



(12) **United States Patent**  
**Kahook**

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(54) **INTRAOCULAR DEVICE FOR DUAL INCISIONS**

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**A61F 9/007** (2006.01)

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CPC ..... **A61F 9/0133** (2013.01); **A61B 17/3209** (2013.01); **A61F 9/00736** (2013.01); **A61F 9/00781** (2013.01)

(58) **Field of Classification Search**  
CPC .. A61F 9/007; A61F 9/00736; A61F 9/00754; A61F 9/00781; A61F 9/013;  
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(56) **References Cited**

U.S. PATENT DOCUMENTS

2,130,949 A 9/1938 Collens  
3,776,238 A 12/1973 Peyman  
(Continued)

FOREIGN PATENT DOCUMENTS

EP 0073803 7/1985  
EP 1455698 9/2004  
(Continued)

OTHER PUBLICATIONS

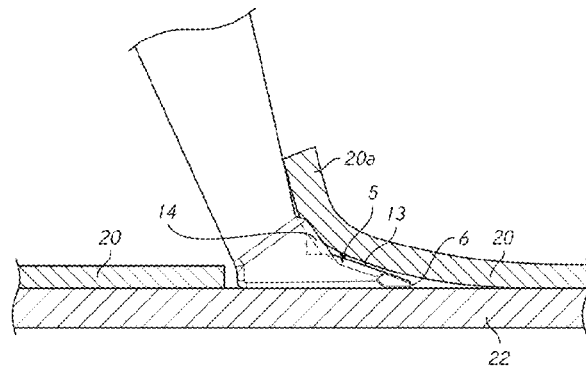
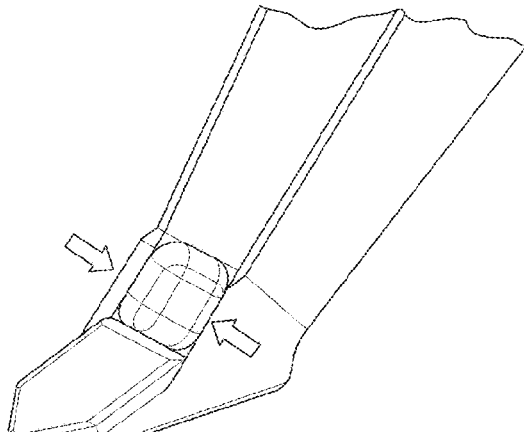
Anderson, "Trabeculotomy compared to goniotomy for glaucoma in children," *Ophthalmology*, 1983, 90(7), pp. 805-806.  
(Continued)

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(57) **ABSTRACT**

A microsurgical device and methods of its use can be used for treatment of various conditions including eye diseases, such as glaucoma, using minimally invasive surgical techniques. A dual-blade device can be used for cutting the trabecular meshwork ("TM") in the eye. The device tip provides entry into the Schlemm's canal via its size (i.e., for example, 0.2-0.3 mm width) and configuration where a ramp elevates the TM away from the outer wall of the Schlemm's canal and guides the TM to first and second lateral elements for creating first and second incisions through the TM. The dimensions and configuration of the blade is such that an entire strip of TM is removed without leaving TM leaflets behind and without causing collateral damage to adjacent tissues.

**20 Claims, 26 Drawing Sheets**



**Related U.S. Application Data**

No. 15/484,041, filed on Apr. 10, 2017, now Pat. No. 9,757,279, which is a division of application No. 15/207,329, filed on Jul. 11, 2016, now Pat. No. 9,872,799, which is a continuation-in-part of application No. 14/375,350, filed as application No. PCT/US2013/037374 on Apr. 19, 2013, now Pat. No. 10,327,947.

