28 Akte vermeerdering eis, akte overlegging producties Sassen 05-09-2016
producties 2
1 Artikel Crama en Klevering
2 Artikel Francesco Baino

balans
letselschade advocaten

Gerechtshof Arnhem – Leeuwarden, locatie Arnhem
Rolzitting : 5 september 2016
Rolnummer : 200.136.030.01

AKTE TOT VERMEERDERING VAN EIS

tevens

AKTE TOT OVERLEGGING VAN PRODUCTIES

inzake:

De heer **J. H. SASSEN** wonende te Nijmegen appellant Advocaat: mr. Z.J. Rittersma	tegen	*De stichting* **KATHOLIEKE UNIVERSITEIT NIJMEGEN (UMC ST RADBOUD)** Gevestigd te Nijmegen Geïntimeerde Advocaat: mr. H. Lebbing

Appellant Sassen vraagt in het principaal appel eerbiedig akte,

I. Inleiding

1. Tijdens het pleidooi zal door Sassen uitvoerig worden ingegaan op de consequenties die verbonden moeten worden aan de nieuwe feiten die hem over de wetenschap van prof. Keunen met betrekking tot het toegepast zijn van de Miragelplombe enerzijds, het beleid van het NOG anderzijds en het behandelprogramma voor patiënten met een Miragel plombe in het Radboud in de afgelopen periode bekend zijn geworden.

   Op grond van deze nieuwe feiten werpt Sassen een nieuwe grief op en vermeerdert hij zijn eis als volgt:

II. Vermeerdering eis / nieuwe grief

2. In de onderhavige procedure heeft het Radboud ziekenhuis in twee instanties de onjuiste voorstelling van zaken gegeven dat prof. Keunen in de periode april 2005 tot en met september 2006 heeft geweten dat hij Sassen behandelde vanwege een zwellende Miragel plombe en hij met het oog daarop een expectatief beleid heeft gevoerd vanwege de aan de operatieve verwijdering van de plombe verbonden grote risico's zoals door het NOG was geadviseerd.
3. In werkelijkheid – naar blijkt uit diens de bij memorie van antwoord in het principaal appel als productie 2 overgelegde getuigenverklaring – heeft prof. Keunen niet geweten dat bij Sassen een Miragel plombe was toegepast, omdat die toepassing niet in Sassen's medisch dossier was vermeld

en hij deze plombe ook niet kon visualiseren.

4. Bovendien blijkt het NOG in werkelijkheid te hebben geadviseerd om bij het ontbreken van klachten een expectatief beleid te voeren en als symptomen optreden die gerelateerd zijn aan zwelling van de plombe, de gehele plombe te verwijderen in een gespecialiseerd centrum.

5. Tenslotte is begin 2016 aan het licht gekomen dat in een dergelijk gespecialiseerd centrum binnen het Radboud ziekenhuis in de jaren van 1998 tot 2011 bij 457 patiënten (467 ogen) na compleet oogheelkundig onderzoek symptomatisch gezwollen Miragel plombes operatief zijn verwijderd met slechts 4,4% recidief netvliesdefect. Sassen behoorde niet tot deze patiënten.

6. Het Radboud ziekenhuis blijkt aldus de voor de rechterlijke beslissing van belang zijnde feiten niet volledig en naar waarheid te hebben aangevoerd.

7. De 'medische misser' van prof. Keunen, te weten tekortschietend onderzoek, diagnose en behandeling, en de aanwezigheid van het 'gespecialiseerd centrum' binnen het Radboud hadden in twee instanties onderwerp van debat tussen partijen moeten zijn en zouden dan ook aan de deskundige voor onderzoek en beoordeling zijn voorgelegd.

8. Daarom is de rechtbank Arnhem in de tussenvonnissen van 7 oktober 2009, 3 maart 2010, 28 juli 2010 en 27 oktober 2010 en het eindvonnis van 30 november 2012 uitgegaan van een onjuist en onvolledig feitencomplex. Dit is van bijzonder grote invloed is geweest op de vonnissen van 3 maart 2010 en van 28 juli 2010 (dit betreft de vraagstelling aan en de benoeming van de deskundige) en het eindvonnis van 30 november 2012.

9. De vonnissen moeten daarom worden vernietigd.

10. In hoger beroep is reeds vernietiging verzocht van het tussenvonnis van 3 maart 2010 en het eindvonnis van 30 november 2012, zij het op andere gronden.

