Long-term Complications of the MAl Hydrogel Intrascleral Buckling Implant

Jesus F. Marin, MD; Felipe 1. Tolentino, MD; Miguel F. Refojo, DSc; Charles L. Schepens, MD

• Seven cases in which long-term complications developed from swelling of the MAl hydrogel intrascleral buckling implant are reported herein. Micro–Fourier transform infrared spectroscopic analysis of two recovered implants demonstrated the occurrence of chemical changes leading to increased swelling. Clinical problems with the implants appeared 7 to 11 years after surgery, suggesting the need for periodic, long-term follow-up. It is possible that the present-day MIRAgel implant, which has the same chemical composition as the MAl implant, may require similar precautions.
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The MAl implant, also known as the Refojo implant, is a synthetic, hydrophilic scleral buckling material introduced in the late 1970s.[1,2] MAl is made of poly(methyl acrylate-co-2-hydroxyethyl acrylate) cross-linked with ethylene diacrylate with 15% water. The material is soft, elastic, and smooth and can be heat sterilized.

See also p 12.

The MAl implants were first used in 1979 at equilibrium hydration (15%) and functioned as either the primary episcleral or intrascleral buckling elements or as meridional implants under solid intrascleral silicone rubber buckles. Seven of 82 patients in whom this material was used intrasclerally for buckling from 1979 to 1982 developed complications from swelling of the implant. We report this compli'cation in seven patients treated at Retina Associates, Boston, Mass.

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From the Eye Research Institute (Drs Marin, 'Iblentino, Refojo, and Schepens), Retina Associates (Drs Marin, 'Iblentino, and Schepens), and Department of Ophthalmology, Harvard Medical School, Boston, Mass (Drs 'Iblentino, Refojo, and Schepens).

Reprint requests to the Library, Eye Research Institute, 20 Staniford St, Boston, MA 02114 (Dr 'Iblentino).

REPORT OF CASES

MAl Implants as a Primary Intrascleral Buckle

CASE 1.-An 18-year-old man was seen in April 1990 for a prominent temporal subconjunctival implant in the left eye. He had undergone a scleral buckling procedure in the eye 7 years earlier for an inferotemporal dialysis with retinal detachment. An 8.0-rom MAl implant was placed intrasclerally from the 2-o'clock position to the 7:30 position. The postoperative course was uneventful, and the patient was unavailable for follow-up until the latest visit, at which his visual acuity was 20/30 as. Examination revealed a scleral buckling implant that was indenting the sclera excessively and bulging subconjunctivally.

In May 1990, the implant was removed surgically and was noted to be swollen, cream-colored, friable, encapsulated, and fused with a calcified scleral bed. The capsule was opened carefully, and the implant was removed completely in a piecemeal fashion. Portions of the calcified capsule, scleral bed, and implant were submitted for histologic examination, which revealed the presence of calcium in the tissues surrounding the implant but not in the implant itself. On the patient's last visit 6 months after sm'gery, the retina remained attached with visual acuity stabilizing at 20/25-2 as.

MAl Implant as a Meridional Intrascleral Buckle

CASE 2.-A 70-year-old man was seen in September 1990 for a "ballooning" scleral buckle in the right eye. He had undergone a scleral buckling procedm'e for a rhegmatogenous retinal detachment 8 years earlier. Because the retinal tear tended to fish mouth, an MAl implant was used under a 77G solid silicone implant. The postoperative course was uneventful, with visual acuity stabilizing at 20/70 aD. The latest examinatibn revealed an int111ding buckle with minimal overlying retinal detachment. This area was "walled off" by laser before the implant was removed.

Dming sm'gery, dehiscence of the scleral bed was noted, with spontaneous minimal drainage of subretinal fluid. The MAl implant was removed in toto and was found to be moderately swollen, measming 17.2x12.2x5.3 rom. The implant was submitted for laboratory analysis. The retina remained attached after smgery with some vitreous bleeding. Visual acuity was reduced to counting fingers at 6 feet because of vitreous hemorrhage. At the last examination, 4 months after implant removal, visual acuity returned to 20/70 aD, vitreous hemorrhage had cleared, and the retina remained completely reattached.

