Complications of Hydrogel Explants Used in Scleral Buckling Surgery

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• PURPOSE: To report a group of patients with symptoms of pain, strabismus, sensation of orbital fullness, and presence of a subconjunctival mass many years after successful scleral buckling surgery using hydrogel explants.

• DESIGN: We present an interventional consecutive case series of patients who underwent scleral buckling surgery using hydrogel explants from 4 to 14 years before onset of clinical symptoms.

• SETTING: This is a retrospective, multicenter clinical study. Patient population: 17 eyes of 15 patients presented with this disorder. All patients were examined; Snellen acuity, ocular motility, tonometry, slit lamp, and fundus examination were recorded. Two patients underwent either computed tomography or magnetic resonance imaging. Removal of the hydrogel explant was attempted in all patients. Removal of the buckle was technically difficult; the hydrogel material was fragile and fragmented when handled.

• RESULTS: All patients had prompt relief of pain and discomfort. Ocular motility and diplopia were greatly improved. Extraocular muscle surgery was not required in any case. Three eyes had intraoperative eye wall perforation. One eye developed postoperative bacterial endophthalmitis. Five eyes had recurrence of retinal detachment. One eye had additional complications of corneal edema and glaucoma.

• CONCLUSIONS: Patients who develop this clinical condition should be considered for removal of the hydrogel scleral buckle. Early recognition of this condition may prevent serious complications associated with delayed removal. (Am J Ophthalmol 2004;137:96–100.

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IN 1979 THE HYDROGEL IMPLANT, COPOLY/METHYL ACRYlate-2-Hydroxyethyl acrylate (Miragel, Medical Instruments Research Associates, Waltham, Massachusetts, USA), a soft, pliable material that could withstand tension of sutures (except nylon), was introduced as a new scleral buckling material in the surgical management of retinal detachment.[1] It was meant to be hydrated by tissue fluids, allowing it to enlarge postoperatively and increase buckle height. The original intent in its use was to supplement an intrascleral solid silicone element, but it was soon found suitable as an explant and as a principal buckling element (Figure 1). Early reports showed that the material was well tolerated and produced the desired effect with few complications.[2]

In 1992 a report by Marin and associates of complications 7 to 11 years after scleral buckling with a similar hydrogel element suggested that a clinical disorder resulting from continued swelling of this material might soon become a problem.[3] Recently, this disorder, related to continued swelling and subconjunctival protrusion of the scleral buckling element, was recognized.[4,5]

In this report we present a series of 17 eyes of 15 patients that developed this disorder between 4 and 14 years after scleral buckling surgery. These patients presented with some or all of the following symptoms and findings: ocular pain and discomfort, poor lid–globe apposition with exposure keratopathy, oculomotor restriction with progressively worsening diplopia, the sensation of eye "bulging," and the presence of a visible or palpable mass beneath the conjunctiva or eyelid (Figures 2, 3).

METHODS

BETWEEN 1999 AND 2001 WE EXAMINED A CONSECUTIVE series of 15 patients who had previously undergone a scleral buckling procedure for retinal detachment and several years later developed ocular pain, diplopia, a sense of orbital fullness, external eye inflammation or a mass beneath the conjunctiva or eyelid, or a combination of these complaints. These patients had undergone scleral

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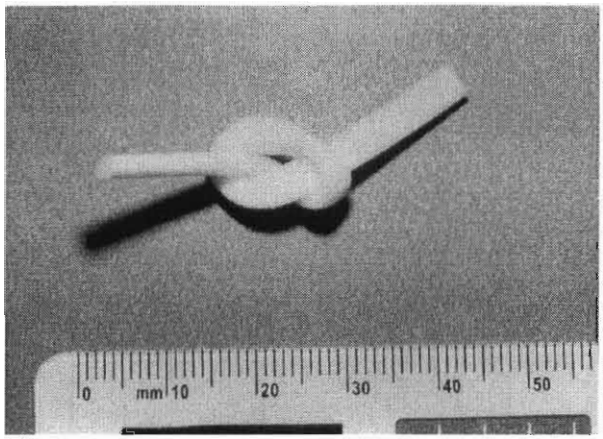

FIGURE 1. An oval hydrogel explant. Note that it appears soft and pliable.

