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D.O.R.C. Dutch Ophthalmic Research Center (International) B.V. te Zuidland.

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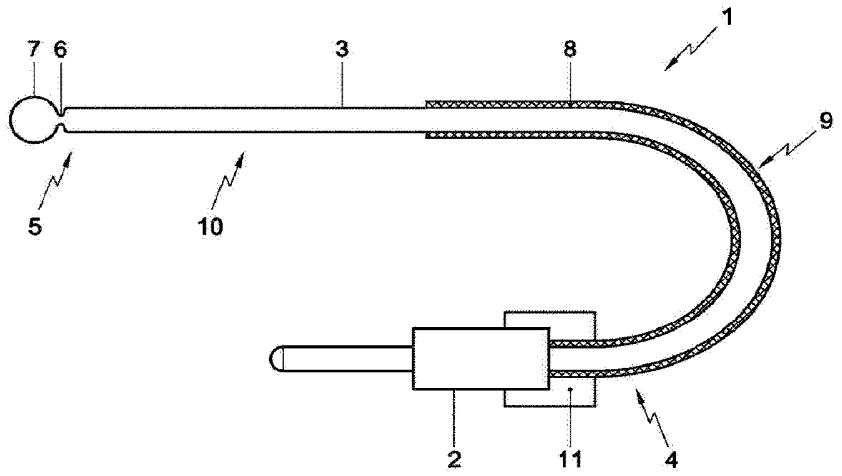
(54) **An ophthalmic surgical device and a method of performing ophthalmic surgery.**

(57) The invention relates to an ophthalmic surgical device for the treatment of glaucoma. The device comprises a fiber connector and a fiber. The fiber is provided with a proximal end connected to the fiber connector. Further, the fiber is provided, near its distal end, with a notch. Preferably, the distal end of the fiber forms a rounded tip.



NL C 2004047

P89806NL00

Title: An ophthalmic surgical device and a method of performing ophthalmic surgery

The invention relates to an ophthalmic surgical device for the treatment of open angle glaucoma through direct surgery.

About two percent of people in Europe and in the United States have glaucoma. Glaucoma is a group of eye diseases that can damage the eye's optic nerve and can cause corresponding visual field loss resulting in blindness if left untreated.

A considerable rise in intraocular pressure appears to be a major etiologic factor in glaucoma.

The eyeball is basically a rigid sphere filled with fluids. There are three chambers of fluid in the eye: Anterior Chamber (between the cornea and the iris), Posterior Chamber (between iris, zonule fiber and lens) and the Vitreous Chamber (between the lens and the retina). The first two chambers are filled with a clear fluid called aqueous humour whereas the vitreous chamber is filled with a more viscous fluid, the vitreous humour. The aqueous humour or "aqueous" carries nutrients to the lens and cornea, both of which have no blood supply. The aqueous is constantly secreted by the ciliary body (which is located behind the iris and around the lens) and flows from the posterior chamber through the pupil into the anterior chamber and drains out of the eye through a spongy tissue called trabecular meshwork (TM).

TM is located in the drainage angle of the anterior chamber, between the internal periphery of the cornea and the outer rim of the iris at the location where the iris meets the external wall of the eye (sclera). The fluid drains from the TM into a small canal (the Schlemm canal), then into aqueous collector channels and into aqueous veins.

Aqueous is produced by the ciliary body and removed from the eye at a constant rate to maintain a constant pressure in the anterior chamber of the eye. If the resistance to fluid flow increases, pressure inside the eye increases

and the circulation of blood to the optic nerve is restricted. If the ocular pressure remains elevated for prolonged periods of time, the fibres of the optic nerve may cause atrophy resulting in loss of vision in the afflicted eye.

Glaucoma is roughly classified into two categories: closed angle glaucoma and open angle glaucoma. The closed angle glaucoma is caused by closure of angle of the anterior chamber by contact between the iris and the inner surface of the TM. Closure of this anatomical angle prevents normal drainage of aqueous from the anterior chamber. In open angle glaucoma the angle of the anterior chamber remains open, but the exit of aqueous through the TM is diminished. The source of resistance to outflow is in the TM.

Many of the current therapies for glaucoma are directed at reducing intraocular pressure. This is initially treated using medical therapy with drops or pills that reduce the production of aqueous or increase the outflow of aqueous. However, these various drug therapies for glaucoma are sometimes associated with considerable side effects, such as headaches, blurred vision, allergic reactions, cardiopulmonary complications and potential interactions with other drugs.

When the drug therapy fails, surgical therapy is used.

Surgical therapy for open angle glaucoma includes laser and surgery methods. The surgery methods can be classified as follows.

Goniotomy/trabeculotomy: These are simple and direct microsurgical dissection techniques with mechanical destruction of the TM. Initially this surgery provided favourable responses, however long term results showed only limited success in adults. These procedures probably failed later following repair mechanisms and "filling" processes. The "filling in" effect is the result of the healing process forming scars, which have the detrimental effect of collapsing and closing the opening that has been created in the TM. Once this opening is closed the pressure builds up inside once more and the surgery fails.

