

Expanding MIRAgel Scleral Buckle Simulating an Orbital Tumor in Four Cases

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Purpose: To describe four patients with an enlarging orbital mass from a swollen MIRAgel scleral buckle that simulated an orbital neoplasm.

Methods: In a retrospective, single-center case series at the Ocular Oncology Service at Wills Eye Hospital of Thomas Jefferson University, 4 eyes of 4 patients were referred for evaluation and treatment of a suspected orbital tumor.

Results: The initial presenting features were orbital mass (case 1), strabismus (case 2), and conjunctival mass with orbital extension (cases 3 and 4). Each patient vaguely recalled previous uncomplicated retinal detachment surgery 12 to 20 years earlier. Confirmation of the buckling implant material was made with the retina surgeon in 3 cases. A nontender, forniceal conjunctival mass, deep to the Tenon fascia and appearing as a translucent firm elevation was seen in all 4 cases. Axial CT (case 1) revealed a circumscribed anterior temporal orbital mass, believed to be a large inclusion cyst, 4 times thicker than the nasal scleral buckle. Ocular ultrasonography depicted an echolucent mass in the episcleral region (cases 3 and 4) that was 2 times thicker than the nasal scleral buckle (case 3). Excision was attempted in case 1, but only piecemeal removal was achieved, leading to extensive postoperative inflammation and decreased vision. The other 3 cases were followed conservatively without excision because they were each recognized to be a swollen MIRAgel implant and not an orbital tumor.

Conclusions: MIRAgel scleral buckle material can greatly enlarge over a period of 10 years and simulate an orbital tumor or orbital cyst. Patients often do not recall details of the retinal surgery. Caution is advised regarding excision of this material because it is friable and can lead to extensive postoperative inflammation.

Several materials have been used as scleral buckling elements, including silicone sponge, silicone rubber, and hydrogel. The hydrogel implant (commercial name MIRAgel, Waltham, Massachusetts) was a popular scleral buckle in the 1980s and early 1990s, as it was marketed

as a soft, flexible implant with physical properties allowing it to swell slowly over time, improving the buckling effect, lacking dead space, and minimizing infection.¹⁻⁴

Complications of MIRAgel have been reported. A study of 757 eyes with a scleral buckle followed for a mean of 6 years revealed that removal of the element was necessary in 9% of those with silicone sponge, 1% of silicone rubber, and 1% of MIRAgel.⁵ However, most authors have noted that extrusion or complications of MIRAgel happen after 10 years' follow-up, and, more importantly, that removal of MIRAgel is challenging because it typically undergoes fragmentation and can lead to serious periocular inflammation.⁵⁻¹⁵ In 1997, Hwang and Lim¹⁰ reported the first case of MIRAgel

Accepted July 21, 2004.

Supported by the Eye Tumor Research Foundation, Philadelphia, Pennsylvania (C.L.S.), the Macula Foundation, New York, New York (C.L.S.), the Rosenthal Award of the Macula Society (C.L.S.), and the Paul Kayser International Award of Merit in Retina Research, Houston Texas, U.S.A. (J.A.S.).

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DOI: 10.1097/01.IOP.0000148409.31127.F5

scleral buckle extrusion and emphasized the long-term friability of this material, leading to fragmentation at the time of removal.

In this report we describe 4 patients who were referred to us with an enlarging orbital mass, presumed to be a malignancy. All 4 patients vaguely recalled retinal detachment surgery 12 to 20 years earlier without postoperative problems. None of the patients had any information regarding the surgical technique or scleral buckling element. We suspected MIRAgel implant in 3 patients and avoided surgery, but 1 patient underwent orbital exploration for presumed orbital cyst, and piecemeal removal of the "friable soft mass" was necessary, leading to extensive postoperative inflammation. We caution the orbital surgeon to recognize this implant and anticipate postoperative clinical challenges if this implant is partially removed or disturbed.

CASE REPORTS

A summary of the 4 cases is listed in the Table.

