EXHIBIT 1

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

New World Medical, Inc., Petitioner

v.

MicroSurgical Tech., Inc., Patent Owner

Case Nos. IPR2020-01573; IPR2020-01711; IPR2021-00017; IPR2021-00065; IPR2021-00066

U.S. Patent Nos. 9,107,729; 9,358,155; 9,820,885; 10,123,905; 9,999,544

PETITIONER'S NOTICE OF DEPOSITION OF GARRY P. CONDON, M.D.



Please take notice that in accordance with 37 C.F.R. § 42.53, Petitioner New World Medical, Inc., by and through its attorneys, will take the deposition of Garry P. Condon, M.D., upon oral examination. The deposition will be taken on August 17 and 18, 2021 beginning at 9:00 a.m. local time at the Embassy Suites in Sarasota, FL, 202 N Tamiami Trail, Sarasota, FL, 34236. The deposition will be recorded by audio, audio visual, and/or stenographic means by a court reporter licensed to administer oaths, arranged for by Petitioner New World Medical, Inc.'s counsel. In accordance with 37 C.F.R. § 42.53(d)(1), the parties have conferred and agreed upon the date, time, and location of the deposition.

Dated: August 14, 2021

Respectfully submitted,

/s/ Todd R. Tucker

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing PETITIONER'S NOTICE OF

DEPOSITION OF GARRY P. CONDON, M.D. was served as of the below date

by e-mail on the following individuals and email addresses of record:

Lawrence M. Sung (lsung@wiley.law)

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Dated: August 14, 2021 /s/ John L. Reulbach III

John L. Reulbach III

Attorney for Petitioner

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EXHIBIT 2

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC., Petitioner,

v.

MICROSURGICAL TECHNOLOGY, INC., Patent Owner.

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

Filed: June 8, 2021

DECLARATION OF GARRY P. CONDON, M.D. IN SUPPORT OF PATENT OWNER'S RESPONSE



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EXHIBIT LIST

Exhibit	Description
2020	Sworn Affidavit of Manuel Quintana, M.D.
2023	DORLAND'S MEDICAL DICTIONARY SHORTER EDITION abridged from 25th ed. (1980) excerpt at 605 (definition of "section")
2024	BLACKS MEDICAL DICTIONARY 47th ed. (1992) excerpt at 519 (definition of "section")

I, Garry P. Condon, M.D., hereby declare as follows:

I. INTRODUCTION

1. I have been retained by Wiley Rein LLP as an expert witness on behalf of MicroSurgical Technology, Inc. ("MST") in support of Patent Owner's Response in this Inter Partes Review ("IPR") of U.S. Patent No. 9,107,729 (Ex. 1001) ("the '729 Patent"). I am being compensated for my time in connection with this IPR at a consulting rate of \$575 (USD) per hour. My compensation is in no way dependent on the outcome of this matter.

II. QUALIFICATIONS

2. Attached to this Declaration as Appendix A is my curriculum vitae, which provides a more detailed description of my education, training, and experience in the relevant technology.

III. MATERIALS CONSIDERED

3. I provide opinions in this declaration based on my education, training, background, and experience, as well as the documents I have reviewed to date, including the '729 Patent and the Petition (including the following documents: Declaration of Dr. Peter Netland (Ex. 1003) ("the Netland Declaration"); Manuel Quintana, Gonioscopic Trabeculotomy. First Results, in 43 Second European Glaucoma Symposium, Documenta Ophthalmologica Proceedings Series 265 (E.L. Greve, W. Leydhecker, & C. Raitta ed., 1985) (Ex. 1004) ("Quintana");

M. Johnstone et al., "Microsurgery of Schlemm's Canal and the Human Aqueous Outflow System," Am. J. Ophthalmology 76(6):906-917 (1973) (Ex. 1005) ("Johnstone"); U.S. Patent No. 4,900,300 (Ex. 1006) ("Lee"); Philipp C. Jacobi et al., "Technique of goniocurettage: a potential treatment for advance chronic open angle glaucoma," 81 British J. Ophthalmology 302-07 (1997) (Ex. 1007) ("Jacobi"); Philipp C. Jacobi et al., "Perspectives in trabecular surgery," Eye 2000;14(Pt 3B)(3b):519-30 (2000) (Ex. 1013) ("Jacobi 2000"); and Sworn Affidavit of Manuel Quintana, M.D. (Ex. 2020). Those documents, and the other materials cited in this declaration, are listed in Appendix B. I have either read the materials listed in Appendix B or reviewed summarized data provided by counsel.

IV. LEGAL STANDARDS

4. I am not a lawyer, nor do I have any legal training. In preparing this declaration, I have relied upon the explanation by counsel of certain patent law concepts, including the legal standard for interpreting claims, as well as those for assessing written description, definiteness, enablement, entitlement of priority, anticipation, and obviousness.

A. Written Description

5. I have been informed by counsel that a claim in a granted patent must be sufficiently supported by the disclosure in the patent's specification, read in the

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context of what a person of ordinary skill in the art would have known at the time of the claimed invention. I understand that the basic inquiry for written description is whether the specification provides sufficient information for the person or ordinary skill to recognize that the named inventors possessed the full scope of the claimed invention.

B. Definiteness

6. I have been informed by counsel that, in addition to written description, a patent specification must also describe the claimed invention so as to inform a person of ordinary skill in the art of the scope of the claimed invention with reasonable certainty. A claim may also be indefinite when it contains words or phrases whose meaning is unclear. Conflicting information between the patent claims and the rest of the patent application, including the figures, may affect that certainty and/or clarity.

C. Enablement

7. I have been informed by counsel that, in addition to written description, a patent specification must also enable a person of ordinary skill in the art to make and use the full scope of the claimed invention without undue experimentation as of its effective filing date. I understand that multiple factors should be considered when making this determination. These factors include (1)

the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

D. Priority

8. I have been informed by counsel that, for the claims of an application to be entitled to an earlier application's filing date, the earlier application must provide written description and enablement of the claims, as of the earlier application's filing date. I have been informed by counsel that the undisputed and applicable priority date in this IPR is June 10, 2003.

E. Anticipation and Obviousness

9. I have been informed by counsel that a claim is anticipated when a single prior art reference discloses, either expressly or inherently, each and every claim element arranged in the order specified by the claim. I also understand that whether a document qualifies as prior art against a claim depends on the effective filing date to which the claim is entitled. I have been informed that even if a claim is not anticipated, it may be invalid for obviousness where a person having ordinary skill in the relevant art at the time the alleged invention was made would have considered the claimed invention as a whole to have been obvious given the

prior art. I understand that a claim may be obvious in light of one or more prior art references.

F. Claim Construction

- Board ("PTAB") applies the same claim construction standard used in district courts, where the claims are given their ordinary meaning as understood by one skilled in the art at the time of the invention, informed by the claim language itself, the specification, and the prosecution history. I also understand that "extrinsic evidence"—i.e., evidence other than the patent and prosecution history, such as dictionaries and treatises—can be relevant in determining how a skilled artisan would understand terms of art used in the claims. I have been informed, however, that extrinsic evidence may not be used to contradict the meaning of the claims as described in the intrinsic evidence—i.e., evidence in the claim language itself, the specification, and the prosecution history.
- 11. I have been informed by counsel that the PTAB, at least as of its

 March 16, 2021 institution of this IPR, has declined to expressly adopt any
 proposed construction of the claim language set forth in the Petition, but instead,
 assigned the claim language its ordinary meaning as it would have been understood
 by a person of ordinary skill in the art ("POSA"). Accordingly, in making the

findings and reaching the conclusions in this declaration, I too have applied the ordinary meanings of the claim terms as they would have been understood by a POSA. To the extent that the PTAB adopts specific claim constructions regarding the '729 Patent claims, I reserve the right to amend my findings and conclusions accordingly.

G. Person of Ordinary Skill of the Art

12. In my opinion, a POSA as of the date of invention would have been at least (1) a medical degree and at least two years' experience with treating glaucoma and performing glaucoma surgery; or (2) an undergraduate or graduate degree in biomedical or mechanical engineering and at least five years of work experience in the area of ophthalmology, including familiarity with ophthalmic anatomy and glaucoma surgery. For purposes of my Declaration, I do not disagree with the characterization of a POSA proposed by Petitioner. See Ex. 1003 ¶27.

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V. SUMMARY OF MY OPINIONS

- disclose each and every element of the '729 Patent claims, at least because Quintana does not mention or suggest any of the following: (1) the removal of trabecular meshwork ("TM") tissue; (2) the use of a dual blade device; (3) the cutting of the TM by first and second cutting edges concurrently to create a strip of TM of defined width. Furthermore, in my opinion, a POSA reading Quintana would not necessarily have found it to disclose one or both of: (1) a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees; and (2) an *ab interno* method for forming an opening in the TM of a patient's eye.
- 14. I find numerous statements in the Netland Declaration, Ex. 1003, about the prior art identified in the Petition to be erroneous, and I find many of Dr. Netland's conclusions to be based solely on his own speculation, conjecture, and hindsight. I address each of these erroneous statements and unfounded conclusions below.
- 15. In my opinion, not only would a POSA have found Quintana lacking with respect to elements of the '729 Patent claims, but a POSA would not have read Lee, Johnstone and/or Jacobi, or applied the general knowledge in the art, to

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make up for Quintana's shortfalls in this regard. Similarly, not only would a POSA have found Jacobi lacking with respect to elements of the '729 Patent claims, but a POSA would not have read Quintana, Johnstone and/or Lee, or applied the general knowledge in the art, to make up for Jacobi's shortfalls in this regard. Therefore, I conclude that a POSA would not have found that any of the prior art identified in the Petition, alone or in combination, anticipated and/or rendered obvious the '729 Patent claims according to the applicable legal standards as I understand them.

16. For purposes of this declaration, I do not disagree with the background of the technology as set forth generally in Sections VII.A.-VII.D.2. of the Netland Declaration. See Ex. 1003 ¶34-55.

VI. DETAILS OF MY OPINIONS

A. Prior Art

17. I have been asked to review the '729 Patent (Ex. 1001) and its prosecution history (Ex. 1002), the Netland Declaration (Ex. 1003), the prior art identified in the Petition (including Exs. 1004-1007, 1013), and the Sworn Affidavit of Manuel Quintana, M.D. (Ex. 2020). Among other things, I have been asked to provide my opinion about what a POSA would have known from the prior art available on or before the priority date of June 10, 2003, including the general

knowledge in the art; to comment on my agreement or disagreement with various statements in the Netland Declaration; and to compare the prior art to the '729 Patent claims according to the applicable legal standards as I understand them.

i. Quintana

- 18. I have reviewed the publication known as Quintana (Ex. 1004).

 Quintana is a 7-page journal article containing one of each of a drawing (labeled as Figure 1), a photograph (labeled as Figure 2), a table (labeled as Table 1), and a graph (labeled as Figure 3). Quintana states that it was published in 1985. Ex. 1004 at 3.
- 19. In my opinion, the most natural reading of Quintana to a POSA would have been the reporting of a new way to move the TM in a patient's eye away from the lumen of Schlemm's Canal by following a tangential approach to the TM with a standard hypodermic needle, the tip of which is bent and angled toward the anterior chamber of the eye, so as to avoid injuring the external wall of Schlemm's Canal. A POSA would have understood that a key concern of Quintana was minimizing the risk of damaging the external wall of Schlemm's Canal during this procedure. A POSA would have recognized that Quintana did not describe a

method or device for removing TM for any reason, including tissue biopsy or patient diagnosis or therapy.

- 20. Quintana teaches a POSA how to make a trabeculotome by bending the tip of a standard hypodermic needle ("a 0.4 x 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."). Ex. 1004 at 3. Quintana does not specify exactly what is meant by the needle tip, or where at the needle tip, or along what axis of the needle shaft, the bend is made.
- 21. Quintana teaches a POSA that the working end of its trabeculotome is the "tip of the needle." In this regard, Quintana reads:

"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."

Ex. 1004 at 4 (emphasis in original).

In its Figure 2 legend, Quintana also reads: "Goniophotography at operation. The tip of the needle stripping the trabecular meshwork." Ex. 1004 at 5.

- 22. In my opinion, a POSA would have understood the Quintana trabeculotome, other than its needle tip bend, to be the same as an unbent standard hypodermic needle, the tip of which has a single bevel with a sharp point and sides. A POSA would have understood that the intended use of a standard hypodermic needle is to penetrate tissue through an incision created by the sharp point at the distal end of the single beveled tip. The drawing labeled as Quintana Figure 1 shows a needle tip consistent with this understanding. Ex. 1004 at 4.
- 23. In my opinion, a POSA would have determined that the beveled sides of the Quintana trabeculotome, like those of a standard hypodermic needle, may act alongside the sharp point as part of a single blade to allow the needle to create a slit-like incision in the TM. A POSA reading Quintana would not have found the beveled sides of the Quintana trabeculotome to be otherwise sharp or intended to cut tissue. A POSA would have read nothing in Quintana to lend support to Dr. Netland's statement that the beveled sides of the Quintana trabeculotome tip are distinct cutting edges, much less the "first and second cutting edges" described in the '729 Patent. See Ex. 1003 ¶121.

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- 24. Dr. Netland's re-drawing of Quintana Figure 1 to depict the beveled sides of the needle tip of the Quintana trabeculotome as cutting edges has no basis in Quintana. See Ex. 1003 ¶121. A POSA reading Quintana would not have seen any reference to the beveled sides of the Quintana trabeculotome tip as sharp or any definition of what sharpness might mean in that context. In my opinion, Dr. Netland's assertion that Quintana Figure 1 shows cutting edges is wrong and is based solely on his own speculation, conjecture and hindsight.
- 25. In my opinion, Dr. Netland misreads the '729 Patent in reaching his conclusion that the beveled sides of the Quintana trabeculotome tip must be the "first and second cutting edges" described in the '729 Patent.
- 26. In at least Paragraphs 85-86 of his declaration, Dr. Netland asserts erroneously that the '729 Patent "does not specify how sharp the cutting edges must be"; that "the edges must simply be capable of cutting a strip of tissue"; and that "the patent merely requires that the cutting edges are capable of cutting tissue, regardless of how 'sharp' the cutting edges actually are." Ex. 1003 ¶85-86. Dr. Netland refers only to a single sentence from the '729 Patent as the basis for these mistaken assertions, and states that "[the '729 Patent] indicates that cutting edges 20, 22 are simply 'sharp and intended to cut tissue." Ex. 1003 (quoting Ex. 1001 at 3:16-17).

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27. The actual sentence in the '729 Patent to which Dr. Netland refers, however, does not say what Dr. Netland says it does. The full context for this statement may be found in the '729 Patent, which reads:

"[i]n 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."

Ex. 1001 at 3:10-17 (emphasis added).

In my opinion, a POSA would have understood the '729 Patent to say that only the lateral cutting edges 20, 22 of the disclosed device are sharp (as opposed to, for example, the protruding tip 24 or the top edge 26), and not to say that anything sharp may constitute a cutting edge, as Dr. Netland wrongly asserts. Accordingly, I disagree with Dr. Netland that the beveled sides of the Quintana trabeculotome tip must be the "first and second cutting edges" described in the '729 Patent.

28. Furthermore, the properly quoted '729 Patent disclosure precludes viewing the Quintana trabeculotome as a dual blade device. If the beveled sides of

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the Quintana trabeculotome tip were deemed to be "sharp and intended to cut tissue," which they are not, then the entire surface of the single bevel (including the sharp point and sides) must also be deemed a *single* cutting edge. This further militates against Dr. Netland's characterizations of the beveled sides of the Quintana trabeculotome tip to be two cutting edges or the Quintana trabeculotome to be a dual blade device, as described in the '729 Patent.

29. Quintana never describes its trabeculotome as a device having cutting edges, much less as a dual blade device. The assertions in the Netland Declaration to the contrary are inconsistent with the plain statements in Quintana, the most natural reading of which to a POSA, in my opinion, would have been simply disclosing a way to move the TM in a patient's eye away from the lumen of Schlemm's Canal by following a tangential approach to the TM using a standard hypodermic needle, the tip of which is bent and angled toward the anterior chamber of the eye, so as to avoid injuring the external wall of Schlemm's Canal. A POSA would not have understood Quintana to disclose a dual blade device having two spaced-apart cutting edges that concurrently cut the TM to create and/or remove a strip of TM of defined width equal to the distance between the cutting edges.

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- 30. Quintana never describes its procedure as involving the removal of TM as set forth in the '729 Patent. Nor does Quintana even suggest that its trabeculotome would be capable of being used in any way to remove TM.
- 31. The Netland Declaration seizes on the words "section" and "stripping" used in Quintana in an attempt to rationalize that TM must have been removed even though Quintana never actually says so. *See, e.g.*, Ex. 1003 ¶92. I disagree that a POSA would have understood Quintana to refer in any way to the removal of TM.
- 32. In its Abstract, Quintana describes "a surgical method of goniotrabeculotomy which achieves a *section* of the trabecular meshwork without damage to the external wall of Schlemm's canal." Ex. 1004 at 3 (emphasis added). In my opinion, a POSA would have understood Quintana's reference to "section" in this sentence to mean incising or opening the TM, as opposed to creating or removing a strip of TM.
- 33. Medical dictionaries around the time of Quintana typically referred to alternative meanings for "section." See, e.g., Ex. 2023 at 605 (defining "section" to mean "1. an act of cutting. 2. a cut surface. 3. a segment or subdivision of an organ."); Ex. 2024 at 519 ("(1) A thin slice of a tissue specimen taken for examination under a microscope. (2) The act of cutting in surgery; for example, an

abdominal section is done to explore the abdomen."). Although listed as an alternative definition in these dictionaries, the meaning of "section" as "cutting" is most consistent with other statements in Quintana.

- 34. Quintana only ever refers to "incising" or "opening" the TM. Ex. 1004 at 3 ("Thus, the rational treatment of the trabecular glaucomas should consist in *opening* the trabecular meshwork (TM).") (emphasis added); *id.* at 4 ("The TM is *incised* with the tip of the needle.") (emphasis added).
- less the study of any TM samples by microscopic examination. In addition, the last sentence in Quintana reads: "Further studies are necessary to disclose the 'in vivo' behaviour of the sectioned trabecular meshwork." I note that Dr. Netland does not explain why or how an "in vivo" observation would be relevant if "strips of tissue" from the TM must have been removed in the Quintana procedure, as he asserts. See Ex. 1003 ¶97-98. In my opinion, if that were true, a POSA would have expected Quintana's reference to an *in vitro*, not *in vivo*, study for example, to examine a removed TM "section" under a microscope. Because Quintana instead refers specifically to the study of the *in vivo* behaviour, the most natural read to a POSA would have been to interpret "sectioned trabecular meshwork" to refer merely to

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TM that had been incised or opened, not TM from which a strip(s) of tissue had been created or removed.

- 36. Dr. Netland ignores the exclusive and consistent use in Quintana of the terms "goniotrabeculotomy," "trabeculotomy," and "goniotomy," referring to incising, cutting, sectioning, opening, or stripping tissue all fundamentally different procedures than excising or removing tissue that a POSA would equate instead with "goniotrabeculectomy," "trabeculectomy," and "goniectomy," which are familiar terms of art Quintana apparently chose not to use to describe its procedure. Without any support, Dr. Netland offers only a conclusory statement that "[i]t is my expert opinion that despite using different terminology for the procedure, Quintana discloses a goniectomy procedure for excising and removing trabecular meshwork tissue from the eye." Ex. 1003 ¶59. In my opinion, Dr. Netland disregards what Quintana actually says and is substituting his own words, and therefore, I disagree with his unsupported statement.
- 37. Dr. Netland refers to bent *ab interno* needle goniectomy ("BANG") procedures purportedly published almost 15 years after the priority date of the '729 Patent. *See* Ex. 1003 ¶¶98-100. I have been informed by counsel that the PTAB may ultimately deem this information irrelevant and/or inadmissible. But to me, this shows Dr. Netland's own admission that a POSA describing the removal

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of TM would have used the terms "excise" or "excising" (as did the authors of the BANG videos), rather than "section" or "stripping." *See* Ex. 1003 ¶¶98-100.

- 38. Quintana describes a procedure where "[o]nly 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)." Quintana's Figure 2 legend additionally reads: "Goniophotography at operation. The tip of the needle *stripping* the trabecular meshwork." In my opinion, a POSA would have understood Quintana's reference to "stripped" and "stripping" in these sentences to mean simply cutting or tearing the TM to move it away from the lumen of Schlemm's Canal while avoiding injuring the external wall of Schlemm's Canal, which was Quintana's key concern, *see* Ex. 1004 at 4 ("This is why we bend the tip and we point it towards the anterior chamber."), and not to mean creating or removing segments or strips of TM, as Dr. Netland asserts, *see*, *e.g.*, Ex. 1003 ¶98.
- 39. The demonstrative diagrams shown at Paragraph 95 or the purported cartoon rendering of Quintana's Figure 2 photograph shown at Paragraph 96 of the Netland Declaration do not change the fact that Quintana never mentions or suggests creating or removing a strip(s) of TM. In my opinion, Dr. Netland's

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conclusions are wrong and are based solely on his own speculation, conjecture and hindsight.

- 40. While my conclusion that Quintana does not describe creating or removing a strip of TM set forth in the '729 Patent is based on my own perspective of what a POSA would have understood from a plain reading of Quintana, I note additionally that the author, Dr. Manuel Quintana, has confirmed that neither his work, nor his article reporting that work, ever involved the removal of TM for any reason. See Ex. 2020 ¶3-7. Moreover, Dr. Quintana's sworn statements directly and completely refute Dr. Netland's assertions about Quintana in this regard. To me, Dr. Quintana's explanation increases my confidence that Quintana does not describe the removal of TM as set forth in the '729 Patent.
- 41. Although it is my opinion that a POSA would have understood Quintana not to disclose a dual blade device having spaced-apart first and second cutting edges concurrently cutting the TM to create or remove a strip of TM of defined width equal to the distance between the cutting edges, I will address below several additional points of disagreement with the Netland Declaration.
- 42. In at least Paragraphs 193-194 of his declaration, Dr. Netland asserts that not only must a strip of TM have been created by the Quintana trabeculotome, but that this strip of tissue must have been of a defined width and have resulted

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from the concurrent cutting of TM by the beveled sides of the Quintana trabeculotome tip that Dr. Netland characterizes as first and second cutting edges. To me, Dr. Netland is engaging in unsubstantiated, circular reasoning that Quintana's description of "[t]he tip of the needle stripping the trabecular meshwork" must mean that Quintana obtained a strip of TM of certain width necessarily from the concurrent cutting of TM by the beveled sides (and not, for example, the sharp point) of the Quintana trabeculotome tip, that according to Dr. Netland must have been sharp enough to constitute first and second cutting edges merely because there would be no other way to obtain this hypothetical strip of TM of defined width, which Quintana never actually describes.

43. Quintana never mentions or suggests removing TM or that its disclosed trabeculotome would be capable of being used in any way to create and remove a strip of TM, much less to create and remove a strip of TM of defined width. Even assuming that the beveled sides of the Quintana trabeculotome tip could be deemed to be "sharp and intended to cut tissue," which they are not, Quintana never mentions or suggests that the beveled sides (as opposed, for example, to the sharp point) of the Quintana trabeculotome tip can create or remove a strip of TM. Furthermore, nothing in Quintana would teach a POSA that the beveled sides of the Quintana trabeculotome contact the TM, much less

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concurrently cut the TM to create a strip of TM of defined width. For example, even if the Quintana trabeculotome could somehow be manipulated in a way to possibly obtain a strip of TM, such a strip of TM would not be of a defined width as described in the '729 Patent unless it was actually cut from the TM concurrently by the two beveled sides. In other words, cutting or tearing the TM using only the sharp point, or one or the other of the beveled sides, of the Quintana trabeculotome tip (even if possible, which it would not be), would not have resulted in a strip of TM of defined width equal to the distance between the beveled sides (the measurement of which is also unclear).

- 44. Quintana describes the use of a specific trabeculotome formed by bending a standard hypodermic needle tip 20-30° with a needle-holder. Quintana does not describe or depict precisely where at the needle tip, or along what axis of the needle, the bend is made. A POSA would also have understood that this bend is most likely done by the surgeon by hand for each patient procedure (as opposed to being machined precisely and consistently). In my opinion, Quintana does not necessarily disclose a bend or curve having an angle of at least 30° as described in the '729 Patent.
- 45. Dr. Netland states that that "[t]he term 'ab interno' and the related term 'ab externo' had common well-understood meanings to persons of ordinary

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skill in the art at the time of filing of the '729 patent. Persons of ordinary skill in the art would have understood the term 'ab interno' to generally mean *from the inside* and would have understood the term 'ab externo' to generally mean *from the outside*." Ex. 1003 ¶74 (emphasis in original). I agree with these statements.

- 46. However, Dr. Netland goes beyond the common meanings to propose a definition of an *ab interno* procedure to mean "entering the eye through the anterior chamber and approaching the trabecular meshwork from within the anterior chamber." Ex. 1003 ¶76. I understand that the PTAB has declined to adopt Dr. Netland's particularized definition of *ab interno* in favor of its ordinary and customary meaning. Paper 22 at 17. The Netland Declaration, however, appears to base its conclusion that Quintana discloses an *ab interno* procedure based solely on Dr. Netland's particularized definition that the PTAB declined to adopt. Ex. 1003 ¶¶114-116.
- 47. In my opinion, a POSA would not have known definitively whether or not Quintana described an *ab interno* procedure. Quintana never states that its method is *ab interno*. Because nothing in the Quintana text or figures provides a clear indication whether or not the Quintana trabeculotome enters the TM only after first entering Schlemm's Canal, a POSA would be unable to conclude with certainty that Quintana's surgical procedure must be *ab interno*.

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- 48. While my conclusion that Quintana does not conclusively show an *ab* interno procedure is based on my own perspective of what a POSA would have understood from a plain reading of Quintana, I note additionally that the author, Dr. Manuel Quintana, has stated that his article describes "a surgical approach where the needle tip enters and follows Schlemm's Canal before tearing the TM." Ex. 2020 ¶6. To the extent this was the case, such a procedure would not have been *ab interno* by definition.
- 49. I, therefore, disagree with Dr. Netland's statement in his declaration that "[t]he *only way* to interpret Quintana's description is that the procedure is an 'ab interno' method. Persons of ordinary skill in the art could not interpret Quintana's procedure as an 'ab externo' method." See Ex. 1003 ¶117 (emphasis in original). Dr. Netland has created a false dichotomy where Quintana must teach either an ab interno or an ab externo procedure, despite his own recognition that Quintana is silent or less than clear about whether the described procedure is ab interno or ab externo. See Ex. 1003 ¶118 ("Quintana discloses inserting the needle 'through the scleral side of the limbus' [and] in no case does Quintana describe making an incision on the exterior of the eye to access Schlemm's Canal as would be required in an 'ab externo' procedure."). Dr. Netland strains to conclude that

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Quintana's method must be *ab interno* based solely on his own particularized definition of that term, which the PTAB expressly declined to adopt.

or *ab externo* is a different matter than whether a POSA would have known with reasonable certainty from reading an article which of these types of procedure is described. In my opinion, Quintana teaches neither because a POSA is without sufficient information to tell for sure whether Quintana's procedure is *ab interno* or *ab externo*. Dr. Netland's conclusion that Quintana's procedure must be *ab interno* is wrong and is based solely on his own speculation, conjecture and hindsight.

ii. Johnstone

- 51. I have reviewed the publication known as Johnstone (Ex. 1005).
- 52. Unlike Quintana, Lee, Jacobi and Jacobi 2000, Johnstone does not report work done with patients. Instead, Johnstone discloses the quantitative aqueous perfusion and light and scanning electron microscopy of postmortem enucleated human eyes to compare the flow rates achieved by known clinical ab externo probe and suture trabeculotomy procedures versus a known diathermy trabeculotomy technique. Ex. 1005 at 12.
- 53. Johnstone reads: "The present study was carried out to compare in postmortem enucleated human eyes the changes induced in the structure and

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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." Ex. 1005 at 1. Johnstone also reads: "Internal cystotome trabeculotomy was performed in 180 degrees of the circumference in the same manner as by Grant and by Ellingsen and Grant. This was done through the 5-mm corneal trephine opening under direct visualization with an operating microscope at 25 to 40× magnification, employing a cystotome with the point oriented at right angles to the shaft. We inserted the point from within the anterior chamber through the trabecular meshwork to Schlemm's canal, and passed it along in the canal circumferentially, with the blunt surface 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." Ex. 1005 at 2 (internal citations omitted).

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iii. Lee

- 54. I have reviewed the publication known as Lee (Ex. 1006).
- 55. I have read the PTAB's discussion of Lee at Section 1.F. of the March 11, 2021 Institution Decision in this IPR. Paper 22 at 10-12. I agree generally with the PTAB's statements about Lee.
- 56. I have read the prosecution history of the '729 Patent (Ex. 1002). In particular, I am aware that in the patent examiner's statement of reasons for allowance, the patent examiner stated the following about Lee:

"The closest prior art includes Lee USP 4,900,300 which teaches a method of excising a piece of tissue from the anterior chamber angle (trabecular meshwork and the inner wall of Schlemm's Canal) utilizing a device with a U-shaped cutting edge (14) which has dual blades corresponding to the U-shape. However, Lee fails to teach a device comprising a shaft and a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees. It would not have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Lee to include using a device with a shaft and a distal

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protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees."

Ex. 1002 at 320-321.

I agree with the patent examiner that Lee does not teach a device comprising a shaft and a distal protruding tip that extends from a distal end of the shaft to form <u>a</u> bend or curve having an angle of at least 30 degrees. Based on my understanding of the applicable patent law standards, I also agree with the patent examiner that it would not have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Lee to include using a device with a shaft and a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees.

57. I disagree, however, with the patent examiner's statement that Lee teaches a method of excising a piece of tissue from the anterior chamber angle (trabecular meshwork and the inner wall of Schlemm's Canal) utilizing a device with a U-shaped cutting edge (14) which has *dual blades* corresponding to the U-shape. I disagree with the patent examiner to the extent her statement was characterizing the Lee device as a dual blade device. Lee itself clearly reads otherwise.

58. First, Lee reads unambiguously:

"The forward end of shaft 10 comprises a parabolic, bowl-like cavity 12 having a sharpened rim which creates a <u>single</u>, more or less U-shaped cutting edge 14 integral with the sides of shaft 10. The cutting edge is approximately 2.0 mm. in length and about 0.3 to 0.4 mm. in width. The distal end 15 of cutting edge 14 protrudes a distance of about 0.5 to 1.0 mm. for ease of tissue penetration and cutting. The cutting edge is softly rounded at its distal end and is generally parabolic in shape in order to avoid damage to the outer wall of Schlemm's Canal."

Ex. 1006 at 4 (4:38-48).

Second, Lee is consistent in describing its cutting blade as a singular element. See, e.g., Ex. 1006 at 1 (Abstract) ("The surgical instrument of this invention comprises in combination; a hollow tapered shaft having <u>a</u> 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.") (emphasis added); id. at 5 (6:28-30) ("<u>The</u> cutting edge 14 is used to excise the angle tissue 40 for approximately one-third of the angle circumference.") (emphasis added).

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- 59. In my opinion, a POSA would have understood Lee to disclose a device having a *single* cutting blade. Although this U-shaped cutting blade is shown to have a sharpened rim with side edges and a distal tip, Lee never describes or depicts its cutting blade as anything other than an unitary element, which differs from the "first and second cutting edges being separated by a distance D" of the dual blade device described in the '729 Patent.
- 60. I similarly disagree with Dr. Netland's repeated statements asserting that Lee disclosed a dual blade device. *See, e.g.*, Ex. 1003 ¶¶181, 235.
- having a sharpened rim which creates a <u>single</u>, more or less U-shaped cutting edge 14 integral with the sides of shaft 10," in my opinion, a POSA would have understood that trying to remove TM using the Lee device would not have necessarily created a strip of tissue of *defined width* due solely to the *concurrent* cutting of the TM by the side edges of the single, U-shaped cutting blade.

 Therefore, neither Quintana or Lee alone, nor in combination with each other, would have taught or motivated a POSA to make a device for removing TM in the manner described in the '729 Patent with any reasonable expectation of success, according to the applicable legal standards as I understand them.

iv. Jacobi and Jacobi 2000

- 62. I have reviewed the publications known as Jacobi (Ex. 1007) and Jacobi 2000 (Ex. 1013).
- 63. I have read the PTAB's discussion of Jacobi at Section 1.G. of the March 11, 2021 Institution Decision in this IPR. Paper 22 at 12-14. I agree generally with the PTAB's statements about Jacobi.
- 64. I have read the prosecution history of the '729 Patent (Ex. 1002). In particular, I am aware that Jacobi was known to the patent examiner through at least the identification of Jacobi in a March 9, 2015 Information Disclosure Statement. Ex. 1002 at 52. Jacobi 2000 appears to be a review article that addresses information similar to that disclosed in Jacobi with different figures.
- 65. I disagree with Dr. Netland's repeated statements asserting that Jacobi disclosed a dual blade device. *See, e.g.*, Ex. 1003 ¶233-235. Jacobi never mentions or suggests a device designed to cut the TM, much less a device with dual cutting blades.
 - 66. First, Jacobi reads:

"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* <u>rather than</u> incise uveal meshwork; this novel method, therefore, is termed goniocurettage."

Ex. 1007 at 2 (emphasis added).

In my opinion, a POSA would have understood Jacobi to promote a method using a device to scrape or abrade the TM to obtain ragged strings of TM instead of cutting the TM to create a strip of TM of defined width. Indeed, this reading most naturally aligns with Jacobi's further description that "[i]n 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). . . . Gonioscopically, *strings* of trabecular tissue could be observed intraoperatively to be removed by goniocurettage, leaving a 'denuded' grey-white scleral sulcus." Ex. 1007 at 2 (emphasis added). Jacobi essentially disclaims excising TM using a cutting instrument in favor of removing TM using a scraping tool. Based on my understanding of the applicable patent law standards, Jacobi encourages a POSA to use its described gonioscraper, *i.e.*, teaches away from a cutting implement, including the dual blade device described in the '729 Patent.

67. Second, Jacobi reads:

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"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."

Ex. 1007 at 2.

This description contradicts Dr. Netland's characterization of the Jacobi gonioscraper as a device having, among other things, (1) first and second cutting edges separated by a distance D; and (2) a bend or curve having an angle of at least 30 degrees at the distal end of the shaft, that is capable of being used to create a strip of tissue of defined width from the concurrent cutting of the TM by first and second cutting edges.

