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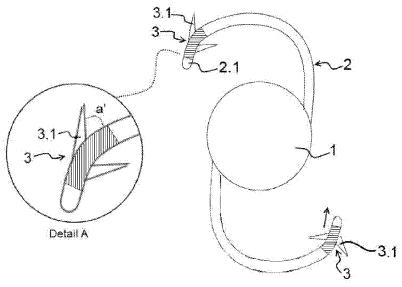


Figure 1

(57) **Abstract**: The invention particularly relates to a haptic (2) tip apparatus (3) with anchor mechanism (3.1) which is developed of aphakic patients who lost capsule support due to cataract surgery or another reason, prevents displacement of three-piece IOL that is implanted from a small corneal laceration to eye via fitting at the haptics (2) of the lens.



Anchor-Winged Haptic Tip Apparatus for Intraocular Lenses

5 THE RELATED ART

The invention relates to a haptic tip apparatus used in the field of eye surgery which in cataract and refractive surgeries, attached intraoperatively to standard IOL haptic, and therefore developed for suture-less intrascleral haptic fixation of standard three-piece lenses.

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The invention particularly relates to a haptic tip apparatus with anchor mechanism developed for aphakia patients who have lost capsule support due to cataract surgery or any other reason; and for preventing displacement of three-piece IOLs from their attached position, by means of providing intrascleral fixation of haptics without using sutures via intraoperative attachment on the three-piece IOL haptics.

STATE OF THE ART

Posterior Chamber Lens Implantation Fixated from Ciliary Sulcus to Sclera with a Suture:

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Posterior chamber lens implantation fixated from ciliary sulcus to sclera may be performed with or without a scleral flap formation. In this technique, the conjunctiva is opened, a cautery is applied to the scleral surface, and a scleral flap is formed based on the used method.

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Recently, rigid lenses have been used until foldable intraocular lenses are used in sutured scleral-fixated intraocular lens surgery. This lens requires a large incision region for displacement of the lens. Although the problem of the incision region is overcome by foldable lenses being used in this surgery method, suture-associated complications constitute some of the main problems of this technique as a suture is used. In this technique lens dislocations may be seen due to suture-related erosion, suture breaks or suture lysis in the long-term.

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One of the biggest disadvantages is that the lens introduced is fixated by a 10/0 nylon suture and that keeping the IOL in place depends on the durability of the suture. In addition, posterior segment complications occur more than the other methods.

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Sutureless scleral-fixated intraocular lens implantation:

This technique has been recently developed to eliminate the problems arising from sutured scleral-fixated intraocular lens implantation, particularly related to the suture.

This technique is applied with or without a tissue adhesive.

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In the method using a tissue adhesive, the conjunctiva is opened, a scleral flap forms a scleral tunnel and sclerotomy that are parallel to the limbus, and a three-piece foldable lens is introduced into the anterior chamber through a corneal incision of 3 mm. After that, by holding haptics with appropriate forceps, these haptics removed out of the extraocular from the prepared sclerotomies and haptic ends are introduced into the scleral tunnel. Subsequently, the flap is adhered with a tissue adhesive. Moreover, in the last step of this method, the scleral flap may also be closed by a suture without using a tissue adhesive.

In the method in which a tissue adhesive is not used, the eye is accessed by a perpendicular entry into the sclera from a distance of about 1,5 mm to limbus by a needle, thereby a sclerotomy is formed. Thereafter a scleral tunnel of about 3 mm which is parallel to horizontal limbus is formed via a needle, and three-piece foldable IOL haptics are introduced into this tunnel.

Conjunctiva should be opened in these methods. In the sutureless scleral fixated IOL implantation using a trocar, which is newly developed by us, two opposed scleral tunnels of 3 mm in length at a distance of 1,5 mm to limbus are prepared by a transconjunctival sutureless vitrectomy without conjunctival flap formation and three-piece foldable IOL haptics are introduced into this tunnel. A safety suture which will be removed after one week is introduced close to the scleral tunnel exit by a 10/0 nylon suture. An adverse event that may be encountered in these methods is that IOL dislocation may develop in some patients with or without any traumas.

