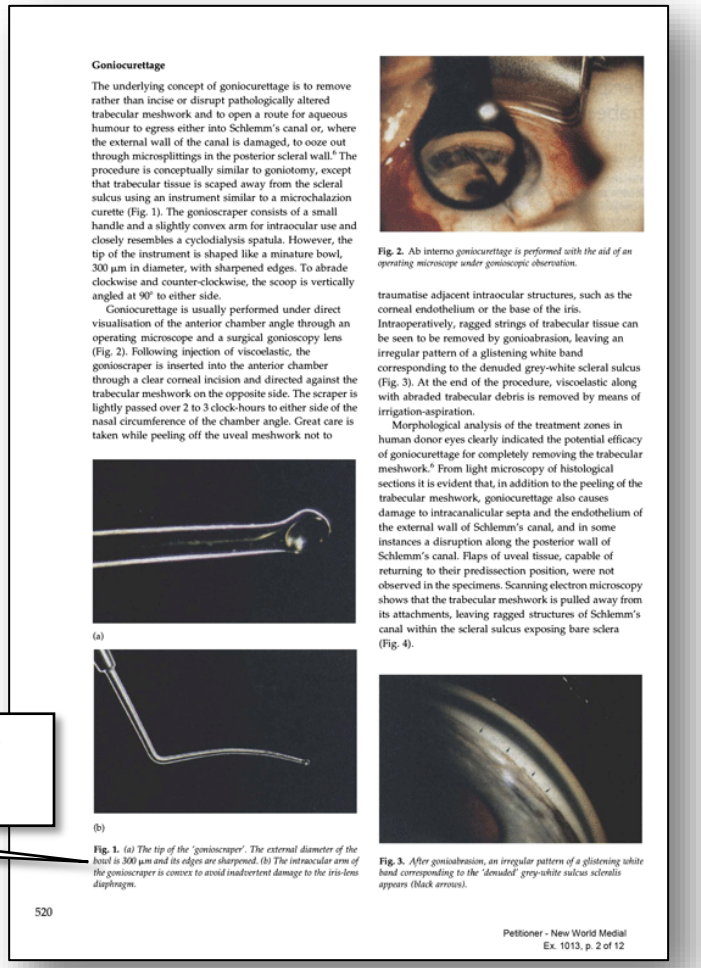

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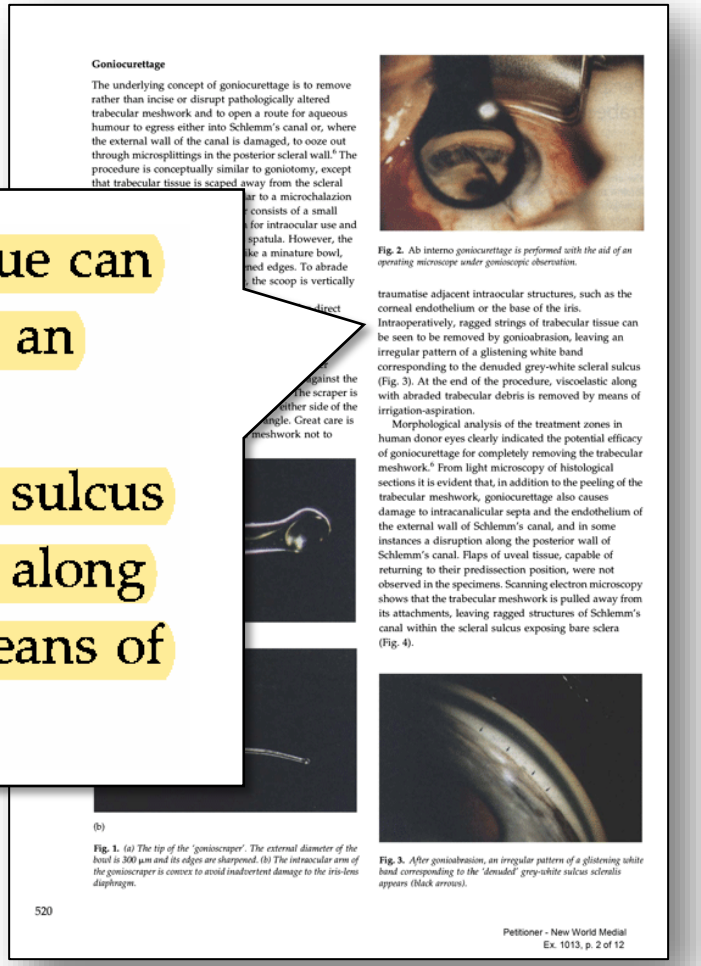

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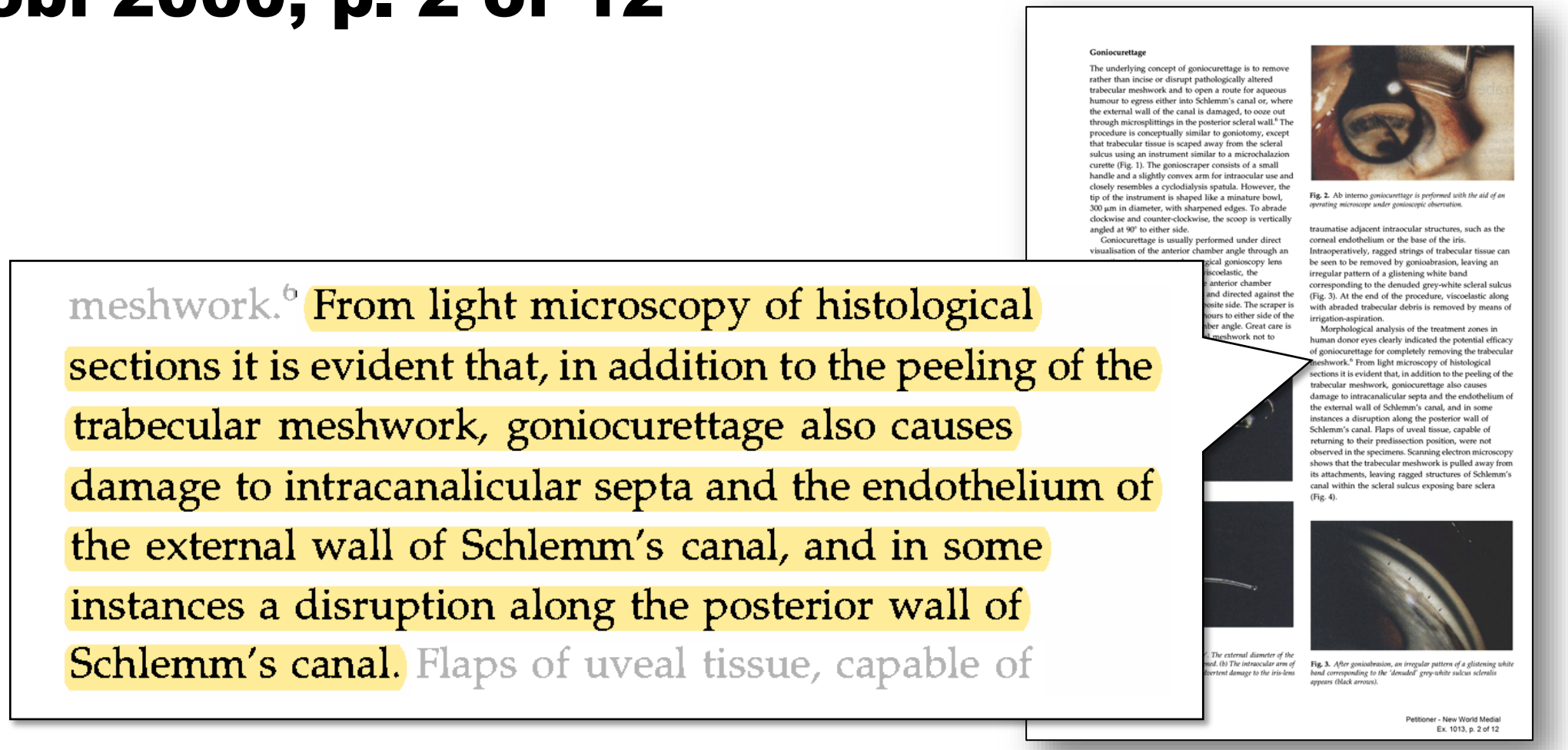

