# The Ultima<sup>®</sup> foldable scleral fixation intraocular lens: A 2-year follow-up

## G. MIGLIORATI, P. BRUSINI

Department of Ophthalmology, Santa Maria della Misericordia Hospital, Udine - Italy

PURPOSE. To describe a new scleral fixation foldable intraocular lens (IOL): the Ultima<sup>®</sup>. METHODS. The novel IOL is a new scleral fixation acrylic hydrophilic foldable lens that offers a 360° sulcus support due to its round geometry. It can be folded and inserted through a 4 mm clear cornea incision. Twenty-five eyes implanted with the Ultima<sup>®</sup> lens were followed for 2 years.

RESULTS. Twenty-two eyes showed visual improvement, two eyes had no functional improvement, and one eye had visual deterioration. The IOL remained well centered and showed no signs of tilting in all patients during the entire follow-up.

CONCLUSIONS. The main advantages of the Ultima<sup>©</sup> IOL include the lack of tilting and the minimum postoperative astigmatism. It also allows a clear retinal examination and provides an excellent barrier for silicone oil between vitreous cavity and anterior chamber. (Eur J Ophthalmol 2008; 18: 895-902)

Key Words. Cataract surgery, Pseudophakia, Foldable intraocular lens, Scleral fixation

Accepted: May 14, 2008

#### INTRODUCTION

For subjects who show little or no capsular support for intraocular lens (IOL) implantation, different surgical options can be used, which may vary according to the anatomic and functional status of the eye. Patients who show sufficient iris support can undergo one of the following types of lens insertions: an anterior chamber intraocular lens (AC-IOL); an IOL fixated to either the anterior or posterior side of the iris; or a scleral fixation IOL.

Currently, there is no consensus as to which type of IOL offers the best solution (1, 2). In cases that lack both capsular and complete or partial iris support, scleral fixation of the IOL is the only solution. IOL positioning in the posterior chamber offers the advantages of having the lens closer to the nodal point of the eye, and there is less risk of anterior synechiae formation and endothelial cell loss (3, 4). The various surgical scleral fixation techniques and the different IOLs currently available, however, show the following disadvantages (1, 2, 5-8): prolonged surgery; blind needling of sutures through the ciliary sulcus with the risk of uveal trauma; hemorrhage; primary or secondary tilting and decentration; postsurgical induced astigmatism (when rigid lenses are used); and vitreoretinal complications.

A new one-piece foldable scleral-fixation hydrophilic IOL has recently been designed by one of us (G.M.). Compared to the other scleral fixation IOLs, the Ultima<sup>©</sup> IOL (Fig. 1) is foldable and can easily be inserted through a smaller incision (that still requires blind needling), offering potential permanent refractive stability and better short and long-term quality of vision.

#### METHODS

## The lens

The Ultima<sup>®</sup> (Fig. 1A) is a foldable scleral fixation IOL (Corneal Industries, Paris, France, patent #2.841.122) made of a PHEMA hydrophilic material with a water content of 26%. This material offers good uveal biocompati-

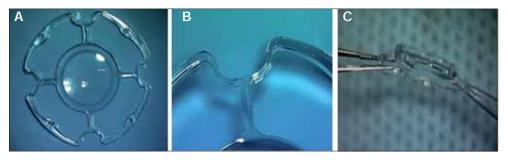


Fig. 1 - (A) Front view of the Ultima<sup>®</sup> lens. We can note the circular shape with 4 suture holes and the "omega" loops. Total diameter: 13 mm. Optic disc diameter: 6.5 mm. Material: Hydrophilic PHEMA with 26% of water content. (B) Particular of the "omega" loop. It behaves like a shock absorber and lets the lens fit different sulcus diameters. (C) Lateral view showing the 0 degree angulation of the lens.

bility (9-12) and bacterial adhesion and density on its surface tends to be low (13). This hydrophilic material offers high compressibility and resistance to tearing and forceps contact during the IOL manipulation and insertion through the small incision.

