articles

Intraoperative floppy iris syndrome associated with tamsulosin

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Purpose: To assess the incidence and possible causative factors of a newly recognized syndrome, the intraoperative floppy iris (IFIS).

Setting: Clinical practices in Los Altos and San Rafael, California, USA.

Methods: A retrospective chart review of consecutive cataract surgeries performed in a 2-surgeon practice over a 12-month period (706 eyes; 511 patients) was used to assess the percentage of cataract patients on systemic sympathetic α-1 antagonist medications as well as the percentage of patients who manifested the IFIS. A separate prospective study of 900 consecutive cases (741 patients) performed by another surgeon was used to determine the incidence of IFIS and the percentage of these patients who were taking α-1 antagonist medications.

Results: Three percent (16/511) of the patients in the retrospective study, representing 3.0% (25/706) of the total eyes, were taking tamsulosin (Flomax) for benign prostatic hypertrophy. The overall prevalence of IFIS was 2.0% (10/511 patients). The syndrome was noted intraoperatively in 63.0% (10/16) of the tamsulosin patients but in none of the 11 patients on other systemic α-1 blockers. In the prospective study of 900 consecutive cataract surgeries, the prevalence of IFIS was 2.2% (16/741 patients). Ninety-four percent (15/16) of the IFIS patients were taking or had taken systemic tamsulosin. Twenty-six patients (36 eyes) in the 2 studies had IFIS associated with systemic tamsulosin. Sphincterotomies and mechanical pupil stretching were ineffective in maintaining adequate pupil dilation in this surgical population.

Conclusion: Intraoperative floppy iris syndrome occurred in approximately 2% of a cataract surgery population and appeared to be caused by tamsulosin, a systemic sympathetic α-1A antagonist medication that is the most frequently prescribed medication for benign prostatic hypertrophy.

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Inadequate pupil dilation compromises cataract surgery and increases the risk for complications.[1] Numerous surgical techniques for enlarging the pupil diameter and preventing intraoperative constriction have been described.[2–14] Typically, mechanically stretching the pupil sufficiently expands and maintains the intraoperative pupil diameter by creating microscopic tears within the iris sphincter muscle.[1,2,4–8,14] However, this technique fails to adequately expand the pupil in some eyes.[1]

We describe a new small-pupil syndrome associated with tamsulosin (Flomax), a systemic sympathetic α-1A receptor blocker (Figures 1 to 3). This medication improves lower urinary tract flow by relaxing bladder

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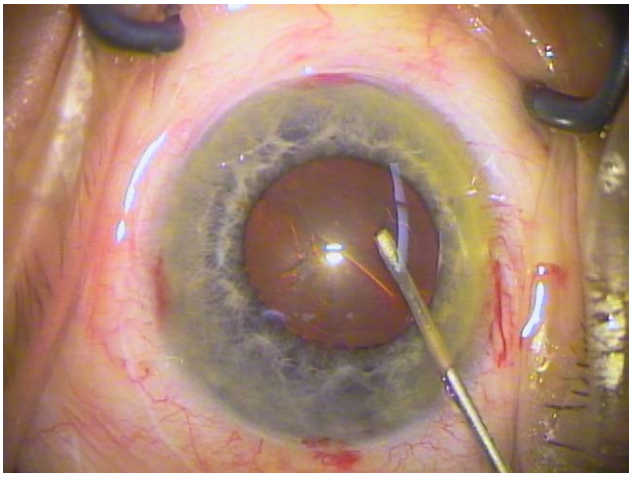

Figure 1. Moderate pupil dilation permits capsulorhexis in a tamsulosin patient.

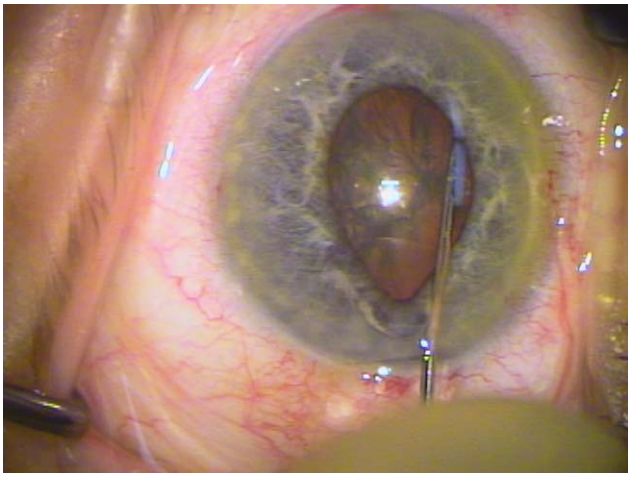

Figure 2. Iris immediately prolapses during initiation of hydrodissection.