Case 1

In 2003, an 82-year-old man noted the onset of a lump on the temporal side of the right eye for 2 weeks. His local ophthalmologist diagnosed orbital tumor and referred the patient for treatment. He reported no trauma, pain, or knowledge of a foreign body. He recalled cataract surgery OD in 1984 followed by retinal detachment surgery in 1988. On examination, visual acuity was 20/50 OD and 20/25 OS. There was no diplopia or proptosis. Ocular motility was 30% limited in abduction OD. In the temporal conjunctival fornix, there was a translucent mass with overlying intact white Tenon fascia and prominent conjunctival vessels (Fig. 1). The firm mass measured 20 mm vertically and 15 mm horizontally. On ophthalmoscopy, the retina was flat and scleral buckling effect was noted.

Axial CT revealed a circumscribed epibulbar mass in the right lacrimal gland fossa indenting the globe and showing density similar to brain tissue in its lateral aspect but similar to a cyst in its medial aspect. On CT, the temporal "mass" was 4 times thicker than the nasal portion of the buckle. Our initial diagnosis was chronic postoperative inclusion cyst, and surgical excision was advised.

At surgery, the mass was exposed through a conjunctival approach and found to be a swollen foreign body that had folded on itself, consistent with MIRAgel buckle. The temporal mass was friable and removed

Clinical features of four patients with expanding MIRAgel scleral buckle that simulated orbital tumor

Patient			Tumor features					Imaging						
Case No.	Age/race/sex	Interval (y) MIRAgel implant and orbital mass	Main finding	Conjunctival location quadrant	Location depth	Color	Diameter of mass (mm)	Texture palpation	Conjunctival vessels	Ultrasonography	Computed tomography	Magnetic resonance imaging	Follow-up (mo)	
1	82/W/M	15	Lump	T	Deep to Tenon fascia	White-translucent	20	Smooth firm	Dilated	ND	Circ mass	ND	Exc bx	Inflammation (10)
2	79/W/F	13	Esotropia	ST	Deep to Tenon fascia	White-translucent	20	Smooth firm	Dilated	ND	Circ mass	ND	Obs	Stable (6)
3	46/B/M	12	Lump	ST	Deep to Tenon fascia	White-translucent	10	Smooth firm	Dilated	Hollow mass with shadowing	ND	ND	Obs	Stable (3)
4	38/W/M	20	Lump	SN	Deep to Tenon fascia	Blue-gray translucent	12	Smooth firm	Dilated	Hollow mass with shadowing	ND	ND	Obs	No follow-up

W indicates white; B, black; F, female; M, male; T, temporal; ST, superotemporal; SN, superonasal; circ, circumscribed; Obs, observation; ND, not done; Exc bx, excisional biopsy.

