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Globe Loss from Intraocular Invasion of MIRAgel Scleral Buckle Components

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Abstract

Purpose—To describe intraocular invasion of MIRAgel scleral buckles requiring enucleation.

Methods—This is an IRB-approved retrospective consecutive case series of eyes requiring enucleation secondary to intraocular intrusion of MIRAgel implants performed at the Cole Eye Institute from 2000 to 2014. Charts were reviewed for age at surgery, gender, laterality, time between MIRAgel placement to enucleation, preoperative examination and imaging results, intraoperative findings, postoperative complications, and duration of follow-up.

Results—Five eyes of five patients underwent enucleation due to a blind, painful eye secondary to MIRAgel expansion. The mean time between MIRAgel placement and enucleation was 21 years (range: 17 to 30 years). Preoperative ultrasound identified intraocular MIRAgel in 3/5 cases; however, intraocular MIRAgel was identified during surgery in all 5 cases. A transscleral-approach orbitotomy was performed at the time of enucleation in an effort to remove the MIRAgel. Postoperative complications included ptosis and inability to retain an ocular prosthesis. No cases of orbital implant extrusion occurred.

Conclusion—Scleral invasion and intraocular penetration of MIRAgel may occur decades after placement. This may result in a blind, painful eye requiring enucleation and orbitotomy to remove residual material. Suspicion of intraocular penetration of implant should be high in blind, painful eyes. Surgical removal can be difficult due to MIRAgel fragmentation. Conjunctival insufficiency may result in the need for further surgery after enucleation.

Introduction

The hydrogel scleral buckle for rhegmatogenous retinal detachments was first introduced in 1979 as the MAI implant and later popularized by the chemically equivalent MIRAgel implant (Mira, Inc., Waltham, MA, USA).^{1,2} The material has been associated with uncommon, but serious, complications. A large study of 386 patients with hydrogel scleral buckles found that 1.3% of cases required explantation.² Other severe complications include implant expansion and fragmentation,^{3–5} orbital pseudo-cellulitis,⁶ orbital pseudotumor,^{6–9} diplopia,^{3,4,7,8} ptosis,³ anterior erosion through the orbital septum and orbicularis oculi muscle,¹⁰ spontaneous expulsion from the eye,¹¹ and infection of the scleral buckle.¹²

Scleral erosion and intraocular penetration of the scleral buckle may also occur, potentially resulting in endophthalmitis and/or necessitating removal of the buckle and surgical closure of the scleral defect.^{1,5,13–17} In a large review of 38 eyes with MIRAgel buckles, Le Rouic *et al.* identified two eyes with scleral bed necrosis and two eyes that perforated during removal.¹⁸ Case reports and small case series in the English language literature describe a total of 11 eyes with scleral bed erosion with and without intraocular invasion.^{1,5,13–17} In these cases, surgical correction was performed 8–20 years after MIRAgel implantation and resulted in visual acuity ranging from 20/25 to no light perception. To the author's knowledge, the English language literature does not describe a patient requiring removal of a blind, painful eye with intraocular MIRAgel.

Although MIRAgel scleral buckles were removed from the market in 1995, patients continue to present with the most severe complications (e.g., blind and painful eye, scleral intrusion) related to the MIRAgel implant many years following placement. In this report the authors demonstrate the clinical findings of this grave consequence of MIRAgel implantation and describe a surgical approach to treat this complication.

Methods

This study was approved by the Cleveland Clinic Foundation Institutional Review Board and adhered to HIPAA regulations and to the principles of the Declaration of Helsinki. This was a retrospective consecutive case series of eviscerations performed at the Cleveland Clinic Cole Eye Institute by one physician (JDP) between the years 2000 to 2014. Inclusion criteria included eyes undergoing evisceration with associated MIRAgel scleral buckles. Charts were examined for age at surgery, gender, laterality, time between MIRAgel to evisceration, preoperative examination details, preoperative imaging results, intraoperative findings, postoperative complications, and duration of follow up.

Each evisceration was performed in a fashion similar to a previously described technique,¹⁹ calling for a creation of a 360-degree conjunctival peritomy, removal of a corneoscleral cap and the intraocular contents, and formation of scleral relaxing incisions. In each case, the orbital compartments were accessed via a trans-ocular approach through the scleral defect, the relaxing incision, or a posterior sclerotomy circumferential about the nerve to remove intraorbital MIRAgel fragments. An orbital implant was placed and the wound closed in a layered fashion.

Results

One hundred ninety-nine patients who underwent evisceration were initially reviewed, and five patients met criteria. Mean age at evisceration was 65.4 years (range, 55–80 years). One patient underwent evisceration in 2002 and four others underwent evisceration between 2011 and 2013. The average time from MIRAgel implantation to evisceration was 21 years (range, 17–30 years). Table 1 summarizes specific patient findings.

The indication for surgery in all patients was a blind, painful eye. One patient (patient 1) additionally failed intravitreal antibiotic therapy for recent endophthalmitis; there was no evidence of prior endophthalmitis in the other patients. Another patient (patient 4) failed

pars plana vitrectomy and repair of open globe for penetrated MIRAgel, resulting in retention of some intravitreal MIRAgel.