68. In my opinion, a POSA would not have considered the sharpened edges of the bowl of the Jacobi gonioscraper to be a cutting blade. But even if that were the case, a POSA would have understood this to be a *single* cutting blade. Although the bowl of the Jacobi device is shown to have sharpened edges, Jacobi never describes or depicts the edges of this bowl as anything other than an unitary

element, which differs from the "first and second cutting edges being separated by a distance D" of the dual blade device described in the '729 Patent.

- 69. Dr. Netland's re-drawing of Jacobi Figure 1 to depict first and second cutting edges has no support in Jacobi and, in my opinion, is wrong and is based solely on his own speculation, conjecture and hindsight. See Ex. 1003 ¶242, 244.
- 70. In at least Paragraphs 85-86 of his declaration, Dr. Netland asserts erroneously that the '729 Patent "does not specify how sharp the cutting edges must be"; that "the edges must simply be capable of cutting a strip of tissue"; and that "the patent merely requires that the cutting edges are capable of cutting tissue, regardless of how 'sharp' the cutting edges actually are." Ex. 1003 ¶85-86. Dr. Netland seems to base these mistaken conclusions solely on the flawed premise that "[the '729 Patent] indicates that cutting edges 20, 22 are simply 'sharp and intended to cut tissue." *See* Ex. 1003 (quoting '729 Patent at 3:16-17).
- 71. The actual sentence in the '729 Patent to which Dr. Netland cites as the sole basis for his erroneous proposition, however, does not say what Dr. Netland says it does. Dr. Netland appears to have cropped and misquoted this sentence out of context. Dr. Netland wrongly disregarded and contravened the actual '729 Patent disclosure, which reads:

"[i]n 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."

Ex. 1001 at 3:10-17 (emphasis added).

In my opinion, a POSA would have understood the '729 Patent to say that only the lateral cutting edges 20, 22 of the disclosed device are sharp (as opposed to, for example, the distal protruding tip), and not to say that anything sharp may constitute a cutting edge, as Dr. Netland wrongly asserts. Accordingly, I disagree with Dr. Netland that the Jacobi gonioscraper must have the "first and second cutting edges" described in the '729 Patent.

72. Jacobi does not describe or depict a device having "a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees." See Ex. 1001 at 9 (6:50-52). I disagree with Dr. Netland's assertion that "Jacobi's gonioscraper has a number of 'bends or curves' that meet this claim limitation." Ex. 1003 ¶239; see also id. ¶106. Jacobi expressly

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describes its gonioscraper as a device that includes "a slightly convex-shaped arm for intraocular use and very much resembles a cyclodialysis spatula." Ex. 1007 at 2. Jacobi never describes or depicts a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees. Dr. Netland re-draws Jacobi Figure 2 to depict a hypothetical bend or curve in the otherwise blurry image. Ex. 1003 ¶239. In so doing, Dr. Netland seems to acknowledge that a POSA would not have recognized a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees, but instead (at most) would have seen a device that very much resembles a cyclodialysis spatula, just as Jacobi described. In my opinion, a POSA would not have understood Jacobi to describe a device with a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees, as described in the '729 Patent.

73. Dr. Netland next asserts, without any support, that a later Jacobi article, Phillipp C. Jacobi *et al.*, "Perspectives in trabecular surgery," Eye 2000; 14(Pt 3B)(3b): 519-30 (2000) ("Jacobi 2000") (Ex. 1013), describes the same device from the earlier Jacobi article. *See* Ex. 1003 ¶240. Without more information, I am unable to agree with Dr. Netland's assertion in this regard. What

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I do read, however, is that Jacobi 2000 similarly describes its gonioscraper as closely resembling a cyclodialysis spatula. Ex. 1013 at 2.

74. The Netland Declaration re-drawing of Jacobi 2000 Figure 1(b) to depict three, separate bends or curves in the Jacobi 2000 device is baseless. *See* Ex. 1003 ¶240. Dr. Netland also asserts:

"Based on this image, persons of ordinary skill in the art would appreciate that each of the 'bends or curves' in the image above have 'an angle of at least 30 degrees.' In my opinion, bend or curve (3) must be included in the device due to the generally downwardly sloping plane of the portion of the convex-shaped arm near the bowl-shaped tip (*i.e.*, 'distal protruding tip'). This allows the tip to be oriented properly to allow the dual cutting edges of the bowl to contact and cut TM during performance of Jacobi's method."

Id.

I disagree with each of these assertions. First, even if a POSA would have recognized three bends or curves in Jacobi Figure 1(b) as Dr. Netland asserts, which I dispute, a POSA would not have understood this figure to show a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees. Indeed, only Dr. Netland's "bend or

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curve (1)" might possibly exhibit an angle of at least 30 degrees, and in the Jacobi 2000 device, this bend or curve does not relate to a distal protruding tip (even according to Dr. Netland). Second, there is nothing in Jacobi 2000, including Figure 1(b), to support the existence of Dr. Netland's hypothetical "bend or curve (3)," much less a bend or curve having an angle of at least 30 degrees. In my opinion, Dr. Netland's assertion that Jacobi 2000 Figure 1(b) shows a device with a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees is wrong and is based solely on his own speculation, conjecture and hindsight.

75. Because the Jacobi gonioscraper comprises a device having a "tip . . . shaped as a tiny bowl with 300 μm diameter and with its edges sharpened," in my opinion, a POSA would have understood that trying to remove TM using the Jacobi device would not have necessarily created a strip of TM of *defined width* due solely to the *concurrent* cutting of the TM, if any, by the single sharpened edge of the bowl. Therefore, neither Quintana or Jacobi alone, nor in combination with each other, would have taught or motivated a POSA to build a device for creating a strip of TM in the manner described in the '729 Patent with any reasonable expectation of success, according to the applicable legal standards as I understand them.

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B. The Netland Declaration

- 76. In addition to the statements in the Netland Declaration addressed above regarding the prior art identified in the Petition, I have the following comments regarding other statements about which I have concerns and/or disagree.
- 77. In at least Paragraphs 56-57 of his declaration, Dr. Netland coins the term "excisional goniotomy" and applies this perspective in at least Paragraphs 58-61 to his review of Quintana, Lee and Jacobi. I note that Dr. Netland never cites any reference, prior art or otherwise, where "excisional goniotomy" is defined or adopted. In my opinion, a POSA would not have known or used the term "excisional goniotomy" on or before the June 10, 2003 priority date. A POSA would not have applied this terminology in reading the prior art identified in the Petition.
- 78. In at least Paragraph 63 of his declaration, Dr. Netland states that "the inventors of the '729 patent claim invention of a device that is, in effect, a needle having a tip bent at an angle." I disagree with this statement. Nowhere in the '729 Patent or its prosecution history have I found any mention or suggestion that the claimed dual blade device may be achieved by simply bending a hypodermic needle. Indeed, in at least Paragraphs 64-65, Dr. Netland acknowledges, as he must, that the '729 Patent clearly teaches that the claimed dual blade device is

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made from "standard tubing (e.g., stainless steel hypodermic tubing) . . . cut to form the lateral cutting edges 20, 22, the protruding tip 24 and the blunt top edge 26." Ex. 1001 at 4:62-65. These specific structures cannot be obtained by simply bending a hypodermic needle. In my opinion, a POSA would not have read the hypodermic tubing described in the '729 Patent to refer to, or to suggest using, a hypodermic needle instead.

Paragraph 65 of his declaration that "[a]ccording to the patent, 'bends or curves' can be made in the tube 14 by using angular cut out(s) 30 or by simply bending the tube." In my opinion "simply bending the tube," as Dr. Netland proposes, is inconsistent with the clear teaching of the '729 Patent, which reads that while "the tube 14 may be directly bent to form said curves or bends without the use of angular cut outs(s) 30 the use of angular cut-out(s) 30 allow a tube 10 of a given diameter to incorporate a curve or angle in a more compact form than is possible by bending tubing 10 of a given diameter to said curve or angle without kinking or damaging tube 10." *Id.* at 5:6-14. A POSA, therefore, would understand the '729 Patent to recommend an angular cut-out(s) especially where the desired angle of bend or curve might kink or damage the tube, such as with an angle of at least 30 degrees.

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- 80. In at least Paragraphs 167-170, 226-229, and 273-279 of his declaration, Dr. Netland asserts that a POSA would have been motivated to vary the angle of a purported bend or curve in the Quintana and Jacobi devices to arrive at a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having a particular angle, including one of at least 30 degrees (as '729 Patent Claim 1), less than approximately 90 degrees (as in '729 Patent Claim 9), and approximately 90 degrees (as in '729 Patent Claim 10). I disagree with each of these assertions.
- as being formed by bending a standard hypodermic needle tip 20-30° with a needle-holder. Quintana does not describe or depict precisely where at the needle tip, or along what axis of the needle, the bend is made. A POSA would also have understood that this bend is most likely done by the surgeon by hand for each patient procedure (as opposed to being machined precisely and consistently). In my opinion, Quintana does not necessarily disclose a bend or curve having an angle of at least 30° as described in the '729 Patent. In any event, the sole purpose of this bend according to Quintana is to avoid damaging the external wall of Schlemm's Canal. Ex. 1004 at 4 ("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

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towards the anterior chamber."). Based on this statement in Quintana, a POSA would have been advised against changing the angle of the needle tip bend for fear that using any such altered device to perform Quintana's procedure might reduce the effectiveness of the Quintana trabeculotome, including its ability to move along the lumen of Schlemm's Canal in a tangential approach, and/or heighten the risk of undesirable injury to the external wall of Schlemm's Canal. For these same reasons, a POSA would be advised against increasing the angle of the needle tip bend, especially approaching 90 degrees because the device would no longer be usable in the specific surgical approach described in Quintana. None of the prior art cited in the Petition supports Dr. Netland's contrary assertions in this regard, which, in my opinion, are wrong and are based solely on his own speculation, conjecture and hindsight.

82. In particular, Dr. Netland's assertion that a POSA, reading Quintana and Johnstone together, would have bent the needle tip of the Quintana trabeculotome to approximately 90 degrees is baseless. *See* Ex. 1003 ¶¶226-229. Johnstone's acknowledgement that its internal cystotome trabeculotomy damaged the external wall of Schlemm's Canal runs directly counter to Quintana's sole objective in describing a surgical approach to the TM with a tool that minimized the risk of injury to the external wall of Schlemm's Canal. *Compare* Ex. 1005 at 11

("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 ") with Ex. 1004 at 4 ("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."). A POSA, reading Quintana and Johnstone together, therefore would have been advised against bending the needle tip of the Quintana trabeculotome at a greater angle, and instead, would have been motivated to keep the Quintana trabeculotome as-is in this respect. Dr. Netland's attempts to justify his hindsight reconstruction of an altered Quintana trabeculotome are contrary to what Quintana actually tells a POSA. For example, by asserting that a hypothetical Quintana trabeculotome with a needle tip bent at approximately 90 degrees might still work if used (1) in a perpendicular approach or (2) in a tangential approach so long as the syringe portion of the device is repositioned outside the patient's eye, Dr. Netland ignores Quintana's choice of a tangential versus perpendicular approach and makes up using the hypothetical altered device in a way that Quintana never mentions or suggests. See Ex. 1003 ¶170. None of the prior art cited in the Petition supports Dr. Netland's assertions in this regard, which, in my

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opinion, are wrong and are based solely on his own speculation, conjecture and hindsight.

- described only as very much or closely resembling a cyclodialysis spatula. See Ex. 1007 at 2; Ex. 1013 at 2. Neither Jacobi nor Jacobi 2000 describe or depict a distal protruding tip that extends from a distal end of the shaft to form any bend or curve, much less a bend or curve having an angle of at least 30 degrees (as '729 Patent Claim 1), less than approximately 90 degrees (as in '729 Patent Claim 9), or approximately 90 degrees (as in '729 Patent Claim 10). Furthermore, I disagree with Dr. Netland that Quintana and Johnstone would have motivated a POSA to alter the gonioscraper of either Jacobi or Jacobi 2000 to form such a bend or curve. See Ex. 1003 ¶272-279.
- 84. In my opinion, a POSA would have understood that Jacobi and Jacobi 2000 both acknowledged that the use of their gonioscrapers injured the external wall of Schlemm's Canal, and that both were otherwise unconcerned with this result. See Ex. 1007 at 3 ("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

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canal."); Ex. 1013 at 2 (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."). Similarly, a POSA would have understood that Johnstone acknowledged that its internal cystotome trabeculotomy damaged the external wall of Schlemm's Canal. See Ex. 1005 at 11 ("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. ..."). In my opinion, a POSA, reading Jacobi, Jacobi 2000, and Johnstone together with Quintana, would not have been motivated to alter the gonioscraper of either Jacobi or Jacobi 2000 to form any bend or a curve, much less a bend or curve having an angle of at least 30 degrees (as '729 Patent Claim 1), less than approximately 90 degrees (as in '729 Patent Claim 9), or approximately 90 degrees (as in '729 Patent Claim 10).

85. In my opinion, because a POSA would have understood Quintana to be keenly concerned with describing a surgical approach to the TM with a tool that minimized the risk of injury to the external wall of Schlemm's Canal, Ex. 1004 at 4 ("Since the convexity of the tip is facing the external wall of the canal, this

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structure is not damaged. This is why we bend the tip and we point it towards the anterior chamber."), a POSA would have understood the Quintana trabeculotome to be a different device designed for a different purpose than the Jacobi and Jacobi 2000 gonioscrapers. A POSA, therefore, would have understood, reading Jacobi, Jacobi 2000, Johnstone, and Quintana together, that there was no need to alter the Jacobi or Jacobi 2000 gonioscraper to form any bend or curve, much less a bend or curve having an angle of at least 30 degrees (as '729 Patent Claim 1), less than approximately 90 degrees (as in '729 Patent Claim 9), or approximately 90 degrees (as in '729 Patent Claim 10). None of the prior art cited in the Petition supports Dr. Netland's contrary assertions in this regard, which, in my opinion, are wrong and are based solely on his own speculation, conjecture and hindsight.

86. Lee, Jacobi, and the other prior art cited in the Petition, never mention or suggest the use of a hypodermic needle or similar device to create or remove a strip of TM. I have read nothing in these references that, alone or in combination, would have motivated a POSA to alter a standard hypodermic needle by sharpening the beveled sides of the needle tip to try to create cutting edges to create or remove a strip of TM. I disagree with Dr. Netland that a POSA would have been motivated by Lee, Jacobi, or any of the other prior art cited in the Petition, to sharpen the beveled sides of the needle tip of the Quintana

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frabeculotome to try to create cutting edges to remove a strip of TM. See Ex. 1003 ¶180. A POSA would have been wary of modifying the Quintana trabeculotome for fear that using any such altered device used to perform Quintana's procedure would heighten the risk of undesirable injury to the external wall of Schlemm's Canal. None of the prior art cited in the Petition supports Dr. Netland's assertions in this regard, which, in my opinion, are wrong and are based solely on his own speculation, conjecture and hindsight.

C. Application of the Prior Art to the '729 Patent Claims

87. For ease of reference, and for purposes of the following statements of my declaration only, I refer to the '729 Patent claims according to the format used by the Netland Declaration (for example, parsing Claim 1 into claim elements 1a-k).

i. Petition Ground 1 (Claims 1-4 and 7-9 are not anticipated by Quintana)

88. Claim 1 of the '729 Patent reads (in pertinent part corresponding to element a as referenced in the Netland Declaration): "An ab interno method for forming an opening in trabecular meshwork of a patient's eye, said method comprising the steps of."

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- 89. At Paragraphs 113-119, the Netland Declaration asserts that Quintana discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶45-50 above.
- 90. In my opinion, a POSA would not have known definitively whether or not Quintana described an *ab interno* procedure because Quintana is less than clear on this point.
- 91. Claim 1 of the '729 Patent reads (in pertinent part corresponding to element b as referenced in the Netland Declaration): "obtaining a dual blade device which comprises."
- 92. At Paragraphs 120-122, the Netland Declaration asserts that Quintana discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶21-29 above.
- 93. In my opinion, a POSA would have understood Quintana to describe using the sharp point of the needle tip of the Quintana trabeculotome to incise or tear the TM away from the lumen of Schlemm's Canal in a tangential approach where the convex side of the bent needle tip faces the exterior wall of Schlemm's Canal to avoid injuring this structure. A POSA would have understood that Quintana never describes the beveled sides of the standard hypodermic needle tip

of the Quintana trabeculotome as sharp, capable of cutting tissue, or to be cutting edges, and never describes the Quintana trabeculotome as a dual blade device.

- 94. Claim 1 of the '729 Patent reads (in pertinent part corresponding to element e as referenced in the Netland Declaration): "ii) a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees."
- 95. At Paragraphs 125-127, the Netland Declaration asserts that Quintana discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶44 above.
- 96. In my opinion, a POSA would not have known definitively whether or not Quintana described a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees because Quintana is less than clear on this point.
- 97. Claim 1 of the '729 Patent reads (in pertinent part corresponding to element g as referenced in the Netland Declaration): "iii) first and second cutting edges located at a junction of the shaft and the distal protruding tip, said first and second cutting edges being formed at spaced-apart locations on the distal end of the shaft, said first and second cutting edges being separated by a distance D."

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- 98. At Paragraphs 129-130, the Netland Declaration asserts that Quintana discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶21-29 above.
- 99. In my opinion, a POSA would have understood Quintana to describe using the sharp point of the needle tip of the Quintana trabeculotome to incise or tear the TM away from the lumen of Schlemm's Canal in a tangential approach where the convex side of the bent needle tip faces the exterior wall of Schlemm's Canal to avoid injuring this structure. A POSA would have understood that Quintana never describes the beveled sides of the standard hypodermic needle tip of the Quintana trabeculotome as sharp, capable of cutting tissue, or to be cutting edges, and never describes the Quintana trabeculotome as a dual blade device.
- disclose cutting edges, a POSA would also have understood that Quintana cannot disclose first and second cutting edges. However, even if one were to assume Dr. Netland's erroneous premise that the beveled sides of the needle tip of the Quintana trabeculotome are cutting edges, which they are not, then by Dr. Netland's definition, the entire surface of the needle bevel (including the sharp point) then would be a *single* cutting edge. In that case, a POSA would have understood that Quintana does not disclose "first and second cutting edges located

at a junction of the shaft and the distal protruding tip, said first and second cutting edges being formed at spaced-apart locations on the distal end of the shaft, said first and second cutting edges being separated by a distance D."

- 101. Claim 1 of the '729 Patent reads (in pertinent part corresponding to element j as referenced in the Netland Declaration): "advancing the elongate probe through the anterior chamber, while the anterior chamber is filled with fluid, to an operative position where the distal protruding tip is positioned within Schlemm's Canal and the first and second cutting edges are contacting the trabecular meshwork."
- 102. At Paragraphs 133-135, the Netland Declaration asserts that Quintana discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶21-29 above.
- 103. In my opinion, a POSA would have understood Quintana to describe using the sharp point of the needle tip of the Quintana trabeculotome to incise or tear the TM away from the lumen of Schlemm's Canal in a tangential approach where the convex side of the bent needle tip faces the exterior wall of Schlemm's Canal to avoid injuring this structure. A POSA would have understood that Quintana never describes the beveled sides of the standard hypodermic needle tip

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of the Quintana trabeculotome as sharp, capable of cutting tissue, or to be cutting edges, and never describes the Quintana trabeculotome as a dual blade device.

- disclose cutting edges, a POSA would also have understood that Quintana cannot disclose first and second cutting edges. However, even if one were to assume Dr. Netland's erroneous premise that the beveled sides of the needle tip of the Quintana trabeculotome are cutting edges, which they are not, then by Dr. Netland's definition, the entire surface of the needle bevel (including the sharp point) then would be a *single* cutting edge. In that case, a POSA would have understood that Quintana does not disclose "first and second cutting edges."
- premise that the beveled sides of the needle tip of the Quintana trabeculotome are first and second cutting edges, which they are not, then a POSA would have understood that Quintana does not disclose that the purported first and second cutting edges are contacting the TM. Quintana never describes or depicts contacting the TM with the beveled sides of the needle tip of the Quintana trabeculotome. I disagree with Dr. Netland's assertion that Quintana Figure 2 shows this. *See* Ex. 1003 ¶133. In my opinion, a POSA reading Quintana would not have been reasonably certain that this was the case.

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- element k as referenced in the Netland Declaration): "thereafter causing the distal protruding tip to advance through a sector of Schlemm's Canal with the first and second cutting edges concurrently cutting, from the trabecular meshwork, a strip of tissue having approximate width W, said approximate width W being approximately equal to the distance D between the first and second cutting edges."
- 107. At Paragraphs 136-137, the Netland Declaration asserts that Quintana discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶21-29 and 42-43 above.
- using the sharp point of the needle tip of the Quintana trabeculotome to incise or tear the TM away from the lumen of Schlemm's Canal in a tangential approach where the convex side of the bent needle tip faces the exterior wall of Schlemm's Canal to avoid injuring this structure. A POSA would have understood that Quintana never describes the beveled sides of the standard hypodermic needle tip of the Quintana trabeculotome as sharp, capable of cutting tissue, or to be cutting edges, and never describes the Quintana trabeculotome as a dual blade device.
- 109. To the extent a POSA would have understood that Quintana does not disclose cutting edges, a POSA would also have understood that Quintana cannot

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Netland's erroneous premise that the beveled sides of the needle tip of the Quintana trabeculotome are cutting edges, which they are not, then by Dr. Netland's definition, the entire surface of the needle bevel (including the sharp point) then would be a *single* cutting edge. In that case, a POSA would have understood that Quintana does not disclose "first and second cutting edges."

premise that the beveled sides of the needle tip of the Quintana trabeculotome are first and second cutting edges, which they are not, then a POSA would have understood that Quintana does not disclose that the purported first and second cutting edges are "concurrently cutting, from the trabecular meshwork, a strip of tissue having approximate width W, said approximate width W being approximately equal to the distance D between the first and second cutting edges." Quintana never describes or depicts contacting the TM with the beveled sides of the needle tip of the Quintana trabeculotome, much less concurrently cutting the TM with these beveled sides to form a strip of TM of defined width. In my opinion, a POSA reading Quintana would not have been reasonably certain that this was the case. For example, TM removed by tearing, or by excision using only the sharp point of the needle tip, would not be a strip of TM of defined width.

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- 111. Claim 2 of the '729 Patent reads: "A method according to claim 1 further comprising the step of infusing fluid into the anterior chamber under controlled pressure to keep the anterior chamber filled with fluid during performance of the method."
- 112. At Paragraphs 138-140, the Netland Declaration asserts that Quintana discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶89-111 above.
- 113. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 2 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 2.
- 114. Claim 3 of the '729 Patent reads: "A method according to claim 1 wherein the strip of tissue cut from the trabecular meshwork has a length of about 2 to 10 millimeters."
- 115. At Paragraphs 141-144, the Netland Declaration asserts that Quintana discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶89-111 above.

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- 116. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 3 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 3.
- 117. In addition, Quintana never describes its procedure as involving cutting the TM to form a strip of tissue, much less a strip of tissue of defined width. I disagree with Dr. Netland's assertion that Quintana's disclosure of a 100-120° trabeculotomy in any way describes cutting the TM to form a strip of tissue, much less that it must equate to a tissue strip length of about 2 to 10 millimeters. See Ex. 1003 ¶144. In my opinion, nothing in Quintana supports Dr. Netland's assertion in this regard, which, in my opinion, is wrong and is based solely on his own speculation, conjecture and hindsight.
- 118. Claim 4 of the '729 Patent reads: "A method according to claim 1 further comprising the step of: removing the strip of tissue from the patient's eye."
- 119. At Paragraphs 145-147, the Netland Declaration asserts that Quintana discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶89-111 above.

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- 120. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 4 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 4.
- 121. In addition, Quintana never describes its procedure as involving creating or removing a strip of TM, much less removing from a strip of TM from the patient's eye. I disagree with Dr. Netland to the extent he suggests that a POSA would have understood the act of removing TM from a patient's eye to be the same as the act of creating and/or removing a strip of TM. In my opinion, nothing in Quintana supports Dr. Netland's assertion in this regard, which, in my opinion, is wrong and is based solely on his own speculation, conjecture and hindsight.
- 122. Claim 7 of the '729 Patent reads: "A method according to claim 1 wherein the step of forming an opening into the anterior chamber of the eye comprises forming an incision through a cornea of the eye."
- 123. At Paragraphs 148-149, the Netland Declaration asserts that Quintana discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶89-111 above.

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- 124. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 7 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 7.
- 125. Claim 8 of the '729 Patent reads: "A method according to claim 1 wherein the method is performed under direct visualization through a lens device positioned on an anterior aspect of the eye."
- 126. At Paragraphs 150-151, the Netland Declaration asserts that Quintana discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶89-111 above.
- 127. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 8 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 8.
- 128. Claim 9 of the '729 Patent reads: "A method according to claim 1 wherein the angle is less than approximately 90 degrees."

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- 129. At Paragraphs 152-154, the Netland Declaration asserts that Quintana discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶89-111 above.
- 130. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 9 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 9.
 - ii. Petition Ground 2 (Claims 4-6 and 10 are not obvious over Quintana in view of the knowledge in the art)
- 131. Claim 4 of the '729 Patent reads: "A method according to claim 1 further comprising the step of: removing the strip of tissue from the patient's eye."
- 132. At Paragraphs 155-159, the Netland Declaration asserts that Quintana in combination with the knowledge in the art discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶89-111 above.
- 133. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 4 incorporates each and every element of Claim 1. For the

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same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 4.

- 134. In particular, because Quintana never describes its procedure as involving creating a strip of TM, a POSA would not have even considered removing a strip of TM from the patient's eye. In this regard, Dr. Netland's assertions about Johnstone, Jacobi, Ferrari (Ex. 1018), Lee, and the general knowledge in the art, are irrelevant. See Ex. 1003 ¶157-159. In my opinion, nothing in Quintana, alone or in combination with any of the other cited prior art in the Petition, or the general knowledge in the art, supports Dr. Netland's assertion that it would have been obvious to somehow modify the Quintana method to include the step of removing a strip of TM from the patient's eye, according to the applicable legal standards as I understand them.
- 135. Claim 5 of the '729 Patent reads: "A method according to claim 4 wherein, after the first and second cutting edges have cut the strip of tissue from the trabecular meshwork, the strip of tissue remains connected to the trabecular meshwork and wherein the method further comprises the step of: disconnecting the strip of tissue such that it may be removed from the eye."
- 136. At Paragraphs 160-162, the Netland Declaration asserts that Quintana in combination with the knowledge in the art discloses, among other things,

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everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶89-111 above.

- 137. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 5 incorporates each and every element of Claims 1 and 4. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claims 1 and 4.
- 138. In particular, because Quintana never describes its procedure as involving creating a strip of TM, a POSA would not have even considered disconnecting a strip of TM such that it may be removed from the eye. In this regard, Dr. Netland's assertions about Johnstone, Jacobi, and the general knowledge in the art, are irrelevant. See Ex. 1003 ¶¶161-162. In my opinion, nothing in Quintana, alone or in combination with any of the other cited prior art in the Petition, or the general knowledge in the art, supports Dr. Netland's assertion that it would have been obvious to somehow modify the Quintana method to include the step of disconnecting the strip of tissue such that it may be removed from the eye, according to the applicable legal standards as I understand them.

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- 139. Claim 6 of the '729 Patent reads: "A method according to claim 5 wherein the disconnecting step comprises using a tissue severing apparatus to transect or sever the strip of tissue so as to disconnect it from the patient's body."
- 140. At Paragraphs 163-165, the Netland Declaration asserts that Quintana in combination with the knowledge in the art discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶89-111 above.
- each and every element of the claim from which it depends. In this regard, I understand that Claim 6 incorporates each and every element of Claims 1, 4 and 5. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claims 1, 4 and 5.
- 142. In particular, because Quintana never describes its procedure as involving creating a strip of TM, a POSA would not have even considered using a tissue severing apparatus to transect or sever the strip of tissue so as to disconnect it from the patient's body. In this regard, Dr. Netland's assertions about Jacobi, Ferrari, and the general knowledge in the art, are irrelevant. *See* Ex. 1003
 ¶¶161-162. In my opinion, nothing in Quintana, alone or in combination with any of the other cited prior art in the Petition, or the general knowledge in the art,

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supports Dr. Netland's assertion that it would have been obvious to somehow modify the Quintana method to include the step of using a tissue severing apparatus to transect or sever the strip of tissue so as to disconnect it from the patient's body, according to the applicable legal standards as I understand them.

- 143. Claim 10 of the '729 Patent reads: "A method according to claim 9 wherein the angle is approximately 90 degrees."
- 144. At Paragraphs 166-170, the Netland Declaration asserts that Quintana in combination with the knowledge in the art discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶89-111 above.
- each and every element of the claim from which it depends. In this regard, I understand that Claim 10 incorporates each and every element of Claims 1 and 9. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claims 1 and 9.
- 146. In addition, for at least the reasons set forth in ¶¶82-83 above, a POSA would not have been motivated by any of the cited prior art in the Petition or the general knowledge in the art to modify the Quintana trabeculotome by bending the needle tip at an angle greater than what Quintana disclosed, and certainly not to

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approximately 90 degrees, as Dr. Netland asserts. See Ex. 1003 ¶¶167-170. Rather, a POSA reading Quintana together with Johnstone (the only reference upon which Dr. Netland relies for this argument), in my opinion, would have come to an understanding exactly opposite from Dr. Netland.

147. First, a POSA would have understood that Quintana's sole reason for bending the needle tip of its trabeculotome is to avoid damaging the external wall of Schlemm's Canal. See Ex. 1004 at 4 ("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."). Second, a POSA would have understood that Johnstone acknowledges that its internal cystotome trabeculotomy damaged the external wall of Schlemm's Canal, but that Johnstone is otherwise unconcerned with this result. See Ex. 1005 at 11 ("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 "). Given these inconsistent teachings in Quintana and Johnstone, a POSA would have been wary of modifying the angle of the needle tip bend in the Quintana trabeculotome for fear that using any such altered device used to perform Quintana's procedure would heighten the risk of undesirable injury to the external wall of Schlemm's Canal. Moreover, a POSA

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would have been advised especially against modifying the angle of the needle tip bend in the Quintana trabeculotome, as Dr. Netland asserts, to be approximately 90 degrees based on Johnstone, which specifically described damaging the external wall of Schlemm's Canal with its internal cystotome trabeculotomy.

altered Quintana trabeculotome are contrary to what Quintana actually tells a POSA. For example, by asserting that a hypothetical Quintana trabeculotome with a needle tip bent at approximately 90 degrees might still work if used (1) in a perpendicular approach or (2) in a tangential approach so long as the syringe portion of the device is repositioned outside the patient's eye, Dr. Netland ignores Quintana's choice of a tangential versus perpendicular approach and makes up using the hypothetical altered device in a way that Quintana never mentions or suggests. See Ex. 1003 ¶170. None of the prior art cited in the Petition supports Dr. Netland's assertions in this regard, which, in my opinion, are wrong and are based solely on his own speculation, conjecture and hindsight.

iii. Petition Ground 3 (Claims 1-4 and 7-9 are not obvious over Quintana in view of Lee)

149. Claim 1 of the '729 Patent reads (in pertinent part corresponding to element a as referenced in the Netland Declaration): "An ab interno method for

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forming an opening in trabecular meshwork of a patient's eye, said method comprising the steps of."

- 150. At Paragraphs 171-178, the Netland Declaration asserts that Quintana in combination with Lee discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶45-50 above.
- both Quintana and Lee in this regard depend on his own particularized definition of ab interno, which the PTAB expressly declined to adopt. In my opinion, a POSA would not have known definitively whether or not Quintana described an ab interno procedure because Quintana does not provide enough information to be clear on this point. In addition, I disagree that a POSA would have been motivated with a reasonable expectation of success to modify the Quintana method in accordance with Lee as Dr. Netland asserts, see Ex. 1003 ¶176 ("by inserting the needle through the cornea, rather than the 'scleral side of the limbus'"). There is nothing in Quintana to indicate or suggest that the described approach would be improved, or otherwise more desirable, in any way by substituting the Lee approach, for example. Dr. Netland's assertions in this regard, in my opinion, are wrong and are based solely on his own speculation, conjecture and hindsight.

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- 152. Claim 1 of the '729 Patent reads (in pertinent part corresponding to element b as referenced in the Netland Declaration): "obtaining a dual blade device which comprises."
- 153. At Paragraphs 179-182, the Netland Declaration asserts that Quintana in combination with Lee discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶21-29 and ¶¶79-80 above.
- using the sharp point of the needle tip of the Quintana trabeculotome to incise or tear the TM away from the lumen of Schlemm's Canal in a tangential approach where the convex side of the bent needle tip faces the exterior wall of Schlemm's Canal to avoid injuring this structure. A POSA would have understood that Quintana never describes the beveled sides of the standard hypodermic needle tip of the Quintana trabeculotome as sharp, capable of cutting tissue, or to be cutting edges, and never describes the Quintana trabeculotome as a dual blade device. In addition, there is nothing in Lee or any of the other prior art cited in the Petition that would have motivated a POSA to sharpen the beveled sides of the needle tip of the Quintana trabeculotome to try to create cutting edges capable of being used to remove TM.

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examiner's characterization during the prosecution of the '729 Patent application of Lee as having disclosed a dual blade device. In my opinion, a POSA instead would have understood Lee to disclose a device having a single cutting blade. Although this U-shaped cutting blade is shown to have a sharpened rim with side edges and a distal tip, Lee never describes or depicts its cutting blade as anything other than an unitary element, which differs from the "first and second cutting edges being separated by a distance D" of the dual blade device described in the '729 Patent. Therefore, a POSA reading Quintana and Lee together, would not have been motivated to arrive at a method of using a dual blade device for creating and/or removing TM in the manner described in the '729 Patent with any reasonable expectation of success, according to the applicable legal standards as I understand them.

156. Claim 1 of the '729 Patent reads (in pertinent part corresponding to element e as referenced in the Netland Declaration): "ii) a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees."