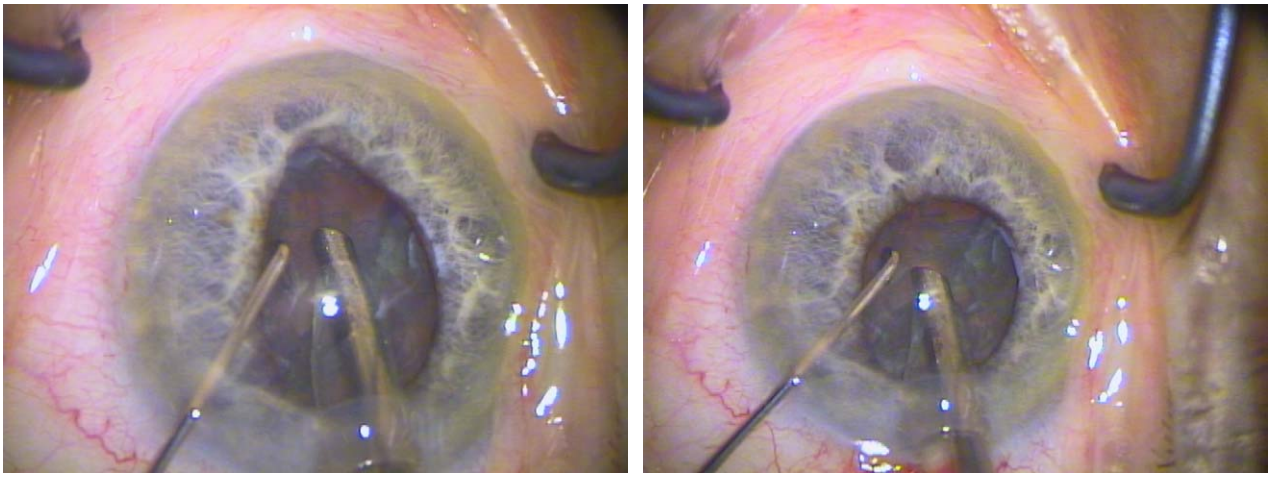

Figure 3. Iris billows, prolapses to both incisions, and the pupil constricts.

neck and prostatic smooth muscle and is the most commonly prescribed drug for treating the symptoms of benign prostatic hypertrophy (BPH). We observed a triad of characteristic intraoperative features that distinguish the intraoperative floppy iris syndrome (IFIS): a flaccid iris stroma that undulates and billows in response to ordinary intraocular fluid currents (Figure 3, *left*), a propensity for the floppy iris stroma to prolapse toward the phaco and side-port incisions despite proper wound construction (Figures 2 and 3), and progressive intraoperative pupil constriction despite standard preoperative pharmacologic measures designed to prevent this (topical cyclopentolate, phenylephrine, and nonsteroidal antiinflammatory medications) (Figure 3, *right*).[15]

Patients and Methods

To study this syndrome and the possible pharmacologic association with alpha blockers, 2 companion studies were done. In the first clinical study, a retrospective chart review of all cataract surgery performed during the 2003 calendar year in a 2-surgeon practice (J.R.C.) was performed. A standard dilating regimen consisting of instillation of lidocaine 2% jelly mixed with topical cyclopentalate, phenylephrine, and ketorolac was used. This was routinely supplemented with 1 drop each of topical cyclopentolate 1% and phenylephrine 2.5% if the pupil did not dilate well before surgery. Each chart was reviewed for concurrent use of any systemic sympathetic α-1 antagonist medication and for the presence of IFIS, as recorded in the operative report.

In the second study, the prevalence of IFIS in a prospective series of 900 consecutive cases in a single-surgeon

practice (D.F.C.) was determined. Unless IFIS had been noted in the fellow eye (6 cases), the surgeon was masked preoperatively to whether the patients were taking α-1 antagonist drugs. A standard dilating regimen consisting of 1 drop each of topical cyclopentolate 1% and phenylephrine 2.5% followed by instillation of lidocaine 2% jelly mixed with topical cyclopentolate, phenylephrine, and ketorolac was used. If IFIS was diagnosed intraoperatively, concomitant use of α-1 antagonist drugs was subsequently ascertained by chart review or patient interview.