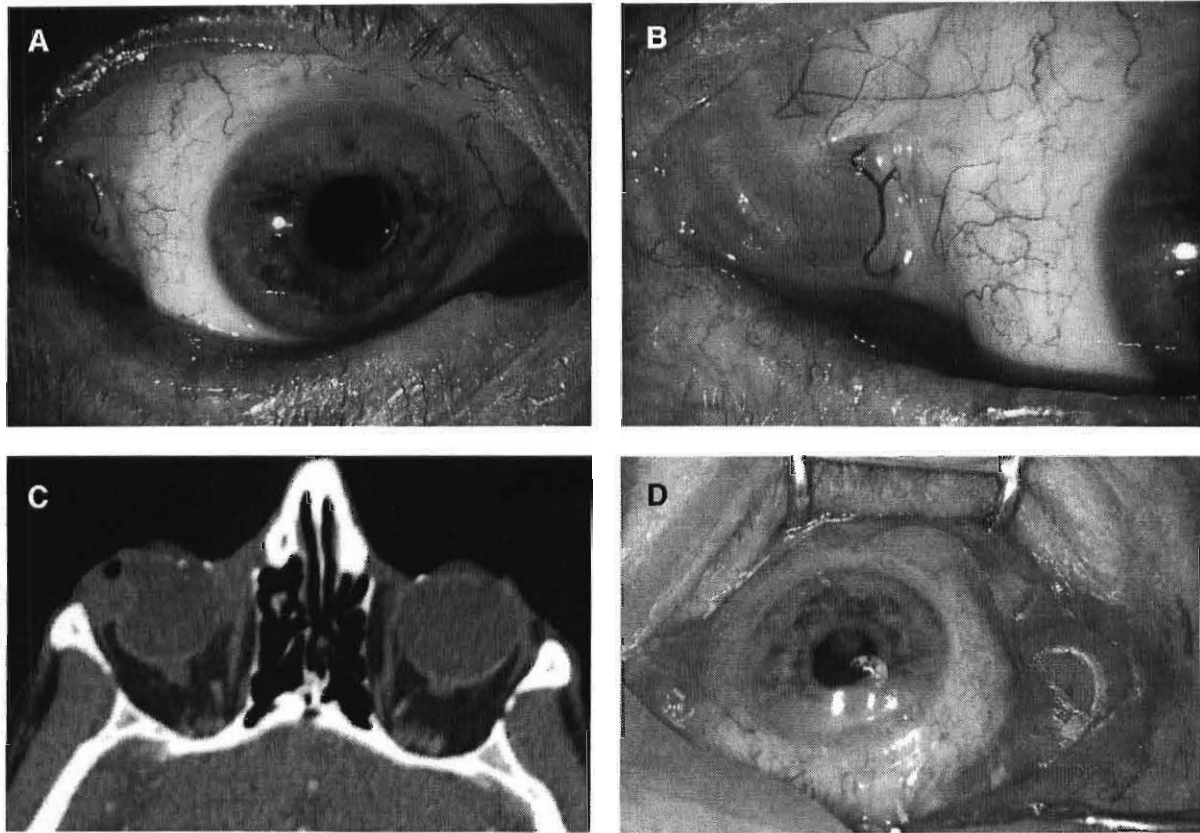


FIG. 1. Case 1. An 82-year-old man had an orbital mass that proved to be a swollen MIRAgel scleral buckle used for retinal detachment repair 15 years earlier. **A**, Mass was palpable through the temporal eyelid; deep conjunctival involvement was noted. **B**, Close-up view of mass reveals translucent material underlying white, fibrous Tenon capsule and prominent vessels. Note that the eye is pushed 10 mm nasally by the mass. This appearance is similar to a large orbital inclusion cyst. **C**, CT shows temporal mass indenting the globe with dense temporal portion and more lucent medial portion. Much smaller nasal portion of scleral buckle is noted at nasal equator of the eye. **D**, At surgery, the mass proved to be a swollen MIRAgel implant that had buckled on itself.

piecemeal, and the remainder of the buckle was left intact. The underlying sclera was thin. After surgery, massive orbital swelling ensued with eyelid edema, corneal striae, keratic precipitates, hypopyon, and poor view of the fundus caused by corneal changes. Systemic and topical antibiotics were instituted for concern for possible endophthalmitis. One month and 4 months later, repeat surgery to remove the remainder of the dis cohesive buckle was performed. On follow-up, 10 months later, the eye was hypotonous and quiet, with visual acuity of 20/200 as the result of striate keratopathy. The retina was attached.

Case 2

In 2004, a 79-year-old woman with breast cancer was noted to have a mass in the left anterior orbit, near the lacrimal gland fossa and referred with the diagnosis of

possible metastatic tumor. She gave a history of long-standing amblyopia and mild esotropia OS from age 2 years, but over the past 6 months, the esotropia had progressively worsened (Fig. 2). In 1991, a retinal detachment OS was repaired with a scleral buckle. On our examination, the visual acuity was 20/60 OD and 20/400 OS. There was 45 prism diopters of left esotropia with only 10% abduction, 20% supraduction, 80% infraduction, and full adduction. In the temporal conjunctival fornix, deep to the Tenon fascia, there was a translucent mass measuring 20 mm vertically and 15 mm horizontally. The mass could be barely palpated for 250° around the globe and was believed to represent a swollen scleral buckle. Axial CT disclosed a mass in the lacrimal gland fossa adherent to the globe. Coronal CT showed the mass partially encircling the globe. The final diagnosis was swollen MIRAgel buckle, and observation was advised.

