microcannula. A particularly effective embodiment comprises a microcannula with a communicating element such as an optical fiber to provide a signaling beacon at the microcannula tip and a second communicating element to deliver a fluid such as a solution of hyaluronic acid to the microcannula tip while the signaling beacon is active. Such a microcannula may be manually manipulated and used to deliver fluids to aid microcannula advancement while simultaneously observing the microcannula tip location along the tissue space. The combination of fluid delivery in the path of the microcannula and the observation of the microcannula tip when advanced, retracted and torsioned allows precisely controlled manipulation and advancement in tight tissue spaces. The ease of manipulation is further aided with the addition of a reinforcing member to the communicating element of the microcannula.

Examples:

Example 1:

In the following example, a composite microcannula with two communicating elements was fabricated. A communicating element with a lumen (Polyimide Tubing 76 micron (0.003 inch) ID x 100 micron (0.004 inch) OD), a second communicating element comprising a plastic optical fiber (85-100 microns, (0.0034-0.0039 inch) OD), a reinforcement element (304SS wire ground to 25 microns (0.001 inches) in the distal 6.4 centimetres (2.5 inches) tapering up over a 2.5 centimetre (1.0 inch) length to a diameter of 76 microns (0.003 inches) for the remaining length of the microcannula), and an outer sheath comprising polyethylene teraphthalate (PET) shrink tubing (200 micron (0.008 inch) ID and 6.4 micron (0.00025 inch) wall thickness), were all cut to lengths appropriate for setting the final overall length of the microcannula. The distal ends of the inner components were then aligned flush and joined with an adhesive. The reinforcing element was tapered and aligned to provide more flexibility distally and stiffer reinforcement more proximal in the microcannula. The three elements were aligned in a triangular pattern rather than an in-line pattern to create an assembled profile with the smallest major-axis dimension. The assembly of multiple components was then inserted into the heat shrink tubing outer sheath so that the inner elements were aligned for capture in the heat shrink tubing. At the proximal end of the microcannula assembly, the two communicating elements were extended outside of the heat shrink tubing and separated.

The assembly was placed in a hot air stream at 220-240 degrees F, so the heat shrink recovered and the inner elements were captured to form a multi-component shaft of the microcannula. The composite microcannula demonstrated a final outer dimension of 200 to 230 microns with a lumen of 75 microns. To finish the assembly, extension communicating elements were bonded to the proximal end of the two communicating

elements respectively. The extensions were finished by adding a Luer infusion connector and an optical connector to serve as interfaces to the communicating elements. Testing of the completed microcannula was performed, demonstrating simultaneous fluid delivery from the Luer connector and light delivery from the optical connector to the microcannula tip.

Example 2:

The microcannula fabricated in Example 1 was tested in accessing Schlemm's Canal of an enucleated human eye. The first communicating element, the infusion lumen, was attached to a syringe filled with fluid at the proximal Luer connection. The second communicating element, the optical fiber, was attached to a light emitting source at the proximal connection. Operating at the temporal-superior segment of the anterior portion of the eye, two radial incisions were made to a depth of Schlemm's Canal and extending from the clear cornea approximately 3 mm posterior. A third incision was made across the posterior end of the radial incisions to define a surgical flap. The flap was then excised up toward the limbus, exposing Schlemm's Canal. The distal tip of the composite microcannula was inserted into Schlemm's Canal. The light source for the second communicating element was activated and the microcannula was advanced along Schlemm's Canal. The light emitting from the microcannula tip was seen through the sclera and used to help guide the microcannula. The microcannula was advanced along Schlemm's Canal until the tip was seen reaching an appropriate location. The syringe connected to the first communicating element extension was used to inject fluid (Healon GV, Advanced Medical Optics, Inc.) into Schlemm's Canal as needed to aid microcannula advancement. After the desired microcannula positioning was completed, the microcannula was repositioned for additional fluid injections and subsequently completely retracted from Schlemm's Canal.