Goniocurettage: This is an ab-interno (performed from the inside) mechanical destructive technique. An instrument similar to a cyclodialysis

spatula is used with a microcurette on the tip. Initial results are similar to trabeculotomy with subsequential failure following repair mechanisms and the filling in process.

Trabeculectomy: This is the most commonly performed filtering surgery. It involves creating a tiny filtering valve in the sclera. This procedure controls pressure by creating a new drainage channel through the angle structures to the extracellular space beneath the conjunctiva.

Trabeculectomy is a major surgery and is aided with locally applied anticancer drugs such as 5-flurouracil or mitomycin-c to reduce scarring and increase surgical success. Current mortality associated with trabeculectomy consists of failure (10-15%), infections (a life long risk about 2-5%), choroidal haemorrhage (1%, a severe internal haemorrhage from insufficient pressure resulting in visual loss), cataract formation, and hypotony maculopathy (potentially reversible visual loss from insufficient pressure). Another disadvantage of this procedure is that the body's natural healing process may gradually close the filter, causing the pressure to rise again.

Viscocanulostomy (VC) and Non Penetrating Trabeculectomy (NPT) are two new variations of filtering surgery. These are both major surgery procedures in which the Schlemm canal is surgically exposed by making a large and very deep scleral flap. In the VC procedure, the Schlemm canal is canulated and a viscoelastic substance injected (which dilates the Schlemm canal and aqueous collector channels). In the NPT procedure, the inner wall of the Schlemm canal is stripped away after the canal has been surgically exposed.

Trabeculectomy, VC and NPT are performed under a conjunctival and scleral flap so that the aqueous is drained onto the surface of the eye or into the tissues located near the lateral wall of the eye. Normal physiological outflows are not used.

Drainage devices: When Trabeculectomy, VC and NPT are not considered to have good probabilities of success, a number of implantable

drainage devices are used to ensure that the desired filtration and outflow of aqueous through the surgical opening can continue. Placing glaucoma drainage implants also increases the risk of haemorrhage, infection and postoperative double vision that is a complication unique to drainage implants.

The treatment procedures and variations described above have numerous disadvantages and are generally only moderately successful. They involve considerable trauma to the eye and require great surgical skill to create a hole in the total thickness of the sclera/cornea in the sub-conjunctival space. Furthermore, normal physiological outflow pathways are not used. Procedure is lengthy and requires an operating theatre and the presence of an anaesthesiologist with all the costs involved, and the vision recovery time is also a long process.

The complications of filtration surgery have induced ophthalmic surgeons to look into alternative approaches for lowering intraocular pressure. The TM and the juxtacanalicular tissues both create the main resistance to aqueous outflow and for this reason they are the logical targets for surgical treatment of open angle glaucoma. Trabecular surgery has a much lower potential risk of choroidal haemorrhage, infections and furthermore, it aims at restoring physiologic outflow mechanisms. This surgery can be performed under local anaesthesia with rapid visual recovery.

The aim of the present invention is to eliminate at least one of the disadvantages of the prior art. More specifically, the invention aims at providing an ophthalmic surgical device for the efficacious treatment of open angle glaucoma. Thereto, the device according to the invention comprises a fiber connector and a fiber having a proximal end connected to the fiber connector, wherein the fiber is provided, near its distal end, with a notch.

The invention also relates to a method of performing ophthalmic surgery, comprising the steps of forming an incision in the eye's Schlemm's canal, inserting a fiber's distal end through the incision into the Schlemm's canal, advancing the fiber's distal end around in the Schlemm's canal,

attaching a suture to the fiber's distal end, retracting the fiber backwardly through the Schlemm's canal, and connecting the suture ends.

By drawing a suture through the Schlemm's canal and connecting the suture ends, in an elegant way, the canal can be opened re-establishing a natural outflow and reducing the intraocular eye over pressure. As a result, an efficacious treatment of open angle glaucoma is obtained. In an advantageous way, the suture can be drawn through the Schlemms's canal by attaching the suture to the notch a the fiber's distal end, thereby counteracting additional injury during the process of retracting the fiber backwardly.

Further advantageous embodiments according to the invention are described in the following claims.

By way of example only, embodiments of the present invention will now be described with reference to the accompanying figures in which

Fig. 1 shows a schematic cross sectional view of an ophthalmic surgical device according to the invention;

Fig. 2 shows a schematic partial cross sectional view of the human eye;

Fig. 3a shows a schematic view of the device in a first state;

Fig. 3b shows a schematic view of the device in a second state;

Fig. 3c shows a schematic view of the device in a third state; and

Fig. 4 shows a flow chart of steps of a method according to the invention.