Preoperative B-scan ultrasonography was performed in each patient. Ultrasonography identified intraocular foreign bodies consistent with MIRAgel intrusion or scleral invasion in three cases (Figure 1). In two cases, no intraocular foreign body identified as MIRAgel was recognized by ultrasonography. Two ultrasonographers performed and interpreted the ultrasounds. One experienced ultrasonographer performed two of the ultrasounds with one false negative. The other experienced ultrasonographer performed three of the ultrasounds with the other false negative. The latter ultrasonographer (BHL) has co-authored textbooks in the subject of ophthalmic ultrasonography and is considered an expert in the field.

All five patients underwent evisceration of the involved eye and orbitotomy. In all five patients intraocular MIRAgel fragments were identified and removed. In two patients, a 360-degree posterior sclerotomy about the nerve was performed to approach the intraconal orbital compartment. In the other three patients, the intraconal space was approached through a large existing scleral erosion site and/or through additional posterior scleral incisions. MIRAgel fragments were friable and difficult to remove. Optimal removal was often achieved utilizing suction devices.

Mean postoperative follow-up was 16.4 months (range, 1–36 months). Two patients were lost to follow up after one and three months, respectively. No patient had orbital implant extrusion or extrusion of any remaining orbital MIRAgel. Postoperative complications included ptosis requiring external levator advancement (n=2), giant papillary conjunctivitis (n=1), and conjunctival adhesions in area of previous MIRAgel implant with forniceal foreshortening (n=1). Three patients were unable to tolerate an ocular prosthesis due to adhesions or lid issues as outlined above. Ptosis repair improved the ability to comfortably wear an ocular prosthesis in the two patients. The patient with forniceal foreshortening was lost to follow up without additional surgery.

Discussion

Hydrophilic scleral buckles were thought to be advantageous for rhegmatogenous retinal detachment repair for their soft structure, elasticity, and formation of a fibrous capsule, theoretically reducing the risk of scleral erosion.²⁰ Paradoxically, our findings support previous reports in the English language literature demonstrating that scleral erosion and intraocular penetration constitute rare, but important, late-onset complications of hydrogel scleral buckles. This complication is likely due to the expanding size of the hydrophilic hydrogel material, which can reach up to four times the original size.⁷ Implantation techniques may also be a factor, but surgical reports were unavailable in this set of cases as they were all performed by outside institutions. The multitude of MIRAgel-related complications led to the discontinuation of the product in 1995.

To the authors' knowledge, no previous reports describe patients requiring eye removal for intraocular penetration of the MIRAgel material. It remains unknown how many eyes received hydrogel scleral buckles during the 1980's and 1990's. One report describes

implantation in patients as young as nine years old.²⁰ Given that the average time from MIRAgel implantation to evisceration in the authors' current study was 21 years, with an upper range of 30 years, ophthalmologists may be challenged by such eyes for decades to come.

Corrective surgery for intraocular MIRAgel penetration may spare the eye, but the friable consistency of the MIRAgel material makes grasping it with forceps difficult.¹⁸ Çekiç *et al.* described the use of the Fragmatome ultrasound for intravitreal fragmentation and aspiration with globe salvage.⁵ Other surgeons manually remove the intraocular MIRAgel through a sclerostomy and repair the scleral opening, with or without vitrectomy and a tamponade agent.^{13,15,16} In addition to manual dissection, the friable and fragmented extraocular components have been removed by the cryoprobe,^{14,21} suction,²² boric acid,²³ or outward flotation of the buckle using balanced salt solution.²⁴ We recommend initial surgical attempt to repair the open globe and to extract intraocular and extraocular MIRAgel, reserving evisceration or enucleation only for cases of a blind, painful eye. This study's methodology involved only cases of evisceration due to surgeon preference, which may have resulted in an underrepresentation of cases.

In the literature, B-scan ultrasonography has identified extraocular MIRAgel scleral buckle as an anechoic expanded mass.^{14,25} B-scans of the patients in this series identified intraocular MIRAgel as a hyperechoic substance. In our series, B-scan evaluation identified intraocular MIRAgel in only three of the five patients. False-negative ultrasounds in eyes with intraocular MIRAgel may occur secondary to heterogeneous intraocular diseases, prior surgeries, different volumes of MIRAgel, different intrusion depths, and complex intraocular pathology such as cysts and membranes that may obscure identification of intraocular MIRAgel. In one of the false negative ultrasounds (patient 3), additional findings of vitreous opacities, membrane formation, calcification of the fundus, and an otherwise unidentified hyperreflective material (not identified as MIRAgel) overlying the fundus may have complicated the interpretation. In the other (patient 4), the ultrasound was performed before initial vitrectomy and open globe repair that confirmed the intraocular MIRAgel. It is possible that depth of penetration was small, which could lead to difficulty in ultrasound identification. Based on the literature, this study represents the largest series of B-scans in patients with intraocular MIRAgel. In patients with prior MIRAgel scleral buckles and a blind, painful eye, we advise a high index of suspicion for intraocular penetration, even in the setting of negative ultrasound imaging.