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,882,872	A	5/1975	Douvas et al.
4,011,869	A	3/1977	Seiler, Jr.
4,111,207	A	9/1978	Seiler, Jr.
4,428,748	A	1/1984	Peyman et al.
4,501,274	A	2/1985	Skjaerpe
4,559,942	A	12/1985	Eisenberg
4,577,629	A	3/1986	Martinez
4,649,919	A	3/1987	Thimsen et al.
4,682,597	A	7/1987	Myers
4,900,300	A	2/1990	Lee
5,042,008	A	8/1991	Iwasa et al.
5,163,433	A	11/1992	Kagawa et al.
5,217,476	A	6/1993	Wishinsky
5,222,959	A	6/1993	Anis
5,224,950	A	7/1993	Prywes
5,258,002	A *	11/1993	Jeffers ..... A61F 9/0133 30/348
5,342,370	A	8/1994	Simon et al.
5,431,671	A	7/1995	Nallakrishnan
5,478,338	A	12/1995	Reynard
5,487,747	A	1/1996	Stagmann et al.
5,558,637	A	9/1996	Allonen et al.
5,569,283	A	10/1996	Green et al.
5,620,453	A	4/1997	Nallakrishnan
5,674,233	A	10/1997	Dybbbs
5,713,915	A	2/1998	Van Heugten et al.
5,817,115	A	10/1998	Nigam
5,865,831	A	2/1999	Cozean et al.
6,013,049	A	1/2000	Rockley et al.
6,139,559	A	10/2000	Nordan et al.
6,213,997	B1	4/2001	Hood et al.
6,241,721	B1	6/2001	Cozean et al.
6,251,103	B1	6/2001	Berlin
6,264,668	B1	7/2001	Prywes
6,388,043	B1	5/2002	Langer et al.
6,428,501	B1	8/2002	Reynard
6,497,712	B1	12/2002	Feaster
6,503,262	B1	1/2003	Edens
6,720,402	B2	4/2004	Langer et al.
6,759,481	B2	7/2004	Tong
6,979,328	B2	12/2005	Baerveldt et al.
7,374,566	B1	5/2008	Schossau
7,604,663	B1	10/2009	Reimink et al.
7,632,303	B1	12/2009	Stalker et al.
7,648,591	B2	1/2010	Furst et al.
7,785,321	B2	8/2010	Baerveldt et al.
7,935,131	B2	5/2011	Anthamatten et al.
7,955,387	B2	6/2011	Richter
7,959,641	B2	6/2011	Sorensen et al.
8,038,923	B2	10/2011	Berger et al.
9,107,729	B2	8/2015	Sorensen et al.
9,757,279	B2	9/2017	Kahook

2001/0029386	A1	10/2001	Matsutani et al.
2002/0026205	A1	2/2002	Matsutani et al.
2002/0111608	A1	8/2002	Baerveldt et al.
2003/0208217	A1	11/2003	Dan
2005/0070941	A1	3/2005	Isogimi
2005/0113644	A1	5/2005	Obenchain et al.
2005/0216019	A1	9/2005	Eckman
2005/0245953	A1	11/2005	Cote
2006/0015128	A1	1/2006	Fard
2006/0106370	A1	5/2006	Baerveldt et al.
2006/0149194	A1	7/2006	Conston et al.
2006/0241580	A1	10/2006	Mittelstein et al.
2006/0271074	A1	11/2006	Ewers et al.
2007/0073275	A1	3/2007	Conston et al.
2007/0100363	A1	5/2007	Dollar et al.
2007/0276420	A1	11/2007	Sorensen et al.
2009/0248141	A1	10/2009	Shandas et al.
2009/0287233	A1	11/2009	Huculak
2009/0306689	A1	12/2009	Welty et al.
2010/0152609	A1	6/2010	Zwolinski et al.
2010/0268175	A1	10/2010	Lunsford
2011/0077626	A1	3/2011	Baerveldt et al.
2011/0202049	A1	8/2011	Jia et al.
2011/0230877	A1	9/2011	Huculak
2012/0083727	A1	4/2012	Barnett
2012/0239056	A1	9/2012	Dijkman et al.
2014/0030273	A1	1/2014	Verploegen et al.
2014/0121697	A1	5/2014	Scheller et al.
2015/0045820	A1	2/2015	Kahook
2016/0354248	A1	12/2016	Kahook
2017/0181892	A1	6/2017	Kahook et al.
2017/0367890	A1	12/2017	Kahook
2018/0133056	A1	5/2018	Kahook

FOREIGN PATENT DOCUMENTS

EP	1615604	1/2006
EP	2303203	4/2011
KR	1020040058309	9/2004
WO	WO-9306800	4/1993
WO	WO-2001078631	10/2001
WO	WO-2003045290	6/2003
WO	WO-2004093761	11/2004
WO	WO-2004110501	12/2004
WO	WO-2009140185	11/2009
WO	WO-2011030081	3/2011
WO	WO-2012044952	4/2012
WO	WO-2012137186	10/2012
WO	WO-2013163034	10/2013
WO	WO-2017112893	6/2017

OTHER PUBLICATIONS

European Office Action for Application No. 13781487.7, dated Dec. 20, 2018, 4 pages.