The lens has a circular shape with an external loop of 13 mm in diameter. The 6.5 mm optic is connected to the external loop by four radial direct arms positioned at 12-3-6-9 o'clock. The arms have four omega shape connecting loops (0.18 mm in width) that continue with the external loop. The thickness of the external loop and of the direct arms is 0.40 mm. The thickness of the union point between the central optic and the direct arm is 0.25 mm. There are four holes in the external loop, with a diameter of 0.45 mm, which can be used for suturing. The design and material of this IOL permit the IOL to be compressed to a diameter of 11 mm, causing neither distortion of the optic disc nor displacement of the entire lens. The omega-like deformable loops that behave like compression shock absorbers allow the lens to adapt to different ciliary sulcus diameters (Fig. 1B). The lens is not angulated (Fig. 1C).

# Population

The novel IOL was implanted in 25 eyes of 24 patients (mean age: 66.6 years, range: 32–89 years). All 24 patients were secondary implantations with total or partial absence of capsular support. Patients were recruited from the Department of Ophthalmology of the S. Maria della Misericordia Hospital in Udine, Italy. The research was conducted following the guidelines of the Tenets of the Declaration of Helsinki, and was approved by the Human Subjects Committee of our hospital. All of our subjects underwent a complete ophthalmic examination including a best-corrected visual acuity (BCVA) evaluation, slit-lamp examination, corneal endothelial specular microscopy, Goldmann applanation tonometry, gonioscopy, and fundus biomicroscopy. All patients signed an informed consent.

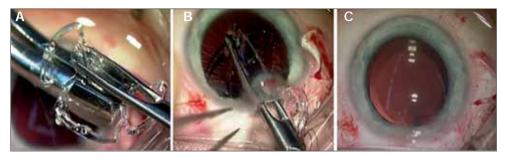
The specific ophthalmic case situations considered in this study included the following: 4 aphakic eyes with previous intracapsular cataract extraction; 7 cases of ocular trauma (6 with crystalline lens displacement in the vitreous body and 1 with IOL displacement in the vitreous body); 2 cases of corneal pathology (1 with corneal leukoma associated with aphakia from a previous perforating trauma and 1 with bullous keratopathy with an AC IOL); 5 cases of IOL dislocation with pseudoexfoliation syndrome (3 partial dislocations and 2 totally luxated IOLs in the vitreous body); 2 cases associated with vitreoretinal surgery for retinal detachment (phakic eyes before surgery); 3 cases involving a large posterior lens capsule rupture; 1 case of IOL exchange due to previous IOL opacification; 1 case of aphakia postvitrectomy for endophthalmitis. The follow-up period ranged between 21 and 28 months (mean 23.72±2.1).

# Surgical technique

The lens was introduced through a corneal incision in all patients except for those undergoing penetrating keratoplasty. A polypropylene 10/0 (Prolene) suture thread was used to fix the lens to the sclera. The lens was sutured with all four points (12, 3, 6, and 9 o'clock position) in the subject having post-traumatic aphakia and aniridia. For all other cases requiring sutures, only two suture points were used (at 3–9, or 2–8 o'clock positions). The corneal incision size ranged from 4 to 4.5 mm in all cases, except for those associated with keratoplasty and a rigid lens exchange for PMMA IOL dislocation. In two cases (one after vitreoretinal surgery and the other with a large posterior capsule rupture), providing a residual capsular support was enough to avoid having to suture the lens.

When the insertion of the Ultima<sup>®</sup> IOL was not associated with any other surgical procedures, the following implan-

Fig. 2 - (A) The Ultima<sup>®</sup> lens folded. (B) Introduction of the distal part of the external loop. (C) The unfolded Ultima<sup>®</sup> lens positioned in the posterior chamber.



tation technique was used: local limbal peritomy; preparation of two scleral flaps at 3 and 9 as usual, or 2–8 o'clock; two paracenteses; self-sealing corneal incision (from 4 to 5 mm in length); anterior vitrectomy, when necessary; suture thread fixation (polypropylene 10/0, long needle) to the lens holes (in the haptics); suture needle passage directly through the ciliary sulcus with the needle holder or with a needle injector; lens folding with a soft IOL folder (Fig. 2A); lens introduction with forceps through the corneal incision (Fig. 2, B and C); lens positioning by pulling up the suture threads; loops position control; suture of the conjunctiva; corneal incision closure by hydration or suture (surgical decision on a patient-to-patient basis).