Intraocular lens embodiments developed in the technical field may be exemplified by European Patent Application Publication EP2042124B1, titled "Intraocular Lens"; Turkish Application Publication No. 2012/10713, titled "Intraocular Lens"; and European Patent Application Publication No. EP2503962B1.

As a result, for intraocular lenses an improvement or development different from known methods is needed due to the abovementioned drawbacks and inability of current solutions to solve the subject problems.

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OBJECT OF THE INVENTION

The main purpose of the invention is to eliminate the above-disclosed problems in the application of standard three-piece intraocular lenses on patients and minimize the complication rate encountered in these applications.

An object of the invention is to provide a sutureless scleral fixated lens implantation in aphakic patients who lost capsule support and to prevent IOL dislocations.

Another object of the invention to eliminate conventional scleral fixated IOL application known in the art and to provide an embodiment which is suitable for a surgery technique in which a completely sutureless implantation is performed and which may be used in all sutureless scleral fixated IOL implantation surgeries.

A further object of the invention is to perform sutureless intrascleral haptic fixation method using the intraocular lens of the invention which is only developed for this surgical method and to prevent possible complications.

Another object of the invention is to prevent the movement of lens haptics to the inside and the outside of the eyes owing to both anchor mechanism introduced intrasclerally in an opposite direction and thereby to provide a good axial and sagittal stability in the eyes.

A purpose of the invention is to enable use of three-piece lenses with J-haptics in sutureless scleral fixation methods.

In order to achieve the above said purposes, the invention is an apparatus which is attached to the haptic tip, used in cataract and refractive surgeries in the field of eye surgery; can be used in patients who do not have adequate capsule support; and allowing implantation of three-piece foldable intraocular lenses into the eye through a small corneal laceration and their use in sutureless implantation surgery. In order to perform intraocular lens implantation via sutureless intrascleral scleral fixation, this apparatus comprises:

- A cylinder-shaped body with two open ends that is comprising a space that allows advancement of the haptic within the body in order to ensure attachment of the apparatus on the haptic, and
- anchor wings beared on the apparatus body.

In a preferred embodiment; the closed sides of the anchor wings are found at 1 mm distance to the tip of the apparatus and positioned on the body. Moreover, the anchor wings are positioned at a' angle with regard to the body. Said a' angle may be 30 degrees or 45 degrees or may be between

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30 degrees and 45 degrees. Said anchor wings are 1 mm or 2 mm or between 1 mm and 2 mm in length.

DRAWINGS WHICH HELP UNDERSTANDING OF THE INVENTION

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The structural and characteristic features and all advantages of the invention will be understood more clearly with respect to the figures provided below and the detailed description provided by referring to these figures, and thus, an evaluation should be made by taking into consideration these figures and the detailed description.

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Figure 1 is the general view of the apparatus according to the invention applied to an intraocular lens. Here, an apparatus with two open ends is preferred.

Figure 2 is the general view of an embodiment of the apparatus according to the invention with two open ends.

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DESCRIPTION OF REFERENCES

- 1. Optic
- 2. Haptic
 - 2.1. End part
- 3. Apparatus
 - 3.1. Anchor wing
 - 3.2. Body
 - 3.3. First Open End
 - 3.4. Second Open End

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a': The angle between the anchor wings and the haptic.

The drawings do not need to be scaled, and unnecessary details which are not needed in order to understand the present invention may be omitted. Moreover, the elements which are substantially identical or which have substantially identical functions are denoted by same number.

DETAILED DESCRIPTION OF THE INVENTION

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In this detailed description apparatus of the tip of haptic for intraocular lens embodiments according to the invention in accordance with the sutureless scleral fixated IOL implantations are presented only for better understanding of the subject matter.

The haptic tip apparatus (3) are developed for intraocular lenses made of optic (1) and polypropylene, propylene, or PMMA materials and formed of haptic (2) ("C"- or "J"-shaped) comprises:

- anchor wings (3.1) on the apparatus (3) body (3.2), at 1 mm distance to said apparatus (3) end part (2.1), when it is fitted on the haptics (2) of the lens.