It is noted that the figures show merely a preferred embodiment according to the invention. In the figures, the same reference numbers refer to equal or corresponding parts.

Figure 1 shows a schematic cross sectional view of an ophthalmic surgical device 1 according to the invention. The surgical device 1 is intended for use in a surgical method for treatment of glaucoma, as explained in more detail below.

The device 1 comprises a fiber connector 2 and a fiber 3. The fiber 3 has a proximal end 4 and a distal end 5. The proximal end 4 is connected to the fiber connector 2, while the fiber 3 is further provided, near its distal end, with a notch 6. The distal end 5 of the fiber forms a rounded tip 7 to minimize tissue trauma and allow the fiber to advance in small tissue spaces, such as the eye's Schlemm's channel. In addition, light propagating through the fiber 3 is dispersed by the rounded tip 7, thereby visualizing the channel's interior under a range of incidence angles.

The fiber 3 has a substantially constant diameter, advantageously less than circa 0.2 mm, e.g. circa 0.15 mm. Preferably, the fiber diameter is smaller than the diameter of the rounded tip 7, thus further facilitating movement of the fiber through Schlemm's channel. As an example, the rounded tip diameter is circa 0.2 mm. However, in another embodiment, the rounded tip diameter is equal or smaller than the fiber diameter, e.g. for the purpose advancing through extremely small tissue apertures. Further, instead of applying a rounded distal tip, the fiber can also be provided with another distal tip geometry, e.g. a tapered distal tip to enable puncturing through tissue.

As shown in Fig. 1, the notch 6 is located close to the rounded tip 7, just behind the tip 7. In principle, the notch 6 can also be realized at a location offset from the tip 7. However, in order to draw a suture through the Schlemm's channel properly, the offset between the tip 7 and the notch 6 is relatively small.

The device 1 further comprises an optional coating layer 8 covering a proximal end section 9 the fiber 3. The coating layer 8 provides mechanical protection to the fiber 3. A distal end section 10 of the fiber 3 is free of a coating layer 8 to minimize its radial thickness. As an example, the distance of the free distal end section 10 is circa 40 cm. However, also other distances can be applied, e.g. more than 40 cm such as circa 50 cm, or less than 40 cm such as circa 30 cm. The device 1 according to the invention may have a total length in a range between circa 50 cm and circa 250 cm, e.g. 2 m.

In the transition area between the fiber proximal end 4 and the fiber connector 2, a silicone layer 11 is provided on top of the connector exterior surface and the coating layer 8.

Figure 2 shows a schematic partial cross sectional view of the human eye 20. The eye contains a so-called canal of Schlemm 21 for flowing aqueous humour from the anterior chamber 22 into aqueous collector channels 23 and into aqueous veins.

According to an aspect of the invention, treatment of open angle glaucoma is performed through direct surgery, using the ophthalmic surgical device 1 shown in Fig. 1.

Figures 3a,b,c show a schematic view of the device 1 in a first, second and third state, respectively. In the process of treating the glaucoma, an incision is formed in the eye's Schlemm's canal 30. By making the incision, a trabeculectomy flap 31 is created for opening the canal 30. Then, the fiber's distal end 5 is inserted through the incision 31 into the canal 30, as shown in Fig. 3a. The fiber's distal end 5 is advanced in the Schlemm's canal 30, all around, and protrudes through the same incision 31, as shown in Fig. 3b. Subsequently, a suture 32 is attached to the neck of the distal end, formed by the rounded end tip 7 and the notch 6 behind the tip 7. Then, the fiber 3 is retracted backwardly through the Schlemm's canal 30 until the fiber 3 is removed from the canal 30 and the suture 32 is thus drawn all around in the canal 30. The suture 32 can be released from the fiber 3 so that the suture ends 33, 34 can now be connected, preferably with a little tension to stretch and open the Schlemm's canal 30.

By advancing the fiber's distal end 5 over 360°, the incision 31 can be used both for inserting the tip 7 into and from the canal 30, thereby reducing additional trauma. The suture 32 can be manufactured from a variety of materials, e.g. from 10,0 prolyne.

According to an aspect of the invention, the fiber 3 is illuminated while advancing the fiber's distal end 5 in the Schlemm's canal 30, thereby

facilitating the advancing process since the person operating the ophthalmic surgical device 1 can easily keep track of progress of the fiber 3 in the canal 30. Thereto, the fiber connector 2 is connected to a light source generating light that propagates through the fiber 3.

Figure 4 shows a flow chart of method steps according to the invention. The method includes performing ophthalmic surgery. The method comprises the step 110 of forming an incision in the eye's Schlemm's canal, a step 120 of inserting a fiber's distal end through the incision into the Schlemm's canal, a step 130 of advancing the fiber's distal end around (360 graden, all around) in the Schlemm's canal, a step 140 of attaching a suture to the fiber's distal end, a step 150 of retracting the fiber backwardly through the Schlemm's canal, and a step 160 of connecting the suture ends.