CASE 3.-A 66-year-old woman was first seen in July 1979 for a recmrent retinal detachment in the left eye despite two previous scleral buckling procedm'es performed elsewhere. A buckle revision was done in which a simple encircling band was replaced with a 360° 279 intrascleral implant. Further indentation at the site of the break was achieved by placing two MAl implants circmnferentially side by side under the solid silicone implant from the 5:30 to 7:30 positions. The immediate postoperative com'se was smooth, with a best corrected visual acuity of 20/70 as and a prominent buckle.

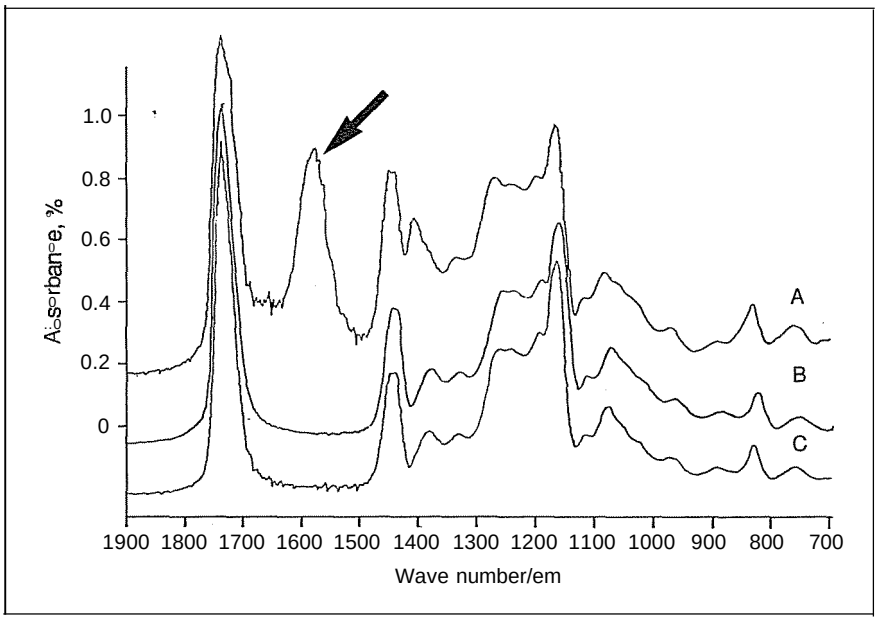
The patient was unavailable for follow-up for 10 years and returned because of an eroding buckle. On examination, visual acuity was counting fingers. Indirect ophthalmoscopy revealed a prominent inferior subretinal implant obscming the disc as well as a superiorly eroding buckle. The eroding inferior subretinal implants were removed and the buckle was revised. The implants were greatly swollen, gel-like, and friable. A segment (measming 14.5 x 12.4 x 7.0 rom, about two to three times the width and thickness of the Oliginal implant) was removed after dissection, but the rest of the implant was removed in pieces because it c111mbled easily. A large segment was submitted for laboratory analysis. Since dehiscence of the scleral bed was noted, the solid silicone rubber implant was left in place. After sm'gery, a massive vitreous hemorrhage obscmed fundus view. IDtrasonography revealed an attached retina. The patient refused further sm'gery. Fomteen months after implant removal, visual acuity was hand motions. Repeated ultrasonography reconfirmed the presence of a reat-. tached retina and a persistently dense vitreous hemorrhage.

CASE 4.-A 66-year-old man underwent a

Data on Seven Patients With Long-term Complications After the Intrascleral Implantation of the MAI Implant With Diathermy Treatment of the Scleral Bed

Patient No.1 Age,yl Sex	Eye	Procedure	Indication	Implant Use	Interval for Appearance of Signs and Symptoms, y
1/18/M	Left	Primary	Traumatic dialysis in the young	Primary implant without band	7.0
2/70/M	Right	Primary	Giant tear with fish mouthing	Meridional implant under 77G silicone rubber implant with 240 band	7.5
3/66/F	Left	Secondary	Persistent traction on the break	Meridional implant under 279 silicone rubber implant	10.5
4/66/M	Left	Primary	Persistent subretinal fluid	Meridional implant under 279 silicone rubber implant with 40 band	10.5
5/67/F	Left	Primary	Segmental implant for horseshoe tear	Meridional implant under 240 band	7.0
6/57/M'	Right	Secondary	Persistent traction	Meridional implant under 279 silicone rubber implant with 40 band	10.0
7/65/M'	Left	Primary	Tear with 'fish mouthing	Meridional implant under 279 silicone rubber implant with 40 band	8.5

'Implant was not removed.