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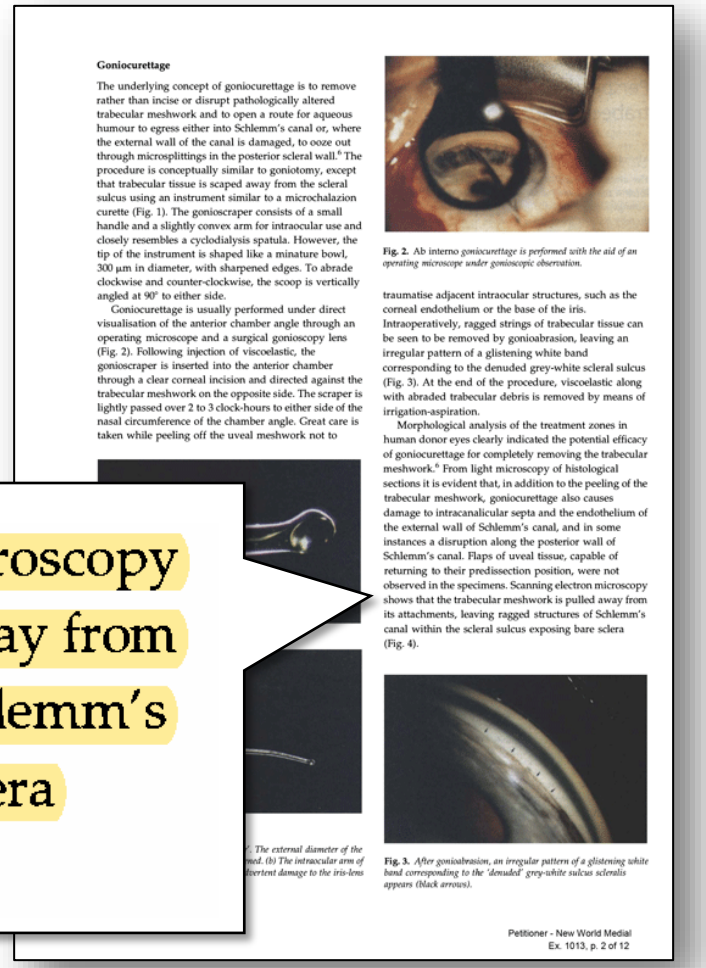

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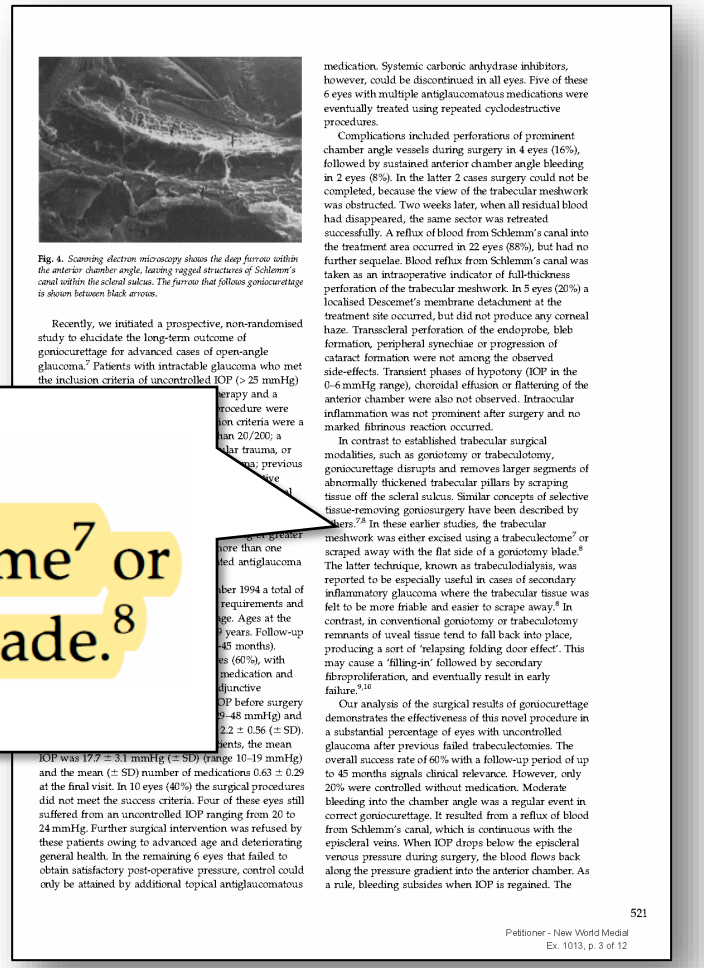

Fig. 4. *Scanning electron microscopy shows the deep furrow within the anterior chamber angle, leaving ragged structures of Schlemm's canal within the scleral sulcus. The furrow that follows goniocurettage is shown between black arrows.*

Recently, we initiated a prospective, non-randomised study to elucidate the long-term outcome of goniocurettage for advanced cases of open-angle glaucoma.[7] Patients with intractable glaucoma who met the inclusion criteria of uncontrolled IOP (> 25 mmHg) [illegible] and a [illegible] were a [illegible] 20/200; a [illegible] trauma, or [illegible]; previous [illegible] greater [illegible] than one [illegible] antiglaucoma [illegible] ber 1994 a total of [illegible] requirements and [illegible]ge. Ages at the [illegible] years. Follow-up [illegible]45 months). [illegible]es (60%), with [illegible] medication and [illegible]djunctive [illegible]OP before surgery [illegible]9–48 mmHg) and [illegible]2.2 ± 0.56 (± SD). [illegible]ients, the mean IOP was 17.7 ± 3.1 mmHg (± SD) (range 10–19 mmHg) and the mean (± SD) number of medications 0.63 ± 0.29 at the final visit. In 10 eyes (40%) the surgical procedures did not meet the success criteria. Four of these eyes still suffered from an uncontrolled IOP ranging from 20 to 24 mmHg. Further surgical intervention was refused by these patients owing to advanced age and deteriorating general health. In the remaining 6 eyes that failed to obtain satisfactory post-operative pressure, control could only be attained by additional topical antiglaucomatous medication. Systemic carbonic anhydrase inhibitors, however, could be discontinued in all eyes. Five of these 6 eyes with multiple antiglaucomatous medications were eventually treated using repeated cyclodestructive procedures.