Statistical Analysis

Because of the rarity of IFIS cases, the Poisson test was used to evaluate the rate of IFIS compared to the expected natural rate. The natural rate was estimated from the non-tamsulosin cases of IFIS found in the prospective series (clinical study 2). Statistical significance was accepted at 5% probability.

Results

Clinical Study 1

In the retrospective study, 511 patient charts were reviewed. Cataract surgery had been performed in 706 eyes of the 511 patients. Twenty-seven patients (5.3%), representing 40 eyes, had been on systemic α-1 antagonists at the time of surgery. All 27 patients were men. Sixteen patients (25 eyes) were taking tamsulosin (Flomax) for BPH; 11 patients (15 eyes) were taking other α-1 blockers such as prazosin (Minipres), terazosin (Hytrin), and doxazosin (Cardura). The tamsulosin cases made up 3% of the total patients and the total eyes in the study.

Poor preoperative dilation was common among the 27 patients on systemic α-1 blockers. Of the 40 eyes having cataract surgery, 68% (27/40) had poor or moderately poor dilation noted in the records. All 15 eyes of the 11 patients on systemic prazosin, terazosin, or doxazosin had cataract surgery without a diagnosis of IFIS.

Ten of the 16 patients on tamsulosin (63%) had a diagnosis of IFIS in the operative report (Table 1). All but 1 tamsulosin patient having bilateral surgery demonstrated IFIS in both eyes. One patient received extra dilating drops before second-eye surgery because of IFIS in the first eye. The prevalence of IFIS in the 511 patients in the retrospective study was 2.0% (10/511 patients). All these patients were taking tamsulosin for BPH.

Table 1. Clinical characteristics of IFIS cases in the retrospective study. All cases were in patients taking tamsulosin.

Case	Patient	Age (y)	Iris Color	Eye	DM	PXF	Pupilloplasty	Elev IOP POD1	Complications	Postop BCVA
1	1	82	Blue	L	Y	N	N	N		20/200*
2	2	73	Blue	L	N	N	N	N		20/20
3	3	81	Blue	L	N	N	Y retractors	N		20/20
4	3	81	Blue	R	N	N	Y retractors	N		20/25
5	4	90	Brown	L	Y	N	N	N		20/30
6	4	90	Brown	R	Y	N	N	N	Vitreous loss	20/30
7	5	76	Blue	L	N	N	N	Y	Increased IOP	20/20
8	5	76	Blue	R	N	N	N	N		20/25
9	6	78	Blue	L	N	N	N	N		20/25
10	6	78	Blue	R	N	N	N	Y		20/25
11	7	78	Blue	L	N	N	N	Y		20/25
12	8	88	Brown	L	N	N	N	N		20/30
13	9	83	Blue	R	N	N	N	N		20/40
14	9	83	Blue	L	N	N	Y retractors	N	Vitreous loss	20/70*
15	10	85	Brown	R	N	N	Y retractors	N		20/20
16	10	85	Brown	L	N	N	Y retractors	Y		20/20

BCVA = best corrected visual acuity; DM = diabetes mellitus; IOP = intraoperative pressure; POD = postoperative day; PXF = pseudoexfoliation

*Has age-related macular degeneration

Sixteen eyes (10 patients) demonstrated IFIS during surgery. Mechanical pupil stretching was not used, but iris retractors were used in 5 eyes. Posterior capsule rupture and vitreous loss occurred in 2 cases (12%). An intraocular pressure (IOP) spike on the first postoperative day occurred in 4 cases (25%). All patients regained a best corrected visual acuity (BCVA) of 20/40 or better except 2 with age-related macular degeneration (BCVA of 20/70 and 20/200).

Clinical Study 2

In the prospective assessment of IFIS in 900 consecutive cataract surgeries (741 patients), IFIS was diagnosed in 16 patients (2.2%) (Table 2). All the patients were men.

After IFIS was recognized intraoperatively, the systemic medication history revealed concurrent tamsulosin use in 14 of the 16 patients. Another IFIS patient had been on tamsulosin in the past but had stopped the medication for more than 1 year before surgery; IFIS was not noted during recent surgery in the opposite eye. Therefore, 15 IFIS patients (94%) had a history of concurrent or prior tamsulosin use. Review of the charts of the 725 non-IFIS patients revealed that none of them was taking tamsulosin.