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- 157. At Paragraph 185, the Netland Declaration asserts that Quintana in combination with Lee discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶44 and ¶80 above.
- 158. In my opinion, a POSA would not have known definitively whether or not Quintana described a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees because Quintana is less than clear on this point. In addition, there is nothing in Lee, Johnstone or any of the other prior art cited in the Petition that would have motivated a POSA to try to bend the needle tip of the Quintana trabeculotome at various random angles to arrive at a method using a device with a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees.
- 159. Claim 1 of the '729 Patent reads (in pertinent part corresponding to element g as referenced in the Netland Declaration): "iii) first and second cutting edges located at a junction of the shaft and the distal protruding tip, said first and second cutting edges being formed at spaced-apart locations on the distal end of the shaft, said first and second cutting edges being separated by a distance D."

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- 160. At Paragraphs 187-188, the Netland Declaration asserts that Quintana in combination with Lee discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶21-29 above.
- using the sharp point of the needle tip of the Quintana trabeculotome to incise or tear the TM away from the lumen of Schlemm's Canal in a tangential approach where the convex side of the bent needle tip faces the exterior wall of Schlemm's Canal to avoid injuring this structure. A POSA would have understood that Quintana never describes the beveled sides of the standard hypodermic needle tip of the Quintana trabeculotome as sharp, capable of cutting tissue, or to be cutting edges, and never describes the Quintana trabeculotome as a dual blade device.
- disclose cutting edges, a POSA would also have understood that Quintana cannot disclose first and second cutting edges. However, even if one were to assume Dr. Netland's erroneous premise that the beveled sides of the needle tip of the Quintana trabeculotome are cutting edges, which they are not, then by Dr. Netland's definition, the entire surface of the needle bevel (including the sharp point) then would be a single cutting edge. In that case, a POSA would have understood that Quintana does not disclose "first and second cutting edges located"

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at a junction of the shaft and the distal protruding tip, said first and second cutting edges being formed at spaced-apart locations on the distal end of the shaft, said first and second cutting edges being separated by a distance D."

- 163. For at least the reasons set forth at ¶87, I disagree with Dr. Netland that a POSA would have been motivated by Lee, Jacobi, or any of the other prior art cited in the Petition, to sharpen the beveled sides of the needle tip of the Quintana trabeculotome to try to create cutting edges capable of being used to remove TM. See Ex. 1003 ¶180. Lee, Jacobi, and the other prior art cited in the Petition, never mention or suggest the use of a hypodermic needle or similar device to remove TM. I have read nothing in these references that, alone or in combination, would have motivated a POSA to alter a standard hypodermic needle by sharpening the beveled sides of the needle tip to try to create cutting edges capable of being used to remove TM. None of the prior art cited in the Petition supports Dr. Netland's assertions in this regard, which, in my opinion, are wrong and are based solely on his own speculation, conjecture and hindsight.
- 164. Claim 1 of the '729 Patent reads (in pertinent part corresponding to element j as referenced in the Netland Declaration): "advancing the elongate probe through the anterior chamber, while the anterior chamber is filled with fluid, to an operative position where the distal protruding tip is positioned within Schlemm's

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Canal and the first and second cutting edges are contacting the trabecular meshwork."

- 165. At Paragraphs 191-192, the Netland Declaration asserts that Quintana in combination with Lee discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶21-29 above.
- using the sharp point of the needle tip of the Quintana trabeculotome to incise or tear the TM away from the lumen of Schlemm's Canal in a tangential approach where the convex side of the bent needle tip faces the exterior wall of Schlemm's Canal to avoid injuring this structure. A POSA would have understood that Quintana never describes the beveled sides of the standard hypodermic needle tip of the Quintana trabeculotome as sharp, capable of cutting tissue, or to be cutting edges, and never describes the Quintana trabeculotome as a dual blade device.
- 167. To the extent a POSA would have understood that Quintana does not disclose cutting edges, a POSA would also have understood that Quintana cannot disclose first and second cutting edges. However, even if one were to assume Dr. Netland's erroneous premise that the beveled sides of the needle tip of the Quintana trabeculotome are cutting edges, which they are not, then by Dr. Netland's definition, the entire surface of the needle bevel (including the sharp

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point) then would be a *single* cutting edge. In that case, a POSA would have understood that Quintana does not disclose "first and second cutting edges."

- premise that the beveled sides of the needle tip of the Quintana trabeculotome are first and second cutting edges, which they are not, then a POSA would have understood that Quintana does not disclose that the purported first and second cutting edges are contacting the TM. Quintana never describes or depicts contacting the TM with the beveled sides of the needle tip of the Quintana trabeculotome. I disagree with Dr. Netland's assertion that Quintana Figure 2 shows this. *See* Ex. 1003 ¶191. In my opinion, a POSA reading Quintana would not have been reasonably certain that this was the case.
- 169. For at least the reasons set forth in ¶56-61, a POSA would have understood Lee to disclose a device having a single cutting blade. Although this U-shaped cutting blade is shown to have a sharpened rim with side edges and a distal tip, Lee never describes or depicts its cutting blade as anything other than a unitary element, which differs from the "first and second cutting edges being separated by a distance D" of the dual blade device described in the '729 Patent. Therefore, a POSA reading Quintana and Lee together would not have been motivated to arrive at a method of using a device having first and second cutting

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edges that contact the trabecular meshwork as described in the '729 Patent with any reasonable expectation of success, according to the applicable legal standards as I understand them.

- 170. Claim 1 of the '729 Patent reads (in pertinent part corresponding to element k as referenced in the Netland Declaration): "thereafter causing the distal protruding tip to advance through a sector of Schlemm's Canal with the first and second cutting edges concurrently cutting, from the trabecular meshwork, a strip of tissue having approximate width W, said approximate width W being approximately equal to the distance D between the first and second cutting edges."
- 171. At Paragraphs 193-194, the Netland Declaration asserts that Quintana in combination with Lee discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶21-29 and ¶¶42-43 above.
- 172. In my opinion, a POSA would have understood Quintana to describe using the sharp point of the needle tip of the Quintana trabeculotome to incise or tear the TM away from the lumen of Schlemm's Canal in a tangential approach where the convex side of the bent needle tip faces the exterior wall of Schlemm's Canal to avoid injuring this structure. A POSA would have understood that Quintana never describes the beveled sides of the standard hypodermic needle tip

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of the Quintana trabeculotome as sharp, capable of cutting tissue, or to be cutting edges, and never describes the Quintana trabeculotome as a dual blade device.

disclose cutting edges, a POSA would also have understood that Quintana cannot disclose first and second cutting edges. However, even if one were to assume Dr. Netland's erroneous premise that the beveled sides of the needle tip of the Quintana trabeculotome are cutting edges, which they are not, then by Dr. Netland's definition, the entire surface of the needle bevel (including the sharp point) then would be a *single* cutting edge. In that case, a POSA would have understood that Quintana does not disclose "first and second cutting edges."

174. In addition, even if one were to assume Dr. Netland's erroneous premise that the beveled sides of the needle tip of the Quintana trabeculotome are first and second cutting edges, which they are not, then a POSA would have understood that Quintana does not disclose that the purported first and second cutting edges are "concurrently cutting, from the trabecular meshwork, a strip of tissue having approximate width W, said approximate width W being approximately equal to the distance D between the first and second cutting edges." Quintana never describes or depicts contacting the TM with the beveled sides of the needle tip of the Quintana trabeculotome, much less concurrently cutting the

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TM with these beveled sides to form a strip of TM of defined width. In my opinion, a POSA reading Quintana would not have been reasonably certain that this was the case. For example, TM removed by tearing, or by excision using only the sharp point of the needle tip, would not be a strip of TM of defined width.

might make up for this lack in Quintana. See Ex. 1003 ¶¶193-194. Because the Lee device 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," in my opinion, a POSA would have understood that trying to remove TM using the Lee device would not have necessarily created a strip of tissue of defined width due solely to the concurrent cutting of the TM by the side edges of the single, U-shaped cutting blade. In my opinion, a POSA reading Quintana and Lee together would not have been motivated to arrive at a method of using a device having first and second cutting edges that concurrently cut from the TM a strip of tissue of defined width as described in the '729 Patent with any reasonable expectation of success, according to the applicable legal standards as I understand them.

176. Claim 2 of the '729 Patent reads: "A method according to claim 1 further comprising the step of infusing fluid into the anterior chamber under

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controlled pressure to keep the anterior chamber filled with fluid during performance of the method."

- 177. At Paragraphs 195-196, the Netland Declaration asserts that Quintana in combination with Lee discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶150-176 above.
- 178. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 2 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 2.
- 179. Claim 3 of the '729 Patent reads: "A method according to claim 1 wherein the strip of tissue cut from the trabecular meshwork has a length of about 2 to 10 millimeters."
- 180. At Paragraphs 197-200, the Netland Declaration asserts that Quintana in combination with Lee discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶150-176 above.
- 181. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 3 incorporates each and every element of Claim 1. For the

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same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 3.

- cutting the TM to form a strip of tissue, much less a strip of tissue of defined width. I disagree with Dr. Netland's assertion that Quintana's disclosure of a 100-120° trabeculotomy in any way describes cutting the TM to form a strip of tissue, much less that it must equate to a tissue strip length of about 2 to 10 millimeters. See Ex. 1003 ¶144. In my opinion, nothing in Quintana supports Dr. Netland's assertion in this regard, which, in my opinion, is wrong and is based solely on his own speculation, conjecture and hindsight. In addition, I note that Dr. Netland offers no explanation or basis for how Lee might make up for this lack in Quintana. See Ex. 1003 at ¶¶198-200.
- 183. Claim 4 of the '729 Patent reads: "A method according to claim 1 further comprising the step of: removing the strip of tissue from the patient's eye."
- 184. At Paragraphs 201-204, the Netland Declaration asserts that Quintana in combination with Lee discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶150-176 above.
- 185. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I

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understand that Claim 4 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 4.

186. In addition, Quintana never describes its procedure as involving creating or removing a strip of TM, much less removing from a strip of TM from the patient's eye. I disagree with Dr. Netland to the extent he suggests that a POSA would have understood the act of removing TM from a patient's eye to be the same as the act of creating and/or removing a strip of TM. In my opinion, nothing in Quintana supports Dr. Netland's assertion in this regard, which, in my opinion, is wrong and is based solely on his own speculation, conjecture and hindsight.

187. In particular, because Quintana never describes its procedure as involving creating a strip of TM, a POSA would not have even considered removing a strip of TM from the patient's eye. In this regard, Dr. Netland's assertion about Lee is irrelevant. See Ex. 1003 ¶204. In my opinion, nothing in Quintana, alone or in combination with Lee, supports Dr. Netland's assertion that it would have been obvious to somehow modify the Quintana method to include the step of removing a strip of TM from the patient's eye, according to the applicable legal standards as I understand them.

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- 188. Claim 7 of the '729 Patent reads: "A method according to claim 1 wherein the step of forming an opening into the anterior chamber of the eye comprises forming an incision through a cornea of the eye."
- 189. At Paragraphs 205-208, the Netland Declaration asserts that Quintana in combination with Lee discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶150-176 above.
- 190. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 7 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 7.
- 191. In addition, I disagree that a POSA would have been motivated with a reasonable expectation of success to modify the Quintana method in accordance with Lee as Dr. Netland asserts, *see* Ex. 1003 ¶207 ("nothing more than simple substitution of one known procedure (*e.g.*, Quintana's 'scleral side of the limbus approach') for another (*e.g.*, Lee's clear cornea approach)"). There is nothing in Quintana to indicate or suggest that the described approach would be improved, or otherwise more desirable, in any way by substituting the Lee approach, for

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example. Dr. Netland's assertions in this regard, in my opinion, are wrong and are based solely on his own speculation, conjecture and hindsight.

- 192. Claim 8 of the '729 Patent reads: "A method according to claim 1 wherein the method is performed under direct visualization through a lens device positioned on an anterior aspect of the eye."
- 193. At Paragraph's 209-210, the Netland Declaration asserts that Quintana in combination with Lee discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶150-176 above.
- 194. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 8 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 8.
- 195. Claim 9 of the '729 Patent reads: "A method according to claim 1 wherein the angle is less than approximately 90 degrees."
- 196. At Paragraphs 211-212, the Netland Declaration asserts that Quintana in combination with Lee discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶150-176 above.

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- 197. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 9 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 9.
 - iv. Petition Ground 4 (Claims 4-6 and 10 are not obvious over Quintana in view of Lee and the knowledge in the art)
- 198. Claim 4 of the '729 Patent reads: "A method according to claim 1 further comprising the step of: removing the strip of tissue from the patient's eye."
- 199. At Paragraphs 213-218, the Netland Declaration asserts that Quintana in combination with Lee and the knowledge in the art discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶150-176 and ¶184-188 above.
- 200. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 4 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 4.
- 201. In particular, because Quintana never describes its procedure as involving creating a strip of TM, a POSA would not have even considered

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removing a strip of TM from the patient's eye. In this regard, Dr. Netland's assertions about Johnstone, Jacobi, Ferrari, Lee, and the general knowledge in the art are irrelevant. See Ex. 1003 ¶¶216-218. In my opinion, nothing in Quintana, alone or in combination with any of the other cited prior art in the Petition, or the general knowledge in the art, supports Dr. Netland's assertion that it would have been obvious to somehow modify the Quintana method to include the step of removing a strip of TM from the patient's eye, according to the applicable legal standards as I understand them.

- 202. Claim 5 of the '729 Patent reads: "A method according to claim 4 wherein, after the first and second cutting edges have cut the strip of tissue from the trabecular meshwork, the strip of tissue remains connected to the trabecular meshwork and wherein the method further comprises the step of: disconnecting the strip of tissue such that it may be removed from the eye."
- 203. At Paragraphs 219-221, the Netland Declaration asserts that Quintana in combination with Lee and the knowledge in the art discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶150-176 above.
- 204. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I

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understand that Claim 5 incorporates each and every element of Claims 1 and 4.

For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claims 1 and 4.

205. In particular, because Quintana never describes its procedure as involving creating a strip of TM, a POSA would not have even considered disconnecting a strip of TM such that it may be removed from the eye. In this regard, Dr. Netland's assertions about Johnstone, Jacobi, and the general knowledge in the art, are irrelevant. See Ex. 1003 ¶¶220-221. In my opinion, nothing in Quintana, alone or in combination with any of the other cited prior art in the Petition, or the general knowledge in the art, supports Dr. Netland's assertion that it would have been obvious to somehow modify the Quintana method to include the step of disconnecting the strip of tissue such that it may be removed from the eye, according to the applicable legal standards as I understand them.

206. Claim 6 of the '729 Patent reads: "A method according to claim 5 wherein the disconnecting step comprises using a tissue severing apparatus to transect or sever the strip of tissue so as to disconnect it from the patient's body."

207. At Paragraphs 222-224, the Netland Declaration asserts that Quintana in combination with Lee and the knowledge in the art discloses, among other

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things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶150-176 above.

208. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 6 incorporates each and every element of Claims 1, 4 and 5. For the same reasons that I disagree with Dr. Netland's assertions regarding Claims 1, I disagree with Dr. Netland's assertions regarding Claims 1, 4 and 5.

209. In particular, because Quintana never describes its procedure as involving creating a strip of TM, a POSA would not have even considered using a tissue severing apparatus to transect or sever the strip of tissue so as to disconnect it from the patient's body. In this regard, Dr. Netland's assertions about Jacobi, Ferrari, and the general knowledge in the art, are irrelevant. *See* Ex. 1003 ¶¶223-224. In my opinion, nothing in Quintana, alone or in combination with any of the other cited prior art in the Petition, or the general knowledge in the art, supports Dr. Netland's assertion that it would have been obvious to somehow modify the Quintana method to include the step of using a tissue severing apparatus to transect or sever the strip of tissue so as to disconnect it from the patient's body, according to the applicable legal standards as I understand them.

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- 210. Claim 10 of the '729 Patent reads: "A method according to claim 9 wherein the angle is approximately 90 degrees."
- 211. At Paragraphs 225-229, the Netland Declaration asserts that Quintana in combination with Lee and the knowledge in the art discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶150-176 above.
- 212. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 10 incorporates each and every element of Claims 1 and 9. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claims 1 and 9.
- 213. In addition, for at least the reasons set forth in ¶¶82-83 above, a POSA would not have been motivated by any of the cited prior art in the Petition or the general knowledge in the art to modify the Quintana trabeculotome by bending the needle tip at an angle greater than what Quintana disclosed, and certainly not to approximately 90 degrees, as Dr. Netland asserts. *See* Ex. 1003 ¶¶226-229. Rather, a POSA reading Quintana together with Johnstone (the only reference upon which Dr. Netland relies for this argument), in my opinion, would have come to an understanding exactly opposite from Dr. Netland's.

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214. First, a POSA would have understood that Quintana's sole reason for bending the needle tip of its trabeculotome is to avoid damaging the external wall of Schlemm's Canal. See Ex. 1004 at 4 ("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."). Second, a POSA would have understood that Johnstone acknowledges that its internal cystotome trabeculotomy damaged the external wall of Schlemm's Canal, but that Johnstone is otherwise unconcerned with this result. See Ex. 1005 at 11 ("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 "). Given these inconsistent teachings in Quintana and Johnstone, a POSA would have been wary of modifying the angle of the needle tip bend in the Quintana trabeculotome for fear that using any such altered device to perform Quintana's procedure would heighten the risk of undesirable injury to the external wall of Schlemm's Canal. Moreover, a POSA would have been advised especially against modifying the angle of the needle tip bend in the Quintana trabeculotome, as Dr. Netland asserts, to be approximately 90 degrees based on Johnstone, which specifically described damaging the external wall of Schlemm's Canal with its internal cystotome trabeculotomy.

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215. Dr. Netland's attempts to justify his hindsight reconstruction of an altered Quintana trabeculotome are contrary to what Quintana actually tells a POSA. For example, by asserting that a hypothetical Quintana trabeculotome with a needle tip bent at approximately 90 degrees might still work if used (1) in a perpendicular approach or (2) in a tangential approach so long as the syringe portion of the device is repositioned outside the patient's eye, Dr. Netland ignores Quintana's choice of a tangential versus perpendicular approach and makes up using the hypothetical altered device in a way that Quintana never mentions or suggests. See Ex. 1003 ¶229. None of the prior art cited in the Petition supports Dr. Netland's assertions in this regard, which, in my opinion, are wrong and are based solely on his own speculation, conjecture and hindsight.

- v. Petition Ground 5 (Claims 1-4 and 7-8 are not anticipated by Jacobi)
- 216. Claim 1 of the '729 Patent reads (in pertinent part corresponding to element b as referenced in the Netland Declaration): "obtaining a dual blade device which comprises."
- 217. At Paragraphs 233-235, the Netland Declaration asserts that Jacobi discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶62-69 above.

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- 218. In my opinion, a POSA would have understood Jacobi to describe a method using a device to scrape or abrade the TM instead of cutting defined strips of TM. A POSA would have understood that Jacobi never describes its gonioscraper as a dual blade device. Indeed, even if that the tiny bowl with sharpened edges of the gonioscraper tip were deemed to have a cutting edge, which it does not, there would be only a single cutting edge. A POSA would not have understood Jacobi to describe a dual blade device.
- 219. Claim 1 of the '729 Patent reads (in pertinent part corresponding to element e as referenced in the Netland Declaration): "ii) a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees."
- 220. At Paragraphs 238-240, the Netland Declaration asserts that Jacobi discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶73-76 above.
- 221. In my opinion, a POSA would have understood Jacobi to describe a gonioscraper closely resembling a cyclodialysis spatula. Jacobi never mentions or depicts a bend or curve having an angle of at least 30 degrees formed from a distal protruding tip that extends from a distal end of the shaft.

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- 222. Claim 1 of the '729 Patent reads (in pertinent part corresponding to element g as referenced in the Netland Declaration): "iii) first and second cutting edges located at a junction of the shaft and the distal protruding tip, said first and second cutting edges being formed at spaced-apart locations on the distal end of the shaft, said first and second cutting edges being separated by a distance D."
- 223. At Paragraphs 242-244, the Netland Declaration asserts that Jacobi discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶65-72 and ¶219 above.
- 224. In my opinion, a POSA would have understood Jacobi to describe a method using a device to scrape or abrade the TM instead of cutting defined strips of TM. A POSA would have understood that Jacobi never describes its gonioscraper as a dual blade device. Indeed, even if the tiny bowl with sharpened edges of the gonioscraper tip were deemed to have a cutting edge, which it does not, there would be only a single cutting edge. In that case, a POSA would have understood that Jacobi does not disclose "first and second cutting edges located at a junction of the shaft and the distal protruding tip, said first and second cutting edges being formed at spaced-apart locations on the distal end of the shaft, said first and second cutting edges being separated by a distance D."

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- 225. Claim 1 of the '729 Patent reads (in pertinent part corresponding to element j as referenced in the Netland Declaration): "advancing the elongate probe through the anterior chamber, while the anterior chamber is filled with fluid, to an operative position where the distal protruding tip is positioned within Schlemm's Canal and the first and second cutting edges are contacting the trabecular meshwork."
- 226. At Paragraphs 247-250, the Netland Declaration asserts that Jacobi discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in \$\pi\$65-72 and \$\pi\$219 above.
- 227. In my opinion, a POSA would have understood Jacobi to describe a method using a device to scrape or abrade the TM instead of cutting defined strips of TM. A POSA would have understood that Jacobi never describes its gonioscraper as a dual blade device. Indeed, even if that the tiny bowl with sharpened edges of the gonioscraper tip were deemed to have a cutting edge, which it does not, there would be only a single cutting edge. In that case, a POSA would have understood that Jacobi does not disclose "first and second cutting edges."
- 228. Claim 1 of the '729 Patent reads (in pertinent part corresponding to element k as referenced in the Netland Declaration): "thereafter causing the distal protruding tip to advance through a sector of Schlemm's Canal with the first and

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second cutting edges concurrently cutting, from the trabecular meshwork, a strip of tissue having approximate width W, said approximate width W being approximately equal to the distance D between the first and second cutting edges."

- 229. At Paragraphs 251-252, the Netland Declaration asserts that Jacobi discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶65-72 and ¶219 above.
- 230. In my opinion, a POSA would have understood Jacobi to describe a method using a device to scrape or abrade the TM instead of cutting defined strips of TM. A POSA would have understood that Jacobi never describes its gonioscraper as a dual blade device. Indeed, even if that the tiny bowl with sharpened edges of the gonioscraper tip were deemed to have a cutting edge, which it does not, there would be only a single cutting edge. In that case, a POSA would have understood that Jacobi does not disclose "first and second cutting edges."
- 231. In addition, even if one were to assume Dr. Netland's erroneous premise that the sharpened edges of the tiny bowl of the gonioscraper tip are first and second cutting edges, which they are not, then a POSA would have understood that Jacobi does not disclose that the purported first and second cutting edges are "concurrently cutting, from the trabecular meshwork, a strip of tissue having approximate width W, said approximate width W being approximately equal to the

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distance D between the first and second cutting edges." Jacobi never describes or depicts concurrently cutting the TM with the sharpened edges of the tiny bowl of the gonioscraper tip to form a strip of TM of defined width. I disagree with Dr. Netland's assertions that using a gonioscraper "to abrade rather than incise uveal meshwork to peel off strings of trabecular tissue" must equate with using a dual blade device having first and second cutting edges cutting the TM to form strips of tissue of defined width. See Ex. 1003 ¶251 (quoting Ex. 1007 at 2). In my opinion, a POSA reading Jacobi would have understood the opposite, i.e., Jacobi could not have been reasonably certain that this was the case. For example, Jacobi's gonioscraper is different than a cutting implement, including the dual blade device described in the '729 Patent.

- 232. Claim 2 of the '729 Patent reads: "A method according to claim 1 further comprising the step of infusing fluid into the anterior chamber under controlled pressure to keep the anterior chamber filled with fluid during performance of the method."
- 233. At Paragraphs 253-255, the Netland Declaration asserts that Jacobi discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶65-72 and ¶219 above.

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- 234. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 2 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 2.
- 235. Claim 3 of the '729 Patent reads: "A method according to claim 1 wherein the strip of tissue cut from the trabecular meshwork has a length of about 2 to 10 millimeters."
- 236. At Paragraphs 256-259, the Netland Declaration asserts that Jacobi discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶65-72 and ¶219 above.
- 237. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 3 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 3.
- 238. In addition, Jacobi never describes its procedure as involving cutting the TM to form a strip of tissue, much less a strip of tissue of defined width. I disagree with Dr. Netland's assertion that Jacobi's disclosure of a 90-120°

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goniocurettage in any way describes cutting the TM to form a strip of tissue, much less that it must equate to a tissue strip length of about 2 to 10 millimeters. *See*Ex. 1003 ¶258-259. In my opinion, nothing in Jacobi supports Dr. Netland's assertion in this regard, which, in my opinion, is wrong and is based solely on his own speculation, conjecture and hindsight.

- 239. Claim 4 of the '729 Patent reads: "A method according to claim 1 further comprising the step of: removing the strip of tissue from the patient's eye."
- 240. At Paragraphs 260-262, the Netland Declaration asserts that Jacobi discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶65-72 and ¶219 above.
- 241. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 4 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 4.
- 242. In addition, Jacobi never describes its procedure as involving creating or removing a strip of TM, much less removing from a strip of TM from the patient's eye. I disagree with Dr. Netland to the extent he suggests that a POSA would have understood the act of removing TM from a patient's eye to be the same

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as the act of creating and/or removing a strip of TM. In my opinion, nothing in Jacobi supports Dr. Netland's assertion in this regard, which, in my opinion, is wrong and is based solely on his own speculation, conjecture and hindsight.

- 243. Claim 7 of the '729 Patent reads: "A method according to claim 1 wherein the step of forming an opening into the anterior chamber of the eye comprises forming an incision through a cornea of the eye."
- 244. At Paragraphs 263-264, the Netland Declaration asserts that Jacobi discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶65-72 and ¶219 above.
- 245. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 7 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 7.
- 246. Claim 8 of the '729 Patent reads: "A method according to claim 1 wherein the method is performed under direct visualization through a lens device positioned on an anterior aspect of the eye."

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- 247. At Paragraphs 265-266, the Netland Declaration asserts that Jacobi discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶65-72 and ¶219 above.
- 248. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 8 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 8.
 - vi. Petition Ground 6 (Claims 5-6 and 9-10 are not obvious over Jacobi in view of the knowledge in the art)
- 249. Claim 5 of the '729 Patent reads: "A method according to claim 4 wherein, after the first and second cutting edges have cut the strip of tissue from the trabecular meshwork, the strip of tissue remains connected to the trabecular meshwork and wherein the method further comprises the step of: disconnecting the strip of tissue such that it may be removed from the eye."
- 250. At Paragraphs 267-269, the Netland Declaration asserts that Jacobi in combination with the knowledge in the art discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶65-72 and ¶219 above.

- 251. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 5 incorporates each and every element of Claims 1 and 4. For the same reasons that I disagree with Dr. Netland's assertions regarding Claims 1 and 4, I disagree with Dr. Netland's assertions regarding Claim 5.
- 252. In particular, because Jacobi never describes its procedure as involving creating a strip of TM, a POSA would not have even considered disconnecting a strip of TM such that it may be removed from the eye. In this regard, Dr. Netland's assertions about Johnstone are irrelevant. *See* Ex. 1003 ¶269. In my opinion, nothing in Jacobi, alone or in combination with any of the other cited prior art in the Petition, or the general knowledge in the art, supports Dr. Netland's assertion that it would have been obvious to somehow modify the Jacobi goniocurettage method to include the step of disconnecting the strip of tissue such that it may be removed from the eye, according to the applicable legal standards as I understand them.
- 253. Claim 6 of the '729 Patent reads: "A method according to claim 5 wherein the disconnecting step comprises using a tissue severing apparatus to transect or sever the strip of tissue so as to disconnect it from the patient's body."

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- 254. At Paragraphs 270-271, the Netland Declaration asserts that Jacobi in combination with the knowledge in the art discloses, among other things, everything in this claim or claim element. I disagree, for at least the reasons set forth in ¶¶65-72 and ¶219 above.
- 255. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 6 incorporates each and every element of Claims 1, 4 and 5. For the same reasons that I disagree with Dr. Netland's assertions regarding Claims 1, 4 and 5, I disagree with Dr. Netland's assertions regarding Claim 6.
- 256. In particular, because Jacobi never describes its procedure as involving creating a strip of TM, a POSA would not have even considered using a tissue severing apparatus to transect or sever the strip of tissue so as to disconnect it from the patient's body. In this regard, Dr. Netland's assertions about Quintana, Ferrari, and the general knowledge in the art, are irrelevant. *See* Ex. 1003 ¶272. In my opinion, nothing in Jacobi, alone or in combination with any of the other cited prior art in the Petition, or the general knowledge in the art, supports Dr. Netland's assertion that it would have been obvious to somehow modify the Jacobi goniocurettage method to include the step of using a tissue severing apparatus to

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transect or sever the strip of tissue so as to disconnect it from the patient's body, according to the applicable legal standards as I understand them.

- 257. Claim 9 of the '729 Patent reads: "A method according to claim 1 wherein the angle is less than approximately 90 degrees."
- 258. At Paragraphs 272-275, the Netland Declaration asserts that Jacobi in combination with the knowledge in the art discloses, among other things, a method using a device with a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of less than approximately 90 degrees. I disagree, for at least the reasons set forth in ¶65-72 and ¶219 above.
- 259. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 9 incorporates each and every element of Claim 1. For the same reasons that I disagree with Dr. Netland's assertions regarding Claim 1, I disagree with Dr. Netland's assertions regarding Claim 9.
- 260. At least for the reasons set forth in ¶¶73-75 above, Jacobi does not describe a device having a distal protruding tip that extends from a distal end of the shaft to form a bend or curve. In particular, Dr. Netland's re-drawing of Jacobi 2000 Figure 1(b) to show a hypothetical "bend or curve (3)" is wrong and is based solely on his own speculation, conjecture, and hindsight. No such bend or

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curve is actually shown in either Jacobi or Jacobi 2000. Therefore, a POSA would not have been motivated by Jacobi to arrive at a method using a device with a distal protruding tip that extends from a distal end of the shaft to form a bend or curve, much less one having an angle of less than approximately 90 degrees. The knowledge in the art does not make up for this lack in Jacobi.

- 261. In my opinion, Dr. Netland's conclusion that: "Persons of ordinary skill in the art also would have found it obvious to try variations to Jacobi's device, such as by modifying the bend or curve of the device to use different angles," Ex. 1003 ¶275, is unsupported and erroneous. Jacobi, Quintana, and Johnstone involve very different devices used for different intended purposes. *See, e.g.*, Ex. 1005 at 1 (Johnstone reporting internal cystotome trabeculotomy by *ab externo* probing of Schlemm's Canal in postmortem enucleated human eyes); Ex. 1004 at 3 (Quintana reporting the use of a hypodermic needle tip bent 20-30° to avoid injuring the external wall of Schlemm's Canal). None alone or together would have suggested to a POSA to modify the Jacobi gonioscraper to form a bend or curve at the distal end of the shaft.
- 262. Claim 10 of the '729 Patent reads: "A method according to claim 9 wherein the angle is approximately 90 degrees."

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- 263. At Paragraphs 276-279, the Netland Declaration asserts that Jacobi in combination with the knowledge in the art discloses, among other things, a method using a device with a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of approximately 90 degrees. I disagree, for at least the reasons set forth in \$\infty\$65-72 and \$\infty\$219 above.
- 264. I have been informed by counsel that a dependent claim incorporates each and every element of the claim from which it depends. In this regard, I understand that Claim 10 incorporates each and every element of Claims 1 and 9. For the same reasons that I disagree with Dr. Netland's assertions regarding Claims 1 and 9, I disagree with Dr. Netland's assertions regarding Claim 10.
- 265. At least for the reasons set forth in ¶¶73-75 above, Jacobi does not describe a device having a distal protruding tip that extends from a distal end of the shaft to form a bend or curve. In particular, Dr. Netland's re-drawing of Jacobi 2000 Figure 1(b) to show a hypothetical "bend or curve (3)" is wrong and is based solely on his own speculation, conjecture, and hindsight. No such bend or curve is actually shown in either Jacobi or Jacobi 2000. Therefore, a POSA would not have been motivated by Jacobi to arrive at a method using a device with a distal protruding tip that extends from a distal end of the shaft to form a bend or

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curve, much less one having an angle of approximately 90 degrees. The knowledge in the art does not make up for this lack in Jacobi.

obvious to modify Jacobi's gonioscraper by altering the angle of the bend or curve based on the knowledge of persons skilled in the art as informed by, for example, Quintana and Johnstone," Ex. 1003 ¶278, is unsupported and erroneous. Jacobi, Quintana, and Johnstone involve very different devices used for different intended purposes. *See, e.g.*, Ex. 1005 at 1 (Johnstone reporting internal cystotome trabeculotomy by *ab externo* probing of Schlemm's Canal in postmortem enucleated human eyes); Ex. 1004 at 3 (Quintana reporting the use of a hypodermic needle tip bent 20-30° to avoid injuring the external wall of Schlemm's Canal). None alone or together would have suggested to a POSA to modify the Jacobi gonioscraper to form a bend or curve at the distal end of the shaft.

D. CONCLUSION

267. In my opinion, according to the applicable legal standards as I understand them, a POSA reading the cited prior art in the Petition along with the general knowledge in the art would have concluded with a reasonable scientific certainty that Claims 1-10 of the '729 patent are not invalid, and specifically would

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have found that: (I) Claims 1-4 and 7-9 are not anticipated under 35 U.S.C. § 102 by Quintana (Ex. 1004); (II) Claims 4-6 and 10 are not rendered obvious under 35 U.S.C. § 103 by Quintana (Ex. 1004) in view of the knowledge of a person of ordinary skill in the art; (III) Claims 1-4 and 7-9 are not rendered obvious under 35 U.S.C. § 103 by Quintana (Ex. 1004) in view of Lee (Ex. 1006); (IV) Claims 4-6 and 10 are not rendered obvious under 35 U.S.C. § 103 by Quintana (Ex. 1004) in view of Lee (Ex. 1006) in further view of the knowledge of a person of ordinary skill in the art; (V) Claims 1-4 and 7-8 are not anticipated under 35 U.S.C. § 102 by Jacobi (Ex. 1007); and (VI) Claims 5-6 and 9-10 are not rendered obvious under 35 U.S.C. § 103 by Jacobi (Ex. 1007) in view of the knowledge of a person of ordinary skill in the art.

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268. I declare under penalty of perjury that the foregoing is true and correct. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: June 4, 2021

Respectfully submitted,

y P. Condon, M.D.

Appendix A

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CURRICULUM VITAE

Name: GARRY PASCAL CONDON, M.D.