Composite micro-Fourier transform infrared spectra of the recovered implant segment (A), MIRAgel stock sample (B), and MAl stock sample (C). Note the extra peak (arrow) at the 1570/cm wave number in graph A corresponding to the carboxylic group.

scleral buckling procedure in April 1979 for rhegmatogenous retinal detachment. During surgery, subretinal fluid ch'ainage was complicated by retinal perforation and vitreoretinal incarceration. To augment indentation, two MAl implants were placed side by side in a meridional fashion under the 279 solid silicone implant from the 9:30 to 11:30 positions. The postoperative course was uneventful, and the patient was unavailable for follow-up.

Ten years later, the patient returned with a vitreous hemorrhage secondary to implant erosion. Two months later, after partial clearance of the hemorrhage, he underwent a buckle revision for recm'rent retinal detachment. Removal of the implant was incomplete because the friable implant broke into pieces. Subretinal and vitreous fluid ch'ained spontaneously. Choroidal detachment and proliferative vitreoretinopathy (class D3) developed after surgery.

Three months later, the patient underwent a closed vitrectomy with membrane peeling. During surgery, the remaining implant passed into the vitreous cavity through a large retinal break and was subsequently removed via the pars plana. At the end of the procedure, silicone oil was injected intravitreously to restore the ocular volume and maintain retinal tamponade. After smgery, a pupillary membrane developed and vitreoretinal disorganization ensued, leading to globe atrophy despite a third surgical intervention. Nine months after implant removal, the eye was comfortable but had no light perception.

Additional Cases

We observed three additional cases from the 82 initial intrascleral :MAI implantations performed from 1979 to 1982. One of the three patients (patient 5, Table) had a meridional intrascleral implant underneath a 240 encircling band. Because the implant showed an increased bulge 10 years after sm'gery, the encircling band was cut to release pressme on the implant. Despite this procedure, vitreous hemorrhage and migration of the implant into the vitreous cavity occurred 1 year later. Removal of the implant from the vitreous was complicated by a retinal detachment and proliferative vitreoretinopathy. Despite vitrectomy to remove traction, endolaser therapy to close all retinal breaks, and perfluorocarbon gas tamponade, the retina remained detached. Two months after surgery, the eye had questionable light perception and was atrophic.

In two of the three cases (patients 6 and 7, Table), the presence of normal visual acuity in the fellow eye and poor visual acuity (light perception) as well as a lack of potential improvement in the complicated eye did not warrant the risk of additional sm'gery.

ANCILLARY LABORATORY.' INVESTIGATIONS

The equilibrium hych'ation of the recovered implants from patients 2 and 3 was determined. In the first specimen (patient 2, Table), hych'ation was measm'ed at 62% but increased to 94% when the specimen was allowed to swell freely in distilled water. The other specimen (patient 3, Table) equilibrated at 85% hydration in distilled water.

To determine the chemical composition of the implants and detect any alterations, micro-Fomier transform infrared spectroscopy (PhotoMetrics Inc, Wobmn, Mass)3 was performed on the implant segments recovered from patients 2 and 3, and the results were compared with those from stock MIRAgel (MIRA, Waltham, Mass) and MAl implant samples, The analysis involved using an infrared (IR) detector to

yield an 1R spectrum dependent on the atomic composition, structure, and thickness of a given sample. With this technique, the MAl implant was found to be compositionally equivalent to MIRAgel with the poly(methyl acrylate-co-2-hydro),:yethyl acrylate) as the basic building block.

The Figure shows a composite tracing of the micro-Fomier transform 1R spectrographic recordings among the retention stock samples of MIRAgel and MAl hydrogel and a recovered implant segment (patient 3). The extra peak at the 1570/cm wave number indicated the presence of carboxylic groups in the recovered implant segment. The recordings indicated hydrolytic degradation of the implant.