Extended European Search Report and Written Opinion for Application No. 16880112.4, dated Aug. 2, 2019, 6 pages.

Francis et al., "Ab interno trabeculectomy: development of a novel device (Trabectome®) and surgery for open-angle glaucoma," *Journal of Glaucoma*, 2006, 15(1), pp. 68-73.

Grant, "Clinical measurements of aqueous outflow," *AMA Archives of Ophthalmology*, 1951, 46(2), pp. 113-131.

Grant, "Experimental aqueous perfusion in enucleated human eyes," *Archives of Ophthalmology*, 1963, 69(6), pp. 783-801.

Herschler et al., "Modified goniotomy for inflammatory glaucoma. Histologic evidence for the mechanism of pressure reduction," *Archives of Ophthalmology*, 1980, 98(4), pp. 684-687.

International Search Report and Written Opinion for Application No. PCT/US2016/068393, dated Apr. 17, 2017, 29 pages.

International Search Report and Written Opinion for Application No. PCT/US2018/056935, dated Jan. 31, 2019, 12 pages.

Jacobi et al., "Goniocurettage for removing trabecular meshwork: clinical results of a new surgical technique in advanced chronic

(56)

**References Cited**

## OTHER PUBLICATIONS

Jacobi et al., "Technique of goniotomy: a potential treatment for advanced chronic open angle glaucoma," *British Journal of Ophthalmology*, 1997, 81(4) pp. 302-307.

Jea et al., "Ab Interno Trabeculectomy Versus Trabeculectomy for Open-Angle Glaucoma," *Ophthalmology*, 2012, 119(1), pp. 36-42.

Johnson et al., "Human trabecular meshwork organ culture. A new method," *Investigative Ophthalmology & Visual Science*, 1987, 26(6), pp. 945-953.

Luntz et al., "Trabeculectomy ab externo and trabeculectomy in congenital and adult-onset glaucoma," *American Journal of Ophthalmology*, 1977, 83(2), pp. 174-179.

Minckler et al., "Clinical Results with the Trabectome® for Treatment of Open-Angle Glaucoma," *Ophthalmology*, 2005, 112(6), pp. 962-967.

Pantcheva et al., "Ab Interno Trabeculectomy," *Middle East African Journal of Ophthalmology*, 2010, 17(4), pp. 287-289.

PCT International Search Report of International Application No. PCT/US2013/037374 dated Jul. 25, 2013.

Quigley et al., "The number of people with glaucoma worldwide in 2010 and 2020," *British Journal of Ophthalmology*, 2006, 90(3), pp. 262-267.

Seibold et al., "Preclinical Investigation of Ab Interno Trabeculectomy Using a Novel Dual-Blade Device," *American Journal of Ophthalmology*, 2013, 155(3), pp. 524-529.e522.

Supplementary European Search Report for Application No. 13781487.7, dated Jul. 9, 2015, 7 pages.

Tan et al., "Postoperative complications after glaucoma surgery for primary angle-closure glaucoma vs primary open-angle glaucoma," *Archives of Ophthalmology*, 2011, 129(8), pp. 987-992.

Ting et al., "Ab interno trabeculectomy: Outcomes in exfoliation versus primary open-angle glaucoma," *Journal of Cataract & Refractive Surgery*, 2012, 38(2), pp. 315-313.

Ellingsen, Bruce A. et al., "Trabeculectomy and sinusotomy in enucleated human eyes," *Investigative Ophthalmology & Visual*

*Science Jan.* 1972, vol. 11, Issue 1, pp. 21-28, downloaded from [iovs.arvojournals.org](http://iovs.arvojournals.org) on Feb. 23, 2019.