The invention is not restricted to the embodiments described herein. It will be understood that many variants are possible.

These and other embodiments will be apparent for the person skilled in the art and are considered to lie within the scope of the invention as defined in the following claims.

Conclusies

1. Oogheelkundig chirurgisch apparaat voor de behandeling van glaucoom, omvattende een fiberverbindingsstuk en een fiber met een proximaal uiteinde verbonden met het fiberverbindingsstuk, waarbij de fiber, nabij zijn distale uiteinde, is voorzien van een inkeping.

2. Oogheelkundig chirurgisch apparaat volgens conclusie 1, waarbij het distale uiteinde van de fiber een afgeronde tip vormt.

3. Oogheelkundig chirurgisch apparaat volgens conclusie 1, waarbij de fiber een in hoofdzaak constante diameter heeft die kleiner is dan de diameter van de afgeronde tip.

4. Oogheelkundig chirurgische apparaat volgens één van de voorgaande conclusies, waarbij de inkeping zich dicht bij de afgeronde tip bevindt.

5. Oogheelkundig chirurgisch apparaat volgens één van de voorgaande conclusies, waarbij de in hoofdzaak constante diameter van de fiber kleiner is dan circa 0,2 mm.

6. Oogheelkundig chirurgisch apparaat volgens één van de voorgaande conclusies, waarbij een distaal eindgedeelte van de fiber vrij is van een deklaag.

7. Werkwijze voor het uitvoeren van oogheelkundige chirurgie, omvattende de stappen van:

- het vormen van een incisie in het kanaal van Schlemm van het oog;
- het inbrengen van een distaal fiberuiteinde door de incisie in het kanaal van Schlemm;
- het rondom voortbewegen van het distaal fiberuiteinde in het kanaal van Schlemm;
- het vastmaken van een hechtdraad aan het distaal fiberuiteinde;
- het achterwaarts terugtrekken van de fiber door het kanaal van Schlemm; en
- het verbinden van de uiteinden van de hechtdraad.

8. Werkwijze volgens conclusie 7, voorts omvattende de stap van het verlichten van de fiber tijdens het voortbewegen van het distaal fiberuiteinde in het kanaal van Schlemm;