Address: Coastal Eye Institute

217 Manatee Avenue E. Bradenton, FL 34208

Date of Birth: May 17, 1958

Place of Birth: Winnipeg, Manitoba, Canada

Citizenship: U.S. Canadian

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Education:

1979 B. Med. Sc. Memorial University of Newfoundland

St. John's, Newfoundland, Canada

1981 M.D. Memorial University of Newfoundland

St. John's, Newfoundland, Canada

Internship and Residency:

1981-82 Intern (Straight Internal Medicine)

Memorial University of Newfoundland, St. John's, Newfoundland, Canada

1983-86 Resident in Ophthalmology, University of Western Ontario,

London, Ontario, Canada

Fellowships:

1982-83 Fellow in Ophthalmic Pathology, McGill Pathology Institute

(Dr. Seymour Brownstein), Montreal, Quebec, P.Q., Canada

1986-88 Fellow, New England Glaucoma Research Foundation

(Dr. Richard J. Simmons), Boston, MA

Licensure and Certification:

1983	Licentiate of the College of Physicians and Surgeons of Ontario, Canada
1983	Licentiate of the State of New York in Medicine and Surgery
1984	Licentiate of the Medical Council of Canada
1986	Licentiate of the Commonwealth of Massachusetts Board of Registration in Medicine
1986	Fellow of the Royal College of Surgeons (Canada) - Ophthalmology
1987	Diplomate - American Board of Ophthalmology
1987	Licentiate of the Commonwealth of Pennsylvania State Board of Medicine

Current Medical Licensure:

State of Florida Medical License Initial License Date: 08/29/2014 ME 121450 Expiration Date: 01/31/2023

Speciality Certification:

American Board of Ophthalmology Issue Date: 10/27/1987 (No certification #) (No expiration date)

Professional Memberships:

1988 - 2019 Fellow of The American Academy of Ophthalmology

1988 - 2018	Member of the Pittsburgh Ophthalmology Society
1988 - Present	Member Chandler-Grant Glaucoma Society
1989 - 2018	Member of the Allegheny County Medical Society
1989 - 2018	Member of the Pennsylvania Medical Society
1989 - Present	Member of the American Medical Association
1992 - 2018	Member of the Pennsylvania Academy of Ophthalmology
2000 - Present	Member of the American Society of Cataract and Refractive
	Surgery
2004 - Present	Member of the American Glaucoma Society
2005 - Present	Member of the International Intra-Ocular Implant Club
2015 - Present	Member of the Florida Medical Association
2019 - Present	Life Member of The American Academy of Ophthalmology

Appointments:

1987 - 1988	Clinical Instructor in Ophthalmology Harvard Medical School, Boston
1988 - 1996	Assistant Professor of Surgery (Ophthalmology) Medical College of Pennsylvania, Pittsburgh, PA
1990 - 2018	Director, Division of Glaucoma, Department of Ophthalmology Allegheny General Hospital, Pittsburgh, PA
1991 - 2003	Adjunct Clinical Instructor in Ophthalmology University of Pittsburgh, Pittsburgh, PA
1996 - 2000	Assistant Professor of Ophthalmology in the Department of Ophthalmology, MCP□Hahnemann School of Medicine, Allegheny General Hospital Campus, Pittsburgh, PA
2000 - 2014 Assoc	ciate Professor of Ophthalmology in the Department of Ophthalmology, Drexel University College of Medicine, Allegheny General Hospital Campus, Pittsburgh, PA
2002 - 2007	Vice Chairman, Department of Ophthalmology, Allegheny General Hospital, Pittsburgh, PA
2004 - Present	Clinical Assistant Professor in the Department of Ophthalmology, University of Pittsburgh, Pittsburgh, PA

Appointments:-cont'd

2007 – 2018	Chairman in the Department of Ophthalmology, Allegheny General Hospital, Pittsburgh, PA
2015 - Present	Professor in the Department of Ophthalmology, Drexel University College of Medicine, Philadelphia, PA

Societies / Committees Positions:

1990 - 1994	Continuing Medical Education Committee Allegheny General Hospital
1991 - 1993	Executive Committee, Pittsburgh Ophthalmology Society
1992 - 1995	Operating Room Adhoc Committee for Minimally Invasive Surgery
2001 - 2003	Secretary-Treasurer, Chandler – Grant Glaucoma Society
2001 - 2004	Operating Room Committee
2002 - 2018	Program Committee, Pittsburgh Ophthalmology Society
2005 - Present	Member ASCRS Glaucoma Clinical Committee
2007 – Present	Member of the Special Projects Committee, American Academy of Ophthalmology

Awards:

1984	Percy Hermant Fellowship in Ophthalmology, University of Western Ontario, London, Ontario, Canada
2001	Achievement Award, American Academy of Ophthalmology
2005	– Present The Best Doctors in America
2008	"Doctor's Choice Award", XXII Annual American College of Eye Surgeons Meeting. San Juan, Puerto Rico

Awards:-cont'd

- 2008 "America's Top Ophthalmologists", Cataract/Glaucoma Surgery, Consumers' Research Council of America
- 2008 Contributions in the Advancement of Surgical Treatment for Glaucoma, Optonol, Inc., American Society of Cataract and Refractive Surgeons Meeting, Chicago, IL
- 2010 Senior Achievement Award, American Academy of Ophthalmology
- 2011 "America's Top Ophthalmologists", Cataract/Glaucoma Surgery, Consumers' Research Council of America
- 2012 Best Physicians As Chosen By Their Peers, Pittsburgh Magazine
- 2017 2020 Castle Connelly Top Doctor
- 2018 2020 'Top Doctor' Sarasota Magazine

Abstracts:

Savage JA, Condon GP, Lytle RA, Simmons RJ: A Hybrid Glaucoma Filtration Operation: Controlled Post-Operative Argon Laser Suture Lysis with Small Flap Trabeculectomy. Annual meeting of the American Academy of Ophthalmology, Dallas TX, October 1987

Lytle RA, Reed JA, Condon GP, Maestre F, Simmons RJ: "Internal Revision in Glaucoma Filtration Surgery", American Academy of Ophthalmology Meeting, Las Vegas, NV: October 8-12, 1988. (poster)

Lehrer RA, Condon GP, Baker KS, Spanich CG: "Primary Trabeculectomy with Adjusted Mitomycin Exposure Time", American Academy of Ophthalmology Meeting, Chicago, IL: November 14-18, 1993. (poster)

Lehrer RA, Condon GP, Baker KS, Spanich CG: "Combined Phacoemulsification and Trabeculectomy with Adjusted Mitomycin Exposure", American Academy of Ophthalmology Meeting, Chicago, IL: November 14-18, 1993. (poster)

Lehrer RA, Condon GP, Baker KS, Spanich CG: "Adjusted Mitomycin Exposure Time in Poor Prognosis Trabeculectomy Surgery", American Academy of Ophthalmology Meeting, Chicago, IL: November 14-18, 1993. (poster)

Abstracts:-cont'd

Baker KS, Condon GP, Lehrer RA: "Occurrence of Branch Retinal Vein and Central Retinal Vein Occlusion Following Trabeculectomy Surgery", ARVO Annual Meeting, Ft. Lauderdale, FL: April 21-26, 1996. (poster)

Suh SH, Baker KS, Condon GP, Lehrer RA: "Outcomes and Complications Following Combined Cataract and Trabeculectomy Surgery Using Mitomycin C", ARVO Annual Meeting, Ft. Lauderdale, FL: May 11-16, 1997. (poster)

Condon GP. Application of a Single-Piece Acrylic Lens in Glaucomatous Eyes, Annual Meeting of American Society of Cataract and Refractive Surgery, Boston, MA, May 2000

Bindlish R, Condon GP, Lehrer RA et al. Efficacy and safety of mitomycin-c in primary trabeculectomy – five year follow up. Meeting of the American Academy of Ophthalmology, Dallas TX, November 2000

Bindlish R, Condon GP, Lauer KB et al. Scleral reinforcement surgery for late hypotony after trabeculectomy with mitomycin-c. Meeting of the American Academy of Ophthalmology, Dallas TX, November 2000 (poster)

Condon GP. Biomechanical attributes of a single-piece acrylic intraocular lens in glaucomatous eyes. Annual Meeting of American Society of Cataract and Refractive Surgery, San Diego CA, April 2001

Condon GP. Secondary small incision iris fixation of an acrylic intraocular lens in the absence of capsular support. Annual Meeting of the American Society of Cataract and Refractive Surgery, Philadelphia PA, June 2002

Lauer KB, Herzig D, **Condon GP**. Trabeculectomy with mitomycin-c in neovascular glaucoma: long-term efficacy and complications. Annual Meeting of the American Academy of Ophthalmology, Orlando FL 2002 (poster)

Monsul NT, Cockerham KP, Condon GP. Retinal topography in unilateral optic neuropathy. Annual Meeting of the American Academy of Ophthalmology, Orlando FL 2002 (poster)

Abstracts:-cont'd

Condon GP, Ahmed IK, Masket S et al. Iris fixation of foldable PC IOL with modified McCannel slip-knot. Annual Meeting of the American Society of Cataract and Refractive Surgery, San Francisco, April 2003

Condon GP, Ahmed I, Masket S, Kranemann C, Crandall AS. Peripheral Iris Fixation of Foldable Acrylic Posterior Chamber IOLs: Efficacy and Complications. Annual meeting of the AAO New Orleans LA 2004 (poster)

Chiniwalla RN, Condon GP. Long-term Results of Conjunctivoplasty for Bleb Related Complications. Annual meeting of the AAO New Orleans LA 2004 (poster)

Mura J, Ahmed I, Kranemann C, Pavlin C, Condon GP, Ishikawa H. Ultrasound Biomicroscopy Analysis of Iris-Fixated Posterior Chamber IOLs. Annual Meeting of the ASCRS Washington DC, 2005.

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Condon GP, Comparison of ExPRESS Miniature Glaucoma Device Implanted Under Scleral Flap with Trabeculectomy, Co-Author (Paper) PA093 AAO Chicago IL 2012

Netland PA, Sarkisian SR, Moster MR, Ahmed IK, Condon GP, Salim S, Sherwood MB, Siegfried CJ. Randomized, Prospective, Comparative Trial of EX-PRESS Glaucoma Filtration Device Versus Trabeculectomy (XVT Study) 2013

Publications:

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Brownstein S, Barsoum-Homsy M, Conway VH, Sales C, Condon GP: Nonteratoid Medulloepithelioma of the Ciliary Body. *Ophthalmology* 1984: 91:1118-1122.

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Bindlish R, Condon GP, Lehrer RA, Lauer KB, Schlosser MS, d'Antonio JD. Efficacy and safety of mitomycin-c in primary trabeculectomy–Five year followup. *Ophthalmology* 2002; 109: 1336-1341

Condon GP. Response to consultation section. J Cataract Refract Surg 2002; 28: 214-216

Condon GP. Simplified small incision peripheral iris fixation of an Acrysof intraocular lens in the absence of capsular support. *J Cataract Refract Surg* 2003; 29: 1663-1667

Condon GP. Flap technique addresses bleb-related hypotony. Review of Ophthalmology, Jobson Publishing, New York, 2003; 10: 52-55

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Condon GP. Response to Consultation Section. Sam Masket MD ed. General Cataract and Refractive Surgery. February 2008

Mura J, Ahmed I, Kranemann C, Pavlin C, Condon GP, Ishikawa H. Ultrasound Biomicroscopy Analysis of Iris-Fixated Posterior Chamber IOLs. *Ophthalmology* (in press)

Dorey MD, Condon GP. Management of Dislocated Intraocular Lenses. Focal Points: Clinical Modules for Ophthalmologists. Published by AAO, (in press)

Condon GP. A Limbus- or Fornix-Based Flap? Glaucoma Today. March/April 2008 – Vol 6, No. 2

Condon GP, Davis EA, MacDonald SM. Tips for Easier, Safer Phacoemulsification: Part 2. Cataract & Refractive Surgery Today. July 2008

Condon GP, A "Cornea Conscious" Approach to Dense Nuclei. OVD Strategies for Complex Cases. Supplement to Cataract & Refractive Surgery Today. August 2008

Devgan U., Condon GP, Drandall AS. Subluxated Lenses in a Pediatric Patient. Cataract & Refractive Surgery Today. May 2009

Condon GP, Closing the Fornix-Based Flap. Glaucoma Today. October 2009 – Vol 7, No. 7

Condon GP, Closing the Fornix-Based Flap. EyeTube.Net 2009

Publications:-cont'd

Condon GP, Traumatic Cataract with Vitreous in Anterior Chamber for "OVD's in Challenging Cases". Video Supplement

Mura JJ, Pavlin CJ, Condon GP, Belovay GW, Kranemann CF, Ishikawa H, Ahmed II, Ultrasound Biomicroscopic Analysis of Iris-Sutured Foldable Posterior Chamber Intraocular Lenses. American Journal of Ophthalmology, 2010 Feb; 149(2):245-252

Condon GP, Laser Treatment, PNT versus ALT. *International Glaucoma Review*, Editor's Selection. Volume 12-1. 2010

Condon GP, Vitreous in the Anterior Chamber: Maintaining Control During Surgery

Condon GP, Single-Piece Syndrome. The Newest Form of IOL-Induced Glaucoma. Glaucoma Today. Early Summer 2011 – Volume 9, No. 3

Condon GP, Will Surgery Become the First Line of Glaucoma Treatment in the United States? Point/Counterpoint/Safer, more Efficacious Procedures will mean Earlier Surgery. (It is Highly Unlikely, Lin SC) Glaucoma Today. Summer 2011

Condon GP, Samuelson TW, Shingleton BJ, Singh K, Zabriskie N. Simultaneous, Combined Cataract and Glaucoma Surgery. Glaucoma Today May/June 2012

Condon GP, When a Torn Capsule Becomes a Total Capsulectomy. Cataract & Refractive Surgery Today June 2012

Condon GP, Brown RH, Crandall AS, Donnenfeld ED. Cataract Surgery in the High Hyperope. Glaucoma Today September/October 2012

Kirk TQ, Condon GP. Simplified Ab Externo Scleral Fixation for Late In-the-Bag Intraocular Lens Dislocation. J Cataract Refract Surg 2012; 38:1711-1715

Kirk TQ, Condon GP. Tools & Techniques. Simplifying Management of the Dislocated In-the-Bag Intraocular Lens. Eyeworld 2014-5-8; 16:53:33

Kirk TQ, Condon GP. Modified Wise Closure of the Conjunctival Fornix-based Trabeculectomy Flap. J Cataract Refract Surg 2014; 40:349-353

Condon GP. The Siepser Sliding Knot (Eyetube Video). Cataract & Refractive Surgery Today Europe March 2014

Publications:-cont'd

Condon GP. Noecker RJ, Radcliffe NM, Vold SD, Raviv T. Cataract Surgery Complex Case Management. Cataract with an Overhanging Bleb. Cataract & Refractive Surgery Today June 2014

Condon GP, Crandall AS, MacDonald SM, McCabe CM, Arbisser LB. Progressive Cataract Elevated IOP and Flat Anterior Chamber after PPV and Trabeculectomy. Cataract & Refractive Surgery Today July 2014

Condon GP, Moster MR. Minimizing the Invasiveness of Traditional Trabeculectomy Surgery. J Cataract Refract Surg 2014; 40:1307-1312

Condon GP. Response to Consultation Question (Cataract Surgical Problem) Posed by Dr. Samuel Masket. J Cataract Refract Surg 2014; 40:1394-1395

Condon GP, Masket S, Consultants. Placement of Endocapsular IOL's in Eyes with Zonular Compromise. Focal Points AAO. Vol XXXII, Number 7, Sept 2014

Condon GP. When Should I Perform Lens Extraction Alone for the Primary Angle – Closure Suspect? Comment PACS 'The Undisputed Mainstay of Treatment." Glaucoma Today March/April 2015

Condon GP, Crandall AS, Masket S. Decentration After IOL Exchange for UGH Syndrome. Cataract & Refractive Surgery Today June 2015

Grove K, Condon GP, Emy B, Chang DF, Kim T. Complication from Combined Use of Capsule Retractors and Capsular Tension Rings in Zonular Dehiscence. J Cataract Refract Surg 2015; 41:2576-2579

Siegel M, Condon GP. Single Suture Iris-to-Capsulorhexis Fixation for In-the-Bag Intraocular Lens Subluxation. J Cataract Refract Surg 2015; 41:2347-2352

Book Chapters:

Condon GP. Lu LW. Phacoemulsification in the Previously Filtered Eye. In: Mehta KR, Alpar JJ (Ed): *The Art of Phacoemulsification,* Jaypee Brothers: New Delhi, 2001; chap 31

Critchton AC, Condon GP, Trope GE. Management of the Leaking Bleb. In: Trope GE (Ed): Glaucoma Surgery, Taylor & Francis: New York, 2005; chap 23

Book Chapters:-cont'd

Alunni MA, Condon GP. Treatment of Occludable Angles and Angle Closure with Cataract Extraction. In: Kahook MY, Schuman JS, eds. Chandler and Grant's Glaucoma. 5th ed. Thorofare, NJ: SLACK Incorporated; 2013

Condon GP. Curbside Consultation in Cataract Surgery 49 Clinical Questions, 2nd Updated Edition) Question 48: "Following a Posterior Capsular Rent, the Sulcus Fixated Intraocular Lens has become Decentered. How Should Proceed?" Slack Incorporated, 2013

Condon GP, Chan CK, Agarwal A. Posterior Capsular Rupture. A Practical Guide to Prevention and Management. -15- "Management of Dislocated Intraocular Lenses." Slack Incorporated, 2014

Kirk TQ, Condon GP, Siegel MJ. Fixation for Delayed Bag-IOL Dislocation. In: Chang DF, Lee BS, Agarwal A, eds. Advanced IOL Fixation Techniques. Slack Inc. Thorofare NJ, 2019

Condon GP. Peripheral Iris IOL Fixation. . In: Chang DF, Lee BS, Agarwal A, eds. Advanced IOL Fixation Techniques. Slack Inc. Thorofare NJ, 2019

Named Lectures:

- 2009 The GV Simpson Lectureship in Ophthalmology. Western University. London Canada
- 2009 Joseph H. Bowlds, M.D. Lecture. Lahey Clinic Eye Institute. Late IOL Dislocation: The Real Deal. Burlington MA
- 2010 The Ruthanne and Richard Simmons Lecture. Glaucoma Challenges. New England Ophthalmology Society. Boston MA
- 2011 David Kozart Annual Lectureship. Pseudoexfoliation: Zonule Compromise
 & Counter Measures. Scheie Eye Institute, University of Pennsylvania.
 Philadelphia PA
- 2011 William Evans Bruner, M.D. Lecture. Trabeculectomy 2011: Is There Still a Role? Case Western Reserve University. Cleveland OH
- 2012 20th Annual Arthur Light, M.D. Memorial Lectureship in Ophthalmology. 5th Annual Glaucoma / Cataract Symposium. Innovations in Cataract Surgery

- and Glaucoma Management. Loyola Medicine Chicago IL
- 2013 The 2013 Stephen A. Obstbaum, MD, Honored Lecture, "Pseudoexfoliation: My Life as a "Zonulist." What we Know, Don't Know, and Shouldn't Know." ASCRS Glaucoma Day, San Francisco CA
- 2015 The Gettes Lecture. 67th Annual Wills Eye Hospital Conference. Philadelphia PA
- 2018 The 2018 Annual Alan Crandall Lecture. 'Pseudoexfoliation' ASCRS annual Surgical Summit, Deer Valley, Utah.

AUDIO DIGEST LECTURES

- 2013 Zonular Compromise, Audio-Digest Ophthalmology, Vol 51 Issue 16 Aug 21, 2013 (81st Midwinter Conference Controversies in Medicine)
- 2013 Cataract Surgery and Glaucoma, Audio-Digest Ophthalmology, Vol 51 Issue 16 Aug 21, 2013 (81st Midwinter Conference Controversies in Medicine)
- 2013 Acute Angle Closure Glaucoma, Audio-Digest Ophthalmology, Vol 51 Issue 16 Aug 21, 2013 (81st Midwinter Conference Controversies in Medicine)

Participation in Symposia:

- 1989 "Argon Laser Suture Lysis Following Trabeculectomy", Glaucoma-Into the 1990's Symposium, co-chairman. Pittsburgh, PA
- 1994 "Target IOP and Mitomycin", Nantucket Glaucoma Meeting, Joel Schumann Chairman. Nantucket, MA
- 1997 "Coexistent Glaucoma and Cataract," 48th Annual Post-graduate Review Course: Ophthalmology, SUNY Health Science Center, Syracuse, New York
- 1999 "Co-existent Glaucoma and Cataract", Capital Glaucoma Meeting: The Executive Summary, Alan Robin MD, Chairman. Washington, D.C.
- 1999 "Phacoemulsification in the Previously Filtered Eye", Capitol Glaucoma

- Meeting: The Executive Summary. Alan Robin MD, Chairman. Washington, D.C.
- 2002 Session Panelist: IOL power calculation after refractive surgery. Annual Meeting of the American Society of Cataract and Refractive Surgery, Philadelphia PA

- 2002 Selected case presentation at the 'Challenging Cataract Case Symposium'. Annual Meeting of the American Society of Cataract and Refractive Surgery, Philadelphia PA
- 2003 Session Panelist: New IOL designs. Annual Meeting of the American Society of Cataract and Refractive Surgery, San Francisco, CA
- 2003 Phacoemulsification in the previously filtered eye. Glaucoma Management Trends. Alan Robin MD, Vitale Costa MD co-chairs. San Juan PR
- 2003 Non-penetrating glaucoma surgery: Indications and techniques. The Glaucoma Summit. David Dueker MD, Edward Rockwood MD co-chairs. Cole Eye Institute, Cleveland Clinic, Cleveland OH, Jan 31- Feb 1,2003
- 2003 Simplified Peripheral Iris Fixation of an Acrylic IOL. Advances in Glaucoma. Fabian Lerner, Chairman. Buenos Aires, Argentina.
- 2003 Discussant for Paper: Late dislocation of in-bag IOLS associated with pseudoexfoliation. American Academy of Ophthalmology Annual Meeting 2003, Anaheim, CA
- 2004 Blebitis: The Growing Dilemma-The Persistent Challenge. Advances in Glaucoma Management. Eye World Educational Symposium, San Diego CA
- 2004 Peripheral Iris Fixation of PC IOLs. American College of Eye Surgeons Quality Surgery IVIII. Marco Island FL
- 2004 Endocyclophotocoagulation: Point/Counterpoint. American College of Eye Surgeons Quality Surgery XVIII. Marco Island FL
- 2004 Eyepass: Ready for Prime Time? New Surgical Interventions in Glaucoma Symposium. Sponsored by ASCRS Glaucoma Clinical Committee, San Diego CA

- 2004 Session Panelist: Cataract/IOL. Annual meeting of the ASCRS, San Diego CA
- 2004 Phacoemulsification in Angle Closure Glaucoma. Asia-Far East Glaucoma Symposium. Ivan Goldberg MD moderator. Male Maldives

- 2004 Peripheral Iris Fixation of PC IOLs in the Absence of Capsule Support.
 Ophthalmic Symposium. Douglas Koch MD moderator. San Antonio TX
- 2004 Hydrodissection. Ophthalmic Symposium. Douglas Koch moderator. San Antonio TX
- 2004 Combined Cataract and Glaucoma Surgery. Ophthalmic Symposium. Douglas Koch MD moderator. San Antonio TX
- 2005 Innovations in Glaucoma Surgery. Phaco Foldables and Refractive Results Symposium. Alan S Crandall MD moderator. Sponsored by Alcon. Park City Utah
- 2005 Iris Fixated versus Scleral Fixated IOLs. Point-counterpoint. Phaco Foldables and Refractive Results Symposium. Alan S Crandall MD moderator. Sponsored by Alcon. Park City Utah
- 2005 Management of dislocated IOLs. Phaco Foldables and Refractive Results Symposium. Alan S Crandall MD moderator. Sponsored by Alcon. Park City Utah
- 2005 Presidential Forum on Phaco: Zonular weakness. Challenge Cup Session. Manus Kraff MD moderator. Annual Meeting of the ASCRS, Washington DC
- 2005 Innovations in Glaucoma Surgery. Annual Wills Eye Hospital Glaucoma Symposium. St. John, Virgin Islands
- 2005 Pearls for a successful filter in combined cataract and glaucoma surgery. Advances in Anterior Segment and Refractive Surgery. San Antonio TX
- 2005 Phaco techniques. Advances in Anterior Segment and Refractive Surgery. San Antonio TX
- 2005 Subluxed crystalline lens Iris sutured IOL. Advances in Anterior Segment and Refractive Surgery. San Antonio TX

2005 Complex cataract – IOL cases. Advances in Anterior Segment and Refractive Surgery. San Antonio TX

- 2006 Iris sutured PC IOLs Where are they now? UBM and Late term results. Phaco Foldables and Refractive Results. Park City Utah
- 2006 New Instrumentation in anterior segment surgery. Phaco Foldables and Refractive Results. Park City Utah
- 2006 Capsular Tension Segments for compromised zonules. Phaco Foldables and Refractive Results. Park City Utah
- 2006 IOL Malposition puzzlers. Phaco Foldables and Refractive Results. Park City Utah
- 2006 Iris sutured PC IOLs in the Absence of Capsule support. World Ophthalmology Congress. Sao Paulo Brazil
- 2006 Trabeculectomy Pearls: How I Do It. Annual Meeting of the American Glaucoma Society. Charleston SC
- 2006 Phaco / IOL in the Management of Acute Angle-Closure Glaucoma.

 'Glaucoma Day' preceding the Annual Meeting of the American Society of Cataract and Refractive Surgery. San Francisco CA
- 2006 Peripheral Iris Fixation of Late In-the-bag IOLs. 'Glaucoma Day' preceding the Annual Meeting of the American Society of Cataract and Refractive Surgery. San Francisco CA
- 2006 New Operating Issues. Hot Topics Symposium. ASCRS Glaucoma Clinical Committee. Annual Meeting of the American Society of Cataract and Refractive Surgery. San Francisco CA
- 2006 Conjunctival Closure Techniques. Symposium: Innovations and Expertise in Practical Glaucoma Surgery. Annual Meeting of the American Society of Cataract and Refractive Surgery. San Francisco CA
- 2006 Session Moderator: Glaucoma Techniques and Technology. Annual Meeting of the American Society of Cataract and Refractive Surgery. San Francisco CA
- 2006 Glaucoma Surgery Update: Are Blebs Obsolete? 28th Annual Dallas Spring Ophthalmology Symposium, Dallas TX

- 2006 Complicated Anterior Segment Surgical Problems: Dislocated IOL, Iris-Sutured IOL, Loose Zonles – A Video Potpourri. 28th Annual Dallas Spring Ophthalmology Symposium. Dallas TX
- 2006 Surgical Management of Uncontrolled Angle Closure Glaucoma. 28th Annual Dallas Spring Ophthalmology Symposium. Dallas TX
- 2006 Phacoemulsification in the Management of Acute Angle Closure Glaucoma.

 Memphis Eye Society Annual Convention. Memphis TN
- 2006 Iris Fixation of Foldable IOL's: Technique & Results. Memphis Eye Society Annual Convention. Memphis TN
- 2006 Complications & Innovations in Challenging Cataract and IOL Cases: A Video Potpourri. Memphis Eye Society Annual Convention. Memphis TN
- 2006 Late Lens Subluxation: Diagnosis and Management. Glaucoma 2006: Secrets of the Glaucoma Surgeon. New York, NY
- 2006 Nonpenetrating Trabeculectomy. Glaucoma 2006: Secrets of the Glaucoma Surgeon. New York, NY
- 2006 Iris Repair Surgical Techniques. Invited Guest Speaker, Canadian Society of Ophthalmology Annual Meeting. Toronto Canada
- 2006 Iris Sutured IOLS Surgical Technique. Invited Guest Speaker, Canadian Society of Ophthalmology Annual Meeting. Toronto Canada
- 2006 Iris Sutured IOLS Results and Complications Update. Invited Guest Speaker, Canadian Society of Ophthalmology Annual Meeting. Toronto Canada
- 2006 A Perspective on Antimetabolites in Glaucoma Surgery.
 29th Annual Midwest Glaucoma Symposium. Pittsburgh PA
- 2006 Surgical Complications in Glaucoma Surgery. Moderator. 29th Annual Midwest Glaucoma Symposium. Pittsburgh PA
- 2006 Conjunctival Closure Technique for Trabeculectomy. Annual Meeting of the American Glaucoma Society, Charleston SC

- 2006 Innovations in Glaucoma Surgery What's Hot? The Advances in Anterior Segment and Refractive Surgery. San Antonio TX
- 2006 Zonular Compromise Support Options. The Advances in Anterior Segment and Refractive Surgery, San Antonio TX
- 2006 Late IOL / Bag Dislocation. The Advances in Anterior Segment and Refractive Surgery, San Antonio TX
- 2006 New Instrumentation in Anterior Segment Surgery. The Advances in Anterior Segment and Refractive Surgery, San Antonio TX
- 2007 "Newer Surgical Approaches to Zonular Weakness", Invited Guest Speaker, American College of Eye Surgeons/Society for Excellence in Eyecare. SEE Island/Quality Surgery XXI Seminar. Atlantis, Paradise Island, Bahamas.
- 2007 Cataract Surgery and Zonular Weakness in Pseudoexfoliation. Annual Meeting of the American Glaucoma Society, San Francisco CA
- 2007 Trabeculectomy My Preferred Technique. "Glaucoma Day" preceding the Annual Meeting of the American Society of Cataract and Refractive Surgery. San Diego CA
- 2007 New Operating Issues. Hot Topics Symposium. ASCRS Glaucoma Clinical Committee. Annual Meeting of the American Society of Cataract and Refractive Surgery. San Diego CA
- 2007 Zonular Problems in Glaucoma Patients. Symposium: Innovations and Expertise in Practical Glaucoma Surgery. Annual Meeting of the American Society of Cataract and Refractive Surgery. San Diego CA
- 2007 Modifying Cionni's Modified Capsular Tension Ring. Phaco Foldables and Refractive Results. Park City Utah
- 2007 Innovations in Glaucoma Surgery. Phaco Foldables and Refractive Results. Park City Utah
- 2007 Breaking Capsules Without Breaking Hearts. Phaco Foldables and Refractive Results. Park City Utah

Participation in Symposia:-cont'd

- 2007 Pearls for Managing the White Cataract. Phaco Foldables and Refractive Results. Park City Utah
- 2007 Avoiding and Managing Complications with Cataract Surgery in Pseudoexfoliation. Exfoliation Syndrome: Expanding Horizons. The 2007 Lindberg Symposium SOE, Vienna Austria, June 9-12, 2007. Joint Congress of SOE/AAO 2007 Vienna Austria
- 2007 Trabeculectomy: Avoiding Complications Glaucoma Subspecialty Day, November 10, 2007. New Orleans LA
- 2007 A Case for Individualized Patient Care A Lesson from RJS. The Chandler Grant Glaucoma Society Annual Meeting. June 2007. Boston, MA
- 2007 Difficult Anterior Segment Surgery Cases. 35th Annual Alumni Meeting Ophthalmology 2007. SUNY Downstate Medical Center, Brooklyn NY
- 2008 "Phaco in the Management of Acute Angle Glaucoma" American College of Eye Surgeons / Society for Excellence in Ophthalmology Annual Meeting SEE Island / Quality Surgery XXII Seminar, San Juan Puerto Rico
- 2008 A Safer Trabeculectomy? Beautifying a Dinosaur. New Techniques and Controversies in Cataract and Refractive Surgery. Park City Utah
- 2008 Cataract in Pseudoexfoliation Early and Late Surgical Pearls. New Techniques and Controversies in Cataract and Refractive Surgery, Park City Utah
- 2008 The White Cataract Keeping It Simple. New Techniques and Controversies in Cataract and Refractive Surgery. Park City Utah
- 2008 IOL Exchange Making it Right. New Techniques and Controversies in Cataract and Refractive Surgery. Park City Utah
- 2008 "Contrary to Ordinary" Life Styles Symposium. Royal Hawaiian Eye Meeting, Kona Hawaii
- 2008 Conjunctiva Closure in Trabeculectomy, Glaucoma Video Symposium. Royal Hawaiian Eye Meeting, Kona Hawaii

- 2008 New Aqueous Drainage Devices Any Ready for Prime Time. Symposium on Glaucoma Drainage Devices. Moderators Jonathan Myers and David Greenfield. Annual Meeting American Glaucoma Society, Washington DC.
- 2008 Beautifying the Dinosaur: Improving on Trabeculectomy. ASCRS
 Glaucoma Day. Annual Meeting of the American Society of Cataract and
 Refractive Surgery. Chicago IL.
- 2008 Making it Right: Pearls for IOL Exchange. ASCRS Glaucoma Day. Annual Meeting of the American Society of Cataract and Refractive Surgery. Chicago IL:
- 2008 Moderator: Complications. ASCRS Glaucoma Day. Annual Meeting of the American Society of Cataract and Refractive Surgery. Chicago IL.
- 2008 Pseudoexfoliation My Favorite Mistake. ASCRS Glaucoma Day. Annual Meeting of the American Society of Cataract and Refractive Surgery. Chicago IL.
- 2008 Tube Pearls. ASCRS Glaucoma Day. Annual Meeting of the American Society of Cataract and Refractive Surgery. Chicago IL.
- 2008 Laser Trabeculoplasty. Which Laser? Which Glaucoma Types? When to Perform? Subspecialty Day – Glaucoma. World Ophthalmology Congress 2008. Hong Kong China
- 2008 Sutured Intraocular Lenses in Glaucomatous Eyes. Glaucoma and Cataract Management. World Ophthalmology Congress 2008. Hong Kong China
- 2008 ESCRS Live Surgery, Toric Implant, Berlin Germany
- 2008 Angle Closure Glaucoma: Better Surgical Management, Phillips Eye Institute, 2008 Ophthalmology Nightmares Conference, Minneapolis MN
- 2008 Glaucoma Surgery: Early & Late Complications & Pearls, Phillips Eye Institute, 2008 Ophthalmology Nightmares Conference, Minneapolis MN
- 2008 Trabeculectomy My Approach. Glaucoma Subspecialty Day. AAO, Atlanta GA