Grant, Morton W., "Symposium: Microsurgery of the Outflow Channels", *Trans Am Acad Ophthalmol Otolaryngol.* Mar.-Apr. 1972;76(2):398-404.

Manuel Quintana, *Gonioscopic Trabeculectomy: First Results*, in 43 Second European Glaucoma Symposium, *Documenta Ophthalmologica Proceedings Series 265* (E.L. Greve, W. Leydhecker, & C. Raitta eds., 1985) ("Quintana 1985").

M. Johnstone et al., "Microsurgery of Schlemm's Canal and the Human Aqueous Outflow System," *Am. J. Ophthalmology* 76(6):906-917 (1973) ("Johnstone 1973").

Am. Acad. of Ophthalmology Section 10 Glaucoma, in *Basic and Clinical Science Course 2000-2001* (2000), pp. 3-24 and 147-174.

Am. Acad. of Ophthalmology, Section 8 External Disease and Cornea, in *Basic and Clinical Science Course 2001-2002* (2001), pp. 437-442.

Barkan, O., "Goniotomy for the Relief of Congenital Glaucoma", *Br J Ophthalmol.* Sep. 1948;32(9):701-708.

Dominguez, A., "Trabeculectomie Ab Interno", *Bulletins et mémoires de la Société française d'ophtalmologie*, 86(0):100-105 (1973).

File History for U.S. Appl. No. 13/159,356.

File History for U.S. Pat. No. 9,107,729.

Hogan, M. J., "History of the Human Eye: An Atlas and Textbook", Philadelphia, Pennsylvania: W. B. Saunders Company (1971), p. 135.

Jacobi, P. C. et al., "Perspectives in trabecular surgery", *Eye* 2000;14(Pt 3B)(3b):519-530 (2000).

Latimer, K. et al., "Insight Into Glaucoma Treatment in the Early 1900s: Harvey Cushing's 1905 Operation", *Arch Ophthalmol.* 2012;130(4):510-513 (Apr. 2012).

Shields, M. B., *Textbook of Glaucoma*, Fourth Edition. Baltimore, Maryland: Williams & Wilkins (1998), pp. 1-31, 351-352, 456-460, and 470-489.

U.S. Office Action for U.S. Appl. No. 15/701,306, dated May 18, 2020, 11 pages.