9. Werkwijze volgens conclusie 7 of 8, waarbij de uiteinden van de hechtdraad onder spanning zijn verbonden.

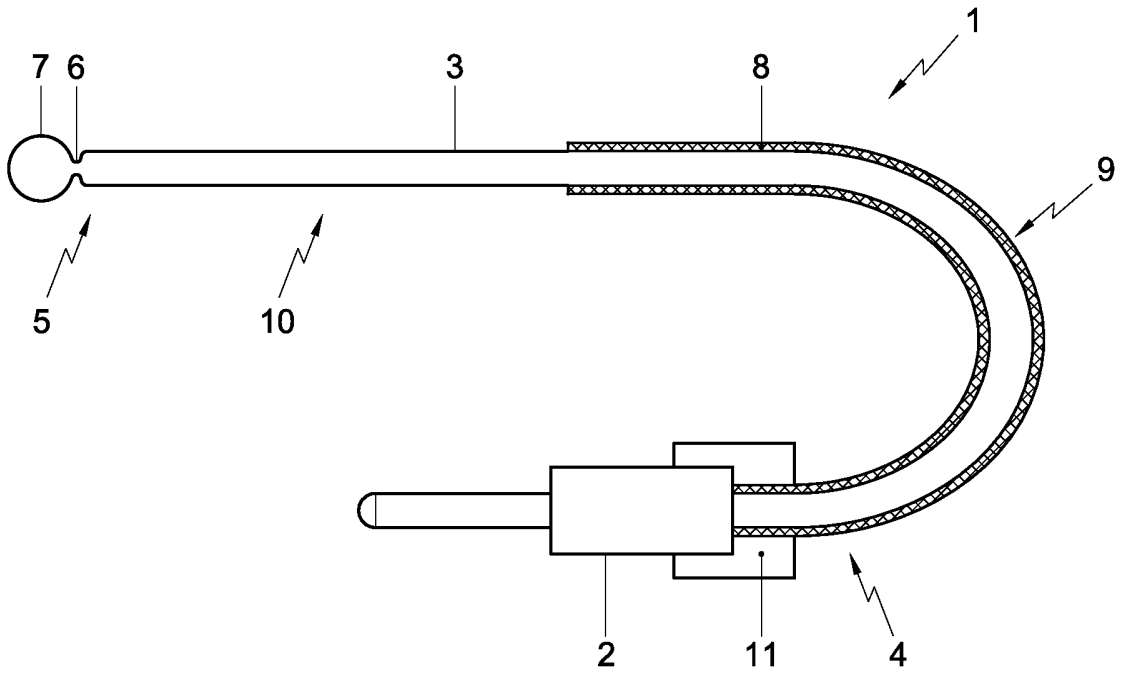


Fig. 1

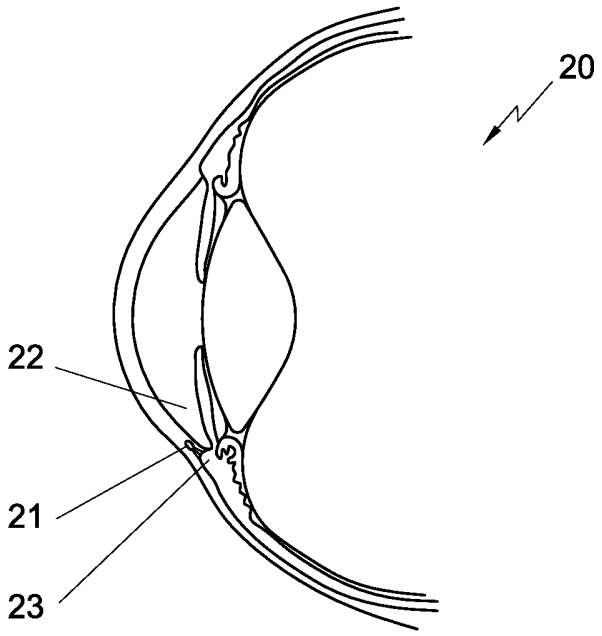


Fig. 2

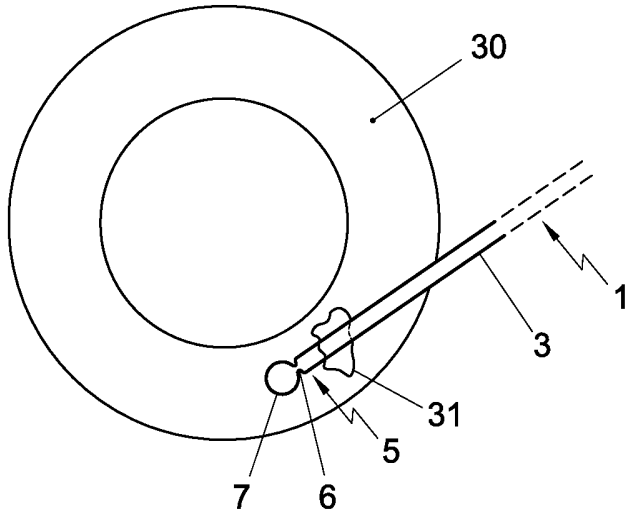


Fig. 3a

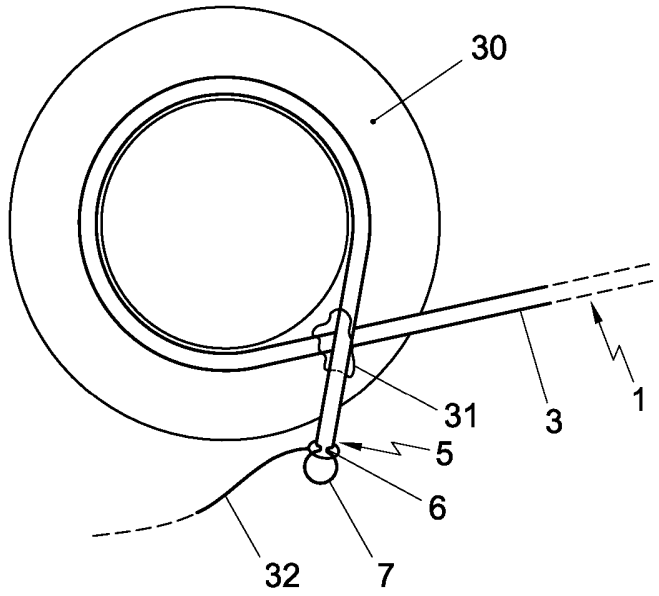


Fig. 3b

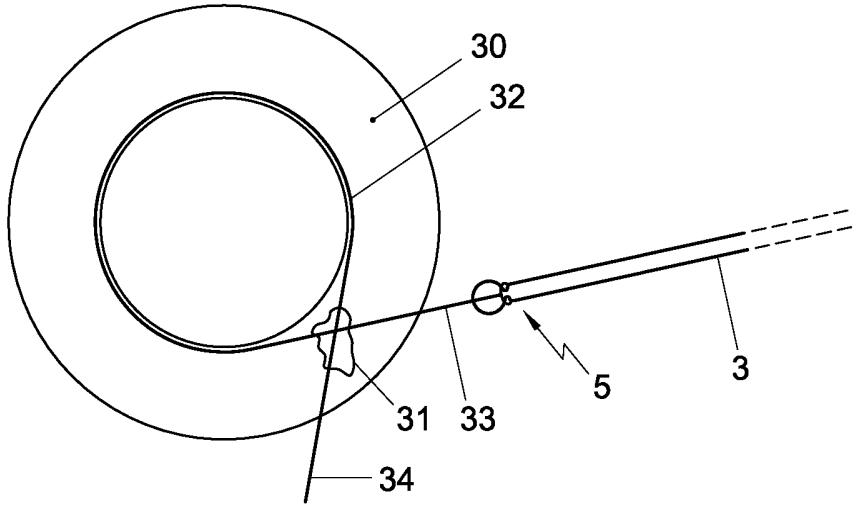


Fig. 3c

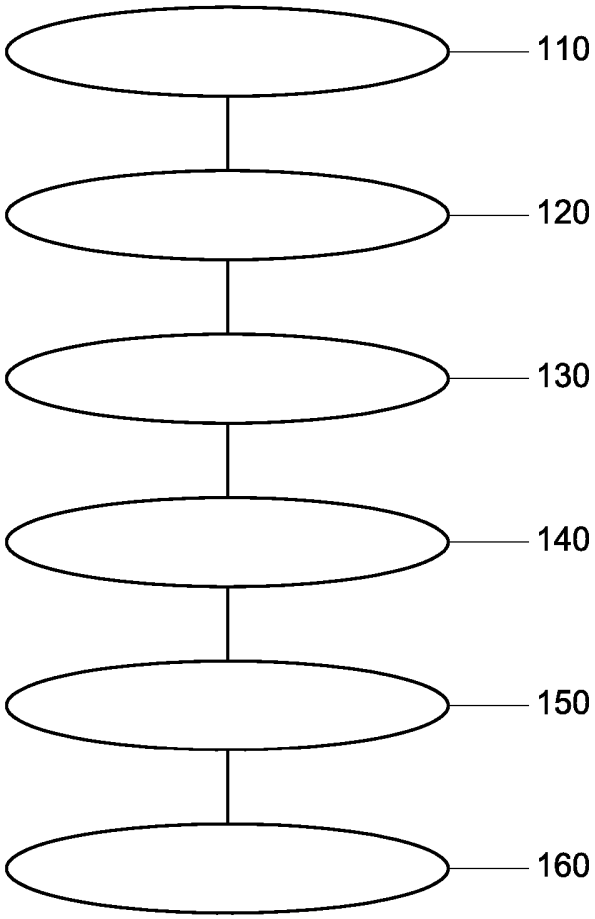


Fig. 4

SAMENWERKINGSVERDRAG (PCT)

RAPPORT BETREFFENDE NIEUWHEIDSONDERZOEK VAN INTERNATIONAAL TYPE

IDENTIFICATIE VAN DE NATIONALE AANVRAGE	KENMERK VAN DE AANVRAGER OF VAN DE GEMACHTIGDE
	P89806NL00
Nederlands aanvraag nr. **2004047**	Indieningsdatum **04-01-2010**
	Ingeroepen voorrangsdatum

Aanvrager (Naam)

D.O.R.C. Dutch Ophthalmic Research Center (International) B.V.

Datum van het verzoek voor een onderzoek van internationaal type	Door de Instantie voor Internationaal Onderzoek aan het verzoek voor een onderzoek van internationaal type toegekend nr.
19-06-2010	**SN 54369**

I. CLASSIFICATIE VAN HET ONDERWERP (bij toepassing van verschillende classificaties, alle classificatiesymbolen opgeven)

Volgens de internationale classificatie (IPC)

A61F9/007 **G02B6/26** **A61B17/04**
A61F9/008 **A61F9/011**

II. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte minimumdocumentatie

Classificatiesysteem	Classificatiesymbolen		
IPC	**A61F**	**G02B**	**A61B**

Onderzochte andere documentatie dan de minimum documentatie, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