Participation in Symposia:-cont'd

- 2008 Spotlight on Glaucoma: The Medical and Surgical Care of the Glaucoma Patient Practical and Proven Approaches. Moderator. AAO, Atlanta GA
- 2008 Spotlight on Glaucoma: Presenter: Late IOL Dislocation-The Real Deal. AAO, Atlanta GA
- 2008 Academy Café: Glaucoma. Moderator. AAO, Atlanta GA
- 2008 Spotlight on Cataract Surgery: Cataract Complications Video Case Studies: Why? What Now? How? IOL in Absence of Capsule Support – Posterior Chamber Technique. AAO, Atlanta GA
- 2008 Up Close and Personal: Hobbies of Leading Ophthalmologists (formerly Lifestyles Symposium). AAO, Atlanta GA
- 2009 Glaucoma Mid-Winter Symposium 2009, Miami Meltdown: The Glaucoma International Hockey Cup. 1st Period: Decision Making in Glaucoma; 2nd Period: Glaucoma Treatment; 3rd Period: Pearls and the Future of Glaucoma. Miami FL
- 2009 Glaucoma Surgery 2009: New Twists Techniques and Results. Park City UT
- 2009 "Alley Oop" for a Dislocated IOL. Park City UT
- 2009 Late IOL Dislocation: The Real Deal. Park City UT
- 2009 An Ugly Case Scenario. Park City UT
- 2009 Late IOL Dislocation-The Real Deal. Caribbean Eye 2009. ACES/SEE Jamaica
- 2009 Phaco and Acute Angle Closure Glaucoma. Caribbean Eye 2009. ACES/SEE Jamaica
- 2009 Complications Avoidance & Management: Video Case Presentations, Moderator. ASCRS Glaucoma Day, San Francisco CA

- 2009 Tube Malpositioned in Visual Axis. ASCRS Glaucoma Day, San Francisco CA
- 2009 Acute Angle Closure Better Surgical Management. Speaker, Cape Cod MA
- 2009 Late IOL Dislocation The Real Deal. Speaker, Cape Cod MA
- 2009 Exfoliation Syndrome and Exfoliative Glaucoma (Presenter), "Cataract Surgery in Exfoliation Syndrome". World Glaucoma Congress, Boston MA
- 2009 Video Session Glaucoma Surgery (Presenter), "Trabectome". World Glaucoma Congress, Boston MA
- 2009 WGA-ASCRS Video Session Glaucoma & Cataract (Presenter), "Late IOL Dislocation: The Real Deal". World Glaucoma Congress, Boston MA
- 2009 Angle Closure Glaucoma A New Era of Effective Surgical Therapy. Western University, London Canada
- 2009 Cataract Surgical Challenges in Pseudoexfoliation Syndrome. OSN New York Symposium
- 2009 "Trabs and Tubes Let's Raise the Bar?" Surgical Glaucoma. OSN New York Symposium
- 2009 Glaucoma: New Surgical Options in Glaucoma. Chicago Ophthalmic Symposium: Prepare for 2010
- 2009 Complications and Challenging Cases, New Tricks and New Instrumentation: Video Presentations: IOL ExChange and Dislocated IOL Fix It to the Iris. Chicago Ophthalmic Symposium: Prepare for 2010
- 2010 What's New in Glaucoma Surgery? From Trabs to tubes to Canaloplasty and More. Park City UT
- 2010 IOL Exchange Things You Should Know. Park City UT
- 2010 Traumatic Cataract. Park City UT
- 2010 Posterior Polar Cataract. Park City UT
- 2010 Things to Put in the Bag: IOL's, Ring, and Segments. Faculty. Stephen S. Lane, MD Moderator. ASCRS Winter Update, Cancun Mexico

- 2010 Surviving Disaster: Practical Approaches to Deal with Anterior Segment Complications and Challenges. Faculty. Stephen S. Lane, MD Moderator. ASCRS Winter Update, Cancun Mexico
- 2010 Surgical Management of Angle-Closure Glaucoma. Garry P. Condon MD and Robert D. Fechter MD Moderators. AGS-ASCRS Joint Symposium. American Glaucoma Society, Naples FL
- 2010 Is Gonioscopy Enough? Point-Counter-Point. Surgical Management of Angle-Closure Glaucoma. AGS-ASCRS Joint Symposium. American Glaucoma Society, Naples FL
- 2010 Techniques for Cataract Surgery in the Angle Closure Eye with a Shallow Chamber. Surgical Management of Angle-Closure Glaucoma. AGS-ASCRS Joint Symposium. American Glaucoma Society, Naples FL
- 2010 Peer to Peer Discussion on the ExPRess Mini Shunt. AGS-ASCRS Joint Symposium. American Glaucoma Society, Naples FL
- 2010 Eye World Education, Surgical Innovations to Optimize Glaucoma Treatment, Program Chair, "2010 Trab: Re-call or Tune-up?" ASCRS, Boston MA
- 2010 "Where Are We with Laser Trabeculoplasty in 2010?" ASCRS Glaucoma Day. Annual Meeting of the ASCRS. Boston MA
- 2010 "Complications Avoidance & Management," Video Case Presentation. ASCRS Glaucoma Day. Annual Meeting of the ASCRS. Boston MA
- 2010 "Techniques for Cataract Surgery in the Eye with a Shallow Chamber." Annual Meeting of the ASCRS. Boston MA
- 2010 Glaucoma Cataract Conference Main Speaker. University of Louisville KY
- 2010 Phaco to Better Manage Acute Angle Closure. Atlantic Eye Symposium. Halifax Nova Scotia

2010	Pseudoexfoliation – Zonule Compromise and Counter Measures. Atlantic Eye Symposium. Halifax Nova Scotia
2010	Alcon's Live Surgery, Panelist. AAO. Chicago IL
2010	"Managing Complications of the Ex-PRESS." Subspecialty Day / Glaucoma 2010. AAO. Chicago IL
2010	Panel Discussion. AAO Cataract Spotlight Symposium AAO. Chicago IL
2010	Late Breakers Symposium. Chair AAO. Chicago IL
2010	Glaucoma Management:: Current and Future Treatment Options / Alcon. Miami Ophthalmic Symposium – Nurse & Technician Sessions. Miami FL
2010	Zonular Compromise / Alcon. Miami Ophthalmic Symposium. Miami FL
2010	Q&A Panel / Alcon. Miami Ophthalmic Symposium. Miami FL
2010	Video Symposium of IOL Malposition – Etiology & Treatment with Panel / Alcon. Miami Ophthalmic Symposium. Miami FL
2010	IOL Repositioning / Alcon. Miami Ophthalmic Symposium. Miami FL
2010	Glaucoma Surgery Update / Alcon. Miami Ophthalmic Symposium. Miami FL
2011	UGH! Single-Piece IOL Malposition. Getting the Red Out. Park City UT
2011	Update on Iris Fixation Technique, Video. Problem: Too Much Light. Park City UT
2011	"Post Traumatic Anterior Segment Reconstruct." Park City UT
2011	Trabeculectomy 2011 – Is There Still a Role? Park City UT
2011	Master the Shallow ACIn a Single Stroke, 3 Videos. Pressure RisingLosing Support. Park City UT
2011	Challenging IOL Dislocation Dilemmas. Park City UT
2011	Toric IOLs in Glaucoma Patients. Park City UT

- 2011 Zonule Compromise: New "Stuff" to Put in the Bag. Snowmass Ophthalmology Conference. Snowmass UT
- 2011 Breakfast with the Experts Conjuntival Closure. American Glaucoma Society 21st Annual Meeting. Dana Point CA
- 2011 National Master Club: "Don't Ice the Trab." / Alcon Canada. Scottsdale AZ
- 2011 Case Presentations & Panel Discussion. Using Imaging Technology in the Real World. ASCRS. San Diego CA
- 2011 Into the Abyss and Back: Video Complications Steps to Return from the Unknown. ASCRS. San Diego CA
- 2011 Ex-PRESS Glaucoma Filtration Device: Techniques and Pearls from the Experts. ASCRS. San Diego CA
- 2011 Acute Angle Closure Glaucoma: Better Surgical Management. 29th Annual Meeting-Update for the Comprehensive Ophthalmologist. Case Western Reserve University. Cleveland OH
- 2011 UGH? A Problematic Single-Piece IOL Syndrome. Kiawah 2011 Eye. Kiawah Island SC
- 2011 ExPRESS Glaucoma Filtration Device: Techniques and Pearls from the Experts / AAO Dinner Symposium. "Is Traditional Trabeculectomy Still Our Best Surgical Option?" AAO, Orlando FL
- 2011 Annual Meeting: Panelist. AAO, Orlando FL
- 2011 Spotlight on Cataract Complications: M&M Rounds Learning From My Mistakes / AAO, Orlando FL
- 2011 Dealing With the Traumatic Cataract It Hurts Just to Think of It. Chicago Ophthalmic Symposium, Chicago IL
- 2011 Why Am I Still Doing Trabs? All the New Hardware in Glaucoma Surgery. Chicago Ophthalmic Symposium, Chicago IL
- 2011 UGH! Chicago Ophthalmic Symposium, Chicago IL

- 2011 Complications and Challenging Cases, New Tricks and New Instrumentation: My Favorite Case of the Year. Video Presentation. Chicago Ophthalmic Symposium, Chicago IL
- 2011 Update on Glaucoma. ASORN Ophthalmic Symposium: Prepare for 2012, Chicago IL
- 2012 Traumatic Cataracts-New Technology for Better Results. Park City Utah
- 2012 A Positive Spin on the Negative and Other Dark Shadows. Evening Video Session. Park City Utah
- 2012 Complex Cataract Case Video. Park City Utah
- 2012 Can't Take the Pressure, Make My IOL Work, Moderator Glaucoma Surgery 2012. Park City Utah
- 2012 Negative Spin on the Positive Shadow of Doubt & Positive Gain. Park City Utah
- 2012 Complex Glaucoma Case Video. Park City Utah
- 2012 New Variations for Late IOL Dislocation. Park City Utah
- 2012 Glaucoma Grand Rounds: FACE OFF! Faculty. ASCRS Winter Update 2012. Riviera Maya Mexico
- 2012 Traditional Trabeculectomy: Still the Gold Standard?" Breakfast Symposium / Alcon, ASCRS Chicago IL
- 2012 Glaucoma Surgery: Advances You and Your Patients Will Appreciate, Moderator. Alcon ASCRS, Chicago IL
- 2012 Surgical Glaucoma Spotlight: Novel and Traditional, Co-Moderator. ASCRS Glaucoma Day 2012. Chicago IL
- 2012 Meanwhile, Refining the Time Tested...Doing What We Really Do...Better. Introduction ASCRS Glaucoma Day 2012. Chicago IL
- 2012 Eye World Corporate Mornings Program / MST. ASCRS 2012. Chicago IL

- 2012 Iris Suture Repair and IOL Fixation. ASCRS Glaucoma Day 2012. Chicago IL
- 2012 Pseudoexfoliation from A-Z. ASCRS Glaucoma Day 2012. Chicago IL
- 2012 Saving the Day: Falling One-Piece and 3-Piece IOLs. ASCRS Glaucoma Day 2012. Chicago IL
- 2012 ASCRS Town Hall: Glaucoma, Moderator. ASCRS, Chicago IL
- 2012 Intraocular Lens Exchange and Repositioning Techniques. ASCRS, Chicago IL
- 2012 Surgical Glaucoma, Faculty. Kiawah Eye 2012, Charleston SC
- 2012 Glaucoma Management: The New Era. Program Moderator / Alcon. Chicago IL
- 2012 Trabeculectomy 2012: Is There Still a Role? Loyola 5th Annual glaucoma Cataract Symposium, Chicago IL
- 2012 Acute Angle Closure Glaucoma: Better Surgical Management? Loyola 5th Annual Glaucoma Cataract Symposium, Chicago IL
- 2012 Glaucoma Case Presentations with Panel Discussion. Loyola 5th Annual Glaucoma Cataract Symposium, Chicago IL
- 2012 ExPRESS Glaucoma Management: The New Era. Alcon, Washington DC
- 2012 Surgical Approaches for Coexisting Cataract and Glaucoma. Vindico, Faculty Member CME Symposium, AAO, Chicago IL
- 2012 OSN New York 2012, Participation as a Faculty Member. Slack Incorporated, New York City NY
- 2012 Challenging Glaucoma Treatment Dilemmas, Chicago Ophthalmic Symposium, Chicago IL
- 2012 Glaucoma Surgical Update, Chicago Ophthalmic Symposium, Chicago IL

- 2012 Simplifying In-Bag IOL Dislocation and CTR/Management of Malpositioned IOLs, Chicago Ophthalmic Symposium, Chicago IL
- 2012 Complications and Challenging Cases, New Tricks and New Instrumentation: My Favorite case of the Year. Video Presentations. Jobson, Chicago Ophthalmic Symposium, Chicago IL
- 2013 "Glaucoma Dilemmas I." Cornea/Glaucoma. Park City Utah
- 2013 "Pseudoexfoliation Caveats and Controversies." Cataract Techniques. Park City Utah
- 2013 "What Not to Do, What Not to Do Next, and Then What Not to Do After That." Video Session. Park City Utah
- 2013 "Glaucoma Dilemmas II." Glaucoma/Complex Cases. Park City Utah
- 2013 "Cataract "Plus" for the Glaucoma Patient: Who's on Board?" Glaucoma/Complex Cases. Park City Utah
- 2013 "IOL Exchange...and Exchange." Video Session. Park City Utah
- 2013 "Subluxed IOL: Tweaking Your Technique." Video Session. Park City Utah
- 2013 "Zonule Compromise and Counter Measures." Controversies in Ophthalmology. 81st Midwinter Conference. Los Angeles CA
- 2013 "The Cataract Surgeon's Options to Help Control Glaucoma."
 Controversies in Ophthalmology. 81st Midwinter Conference. Los Angeles CA
- 2013 "Acute Angle Closure Better Surgical Management." Controversies in Ophthalmology. 81st Midwinter Conference. Los Angeles CA
- 2013 "The Cataract Surgeon's Options to Help Control Glaucoma." Glaucoma and Cataract Visiting Professor Dinner. University of Manitoba, Winnipeg Canada

- 2013 "Glaucoma Case Dilemmas What Can We Learn?" Glaucoma and Cataract Visiting Professor Morning. University of Manitoba, Winnipeg Canada
- 2013 "Acute Angle Closure Better Surgical Management." Glaucoma and Cataract Visiting Professor Morning. University of Manitoba, Winnipeg Canada
- 2013 Cataract Surgery: Techniques and Technology Updates Phaco the Rock: My Take. National Master Club. San Diego CA
- 2013 Cataract Surgery: Challenging Cases What not to do, and what not to do next.....National Master Club. San Diego CA
- 2013 Glaucoma Update: Surgical and Medical Cataracts and Glaucoma. National Master Club. San Diego CA
- 2013 Glaucoma Update: Surgical and Medical Pseudoexfoliation Surgical Issues. National Master Club. San Diego CA
- 2013 Glaucoma Update: Surgical and Medical ACG Case. National Master Club. San Diego CA
- 2013 Surgical Glaucoma Spotlight: Part III Back to Basics. "Fornix-based Closure." ASCRS Glaucoma Day. San Francisco CA
- 2013 Angle Closure Symposium: A to Z Co-Moderator, ASCRS Glaucoma Clinical Committee. San Francisco CA
- 2013 Angle Closure Symposium: A to Z Speaker, "Aqueous Misdirection or Malignant Glaucoma and other Challenges." ASCRS Glaucoma Clinical Committee. San Francisco CA
- 2013 From Good to Great: Surgical Pearls Faculty, Panelist (Video-Based Section), Kiawah 2013 Eye. Kiawah Island SC
- 2013 Glaucoma Panelist, Kiawah 2013 Eye. Kiawah Island SC

- 2013 "Out of MIND, Out of SIGHT: Avoiding the Dire Consequences of Nonadherence to Glaucoma Therapy" – VINDICO Medical Education. Faculty Member for a CME Symposium, Kiawah 2013 Eye. Kiawah Island SC
- 2013 "Advancing Filtration Surgery: Surgical Pearls and Clinical Benefits" Program Moderator / Alcon. Boston MA
- 2013 "Managing Compromised Zonules" OSN New York, Waldorf Astoria. New York NY
- 2013 "Does This Patient Need Glaucoma Surgery?" OSN New York, Waldorf Astoria. New York NY
- 2013 Case Conference, Panelist OSN New York, Waldorf Astoria. New York NY
- 2013 Hot Topics in Glaucoma, Panelist OSN New York, Waldorf Astoria. New York NY
- 2013 Glaucoma 2013: "The Future is Now" Panelist. AAO New Orleans LA
- 2013 Cataract Poster Tour Leader. Symposia Chair. AAO New Orleans LA
- 2014 "Refining Late In-the-bag IOL Positioning." Reaching New Peaks 2014. Park City Utah
- 2014 "MITS" (Minimally Invasive Trabeculectomy Surgery). Reaching New Peaks 2014. Park City Utah
- 2014 "Stress Free Phaco In Pseudoexfoliation." Reaching New Peaks 2014. Park City Utah
- 2014 "The Girl, the Ring, Everything." Video. Reaching New Peaks 2014. Park City Utah
- 2014 "Video Symposium of Challenging Cases and Complications Management During Cataract Surgery." Faculty, Case Presentation. ASCRS ASOA Winter Update 2014. Fajardo Puerto Rico
- 2014 "What's New in Technology." Faculty, Case Presentation. ASCRS ASOA Winter Update 2014. Fajardo Puerto Rico

- 2014 "Rapid F-Eye-R: You Make the Call." Faculty. ASCRS ASOA Winter Update 2014. Fajardo Puerto Rico
- 2014 "Café Style Discussion: 10 Years Down the Road What's Still on the "To-do" List." Moderator. ASCRS Glaucoma Day 2014. Boston MA
- 2014 "Dislocated IOL in Glaucoma Patient." Glaucoma Lead. ASCRS Glaucoma/Retina Joint Symposium. Boston MA
- 2014 Paper Session Title: 3-K Glaucoma. Moderator. ASCRS ASOA. Boston MA
- 2014 "Cataract Surgery in Pseudoexfoliation Syndrome." Symposium, Managing Refractive Issues in Glaucoma Patients. ASCRS ASOA. Boston MA
- 2014 "Express Glaucoma Surgery." Kiawah 2014 Eye. Kiawah Island SC
- 2014 "Small Pupil Surgery." Kiawah 2014 Eye. Kiawah Island SC
- 2014 "The Dislocated IOL: New Frontiers." 67th Annual Meeting and National Scientific Meeting. White Sulphur Springs WV
- 2014 "MIGS: Update for Cataract Surgeons." 67th Annual Meeting and National Scientific Meeting. White Sulphur Springs WV
- 2014 "Pseudoexfoliation: Something for Everyone." 67th Annual Meeting and National Scientific Meeting. White Sulphur Springs WV
- 2014 "Traumatic Cataract: Stay in Control." 67th Annual Meeting and National Scientific Meeting. White Sulphur Springs WV
- 2014 "Glaucoma Dilemmas." (interactive). 67th Annual Meeting and National Scientific Meeting. White Sulphur Springs WV
- 2014 "MITS: Minimizing the Invasiveness of Transscleral Glaucoma Surgery." 67th Annual Meeting and National Scientific Meeting. White Sulphur Springs WV
- 2014 "Refined Approaches to IOL Dislocation." Cataracts / New Technology. Winter Ophthalmic Symposium. New York City NY

- 2014 "Surviving Pseudoexfoliation." Glaucoma. Winter Ophthalmic Symposium New York City NY
- 2014 "MIGS Are We There Yet?" Glaucoma. Winter Ophthalmic Symposium New York City NY
- 2014 "You Make the Call" (Intraoperative Management Challenges). Video Presentations: Complications // Challenging Cases // Pearls. Winter Ophthalmic Symposium. New York City NY
- 2014 Cataracts / New Technology. Faculty. Winter Ophthalmic Symposium. New York City NY
- 2014 Choices of IOLs in Current Cataract Surgery How I do It..... Faculty. Winter Ophthalmic Symposium. New York City NY
- 2015 "MIGS": Are We There Yet? It's Time to Wake UP...and Bring the Pressure Down. 2015 Innovative Techniques & Controversies in Ophthalmology. Park City Utah
- 2015 "You Make the Call." Glaucoma Panel. It's Time to Wake Up...and Bring the Pressure Down. 2015 Innovative Techniques & Controversies in Ophthalmology. Park City Utah
- 2015 "Posterior Polar a Backward View." Moderator Video Session. 2015 Innovative Techniques & Controversies in Ophthalmology. Park City Utah
- 2015 "Surviving Pseudoexfoliation." Fun with Femto and Phaco. 2015 Innovative Techniques & Controversies in Ophthalmology. Park City Utah
- 2015 "You Make the Call." Video Session. 2015 Innovative Techniques & Controversies in Ophthalmology. Park City Utah
- 2015 "Refined Approaches to IOL Dislocation." ... And It's Just That Easy. 2015 Innovative Techniques & Controversies in Ophthalmology. Park City Utah
- 2015 "The Surgical Management of Primary and Secondary Pigment Dispersion Glaucoma." (Similarities and Differences from Poag) Video Case Studies. ASCRS Glaucoma Day 2015. San Diego CA

- 2015 Café Style Discussion: Medical Management of Glaucoma-Best Practices When the Real World Gets in the Way. Moderator. ASCRS Glaucoma Day 2015. San Diego CA
- 2015 "Complications and a "Reay of Hope." Video Case. Moderator. ASCRS Glaucoma Day 2015. San Diego CA
- 2015 "Glaucoma Dilemmas." Faculty. Kiawah Eye 2015. Charleston SC
- 2015 "Posterior Polar Cataract Do's and Don'ts." Challenges in Cataract Surgery. 2015 Winter Ophthalmic Symposium. New York City NY
- 2015 "IOL Dislocation." Postoperative Care and Complications. 2015 Winter Ophthalmic Symposium. New York City NY
- 2015 "MIGS." Glaucoma and Other Challenges. 2015 Winter Ophthalmic Symposium. New York City NY
- 2015 "The Broken Pupil." Glaucoma and Other Challenges. 2015 Winter Ophthalmic Symposium. New York City NY
- 2015 "Tougher Than the Rest Ultimate IOL Repositioning." Video Presentation 2015 Winter Ophthalmic Symposium. New York City NY
- 2016 "MIGS": 101 More on Getting It Right. When You Just Can't Take the Pressure. 2016 Innovative Techniques & Controversies in Ophthalmology Park City UT
- 2016 "You Make the Call." Glaucoma Panel. When You Just Can't Take the Pressure. 2016 Innovative Techniques & Controversies in Ophthalmology. Park City UT
- 2016 Video Session. Moderator. 2016 Innovative Techniques & Controversies in Ophthalmology. Park City UT
- 2016 "IOL Dislocation Newer Tricks." Making Lemonade from Lemons -Challenging Cases and Help from New Technology. 2016 Innovative Techniques & Controversies in Ophthalmology. Park City Utah
- 2016 "Tougher than the Rest." Video Session. All Things IOL's "Let Me Count the Ways." 2016 Innovative Techniques & Controversies in Ophthalmology Park City Utah

- 2016 "My Leak-Proof Closure #1." Surgical Faceoff: Let Me Show You How to Do It Better. Surgery Day. American Glaucoma Society 2016 Annual Meeting. Fort Lauderdale FL
- 2016 Café Style Discussion: EHR Moderator. Glaucoma Day. ASCRS ASOA New Orleans LA
- 2016 Complications and a "Reay of Hope," Moderator, Video Case. Glaucoma Day. ASCRS ASOA. New Orleans LA
- 2016 Glaucoma: MIGS. ASCRS Paper Session. Moderator. ASCRS ASOA New Orleans LA
- 2016 Intraluminal Nd: YAG Treatment of Patients with an IOP Rise After Glaucoma Device Implantation. Paper Sessions. ASCRS ASOA New Orleans LA
- 2016 MIGS: How to Incorporate Safer Surgery–Technique, Patient Selection and Enhanced Patient Outcomes. Panelist. ASCRS ASOA. New Orleans LA
- 2016 Stepping Up Your Game: Going from Good to Great: Pearls to Use in Your Practice. Dislocated IOL? New Strings Attached. Kiawah Eye 2016. Kiawah Island SC
- 2016 Glaucoma, Moderator, Kiawah Eye 2016, Kiawah Island SC
- 2016 Newer Tricks for Intraocular Lens Dislocation in Exfoliation. Kiawah Eye 2016. Kiawah Island SC
- 2016 Glaucoma, Video Case Presentation. Kiawah Eye 2016. Kiawah Island SC
- 2017 "Glaucoma Meds New Targets and Modes." 2017 Surgical Summit. Park City Utah
- 2017 "How and When to Use a Trabecular Meshwork Stent." 2017 Surgical Summit. Park City Utah
- 2017 "New MIGS Options." 2017 Surgical Summit. Park City Utah

- 2017 Roundtable: "Glaucoma Surgery: Sorting Out Options for the Comprehensive Ophthalmologist." Moderator. 2017 Surgical Summit. Park City Utah
- 2017 General Session: Video Triumphs and Tragedies I. "Fixation Frustration." 2017 Surgical Summit. Park City Utah
- 2017 General Session: IOLs: New Advances, Same Old Problems. "Dislocated IOLs Hoops and Loops." 2017 Surgical Summit. Park City Utah
- 2017 General Session: Video Triumphs and Tragedies II. "Surprise Package."
 2017 Surgical Summit. Park City Utah
- 2017 Café Style Discussion. Moderator. ASCRS Glaucoma Day. Los Angeles CA
 - 2017 Video Case Presentations: Complications and a "Reay of Hope." Panelist. ASCRS Glaucoma Day. Los Angeles CA
 - 2017 Suture Fixation: Is There Something Better. Kiawah Eye 2017. Kiawah Island SC
 - 2017 Glaucoma iStent For Me: When and How. Kiawah Eye 2017. Kiawah Island SC
 - 2017 Glaucoma Pseudoexfoliation IOL Dislocation: Evolving Fixation Surgery. Kiawah Eye 2017. Kiawah Island SC
 - 2017 Fixation Frustration. Kiawah Eye 2017. Kiawah Island SC
 - 2017 Hot Topics in Glaucoma Case Presentation. Kiawah Eye 2017. Kiawah Island SC
 - 2017 "Posterior Polar: Do's & Don'ts." 16 Annual Downeast Ophthalmology Symposium – Practical Solutions in Ophthalmology. Bar Harbor ME
 - 2017 "Late IOL Dislocation: Evolving Fixation Surgery." 16th Annual Downeast Ophthalmology Symposium Practical Solutions in Ophthalmology. Bar Harbor ME

Participation in Symposia:-cont'd

2017 "Surgical Triumphs and Tragedies: A Video Potpourri." (with Dr. Ayres) 16th Annual Downeast Ophthalmology Symposium – Practical Solutions in Ophthalmology. Bar Harbor ME

Advisory Boards:

- 2010 Allergan Surgical Innovations Advisory Board Meeting. Phoenix AZ
- 2010 Glaucoma Management: The Next Era. Glaucoma Advisory Board Meeting / Incision. Chicago IL
- 2010 New Techniques in Outflow Surgery: Overview and Current Limitations.

 New Directions in the Surgical Management of Glaucoma / Allergan. San Francisco CA
- 2010 Internal (Canal) Shunts. New Directions in the Surgical Management of Glaucoma / Allergan. San Francisco CA
- 2010 Closure Technique / Alcon. Glaucoma Management: The Next Era. Dallas TX
- 2010 Glaucoma and the Toric IOL / Alcon. Glaucoma Management: The Next Era. Dallas TX
- 2010 Panel Discussion / Alcon. Glaucoma Management: The Next Era. Dallas TX
- 2011 Glaucoma Management: The New Era Educational Program / Alcon. Fort Lauderdale FL
- 2011 Glaucoma and the Toric IOL. Glaucoma Management: The New Era / Alcon. Toronto Canada
- 2011 Panel Discussion. Glaucoma Management: The New Era / Alcon. Toronto Canada
- 2011 Roundtable Breakout Discussions: Ex-PRESS Glaucoma Filtration Device. Yellow Group. Glaucoma Management: The New Era / Alcon. Toronto Canada

Advisory Boards:-cont'd

Asheville, NC

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2011 Improving Predictability in Filtration Surgery – ExPRESS Glaucom								
	Filtration Device Breakfast. Speakers Lecture – ExPRESS Latin American							
2011 Allergan Glaucoma Vision for the Future Advisory Board Meeting. York City NY	Allergan Glaucoma Vision for the Future Advisory Board Meeting. New York City NY							
2012 Advanced Glaucoma Surgery Advisory Council. Alcon, Philadelphi	a PA							
2012 Glaucoma Today Editorial Advisory Board. AAO, Chicago IL								
2012 Rescula Regional Advisory Board, SUCAMPO Pharma Americas, Philadelphia PA								
2013 Participation at Alcon's Glaucoma Speaker Training. Dallas TX								
2015 Participation at Alcon's Glaucoma Speaker Training. Coral Gable	Participation at Alcon's Glaucoma Speaker Training. Coral Gable FL							
2015 Alcon Glaucoma Advisory Summit. Boston MA	Alcon Glaucoma Advisory Summit. Boston MA							
2015 Roundtable Advisory Session and NIBR Tour. Novartis Institute of Medical Research	Bio/							
2016 Allergan Round Table Discussion. ASCRS ASOA. New Orleans L	. A							
2016 Allergan XEN 45 Advisory Board Meeting. ASCRS ASOA. New Or	eans LA							
2016 Alcon Advisory Meeting – Engage to Further Alcon's Mission: New Enhance Sight and Improve People's Lives. Fort Worth TX	Ways to							
2017 Hydrus Advisory Panel Meeting. Ivantis Inc. ASCRS. Los Angeles	s CA							
2017 Alcon Surgical Glaucoma Team, Express Advisory Board. ASCRS Los Angeles CA	ASOA							
2017 Georgia Ophthalmology Society Annual Meeting. Keynote speaker Pseudoexfoliation, Complex Cataract Surgery. Amelia Island, FL	,							

2019 North Carolina Eye Society Annual Meeting. Keynote speaker, Pseudoexfoliation, Complex Cataract Surgery, Malignant Glaucoma.