\* cited by examiner

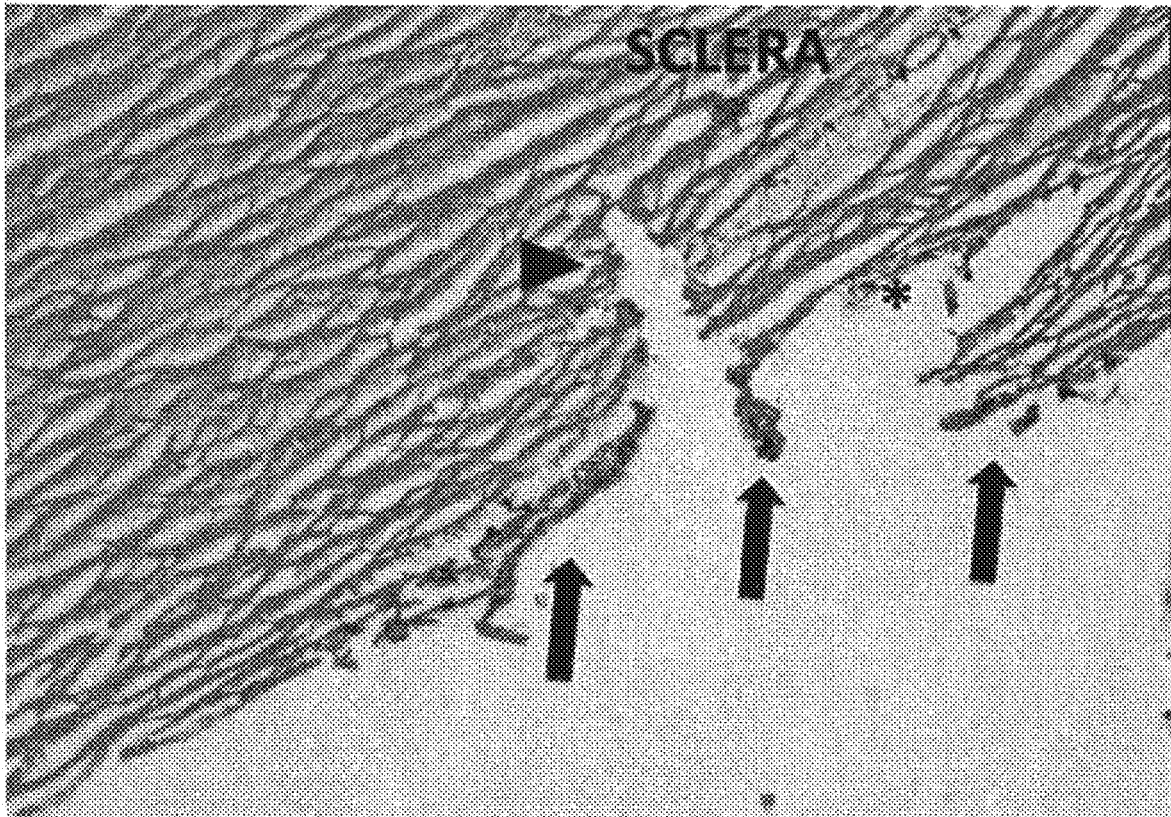


FIG. 1

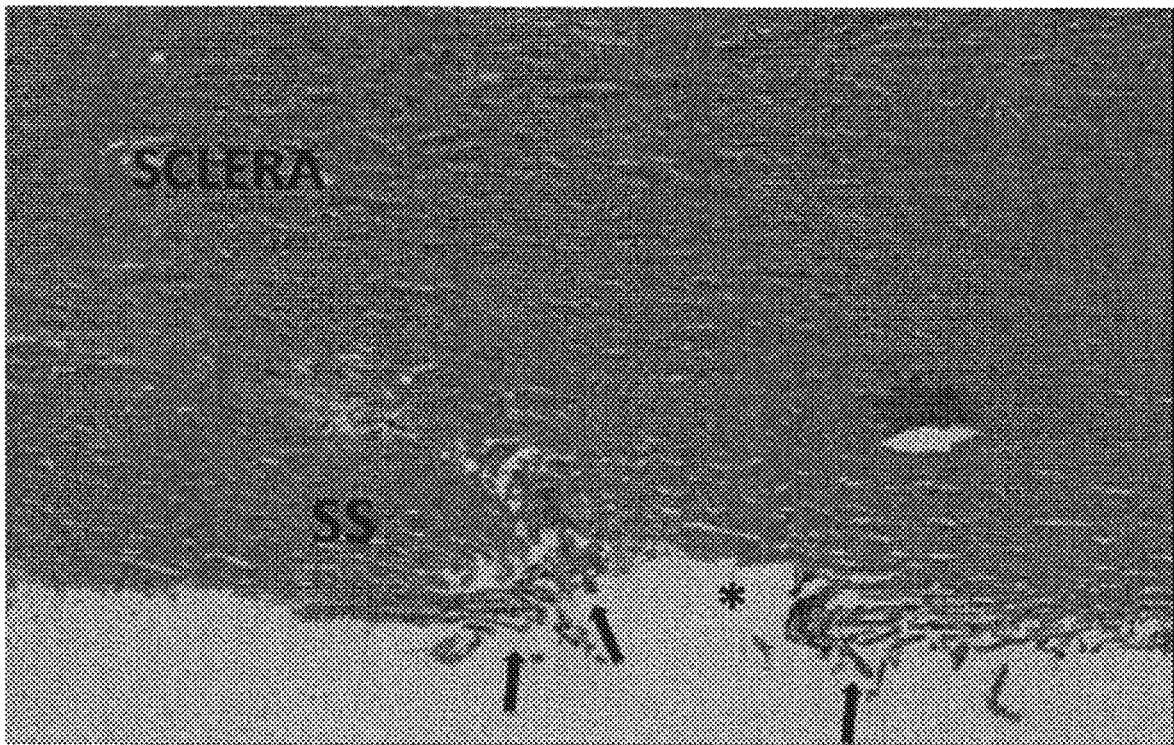


FIG. 2

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