No history of α-1 antagonist medication use was found in 1 patient thought to have the IFIS. This patient had diabetes; mechanical pupil stretching was performed because of poor preoperative dilation. He may have had operative characteristics that mimicked those of the tamsulosin floppy iris rather than true IFIS.

In addition to the patient who had been on tamsulosin in the past, 5 tamsulosin patients had bilateral cataract surgery during the study period and all 5 demonstrated IFIS in both eyes. A sixth patient had

Table 2. Clinical characteristics of IFIS cases in the prospective study divided into tamsulosin and non-tamsulosin cases.

Case	Patient	Age (y)	Iris Color	Eye	DM	PXF	Pupilloplasty	Elev IOP POD1	Complications	Postop BCVA
Tamsulosin cases										
1	1	81	Blue	R	N	N	N	N	None	20/25
2	2	76	Brown	R	N	N	N	N	None	20/20
3	2	76	Brown	L	N	N	N	N	None	20/20
4	3	82	Brown	R	N	Y	Y retractors	Y	None	20/40
5	4	62	Green	R	Y	N	Y stretch	N	None	20/40
6	4	62	Green	L	Y	N	Y stretch	N	None	20/30
7	5	85	Blue	R	N	N	N	N	None	20/30
8	5	85	Blue	L	N	N	Y stretch	N	CCC tear	20/30
9	6	71	Blue	R	N	Y	Y stretch	Y	None	20/20
10	7	74	Blue	R	Y	N	Y stretch	N	None	20/30
11	8	77	Brown	R	N	N	N	N	None	20/20
12	9	75	Blue	R	N	N	N	N	None	20/20
13	9	75	Blue	L	N	N	Y retractors	N	None	20/25
14	10	75	Brown	L	N	N	Y retractors	N	None	20/20
15	11	93	Brown	R	N	N	N	N	None	20/30
16	12	69	Brown	L	N	N	N	N	None	20/20
17	12	69	Brown	R	N	N	N	N	None	20/20
18	13	68	Brown	L	N	N	N	N	None	20/30
19	14	86	Brown	L	N	N	Y retractors	N	None	20/40
20	15	64	Brown	L	N	N	N	N	None	20/25
Non-tamsulosin cases										
21	16	88	Blue	R	Y	N	Y stretch	N	None	20/25

had cataract surgery 2 years earlier by the study surgeon; a diagnosis of floppy iris was recorded in the chart. Three IFIS patients had had cataract extraction in the fellow eye elsewhere. Two of these eyes had an irregular pupil shape or significant iris stromal atrophy, consistent with surgical iris trauma or prolapse. The third patient had a ruptured posterior capsule.

In the masked prospective study, 21 eyes exhibited IFIS during surgery. Mechanical pupil stretching, often combined with partial sphincter cuts, was performed to expand the pupil in approximately one third (6) of these cases. The measures did not prevent constriction of the pupil and iris incisional prolapse. Phaco chop was used in all cases, followed by implantation of a foldable intraocular lens (IOL).

Few intraoperative complications occurred in the prospective study. Momentary aspiration of the iris with the phaco tip was a common occurrence, as was focal iris stromal atrophy caused by prolapse. No patient experienced an irregular or permanently dilated pupil as a result of surgical iris sphincter trauma. Although 1 patient experienced a capsulorhexis tear during phacoemulsification, the IOL was successfully implanted in the capsular bag. There was no case of intraocular hemorrhage, posterior capsule rupture, or vitreous loss in the prospective study. On the first postoperative day, 2 IFIS eyes had a transient elevation of IOP greater than 22 mm Hg. Both patients had pseudoexfoliation. Neither patient experienced protracted IOP elevation. The BCVA was at least 20/40 or better in 100% of eyes by the 1-month follow-up visit.

Of the 26 patients in the 2 surgical series in whom IFIS was diagnosed, 12 (46%) had brown irides and 14 (54%) had blue or blue–green irides. Two (8%) IFIS patients had pseudoexfoliation, and 4 (14%) had diabetes. Using the single case of IFIS in clinical study 2 as the expected natural rate of IFIS yields 1 case per 741 patients per year or 14 per 10 000 patients per year. In clinical study 1, there were 10 cases of IFIS per 511 patients, a rate of 196 per 10 000 patients per year ($P<.002$). In clinical study 2, 15 of 741 patients had tamsulosin-associated IFIS, a rate of 202 cases per 10 000 patients per year ($P<.002$).