Instruction Courses:

- 1987 "Contemporary Glaucoma", Course director Richard J. Simmons.
 American Academy of Ophthalmology Annual Meeting, Dallas, TX
- 1987 "Practical Aspects of Photocoagulation", Course Instructor, Massachusetts Eye and Ear Infirmary, Boston, MA
- 1988 "Solving Glaucoma Problems", Course Instructor, Massachusetts Eye and Ear Infirmary, Boston, MA
- 1992 "Filtering Surgery in Conjunction with Cataract Surgery, Use of Mitomycin", Advanced Phacoemulsification Course (Alcon Surgical), Chicago, IL
- 1993 "Co-existent Cataract and Glaucoma Options and Incisions", Advanced Phacoemulsification Course, (Alcon Surgical), Philadelphia, PA
- 1993 "Special Considerations in Combined Surgery Antimetabolites",
 Advanced Phacoemulsification Course, (Alcon Surgical), Philadelphia, PA
- 1994 "Options, Incisions and Pearls for Managing Coexistent Glaucoma and Cataract", Course Director, American Academy of Ophthalmology Annual Meeting, San Francisco, CA
- 1995 "Options, Incisions, and Pearls for Managing Coexistent Glaucoma and Cataract", Course Director, American Academy of Ophthalmology Annual Meeting, Atlanta, GA
- 1996 "Options, Incisions and Pearls for Managing Coexistent Glaucoma and Cataract", Course Director, American Academy of Ophthalmology Annual Meeting, Chicago, IL
- 1996 "Advanced Phacoemulsification and PhacoRefractive Results", Faculty, Sponsored by Alcon Surgical, Rochester, NY
- 1997 "Advanced Concepts in Phacoemulsification", Faculty, Alcon Surgical Ophthalmic Symposium, Baltimore, MD
- 1997 Glaucoma Surgical Skills Transfer Course. Course director George Cioffi. American Academy of Ophthalmology Annual Meeting, San Francisco CA
- 1998 "Advanced Concepts in Phacoemulsification", Faculty, Alcon Surgical Ophthalmic Symposium, Chicago IL

- 1999 Phacoemulsfication in the Previously Filtered Eye, Sponsored by Alcon Surgical, San Antonio, TX
- 1999 Glaucoma Surgery New Trends & New Complications, Sponsored by Alcon Surgical, San Antonio, TX
- 2001 Diagnosis and management of non-infectious epiphora. Course director Kim Cockerham. Annual Meeting of the American Academy of Ophthalmology, New Orleans LA
- 2002 Advanced Concepts in Anterior Segment Surgeries. Course director Stephen Lane. San Antonio TX
- 2002 Hypotony got you down? Effective surgical management of late blebrelated hypotony. Course director. Annual Meeting of the American Academy of Ophthalmology, Orlando FL
- 2002 Diagnosis and management of non-infectious epiphora. Course director Kim Cockerham. Annual Meeting of the American Academy of Ophthalmology, Orlando FL
- 2002 Managing the patient with both cataract and glaucoma. Course directors Sam Masket and Alan Crandall. Annual Meeting of the American Academy of Ophthalmology, Orlando FL
- 2003 Phaco Foldables and Refractive Results. Course director Alan Crandall. Park City UT
- 2003 The McCannel Suture revisited Applications in managing IOL complications and aphakia. Course director. Annual meeting of the American Society of Cataract and Refractive Surgery, San Francisco CA
- 2003 UPMC Annual Resident Phacoemulsification Course Faculty
- 2003 Hypotony got you down? Effective surgical management of late blebrelated hypotony. Course director. Annual Meeting of the American Academy of Ophthalmology, Anaheim CA
- 2003 Managing the patient with both cataract and glaucoma. Course directors Sam Masket and Alan Crandall. Annual Meeting of the American Academy of Ophthalmology, Anaheim CA

- 2004 Phaco Foldables and Refractive Results. Course director Alan Crandall. Park City UT
- 2004 Postoperative IOL dislocation and decentration management. Ike Ahmed MD Course director. Annual Meeting of the ASCRS, San Diego CA
- 2004 McCannel's Suture and Iris Support: Solving Aphakia and IOL Dislocation. Course director. Annual Meeting of the ASCRS. San Diego CA
- 2004 Managing the Patient with Both Cataract and Glaucoma. Sam Masket MD and Alan Crandall MD course directors. Annual meeting of the AAO, New Orleans LA
- 2004 Hypotony Got You Down? Effective Surgical Therapy for Late Post Filtration Hypotony. Course director. Annual Meeting of the AAO, New Orleans LA
- 2005 Innovations in Iris Fixation: Solving Aphakia and IOL Dislocation. Course director. Annual Meeting of the ASCRS, Washington DC
- 2005 Postoperative IOL dislocation and Decentration. Ike Ahmed MD, Course director. Annual Meeting of the ASCRS, Washington DC
- 2005 Effective Surgical Therapy for Late Post-Filtration Hypotony. Annual Meeting of the AAO, Chicago IL
- 2005 Combined Phaco and Glaucoma Surgery. Annual Meeting of the AAO, Chicago IL
- 2005 Glaucoma filtration surgery for residents. (skills transfer) Annual meeting of the AAO, Chicago IL
- 2006 Innovations in Iris Fixation: Solving Aphakia and IOL dislocation. Annual Meeting of the American Society of Cataract and Refractive Surgery, San Francisco CA
- 2006 Postoperative IOL Dislocation and Decentration Management. Annual Meeting of the American Society of Cataract and Refractive Surgery, San Francisco CA

- 2006 Capsular Tension Rings. (skills transfer) Annual Meeting of the American Society of Cataract and Refractive Surgery, San Francisco CA
- 2006 Iris Abnormalities: Techniques and Devices for Surgical Reconstruction. Annual Meeting of the American Society of Cataract and Refractive Surgery, San Francisco CA
- 2006 Glaucoma Filtration Surgery for Residents. (Skills Transfer) Annual Meeting of the AAO, Las Vegas NV
- 2006 Combined Phaco and Glaucoma Surgery. Annual Meeting of the AAO, Las Vegas NV
- 2006 The Ultimate Guide to Capsular Tension Ring Use. Annual Meeting of the AAO, Las Vegas NV
- 2007 Capsular Tension Rings and Techniques for Capsular-Zonular Stabilization. Annual Meeting of the American Society of Cataract and Refractive Surgery, San Diego CA
- 2007 Postoperative IOL Dislocation and Decentration Management. Annual Meeting of the American Society of Cataract and Refractive Surgery, San Diego CA
- 2007 Innovations in Iris Fixation: Solving Aphakia and IOL Dislocation. Annual Meeting of the American Society of Cataract and Refractive Surgery, San Diego, CA
- 2007 Capsular Tension Rings. Laboratory Skills Transfer Course. Annual Meeting of the American Society of Cataract and Refractive Surgery, San Diego CA
- 2007 "IOL Fixation in the Absence of Capsule Support". Advanced Phacoemulsification. Course Director William Fishkind. AAO, New Orleans LA
- 2007 An Innovative Approach to Iris Fixation of an IOL Without Capsular Support. AAO, New Orleans LA

2007	and Alan Cradall. AAO, New Orleans LA
2007	Advanced Phacoemulsification (Wet Lab). AAO, New Orleans LA
2007	Combined Phaco and Glaucoma Surgery (Wet Lab). AAO, New Orleans LA
2007	Glaucoma Filtration Surgery (Wet Lab) for Ophthalmology Residents. AAO, New Orleans LA
2008	Management of Malpositioned IOL's. Course Director Alan Crandall. Annual Meeting of the American Society of Cataract and Refractive Surgery.
2008	Advanced Phacoemulsification – Iris Suture IOL. AAO, Atlanta GA
2008	Advanced Phacoemulsification (Lab). AAO, Atlanta GA
2008	Glaucoma Filtration Surgery Lab for Ophthalmology Residents. AAO, Atlanta GA
2008	An Innovative Approach to Iris Fixation of an IOL Without Capsular Support. Co-Instructor. AAO, Atlanta GA
2008	Combined Phaco and Glaucoma Surgery – Phaco for Acute Angle Closure. AAO, Atlanta GA
2008	Combined Phaco and Glaucoma Surgery (Lab). AAO, Atlanta GA
2009	Phaco for Acute Angle-Closure Glaucoma. Annual Course - Current Concepts in Ophthalmology, Vail CO
2009	Zonule Complexities and Counter Measures. Annual Course – Current Concepts in Ophthalmology, Vail CO
2009	IOL Exchange – Things You Should Know. Annual Course – Current Concepts in Ophthalmology, Vail CO
2009	Advanced Phacoemulsification, Instructor. AAO, San Francisco CA
2009	Anterior Segment Surgical Challenges, Panelist. AAO, San Francisco CA

- 2009 Combined Phaco and Glaucoma Surgery. Phaco for Managing Angle Closure Glaucoma, Instructor. AAO, San Francisco CA
- 2009 Academy Café: Glaucoma Chair. AAO, San Francisco CA
- 2009 Glaucoma Filtration Surgery Lab for Ophthalmology Residents, Instructor. AAO, San Francisco CA
- 2009 Spotlight on Pseudoexfoliation: New Pearls from Glaucoma and Cataract Experts, Presenter. Advances in Glaucoma Surgery: Any Help in Pseudoexfoliation? AAO, San Francisco CA
- 2009 Innovative Approach to Iris Fixation of an IOL Without Capsular Support, Instructor. AAO, San Francisco CA
- 2010 Intraocular Lens Exchange and Repositioning Techniques, ASCRS Course Faculty. Annual Meeting of the American Society of Cataract and Refractive Surgery. Boston MA
- 2010 Glaucoma Management: ExPRESS Glaucoma Mini-Shunt Training / Incision. Chicago IL
- 2010 Advanced Refractive Cataract Surgery and Anterior Segment Reconstruction Skills Transfer Course. Suture Fixation of IOLS. AAO, Chicago IL
- 2010 Advanced Phacoemulsification LAB162C, Instructor. AAO, Chicago IL
- 2010 An Innovative Approach to Iris Fixation of an IOL Capsular Support: Hands On and Practical, Instructor. AAO, Chicago IL
- 2011 Hanging It on the Iris: Suture Solutions to Anterior Segment Enigmas. ASCRS-ASOA. San Diego CA
- 2011 Intraocular Lens Exchange and Repositioning Techniques. ASCRS. San Diego CA
- 2011 Iris Repair Technique (Siepser). ASCRS. San Diego
- 2011 Dislocated IOL's. ASCRS. San Diego

- 2011 ExPRESS Training Meeting / Alcon. New York City NY
- 2011 Alcon Live Surgery Broadcast / Faculty Panel. AAO, Philadelphia PA (Orlando FL)
- 2011 Managing Angle-Closure Glaucoma With Crystalline Lens Removal and Adjunctive Procedures. Instructor AAO, Orlando FL
- 2011 Advanced Refractive Cataract Surgery and Anterior Segment Reconstruction. Instructor AAO, Orlando FL
- 2011 An Innovative Approach to Iris Fixation of an IOL Without Capsular Support: Hands On and Practical. Instructor AAO, Orlando FL
- 2011 Advanced Refractive Cataract Surgery and Anterior Segment Reconstruction. Lab Instructor AAO, Orlando FL
- 2011 Glaucoma Filtration Surgery Lab for Ophthalmology Residents. Lab Instructor AAO, Orlando FL
- 2012 Challenging Cases for the Comprehensive Clinician: A Multi-Disciplinary Approach to Management of Complex Cases. Faculty, ASCRS Winter Update 2012. Riviera Maya Mexico
- 2012 Glaucoma Management Pearls: From Every Day Decisions to Advancing Surgery. Faculty, ASCRS Winter Update 2012. Riviera Maya Mexico
- 2012 Glaucoma Hardware 2012: So Why As I Still Doing Trabs?? Optometry CE Course. Cranberry PA
- 2012 Skills Transfer Lab STS3: Iris Suture. ASCRS Glaucoma Day 2012. Chicago IL
- 2012 Iris Repair Technique (Siepser). ASCRS. Chicago IL.
- 2012 Dislocated IOL's. ASCRS. Chicago IL
- 2012 Video Grand Rounds: Management of Cataract and Refractive Surgery What I Would Have Done Differently. Panelist Kiawah Eye 2012. Charleston SC

- 2012 Dinner Program / Faculty, Glaucoma Surgery: Filtering Out the Variables. AAO. Chicago IL
- 2012 Advanced Refractive Cataract Surgery and Anterior Segment Reconstruction. Instructor. AAO. Chicago IL
- 2012 An Innovative Approach to Iris Fixation of an IOL Without Capsular Support: Hands-On and Practical. Instructor. AAO. Chicago IL
- 2012 Glaucoma Surgical Lab for Ophthalmology Residents. Instructor. AAO Chicago IL
- 2012 Managing Angle Closure Glaucoma with Crystalline Lens Removal and Adjunctive Procedures. Instructor. AAO. Chicago IL
- 2013 Iris Repair Technique. ASCRS. San Francisco CA
- 2013 Dislocated IOL's. ASCRS. San Francisco CA
- 2013 Tris Suture Skills. Co-Instructor ASCRS. San Francisco CA
- 2013 Transfer Session Lab / Steven Siepser. ASCRS. San Francisco CA
- 2013 Advanced Refractive Cataract Surgery and Anterior Segment Reconstruction. Instructor AAO. New Orleans LA
- 2013 Managing Angle-Closure Glaucoma With Crystalline Lens Removal and Adjunctive Procedures. Instructor AAO. New Orleans LA
- 2013 Advanced Refractive Cataract Surgery and Anterior Segment Reconstruction. Instructor LAB AAO. New Orleans LA
- 2013 Iris Suture Fixation of IOLs. AAO. New Orleans LA
- 2013 Glaucoma Surgical Lab for Ophthalmology Residents. Instructor AAO. New Orleans LA
- 2014 Management of Complex Cataract. Instructor. ASCRS ASOA Winter Update 2014. Farjardo Puerto Rico
- 2014 Lecture Grand Rounds. Faculty Storm Eye Institute MUSC. Charleston Ophthalmology Society. Charleston SC

Instruction Courses:-cont'd

- 2014 Iris Suture Repair and IOL Fixation. Faculty. Didactic Course, Dr. Steven Siepsen. ASCRS ASOA. Boston MA
- 2014 Iris Suture Skills Transfer Session Lab (Dr. Steven Siepsen).
 Co-Instructor. ASCRS ASOA. Boston MA
- 2014 Intraocular Lens Exchange and Repositioning Techniques. ASCRS Course ASCRS ASOA. Boston MA
- 2015 Iris Suturing Techniques. Faculty. ASCRS Clinical Course. ASCRS ASOA. San Diego CA
- 2015 Iris Suture. Skills Lab. Co-Instructor. ASCRS ASOA. San Diego CA
- 2015 Intraocular Lens Exchange and Repositioning Techniques. Faculty. ASCRS Clinical Course. ASCRS ASOA. San Diego CA
- 2016 Iris Suturing Techniques. Faculty. ASCRS ASOA. New Orleans LA
- 2016 STS-6 Iris Suture, Skills Transfer Lab. Co-Instructor. ASCRS ASOA New Orleans LA
- 2016 Training Mission. Teaching and training the KATH Glaucoma surgeons at Komfo Anoyoke Teaching Hospital. Kumasi, Ghana
- 2017 "Iris-Suturing Techniques." Co-Instructor. ASCRS ASOA. Los Angeles CA
- 2017 "Iris Suture" Skills Transfer Labs. Co-Instructor. ASCRS ASOA. Los Angeles CA

Presentations:

- 1987 "Current Adjuncts in The Management of the Filtration Bleb", Department of Ophthalmology, University of Western Ontario, London, Ontario
- 1988 "Post-Operative Adjuncts in Filtration Surgery", Department of Ophthalmology, Memorial University of Newfoundland, St. John's, Newfoundland, Canada
- 1988 "Glaucoma", Guest Lecturer for Lions Club, Pittsburgh, PA

- 1988 "Argon Laser Suture Lysis Following Trabeculectomy", Alumnus, Annual Resident's Day, Department of Ophthalmology, University of Western Ontario, London, Ontario, Canada
- 1988 "Post-Operative Adjuncts in Filtration Surgery", Department of Ophthalmology, St. Francis Medical Center, Pittsburgh, PA
- 1990 "An Approach to the Glaucoma Patient", Beaver Valley Optometric Society
- 1991 "Associated Ocular Trauma", Participant, Contemporary management of Facial Trauma and Concomitant Injuries, Allegheny General Hospital, Pittsburgh, PA
- 1991 "Glaucoma", Lecture to the Pittsburgh Ophthalmology Society for Ophthalmic Medical and Office Personnel
- 1992 "Glaucoma Applanation and Indentation Tonometry", Guest Speaker, Pittsburgh Ophthalmology Society Annual Meeting for Ophthalmic Medical and Office personnel, Pittsburgh, PA
- 1992 "Particulate Glaucoma", Department of Ophthalmology, University of Pittsburgh, Pittsburgh, PA
- 1992 "Management of Glaucoma in Anterior Segment Disease", Participant, Cornea/Anterior Segment Update, Quarterly Visiting Professor Series, Allegheny General Hospital, Pittsburgh, PA
- 1992 "A General Approach to the Glaucoma Patient", Pennsylvania Optometric Association, Annual Congress Meeting, Champion, PA
- 1992 "Anterior Segment Evaluation in the Open Angle Glaucoma Patient", Pennsylvania Optometric Association, Annual Congress Meeting
- 1992 "Pitfalls in Automated Perimetry", Pennsylvania Optometric Association, Annual Congress Meeting
- 1993 "Glaucoma", Presentation at Ophthalmic Grand Rounds for Ophthalmic Medical and Office Personnel, Pittsburgh Ophthalmology Society
- 1993 "Exfoliation Syndrome", Department of Ophthalmology, University of Pittsburgh, Pittsburgh, PA

- 1993 "Mitomycin in Combined Surgery", Nantucket Glaucoma Annual Meeting, Nantucket, MA
- 1993 "Filtering Surgery with Mitomycin: A Case Presentation", Guest Speaker, Association of Technical Personnel in Ophthalmology, Chicago, IL
- 1995 "Co-Existent Cataract and Glaucoma: Options, Incisions and Pearls", Ivey Institute of Ophthalmology, University of Western Ontario, London, Ontario, Canada
- 1995 "Mitomycin in Combined Cataract and Glaucoma Surgery", Ivey Institute of Ophthalmology, University of Western Ontario, London, Ontario, Canada
- 1996 "Coexistent Glaucoma and Cataract -- Options, Incisions and Pearls", West Virginia Ophthalmology Society for Otsuka America Pharmaceutical, Inc., Charleston, WV
- 1996 "Glaucoma Surgery New Trends and New Complications", Current Trends in Optometry Conference, Robert Morris College, Pittsburgh, PA
- 1996 Pennsylvania Assoc. for the Blind, Guest speaker, Sharon PA
- 1997 "Glaucoma: New Trends New Complications", Pennsylvania Association for the Blind 1997 Conference, Sharon, PA
- 1998 Canton Ophthalmology Society, "Glaucoma: New Trends-New Complications", Canton OH
- 1998 New Strategies in Glaucoma Management, "Adjunctive Therapy 1998: Let's be Rational", Atlantic City, NJ
- 1999 Allergan Glaucoma Symposium, "Initial Therapy", Washington, D.C.
- 1999 Buffalo Eye Club, Guest speaker, Buffalo NY "Coexistent Glaucoma and Cataract"
- 1999 "Co-existent Glaucoma & Cataract", University of Alberta, Edmonton, Canada
- 1999 "Glaucoma Surgery New Trends & New Complications", University of Alberta, Edmonton, Canada

1999	"Co-existent Glaucoma & Cataract", University of Saskatchewan, Saskatchewan, Canada
1999	Glaucoma Surgery – New Trends & New Complications", University of Saskatchewan, Saskatchewan, Canada
1999	"Initial Therapy: Let's Be Rational", Open Angle Glaucoma: A Focus on Current Management, New York, NY
2000	"Initial Therapy 2000", Reading PA
2000	"Initial Glaucoma Therapy", Sponsored by Allergan. Toronto, Canada
2000	"Initial Glaucoma Therapy", Sponsored by Allergan. London, Canada
2000	"Surgical Management of Glaucoma", Visiting Professor, Dalhousie University, Halifax, Canada
2000	Initial Glaucoma Therapy. Sponsored by Allergan, St. John's, Canada
2000	Initial Glaucoma Therapy. Sponsored by Allergan, New York NY
2001	Trends and Complications in Glaucoma Surgery. Annual Canadian Master's Club meeting, sponsored by Alcon, Tuscon AZ
2001	Revising the Failing Filter. Annual Canadian Master's Club meeting, sponsored by Alcon, Tuscon AZ
2001	Handle That Leaking Bleb. Annual Canadian Master's Club meeting, sponsored by Alcon, Tuscon AZ
2001	Optics, Haptics and Acrylics. Sponsored by Alcon, Baltimore MD
2001	Glaucoma Therapy – What is Success? Erie Ophthalmology Society meeting, Erie PA
2001	Glaucoma Therapy – What is Success? Sponsored by Alcon, Pittsburgh PA
2001	Optics, Haptics and Acrylics. Atlantic Canada Master's Club meeting, sponsored by Alcon, St. John's, Canada

2002	Glaucoma Therapy – What is Success? Sponsored by Alcon, Charlotte NC
2002	Optics, Haptics and Acrylics. Annual Canadian Master's Club meeting, sponsored by Alcon, Bal Harbour FL
2002	Glaucoma Therapy – What is Success? Cincinnati Eye Institute, Cincinnati OH
2002	Glaucoma Therapy – What is Success? Sponsored by Alcon, Youngstown OH
2002	Simplified peripheral iris fixation of an acrylic IOL in the absence of capsular support. Meeting of the Atlantic Master's Club, sponsored by Alcon, St. Andrew's NB, Canada
2002	Prostaglandins – A View from the Trenches. Sponsored by Alcon, Greenville SC
2003	Glaucoma Therapy – What is Success? Sponsored by Alcon, Englewood NJ
2003	Glaucoma Therapy – What is Success? Sponsored by Alcon, Dayton OH
2003	Glaucoma Therapy – What is Success? Sponsored by Alcon, Columbus OH
2003	Advances in Glaucoma Therapy. Wheeling WV
2003	Advances in Glaucoma Therapy. Holidaysburg PA
2003	Glaucoma Therapy – What is Success? Glaucoma Speaker Training Meeting sponsored by Alcon Labs. Phoenix AZ
2004	Blebitis: The New Challenge. Pittsburgh PA
2004	Advances in Glaucoma Therapy: A Forward and Backward View. New Orleans LA
2004	Non-penetrating Glaucoma Surgery. Annual meeting of the Virginia Society of Ophthalmology. Chantilly VA
2004	Bleb Revision for Late Complications. Annual meeting of the Virginia Society of Ophthalmology. Chantilly VA
2004	Surgical Management of Late Bleb Problems. Annual Walter Reed Alumni Meeting. Washington DC

- 2004 Iris Fixation of Acrylic PC IOLs: Results and Complications. Annual Walter Reed Alumni Meeting. Washington DC
- 2005 Impact of Central Corneal Thickness on the Management of Primary Open Angle Glaucoma. Pittsburgh PA
- 2005 Challenges, Complications and Innovations in Cataract Surgery. Pittsburgh PA
- 2005 Advances in Glaucoma Therapy: A Forward and Backward View. Annual Meeting of the Pittsburgh Ophthalmology Society. Pittsburgh PA
- 2007 Challenging Cataract & IOL Cases A Video Potpourri. Visiting Professor, William Beaumont Hospital, Royal Oak, MI
- 2007 Iris Sutured IOLS Where Are They Now? Visiting Professor. William Beaumont Hospital, Royal Oak, MI
- 2007 "Acute Angle Closure Better Surgical Therapy" CME Dinner. Pittsburgh PA June 28, 2007
- 2007 Phacoemulsification in Acute Angle Closure Glaucoma Resident Lecture Series. University of Pittsburgh Medical Center, Department of Ophthalmology
- 2009 Don't Ice the Trab. Bascom Palmer Eye Institute. University of Miami. Annual Glaucoma Meeting
- 2009 Angle Closure Glaucoma A New Era of Effective Surgical Therapy. Clinical Day in Ophthalmology 2009, London Ontario
- 2009 IOL Malposition Then, Now and the Future. Clinical Day in Ophthalmology 2009, London Ontario
- 2009 G.V.Simpson Lecture 2009. Clinical Day in Ophthalmology 2009, London Ontario
- 2009 Acute Angle Closure Better Surgical Management. Bowlds Lecture Lahey Clinic, Boston MA
- 2009 Late IOL Dislocation The Real Deal. Bowlds Lecture Lahey Clinic, Boston MA

2009	Acute Angle Closure: Better Surgical Therapy. Utah Ophthalmology Society Dinner Meeting
2009	Late IOL Dislocation: the Future is Now. University of Utah Health Care Clinical Faculty Day
2009	Decision Making in Early POAG. Glaucoma Roundtable. Allergan, Pittsburgh PA
2010	Zonule Problems in Pseudoexfoliation, Glaucoma Challenges / Simmons Lecture. Guest Speaker. NEOS, Boston MA
2010	Is There Still a Role for Trabeculectomy? Simmons Lecture. Guest Speaker. NEOS, Boston MA
2010	Panel Discussion, Faculty. Glaucoma Challenges / Simmons Lecture. NEOS, Boston MA
2010	Glaucoma Management – Sponsored by Allergan, Pittsburgh PA
2010	Glaucoma Roundtable / Alcon. Atlanta GA
2010	Glaucoma CORE Program / Allergan. Carnegie House, State College PA
2010	ExPRESS Dinner Meeting / Alcon. Baltimore MD
2010	Speaker, Glaucoma CORE Program / Allergan. Norfolk VA
2011	Speaker / Alcon. Greenville SC
2011	Surgical Management of Glaucoma, Visiting Consultant / Allergan. Irvine CA
2011	Understanding the Approach to Complex Cases. Alcon Speaker's Forum. ASCRS-ASOA. San Diego CA
2011	Speaker, Lumigan 0.01% CORE Program / Allergan. Newport News VA
2011	Glaucoma Therapy, Allergan Dinner Program. Erie PA
2011	Glaucoma Management: A Novel Approach to Trabeculectomies / Alcon. Coral Gables FL

2011	Toric Roundtable / Alcon. Pittsburgh PA						
2011	Cincinnati Eye Institute Glaucoma Dinner ' Alcon. Cincinnati OH						
2011	Lumigan 0.01% CORE Program / Allergan. Altoona PA						
2011	Dinner Meeting / Speakers Alliance Alcon. New York City						
2011	Toric Roundtable / Alcon. DuBois PA						
2011	Discussion of ExPRESS Surgical Glaucoma Device and Advanced Technology IOLs . Alcon Speaker. Granger IN						
2011	Glaucoma Surgery: Maximize Your Options with ExPRESS. Alcon Speaker. Charlotte NC						
2012	ExPRESS Dinner Lecture. Alcon Speaker. Milwaukee WI						
2012	Video Presentations: Complications and Challenging Cases, New Tricks and New Instrumentation: My Favorite Case of the Year. Faculty, ASCRS Winter Update 2012. Riviera Maya Mexico						
2012	Allergan Glaucoma Program Speaker. Kansas City MO						
2012	Alcon ExPRESS Glaucoma Filtration Speaker. San Diego CA						
2012	Roundtable Discussions – Premium IOL Use. American Glaucoma Society 2012 Annual Meeting. New York City NY						
2012	Alcon ExPRESS Glaucoma Filtration Speaker. New York City NY						
2012	Alcon Booth Talk. American Society of Cataract and Refractive Surgery. Chicago IL						
2012	Speaker's Forum, Alcon Presenter. McCormick Place West, Eye World Theater. Chicago IL						
2012	Glaucoma Surgery: Maximize Your Options with ExPRESS. Alcon Dinner Meeting. Chicago IL						

Presentations:-cont'd

- 2012 Glaucoma Surgery: Maximize Your Options with ExPRESS. Alcon Atlanta GA 2012 Alcon ExPRESS Speaker. Washington DC 2012 Allergan Speaker, Johnstown PA 2012 Tools and Techniques With OVD's for Maximizing Outcomes. Speakers Forum AAO. Chicago IL 2013 Controversies in Medicine, Midwestern Conference. Los Angeles CA 2013 Predictable and Minimally Invasive Glaucoma Surgery Techniques, Alcon Speaker, Chicago Glaucoma Society Meeting, Chicago IL. 2013 FORGE III: Detecting and Managing Glaucoma Progression, CORE Speaker Program, Allergan. State College PA 2013 Express Dinner Meeting, Alcon. Chicago IL 2013 Trabeculectomy, Still Our Best Option? Alcon. Annapolis MD 2013 Predictable and Minimally Invasive Glaucoma Surgery Techniques. Alcon Speakers Alliance. Morgantown WV 2013 Express Dinner Meeting, Alcon. Scottsdale AZ 2013 Predictable and Minimally Invasive Glaucoma Surgery Techniques, Alcon Speakers Alliance Event. Valley View OH 2013 Pseudo ex: Something for Everyone. Pittsburgh Ophthalmology Society Quarterly Meeting. Pittsburgh PA 2014 "Challenging Cases in Anterior Segment Surgery." Video Case Presentation. Faculty, ASCRS ASOA Winter Update 2014. Fariardo Puerto Rico
- 2014 Pseudoexfoliation from Stem to Stem. 98th Annual Clinical Assembly of the AOCOO-HNS Foundation. Scottsdale AZ

Winter Update 2014. Farjardo Puerto Rico

2014 "Updating Your Glaucoma Treatment Armamentarium." Faculty. ASCRS ASOA

Presentations:-cont'd

- 2014 Glaucoma Speaker Training. Alcon. Miami FL
- 2014 Trabeculectomy 2014 Is There Still a Role? 98th Annual Clinical Assembly of the AOCOO-HNS Foundation. Scottsdale AZ
- 2014 Pseudoexfoliation from Stem to Stem. 98th Annual Clinical Assembly of the AOCOO-HNS Foundation. Scottsdale AZ
- 2015 "MIGS" 2015: Are We There Yet? Visiting Professor Grand Rounds. Ottawa Canada
- 2015 "Pseudoexfoliation: Something for Everyone." Key Note Speaker (Annual Ophthalmology and Optometry Dinner) Ottawa Canada
- 2017 "New Meds / MIGS Options: Can We Do Better." Featured Speaker. Georgia Society of Ophthalmology Annual Meeting. Amelia Island FL
- 2017 "Posterior Polar Cataract: Do's and Don'ts." Featured Speaker. Georgia Society of Ophthalmology Annual Meeting. Amelia Island FL
- 2017 "Surgical Triumphs and Tragedies: A Video Potpourri." Featured Speaker. Georgia Society of Ophthalmology Annual Meeting. Amelia Island FL

Research Grants:

- 1990 Glaucoma Software Development Program, Pennsylvania Lions Club/Allegheny Singer Research Institute, \$90,000.
- 1996 Postoperative Complications Following Mitomycin-C Assisted Trabeculectomy: Mechanisms and Control by FGF-2, Allegheny Singer Research Institute, \$10,000.
- 1996 Immunologic Reactivity to Human Optic Nerve Tissue of Serum From Patients with Low-Tension Glaucoma, Open-Angle Glaucoma and No Ocular Disease, Allegheny Singer Research Institute, \$10,000

Clinical Trials Participation:

- 1989 Betaxalol vs Betaxalol-S, Clinical Investigator. Sponsored by Alcon Pharmaceuticals
- 1995 Latanoprost. Clinical Investigator, Phase III study site. Sponsored by Pharmacia-Upjohn
- 2003-2006 Bidirectional Glaucoma Shunt (Eyepass) Phase III Study Principal Investigator-Sponsored by GMP/Vision Solutions Inc.
- 2005-Present iScience Schlemm's Canal Dilation / Imaging Phase III Study
- 2008 Trabeculectomy vs Express Shunt. Randomized Multi Center Clinical Trial

Fellows Trained:

1991 - 1992	Karen B. Lauer, M.D. 420 East North Avenue Suite 116 Pittsburgh, PA 15212
1992 – 1993	Richard A. Lehrer, M.D. Alliance Eye 285 Sawburg Alliance, OH 44601
1993 - 1994	Christopher G. Spanich, M.D. 13602 N 46th Street Tampa, FL 33613
1994 - 1995	Ghada Orkubi, M.D. P.O. Box 8447 Jeddah, Saudi Arabia 21482
1995 - 1996	Griffith Steiner, M.D. Physicians Medical Office Building 3340 Providence Drive, Suite 565 Anchorage, AK 99508

Fellows Trained:-cont'd

1996 - 1997	David A. DeRose, M.D. 118 West Lakeshore Drive Rockaway, NJ 07866
1997 - 1998	Bret C. Crumpton, M.D. W. Georgia Eye Care Center 2616 Warm Springs Road Columbus, Georgia 31904
1998 – 1999	Matthew Bilder, M.D. 1945 Queenswood Drive York, PA 17406
1999 – 2000	Rajiv Bindlish, M.D. 1939 Carscadden Chase Mississauga, Ontario L4W3R8
2003 – 2004	Rupal N. Chiniwalla, M.D. 104 Seavey Highlands Drive Pittsburgh, PA 15223
2007 – 2008	Michael Dorey, M.D. School House Apartments, Apt. 215 500 Tripoli Street Pittsburgh, PA 15212
2009 - 2010	Michael A. Alunni, M.D. 248 South St. Clair Street, Apt. 3 Pittsburgh, PA 15206
2011 - 2012	Tyler Q. Kirk, M.D. 7427 Lake Street River Forest, IL 60305
2014 - 2015	Michael J. Siegel, M.D. 411 Martell Drive Bloomfield Hills, MI 48304

Appendix B

List of Materials Considered

Exhibit Number	Description
1001	U.S. Patent No. 9,107,729
1001	U.S. Patent No. 9,107,729 Prosecution History
1002	The Netland Declaration
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1007	Philipp C. Jacobi et al., "Technique of goniocurettage: a potential
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1010	Michael John Hogan, History of the Human Eye: An Atlas and
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1021	Arsham Sheybani, Bent Ab-interno Needle Goniectomy (BANG),				
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2020	Sworn Affidavit of Manuel Quintana, M.D.				
2023	Dorland's Medical Dictionary Shorter Edition abridged from 25th ed. (1980) excerpt at 605 (definition of "section")				
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New World Medical, Inc. v. MicroSurgical Tech., Inc., IPR2020-01573

Petitioner - New World Medical Ex. 1043, p. 177 of 933

EXHIBIT 3



(12) United States Patent

Sorensen et al.

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

(71) Applicant: Neomedix Corporation, Tustin, CA

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

Assignce: 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)

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

Field of Classification Search CPC A61F 2009/00868; A61F 9/007; A61F 9/00736-9/00763; A61F 9/013-9/0133; A611' 9/00781; A61F 9/0079; A61B 17/320016; A61B 18/1482; A61B

2018/00083; A61B 2018/1497 606/107, 161-162, 166-167, 170, 606/184-185; 600/566, 567

See application file for complete search history.

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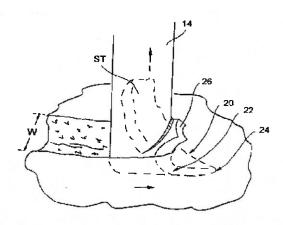
(Continued)

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

(57)ABSTRACT

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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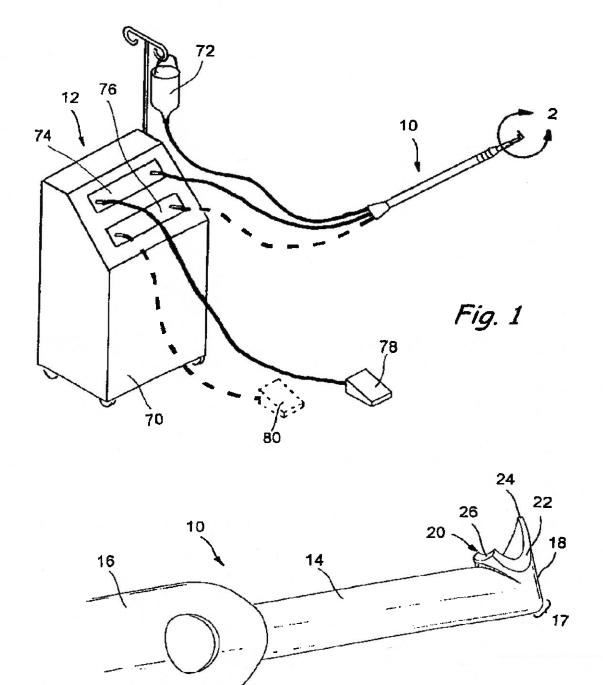
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Fig. 2

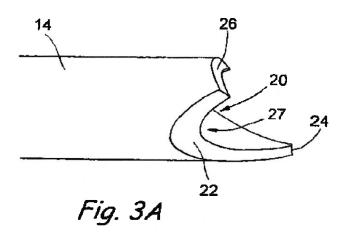


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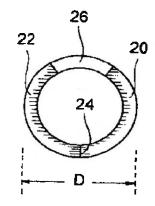
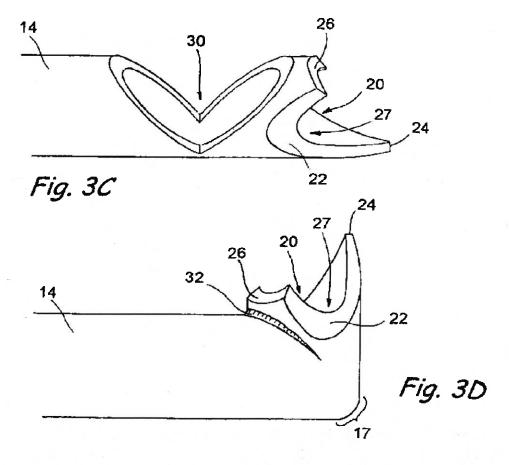


Fig. 3B



U.S. Patent

Fig. 5

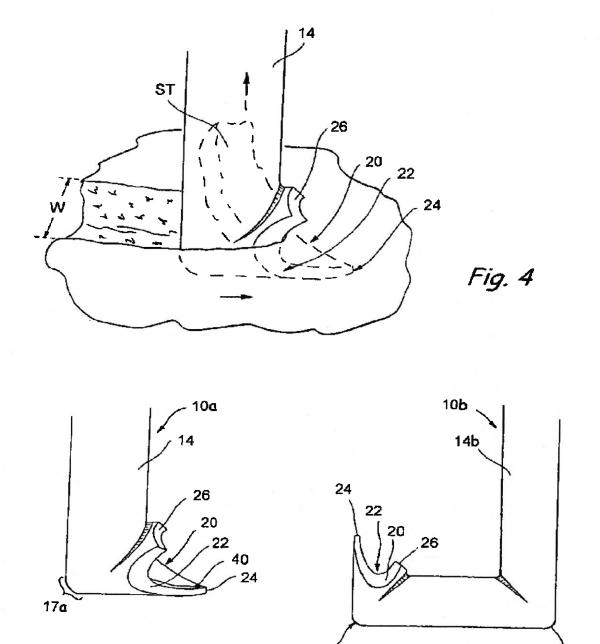
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Fig. 6



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METHODS FOR FORMING AN OPENING IN THE TRABECULAR MESHWORK OF THE EYE OF A PATIENT

RELATED APPLICATIONS

This application is a division of U.S. patent application Ser. No. 13/159,356 filed Jun. 13, 2011 currently abandoned which is a division of U.S. patent application Ser. No. 10/560, 267 filed May 11, 2006 and issued as U.S. Pat. No. 7,959,641 on Jun. 14, 2011, which is a 35 U.S.C. §371 national stage of PCT International Patent Application No. PCT/US2004/018488 filed Jun. 10, 2004, which claims priority to U.S. Provisional Patent Application No. 60/477,258 timed on Jun. 10, 2003, the entire disclosure of each such prior patent and application being expressly incorporated herein by reference.