In order to facilitate the insertion of the IOL, it is important that the distal part of the external loop is initially inserted before the other parts (Fig. 2B). Capsular remnants may cause off-centering of the IOL due to incomplete haptic unfolding, thus it is advisable to remove them with the vitrectomy probe or forceps before insertion. An examination of the IOL haptic positioning is performed at the end of the procedure by moving the iris with a manipulator. Preoperatively, antibiotic (ofloxacin 0.3% solution) and anti-inflammatory (diclofenac 0.1% solution) eyedrops were administrated four times a day for 3 days before surgery. Antibiotics were also given orally in cases of perforating trauma, post-endophthalmitis surgery, and multiple ocular surgeries. Topical antibiotics, cortisone, and mydriatic medication were administrated postoperatively (tobramycin 0.3% and dexamethasone 0.1% solution eyedrops four times a day for 1 month and atropine 1% solution eyedrops three times a day for 15 days). A complete ophthalmologic examination (including visual acuity, intraocular pressure measurement, biomicroscopy examination of the anterior and posterior segment of the eye, specular microscopy of the corneal endothelium) was performed prior to surgery, at 7, 15, and 30 days after surgery, then

every month thereafter. The average duration of the operation was 40 minutes. Two surgeons (G.M., P.B.) performed all the operations.

# RESULTS

Tables I–III provide a complete description of each patient's age, condition requiring an IOL, postoperative complications, best-corrected visual acuity, and phlogistic parameters.

# Refractive status

*Refractive changes.* – The refraction changed in Subject 8 (Ultima<sup>®</sup> insertion and perforating keratoplasty) from +1.5 D sphere (sph) associated with –5 D cylinder (cyl) 60° at 6 months after surgery to +0.50 D sph = –2 D cyl 80° 2 years after surgery; in Case 9 (aphakia) from –0.50 D sph = –1 D cyl 120° at 6 months after surgery to –0.50 D sph = –0.50 D cyl 110° 2 years after surgery; in Case 11 (capsular rupture during cataract surgery) from +2.25 D sph = +2.50 D cyl 145° to +2.50 D sph = +0.50 D cyl 85°; in Case 25 (Ultima<sup>®</sup> insertion associated with perforating keratoplasty) from +4 D sph = –6 cyl 30° to +1 D sph = +3 D cyl 130°. In all other cases refraction was stable for the follow-up period (the mean spherical equivalent was + 0.90 diopters [D]).

# Visual acuity results

*Functional improvements.* – Twenty-two eyes (88%) had a visual improvement (Tab. II).

*Functional deterioration.* – One eye (Subject 23 with postvitrectomy aphakia for endophthalmitis) showed a worsening in visual acuity. This patient had undergone three previous trabeculectomies for advanced glaucoma 2 years prior to IOL insertion and a pars plana vitrectomy

for bacterial endophthalmitis 2 months before. The visual acuity went from 20/200 before surgery to hand motion detection after 6 months, to finally stabilize at only light perception 1 and 2 years later. This eye showed hemovitreous 20 days after surgery and a retinal detachment 5 months later, which was then treated by means of posterior vitrectomy and silicone oil injection.

No functional improvement (two eyes).–One eye (Subject 10 with perforating trauma) had light perception before surgery (pars plana vitrectomy, silicone oil insertion for traumatic retinal detachment), which did not show any changes during the follow-up. One eye (Subject 15 with aphakia for previous intracapsular cataract extraction) had a BCVA of 20/70 before surgery, which did not show any signs of improvement during the follow-up. The patient also had age-related macular degeneration in both eyes.

# Complications

In one eye (Subject 2 with traumatic lens luxation in the vitreous) a cystoid macular edema (CME) developed 2 months after surgery and completely recovered 3 months later under medication (diclofenac 0.1% eyedrops four times a day for 3 months and Indomethacin 100 mg/day per os for 20 days). The BCVA was 20/20 (+1.25 D sph) 20 days after surgery; then 20/50 (+2 D sph) 1 month later when CME was diagnosed; and finally 20/20 after 5 months with a complete CME recovery.