Discussion

Although we believe that the occasional intraoperative occurrence of a floppy iris is commonly recognized, we could find no reports of this syndrome in the peer-reviewed literature. Thus, its clinical features, incidence, and associated risk factors have not been described. We propose basing the clinical definition of IFIS on a triad of intraoperative characteristics that were common to our cases: fluttering and billowing of the flaccid iris stroma caused by ordinary intraocular fluid currents (Figure 3, *left*), a propensity for iris prolapse to the phaco and/or side-port incisions (Figures 2 and 3), and progressive constriction of the pupil during surgery (Figure 3, *right*). Making partial-thickness iris sphincterotomies with microscissors did not prevent this constriction. Iris prolapse can be caused by poor incision construction or by excessive injection of ophthalmic viscosurgical devices (OVDs) or hydrodissection fluid. Other conditions, such as diabetes, can be associated with progressive intraoperative miosis.[16] However, IFIS is distinguishable by the characteristic billowing of the iris stroma that accompanies the iris prolapse and pupil constriction.

Two additional characteristics often accompany the IFIS—poor preoperative pupil dilation and elasticity of the pupil margin. Mechanical stretching of the pupil is usually effective for small pupils caused by prior miotic use, pseudoexfoliation, or posterior synechia and is a commonly used method to expand the pupil diameter intraoperatively.[1–8,14] This maneuver creates microscopic sphincter tears and does not produce floppy iris behavior in these eyes.[14] However, this technique is usually ineffective in IFIS because the iris pupil margin remains elastic. Unlike with nonelastic miotic pupils, the IFIS pupil immediately snaps back to its original size following attempts at stretching it.[1] Because mechanical pupil restraining devices are difficult to safely insert after the capsulorhexis is completed, the ability to anticipate and recognize the IFIS is important for strategizing small pupil management.

After 1 author (J.R.C.) suspected an association between tamsulosin and a floppy iris, a retrospective study was performed to test and quantify the correlation. The surgeon subsequently began to discontinue tamsulosin preoperatively. However, a washout period of 3 to 7 days did not generally prevent the floppy iris behavior from occurring in this small group of patients. The second author (D.F.C.) undertook a separate prospective study to determine the prevalence of this syndrome and to attempt to separately confirm the

association with tamsulosin. The surgeon was masked preoperatively to tamsulosin use, except in the second eye of an IFIS patient. The results in the 2 large studies totaling more than 1600 eyes and 1250 patients suggest that the prevalence of IFIS in a cataract surgery population is approximately 2% and that there is an overwhelming statistically significant association with the use of systemic tamsulosin. This prevalence is consistent with the fact that tamsulosin is a fairly commonly prescribed medication in an elderly male population.

In the prospective study, no non-IFIS patient was on tamsulosin, meaning that 100% of patients taking the medication manifested the IFIS. This contrasts with the retrospective study in which only 63% of patients taking tamsulosin had IFIS. This discrepancy may be explained by the fact that in the retrospective study, the presence of IFIS could be determined only by operative report notation. Because the surgeons were not investigating IFIS at the time of surgery, several cases of IFIS may not have been diagnosed or recorded in the operative report. Another possibility is that the duration of tamsulosin use may have been very brief for some patients by the time of their surgery.

Alpha-1 adrenergic receptor blockers such as tamsulosin competitively inhibit the sympathetic autonomic nervous system, resulting in relaxation of the smooth muscles in peripheral blood vessels and in the bladder neck and prostatic urethra.[17,18] The vascular effect is to lower blood pressure, while the lower urinary tract effects improve outflow and the symptoms associated with BPH. So-called uroselective drugs are those that improve urinary outflow while minimizing vascular side effects such as postural hypotension. The first α-adrenergic blockers approved in the United States for BPH were the α-1 agents terazosin (Hytrin) and doxazosin (Cardura).[17,18]

At least 3 human α-1 receptor subtypes have been identified using binding and molecular cloning techniques: α-1A, α-1B, and α-1D.[19] The distribution varies among human organs. Tamsulosin was the first α-1A subtype-selective blocker to be approved in the U.S. with BPH as its sole indication; it is currently the most commonly prescribed medication for this condition.[20–24] Approximately 70% of the α-1 receptors in the human prostate are the α-1A subtype.[24] Based on animal and in vitro data, tamsulosin has a 24-fold greater affinity for α-1A than α-1B receptors.[19] For this reason, tamsulosin appears to be more uroselective, with fewer cardiovascular side effects than terazosin and doxazosin, which are not subtype-selective α-1 blockers. A new, nonsubtype-selective α-1 blocker, alfuzosin (Uroxatral), has been approved for BPH and was launched in November 2003.[25]

