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# The Removal of Hydrogel Explants

## An Analysis of 467 Consecutive Cases

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***Purpose:*** To describe the complications associated with hydrogel explants and to describe the indications, surgical technique, and risks involved in the removal of a hydrogel explant.

***Design:*** Single-center, retrospective interventional case series.

***Participants:*** Patients who underwent surgical removal of a symptomatic, swollen hydrogel explant.

***Methods:*** We reviewed the medical records of 457 consecutive patients (467 eyes in total) who underwent surgical removal of a symptomatic, swollen episcleral MIRAgel (MIRA Inc., Waltham, MA) explant at the Radboud University Medical Center from 1998 to 2011. We reviewed the initial symptoms, clinical findings, surgical aspects, and intraoperative and postoperative complications.

***Main Outcome Measures:*** Presenting symptoms, retinal redetachment rate, and intraoperative scleral perforation.

***Results:*** The median interval between initial placement of the hydrogel explant and removal of the explant was 159 months. More than 34% of the episcleral hydrogel explants developed symptomatic swelling and required surgical removal. Intraoperative scleral perforation or retinal redetachment related to the removal of the explant occurred in 11% of patients.

***Conclusions:*** The percentage of explants that ultimately develop symptomatic swelling is considerably higher than reported previously. A swollen hydrogel explant can be removed many years after the primary detachment surgery, and 11% of cases develop intraoperative scleral perforation or retinal redetachment. *Ophthalmology 2016;123:32-38 © 2016 by the American Academy of Ophthalmology.*

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In 1985, an episcleral hydrogel explant (MIRAgel, MIRA Inc., Waltham, MA) was introduced as an alternative to silicone explants for the treatment of rhegmatogenous retinal detachment.[1] The original explant (in its original shape and dimensions) is shown in Figure 1. This episcleral buckle originally seemed promising for 2 main reasons. First, the material's soft, pliable characteristics have the potential to minimize scleral erosion. Second, the explant can absorb and then release antibiotics, thereby helping to prevent postoperative infection. Despite these potential advantages, after several years a serious flaw was discovered in the material. Specifically, hydrolytic degradation of the MIRAgel material causes progressive swelling of the explant, which can lead to strabismus, ptosis, scleral erosion, conjunctivitis, and infection around the buckle; in addition, significant cosmetic problems also can arise.[2–8]

When symptomatic swelling occurs, surgical removal of the buckle is usually the only feasible option available. However, removal of the buckle also carries risks, including vision-threatening complications such as retinal redetachment and intraoperative scleral rupture. Irrespective of the material used in the explant, the prevalence of retinal redetachment after removal of the scleral buckle varies widely; several authors have addressed this issue, and the reported overall prevalence of redetachment ranges from 0% to as high as 34%.[9–14] With respect to the removal of a MIRAgel buckle, the retinal redetachment rate has a similarly wide range, reaching as high as 29%.[8,9,15,16] Scleral erosion—and the subsequent intrusion of the scleral buckle—is another vision-threatening complication, with reported rates of intraoperative scleral perforation reaching 8% for silicone buckles and ranging from 0% to 18% for MIRAgel explants.[8,9,12,15,17–19]

Despite the important clinical information provided by these studies of MIRAgel explants, all of these studies were based on relatively small patient series; indeed, the largest series reported included only 38 removed MIRAgel explants, which limits the ability to perform adequate risk analyses.[12] Another aspect that is highly important, yet is addressed only briefly in the literature, is the percentage of MIRAgel explants that eventually develop symptomatic swelling, with only one study reporting a prevalence of 7.6% at the 7-year mark.[16]

We examined 467 consecutive patients in whom a symptomatic MIRAgel explant was removed. This large cohort, which spans a 13-year period, provides important insight into the percentage of MIRAgel explants that ultimately cause serious complications and provides a highly accurate risk analysis regarding the prevalence of intraoperative scleral perforation, retinal redetachment, and other vision-threatening complications associated with the removal of these explants.



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**Figure 1.** An original-size hydrogel (MIRAgel, MIRA Inc., Waltham, MA) explant packaged in isotonic saline.