Example 3:

In the following example, an atraumatic rounded distal tip component was fabricated for placement over a composite microcannula. Polyethylene teraphthalate (PET) shrink tubing (Advanced Polymers, Nashua NH) 200 micron (0.008 inch) ID and 6.4 micron (0.00025 inch) wall thickness was obtained. A length of shrink tubing approximately 2 cm long was placed over a mandrel comprised of a section of hypodermic tubing 76 micron (0.003 inch) x 178 micron (0.007 inch) diameter. Teflon coated steel wire, 64 micron (0.0025 inch) diameter was held inside the hypodermic tubing and extending beyond the end of the shrink tubing. Under stereomicroscope visualization, a point heat source (adjustable soldering iron) set to 500 degrees C was brought into close proximity to the end of the heat shrink tubing. The heat was allowed to melt the end of the tube without touching the heat source to the polymer. The surface tension of the polymer

melt created a rounded "ball-end" tip with a 64 micron (0.0025 inch) diameter lumen. The polymer was allowed to cool and then stripped off of the mandrel and wire. The length of PET shrink tubing held beyond the end of the mandrel determined the final diameter of the rounded tip. Approximately 0.20 centimetres (0.08 inches) of extension yielded tips approximately 200 micron (0.008 inch) ~~or 200 micron~~ outer diameter.

The finished component was then drawn over the distal end of a composite microcannula similar to Example 1, which was 190 microns (0.0075 inches) ~~or 190 microns~~ in largest diameter. The tip component was butted up to the end of the composite elements and then shrunk in place with a hot air stream at 240 degrees F to attach the tip.

Example 4:

In the following example, the body of a composite microcannula was formed out of a wire coil and polymer heat shrink tubing. The coil was fabricated by progressively winding a 76 micron (0.003 inch) by 25 micron (0.001 inch) stainless steel ribbon under 20 grams tension around a 140 micron (0.0055 inch) diameter stainless steel mandrel. Following removal from the mandrel, the resulting wire ribbon coil had an outside diameter of 200 microns (0.008 inches) ~~or 200 microns~~, an inside diameter of 150 microns (0.006 inches) ~~or 150 microns~~, and overall length of approximately 13 centimetres (5 inches). A 15 centimetres (6 inches) long piece of 250 micron (0.010 inch) ~~or 250 micron~~ ID PET heat shrink with a preformed rounded tip at one end was slipped over the coil and recovered using hot air over the entire length of the coil. A 100 micron (0.004 inch) diameter optical fiber was then loaded into the lumen of the microcannula and advanced to the distal end. The proximal ends were terminated into a fluid infusion lumen and 0.5mm diameter optical fiber respectively. The distal portion of the assembly was found to have desirable mechanical characteristics of flexibility and resistance to kinking.

Example 5:

An experiment was performed to test the coil-wound microcannula design as described in Example 3. Whole globe human eyes were obtained from a tissue bank. The enucleated eyes were prepared by first injecting the vitreous chamber with phosphate buffered saline to replace fluid lost post-mortem and bring the globes to a natural tone. Operating at the temporal-superior segment of the anterior portion of the eye, two radial incisions were made to a depth of Schlemm's Canal and extending from the clear cornea approximately 3 mm posterior. A third incision was made across the posterior end of the radial incisions to define a surgical flap. The flap was then excised up toward the limbus, exposing Schlemm's Canal. The microcannula was inserted into Schlemm's

Canal and advanced to approximately 90 degrees around from the access site. The metal coil was able to be seen through the scleral wall allowing the amount of microcannula advancement to be determined.