One patient (patient 1) in our study had preoperative endophthalmitis, likely from a full thickness scleral wound created by the MIRAgel and anterior conjunctival extrusion. Among the several cases in the literature of intraocular MIRAgel penetration, only one exhibited endophthalmitis.¹⁴ The low incidence of endophthalmitis may be due to the formation of a fibrous capsule or the MIRAgel tamponading the scleral wound.^{13,15} Intact conjunctiva may also reduce microbial exposure.

Three of the five patients were unable to comfortably wear their prosthesis without additional surgery. The two patients were able to comfortably retain an ocular prosthesis after external levator advancement for blepharoptosis. The third patient had forniceal

foreshortening likely due to longstanding conjunctival scarring from the implant and did not return for further surgery. The high rate of surgery after evisceration was likely multifactorial and possibly due to prior scarring, the surgical dissection itself, the anophthalmic socket, levator dehiscence, residual orbital MIRAgel, or a combination of these factors. Patients undergoing evisceration of an eye with a MIRAgel scleral buckle should be cognizant of possible additional surgery for comfortable prosthetic retention.

Hydrogel buckles have been associated with prosthetic and scleral shell intolerance due to postoperatively retained buckle material.^{6,22} In our study, no patient developed extrusion of retained MIRAgel material postoperatively, suggesting adequate orbital removal. During surgery, the material was so friable that it could not be entirely removed in any case. However, meticulous efforts and use of the suction instrument to collect the gelatinous material allowed for removal of the vast majority of the material in most cases. Based on these findings, maximal orbital removal of MIRAgel at the time of globe removal is recommended. The trans-ocular approach to the orbital space obviated the need for any further anterior incisions and dissection into the intraconal space, which may have minimized additional postoperative inflammation and scarring. Even though enucleation is another approach to eyes with intraocular MIRAgel, it may disrupt more orbital tissue planes. Additionally, it is the friable nature of the substance that made dissection difficult rather than the visualization, the latter of which would be better in enucleations.

Although hydrogel use for scleral buckles has ceased, similar materials have recently been used for orbital expansion.^{26–28} The long-term expansion potential of these orbital implants is unknown. Similar to earlier hydrogel formulations, these implants may also continue to slowly expand and become friable with fibrosis⁴, impeding future surgical dissection and removal.

Limitations of this study include its retrospective nature and small sample size. However, based on the literature, MIRAgel scleral buckle scleral erosion is a rare complication with no previously published cases of eye removal for this grave complication. Two patients were lost to follow up shortly after evisceration, so longer-term complications may be underreported. Additionally, retrospective surgical data regarding the extent of intraocular penetration were incomplete.

MIRAgel scleral buckle can result in intraocular intrusion, resulting in a blind, painful eye, even decades after placement. Though discontinued, the material is likely to cause such complications for decades to come. If efforts to salvage vision or the globe fail, evisceration with trans-ocular orbitotomy may adequately remove the material and allow for a substrate for an ocular prosthesis. Eyes with MIRAgel implants in place should undergo continued surveillance for ocular complications.

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Figure 1. Representative longitudinal B-scan ultrasound of Patient 2 demonstrating discontinuity of the sclera and choroid (arrowheads); abrupt retinal discontinuity consistent with retinal loss (arrow); intravitreal MIRAgel (diamond).

Table 1

Preoperative, operative, and postoperative details of the five patients with intraocular MIRAgel who underwent evisceration. M = male, F = female, GPC = giant papillary conjunctivitis, IRP = inability to retain prosthesis.

Summary of Patient Findings									
Patient	Sex	Age at evisceration (years)	Time from MIRAgel implant (years)	Preoperative details	B-scan findings	Intraoperative findings	Orbital approach	Complications	Follow up (months)
1	F	57	17	Endophthalmitis	Intraocular MIRAgel	1 × 1.5 cm scleral rupture; intraocular and intraconal MIRAgel	360 degree posterior sclerostomy	Ptosis, IRP	30
2	F	55	20	Prior surgeries to remove extraocular MIRAgel	11.5 mm hole in sclera with intraocular MIRAgel	Intraocular and intraconal MIRAgel; orbital foreign body granuloma	Pre-existing scleral laceration	None	1
3	F	80	30	Iris prolapse through cornea, ptosis, prominent globe	No intraocular MIRAgel noted	2 × 2 cm intraocular MIRAgel	Scleral relaxing incisions	Superotemporal conjunctival adhesions, inferior forniceal foreshortening, IRP	3
4	F	69	18	Prior surgery to remove intraocular MIRAgel and close open globe	No intraocular MIRAgel noted	Intraocular and intraconal MIRAgel	360 degree posterior sclerostomy	Ptosis, IRP	36
5	M	66	20	100% hyphema	MIRAgel compressing and invading sclera	MIRAgel eroding through sclera; intraconal MIRAgel	Scleral relaxing incisions	None	12