Complications included perforations of prominent chamber angle vessels during surgery in 4 eyes (16%), followed by sustained anterior chamber angle bleeding in 2 eyes (8%). In the latter 2 cases surgery could not be completed, because the view of the trabecular meshwork was obstructed. Two weeks later, when all residual blood had disappeared, the same sector was retreated successfully. A reflux of blood from Schlemm's canal into the treatment area occurred in 22 eyes (88%), but had no further sequelae. Blood reflux from Schlemm's canal was taken as an intraoperative indicator of full-thickness perforation of the trabecular meshwork. In 5 eyes (20%) a localised Descemet's membrane detachment at the treatment site occurred, but did not produce any corneal haze. Transscleral perforation of the endoprobe, bleb formation, peripheral synechiae or progression of cataract formation were not among the observed side-effects. Transient phases of hypotony (IOP in the 0–6 mmHg range), choroidal effusion or flattening of the anterior chamber were also not observed. Intraocular inflammation was not prominent after surgery and no marked fibrinous reaction occurred.

In contrast to established trabecular surgical modalities, such as goniotomy or trabeculotomy, goniocurettage disrupts and removes larger segments of abnormally thickened trabecular pillars by scraping tissue off the scleral sulcus. Similar concepts of selective tissue-removing goniosurgery have been described by others.[7,8] In these earlier studies, the trabecular meshwork was either excised using a trabeculectome[7] or scraped away with the flat side of a goniotomy blade.[8] The latter technique, known as trabeculodialysis, was reported to be especially useful in cases of secondary inflammatory glaucoma where the trabecular tissue was felt to be more friable and easier to scrape away.[8] In contrast, in conventional goniotomy or trabeculotomy remnants of uveal tissue tend to fall back into place, producing a sort of 'relapsing folding door effect'. This may cause a 'filling-in' followed by secondary fibroproliferation, and eventually result in early failure.[9,10]

Our analysis of the surgical results of goniocurettage demonstrates the effectiveness of this novel procedure in a substantial percentage of eyes with uncontrolled glaucoma after previous failed trabeculectomies. The overall success rate of 60% with a follow-up period of up to 45 months signals clinical relevance. However, only 20% were controlled without medication. Moderate bleeding into the chamber angle was a regular event in correct goniocurettage. It resulted from a reflux of blood from Schlemm's canal, which is continuous with the episcleral veins. When IOP drops below the episcleral venous pressure during surgery, the blood flows back along the pressure gradient into the anterior chamber. As a rule, bleeding subsides when IOP is regained. The

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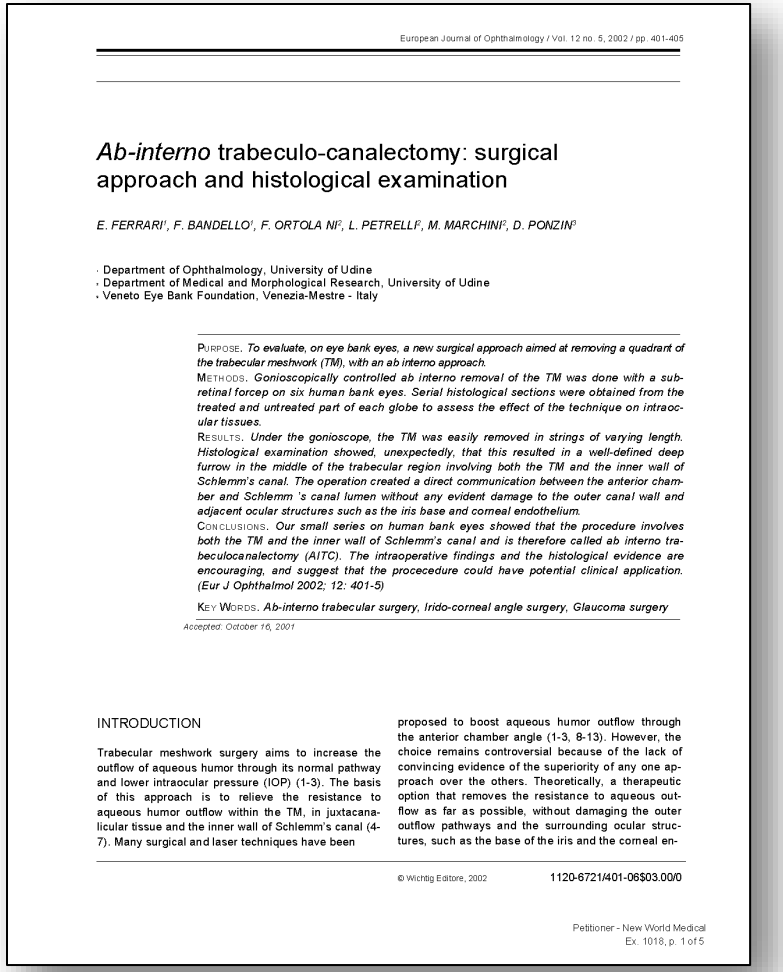
Ex. 1018 (Ferrari)



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Ab-interno trabeculo-canalectomy: surgical approach and histological examination

E. FERRARI[1], F. BANDELLO[1], F. ORTOLA NI[2], L. PETRELLI[2], M. MARCHINI[2], D. PONZIN[3]

[1] Department of Ophthalmology, University of Udine
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[3] Veneto Eye Bank Foundation, Venezia-Mestre - Italy

PURPOSE. *To evaluate, on eye bank eyes, a new surgical approach aimed at removing a quadrant of the trabecular meshwork (TM), with an ab interno approach.*
METHODS. *Gonioscopically controlled ab interno removal of the TM was done with a sub-retinal forcep on six human bank eyes. Serial histological sections were obtained from the treated and untreated part of each globe to assess the effect of the technique on intraocular tissues.*
RESULTS. *Under the gonioscope, the TM was easily removed in strings of varying length. Histological examination showed, unexpectedly, that this resulted in a well-defined deep furrow in the middle of the trabecular region involving both the TM and the inner wall of Schlemm's canal. The operation created a direct communication between the anterior chamber and Schlemm 's canal lumen without any evident damage to the outer canal wall and adjacent ocular structures such as the iris base and corneal endothelium.*
CONCLUSIONS. *Our small series on human bank eyes showed that the procedure involves both the TM and the inner wall of Schlemm's canal and is therefore called ab interno trabeculocanalectomy (AITC). The intraoperative findings and the histological evidence are encouraging, and suggest that the procecedure could have potential clinical application. (Eur J Ophthalmol 2002; 12: 401-5)*