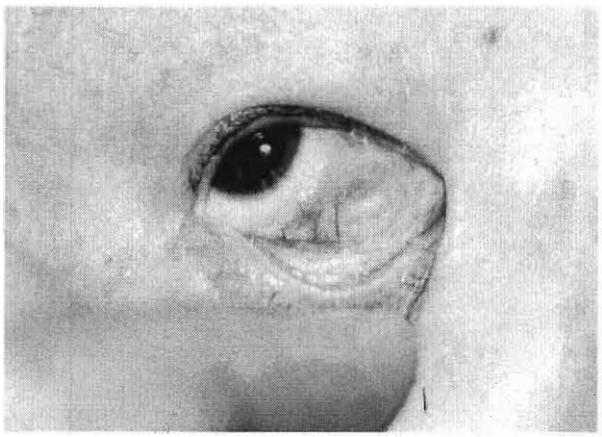

FIGURE 2. Right eye of patient with visible subconjunctival mass, resembling an inclusion cyst.

buckling surgery between 1984 and 1992 using the hydrogel scleral buckle described previously. The medical records of each patient were reviewed.

The ages of the patients ranged from 7 to 72 years, with a mean of 42.9 years. Ten patients were male and five were female. Three patients had myopia between 7 and 9 diopters. Three patients were aphakic, and two were pseudophakic. Five patients had a history of either penetrating or blunt eye trauma. In five cases, there was a history of retinal surgery before undergoing hydrogel scleral buckling. Of these, two had undergone pneumatic retinopexy, one a silicone sponge scleral buckling procedure with postoperative gas and laser retinopexy, and two had laser or cryoretinopexy for retinal tear without detachment.

Three of the 15 patients had undergone hydrogel buckling in both eyes. Of these three patients with bilateral hydrogel buckles, two developed this disorder in both eyes, whereas the other had these complications in only one eye, yielding a series of 17 eyes of 15 patients.

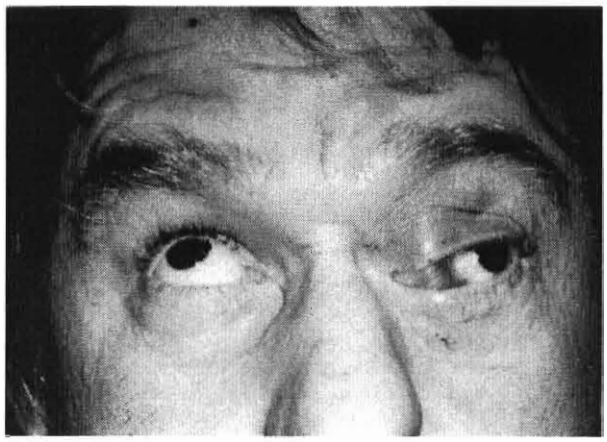

FIGURE 3. A subconjunctival and subpalpebral hydrogel explant interferes with ocular motility, especially on attempted gaze up and to the right.

TABLE 1. Symptoms and Findings in Eyes With Swollen Hydrogel Buckles

Symptom/Finding	Number of Eyes
Pain or discomfort	17 (all)
External eye inflammation	17 (all)
Mass beneath conjunctiva or eyelid	13
Diplopia and strabismus	10
Sensation of "bulging eye"	6
Sudden loss of vision	1
Exposed buckle element	1

Table 1 details the presenting symptoms and findings of these 17 eyes. Three patients in the group with external eye inflammation had poor lid–globe apposition with exposure keratopathy. Several patients complained of increasing diplopia and deviation of the involved eye. The strabismus was noncomitant, resulting from oculomotor restriction, demonstrated by forced duction testing. Deviation was both vertical and horizontal in most cases and was as high as 25 prism diopters vertical and 60 prism diopters horizontal in primary position. Only one eye presented with the typical clinical picture of buckle extrusion—namely pain, discharge, and exposed scleral buckling element.[6] In one eye, there was sudden vision loss resulting from vitreous hemorrhage that was treated by vitrectomy. Intrusion of the hydrogel buckling element was confirmed at this operation.