The mean endothelial loss was 7% (range 3 to 13%). The mean visual improvement was five chart lines (range 20/200–20/20). In one eye (Subject 17 with opaque IOL exchange) a retinal detachment developed 2 months after surgery and a pars plana vitrectomy with silicone oil exchange was performed. The BCVA was finger counting before surgery; then 20/50 (+1 D sph) 6 months later, and

Case	Age, yrs		Intraoperative complications	Complications 0-6 mo	Complications 6-12 mo	Complications 12-18 mo
1	81	Perforating trauma	None	None	None	None
2	55	Luxated lens for contusive trauma	None	None	None	None
3	62	Vitreoretinal surgery for RD	None	None	None	None
4	64	Vitreoretinal surgery for RD	None	None	None	None
5	65	Aphakia	None	None	None	None
6	65	Capsular rupture	None	None	None	None
7	75	IOL dislocation	None	None	None	None
8	78	Bullous keratopathy (IOL in the anterior chamber)	None	None	None	None
9	79	Aphakia	None	None	None	None
10	32	Perforating trauma with RD	None	None	None	None
11	69	Capsular rupture	None	None	None	None
12	49	Contusive trauma	None	None	None	None
13	89	IOL dislocation	None	None	None	None
14	55	IOL luxation in vitreous chamber with macular trauma	None	Hyphema	None	None
15	68	Aphakia	None	None	None	None
16	68	Aphakia	None	None	None	None
17	86	Postendophthalmitis IOL opacity	None	RD	None	None
18	73	Luxated cataract for contusive trauma	IOP increase	None	None	None
19	86	IOL dislocation	None	None	None	None
20	68	IOL dislocation; intraoperative cataract surgery complications	None	Corneal	Descemet	Descemet
				edema	folds	folds
21	68	IOL dislocation	None	None	None	None
22	87	Capsular rupture	None	None	None	None
23	62	Aphakia in multioperated eye for glaucoma and endophthalmitis	None	Hemovitreous	RD	None
24	51	Luxated cataract for contusive trauma	None	None	None	None
25	69	Aphakia in corneal leucoma	None	None	None	None

#### TABLE I - PATIENT AGE, ETIOLOGY, COMPLICATIONS

RD = Retinal detachment; IOL = Intraocular lens; IOP = Intraocular pressure

finally  $20/50 (+0.50 D = +1 D cyl 180^\circ)$  1 and 2 years later. IOL tilting or decentration under maximum mydriasis was never clinically observed in all the subjects during the follow-up. Tyndall, cells, or fibrin could not be detected in the anterior chamber after the first month in all but two cases (Subjects 10 and 23). In the eye that had a perforating trauma (Subject 10) with retinal detachment and in the eye with hemovitreous and retinal detachment (Subject