III.	X	**GEEN ONDERZOEK MOGELIJK VOOR BEPAALDE CONCLUSIES**	(opmerkingen op aanvullingsblad)
IV.		**GEBREK AAN EENHEID VAN UITVINDING**	(opmerkingen op aanvullingsblad)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2004047

A. CLASSIFICATIE VAN HET ONDERWERP
INV. A61F9/007 G02B6/26 A61B17/04 A61F9/008 A61F9/011
ADD.

Volgens de Internationale Classificatie van octrooien (IPC) of zowel volgens de nationale classificatie als volgens de IPC.

B. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte miminum documentatie (classificatie gevolgd door classificatiesymbolen)
A61F G02B A61B

Onderzochte andere documentatie dan de mimimum documentatie, voor dergelijke documenten, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

Tijdens het onderzoek geraadpleegde elektronische gegevensbestanden (naam van de gegevensbestanden en, waar uitvoerbaar, gebruikte trefwoorden)
EPO-Internal

C. VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
	ONVOLLEDIG ONDERZOEK zie aanvullingsblad C -----	
X	US 5 514 125 A (LASSER THEO [DE] ET AL) 7 mei 1996 (1996-05-07)	1,2,4,6
Y	* kolom 1, regel 46 - kolom 2, regel 9; figuur 1 * * kolom 2, regel 63 - kolom 3, regel 19 * -----	3,5
Y	US 2002/111608 A1 (BAERVELDT GEORGE [US] ET AL) 15 augustus 2002 (2002-08-15) * samenvatting; figuren 32A, 32B * * alinea [0161] * -----	3
	-/--	

[X] Verdere documenten worden vermeld in het vervolg van vak C.