Example 6:

In the following example, a composite microcannula with several communicating elements in parallel alignment forming a distal segment with a maximum outer diameter of 250 microns was fabricated. The outer member comprised a tubular structure and the two internal communicating elements comprised elongated linear elements. At the distal end of the outer structure, an atraumatic spherical-shaped distal tip was formed. A communicating lumen was formed in the annular space between the outer tube and the inner members. The inner members comprised an optical fiber and a reinforcement element. The outer member was a tubular structure comprised of three sizes of PEBAX (polyamide/polyether copolymer), 63 durometer tubing:

1) Proximal Section 410 micron (0.016 inch) ID x 660 micron (0.026 inch) OD, 61 centimetre (24 inch) length

2) Mid Section 250 micron (0.010 inch) ID x 350 micron (0.014 inch) OD, 10 centimetre (4 inch) length

3) Distal Section 150 micron (0.006 inch) ID x 200 micron (0.008 inch) OD, 4.6 centimetre (1.8 inch) length

The outer tubular element was constructed by first cutting the individual shaft segments to lengths appropriate for setting the final overall length of the microcannula. The mid section was inserted into the proximal section with appropriate length for an overlapping bond. The tubular elements were then bonded together with an adhesive or by melt-fusing the polymeric tubes together with a controlled heat process. The distal section was bonded to the mid shaft similarly. These tubes were bonded together to form a decreasing outer diameter toward the distal tip.

The reinforcement element comprised 304 Stainless Steel wire size 25+/-13 micron (0.0010 +/-0.0005 inch) OD, and the optical fiber comprised a plastic optical fiber fabricated from polystyrene and polymethylmethacrylate with an 85 to 100 micron OD. The reinforcement element and the optical fiber were cut to lengths appropriate for setting the final overall length of the microcannula. The reinforcement element and optical fiber were inserted into the outer member assembly. The inner elements were aligned with the distal tip of the distal shaft.

An atraumatic rounded tip was formed at the end of the distal section. A quick drying UV curable adhesive (Loctite Brand 4305) was applied to the outer section of the distal

tip. An adhesive of medium to high viscosity was chosen so that the adhesive application formed a bulbous structure approximately 25 micron (0.001 inch) thickness. A small, approximately 0.03 microliter amount of adhesive was used to create the tip. The adhesive was cured to form the spherically shaped atraumatic tip with a diameter of 250 microns (0.010 inches) ~~or 250 microns~~.

The free end of the infusion lumen was terminated with a female Luer port. The proximal end of the optical fiber was connected to a Plastic Optical Fiber (POF) that terminated in an optical SMA connector.

The area of the microcannula assembly where the optical fiber and reinforcement enter the inside of the outer member was sheathed in a protective plastic housing forming a hub. The hub also provided a means for manipulation of the microcannula.

The optical SMA termination was connected to a light source and light was conducted to the tip of the microcannula to provide a signal beacon. The Luer termination was connected to a fluid-filled syringe and activation of the syringe resulted in fluid delivery through the microcannula exiting from the distal tip. Delivery of the signal beacon light and fluid could be activated individually or simultaneously.

Example 7:

In the following example, a composite microcannula with several communicating elements in parallel alignment forming a distal segment with a maximum outer diameter of 350 microns was fabricated similarly to Example 6. In this embodiment the outer member was constructed with three sizes of PEBAX tubing with slightly larger dimensions:

1) Proximal Section 410 micron (0.016 inch) ID x 660 micron (0.026 inch) OD, 61 centimetre (24 inch) length

2) Mid Section 330 micron (0.0130 inch) ID x 380 micron (0.015 inch) OD, 10 centimetre (4 inch) length

3) Distal Section 200 micron (0.008 inch) ID x 300 micron (0.012 inch) OD, 4.6 centimetre (1.8 inch) length

A spherically shaped atraumatic tip was fabricated on the microcannula by the method described in Example 6, forming a distal tip with a diameter of 350 microns (0.014 inches) ~~or 350 microns~~. In this embodiment, no reinforcing element was placed into this cannula construction, however a plastic optical fiber was incorporated similar to Example 6.

The optical SMA termination was connected to a light source and light was conducted to the tip of the microcannula. The Luer termination was connected to a fluid-filled syringe and activation of the syringe resulted in fluid delivery through the microcannula exiting from the distal tip.