Case	BCVA preop	6 mo postop	12 mo postop	24 mo postop	Associated pathologies
1	Hand motion +11.50 sph	Finger counting +1.25 sph	Finger counting +1.25 sph	Finger counting +1.25 sph	None
2	20/30	20/20	20/20	20/20	None
3	Hand motion	20/300	20/300	20/300	Macular atrophy
5		–1 sph=–2 cyl 100°	–1 sph=–2 cyl 100°	–1 sph=–2 cyl 100°	maodial altophy
4	Hand motion	20/50	20/50	20/50	Macular dystrophy
	+12 sph	+0.50 sph	+0.50 sph	+0.50 sph	
5	20/25	20/20	20/20	20/20	None
	–3 sph	+0.75 sph	+0.75 sph	+0.75 sph	
6	20/70	20/20	20/20	20/20	None
0		+0.75 sph	+0.75 sph	+0.75 sph	
7	Finger counting	20/25	20/25	20/25	None
,		+1.50 sph=–5 cyl 60°	+1 sph=–5 cyl 60°	+0.50 sph=–2 cyl 80°	
8	Finger counting	20/50	20/50	20/50	None
	+10 sph=+2 cyl 110°	–0.50 sph=–1 cyl 120°	-0.50 sph = -0.50 cyl 120°	-0.50 sph=-0.50 cyl 120°	
9	20/20	20/20	20/20	20/20	None
10	Light perception	Light perception	Light perception	Light perception	Macular atrophy
	+1 sph	+2.25 sph=+2.50 cyl 145°	+2.50 sph=+0.50 cyl 85°	+2.50 sph=+0.50 cyl 85°	
11	20/100	20/25	20/20	20/20	None
12	Finger counting	-0.25 sph=+1.50 cyl 145°	–0.25 sph=+1.50 cyl 145°	-0.25 sph=+1.50 cyl 145°	Iridocorneal synechiae
	5 5	20/25	20/25	20/25	5
	-4.50 sph	–3.50 sph=–0.75 cyl 180°	–3.50 sph=–0.75 cyl 180°	-3.50 sph=-0.75 cyl 180°	
13	20/200	20/70	20/70	20/70	AMD
	+12 sph	+3.50 sph=+1 cyl 120°	+3.50 sph=+1 cyl 120°	+3.50 sph=+1 cyl 120°	
14	20/200	20/100	20/100		CME; cellophane maculopath
	+13 sph				
15	20/70	20/70	20/70	20/70	Macular dystrophy
	+14 sph	+2 sf	+2 sf	+2 sf	
16	20/50	20/30	20/30	20/30	Macular dystrophy
		+1 sf	+0.50 sph=+1 cyl 180°	+0.50 sph=+1 cyl 180°	
17	Finger counting	20/50	20/50	20/50	None
		+1.50 sf	+1.50 sf	+1.50 sf	
18	Finger counting	20/20	20/20	20/20	None
		+1.50 sf	+1.50 sf	+1.50 sf	
19	20/50	20/25	20/25	20/25	None
	+12 sph	+2 sf	+2 sf	+2 sf	
20	20/100	20/50	20/50	20/50	PEXS; macular dystrophy
	+12 sph=+2 cyl 90°	+2.50 sph=+1.75 cyl 75°	+2.50 sph=+1.75 cyl 75°	+2.50 sph=+1.75 cyl 75°	
21	20/70	20/30	20/30	20/30	PEXS; macular dystrophy
		–0.50 sph	–0.50 sph	–0.50 sph	
22	20/100	20/25	20/25	20/25	PEXS
23	20/200	Hand motion	Light perception	Light perception	Severe glaucoma
		+1.50 sph=+0.50 cyl 100°	+1.50 sph=+0.50 cyl 100°	+1.50 sph=+0.50 cyl 100°	
24	Hand motion	20/35	20/35	20/35	Papillary dysversion
25	+8 sph	+4 sph=–6 cyl 30°	+3.50 sph=–6 cyl 45°	+1 sph=+3 cyl 130°	None
	20/1000	20/50	20/50	20/50	

 TABLE II - PRE- AND POSTOPERATIVE BEST-CORRECTED VISUAL ACUITY (BCVA) AND ASSOCIATED PATHOLOGIES

Sph = Sphere (in Diopters); cyl = Cylinder (in Diopters); AMD = Age-related macular degeneration; CME = Cystoid macular edema; PEXS = Pseudoexfoliation syndrome

23) some cells were still present 6 months after surgery. A rise in intraocular pressure (IOP) was not present in any cases during the postsurgical period. An intraoperative IOP rise was observed in Subject 18 (luxated cataract for contusive trauma) at the beginning of surgery, which also showed vitreous in the anterior chamber and corneal edema. The IOP then stabilized within normal limits soon after the anterior vitrectomy.

In one case we had the rupture of the suture thread during its scleral fixing. It was possible to bring part of the external loop out of the corneal incision and repeat the suture thread passage through the loop hole, reposition the loop in the sulcus, and fix it to the sclera.

## DISCUSSION

When the only surgical option available is scleral fixation, postoperative complications and limited functional improvement are likely to be expected. Large individual dif-

 TABLE III - PHLOGISTIC PARAMETERS (Hogan and Kimura classification) DURING THE FOLLOW-UP