BACKGROUND OF THE INVENTION

There are numerous medical and surgical procedures in which it is desirable to cut and remove a strip of tissue of controlled width from the body of a human or veterinary patient. For example, it may sometimes be desirable to form an incision of a controlled width (e.g., an incision that is wider 25 than an incision made by a typical scalpel or cutting blade) in the skin, mucous membrane, tumor, organ or other tissue or a human or animal. Also, it may sometimes desirable to remove a strip or quantity of tissue from the body of a human or animal for use as a biopsy specimen, for chemical/biological analysis, for retention or archival of DNA identification purposes, etc. Also, some surgical procedures require removal of a strip of tissue of a known width from an anatomical location within the body of a patient.

One surgical procedure wherein a strip of tissue of a known width is removed from an anatomical location within the body of a patient is an ophthalmological procedure used to treat glaucoma. This ophthalmological procedure is sometimes refered to as a goniectomy. In a goniectomy procedure, $_{40}$ a device that is operative to cut or ablate a strip of tissue of approximately 2-10 mm in length and about 50-200 µm in width is inserted into the anterior chamber of the eye and used to remove a full thickness strip of tissue from the trabecular meshwork. The trabecular meshwork is a loosly organized, 45 porous network of tissue that overlies a collecting canal known as Schlemm's canal Afluid, known as aqueous humor, is continually produced in the anterior chamber of the eye. In normal individuals, aqueous humor flows through the trabecular meshwork, into Shlemm's Canal and out of the eye $\,^{50}$ through a series of ducts. In patients who suffer from glaucoma, the drainage of aqueous humor from the eye may be impared by elevated flow resistance through the trabecular meshwork, thereby resulting in an increase in intreoccular pressure. The goniectomy procedure can restore normal 55 drainage of aqueous humor from the eye by removing a full thickness segment of the trabecular meshwork, thus allowing the aqueous humor to drain through the open area from which the strip of trabecular meshwork has been removed. The $_{60}$ goniectomy procedure and certain prior art instruments useable to perform such procedure are described in U.S. patent application Ser. No. 10/052,473, published as No. 2002/ 011608A1 (Baerveldt), the entirety of which is expressly incorporated herein by reference.

At present there remains a need in the art for the development of simple, inexpensive and accurate instruments usuable 2

to perform the goniectomy procedure as well as other procedures where it is desired to remove a strip of tissue from a larger mass of tissue.

SUMMARY OF THE INVENTION

The present invention provides a device for cutting a strip of tissue of approximate width W from a mass of tissue. 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 cutting tube is advanceable through tissue such that the first and second cutting edges will cut a strip of tissue having approximate width W. wherein the approximate width W is approximately equal to the distance between the first and second cutting edges. In some embodiments, the strip of tissue may be aspirated or otherwise removed through the lumen of the cutter tube. In some embodiments, the device may include apparatus useable to sever (e.g., transversely cut or transect) the strip of tissue when the strip of tissue has reached a desired length.

Further in accordance with the invention there is provided a method for cutting a strip of tissue of width W from a tissue mass. This method generally comprises the steps of a) providing a device that comprises i) an elongate cutting tube that has a distal end and a lumen that opens through an opening in the distal end and ii) first and second cutting edges formed on generally opposite edges of the distal end of the cutting tube and separated by a distance D that is approximately equal to the width W of the strip of tissue to be cut; and b) advancing the distal end of the cutting tube through the mass of tissue of approximate width W. I'urther aspects and elements of the invention will be understood by those of skill in the art upon reading the detailed description of specific examples set forth herebelow.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a system incorporating a needle cutting device of the present invention.

FIG. 2 is an enlarged perspective view of section 2 of FIG. 1.

FIGS, 3A-3D show various steps in a method for manufacturing a needle cutter of the present invention.

FIG. 4 is a side view of a distal portion of a needle cutter device of the present invention being used to cut a strip of tissue of approximate width W.

FIG. 5 is a perspective view of the distal portion of a needle cutter device of the present invention incorporating apparatus for severing a strip of tissue cut by the needle cutter device after the strip of tissue has reached a desired length.

FIG. 6 is a side view of the distal portion of another embodiment of a needle cutter device of the present invention having a plurality of curves or bends formed in the cutting tube.

DETAILED DESCRIPTION

The following detailed description, and the drawings to which it refers, are provided for the purpose of describing and illustrating certain preferred embodiments or examples of the invention only, and no attempt has been made to exhaustively describe all possible embodiments or examples of the invention. Thus, the following detailed description and the accompanying drawings shad not be construed to limit, in any way,

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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 5 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 10 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 15 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 20 placed in an anatomical or man made grove or channel (e.g., Schlemm'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 25 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 10b shown in PIG. 6, two separate 30 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 14-35 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 40 more than one bend or curve are formed in the cutting tabe 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 45 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, seissor, 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.

Thereafter, the tube 14 is bent to bring the edges of each 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 $^{-5}$ 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 appreciated that the use of angular cut-out(s) 30 allow a tube 10 of a given diameter to incorporate a curve or angle in a more 10 compact form than is possible by bending tubing 10 of a given diameter to said curve or angle without kinking or damaging

The device 10 and system 12 are useable to perform a .5 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 ST of tissue of a desired width.

One particular procedure that may be performed to treat glaucoma, using the device 10 and system 12 of the present | 20 invention, is a goniectomy. As explained herein a goniectomy procedure is an ab interno surgical procedure wherein a sector of the trabecular meshwork is removed from the eye of the patient to facilitate drainage of aqueous humor from the anterior chamber of the eye through Schlemm's Canal and the 25 it to be aspirated or drawn into or through lumen 27. associated collector channels, thereby relieving elevated intraocular pressure.

To perform a goniectomy procedure using the device 10, first a small incision is made in the comea at about 3 o'clock in the left eye, or at about 9 o'clock in the right eye. A $1.5~\mathrm{mm}^{-30}$ slit knife may be used to make this incision.

The device 10 is attached to the source of irrigation fluid 72 (e.g. basic balanced salt solution) such that irrigation fluid will flow through lumen 19 of the outer tube 16 and out of outflow aperture 11. The device 10 is then inserted through the incision and into the anterior chamber of the eye (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 40 through the lumen 27 of the cutter tube 14. In this manner, irrigation fluid will begin to infuse into the anterior chamber of the eye as soon as the distal end of the cutter tube 14 has entered the anterior chamber, rather than being delayed until the larger outer tube 16 and aperture 11 have been advanced 45 the steps of: through the incision and into the anterior chamber. By this alternative approach, irrigation fluid may be caused to flow out of the distal end of the cutter tube 14 as the device 10 is being inserted, thereby spreading or opening the incision by hydraulic force while in addition increasing the fluid pressure 50 in the anterior chamber. Such spreading or opening of the incision may facilitate advancement of the larger diameter outer tube 16 through the incision. Pressurizing the fluid in the anterior chamber causes the anterior chamber to deepen and may facilitate maneuvering of device 10 within the anterior chamber. In cases where this alternative approach is used, the source of infusion fluid 72 may be disconnected from lumen 27 of the cutter tube 14 after the device 10 has been inserted into the anterior chamber and, thereafter, the infusion fluid source 72 may be reconnected to lumen 19 of outer tube 60 16 such that infusion fluid will flow out of aperture 11. Negative pressure (e.g., via aspiration pump module 74) may then be applied to lumen 27 of the cutter tube 14 so as to aspirate fluid and debris through lumen 27 as shown in FIG. 4. The vertical height of the infusion fluid source 72 may be adjusted 65 to provide sufficient gravity feed of infusion fluid to make up for the volume of fluid or matter being aspirated from the

anterior chamber through lumen 27, thereby maintaining the desired pressure of fluid within the anterior chamber during the precedure.

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 tisue 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

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 chamberthrough 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 nonlimiting 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. An ab interno method for forming an opening in trabecular meshwork of a patient's eye, said method comprising

obtaining a dual blade device which comprises a) an elongate proximal portion sized to be grasped by a hand of a human operator and b) an elongate probe extending from the proximal portion, wherein the elongate probe comprises i) a shaft, ii) a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees, said distal protruding tip being sized to be inserted in Schlemm's Canal and iii) first and second cutting edges located at a junction of the shaft and the distal protruding tip, said first and second cutting edges being formed at spacedapart locations on the distal end of the shaft, said first and second cutting edges being separated by a distance D;

forming an opening into an anterior chamber of the eye; inserting the elongate probe through the opening and into the anterior chamber;

advancing the elongate probe through the anterior chamber, while the anterior chamber is filled with fluid, to an operative position where the distal protruding tip is positioned within Schlemm's Canal and the first and second cutting edges are contacting the trabecular meshwork; and, thereafter

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causing the distal protruding tip to advance through a sector of Schlemm's Canal with the first and second cutting edges concurrently cutting, from the trabecular meshwork, a strip of tissue having approximate width W. said approximate width W being approximately equal to the distance D between the first and second cutting edges.

- 2. A method according to claim 1 further comprising the step of infusing fluid into the anterior chamber under controlled pressure to keep the anterior chamber filled with fluid during performance of the method.
- 3. A method according to claim 1 wherein the strip of tissue cut from the trabecular meshwork has a length of about 2 to 10 millimeters.
- 4. A method according to claim 1 further comprising the ± 5 step of:

removing the strip of tissue from the patient's eye.

 $5.\,\Lambda$ method according to claim 4 wherein, after the first and second cutting edges have cut the strip of tissue from the

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trahecular meshwork, the strip of tissue remains connected to the trahecular meshwork and wherein the method further comprises the step of:

disconnecting the strip of tissue such that it may be

removed from the eye.

6. A method according to claim 5 wherein the disconnecting step comprises using a tissue severing apparatus to transect or sever the strip of tissue so as to disconnect it from the patient's body.

7. A method according to claim 1 wherein the step of forming an opening into the anterior chamber of the eye comprises forming an incision through a cornea of the eye.

8. A method according to claim I wherein the method is performed under direct visualization through a lens device positioned on an anterior aspect of the eye.

9. A method according to claim 1 wherein the angle is less than approximately 90 degrees.

10. A method according to claim 9 wherein the angle is approximately 90 degrees.

* * * * *

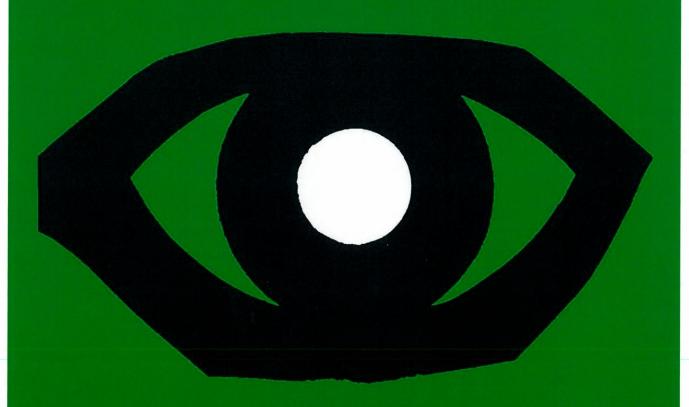
New World Medical, Inc. v. MicroSurgical Tech., Inc., IPR2020-01573

Petitioner - New World Medical Ex. 1043, p. 188 of 933

EXHIBIT 4

Documenta Ophthalmologica Proceedings Series 43

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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, if reinstituted, achieves a better control than before the operation and usually can be less intense.

INTRODUCTION

Increased resistance to the outflow of aqueous through the trabecular meshwork is the most accepted pathogenic mechanism in the majority of openangle glaucomas ("trabecular glaucomas"). Thus, the rational treatment of the trabecular glaucomas should consist in opening the trabecular meshwork (TM). This has been attempted since the last century (11, 12, 13) and many times later on (1, 2, 4, 5, 8, 9), but all the techniques described so far have failed (3, 10) despite the in vitro evidence (6, 7) of the effectiveness of trabeculotomy.

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 \times 10. We favour the Swann lens for angle visualisation. Our trabeculotome is a 0.4 \times 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

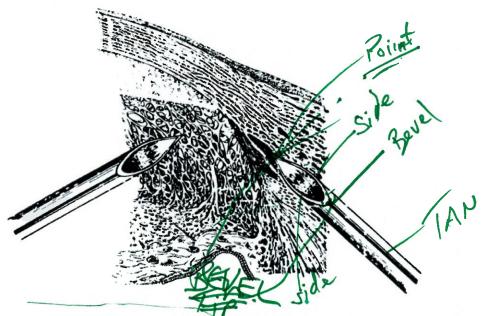


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotra beculotomy.

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 the anterior chamber, the goniolens is inserted, held with the surgeon's left hand. A drop of "healon" is a good wetting agent between cornea and goniolens. 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.

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.

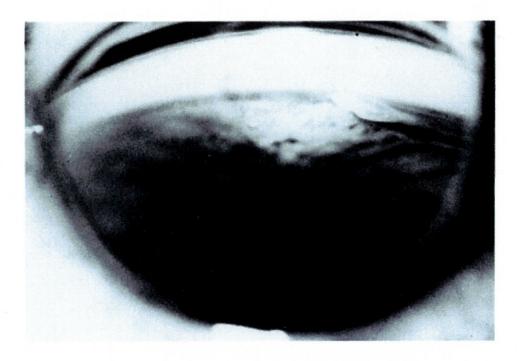


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

Twenty-one eyes of 12 patients have been operated with this technique, with a follow-up period of one year (mean). There are 13 eyes with chronic open-angle glaucoma, 3 with pigmentary glaucoma, 4 disgenetic and 1 steroid-induced. Details are summarized in Table 1.

RESULTS

Complications

There are no operative complications, not even hyphema, provided there is no chamber loss ("ex vacuum" hyphema).

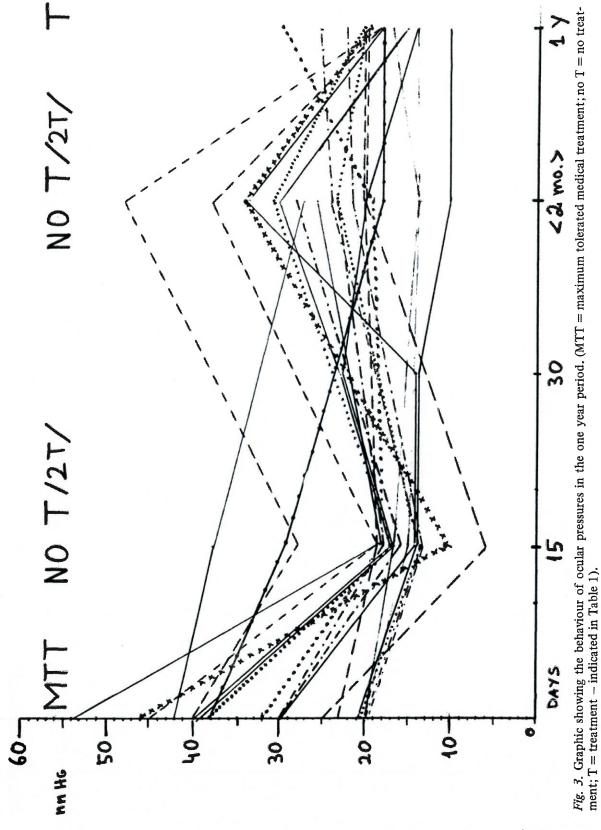
Postoperative complications are hypherma, moderate, in 6 cases; and atropy of the iris in three cases. Iris atrophy does not occur since we give steroids and we dilate the pupils (see discussion).

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,

2/day: A =	acetazolamio	nume 1. raucin data: age, sex, type of gai 2/day: A = acetazolamide, number after A in	name 1. raucut data: age, sex, type of glauconia, ocular pressures, compucations and treatment (r = puocarpine 2% 3/day: T = timolol 0.50% 2/day: A = acetazolamide, number after A indicates mgrs. per day; COAG = chronic open angle glaucoma).	compucations and AG = chronic open	treatment ($F = puloca$ angle glaucoma).	urpine 2% 3/day: 1 =	= timolol 0.50%
Patient	Age	Glaucoma	Po Preop./mmHg	Po 15 d.	Complications	Po 2 Months	Po 1 Year
Mrs. C.	09	C.O.A.G.	40 P-T-A 750 40 P-T-A 750	17 - 18 -	hyphema + -	30 – 23 –	15 P-T 13 T
Mr. N.	75	C.O.A.G.	20 P-T-A 750 20 P-T-A 750	15 – 17 –	Iris atropy _	24 – 23 –	15 T-A 125 17 T-A 125
Mr. Z.	61	disgenetic	21 P-T 30 P-T	14 – 14 –	1 1	14 – 34 –	10 – 17 P-T
Mr. B.	99	C.O.A.G.	34 P-T-A 375 30 P-T-A 375	18 – 38 –	- hyphema + +	26 – 27 –	lost lost
Mr. V.	24	disgenetic	25 T-A 250 23 T-A-250	6 – 19 –	hyphema + hyphema +	22 – 25 –	19 T 16 T
Mrs. S.	80	C.O.A.G.	30 P-T-A 500 30 P-T-A 500	16 – 18 –	Iris atrophy Iris atrophy	28 – 23 –	21 T-A 125 20 T-A 125
Mr. C.	9/	C.O.A.G	45 T-A 500 40 T-A 500	19 – 28 –	– hyphema +	38 – 48 –	18 T-A 250 19 T-A 250
Mr. V.	62	C.O.A.G.	21 P-T-A 500 39 P-T-A 500	14 - 18 -	I 1	23 – 30 –	20 – 20 T
Mrs. N.	41	pigmentary	32 P-T 24 P-T NO OP.	18 –	I	30 –	18 P-T
Miss O.	13	C.O.A.G.	46 – 24 – NO OP.	10 –	I	34 –	19 P-T
Mr. V.	45	pigmentary + disgenetic	20 P-T 20 P-T	14 14	1 1	24 – 20 –	24 – 22 –
Mr. C.	16	cortisonic (R.E.)	38 P-T 14	30 –	l	18 P-T	18 P-T

Dash (-) after Po figures indicates no treatment. Upper half of each patient: right eye; lower half: left eye



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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.

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New World Medical, Inc. v. MicroSurgical Tech., Inc., IPR2020-01573

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EXHIBIT 5

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLN. NO.

13/159,356

CONFIRMATION NO.: 1298

APPLICANT

JOHN T. SORENSEN, ET AL.

FILED

JUNE 13, 2011

TC/A.U.

3734

EXAMINER

AMY R. SHIPLEY

DOCKET NO.

NEOME-019A3US-G

CUSTOMER NO.

33197

TITLE

TUBULAR CUTTER DEVICE AND METHODS FOR

CUTTING AND REMOVING STRIPS OF TISSUE FROM THE

BODY OF A PATIENT

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

AMENDMENT ACCOMPANYING NOTICE OF APPEAL

Madam:

In response to the final Office Action mailed October 9, 2013, please amend the above-identified application as set forth below.

Amendments to the Claims are reflected in the listing of claims which begin on page 2 of this paper.

Remarks/Arguments begin on page 7 of this paper.



Amendment to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A dual blade device useable for performing an *ab* interno surgical procedure wherein a strip of tissue of approximate width W is cut from the trabecular meshwork of the eye of a human subject to improve drainage of fluid from the eye's anterior chamber through Schlemm's Canal, said device comprising:

an elongate proximal <u>hand piece</u> handpeice sized to be grasped by the hand of a human operator;

an elongate probe extending from the <u>hand piece</u> handpeice, said elongate probe comprising i) a shaft, ii) a distal protruding tip that extends at an angle of from 20 degrees to 90 degrees from a distal end of the shaft and is sized to be inserted in Schlemm's Canal and iii) first and second cutting edges located at the junction of the shaft and the distal protruding tip, said first and second cutting edges being separated by a distance D;

said clongate probe being constructed such that it is insertable through a small opening in the anterior chamber and advanceable across the anterior chamber, while the anterior chamber remains filled with fluid, to an operative position wherein the distal protruding tip is positioned within Schlemm's Canal and the first and second cutting surfaces are contacting the trabecular meshwork;

the device being maneuverable, when in said operative position, to cause the distal protruding tip to advance through a sector of Schlemm's Canal with the first and second cutting edges concurrently cutting, from the trabecular meshwork, a strip of tissue having approximate width W, said approximate width W being approximately equal to the distance D between the first and second cutting edges.

2. (Cancelled)

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3,	(Cancelled)
4.	(Cancelled)
5, protru	(Currently Amended) A device according to Claim $\underline{1}$ [[2]] wherein the ding tip is sufficiently blunt to be substantially a traumatic.
6.	(Cancelled)
7.	(Cancelled)
8.	(Cancelled)
9.	(Cancelled)
10.	(Cancelled)
11.	(Previously Presented) A device according to Claim 1 wherein the distal ding tip extends from the shaft at an angle of approximately 90 degrees.
12. plurali	(Previously Presented) A device according to Claim 1 wherein there are a ty of bends or curves formed in the clongate probe.

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- 13. (Previously Presented) A device according to Claim 12 wherein there are a plurality of bends of approximately 20 degrees to approximately 90 degrees each formed in the elongate probe.
- 14. (Previously Presented) A device according to Claim 1 wherein the elongate probe has a lumon.
- 15. (Previously Presented) A device according to Claim 14 further comprising a source of negative pressure connected to the lumen of the elongate probe so as to aspirate fluid or matter through the lumen of the elongate probe.
- 16. (Previously Presented) A device according to Claim 14 wherein the device further comprises a second lumen.
- 17. (Original) A device according to Claim 16 wherein one of the lumens is connected to a source of fluid such that fluid may be infused therethrough and the other of said lumens is connected to a source of negative pressure such that fluid or matter may be aspirated therethrough.
- 18. (Original) A device according to Claim 1 wherein at least one of the cutting edges is heated such that it will cauterize as it cuts.
- 19. (Original) A device according to Claim 1 further comprising apparatus for severing the strip of tissue when the strip of tissue has reached a desired length.

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- 20. (Cancelled)
- 21. (Cancelled)
- 22. (Cancelled)
- 23. (Previously Presented) A device according to claim 1 further comprising a fluid infusion lumen connected to a source of fluid whereby fluid is delivered through the lumen under controlled pressure to keep the anterior chamber filled with fluid while the device is inserted in the anterior chamber.
- 24. (Withdrawn) An *ab interno* method for using a device according to claim 1 to form an opening in the trabecular meshwork of a patient's eye, said method comprising the steps of:

forming an opening into the anterior chamber of the eye;

inserting the clongate probe through the opening;

advancing the elongate probe through the anterior chamber, while the anterior chamber is filled with fluid, to said operative position where the distal protruding tip is positioned within Schlemm's Canal and the first and second cutting surfaces are contacting the trabecular meshwork; and, thereafter

causing the distal protruding tip to advance through a sector of Schlemm's Canal with first and second cutting edges concurrently cutting, from the trabecular meshwork, a strip of tissue having approximate width W, said approximate width W being approximately equal to the distance D between the first and second cutting edges.

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25. (Withdrawn) A method according to claim 24 further comprising the step of infusing fluid into the anterior chamber under controlled pressure to keep the anterior chamber filled with fluid during performace of the method.

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REMARKS/ARGUMENTS

By the foregoing amendments, minor typographical errors have been corrected in claims 1 and 5. No new matter has been added. These corrections overcome the claim objections raised in the final office action. Entry of this amendment is appropriate in that it eliminates minor issues and places the claims in better condition for appeal. A notice of appeal is filed herewith.

Applicant respectfully traverses the stated rejections under 35 U.S.C. §103. Contrary to what is stated in Paragraph 9 of the Office Action, there exists no basis to conclude that the straight tubular device described by Heisler, et al. would be capable of cutting a strip of tissue of a width W from the trabecular meshwork of the eye of a human subject by an ab interno approach. Furthermore, except for impermissible hindsight reconstruction of Applicant's invention, there would be no reason for anyone to modify the Heisler, et al. device to include an angle of 20 to 90 degrees as stated in the office action. These facts are particularly apparent when one considers how a

In the human eye, fluid known as aqueous humor accumulates in a cavity known as the anterior chamber. A circular canal, known as Schlemm's canal, extends around the periphery of the anterior chamber. The outer or peripheral wall of Schlemm's canal is formed by the junction of scleral and corneal tissue (i.e., the scleral-corneal junction) covered by delicate endothelial tissue. The inner "wall" of Schlemm's canal is a normally-porous structure formed of trabecular meshwork tissue. Typically, excess aqueous humor seeps from the anterior chamber, through the porous trabecular meshwork tissue, and into Schlemm's canal. After entering Schlemm's canal, that excess fluid then drains outwardly through small collector channels which open through the scleral wall of Schlemm's canal and is ultimately carried away through veins that drain the eyeball.

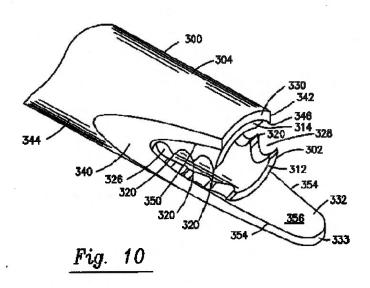
In at least some cases of open angle glaucoma, the porosity of the trabecular meshwork tissue is inadequate or clogged thereby impeding the normal seepage of fluid from the anterior chamber into Schlemm's canal. This impeded fluid drainage results in elevated intraocular pressure (IOP) which, if uncorrected, can lead to optic nerve damage and vision loss.

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The prior art has included stents or shunts that remain implanted in the eye to create an open conduit through the trabecular meshwork and into Schlemm's canal. Also, the prior art has included various devices for ablating or removing segments of trabecular meshwork tissue to improve drainage of fluid from the anterior chamber into Schlemm's canal without the need for placement of an implant.

The devices useable for ablating or removing segments of trabecular meshwork tissue have included some that are useable by an *ab interno* (from the inside) approach and others that are useable by an *ab externo* (from the outside) approach. The *ab externo* approach involves making an incision from the exterior of the eye to access the interior of Schlemm's canal. A segment of trabecular meshwork bordering the exposed portion of Schlemm's canal may then be removed through that external incision. The *ab interno* approach involves inserting operative instrument(s) into the anterior chamber of the eye and then using those instrument(s) to ablate or remove trabecular meshwork tissue from the anterior chamber, without requiring any external incision into Schlemm's canal.

Figure 10 of Heisler et al. is reproduced below:



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The Heisler et al. device is a straight tube with a bevel-cut distal end and a rotating cutting element positioned within the tube. Because it is a straight tube, the Heisler et al. device can only be used to remove a "strip" of tissue if it were advanced longitudinally (i.e., head on) into that tissue. The Office Action provides no suggestion or explanation as to how the Heisler et al. device could possible be advanced longitudinally along the trabecular meshwork tissue to remove a "strip" as required by Applicant's claims by an *ab interno* approach. While it may (arguably at least) be possible to use the Heisler et al. device to cut a strip of trabecular meshwork tissue via an *ab externo* approach, it does not appear feasible to do so by an *ab interno* approach for a number of reasons, including the fact that the Heisler et al. device lacks the claimed 20 to 90 degree angle.

Applicant requests a telephonic interview in advance of the deadline for filing the Appeal Brief to discuss possible insertion of claim term definitions into the prosecution history as a means for facilitating allowance of the present claims. It should not be necessary to expend PTAB resources in this case given that the claimed subject matter is clearly distinguishable over the cited prior art references when the claim language is properly construed.

Fees due will be paid through EFS at the time of filing. The Commissioner is hereby authorized to charge any underpayment, or to credit any overpayment, to Deposit Account No. 50-0878.

Date: April 9, 2014

Respectfully submitted, STOUT, UXA, BUYAN & MULLINS, LLP

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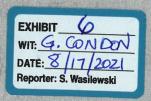
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EXHIBIT 6

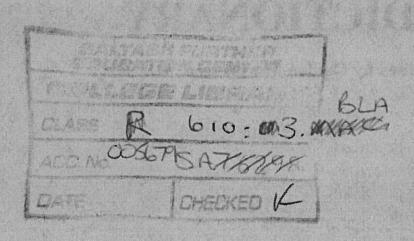
BLACK'S MEDICAL DICTIONARY

Edited by Gordon Macpherson, MB, BS

Thirty-seventh edition



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or the elderly - and screening tests are examples of secondary prevention.

SECONDARY SEXUAL CHARACTERIS-TICS: The physical characteristics that develop during puberty as the body matures sexually. Girl's breasts and genitals increase in size and like boys they grow pubic hair. Boys also grow facial hair, their voice breaks and their genitals grow to adult size.

SECRETIN is a hormone secreted by the mucous membrane of the duodenum, the first part of the small intestine, when food comes in contact with it. On being carried by the blood to the pancreas, it stimulates the secretion of pancreatic juice.

SECRETION is the term applied to the material formed by a gland as the result of its activity. For example, saliva is the secretion of the salivary glands, gastric juice that of the glands in the stomach wall, bile that of the liver. (See GLANDS.) Some secretions consist apparently of waste material which is of no further use in the chemistry of the body. These secretions are often spoken of as excretions: for example, the urine and the sweat. (For further details, see SALIVA; URINE, ENDOCRINE GLANDS, and also under the headings of the various organs.)

SECTION: (1) A thin slice of a tissue specimen taken for examination under a microscope. (2) The act of cutting in surgery; for example, an abdominal section is done to explore the abdomen. (3) The issuing of an order under the United Kingdom's Mental Health Act to admit someone compulsorily to a psychiatric hospi-

SECUNDINES is another name for the afterbirth, consisting of the placenta and membranes expelled in the final stage of labour.

SECUNDUM ARTEM is a Latin expression meaning in a skilful professional manner.

SEDATIVES are drugs and other measures which soothe over-excitement of the nervous system, whether the effect of this excitement is pain, sleeplessness, delirium or muscular spasm. Those sedatives that soothe pain are generally spoken of as anodynes; sedatives in sleeplessness or delirium are known as hypnotics; sedatives of spasm are called antispasmodics. (See ANODYNES; COLIC; HEADACHE; HYPNOTICS; NEURALGIA; PAIN.)

SEDIMENTATION RATE (see ESR).

SELENIUM SULPHIDE is used as a shampoo in the treatment of dandruff (see SEBORRHOEA)

and seborrhoeic eczema (or dermatitis) of the scalp. In view of its potential toxicity it should only be used under medical supervision. It must never be applied to inflamed areas of the scalp, and it must not be allowed to get into the eyes, as it may cause conjunctivitis or keratitis. It is also used in the treatment of timea versicolor. (See RINGWORM.)

SELF-POISONING has increased dramatically over the past 30 years and is now one of the commonest causes of acute admission to hospital. Drugs are usually taken in overdosage on impulse because of a crisis in coping with social or personal difficulties and most patients have previously been prescribed psychotrophic drugs. It is predominently a disease of young people, the mean age being in the 30s with a peak incidence in the 20s. There is a higher incidence of female patients. Fortunately about 98 per cent of patients admitted with drug overdosage will recover. Even so, there were around 300 deaths from suicide by overdose among young people in 1989 in England and Wales. There have been changes in the types of drugs used in deliberate self-poisoning. In 1962 barbiturates were used in 55 per cent of episodes whereas the benzodiazapines are now the most common drug used. The incidence of salicylate poisoning has declined but overdosage with paracetamol has become more common. Admission to hospital for self-poisoning reached its peak in 1977 and the figures have been falling steadily almost every year since then. This is also true of the number of fatal suicidal poisonings. There may be more than one explanation for this decrease but the most likely cause is that since 1976 the annual number of prescriptions for hypnotics and tranquillizers has also fallen steadily. The tranquillizers which are so popular for overdoses are prescribed for the very patients who are most likely to wish to poison themselves. There was, in fact, a parallel decrease in the rate of carbon monoxide poisoning when carbon monoxide was removed from domestic gas.

Treatment: Emptying the stomach by gastric lavage is sometimes necessary but the risks of this procedure must be balanced against the toxicity of the ingested poison. The danger of gastric aspiration is the inhalation of stomach contents and it should not be attempted in drowsy patients unless there is good cough reflex or unless the airway can be protected by a cuffed tube. A tube should not be passed after corrosive poisoning. Emptying the stomach by gastric lavage is of doubtful value more than four hours after ingestion of a poison. There are, however, two exceptions, namely salicylates and tricyclic antidepressants. Salicylates may be recovered up to 24 hours and tricyclic antidepressants up to 8 hours after ingestion. Gastric lavage is seldom practical or desirable before the patient reaches hospital.

The more common poisons seen today include the amphetamine-related drugs, aspirin and other salicylates, tranquillizers, iron salts,

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EXHIBIT 7

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> Abridged from the 25th Edition of Dorland's Illustrated Medical Dictionary

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EXHIBIT 7
WIT: G. CONCON
DATE: 8 | 17 | 202 |
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secretion (se-kre'shun) 1. the cellular process of elaborating and releasing a specific product; this activity may range from separating a specific substance of the blood to the elaboration of a new chemical substance. 2 any substance produced by secretion. external s., one that is discharged upon an external or internal body surface; see also exocrine gland internal s., hormone

secretoinhibitory (se-kre"to-in-hib'í-tor"e) inhibiting secretion.

secretomotor, secretomotory (-mo'tor; -mo'tor-e) stimulating secretion; said of nerves.

secretor (se-kre'tor) in genetics, one who secretes the ABH antigens of the ABO blood group in the saliva and other body fluids; also, the gene determining this trait.

secretory (se-kre'to-re) pertaining to secretion. sectio (sek'she-o), pl. sectio'nes [L.] section.

section (sek'shun) 1. an act of cutting. 2. a cut surface. 3. a segment or subdivision of an organ. abdominal s., laparotomy. cesarean s., delivery of a fetus by incision through the abdominal wall and uterus. frontal s., a section parallel with the long axis, dividing the body into dorsal and ventral parts. frozen s., a specimen cut by microtome from tissue that has been frozen. perineal s., external urethrotomy. Pitres' s's, a series of six frontal sections made at certain specified locations through the brain. Saemisch's s., see under operation sagittal s., a section that follows the sagittal suture, dividing the head or the body into right and left halves. serial s's, histologic sections made in consecutive order and so arranged for the purpose of microscopic examination.

sectorial (sek-to're-al) cutting.

secundigravida (se-kun"dī-grav'ī-dah) a woman pregnant the second time; gravida II. secundines (se-kun'dīnz, -dēnz) afterbirth.

secundipara (se"kun-dip'ah-rah) a woman who has had two pregnancies which resulted in viable offspring; para II.