Example 8:

The composite microcannulae of Example 6 and Example 7 were tested in human eyes similarly to the method of Example 2. The distal tip and distal segments of the microcannulae could be advanced along the entire circumference of Schlemm's Canal for 360 degrees while observing the beacon signal at the microcannula tip through the sclera. Injection of small amounts of hyaluronic acid-based surgical viscoelastic fluid (Healon GV, Advanced Medical Optics Inc.) delivered during advancement of the microcannulae decreased the force required for advancement and provided for more progressive advancement.

Example 9:

A composite microcannula with several collinear elements was fabricated similar to Example 6. In this embodiment, the outer structure had no mid section in that the proximal section was connected directly to the distal section.

Example 10:

In order to determine the optimal flexural properties of a composite microcannula for introduction into small tissue spaces, a family of microcannulae were fabricated with the same outer dimensions and material characteristics but with varying flexural rigidity. Flexural rigidity of a body is equal to the product of the flexural modulus, E, and the moment of inertia of the cross-section, I, and is typically called EI. The outer sheath comprised PEBAX tubing with 200 micron (0.008 inch) ~~(200 micron)~~ OD and 150 micron (0.006 inch) ~~(150 micron)~~ ID. The sample set comprised the tubing alone without reinforcing element(s), the tubing with a 100 micron outer diameter plastic optical fiber placed within the lumen and the tubing with stainless steel reinforcing wires of varying size in the lumen. The ends of the components were secured with adhesive, while

CLAIMS

1. A microcannula for access and advancement into a tissue space of an eye, comprising:

a flexible elongated element with a proximal end, a distal tip and a communicating channel therebetween, and having an outer diameter no more than 350 microns,

wherein said communicating channel is an optical fiber to transport light energy,

wherein said proximal end is adapted to connect to a light source to provide a visual light source at the distal tip, and

wherein said distal tip is rounded~~, and~~

~~wherein, when light is delivered to the rounded distal tip, the rounded distal tip acts to disperse the light for improved off-axis visualization~~.

2. The microcannula of claim 1, wherein the flexible elongated element has a flexural rigidity less than 7.5E-10 $kN*m^2$.

3. The microcannula of claim 1, wherein the flexible elongated element has a flexural rigidity less than 2.86E-10 $kN*m^2$.

4. The microcannula of claim 1, further comprising a lubricious outer coating.

5. The microcannula of claim 1, further comprising a lubricant on an outer surface of the flexible elongated element.

6. The microcannula of claim 1, wherein the flexible elongated element is contained within a polymer tube.

7. The microcannula of claim 1, wherein said distal tip is rounded into a shaped that approximates a portion of a sphere.

8. The microcannula of claim 1, wherein said distal tip is rounded into an approximately spherical shape.

9. The microcannula of claim 1, wherein the rounded distal tip is configured as a ball-end distal tip.

10. The microcannula of claim 1, wherein said flexible elongated element has an outer diameter no more than 250 microns.

11. The microcannula of claim 1, further comprising a light source connected to a proximal end of the optical fiber.

12. The microcannula of claim 1, wherein said light source comprises a laser, a laser diode, a light-emitting diode, an incandescent light, or a mercury halogen lamp.

13. A microcannula for access and advancement into a tissue space of an eye, comprising:

a flexible, tubular communicating element configured to fit within the tissue space and having a proximal end and a distal end;

a proximal connector attached to said proximal end, said proximal connector configured for introduction of materials, energy or tools;

wherein an outer diameter of said microcannula is no more than 350 microns;

wherein the distal end has a rounded distal tip; and

an optical fiber capable of delivering light to the rounded tip ~~and wherein, when light is delivered to said rounded tip, said rounded tip acts to disperse the light for improved off-axis visualization~~.

14. The microcannula of claim 13, wherein the microcannula has a proximal portion and a distal portion, and wherein the proximal portion has a flexural rigidity greater than a flexural rigidity of the distal portion.

15. The microcannula of claim 13, wherein the microcannula has a flexural rigidity of approximately 3.09 E-11 $kN*m^2$ on a distal portion of the microcannula positioned adjacent to the distal end.