To our knowledge, characterization of α-1 receptor subtypes in the human iris smooth dilator muscle has not been established. However, there is indirect evidence that rabbits and humans have similar iris α-1 adrenoreceptors.[26,27] Using binding and reverse transcription-polymerase chain reaction studies, Nakamura et al.[27] determined that α-1A is the predominant subtype in the rabbit iris. Using similar binding and molecular techniques, Suzuki et al.[28] also found that the α-1A receptor was the dominant subtype in the rabbit iris dilator smooth muscle, accounting for more than 90% of all iris receptors. From binding studies in the albino rabbit iris, Wikberg-Matsson and coauthors[29] determined that the predominant receptor subtype was α-1A (60% compared to 40% for α-1B receptors). Finally, Yu and Koss[30] discovered that the systemic α-1 blocker, prazosin, is able to block sympathetic mediated mydriasis in anesthetized rabbits. From a series of additional in vivo rabbit experiments, they concluded that α-1A is the dominant receptor subtype mediating mydriasis in this species.

Based on these animal studies and the known pharmacology of tamsulosin, we hypothesize that in addition to blocking the α-1A receptors in the prostate, tamsulosin selectively blocks the iris dilator muscle in which the same receptor subtype dominates. Tamsulosin has a long half-life, and relatively constant receptor blockade could result in a form of disuse atrophy of the iris dilator smooth muscle. This might explain not only the poor pupil dilation in patients receiving tamsulosin but also the flaccid and floppy iris stroma observed even after the medication is stopped. While the dilator smooth muscle contributes minimally to the overall iris stromal thickness, normal smooth muscle tone may be necessary for the iris rigidity that is ordinarily observed during intraocular surgery. Thus, deficient smooth muscle tone could cause the billowing behavior and the marked propensity for iris prolapse to occur.

The striking tendency toward progressive intraoperative miosis could be explained by prostaglandin

release as a result of excessive mechanical iris stimulation (eg, iris prolapse or billowing due to irrigation currents). Deficient iris dilator smooth muscle tone would also contribute to this tendency. It is not clear why nonselective α-1 blockers such as terazosin and doxazosin inhibit pharmacologic mydriasis but are not strongly associated with the IFIS. However, prostate-binding studies clearly demonstrate that these drugs have different receptor affinity profiles than tamsulosin.[17,24]

We believe that 3 characteristics of IFIS increase the risk for operative complications relative to other small pupil cases. These are the marked tendency for iris prolapse, the progressive and unexpected intraoperative miosis, and the typical failure of sphincterotomies and mechanical stretching to maintain an adequate pupil opening. Vitreous loss occurred in 12% of IFIS cases in the retrospective series. Both of our studies included tamsulosin IFIS patients who had experienced vitreous loss in the fellow eye during surgery performed elsewhere. One of these patients had also developed a postoperative retinal detachment. We also had a referred nonstudy case in which iris prolapse in a tamsulosin eye mimicked a choroidal hemorrhage, forcing abortion of the surgery.

Having determined the pharmacologic cause of the IFIS, we believe that cataract patients should be questioned preoperatively about the use of tamsulosin for BPH. This is particularly important if the pupil dilates poorly. In both clinical studies, all the IFIS patients were men. However, urologists have recently begun prescribing tamsulosin off label for urinary retention in women.[31] We predict that female patients on tamsulosin will also manifest the IFIS.

The serum half-life of tamsulosin is 48 to 72 hours. In our limited experience, we found that discontinuing the medication for 4 to 7 days preoperatively was helpful but not completely effective in preventing this syndrome. One patient manifested mild iris floppiness in both eyes intraoperatively but without the iris prolapse or pupil constriction necessary for the diagnosis of IFIS. On postoperative questioning, the patient described a history of tamsulosin use that was discontinued 3 years before the surgery. We have also seen patients with true IFIS who had been off tamsulosin for 1 year, including the patient reported in the prospective series. These observations may be consistent with our hypothesis of disuse atrophy of the dilator smooth muscle. Nevertheless, because it may increase the surgical pupil diameter, we recommend that ophthalmologists consider temporarily discontinuing tamsulosin in patients for 1 to 2 weeks before surgery and use a maximum dilating regimen in the eyes of these patients.