The technique of hydrogel buckling in these patients was reviewed. Conventional buckling techniques, namely localization and cryopexy of retinal breaks and placement of non-nylon sutures in the sclera to anchor the explant, were performed. Subretinal fluid was released in all but one case. The anchoring buckle sutures were secured with the buckle under slight stretch. The ends of the hydrogel

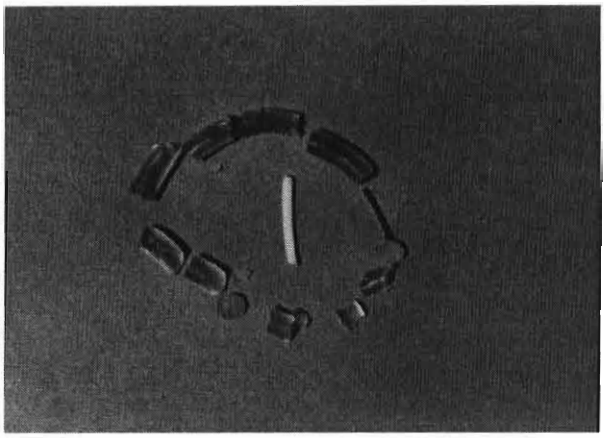

FIGURE 4. A washed 4-mm hydrogel explant showing multiple fragments of a swollen explant and a 3-mm silicone sponge explant for comparison. The sponge was removed at the same surgical sitting as the hydrogel explant.

buckle were sutured to each other to achieve a 360-degree buckling effect in all but one case. In this one case, a localized segmental buckle was used. An encircling silicone band (#40 or #240) was not used, even when the hydrogel buckling element was grooved. The hydrogel explants used were both round (4 and 5 mm) and oval (3–4.5 mm × 5–7.5 mm) in cross section.

Surgical removal of the explant was attempted in these 17 cases. In two of these cases, the removal was incomplete because of difficulties encountered intraoperatively.

Extraocular muscle surgery to correct strabismus was not carried out on any patient.

General anesthesia was used in 12 cases, whereas local anesthesia was used in 5 cases. The local anesthesia consisted of either retrobulbar or peribulbar injection of lidocaine and bupivacaine.

RESULTS

DIFFICULTIES WERE ENCOUNTERED AT SURGERY. THE EXplant material was very friable and fragmented into many pieces when handled with instruments (Figure 4).

The sclera beneath the explant was very thin in some areas in several of the patients. In two cases, an eye wall perforation was recognized during surgical removal of the explant. Both of these perforations were managed by laser retinopexy using the indirect ophthalmoscope delivery system at the time of recognition. One of these patients went on to develop retinal detachment; the other did not. In both of these cases, the sclera was so thin that a small piece of hydrogel material was found fused to the eye wall. It was left in place rather than risk complications of more aggressive attempts at removal. In a third case, the occurrence of an intraoperative eye wall perforation was presumed, because the patient developed bacterial endophthalmitis after surgical removal of the explant.

TABLE 2. Incorrect Diagnoses Before Referral/Diagnosis

	Number of Eyes
Graves disease	3
Idiopathic orbital fibrosis	3
Bizarre neuroophthalmic disorder	1
Subconjunctival inclusion cyst	1
Paresis of third cranial nerve	1

All patients experienced rapid relief of presenting symptoms at the first day's postoperative examination.