COMMENT

In a review of the MAl implant by Ho et al,[4] several features of the implant as a buckling material were emphasized: (1) it was as effective in buckling as solid silicone rubber and silicone sponge; (2) the degree of swelling could be varied by altering the state of hydration; (3) its softness and elasticity were thought to guard against erosion; (4) it was assumed to be less prone to infection because it lacked dead spaces and could absorb and gradually release antibiotics; and (5) it stimulated the production of a surrounding fibrous capsule that strengthened the sclera and presumably ensured the ease and safety of subsequent operations. Because of animal experimentationS and clinical results[6] in 82 eyes of 79 patients who were followed up for 6 to 53 months after surgery, the implant was believed to be a safe, well-tolerated material.[6,7] The dependence of the implant's swelling property and hardness on hydration was viewed as an advantage for custom:iz:ing buckle indentation with minimal risk of scleral erosion.

Seven clinical cases with long-term complications related to the swelling properties of the intrascleral MAl implant were presented herein. Problems ranged from a visible, benign, subconjunctival bulge to intraocular erosion and migration of the implant. The MAr implant was used in patient 1 as a primary buckle without a band, in patient 5 with a band, and in patients 2, 3, 4, 6, and 7 as meridional buckles under solid silicone rubber implants. In seven (8.5%) of 82 cases in which MAl was used intrasclerally, problems surfaced 7 to 11 years after surgery.

Micro-Fourier transform IR spectroscopy (Figure) confirmed the occurrence of chemical changes within the polymer. The presence of carboxylic groups implies ester hydrolysis, which may have led to structural instability. The ionized carboxylic groups result in a hydrogel that absorbs more water than the original polymer. The implant swelled and changed from opaque, soft, spongy, whitish, and compact to translucent, gel-like, cream-colored, and friable. Eventually, the swollen implant protruded and eroded through the diseased or scarred scleral bed into the vitreous cavity. Retrieval of the swollen implant from the vitreous cavity was a serious problem because the implant was large and difficult to grasp. Further, the external sclerotomy had to be extended one to two quadrants to allow external passage of a large implant. An enlarged sclerotomy in a marginally healthy eye may compromise the ciliary body and contribute to globe atrophy. Leaving the implant in the vitreous may be a reasonable option in some of these cases.

Chemical changes in the polymer were confirmed spectrographically in the two intact clinical specimens, even though the segment recovered from patient 2 was neither as swollen nor as physically altered as that from patient 3. We hypothesize that the surrounding fibrous capsule may have played a role in this physical difference. When intact, the capsule may delimit expansion and insulate the implant from body fluids[5]; hence, hydration and swelling would be limited. A physical or functional breakdown in this barrier function may allow further hydration and swelling of the implant, as we noted in an in vitro experiment. We placed the implant from patient 2 in distilled water and allowed the implant to swell freely. It equilibrated at a higher level of hydration (94%) than it did at its immediate postsurgical state (62%) and appeared physically similar to the implant from patient 3. It must be stressed with the hydrolytic degradation process may occur even without physically evident alterations in the implant.

Implant erosion is not unique to the hydrogel implant. This complication reportedly has characterized all implants used to date.[8] It was first noted in the 1950s with polyethylene tubing. This material was noted to harden in the tissues, and its erosion was precipitated by elevation of intraocular pressure. Donor sclera, sutures, and gelatin[9] have also been reported as being capable of causing erosion of the sclera. The shift to silicone materials presumably reduced the risk of erosion but did not eliminate it. For this reason, a lifetime, yearly follow-up was recommended after silicone rubber implants were used.[10] Acute[11] or chronic[8] erosion is sometimes observed under episcleral silicone sponges held in place by scleral sutures. Because of the physical properties of the MAl implants,[4] it was thought to be a better buckling element. Initial reports[4-7] attested to its effectiveness and safety. However, due to some alterations in its chemical composition and eventual swelling, we report the first cases, to our knowledge, of late erosion by the implant.

The MAl implant is the precursor of the present-day MIRAgel; they have the same chemical composition. Hence, potential problems related to swelling of the implant exist and warrant diligent, periodic follow-up of patients for a long time after surgery. However, to our knowledge, similar complications in patients who receive an episcleral implant have not been reported. We have used MIRAgel as an episcleral implant in a large number of patients since 1986 and have not observed such complications.

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The Eye Research Institute (ERn has been assigned US patent No. 4452776 (June 5, 1984) for the hydrogel implant and method. Dr Refojo, as the inventor, receives a portion of the royalties paid by MIRA Inc to 'ERr. None of the other authors has any commercial or proprietary interest in MIRA Inc, the MAI implant, MIRAgel, or Photometries Inc.

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