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The apparatus (3) is fitted with the lens haptic (2), after the three-piece lens haptic (2) is drawn out of the eye from the scleral input position. At the end of this operation, the anchor wings (3.1) face the optical side and form an a' angle (about 30-45 degrees angle) with the haptic (2) (Figure 1, Detail A). In this way, the backward motion of the apparatus is prevented via this apparatus (3).

In an alternative embodiment of the invention; there may be differences on the part of the apparatus (3) where anchor wings (3.1) are found. The anchor wings (3.1) may be circular or flat. Also, the body (3.2) and anchor wing (3.1) thicknesses of the apparatus may also variability. Accordingly, the dimensions of the apparatus (3) would also change.

The apparatus (3) is preferably made of transparent silicone. It has a flexible structure and has a length of about 3 mm. Center of this silicone apparatus (3) is hollow and has openings at both ends. The second open end (4) of the apparatus (3), at which the anchor wing (3.1) openings are faced, may be a little wider than the haptic (2) to allow easy entrance of the haptic (2). As the haptic (2) enters into the apparatus (3), the parts of the apparatus (3) towards the first open end (3.3) get narrower in order to ensure tighter grasp of the haptic (2). Since it is transparent, the advancement and position of the haptic (2) can be easily seen.

25 Surgical application of the intraocular lens with haptic tip apparatus (3) of the invention is performed as follows:

The apparatus (3) according to the invention is attached to the haptics (2) of intraocular lenses. After the intraocular lens haptics are fitted through different scleral tunnels and under flaps are formed by the surgeon; the apparatuses (3) are placed on the haptic tips such that their wing openings would face to the direction of the optic (1).

A corneal entry site is formed using the sutureless scleral fixation methods by forming an incision after a scleral tunnel is conveniently created using 23- or 25-gauge vitrectomy trocar systems. After the necessary anterior vitreous cleaning a three-piece foldable IOL which has anchor wings (3.1) in haptic (2) thereof (its haptic is anchor-shaped) is introduced into the anterior chamber through the corneal incision. Thereafter, lens haptic (2) is applied to a forceps introduced through the scleral tunnel via a forceps introduced through the corneal incision. Haptic (2) is drawn, removed from the

eye through the scleral tunnel and placed into the scleral tunnel. At last, apparatus (3) with anchor wings (3.1) are fitted to haptics (2) of the intraocular lens.

In the method performed via needle without a scleral flap formation; firstly, the conjunctiva is opened. Subsequently, a scleral tunnel of 3 mm in length which is parallel to limbus will be formed from the sclerotomy entry site after sclerotomy is formed by a needle.

IOL haptics (2) are taken out of the eye by forceps as defined in the previous method. Apparatus (3) with anchor wings (3.1) are fitted to two haptics (2) of IOL and introduced into the prepared scleral tunnel. Again, stabilization of the intraocular lens is achieved owing to the anchor mechanism.

In the surgery performed by using a scleral flap, after the haptics (2) of the intraocular lens are brought under the scleral flap, the anchor-winged apparatus (3) is left under this scleral flap.

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CLAIMS

- 1. A haptic tip apparatus (3) which is used in cataract and refractive surgeries in the field of eye surgery; can be used in patients who do not have sufficient capsule support; allows using in sutureless implantation surgery and implantation of the foldable intraocular lens with optics (1) haptic (2) into the eye through a small corneal laceration characterized in that; in order to perform intraocular lens surgery via suture-free scleral fixation, it comprises:
 - a second open end (3.4) and a first open end (3.3) for allowing placement of the apparatus (3) to the haptic (2);
 - a cylinder-shaped body (3.2) comprising a space that allows advancement of the haptic (2) within the body (3.2), and
 - anchor wings (3.1) found on said body (3.2).

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- 2. The apparatus (3) according to Claim 1, characterized in that; said body (3.2) comprises a second open end (3.4) that is wider than the thickness of the haptic (2).
 - **3.** The apparatus (3) according to Claim 1, characterized in that; it comprises anchor wings (3.1) positioned on the body (3.2) of said apparatus (3) and found at 1 mm distance to the first open end (3.3).
 - **4.** The apparatus (3) according to Claim 1, characterized in that; it comprises anchor wings (3.1) positioned in the direction of the second open end (3.4) in an a' angle to the body (3.2).
- 5. The apparatus (3) according to Claim 4, characterized in that; said a' angle is 30 degrees or 45 degrees or between 30 degrees and 45 degrees.
 - **6.** The apparatus (3) according to Claim 4, characterized in that; said anchor wings (3.1) are 1 mm or 2 mm or between 1 mm and 2 mm in length.
 - 7. The apparatus (3) according to Claim 6, characterized in that; said body (3.2) is 3 mm in length.
 - **8.** The apparatus (3) according to Claim 1, characterized in that; it is made of transparent material to provide see-through function.