[X] Leden van dezelfde octrooifamilie zijn vermeld in een bijlage

° Speciale categorieën van aangehaalde documenten

"A" niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft

"D" in de octrooiaanvrage vermeld

"E" eerdere octrooi(aanvrage), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven

"L" om andere redenen vermelde literatuur

"O" niet-schriftelijke stand van de techniek

"P" tussen de voorrangsdatum en de indieningsdatum gepubliceerde literatuur

"T" na de indieningsdatum of de voorrangsdatum gepubliceerde literatuur die niet bezwarend is voor de octrooiaanvrage, maar wordt vermeld ter verheldering van de theorie of het principe dat ten grondslag ligt aan de uitvinding

"X" de conclusie wordt als niet nieuw of niet inventief beschouwd ten opzichte van deze literatuur

"Y" de conclusie wordt als niet inventief beschouwd ten opzichte van de combinatie van deze literatuur met andere geciteerde literatuur van dezelfde categorie, waarbij de combinatie voor de vakman voor de hand liggend wordt geacht

"&" lid van dezelfde octrooifamilie of overeenkomstige octrooipublicatie

Datum waarop het onderzoek naar de stand van de techniek van internationaal type werd voltooid	Verzenddatum van het rapport van het onderzoek naar de stand van de techniek van internationaal type
10 augustus 2010	

Naam en adres van de instantie	De bevoegde ambtenaar
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Fax: (+31–70) 340–3016	Neumann, Elisabeth

2

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2004047

C.(Vervolg). VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
Y	WO 2005/070490 A2 (ISCIENCE SURGICAL CORP [US]; CHRISTIAN JEFFREY [US]; CONSTON STANLEY R) 4 augustus 2005 (2005-08-04) * bladzijde 11, alinea 3; conclusie 23; figuur 7 * * bladzijde 1, alinea 2 * -----	5
X	WO 2006/066103 A2 (ISCIENCE SURGICAL CORP [US]; STEGMANN ROBERT [ZA]; CONSTON STANLEY R [) 22 juni 2006 (2006-06-22)	1-3,5
A	* alinea [0049] - alinea [0050]; conclusie 47; figuren 10a, 10b * -----	6
A	US 6 241 721 B1 (COZEAN COLETTE [US] ET AL) 5 juni 2001 (2001-06-05) * kolom 10, regel 48 - kolom 11, regel 21; figuren 7-10 * -----	1

Formulier PCT/ISA/201 (vervolg tweede blad) (Januari 2004)

ONVOLLEDIG ONDERZOEK
AANVULLINGSBLAD C

Octrooiaanvrage Nr.:
SN 54369
NL 2004047

Volledig onderzoekbare conclusie(s):
1-6

Niet onderzochte conclusie(s):
7-9

Reden voor de beperking van het onderzoek (niet octrooieerbare uitvinding(en)):

Methode van behandeling van het menselijke lichaam door chirurgische ingrepen

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Informatie over leden van dezelfde octrooifamilie

Nummer van het verzoek om een onderzoek naar de stand van de techniek: NL 2004047

In het rapport genoemd octrooigeschrift	Datum van publicatie	Overeenkomend(e) geschrift(en)	Datum van publicatie
US 5514125	A 07-05-1996	DE 9409616 U1	04-08-1994
		DE 29507925 U1	20-07-1995
US 2002111608	A1 15-08-2002	US 2006106370 A1	18-05-2006
WO 2005070490	A2 04-08-2005	AU 2005206212 A1	04-08-2005
		CA 2554257 A1	04-08-2005
		CN 1909859 A	07-02-2007
		EP 1715827 A2	02-11-2006
		JP 2007522836 T	16-08-2007
		SG 149883 A1	27-02-2009
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		BR PI0519087 A2	23-12-2008
		CA 2592459 A1	22-06-2006
		CN 101128171 A	20-02-2008
		EP 1833440 A2	19-09-2007
		JP 2008523917 T	10-07-2008
		KR 20070092279 A	12-09-2007
		US 2006195187 A1	31-08-2006
US 6241721	B1 05-06-2001	GEEN	

OCTROOICENTRUM NEDERLAND

WRITTEN OPINION

File No.	Filing date *(day/month/year)*	Priority date *(day/month/year)*	Application No.
SN54369	04.01.2010		NL2004047

International Patent Classification (IPC)
INV. A61F9/007 G02B6/26 A61B17/04 A61F9/008 A61F9/011

Applicant
D.O.R.C. Dutch Ophthalmic Research Center (International) B.V.