KEY WORDS. *Ab-interno trabecular surgery, Irido-corneal angle surgery, Glaucoma surgery*

Accepted: October 16, 2001

INTRODUCTION

Trabecular meshwork surgery aims to increase the outflow of aqueous humor through its normal pathway and lower intraocular pressure (IOP) (1-3). The basis of this approach is to relieve the resistance to aqueous humor outflow within the TM, in juxtacanalicular tissue and the inner wall of Schlemm's canal (4-7). Many surgical and laser techniques have been proposed to boost aqueous humor outflow through the anterior chamber angle (1-3, 8-13). However, the choice remains controversial because of the lack of convincing evidence of the superiority of any one approach over the others. Theoretically, a therapeutic option that removes the resistance to aqueous outflow as far as possible, without damaging the outer outflow pathways and the surrounding ocular structures, such as the base of the iris and the corneal en-

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We found that the histological effects of AITC were different from with the classical goniotomy and trabeculotomy procedures (25). These latter produce a deep incision in the trabecular tissue with close edges of the wound. The histological picture after AITC also differs from goniocurettage. In this procedure trabecular removal is associated with damage to the posterior wall of Schlemm's canal and collector vessels (13).

Ab-in terno trabeculo-canalectomy: surgical approach and histological examination

our original idea of peeling away the TM alone actually removed both the TM and the inner wall of Sch-lemm's canal. This unexpected result might possibly achieve a better outflow than TM removal alone. Considering that the site of major resistance to the outflow of aqueous humor is at the juxtacanalicular portion of the TM and the inner wall of Schlemm's canal and that often, during non-penetrating filtering surgery better aqueous percolation is achieved by peeling the inner wall of the canal (27, 28), we suggest that removal of both the TM and the inner wall of Sch-lemm's canal would ensure better outflow than removal of the TM alone. However, with non-penetrating filtering surgery outflow can also be improved by an *ab externo* approach, leaving the TM intact (27-30).

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Although our histological findings on cadaver eyes are encouraging problems may be encountered in clinical application of AITC. The fine details of anterior chamber angle structures cannot be clearly visualized in every case: corneal opacities, corneal edema or the presence of blood in the anterior chamber may render gonioscopic observation inadequate.

Like other *ab-interno* procedures, other pre-requisites for AICT are a stable anterior chamber and wide irido-corneal angle. Although viscoelastics can be used to stabilize the anterior chamber, sufficient widening of the irido-corneal angle cannot be achieved in every case. Predictable risks with AITC are: lens or corneal endothelium contacts, bleeding from the trabecular vessels and/or from Schlemm's canal, early intraocular pressure rise due to retention of viscoelastics, iris root damage, inadvertent cyclodialysis, bulbar hypotony.

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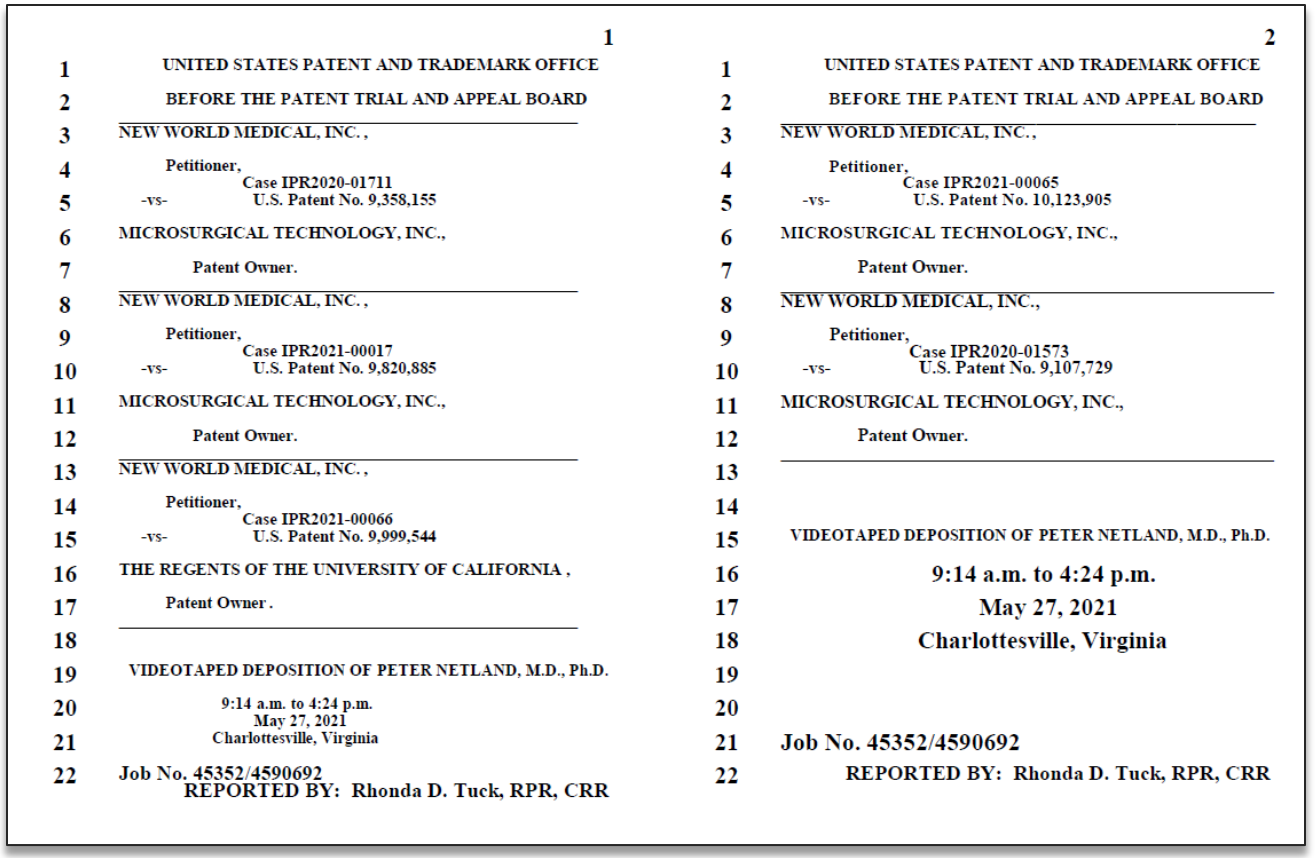
IPR2021-00017 Paper 17 at 33, 42 (citing Ex. 2019 ¶¶ 132, 177).

Ex. 2021 (May 27, 2021 Netland Deposition Transcript)



1

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC.,

Petitioner,

-vs-

Case IPR2020-01711
U.S. Patent No. 9,358,155

MICROSURGICAL TECHNOLOGY, INC.,

Patent Owner.

NEW WORLD MEDICAL, INC.,

Petitioner,

-vs-

Case IPR2021-00017
U.S. Patent No. 9,820,885

MICROSURGICAL TECHNOLOGY, INC.,

Patent Owner.