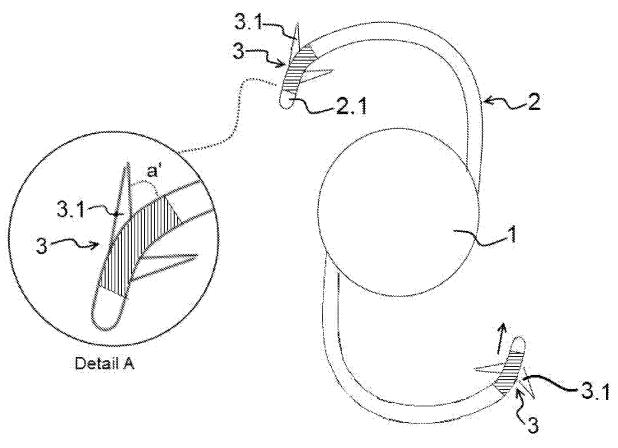


Figure 1

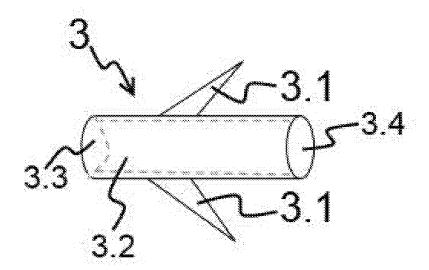


Figure 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/TR2016/050048

A. CLASSIFICATION OF SUBJECT MATTER INV. A61F2/16					
ADD.					
According to	n International Patent Classification (IPC) or to both national classifica	tion and IPC			
B. FIELDS	SEARCHED				
Minimum do A61F	oumentation searched (classification system followed by classificatio	n symbols)			
D					
Documenta	tion searched other than minimum documentation to the extent that su	ion goouments are included in the fields sea	aronea		
Eleotronio d	ata base consulted during the international search (name of data bas	e and, where practicable, search terms use	d)		
EPO-In	ternal				
C. DOCUMI	ENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where appropriate, of the rele	evant passages	Relevant to claim No.		
	, , , , ,				
Х	US 6 193 750 B1 (CUMMING J STUART [US]) 27 February 2001 (2001-02-27) column 1, line 64 - column 3, line 5; figures 4,6		1-8		
Α	JP 2014 014646 A (CHUKYO MEDICAL CO INC) 30 January 2014 (2014-01-30) paragraph [0018] - paragraph [0022]; figure 1		1-8		
А	WO 02/065951 A2 (BEN NUN YEHOSHUA [IL]) 29 August 2002 (2002-08-29) page 3, line 12 - page 5, line 14; figures 1-4		1-8		
Furti	Further documents are listed in the continuation of Box C. X See patent family annex.				
* Special c	ategories of oited documents :	"T" later document published after the inter	national filing date or priority		
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other		date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art			
means being obvious to a person skilled in the art "P" document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family					
Date of the actual completion of the international search Date of mailing of the international search report					
2	5 May 2016	03/06/2016			
Name and r	nailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2	Authorized officer			
	NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Skorovs, Peteris			

INTERNATIONAL SEARCH REPORT

Information on patent family members

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PCT/TR2016/050048

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6193750 B	27-02-2001	CN 1409623 EP 1229869 JP 2003511197 US 6193750	A 30-04-2001 A 27-08-2002 A1 26-04-2001 A 09-04-2003 A1 14-08-2002 A 25-03-2003 B1 27-02-2001 A1 28-06-2001 A1 30-05-2002
JP 2014014646 A	30-01-2014	JP 5398092 JP 2014014646	
WO 02065951 A	29-08-2002		A1 28-04-2005 A1 30-03-2006