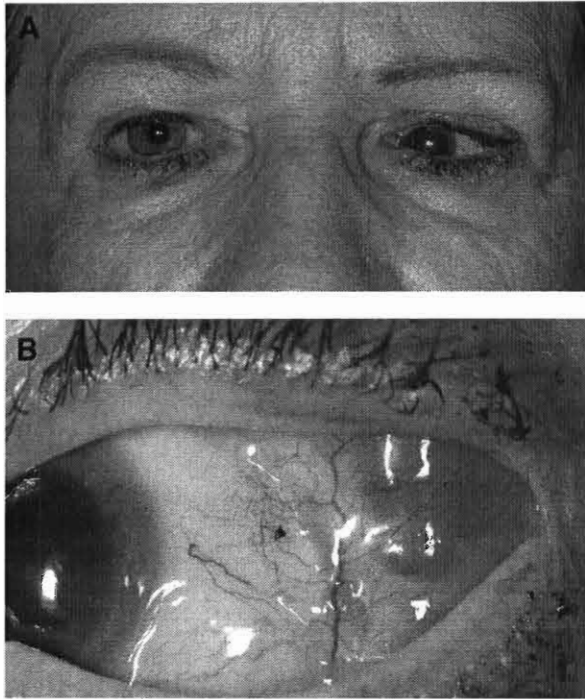


FIG. 2. Case 2. A 79-year-old woman had an orbital mass that proved to be a swollen MIRAgel scleral buckle used for retinal detachment repair 13 years earlier. **A**, Patient presented with worsening left esotropia. **B**, Translucent mass was noted in conjunctival fornix with overlying intact Tenon fascia and prominent conjunctival vessels. Observation was advised.

Phone consultation with the retinal surgeon confirmed the placement of MIRAgel. Follow-up 6 months later showed relatively stable findings.

Case 3

In 2004, a 46-year-old man felt a painless mass superotemporal OD for 1 week. His local ophthalmologist diagnosed orbital-conjunctival tumor and referred the patient for treatment. He denied trauma. He recalled cataract surgery OD in 1992 followed the same year by retinal detachment surgery OD. On examination, visual acuity was 20/100 OD and 20/20 OS. There was no diplopia or proptosis, and ocular motility was intact. The left eye was unremarkable. In the superotemporal fornix of the OD, emanating from the lacrimal gland fossa, was a translucent mass deep to the Tenon fascia and measuring 10 mm in greatest diameter (Fig. 3). The firm mass was noninjected and nontender. Ultrasound confirmed an oval epibulbar mass with scleral indentation and mild shadowing of orbital echoes. By ultrasound, the temporal "mass" was 2 times thicker than the nasal buckle. Oph-

thalmoscopy of the right eye confirmed flat retina with scleral indentation. The diagnosis was swollen scleral buckle (MIRAgel), and observation was advised. Follow-up of 3 months revealed stable findings.

Case 4

In 2004, a 38-year-old man was noted by his ophthalmologist to have a dark mass deep in the right fornix and extending in the orbit, suggestive of a melanocytic tumor. He recalled trauma to the right eye followed by retinal detachment and repair approximately 20 years earlier. On examination, visual acuity was 20/20, both eyes. There was no proptosis or dysmotility. In the superonasal fornix there was a grey-blue mass deep to the Tenon fascia extending for 30 mm circumferentially and 12 mm in thickness (Fig. 4). The mass was fixed to the globe, and overlying remnants of white sutures remained. Ocular ultrasound disclosed an epibulbar dense mass with orbital shadowing, consistent with scleral buckle. The diagnosis was swollen scleral buckle (MIRAgel), and observation was advised. Phone consultation with the retinal surgeon confirmed the placement of MIRAgel.

DISCUSSION

Orbital foreign body simulating an orbital tumor is uncommon. In an analysis of 1264 consecutive patients with orbital tumors and simulating lesions, only 2 (<1%) proved to have a foreign body, and both were young patients, 17 and 28 years of age.¹⁶ Similarly, foreign body in the conjunctiva simulating tumor was found in only 11 (<1%) of 1,643 consecutive patients with conjunctival tumors.¹⁷ In many instances, patients with orbital or conjunctival foreign body give a history of trauma or surgery with specific details of the foreign material, thus avoiding diagnostic confusion. Additionally, enlargement or "growth" of a foreign body, especially the commonly used silicone scleral buckling element, is distinctly unusual. All 4 patients in this report were suspected by the referring physician to have an orbital tumor as the result of the new onset of the orbital mass. In no case was the patient aware of the specific technique or scleral buckling material used by the retina surgeon at the time of previous retinal detachment surgery.