Case	1 mo	6 mo	12 mo	24 mo
1	Tyndall+, cells+	None	None	None
2	Cells±	None	None	None
3	None	None	None	None
4	None	None	None	None
5	None	None	None	None
6	None	None	None	None
7	None	None	None	None
8	Tyndall±, cells±	None	None	None
9	None	None	None	None
10	Tyndall+, cells+	Cells±	None	None
11	None	None	None	None
12	Cells±	None	None	None
13	None	None	None	None
14	Tyndall±, cells++	None	None	None
15	None	None	None	None
16	None	None	None	None
17	Cells+	None	None	None
18	None	None	None	None
19	None	None	None	None
20	Cells+	None	None	None
21	None	None	None	None
22	None	None	None	None
23	Hematic cells+++	Cells+	None	None
24	Cells+	None	None	None
25	None	None	None	None

ferences between eyes and different visual expectations make the comparison difficult. In some cases, a possible alternative to a scleral fixated IOL can be an iris fixated lens, like Artisan. However, this lens can cause localized iris atrophy, rupture of the hematoretinal barrier, and late IOL dislocation. The choice of the IOL to use is also debatable (14), with no general consensus as to the type that is best for the patient (1, 2). The Ultima<sup>©</sup> IOL was initially used in a pilot study (15), and then later implanted in 25 eyes with various ophthalmic conditions.

The protocol regarding the indications for this IOL was identical to those found in literature, with special interest in cases showing partial or no capsular support. To our knowledge, the Ultima<sup>©</sup> lens is the first one-piece foldable hydrophilic scleral-fixation IOL. Other authors (16-18) used a foldable silicone or acrylic IOL originally designed for intracapsular fixation. These IOLs, however, are not specifically designed for a fixation surgery, and thus tilting can occur. The new IOL offers the advantages of an easier insertion through a smaller incision, high functional ability, and anatomic stability. All of the inserted IOLs observed throughout the 2-year follow-up period maintained a centered stable position. In the first surgery utilizing this IOL (traumatic aphakia and aniridia) the lens was sutured with four points to provide optimal stability and minimal tilting. In the second surgery (traumatic lens luxation), and those thereafter that required sutures, we found that two suture points offered sufficient and optimal lens support, not to mention that it was technically much easier to perform. The fibrotic reaction around the haptics that normally occurs a few months later (19) can offer additional support in the long-term fixation. Clinically detectable tilting was not found in any of the implanted eyes.

The hydrophilic material used in the Ultima<sup>©</sup> IOL has been shown to have a good uveal biocompatibility (9-12). In fact, in the large area of uveal contact, we did not observe any chronic uveitis after 6 months during the follow-up period. We only observed two cases with a very mild cell count in the anterior chamber between 1 and 6 months during the follow-up period (Tab. III). The soft compressible omega loops allow the IOL to adapt to the various individual sulcus diameters as well as to the variations caused by age (20). The Greek cross shape with its four connecting loops help avoid the possibility of a pupil capture when a non-angulated scleral fixation IOL is used (21). The acrylic hydrophilic foldable material permits IOL insertion through a 4 mm self-sealing clear corneal incision. The need for a small suture free incision decreases the risk of both surgical-induced astigmatism and bacterial intraocular infections. The acrylic hydrophilic material is also advantageous in that it tends to show decreased bacterial adhesion to the surface, when compared to the other IOL materials currently utilized (14). Moreover, the soft material is less traumatic during the insertion, especially in eyes with miotic and/or fibrotic pupils. Consequently, it decreases the risk of ciliary-vitreous hemorrhages, which is theoretically possible with polymethylmethacrylate haptics (22). In all our cases to date, the suture points never broke or became misplaced, and lens removal was not necessary. But, in this eventuality, the explant maneuvers should not be very difficult, because of the soft material. No IOP rise was registered during the follow-up period.

Postoperative complications appeared to be limited. Two of the 25 eyes in this study resulted in retinal detachment. However, it is important to note that these eves had undergone a previous vitrectomy due to endophthalmitis (one of these two also had three previous trabeculectomies, including the use of mitomycin C) and, thus, this further complication cannot be solely attributed to the IOL insertion. One subject developed CME that completely recovered under medication. Residual Descemet folds were noticed in one of the subjects who had a previous complicated cataract extraction. Scleral flap knot erosions or IOL dislocation were not observed in any of our patients during the 2-year follow-up (23). Among intraoperative complications we had the rupture of the suture thread during scleral fixation maneuvers. In this case the foldable soft material was very useful because it was possible to take back only the affected part of the external loop and repeat the suture thread passage through the loophole and then through the sclera. The two eyes with capsular remnants did not require sutures and yet, sulcus positioning remained stable. The 6.5 mm optic diameter and circular shape are very useful in vitreoretinal surgery.