We compared Snellen visual acuity before, 6 weeks after, and 6 months after hydrogel buckle removal. In 10 cases, there was no change in visual acuity. These 10 patients had a mean acuity of 20/90 (range, 20/25–20/400). In five cases, patients lost 1 to 7 lines (mean, 3 lines) of acuity from a preoperative range of 20/25 to 20/350 (mean, 20/250). Visual acuity of two eyes improved by 4 lines each (20/50 improved to 20/20, and 20/60 improved to 20/25). Four of the five patients who lost acuity had recurrence of retinal detachment. The level of acuity at 6 weeks was maintained at 6 months. One patient developed bacterial endophthalmitis, which was diagnosed on the third postoperative day. In this case, there was pain, reduced vision, and the presence of hypopyon. Cultures grew *Staphylococcus aureus*. Treatment consisted of intravitreous vancomycin and ceftazidime as well as peribulbar and topical antibiotics and corticosteroids. The eye wall was presumed perforated at the time of hydrogel buckle removal, although no perforation was recognized at surgery and surgical exploration of the sclera was minimal.

Five patients developed retinal detachment from 3 weeks to 3 months after hydrogel buckle removal. This was managed in one case by vitrectomy and perfluoropropane gas injection and in three cases by vitrectomy with silicone oil injection. One of these three silicone oil cases was the patient who developed bacterial endophthalmitis. The fifth patient with recurrence of retinal detachment had undergone, 3 weeks before recurrence of detachment, a partial removal of the hydrogel buckle and vitrectomy for vitreous hemorrhage. During this vitrectomy procedure, a portion of the hydrogel buckle was seen to have intruded into the vitreous cavity. When retinal detachment recurred, the patient declined additional retinal surgery. All other patients with recurrence of retinal detachment had successful reattachment procedures. Repeat scleral buckling was not attempted in any of these cases.

The one patient with endophthalmitis followed by retinal detachment required removal of the silicone oil because of corneal edema and glaucoma. The intraocular pressure is well controlled with topical agents, but vision is poor. There is optic nerve pallor and cupping.

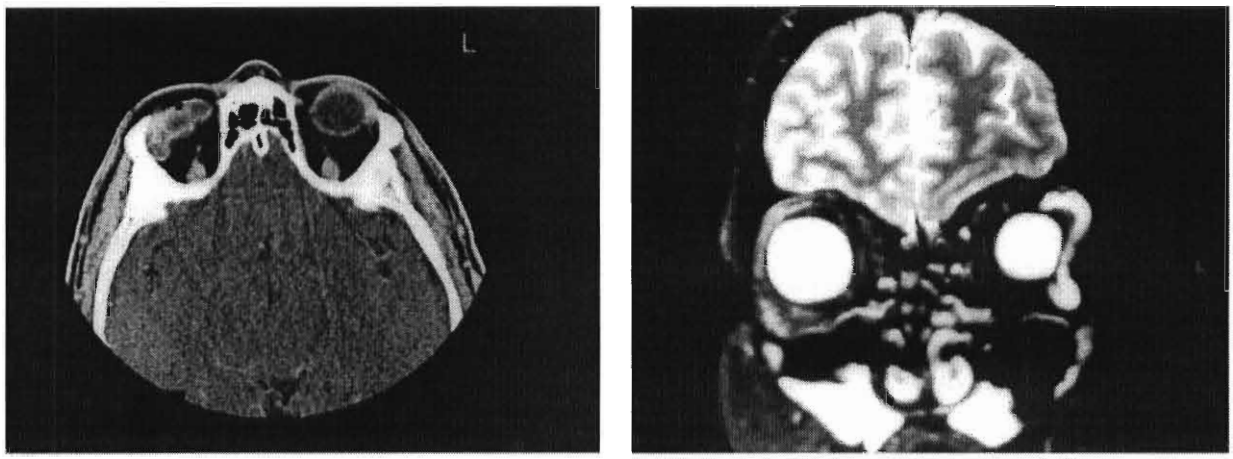

FIGURE 5. (Left panel) Computed tomography scan showing a hydrogel explant in the anterior orbit of the right eye. (Right panel) Magnetic resonance image of the left orbit shows an expanded hydrogel explant.

Because of the large angle of strabismus encountered, and the thinness of the sclera, extraocular muscle surgery was not carried out when the hydrogel buckle was removed. No patient required a second operation for residual strabismus.