MIRAgel is a hydrogel (copoly methylacrylate-2-hydroxyethyl acrylate), which is a hydrophilic material formed from 3-dimensional polymer networks.¹ Hydrogels are low-molecular-weight substances that are permeable to water and can absorb and slowly release water-soluble substances such as antibiotics.³ This elas-

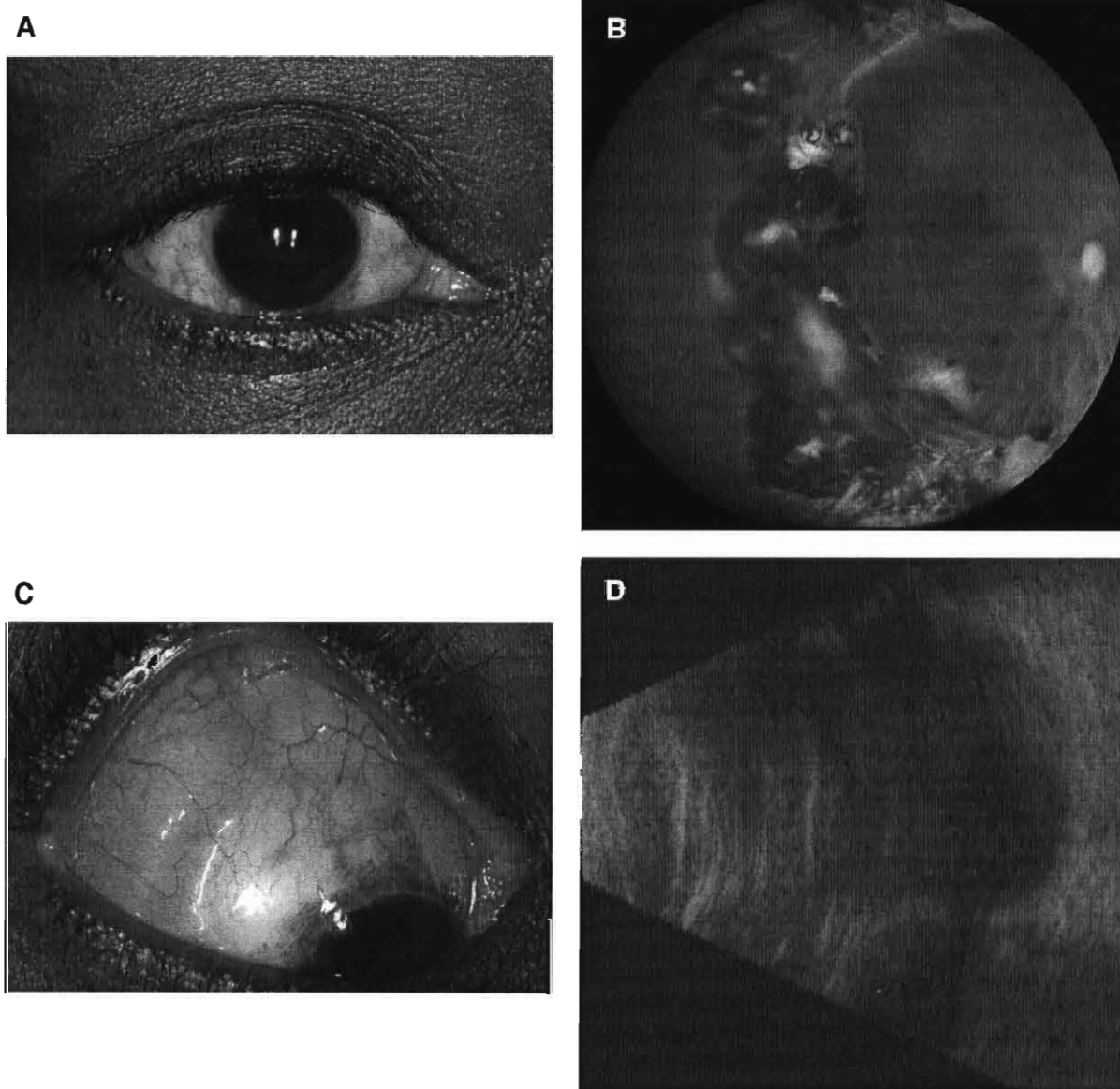


FIG. 3. Case 3. A 46-year-old man had an orbital mass that proved to be a swollen MIRAgel scleral buckle used for retinal detachment repair 12 years earlier. **A**, Patient noted a palpable mass through the eyelid temporally. **B**, Panoramic image shows chorioretinal scars and high scleral buckling effect 12 years after retinal detachment surgery. **C**, Mass was found to be translucent, with overlying prominent conjunctival vessels. Like a circumferential scleral buckle, the large mass appeared to encircle the eye. **D**, Ultrasonography confirmed 6 mm of ocular indentation by echolucent mass with orbital shadowing. This was twice the thickness of the nasal portion of the scleral buckle. Observation was advised.

tic buckling material was shown to be as effective as silicone rubber or sponge and believed to be possibly superior as the result of its low risk for infection. Early related complications in the first 4 to 5 years were reportedly minimal.^{3,4} However, long-term observations of hydrogel implants at approximately 7 to 11 years

revealed some complications related to extensive swelling of the implant.⁷ These included conjunctival bulging, implant migration, and rarely implant erosion in the eye, occasionally with poor visual outcome. Removal of implant material was particularly difficult because fragmentation of the swollen, friable material with piecemeal



FIG. 4. Case 4. A 38-year-old man had a blue-gray orbital mass extending into the conjunctiva 20 years after retinal detachment surgery. Note white sutures overlying the large buckle.

removal was encountered. In one case, a fragment of hydrogel floated through the eroded sclera in the vitreous cavity.⁷