The IOL allows for excellent intraoperative fundus visualization, and does not show any signs of dislocation or distortion during retinal surgical maneuvers (i.e., indentation). The large size of the lens acts as a good barrier, preventing the silicone oil from moving from the vitreous cavity to the anterior chamber. It is also theoretically possible to suture this lens to the iris, especially if a combined penetrating keratoplasty is planned; however, we have not used the Ultima IOL in this type of surgery to date (which may prove to be a difficult technique having a steep learning curve). A possible alternative choice for secondary IOL implantation is Worst's iris-claw anterior chamber IOL. which grips on to the anterior iris surface and seems to offer good long-term results (24, 25). In addition, studies have shown that secondary posterior iris fixation of the iris-claw IOL can also be an effective option for aphakic eyes without capsular support (26). Other studies have reported that the Binder-IOL, a new sutureless iris-fixed ciliary sulcus posterior chamber IOL, can be suitable for aphakic eyes with a loosened iris diaphragm (27). All scleral fixation IOLs are limiting because blind needling is reguired and hemorrhages can occur while passing the needle through the sulcus. The drawbacks of the Ultima<sup>©</sup> IOL, especially during the initial uses of this lens in surgery, include the following: 1) the insertion through a small incision may be difficult at first due to its size, and requires some practice; 2) a difficult visualization of the positioning of the loops in the sulcus, if a small pupil is present; 3) the possible entanglement of suture threads when more than two stitches are required. Our study shows promising preliminary results; however, further long-term multicenter studies are needed to determine the true clinical advantages of this new IOL. We have currently started a study on a larger group of patients with diverse ophthalmic conditions compared to a control group of patients treated with traditional IOLs.

# CONCLUSIONS

The Ultima<sup>©</sup> IOL is the first hydrophilic one-piece IOL especially designed for scleral fixation. It requires a smaller incision in most cases, which consequently lowers surgically induced astigmatism. The IOL is also easier to position and has been shown to remain stable, well centered, and free of tilting in the long term. The hydrophilic material is well tolerated, offering a good uveal biocompatibility. These characteristics make this IOL a good choice in selected surgeries.

#### ACKNOWLEDGEMENTS

The authors thank Dr. Philippe Sourdille, Clinique Sourdille, Nantes, France, for the valuable suggestions provided during the critical review of the manuscript; Professor Jean Marie Parel and Grace Kaissal of the Ophthalmic Biophysics Center, Bascom Palmer Eye Institute, University of Miami, for helping edit the manuscript; and the Corneal Industries, Paris, France, for realizing the Ultima<sup>©</sup> IOL project. In addition, the authors thank their colleagues Dr. Maria Letizia Salvetat and Dr. Marco Zeppieri for their valuable assistance in this study.

Dr. Migliorati had financial interest in the Ultima<sup>©</sup> lens. Dr. Brusini has none.

Reprint requests to: Giuseppe Migliorati, MD Department of Ophthalmology S. Maria della Misericordia Hospital p.le S. Maria della Misericordia, 15 33100 Udine, Italy brusini@libero.it