NEW WORLD MEDICAL, INC.,

Petitioner,

-vs-

Case IPR2021-00066
U.S. Patent No. 9,999,544

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,

Patent Owner.

VIDEOTAPED DEPOSITION OF PETER NETLAND, M.D., Ph.D.

9:14 a.m. to 4:24 p.m.
May 27, 2021
Charlottesville, Virginia

Job No. 45352/4590692
REPORTED BY: Rhonda D. Tuck, RPR, CRR

2

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC.,

Petitioner,

-vs-

Case IPR2021-00065
U.S. Patent No. 10,123,905

MICROSURGICAL TECHNOLOGY, INC.,

Patent Owner.

NEW WORLD MEDICAL, INC.,

Petitioner,

-vs-

Case IPR2020-01573
U.S. Patent No. 9,107,729

MICROSURGICAL TECHNOLOGY, INC.,

Patent Owner.

VIDEOTAPED DEPOSITION OF PETER NETLAND, M.D., Ph.D.

9:14 a.m. to 4:24 p.m.
May 27, 2021
Charlottesville, Virginia

Job No. 45352/4590692
REPORTED BY: Rhonda D. Tuck, RPR, CRR

Ex. 2021 92:14-22

Q. Do you recall testifying that surgical procedures for treating glaucoma can be classified as either ab-interno or ab-externo?

A. Yes.

Q. Must a surgical procedure for treating glaucoma be one or the other only?

A. No. I suppose they -- I don't think it does necessarily. I suppose there can be combinations of both of those.

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A. I believe it is.
Q. What does the term "goniocurettage" mean to you?
A. So a goniocurettage would imply to me an operation of the angle that involves remove of tissue, likely removal of tissue. It can just be a scraping, but it's the scraping-type of procedure and possibly cutting as well, but removal of tissue through a sort of scraping/cutting process.
Q. And you believe your understanding of this term as you've just defined it is commonly shared by others in ophthalmology?
A. I believe so.
Q. Do you recall testifying that surgical procedures for treating glaucoma can be classified as either ab-interno or ab-externo?
A. Yes.
Q. Must a surgical procedure for treating glaucoma be one or the other only?
A. No. I suppose they -- I don't think it does necessarily. I suppose there can be combinations of both of those.

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Q. So it's not an absolutely binary classification?
A. Right. There may be procedures that combine those elements, ab-interno and ab-externo.
Q. And can you explain what you're thinking about that might be an example of that?
A. Right. So I guess I'm saying that the terms themselves don't exclude the possibility. Generally speaking and probably for purposes of this process the ab-interno would be an approach from the inside of the eye to perform the procedure of treating the angle, whereas an ab-externo would be from the outside of the eye. Again, the terms may not exclude those two things occurring during in the same procedure, but most of the procedures that I'm thinking of when I'm using those terms are one or the other.
Q. So you've testified that the ordinary and customary meaning of ab-interno to a person of ordinary skill in the art, or a POSA, is to generally mean from the inside?
MR. DEIGHAN: Objection, form.

IPR2020-01573 Paper 29 at 31-34; 2020-01711 Paper 17 at 35-38; 2021-00066, Paper 17 at 31-34.

Ex. 2021 124:17-21

Q. But the '729 Patent says the sides of its device are sharp and intended to cut tissue. Where does Quintana say that the sides of the Quintana device are sharpened to cut tissue?

A. Quintana does not specify that.

standard hypodermic needle tip that has two cutting blades?

A. Yes.

Q. And you know that they are cutting blades how?

A. Well, we can go to the declaration, but just from -- and the declaration kind of goes through the whole thing, I don't want to contradict that. That would be the primary source for this information, but the blades are similar to the '729 Patent. The blades are at a location that becomes relevant as the instrument is used. So in this case, as it's being passed forward through the trabecular meshwork, the edges that are relevant here would be on the sides, the dual blades on the side of the single beveled [illegible]ge.

Q. But the '729 Patent says the sides of its device are sharp and intended to cut tissue. Where does Quintana say that the sides of the Quintana device are sharpened to cut tissue?

A. Quintana does not specify that.

Q. And so your conclusion that Quintana does

IPR2020-01573 Paper 29 at 21-27; 2020-01711 Paper 17 at 22-28; 2021-00017 Paper 17 at 19-26; 2021-00065 Paper 18 at 19-23; 2021-00066, Paper 17 at 26-30.

Ex. 2021 131:16-19

Q. So is it your testimony that a cystotome is the same as a standard hypodermic needle that's bent at the tip?

A. Yes. In common usage, yes. There are

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A. By bending it, bending the tip. So the common usage would have been that needle holders were used just as Quintana described. Every ophthalmologist would have been familiar with this. And then using a needle holder, which is a little bit stronger, to bend the tip in a way that's controllable.

So Murray Johnstone used standard lens cystotomes which would have had a bent tip just created by the surgeon, and, you know, much like the design shown here in Patent '729, the tip was bent at various places at the distal end of the needle up to and including in the bevel, and the tip was bent using that instrument, and he used that approach which was in common usage at that time.

Q. So is it your testimony that a cystotome is the same as a standard hypodermic needle that's bent at the tip?

A. Yes. In common usage, yes. There are commercially available products now, most of us use those. We don't take the time to bend them ourselves. But at that time it was commonly done by the surgeon

IPR2020-01573 Paper 29 at 35, 37, 54; 2020-01711 Paper 17 at 40-42, 50; 2021-00017 Paper 17 at 31.

Ex. 2021 262:3-6

Q. But you don't show the sides that you label here as needle cutting edges in the trabecular meshwork. Would you agree with that?

A. Correct. But it's a continuous -- it's an

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meshwork?
A. Correct.
Q. But you don't show the sides that you label here as needle cutting edges in the trabecular meshwork. Would you agree with that?
A. Correct. But it's a continuous -- it's an edge. There's a bit of an arc to it. But elsewhere aration, we do describe that the -- you idest point is probably the most relevant e it cuts, but the actual dual blade can her towards the tip and further back as early the widest point is, proximal, most

n this figure, clearly they've got it tle bit back from the widest point, but I point out for purposes of this deposition now, the widest point might be the most int to label. Although, this is correctly ny view.
ollowing up on that, if you look at the t of separation in this depiction, that's rabecular meshwork, is it?