In tamsulosin patients, one should anticipate a strong tendency for intraoperative iris prolapse and progressive miosis. Particular attention should be paid to proper incision construction and to avoiding excessive hydrodissection or OVD injection. A viscoadaptive agent such as sodium hyaluronate 2.3% (Healon5), when properly positioned over the iris, may help to mechanically expand the pupil and block the iris from prolapsing to the incisions. Premature evacuation of the Healon5 can be avoided by using low aspiration flow and vacuum parameters.

Mechanical stretching or partial-thickness iris sphincter cuts made with microscissors are common pupil enlargement techniques.[2,6] However, we found these measures to be ineffective in IFIS and suggest that devices such as iris hooks (Figures 4 to 6) or pupil expansion rings (Figure 7) are a superior strategy for maintaining an enlarged pupil diameter intraoperatively.[9–14] We recommend that iris hooks be positioned in the diamond pattern described by Oetting[11] (Figure 4). Because these devices are expensive and time-consuming to use, they are generally used less frequently than mechanical stretching techniques.[14] In IFIS, the floppy iris behavior is frequently not recognized until hydrodissection is performed. In this event, it may be too late to safely place iris hooks or expansion rings without capturing the capsulorhexis edge. Therefore, the ability to predict IFIS cases in advance may allow surgeons to alter their usual method of managing small pupils.

Bimanual microincisional phacoemulsification may represent a useful surgical strategy in IFIS patients. A maximally watertight seal minimizes the strong tendency for the iris to prolapse to the phaco or side-port incision. This is the case with bimanual microincisional phaco instrumentation, around which the incisions are deliberately sized for a maximally tight fluidic seal.[32,33] A separate front-irrigating chopper also provides a better opportunity to keep irrigation flow circulating anterior to the iris, which can minimize the billowing behavior. While this technique helped in 2 cases, it did not prevent iris prolapse in 2 others.

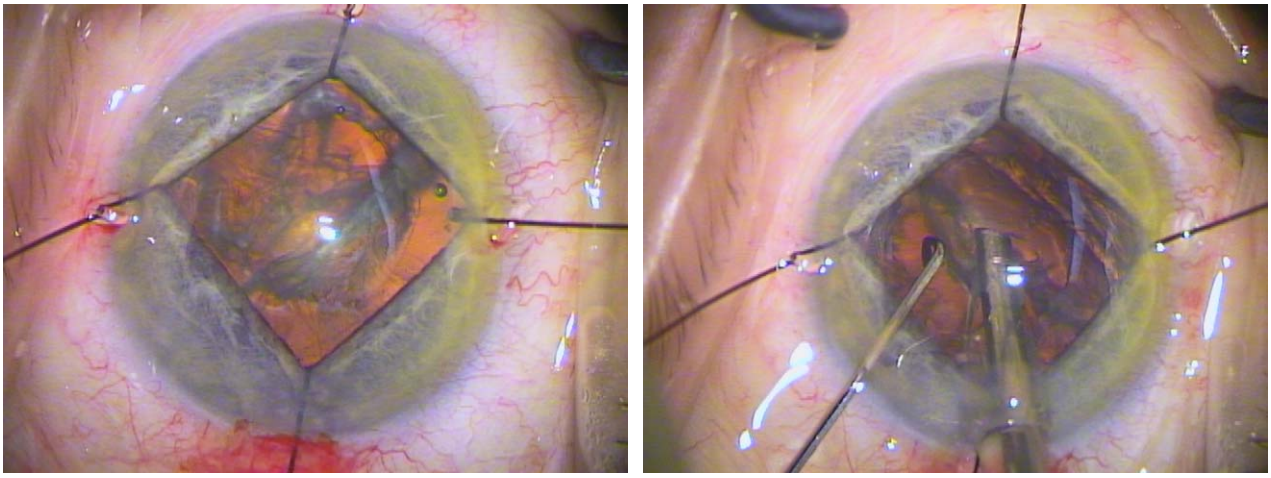

Figure 4. Iris retractors inserted in diamond configuration with subincisional retractor inserted through a stab incision immediately behind the phaco wound.