# REFERENCES

- Wagoner MD, Cox TA, Ariyasu RG, Jacobs DS, Karp CL, America Academy of Ophthalmology. Intraocular lens implantation in the absence of capsular support. Ophthalmology 2003; 110: 840-59.
- Por YM, Lavin MJ. Techniques of intraocular lens suspension in the absence of capsular/zonular support. Surv Ophthalmol 2005; 50: 429-62.
- 3. Zeh WG, Price FW. Iris fixation of posterior chamber intraocular lenses. J Cataract Refract Surg 2000; 26: 1028-34.
- Dick HB, Augustin AJ. Lens implant selection with absence of capsular support. Curr Opin Ophthalmol 2001; 12: 47-57.
- Hayashi K, Hayashi H, Nakao F, Hayashi F. Intraocular lens tilt and decentration, anterior chamber depth, and refractive error after transscleral suture fixation surgery. Ophthalmology 1999; 106: 878-82.
- 6. Teichmann KD, Teichmann IA. The torque and tilt gamble. J Cataract Refract Surg 1997; 23: 413-8.
- Lee JG, Lee JH, Chung H. Factors contributing to retinal detachment after transscleral fixation of posterior chamber intraocular lenses. J Cataract Refract Surg 1998; 24: 697-702.
- Durak I, Öner HF, Koçak N, Kaynak S. Tilt and decentration after primary and secondary transsclerally sutured posterior chamber intraocular lens implantation. J Cataract Refract Surg 2001; 27: 227-32.
- Müllner-Eidenböck A, Amon M, Schauersberger J, et al. Cellular reaction on the anterior surface of 4 types of intraocular lenses. J Cataract Refract Surg 2001; 27: 734-40.
- Amon M. Biocompatibility of intraocular lenses. J Cataract Refract Surg 2001; 27: 178-9.
- Amon M, Menapace R, Radax U, Freyler H. In vivo study of cell reaction on poly(methyl methacrylate) intraocular lenses with different surfaces properties. J Cataract Refract Surg 1996; 22 (Suppl): S825-9.
- Abela-Formanek A, Amon M, Schauersberger J, Schild G, Kruger A. Inflammation nach kataraktchirurgie und implantation zweier unterschiedlicher faltlinsen bei pseudoexfoliatio lentis. Klin Monatsbl Augenheilkd 2000; 217: 10-4.
- Schauersberger J, Amon M, Aichinger D, Georgopoulos A. Bacterial adhesion to rigid and foldable posterior chamber intraocular lenses. J Cataract Refract Surg 2003; 29: 361-6.
- Schwenn O, Binder H. Sutureless ciliary sulcus supported intraocular lens with transiridal anchoring haptics. J Cataract Refract Surg 2003; 29: 875-8.

- Migliorati G, Brusini P. A brand new 360° foldable scleral-fixation intraocular lens. ARVO meeting 2003; poster #264.
- Ramocki JM, Shin DH, Glover BK, Morris DA, Kim YY. Foldable posterior chamber intraocular lens implantation in the absence of capsular and zonular support. Am J Ophthalmol 1999; 127: 213-6.
- Oshima Y, Oida H, Emi K. Transscleral fixation of acrylic intraocular lenses in the absence of capsular support through 3.5 mm self sealing incisions. J Cataract Refract Surg 1998; 24: 1223-6.
- Ahn JK, Yu HG, Chung H, Wee WR, Lee JH. Transscleral fixation of a foldable intraocular lens in aphakic vitrectomized eyes. J Cataract Refract Surg 2003; 29: 2390-6.
- Küchle M, Seitz B, Hofmann-Rummelt C, Naumann GOH. Histopathologic findings in a transsclerally sutured posterior chamber intraocular lens. J Cataract Refract Surg 2001; 27: 1884-8.
- Blum M, Tetz MR, Faller U, Volcker HE. Age-related changes of the ciliary sulcus: implication for implanting sulcus-fixated lenses. J Cataract Refract Surg 1997; 23: 91-6.
- Le Quaoy O, Papaefthymiou Y. Implant intra-oculaire à fixation sclérale associé à la vitrectomie. J Fr Ophtalmol 2003; 26: 1051-8.
- 22. Fu AD, McDonald HR, Jumper JM, et al. Recurrent vitreous hemorrhage after sutured posterior chamber intraocular lenses. Retina 2004; 24: 193-8.
- 23. Price MO, Price FW, Werner L, Berlie C, Mamalis N. Late dislocation of scleral-sutured posterior chamber intraocular lenses. J Cataract Refract Surg 2005; 31: 1320-6.
- 24. Güell JL, Barrera A, Manero F. A review of suturing techniques for posterior chamber lenses. Curr Opin Ophthalmol 2004; 15: 44-50.
- Bellamy JP, Queguiner F, Salamé N, Montard M. Secondary intraocular lens implantation: methods and complications. J Fr Ophtalmol 2000; 23: 73-80.
- Baykara M, Ozcetin H, Yilmaz S, Timucin OB. Posterior iris fixation of the iris-claw intraocular lens implantation through a scleral tunnel incision. Am J Ophthalmol 2007; 144: 586-91.
- 27. Rieck PW, Binder H. A new posterior chamber intraocular lens for sutureless iris-fixated ciliary sulcus implantation in aphakic eyes without capsular support. Ophthalmologe 2007; 104: 577-81.

Copyright of European Journal of Ophthalmology is the property of Wichtig Editore and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.