This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the application
- ☒ Box No. VIII Certain observations on the application

	Examiner
	Neumann, Elisabeth

Application number

WRITTEN OPINION

NL2004047

Box No. I Basis of this opinion

1. This opinion has been established on the basis of the latest set of claims filed before the start of the search.

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ on paper

   ☐ in electronic form

   c. time of filing/furnishing:

   ☐ contained in the application as filed.

   ☐ filed together with the application in electronic form.

   ☐ furnished subsequently for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Application number

WRITTEN OPINION

NL2004047

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step, or to be industrially applicable have not been examined in respect of

☐ the entire application

☒ claims Nos. 7-9

because:

☐ the said application, or the said claims Nos. relate to the following subject matter which does not require a search *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no search report has been established for the whole application or for said claims Nos. 7-9

☐ a meaningful opinion could not be formed as the sequence listing was either not available, or was not furnished in the international format (WIPO ST25).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; or such tables were not available in electronic form.

☐ See Supplemental Box for further details.

Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes:	Claims	3, 5
	No:	Claims	1, 2, 4, 6
Inventive step	Yes:	Claims	
	No:	Claims	1-6
Industrial applicability	Yes:	Claims	1-6
	No:	Claims	

2. Citations and explanations

see separate sheet

Application number

WRITTEN OPINION

NL2004047

Box No. VII Certain defects in the application

see separate sheet

Box No. VIII Certain observations on the application

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 7 - 10 refer to a method of surgery which involves the cutting of an eyeball in order to insert a fiber into the incision. This treatment of the human body by surgery is excluded from patentability.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1	US 5 514 125 A (LASSER THEO [DE] ET AL) 7 mei 1996 (1996-05-07)
D2	US 2002/111608 A1 (BAERVELDT GEORGE [US] ET AL) 15 augustus 2002 (2002-08-15)
D3	WO 2005/070490 A2 (ISCIENCE SURGICAL CORP [US]; CHRISTIAN JEFFREY [US]; CONSTON STANLEY R) 4 augustus 2005 (2005-08-04)
D4	WO 2006/066103 A2 (ISCIENCE SURGICAL CORP [US]; STEGMANN ROBERT [ZA]; CONSTON STANLEY R [) 22 juni 2006 (2006-06-22)
D5	US 6 241 721 B1 (COZEAN COLETTE [US] ET AL) 5 juni 2001 (2001-06-05)

1 INDEPENDENT CLAIM 1

The present application does not meet the criteria of patentability, because the subject-matter of claim 1 is not new.

Document D1 discloses [insert references applying to this document]:

An opthalmic surgical device for the treatment of glaucoma (kolom 1, regel 46 - kolom 2, regel 9; figuur 1), comprising a fiber connector (laser) and a fiber (2) having a proximal end connected to the fiber connector (kolom 2, regel 63 - kolom 3, regel 19), wherein the fiber (2) is provided, near its distal end (4, 5), with a notch (3).

Claim 1 is also not considered inventive in view of document D4 (see alinea [0049] - alinea [0050]; conclusie 47; figuren 10a, 10b) which describes a fiber for insertion of a suture in the trabecular meshwork. The instrument (fiber) has an increased diameter segment 26 at the distal end to facilitate attachment of one end of the implant (suture). Such features may include designs such as an appropriately sized hole or slot at one end of the instrument to insert and attach a portion of the implant.

As such a notch is only a design feature which can be chosen by the skilled person whereby that feature is an equivalent to the features described in D4 and can be interchanged with that feature where circumstances make it desirable.

2 DEPENDENT CLAIMS 2 - 6

Dependent claims 2 - 6 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of novelty and/or inventive step, see for example:

D1, kolom 1, regel 46 - kolom 2, regel 9; figuur 1; kolom 2, regel 63 - kolom 3, regel 19 for claims 2, 4, 6.

D2, samenvatting; figuren 32A, 32B; alinea [0161] for claim 3;

D3, bladzijde 11, alinea 3; conclusie 23; figuur 7; bladzijde 1, alinea 2 for claim 5.

Re Item VII

Certain defects in the application

1 The relevant background art disclosed in documents D1 and D4 is not mentioned in the description, nor are these documents identified therein.

2 Independent claim 1 is not in the two-part form, which in the present case would be appropriate, with those features known in combination from the prior art (D1) being placed in the preamble and the remaining features being included in the characterising part.

3 The features of the claims are not provided with reference signs placed in parentheses.

Re Item VIII

Certain observations on the application

1 The statement in the description on page 6, lines 6 - 8 (light propagation through the fiber) implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity when used to interpret them. Especially, the claims do not reflect the need for the use of a "fiber" as a flexible rod could also be used to insert a suture (also not claimed).

2 Figure 4 is directed to a flow chart of method steps. However, the steps are empty rendering this figure unclear.