S.E.D. skin erythema dose.

Sedamyl (sed'ah-mil) trademark for a preparation of acetylcarbromal.

sedation (se-da'shun) 1, the allaying of irritability or excitement, especially by administration of a sedative. 2, the state so induced.

sedative (sed'ah-tiv) 1. allaying irritability and excitement. 2. a drug that so acts. Sedatives are classified, according to the organ most affected, as cardiac, gastric, etc.

sedentary (sed'en-ter"e) 1. sitting habitually; of inactive habits. 2. pertaining to a sitting pos-

sediment (sed'i-ment) a precipitate, especially that formed spontaneously.

sedimentation (sed"i-men-ta/shun) the settling out of sediment.

seed (sed) 1. the mature ovule of a flowering plant 2 semen 3 a small cylindrical shell of gold or other suitable material, used in application of radiation therapy. 4 to inoculate a culture medium with microorganisms. cardamom s., the dried ripe seed of Elettaria cardamomum, a plant of tropical Asia; used as a

flavoring agent. plantago s., psyllium s., cleaned, dried ripe seed of species of *Plantago*; used as a cathartic.

segment (seg'ment) a demarcated portion of a whole segmen'tal, adj. bronchopulmonary s's, the smaller subdivisions of the lobes of the lungs, separated by connective tissue septa and supplied by branches of the respective lobar bronchi hepatic s's, subdivisions of the hepatic lobes based on arterial and biliary supply and venous drainage uterine s., either of the portions into which the uterus differentiates in early labor, the upper contractile portion (corpus uteri) becomes thicker as labor advances, and the lower noncontractile portion (the isthmus) is expanded and thin-walled.

segmentation (seg"men-ta'shun) 1. division into similar parts. 2. cleavage.

segmentum (seg-men'tum), pl. segmen'ta [L.] segment.

segregation (seg"re-ga'shun) 1. the separation of allelic genes during meiosis as homologous chromosomes begin to migrate toward opposite poles of the cell, so that eventually the members of each pair of allelic genes go to separate gametes. 2. the progressive restriction of potencies in the zygote to the various regions of the forming embryo.

segregator (seg'rĕ-ga"tor) an instrument for obtaining the urine from each kidney separately. seismotherapy (siz"mo-ther'ah-pe) treatment

of disease by mechanical vibration.

seizure (se'zhur) a sudden attack, as of disease or epilepsy.

selection (së-lek'shun) the play of forces that determines the relative reproductive performance of the various genotypes in a population natural s., the survival in nature of those individuals and their progeny best equipped to adapt to environmental conditions sexual s., natural selection in which certain characteristics attract male or female members of a species, thus ensuring survival of those characteristics.

selenium (se-le'ne-um) chemical element (see table), at. no. 34, symbol Se; it causes alkali disease in animals that feed on vegetation grown on soils which contain it. s. sulfide, SeS₂, an antiseborrheic, applied topically to the scalp.

self-antigen (self-an'ti-jen) any constituent of the body's own tissues capable of stimulating autoimmunity.

self-limited (-lim'it-ed) limited by its own peculiarities, and not by outside influence; said of a disease that runs a definite limited course.

self-tolerance (-tol/er-ans) immunological tolerance to self-antigens.

sella (sel'ah), pl. sel'lae [L.] a saddle-shaped depression. sel'lar, adj. s. tur'cica, a depression on the upper surface of the sphenoid bone, lodging the pituitary gland.

semantics (se-man'tiks) study of the meanings of words and the rules of their use; study of the relation between language and significance.

semeiography (se"mi-og'rah-fe) a description of the signs and symptoms of disease.

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EXHIBIT 8

Symposium: Microsurgery of the Outflow Channels

CLINICAL RESEARCH

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and

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RV INVITATION

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Advances in microsurgical techniques and increased understanding of the pathogenesis of primary open-angle glaucoma have prompted the development of a variety of new glaucoma operations. All of them have tended to fractionate the filtering procedure so as to specifically bypass or eliminate the presumed sites responsible for the increased resistance to aqueous outflow.

Exposing Schlemm's canal directly to the anterior chamber aqueous may have been accomplished by trabeculo-canalectomy. The trabecular meshwork has been classically accepted as the major site of resistance. Experimental evidence obtained in vitro showed that in normal human and rhesus monkey eyes, excision of the perilimbal sclera down to Schlemm's canal had little effect on outflow facility. (G. R. Keskey, MD, and B. Becker, MD, unpublished data). However, ab interno

trabeculotomy in vitro increased outflow facility significantly, eliminating 75% to 90% of the resistance. 10,11 In vivo ab externo trabeculotomy in human eyes with primary open-angle glaucoma improved outflow facility and lowered intraocular pressure 12,13 (B. Becker, MD, unpublished data). Unfortunately, most observers found that the increased outflow facility was temporary. This may have been a consequence of regeneration, healing over, and scarring of the trabecular opening or of damage to the outer wall of Schlemm's canal.

In most of the in vivo series for which successful results have been reported, the trabeculotomy or trabeculocanalectomy has been done by an ab externo approach. Therefore, questions about damage to the outer wall of Schlemm's canal and even through-andthrough filtration have been difficult to resolve. In rhesus monkeys, the increase in outflow facility after ab externo trabeculotomy appeared to be only temporary, with evidence indicating regeneration or healing of the meshwork incisions. 14,15 Excised specimens from patients with primary open-angle glaucoma successfully controlled by trabeculo-canalectomy showed absence of filtration tissue or closed ends of Schlemm's canal. In addition, many of



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the long-term trabeculo-canalectomy successes failed to show improved outflow facility. These findings offered evidence against the proposed basis for the operative procedures and also raised questions about the sites of resistance to outflow.

Dvorak-Theobold and Kirk,16 as well as Krasnov and associates,17 suggested that in many eyes with primary openangle glaucoma, intrascleral pathways were obstructed peripheral to Schlemm's canal. Sinusotomy, or externalization of the canal to the sub-Tenon or subconjunctival spaces, was utilized to obviate these sites of resistance. Khasanova and his co-workers18 demonstrated a decrease in resistance to aqueous outflow after sinusotomy in eyes with primary openangle glaucoma. However, as Krasnov17 and others emphasized, one could not rule out microscopic damage to the inner wall of Schlemm's canal. In addition, sinusotomy in the living eye might well eliminate or decrease that portion of the resistance to outflow of aqueous humor influenced by episcleral venous pressure. This could result in as much as an 8 to 10 mm. Hg fall in intraocular pressure. In human eyes enucleated at autopsy, large sinusotomies increased outflow facility, but here again the questions of alterations or bulging of the inner wall have not been resolved.

To clarify the major sites of resistance in primary open-angle glaucoma, we made repeated quantitative measurements of outflow facility during each stage of trabeculo-canalectomy and other ab externo procedures in human eyes with uncontrolled primary open-angle glaucoma. A manometric constant pressure perfusion system was utilized (Fig 1). The anterior chamber was cannulated at the beginning of the operative procedure. Done with care, this presented no significant risk to the patient and only minimal inconvenience to the

surgeon. The rate of flow of fluid into the anterior chamber divided by the differences between the perfusion pressure and intraocular pressure represented the outflow facility (microliters per minute per millimeters of mercury). For example, at various stages of the trabeculo-canalectomy procedure (conjunctival reflection, cutdown through episcleral tissue, raising the scleral flap, entrance of Schlemm's canal, and opening into the anterior chamber), outflow facility was measured. As might be expected, all resistance was lost when the anterior chamber was opened. However, the cannula permitted instant re-formation of the anterior chamber at any time during the procedure. In particular, the eye with a cannulated anterior chamber and constant pressure perfusion afforded a continuous flow of aqueous humor from Schlemm's canal throughout the procedure. This occurred in spite of retrobulbar injections, hyposecretion, and manipulative compression and softening of the globe. It permitted more ready identification of outflow channels during the operation. In the seven consecutive eyes with uncontrolled primary open-angle glaucoma tested to date, outflow facility did not increase through the stage of presumptive entrance into the canal of Schlemm. Admittedly, it is difficult to be certain one has entered the canal. However, the excised specimen from at least one of these eyes showed external opening of Schlemm's canal quite clearly (Fig 2). Therefore; in all of our patients so far tested, it appeared most unlikely that the site of maximum resistance was external to Schlemm's canal.

Using Schi\(\phi\)tz tonography on 18 eyes before and five minutes after removing a scleral strip almost to Schlemm's canal, Nesterov¹⁹ noted no significant increases in outflow facility. In his series, increases in outflow facility were found, however, when Schlemm's canal was un-

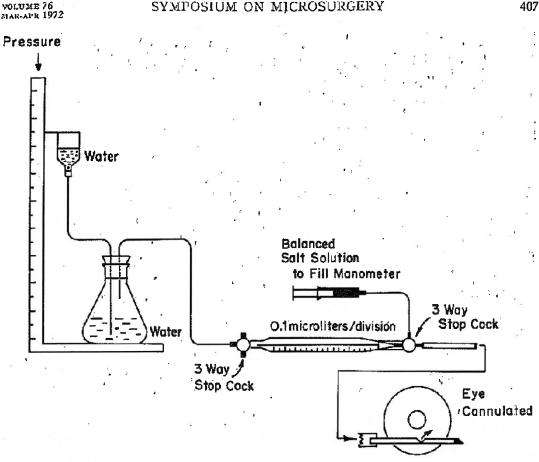


FIG !—Constant pressure perfusion system for measuring outflow facility by determining amount of fluid entering cannulated eye per minute per millimeters of mercury of pressure head.

roofed. As in successful in vitro sinusotomies in eyes enucleated at autopsy, the Nesterov procedure involved large openings (8 to 14 mm long) in Schlemm's canal. In our in vivo experiments where no increase in outflow facility was noted, Schlemm's canal was never opened more than 2 to 3 mm. Microscopic damage to the trabecular meshwork or bulging and leakage of the inner wall of Schlemm's canal would be more apt to occur with the larger openings in Schlemm's canal both in vitro and in vivo.

More difficult to investigate was the possibility that collapse or compression of Schlemm's canal was an important pathophysiologic mechanism in primary open-angle glaucoma. 19-24 Recent evi-

dence for this view stemmed from the decrease in outflow facility in vitro associated with raising perfusion intraocular pressure,21 the increase in outflow facility induced by increasing episcleral venous pressure,20 and the old observation of absence of reflux of blood into Schlemm's canal in primary open-angle glaucoma.22,24,25 Wide externalization of the canal of Schlemin as in sinusotomy might well decrease the resistance to outflow by eliminating compression of the trabecular meshwork against the outer wall of the canal. In our manometric experiments with small entry into the canal, such an effect might not be noted.

Of considerable interest to us was one eye with primary open-angle glaucoma in which a suture was introduced

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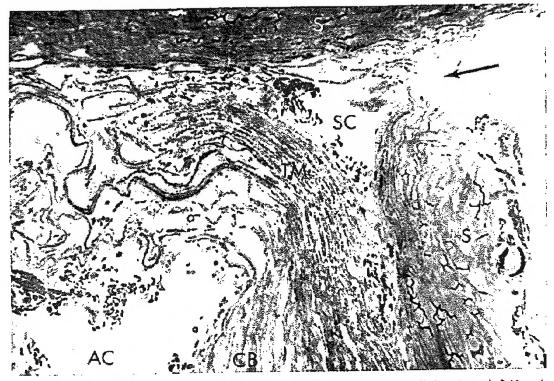


FIG 2—Excised trabeculo-canalectomy specimen illustrating incision through sclera (S) into (arrow) Schlemm's canal (SC). Note relationship of trabecular meshwork (TM), ciliary body (CB), and anterior chamber (AC) (toluidine blue, \times 295).

into the canal in an effort to hold it open. In this patient the initial outflow facility, measured manometrically on the operating room table, was $0.02\mu\mathrm{I}/$ min/mm Hg. After the canal of Schlemm was entered, the outflow facility was still 0.02µ1/min/mm Hg, but after suture insertion, a facility of 0.09 µl/min/mm Hg was recorded. This returned to 0.02µl/min/mm Hg again on suture removal. More work must be done with respect to cannulation of the canal of Schlemm during surgery on patients with primary open-angle glaucoma in order to confirm or deny such facility changes. The information so obtained could be of enormous interest not only in regard to the "collapse" theory of impaired outflow facility but also in respect to its practical therapeutic applications.

Reflux of blood into the canal of Schlemm has been demonstrated readily

in normal eyes but rarely in eyes with ocular hypertension or glaucoma.22-25 These observations could be used as an argument for the collapse of Schlemm's canal in primary open-angle glaucoma. To explore this phenomenon further, we used a standard suction gonioprism device to demonstrate reflux of blood into Schlemm's canal. We selected normotensive corticosteroid-responsive individuals whose eyes showed reflux filling of Schlemm's canal with blood when their outflow facilities and intraocular pressure were normal. Subjecting these eyes to topical corticosteroids resulted in the expected marked decrease in outflow facility and rise in intraocular pressure. However, in 12 out of 18 patients tested to date, the elevated intraocular pressure did not prevent the complete backfilling of Schlemm's caual with blood. Thus, these were examples of decreased outflow facility and elevated intraocular pressure in eyes with open angles but in which Schlemm's canal could be opened.

Application of ab interno, gonioscopically controlled techniques of graded trabeculotomy by dissection, while measuring outflow facility by constant pressure perfusion, offered a more direct approach to learning the site of resistance in the living glaucomatous eye. The cannulated eye permitted the maintenance of a deep anterior chamber for an easier and safer procedure. In addition, it informed the surgeon when the desired amount of surgical manipulation had been accomplished. Additional efforts along these lines should be pursued in normal monkey eyes. Ultimately, the procedures might be applicable to human eyes with primary open-angle glaucoma.

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Symposium: Microsurgery of the Outflow Channels

CONCLUSIONS

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THE conclusions of this symposium can be summed up in three categories.

First, these ingenious microsurgical techniques are particularly attractive because they attempt to interrupt the basic mechanism responsible for the glaucoma. In so doing, they have added clinical evidence that much of the resistance to outflow in the eye with open-angle glaucoma is caused by decreased permeability of the inner wall of Schlemm's canal and the adjacent trabecular meshwork, or perhaps by compression of the inner wall against the outer wall of the canal.

Second, our three surgeons stress the safety of these operations in competent hands. Complications have been minimal. The hydrodynamics of the eye post-operatively approaches normal. The maintenance of the anterior chamber and the absence of thin-walled blebs should

decrease cataract formation and intraocular infection. It is probable that each of the operations may find a particularly effective use in varying types of glaucoma. For example, trabeculotomy ab externo has been most successful in primary congenital glaucoma and will certainly be superior to trabeculotomy ab interno or goniotomy when corneal scarring prevents adequate visualization of the angle.

Third, and finally, I would be remiss if I failed to add a word of caution. The effectiveness of these operations in normalizing pressure without medication ranges between 65% and 85%. This is within the range reported for standard filtering operations. For microsurgery to be safe, familiarity with the operating microscope is mandatory as is a large enough volume of glaticoma surgery to maintain the surgeon's skill,

It is to be hoped that clinical research at medical centers will continue to provide information which gives us a clearer indication of the superiority of these techniques and of the type of glaucoma which will respond best to each operation.

From the University of California Medical School, San Francisco.

Presented at the Seventy-sixth Annual Meeting of the American Academy of Ophthalmology and Otolaryngology, Las Vegas, Nev, Sept 20-24, 1971.

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EXHIBIT 9

Symposium: Microsurgery of the Outflow Channels

HISTOLOGIC EVALUATION OF MICROSURGICAL GLAUCOMA TECHNIQUES

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THE microsurgical procedures under discussion in this symposium have been ingeniously conceived and are designed to localize and to remove specific sites of resistance to aqueous outflow in the anterior segment of glaucomatous eyes. In the long run, the techniques will stand or fall on the basis of their clinical usefulness. Nevertheless, it is important to ask, and to attempt to obtain answers to, several questions pertaining to each procedure. Information which partially answers some of these questions has been obtained from histologic examination of a sampling of the involved tissues. In this report the histologic findings are discussed against the background of their clinical implications.

First, I shall comment on the reliability and the limitations of the histologic findings. Many of the tissues sampled, for example, the trabeculo-canalectomy specimens, were small and sometimes difficult to orient for sectioning. Nevertheless, adequate light microscopic evaluation could be obtained. The art of tissue preparation and staining is limited partially by the manner in which the specimen has been manipulated by the

surgeon and partially by its subsequent preparation. If the tissue has been carefully handled and properly fixed, reliable electron microscopic observations can be made.

TRABECULO-CANALECTOMY

With trabeculo-canalectomy, the surgeon attempts to remove a 4- to 5-mm segment of the trabecular meshwork and the canal of Schlemm together with a portion of the adjacent supporting tissues.1 The procedure is designed to produce an opening into Schlemm's canal at each end of the excised tissue and is predicated on the assumption that the block to aqueous outflow lies in the trabecular meshwork. An attempt is made to identify the scleral spur and to excise trabeculo-canalicular tissue anterior to this surgical landmark (Fig 1, top). In a variation of this procedure an attempt is made to excise a portion of the scleral spur and anterior longitudinal ciliary muscle along with trabecular meshwork and canal of Schlemin (Fig 1, bottom [dotted outline]).2 The latter technique may possibly produce an opening not only into the canal of Schlemm but also into the potential space between the sclera and ciliary body, so that theoretically posterior internal filtration of aqueous could occur as in a cyclodialysis. I know of one case in which a gonioscopically visible cleft has been observed clinically (L. K. Garron, MD, oral communication, 1971).



From the Department of Ophthalmology, University of California, San Francisco.

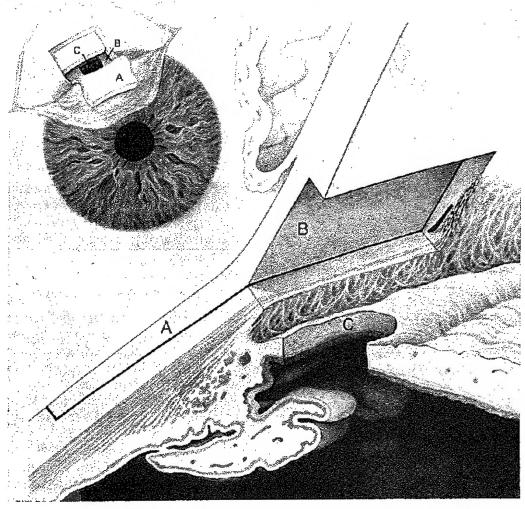
Reprint requests to Eye Pathology Laboratory, S-434, Third and Parmassus avenues, San Francisco 94122.

Presented at the Seventy-sixth Annual Meeting of the American Academy of Ophthalmology and Otolaryngology, Las Vegas, Nev, Sept 20-24, 1971.

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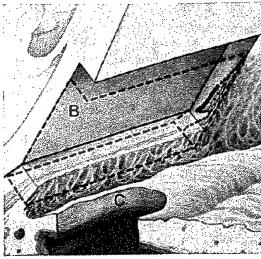


FIG. 1—Top. Trabeculo-canalectomy. Drawing of angle structures shows area of surgical intervention. A partial-thickness scleral flap (A) is prepared, and inner sclera (B) containing canal of Schlemm and trabecular tissue anterior to scleral spur is excised. Peripheral iridectomy (C) is then performed. Bottom, Modified trabeculo-canalectomy. Excised block of inner sclera $(dotted\ outline)$ includes scleral spur and anterior portion of longitudinal ciliary nussele.

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Despite use of the operating microscope, the surgeon attempting a trabeculo-canalectomy for the first time may experience difficulty in precise localization and orientation of the block of tissue to be excised. However, as the surgeon gains experience, errors of this type become less of a problem. A histologic review of a series of 49 trabeculo-canalectomy specimens submitted by the same surgeon showed evidence of this learning experience. Initially, the specimens were excised too far anteriorly and often did not include the canal of Schlemm. Indeed, one of these specimens had been excised anterior to the trabecular meshwork in its entirety (Fig 2, top [dotted outline]), and the specimen was found to be completely covered on its inner surface by Descemet's membrane (Fig 2, bottom). It is of interest that the postoperative intraocular pressure in this patient has been 16 to 18 mm Hg for the past two years without visible clinical evidence of external filtration.

Some of the initial specimens were canted so that one end of the specimen was too far anterior, the other end somewhat posterior, and only the midportion passed through the canal of Schlemm. Histologic review of the excised specimens and communication between the surgeon and the pathologist may therefore serve to assist the surgeon in his initial efforts.

What other pertinent information may be obtained histologically? A key question concerning this surgical procedure relates to the postoperative anatomic results. Do the cut ends of Schlemm's canal remain open? One specimen studied suggests that this does not occur.* The patient, a 53-year-old man with chronic open-angle glaucoma, had a clin-

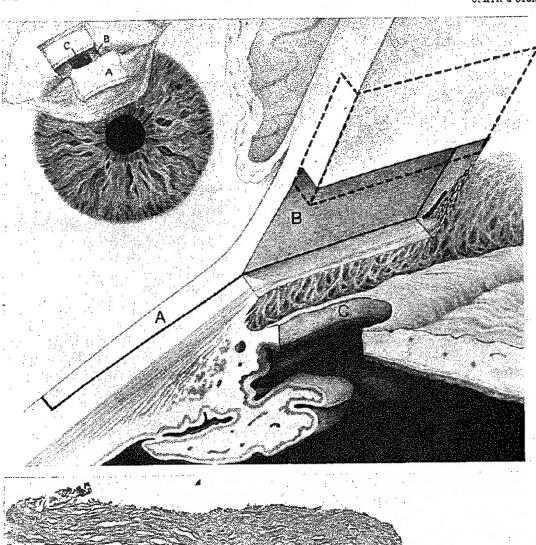
ically successful trabeculo-canalectomy performed. Postoperatively, the intraocular pressure in the eye operated on was controlled without medication. There was no clinical evidence of a filtering bleb. Four months after the operation, the patient had a stroke and died. His treated eye was enucleated at autopsy, and serial sections were prepared through the surgical site. Both ends of the canal of Schlemm and the subjacent trabecular meshwork were observed to be covered by a connective fissue scar. No patent opening into the canal or to any of the intrascleral collector channels could be seen. The intrascieral surgical scar contained traces of pigment along its course and did not appear firmly healed, and these histologic findings suggested that external filtration along this route might have occurred despite the absence of a clinically visible bleb.

It is possible that a successful trabeculo-canalectomy permits increased agueous outflow via several pathways (Fig 3). The aqueous may gain direct access to the patent cut ends of Schlemm's canal (Fig 3 [1]), but the histologic evidence gathered at present casts doubt on this route. Aqueous may leave via the ostia of the intrascleral outflow channels or may permeate the thinned outer scleral lamellae (Fig 3 [2]). It may filter externally along the course of the scleral scar (Fig 3 [3]), producing a bleb which may or may not be visible clinically. Finally, it is possible that aqueous filters internally via a surgically produced cleft between the sclera and the ciliary body (Fig 3 [4]). It will be necessary to examine many more autopsy specimens before reaching a definite conclusion relative to the route of aqueous outflow that is followed most often.

Histologic review of trabeculo-canalectomy specimens may serve still another purpose. When the procedure has

^{*}This specimen and the specimen shown in Fig 2, bottom, were from patients whose cases were cited previously by Herberington.⁹

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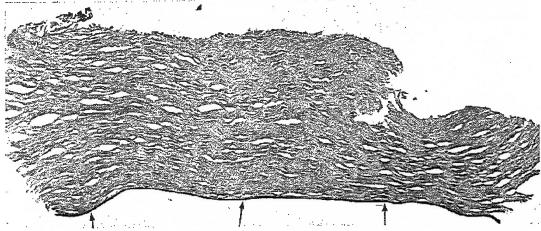


FIG 2—Top, Trabeculo-canalectomy. Dotted outline represents area from which section (bottom) was obtained. Bottom, Light micrograph of corneal tissue inadvertantly excised anterior to trabecular meshwork. Descemen's membrane (arrows) covers entire inner surface of tissue (PAS, ×100).

been performed in an eye with secondary open-angle glaucoma, or in an eye with developmental glaucoma which has been treated unsuccessfully by goniotomy, the specimen may show extensive pigmentation, iris adhesions, or scarring of the excised tissue resulting from previous inflammation, injury, or surgical treatment. The degree of scarring in some specimens has been sufficient to com-

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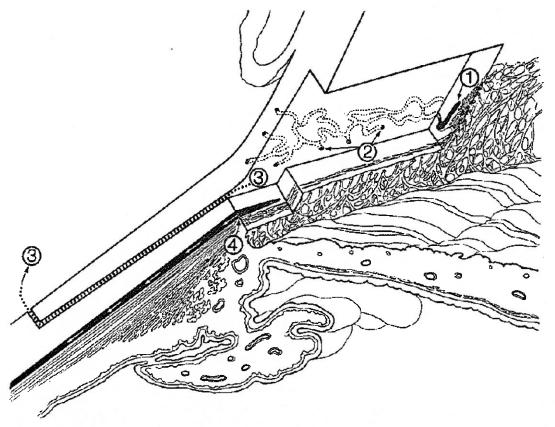


FIG 3. Trabeculo-canalectomy. Possible postoperative routes of exit of aqueous: 1. into cut ends of Schlemm's canal (if these remain patent); 2, into intrascleral outflow channels (if their ostia remain patent), or through thinned scleral lamellae; 3, along course of lamellar scleral-flap and into subconjunctival tissues (dotted out-line); 4, into the potential space between ciliary body and sclera (white arrows) as in cyclodialysis, provided that resection has been performed behind scleral spur.

pletely obliterate Schlemm's canal, and one may infer from this that the likelihood of producing an opening into Schlemm's canal in such eyes is quite small. Conversely, the presence of unscarred tissue may serve to buoy up the surgeon's hopes that intracanalicular flow may possibly be achieved by the operation.

SINUSOTOMY

Sinusotomy is designed to externalize Schlemm's canal by removing a strip of the overlying sclera (Fig 4).⁴ It is based on the assumption that in some cases of open-angle glaucoma, the block to aqueous outflow does not reside primarily in the trabecular meshwork but

rather within the overlying sclera. Exhaustive histologic studies of the trabecular meshwork and of the canal of Schlemm have been performed, but surprisingly little is known about the permeability of the outer sclera, the resistance to aqueous outflow produced by the intrascleral outflow channels, or the manner in which these factors vary with age. It has been suggested that quantitative, and possibly qualitative, variations occur in the mucopolysaccharide content of the sclera overlying the canal of Schlemm and that these may account for a decrease in scleral permeability resulting in scleral-block glaucoma. Alternatively, a similar block may be attributed to an obstruction to the aqueous channels lying within the outer sclera.

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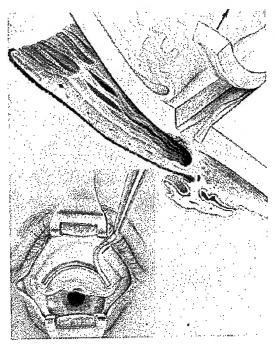


FIG 4—Sinusotomy. Area of surgical intervention, After kimbal-based conjunctival flap is prepared, a lamellar strip of outer sciera (arrow) is removed down to and including outer wall of Schlemm's canal.

Professor Krasnov was kind enough to send me two long scleral strips obtained from successful sinusotomy procedures, along with several shorter specimens of inner sclera containing trabecular tissue obtained from the combined procedure of "sinusotrabeculectomy." The combined operation was utilized for those patients in whom removal of the outer scleral strip and externalization of Schlemm's canal had not resulted in visible external weeping of aqueous from Schlemm's canal.

It is natural to wonder about the possibility that in successful sinusotomy procedures the surgeon may go "too deep" during the process of excising the sinusotomy strip and, in so doing, may remove a portion of the inner trabecular meshwork and canal of Schlemm. To check this out, step cross sections were prepared along the entire course of the sinusotomy strips submitted by Professor Krasnov. These showed no evidence of adherent trabecular tissue. In some

sections, portions of an endothelial-lined structure consistent with the outer wall of Schlemm's canal were seen.

If Krasnov's proposal is correct, histochemical differences should exist between the outer sclera of the sinusotomy strips and the inner sclera surrounding specimens from the trabeculo-canalectomy portions of the combined procedures. Sections from these tissues, along with those from a series of trabeculocanalectomy strips, full-thickness trephine buttons, sections prepared from "normal" eyes and from eyes of patients with chronic open-angle glaucoma, were simultaneously stained for mucopolysaccharide (alcian blue) and amyloid (bromeresyl violet). All sections were observed to contain a small amount of irregularly distributed scleral mucopolysaccharide which was not sensitive to treatment with hyaluronidase. No consistent quantitative differences were observed between normal and glaucomatous tissues with this stain or with a variety of other special stains (amyloid, PAS, and trichrome).

TRABECULOTOMY

With the trabeculotomy procedure, the surgeon attempts to insert a stylet along the course of Schlemin's canal and, subsequently, to rupture the inner wall of the canal and the adjacent trabecular meshwork by rotating the stylet (Fig 5).⁵ Since no tissue is actually excised during this procedure, it is difficult to evaluate histologically.

Initially, difficulty may be encountered in correctly localizing Schlemm's canal and in inserting the probe above its course. However, as shown by Dr. Dannheim, this difficulty can be overcome as the surgeon gains experience. Two specimens which serve to illustrate this initial difficulty have been reviewed.

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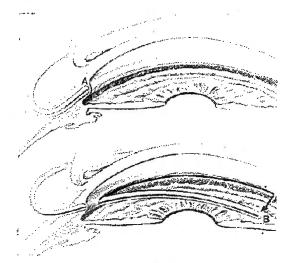


FIG 5—Trabeculotomy. Area of surgical intervention. After limbal-based conjunctival flap is prepared, a small incision is made in superior sciera down to Schlemm's canal. Probe is then inserted along course of canal (A) and rotated to cause disruption of inner wall of Schlemm's canal and trabecular tissue (B).

These specimens consisted of trabeculocanalectomy strips which were removed at the time of a combined trabeculotomytrabeculo-canalectomy procedure. Following identification of Schlemm's canal with the operating microscope and insertion of the stylet along the course of the canal, a trabeculotomy was performed (Fig 5). The stylet was then partially withdrawn, and a small segment of the superior angle structures containing trabecular tissue which had not been ruptured was excised as a trabeculo-canalectomy. The excised tissue, obtained from the area outlined in Fig 6, was submitted to the laboratory with the stylet still in place. Step cross sections showed that the stylet (diameter 0.282 mm) was slightly larger than the canal of Schlemm and that it passed in

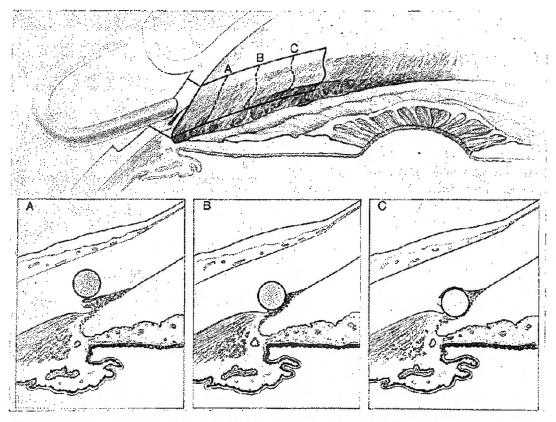


FIG 6 Combined trabeculotomy-trabeculo-canalectomy. Outlined area depicts portions of anterior chamber angle structures which were excised and submitted for examination with probe still in place. Cross-sectional drawings show probe passing external to Schlemm's canal (A), within canal (B), and internal to canal (C).

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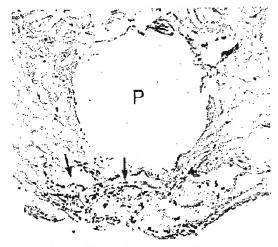


FIG 7—Light micrograph of area depicted in cross-sectional drawing A of Fig 6. Large clear space (P) represents becation of probe. Flattened canal of Schlemm (arrows) lies internal to probe. Diameter of probe is slightly larger than long dimension of canal of Schlemm (hematoxylin-cosin, ×35).

and out of the canal (Fig 6A, B, and C). Throughout most of its course, the stylet had passed intrasclerally, external to the outer wall of Schleim's canal (Fig 7).

The diameter and anatomic configuration of Schlemm's canal are usually quite variable, and septa such as those shown in Fig 8 are frequently present. It seems logical to assume, therefore, that the trabeculotomy procedure may disrupt not only the inner wall of Schlemm's canal and the trabecular meshwork, as it is designed to do, but also portions of the outer wall of the canal, septa within the canal, and lamelate of the adjacent sclera. If the probe passes between scleral lamellae, it seems possible that it may be guided along a course that bypasses the canal.

The great Spanish neuroanatomist, Ramón y Cajal, stated that "discoveries are a function of the methods used." This truism has been appropriately demonstrated by the members of this panel and by the current interest of anatomists, physiologists, and pathologists



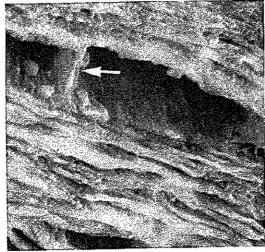


FIG 8—Scanning electron micrograph cross section of Schlemm's canal and trabecular tissues. Septum (arrows) divides Schlemm's canal and trabecular tissues. Septum (arrows) divides Schlemm's canal into two compartments (top, ×725; bottom, ×2,175).

in the outflow pathways. Hopefully, the continued use and refinement of microsurgical techniques such as those under discussion, combined with histologic evaluation, will serve as a fruitful method of controlling glaucoma and of identifying and evaluating its pathologic substrate.

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