## Methods

We reviewed the medical records of all consecutive patients who underwent surgical removal of a symptomatic, swollen episcleral MIRAgel explant at the Radboud University Medical Center in Nijmegen, The Netherlands, from January 1, 1998, to December 31, 2011. Only patients who had a MIRAgel explant that caused severe symptoms were considered for removal. We excluded all cases of silicone explant removal unless it was combined with the removal of a MIRAgel explant in the same session. Before the removal surgery, each patient underwent a complete ophthalmological evaluation, including initial best-corrected visual acuity (Snellen), slit-lamp biomicroscopy, indirect ophthalmoscopy, and Goldmann applanation tonometry. Additional clinical data were also obtained from the medical records and included gender, age, laterality of the involved eye, initial refractive error, presenting symptoms, time interval between implantation and removal of the MIRAgel explant, presence of a silicone encircling band, number of retinal detachment procedures, orientation of the buckle(s), number of clock hours involved, removal technique, occurrence of scleral perforation, other surgical complications, completeness of removal, scleral thinning, final status of the retina, and follow-up duration. The presenting symptoms were classified as cosmetic problems, pain/discomfort, eye motility disorders or diplopia, extrusion or exposure of the buckle, active ocular infection, and other symptoms.

This study was performed in accordance with the tenets of the Declaration of Helsinki. In addition, the Ethics Committee of the Radboud University Medical Center ruled that approval was not required for this retrospective study.

Before surgical removal of the explant, the retina was evaluated, and additional laser was used when scarring in the area of retinal tears was deemed insufficient. To surgically remove the swollen material, the overlying conjunctiva was opened, as was the fibrous tissue encapsulation surrounding the explant (in both the radial and circumferential directions) to maximize the visibility of the explant. If a silicone encircling band was present, it was cut and the sutures were meticulously removed before the swollen and brittle MIRAgel explant was removed from under the conjunctiva. Cryo-assisted extraction was used in some cases, usually when the explant was oriented radially.

Statistical analyses were performed using SPSS (SPSS Inc., Chicago, IL). Specifically, a multivariate logistic regression model was used to analyze the association between all investigated variables and the risk of scleral perforation or retinal redetachment.

To analyze the risk of scleral perforation, we excluded phthisis bulbi and cases with prior enucleation/evisceration. To analyze the risk of retinal redetachment after MIRAgel removal, we excluded eyes that had visual acuity worse than hand movements at 1 m (1/60) at the time of presentation, because these patients might not have noticed postoperative retinal redetachment.

## Results

During the study period, we removed MIRAgel explants from 467 eyes in 457 patients. These MIRAgel explants were originally implanted in patients from 1986 to 1997; 461 were implanted in patients at the Radboud University Medical Center, and 6 were implanted in patients elsewhere. In all cases, the explant was sutured to the sclera using nonabsorbable braided Mersilene 6-0 (Ethicon Inc, Somerville, NJ). Scleral dissection was not performed in any of the 467 cases. Refractive error before MIRAgel placement could be determined accurately from the records of 270 of the 467 eyes; 28% (i.e., 75) of these eyes had high myopia (defined as >6 diopters). The mean age of the study participants at the time of MIRAgel removal was 62 years (range, 17–99 years); 272 participants were male, and 185 were female. The median interval between the initial implantation surgery and the buckle removal was 159 months (range, 54–284 months; standard deviation, 37.5 months). The number of cases in each calendar year is summarized in Figure 2, and the distribution of the interval between implantation and removal is shown in Figure 3. The patients presented with a variety of symptoms that necessitated removal of the explant; however, the majority of patients (70%) presented with pain or discomfort. The indications for surgical removal are summarized in Table 1. Figure 4 shows a patient who developed ptosis and conjunctival erosion.

Segmental scleral buckles were present in 276 cases (59%), radial buckles were present in 129 cases (28%), and a combination of segmental and radial MIRAgel buckles were present in 51 cases (11%); in the remaining 11 cases (2%), the information regarding the initial orientation was incomplete. Eighteen of the 467 cases (4%) had both a MIRAgel buckle and a silicone buckle; these 2 buckles were usually implanted in separate sessions.

The median number of clock hours treated with the MIRAgel explant was 3 (range, 1–12). In 421 cases (91%), the MIRAgel buckle was placed under a silicone encircling band. In 44 cases (9%), no encircling band was used; in 29 of these 44 cases, oral dialysis was the reason for surgery. In 2 cases, full information regarding the encircling band was not available.