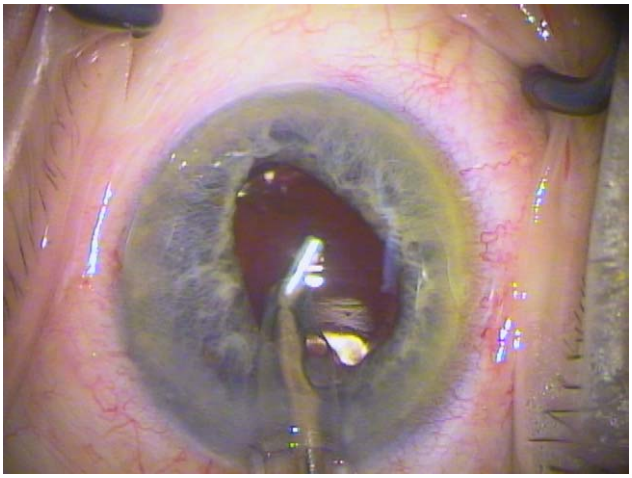

Figure 5. After removal of the iris retractors, iris billowing occurs in response to irrigation currents.

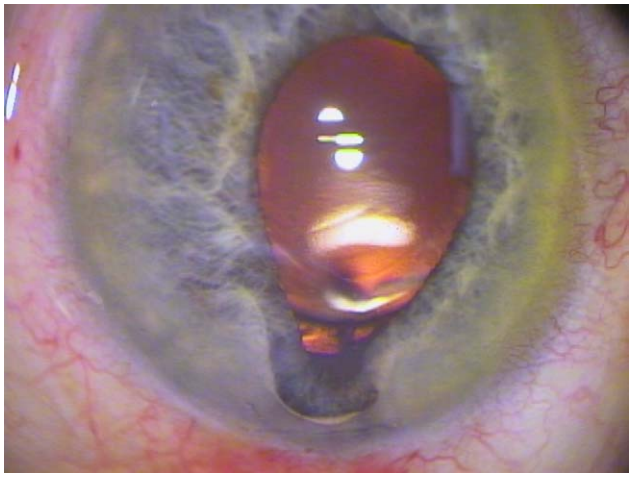

Figure 6. Iris prolapse on withdrawal of irrigation/aspiration tip.

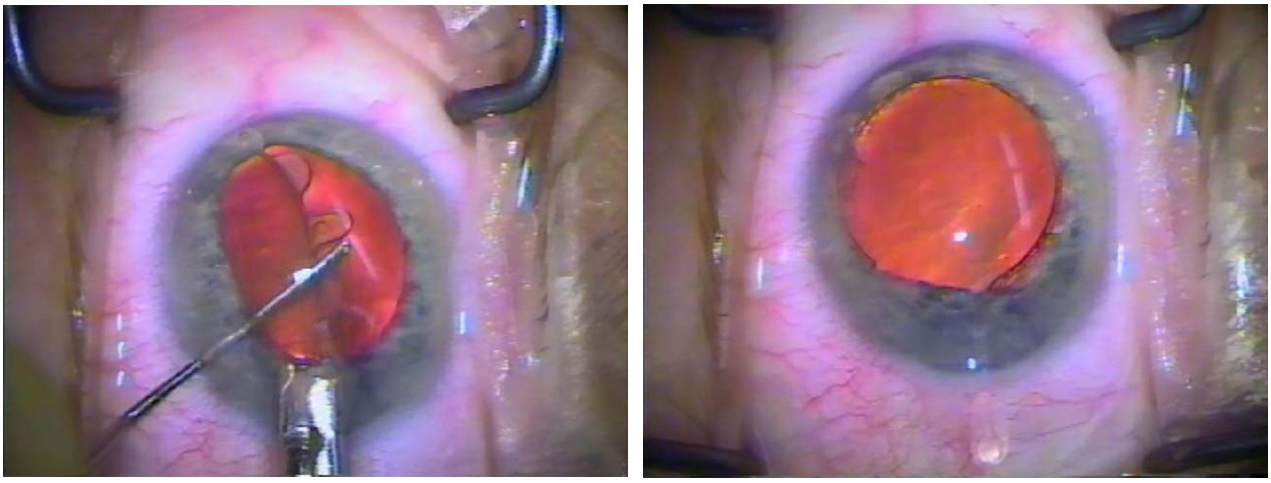

Figure 7. A Perfect Pupil pupil expansion ring is inserted with an injector.

In conclusion, progressive intraoperative miosis, such as that occurring with IFIS, significantly increases the risk for cataract surgical complications. We found a strong association between IFIS and systemic use of the α-1A subtype-specific blocker tamsulosin (Flomax) for BPH. Common pupil stretching techniques are usually ineffective in these eyes, and the use of iris hooks or expansion rings before initiating the capsulorhexis may be preferable. Therefore, knowledge, anticipation, and recognition of this syndrome may lead to a lower incidence of surgical complications in these patients.

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