DISCUSSION

PROBLEMS AFTER HYDROGEL BUCKLING SURGERY OCcurred from 6 months to 14 years postoperatively, with a mean of 8.3 years. Time from successful buckling to surgical removal of the explant was from 6 months to 15 years, with a mean of 10.25 years. Only one patient presented with typical symptoms and signs of infected or early extrusion of buckling element, and this was the one presenting at 6 months. All other patients presented at least 4 years after hydrogel buckling. This long time lapse may explain the difficulty in arriving at a correct diagnosis.

In some cases, the correct diagnosis of swollen explant was made by the referring physician after initial examination. However, in nine of the 17 cases, lack of familiarity with this condition led either to incorrect diagnoses or no diagnosis, as indicated in Table 2. In one case (Figure 2), the appearance of the subconjunctival mass so closely resembled a cyst that an unsuccessful attempt was made to aspirate the mass.

In four cases, the referring physician had also obtained consultation with neurology, neuroophthalmology, or oculoplastic/orbital surgery to assist in diagnosis. In two cases, computed tomography scans and magnetic resonance images were obtained before the correct diagnosis was made (Figure 5, left and right panels).

Strabismus surgery was not done on any of the patients, either at the time of explant removal or as a secondary procedure. Residual strabismus measured approximately 5 prism diopters vertical and 8 to 10 prism diopters horizontal. It was either accepted by the patient using head position or managed by prism spectacles.

We propose the following mechanism for hydrogel buckle expansion, based on recent literature and parallels to experience with other forms of scleral buckling materials. Prolonged exposure of the hydrogel material to tissue fluids resulted in a change in its chemical and physical makeup.[3] The altered explant then became hydrated and swollen to the degree that sutures holding the ends of the buckle cut through the hydrogel, producing a prominent mass. The sutures anchoring the explant were placed under tension and pulled through the sclera, exposing the choroid where sutures had been placed deeply. Those sutures that did not pull through the sclera maintained pressure of the explant on the sclera, thinning it to the point that areas of choroid were exposed. The continued expansion of the explant resulted in its occupation of most of the anterior orbit. This mass effect, plus inflammation and fibrosis of the orbital tissues, resulted in the restrictive myopathy observed.[7] The absence of a nonyielding encircling silicone band further allowed for continued enlargement of the explant.

Hydrogel buckling material is no longer available. It was discontinued by the manufacturer in approximately 1994 (oral communication, Medical Instruments Research Associates). There is, however, a large group of patients who have had this material implanted and might be expected to develop the clinical picture described here.

Patients who have undergone scleral buckling with hydrogel before 1995 are at risk of developing this disorder. Often the nature of the buckling element is unknown and the physician does not consider the possibility of a relation between the scleral buckling surgery and the symptoms of diplopia, pain, and orbital mass. Physicians need to be made more aware of this condition and should consider its possibility in a patient who presents with peculiar orbital

and motility problems and has undergone retinal surgery in the past.

We do not have sufficient experience to determine exact indications for removal of these hydrogel buckling elements or the timing of their removal. In our cases, the decision was not difficult; the patients were very symptomatic and readily agreed to surgical removal. As more experience is gained, we will be able to make this decision in the patient with milder symptoms.

Removal of the buckle is difficult. A single small incision used for silicone buckle removal was found insufficient. A 360-degree conjunctival opening may be preferred. The buckle cannot be grasped easily with instruments. Rather than grasping and pulling on the element, we suggest cutting it in each quadrant and pushing it through the fibrous tunnel to an open quadrant. Because of this difficulty and our incidence of eye wall perforation, we do not believe this is an office procedure. We also recommend against extensive exploration of the sclera and aggressive attempts to remove all traces of the hydrogel material.

The incidence of redetachment of the retina after hydrogel buckle removal was high (nearly one third of our cases). We do not have sufficient experience to allow us to recommend a specific preventive treatment.

Local anesthesia was used in approximately one fourth of our cases and was satisfactory.

Surgery for strabismus does not appear to be necessary. Conservative nonsurgical management was sufficient in our cases.

Repeat scleral buckling for recurrence of retinal detachment may be very difficult. We chose vitrectomy and intraocular gases or silicone oil to manage this complication.

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