263

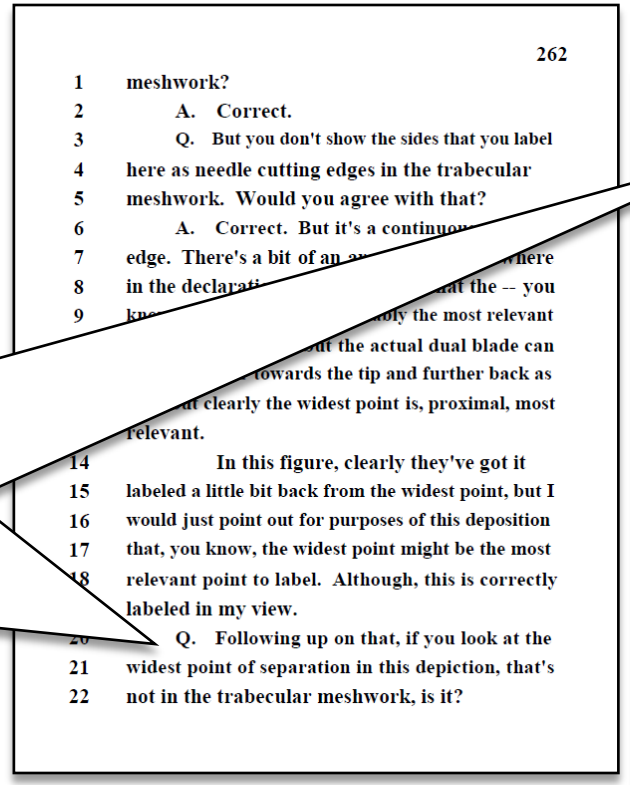
A. Correct, as depicted here. The tissue can stretch, so when it reaches the widest point, I mean, maybe it's a little bit past it, maybe it's a little bit before it when it starts cutting, when it's off center a little bit, you know, one edge cuts a little more than the other edge initially, you know, exactly where it cuts relative to the widest point can vary a little bit in real life. But the widest point is a good thing to measure, as you're pointing out, because that would be the maximal width of the strip that would be removed.
MR. SUNG: Let's go off the record.
THE VIDEOGRAPHER: Okay. The time is approximately 4:24 p.m., And we are off the record.
(Break in proceedings.)
(Deposition adjourned at 4:24 p.m.)
* * * * *

IPR2020-01573 Paper 29 at 22, 25; 2020-01711 Paper 17 at 23; 2021-00017 Paper 17 at 20; 2021-00065 Paper 18 at 20; 2021-00066, Paper 17 at 27.

Ex. 2021 262:20-263:11

Q. Following up on that, if you look at the widest point of separation in this depiction, that's not in the trabecular meshwork, is it?

A. Correct, as depicted here. The tissue can stretch, so when it reaches the widest point, I mean, maybe it's a little bit past it, maybe it's a little bit before it when it starts cutting, when it's off center a little bit, you know, one edge cuts a little more than the other edge initially, you know, exactly where it cuts relative to the widest point can vary a little bit in real life. But the widest point is a good thing to measure, as you're pointing out, because that would be the maximal width of the strip that would be removed.



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meshwork?

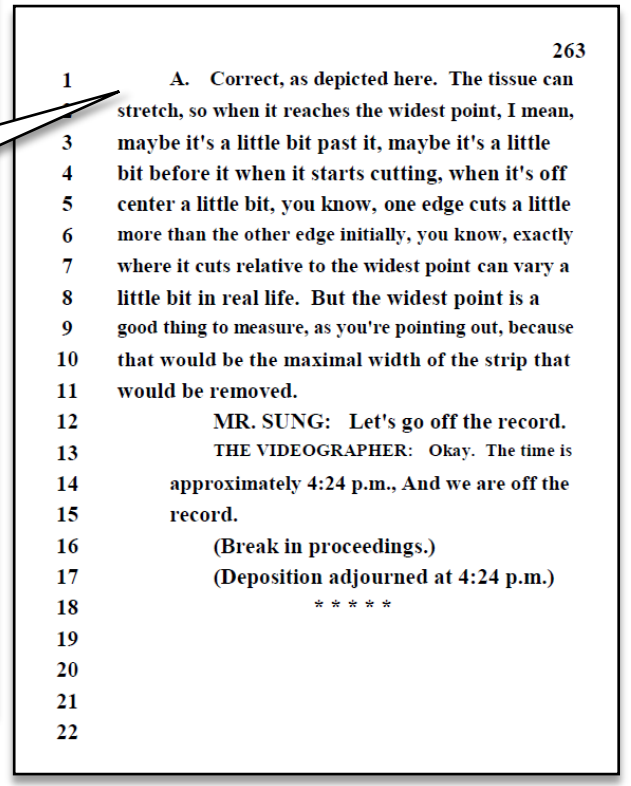
A. Correct.

Q. But you don't show the sides that you label here as needle cutting edges in the trabecular meshwork. Would you agree with that?

A. Correct. But it's a continuou… edge. There's a bit of an a… where in the declarati… at the -- you kn… oly the most relevant …ut the actual dual blade can …towards the tip and further back as …at clearly the widest point is, proximal, most relevant.

In this figure, clearly they've got it labeled a little bit back from the widest point, but I would just point out for purposes of this deposition that, you know, the widest point might be the most relevant point to label. Although, this is correctly labeled in my view.

Q. Following up on that, if you look at the widest point of separation in this depiction, that's not in the trabecular meshwork, is it?



263

A. Correct, as depicted here. The tissue can stretch, so when it reaches the widest point, I mean, maybe it's a little bit past it, maybe it's a little bit before it when it starts cutting, when it's off center a little bit, you know, one edge cuts a little more than the other edge initially, you know, exactly where it cuts relative to the widest point can vary a little bit in real life. But the widest point is a good thing to measure, as you're pointing out, because that would be the maximal width of the strip that would be removed.

MR. SUNG: Let's go off the record.

THE VIDEOGRAPHER: Okay. The time is approximately 4:24 p.m., And we are off the record.

(Break in proceedings.)

(Deposition adjourned at 4:24 p.m.)