In 2003, Le Rouic et al.⁶ compared complications from various buckling elements and found that MIRAgel complications occurred much later (mean, 92 months) than solid silicone (mean, 11 months) and silicone sponges (mean, 19 months). The progressive swelling of MIRAgel led to limitation of ocular motility, diplopia, ocular pain, ocular inflammation, and protrusion of the buckle beneath the eyelids, necessitating removal in 34 of 38 eyes (90%). The rate of buckle infection was much lower with MIRAgel than other buckling materials. In 2003, Li et al.¹³ cautioned that complications of this material could be on the rise because it was used extensively in the past decade, and most complications occur approximately 10 years after placement. Difficult removal should be anticipated.¹³

Swollen MIRAgel can resemble an orbital tumor. In 2002, Braunstein¹² described a patient who had diplopia and an orbital mass 13 years after MIRAgel buckle. On MRI, there was no indentation of the eye and, in fact, the swollen buckle had folded on itself, creating an orbital mass effect. The buckle had expanded 4-fold in volume, and tedious removal was encountered. Case 1 in our series showed similar folding of the buckle on itself secondary to swelling, leading to the appearance of a knuckle. To avoid buckle fragmentation at removal, Le Rouic et al.¹⁸ advised opening the conjunctiva generously and using cryoextraction rather than forceps extraction.

The orbital surgeon should be aware of the orbital complications of retinal detachment surgery. Previous

reports on orbital complications from scleral buckles have described clear or hematic orbital cysts.^{19–21} From the results in this report, we add the complication of MIRAgel that includes marked late onset swelling of the implant, simulating a solid or cystic tumor. In each of our 4 cases, the patient was referred by an ophthalmologist with a newly diagnosed, enlarging orbital mass. In 3 cases, the mass was visible in the superotemporal orbital region near the lacrimal gland fossa, raising concern for a lacrimal gland tumor. In each case, the mass proved to be swollen MIRAgel implant. MIRAgel has subsequently been removed from the market. However, many patients have this implant and are at risk for development of the problems seen in our cases. It is not known if injection of corticosteroids might minimize the tissue swelling. The orbital surgeon should recognize this implant and be prepared for challenging surgical removal if necessary.

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