16. The microcannula of claim 13, wherein the microcannula has a flexural rigidity of approximately 3.76 E-11 kN*m^2 on a distal portion of the microcannula positioned adjacent to the distal end.

17. The microcannula of claim 13, wherein the microcannula has a flexural rigidity of approximately 6.33 E-11 kN*m^2 on a distal portion of the microcannula positioned adjacent to the distal end.

18. The microcannula of claim 13, wherein the microcannula has a flexural rigidity of approximately 9.69 E-11 kN*m^2 on a distal portion of the microcannula positioned adjacent to the distal end.

19. The microcannula of claim 13, wherein the microcannula has a flexural rigidity of approximately 2.86 E-10 kN*m^2 on a microcannula positioned adjacent to the distal end.

20. The microcannula of claim 13, wherein the microcannula has a flexural rigidity of 3.09 E-11 to 9.69 E-11 kN*m^2 on a distal portion of the microcannula positioned adjacent to the distal end.

21. The microcannula of claim 13, wherein the microcannula has a flexural rigidity of 3.09 E-11 to 6.33 E-11 kN*m^2 on a distal portion of the microcannula positioned adjacent to the distal end.

22. The microcannula of claim 13, wherein the microcannula has a flexural rigidity of 3.09 E-11 to 3.76 E-11 kN*m^2 on a distal portion of the microcannula positioned adjacent to the distal end.

23. The microcannula of claim 13, wherein the microcannula has a flexural rigidity of 3.76 E-11 kN*m^2 to 9.69 E-11 kN*m^2 on a distal portion of the microcannula positioned adjacent to the distal end.

24. The microcannula of claim 13, wherein the rounded distal tip of the microcannula is approximately spherical.

25. The microcannula of claim 13, wherein the microcannula has a flexural rigidity in the range of 3.09 E-11 to 2.86 E-10 kN*m^2 on a distal portion of the microcannula positioned adjacent to the distal end.

26. The microcannula of claim 13, further comprising a reinforcing member connected with the flexible, tubular communicating element.

27. The microcannula of claim 26, wherein the reinforcing element comprises a malleable reinforcing member to allow manual shaping of the microcannula.

28. The microcannula of claim 26, wherein the reinforcing element comprises a metal.

29. The microcannula of claim 26, wherein the tubular communicating element comprises a flexible polymer and the reinforcing member comprises a metal.

30. The microcannula of claim 26, wherein the reinforcing element comprises a coil.

31. The microcannula of claim 26, wherein the reinforcing element is tapered toward the distal end of the microcannula.

32. The microcannula of claim 26, wherein the tubular communicating element and the reinforcing element are joined by an outer sheath.

33. The microcannula of claim 32, wherein the outer sheath comprises heat shrink tubing.

34. The microcannula of claim 26, wherein the tubular communicating element and the reinforcing element are joined with an adhesive.

35. The microcannula of claim 13, wherein the microcannula is configured to fit within a tissue space selected from the group consisting of Schlemm's Canal, an aqueous collector channel, an aqueous vein, a suprachoroidal space and a retinal blood vessel of the eye.

36. A microcannula for access and advancement into a tissue space of an eye, comprising:

a flexible elongated element with a proximal end, a distal tip and a communicating channel therebetween, and having an outer diameter no more than 350 microns,

wherein said communicating channel is an optical fiber to transport light energy,

wherein said proximal end is adapted to connect to a light source to provide a visual light source at the distal tip, ~~and~~

wherein said distal tip is rounded, ~~;~~ and

wherein ~~characterized in that~~ the microcannula has a flexural rigidity in the range of 3.09 E-11 to 2.86E-10kN*m^2.

~~37. The microcannula of claim 36 wherein, when light is delivered to said rounded tip, said rounded tip acts to disperse the light for improved off-axis visualization.~~

3738. The microcannula of claim 36, further comprising a lubricious outer coating.

3839. The microcannula of claim 36, wherein the flexible elongated element is contained within a polymer tube.