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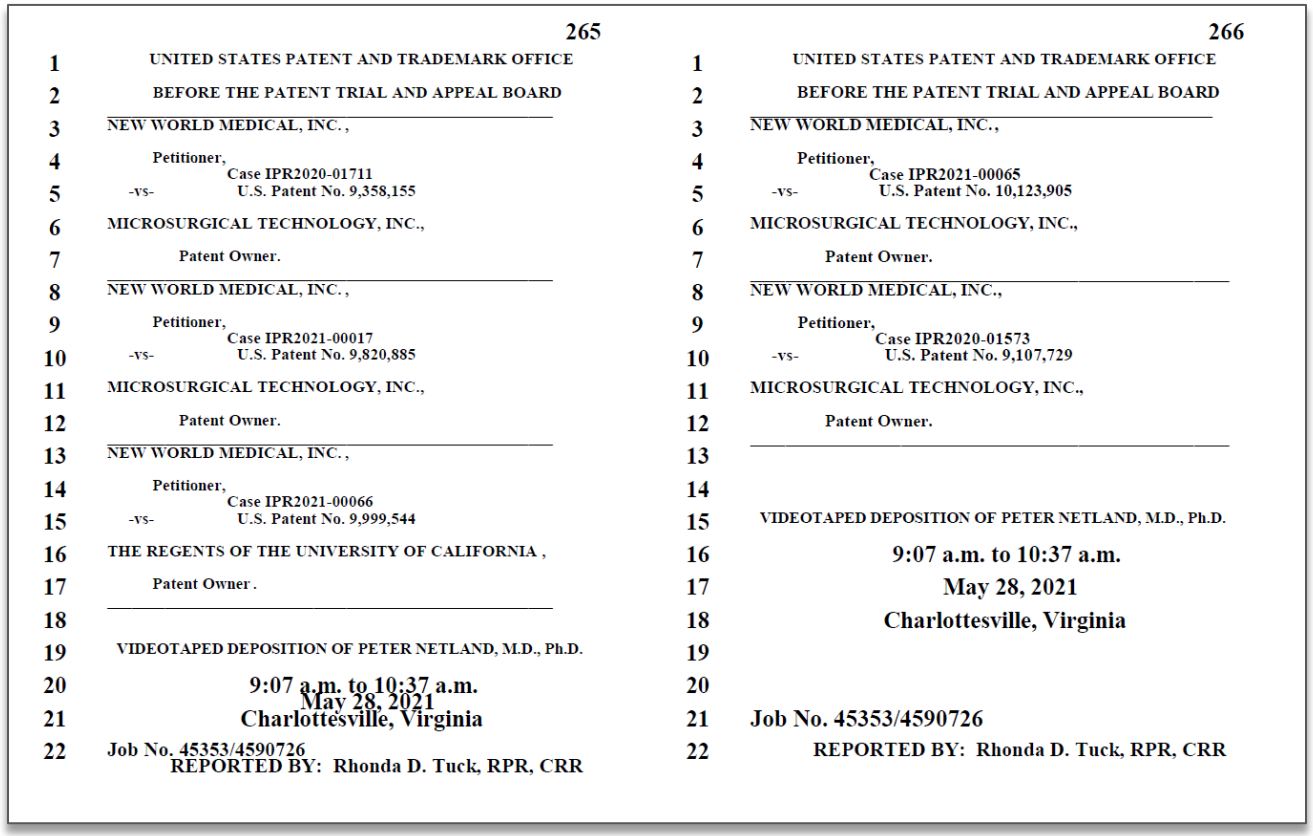
IPR2020-01573 Paper 29 at 25-27; 2020-01711 Paper 17 at 26-27; 2021-00017 Paper 17 at 24-25; 2021-00065 Paper 18 at 21-22; 2021-00066, Paper 17 at 28-29.

Ex. 2022 (May 28, 2021 Netland Deposition Transcript)



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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC.,

Petitioner,

-vs- Case IPR2020-01711
U.S. Patent No. 9,358,155

MICROSURGICAL TECHNOLOGY, INC.,

Patent Owner.

NEW WORLD MEDICAL, INC.,

Petitioner,

-vs- Case IPR2021-00017
U.S. Patent No. 9,820,885

MICROSURGICAL TECHNOLOGY, INC.,

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NEW WORLD MEDICAL, INC.,

Petitioner,

-vs- Case IPR2021-00066
U.S. Patent No. 9,999,544

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,

Patent Owner.

VIDEOTAPED DEPOSITION OF PETER NETLAND, M.D., Ph.D.

9:07 a.m. to 10:37 a.m.
May 28, 2021
Charlottesville, Virginia

Job No. 45353/4590726

REPORTED BY: Rhonda D. Tuck, RPR, CRR

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC.,

Petitioner,

-vs- Case IPR2021-00065
U.S. Patent No. 10,123,905

MICROSURGICAL TECHNOLOGY, INC.,

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9:07 a.m. to 10:37 a.m.
May 28, 2021
Charlottesville, Virginia

Job No. 45353/4590726

REPORTED BY: Rhonda D. Tuck, RPR, CRR

Ex. 2022 285:4-8

Q. Would you agree that the intended purpose of a standard hypodermic needle is not to create a strip of tissue?

A. I would agree that the standard use is not to excise strips of tissue for a hypodermic needle .

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tissue?
A. Yes, I would agree that that is the standard use.
Q. Would you agree that the intended purpose of a standard hypodermic needle is not to create a strip of tissue?
A. I would agree that the standard use is not to excise strips of tissue for a hypodermic needle .
Q. You testified that you recall addressing the issue about sharpness and bluntness somewhere in your declaration. Do you remember that?
A. Yes, I do remember discussing that.
Q. But then I had disagreed with you yesterday about it, but I think that I can help clarify this.
A. Okay.
Q. You did not address sharpness and bluntness in the declaration you made for IPR2020-01573 regarding the '729 Patent, but you did address sharpness and bluntness in the declaration you made for IPR2020-01711 regarding the '155 Patent. Would you agree with that?
A. I'll have to just check the --

IPR2020-01573 Paper 29 at 10; 2020-01711 Paper 17 at 11; 2021-00017 Paper 17 at 8; 2021-00065 Paper 18 at 7; 2021-00066, Paper 17 at 8.

Ex. 2022 297:16-20

Q. Does Quintana provide any quantitative metrics to indicate that the beveled sides of the Quintana device tip are sharp enough to cut trabecular meshwork?

A. No. He made observations that he felt

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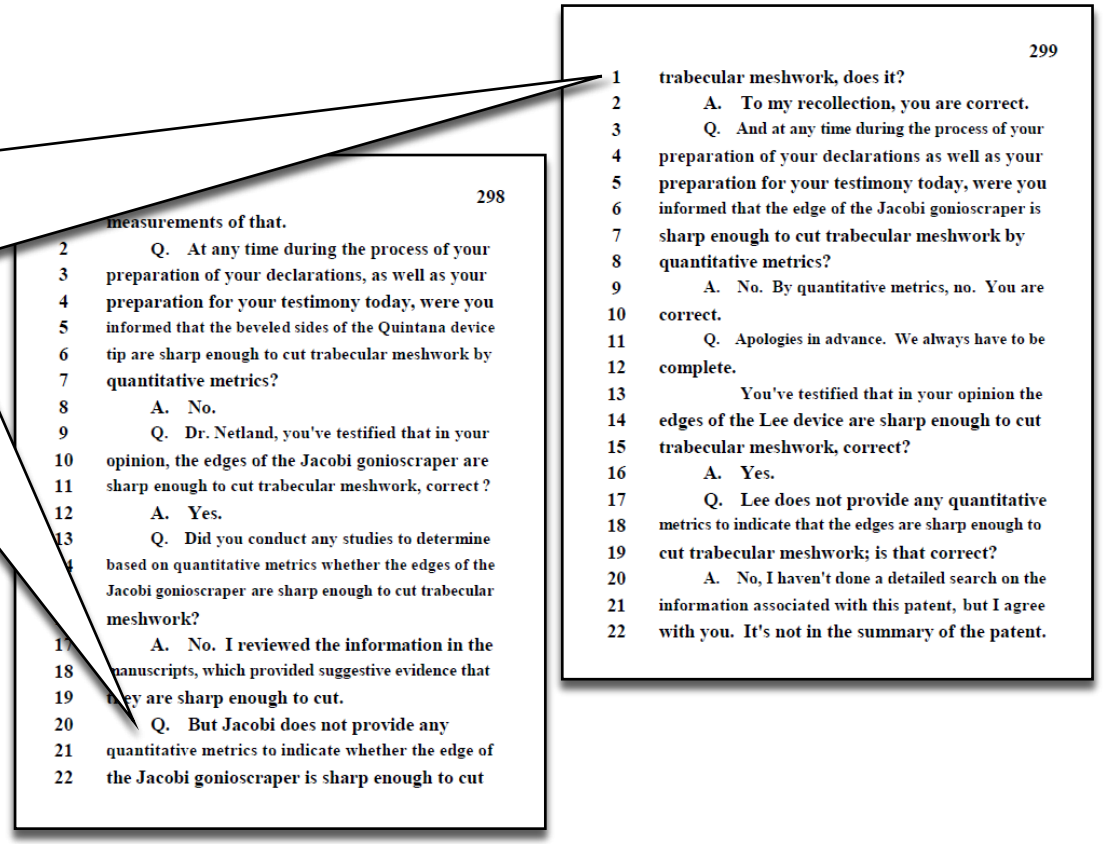
Q. Describe what literature you read and interpreted.
A. Well, in Quintana itself, he does assert many times, and I believe there is evidence for that in the manuscript, that he does remove strips of tissue and sections, quote/unquote of tissue, and so that's the relevant material that would be linked to this discussion.
Q. But I'm asking whether --
A. These claims.
Q. But I'm asking whether you conducted any studies to determine based on quantitative metrics whether the beveled sides are sharp enough to cut trabecular meshwork.
A. No.
Q. Does Quintana provide any quantitative metrics to indicate that the beveled sides of the Quintana device tip are sharp enough to cut trabecular meshwork?
A. No. He made observations that he felt indicated that it was cut ting or removing strips, but he didn't provide specific evidence of that, any

IPR2020-01573 Paper 29 at 22; 2020-01711 Paper 17 at 23; 2021-00017 Paper 17 at 20; 2021-00065 Paper 18 at 21; 2021-00066, Paper 17 at 27.

Ex. 2022 298:20-299:1

Q. But Jacobi does not provide any quantitative metrics to indicate whether the edge of the Jacobi gonioscraper is sharp enough to cut trabecular meshwork, does it?

A. To my recollection, you are correct.



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measurements of that.
Q. At any time during the process of your preparation of your declarations, as well as your preparation for your testimony today, were you informed that the beveled sides of the Quintana device tip are sharp enough to cut trabecular meshwork by quantitative metrics?
A. No.
Q. Dr. Netland, you've testified that in your opinion, the edges of the Jacobi gonioscraper are sharp enough to cut trabecular meshwork, correct?
A. Yes.
Q. Did you conduct any studies to determine based on quantitative metrics whether the edges of the Jacobi gonioscraper are sharp enough to cut trabecular meshwork?
A. No. I reviewed the information in the manuscripts, which provided suggestive evidence that they are sharp enough to cut.
Q. But Jacobi does not provide any quantitative metrics to indicate whether the edge of the Jacobi gonioscraper is sharp enough to cut

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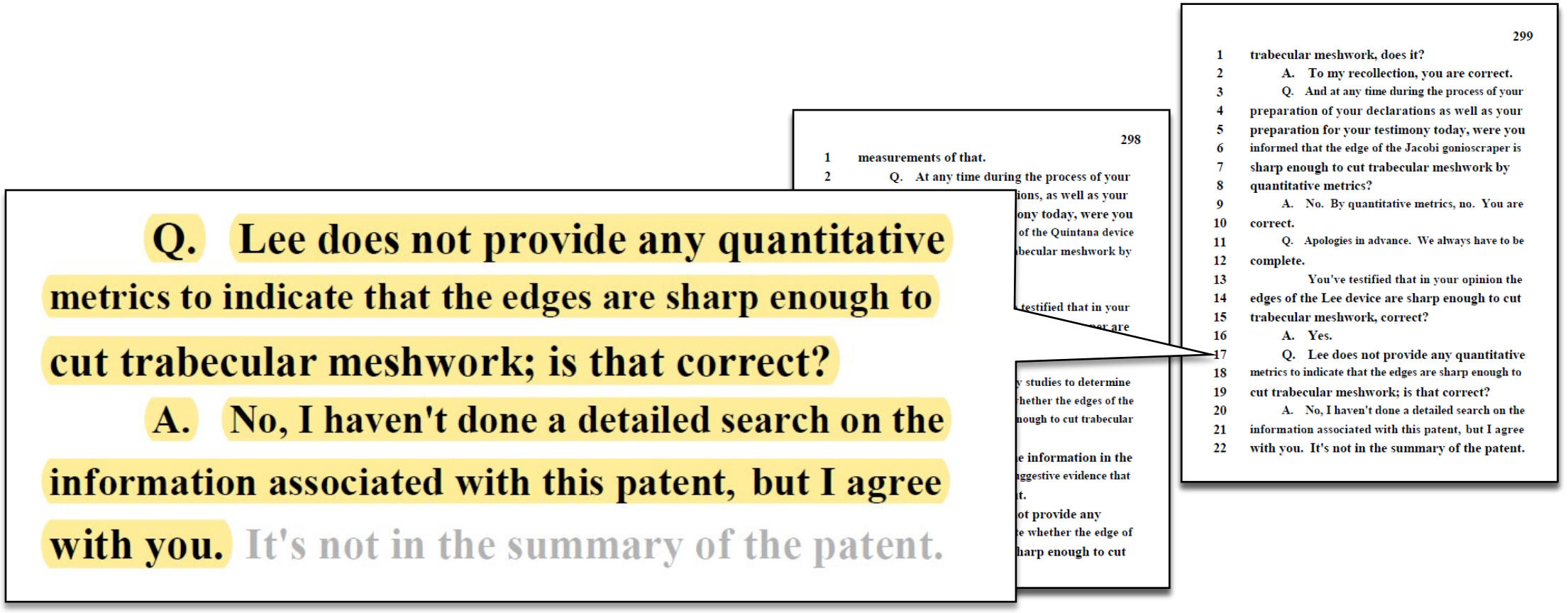
trabecular meshwork, does it?
A. To my recollection, you are correct.
Q. And at any time during the process of your preparation of your declarations as well as your preparation for your testimony today, were you informed that the edge of the Jacobi gonioscraper is sharp enough to cut trabecular meshwork by quantitative metrics?
A. No. By quantitative metrics, no. You are correct.
Q. Apologies in advance. We always have to be complete.
You've testified that in your opinion the edges of the Lee device are sharp enough to cut trabecular meshwork, correct?
A. Yes.
Q. Lee does not provide any quantitative metrics to indicate that the edges are sharp enough to cut trabecular meshwork; is that correct?
A. No, I haven't done a detailed search on the information associated with this patent, but I agree with you. It's not in the summary of the patent.

IPR2020-01573 Paper 29 at 45-49; 2020-01711 Paper 17 at 51-54; 2021-00017 Paper 17 at 35-38; 2021-00065 Paper 18 at 32-36; 2021-00066, Paper 17 at 43-47.

Ex. 2022 299:17-22



IPR2020-01573 Paper 29 at 35, 38-42; 2020-01711 Paper 17 at 44-47.