11. Deze nieuwe grief houdt dus zowel een verbreding van de grondslag van de eis in appel in, als een vermeerdering van eis. Dit is toelaatbaar op grond van HR 19-06-2009, ECLI:NL:HR:2009:BI8771, NJ 2010,154 (Westenbroek/van den Heuvel cs):

> 2.4.4
> Voorts kan in het algemeen het aanvoeren van een grief of een verandering of vermeerdering van eis na het tijdstip van de memorie van grieven of antwoord toelaatbaar zijn, indien daarmee aanpassing wordt beoogd aan eerst na dat tijdstip voorgevallen of gebleken feiten en omstandigheden en de nieuwe grief of de eisverandering of -vermeerdering ertoe strekt te voorkomen dat het geschil aan de hand van inmiddels achterhaalde of onjuist gebleken (juridische of feitelijke) gegevens zou moeten worden beslist, of dat — indien dan nog mogelijk — een nieuwe procedure zou moeten worden aangespannen om het geschil alsnog aan de hand van de juiste en volledige gegevens te kunnen doen beslissen. Onverkort blijft dan gelden dat toelating van de nieuwe grief of de eisverandering of -vermeerdering niet in strijd mag komen met de eisen van een goede procesorde.

12. Van strijd met een goede procesorde kan geen sprake zijn omdat het Radboud ziekenhuis de juiste feiten vanaf de aanvang van de procedure voor de rechter en voor Sassen heeft verzwegen.

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13. Deze nieuwe grief houdt dus een aanvulling op de reeds opgeworpen grieven in.

III. Overlegging producties

14. Verder worden hierbij de volgende stukken in het geding gebracht:

1. Crama en Klevering, "The Removal of Hydrogel Explants, An Analysis of 467 Consecutive Cases", American Academy of Ophthalmology, 2016.
2. Francesco Baino, 'Scleral buckling biomaterials and implants for retinal detachment surgery', 2010, abstract en p. 15-16, § 5,5 Hydrogels.

Waarvan akte !

-Advocaat-

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Productie 1

AMERICAN ACADEMY™ OF OPHTHALMOLOGY

The Removal of Hydrogel Explants

An Analysis of 467 Consecutive Cases

Niels Crama, MD, B. Jeroen Klevering, MD, PhD

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.*

See editorial on page 5.

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.

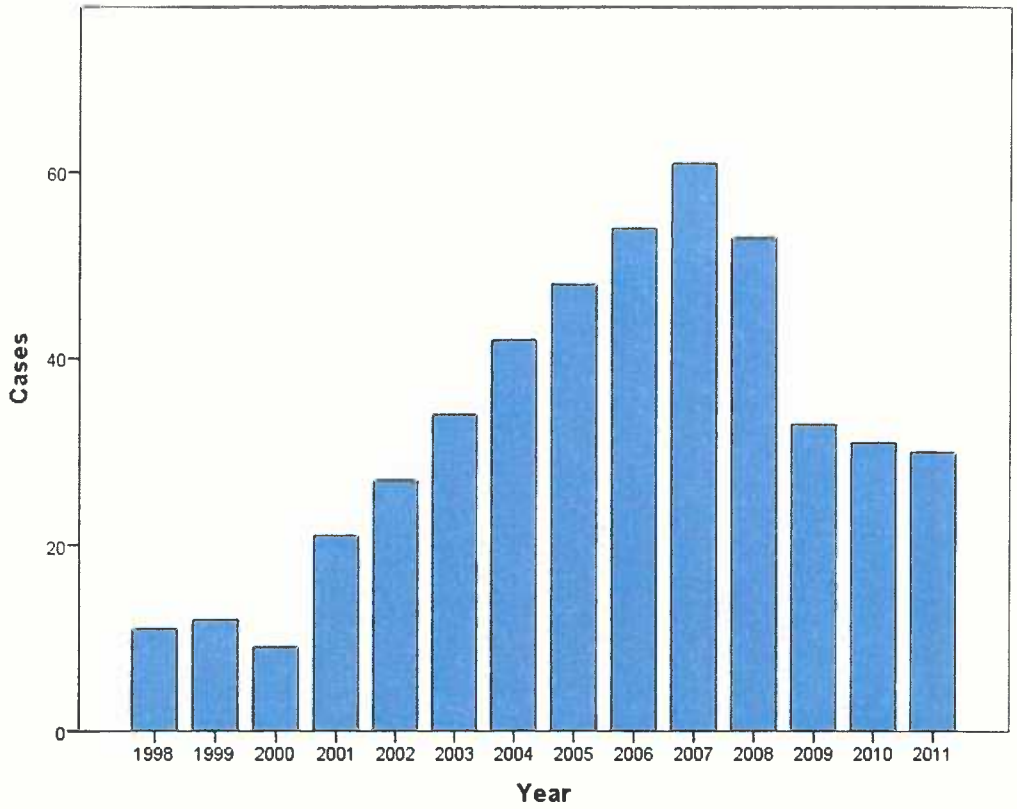

Figure 2. Number of MIRAgel explant removal surgeries performed at Radboud University Medical Center in the indicated years.

During surgery, cryocoagulation-assisted removal was used in 6% of cases (27/459). In 16% of cases (74/467), the MIRAgel was removed in several sessions because of incomplete initial removal of the explant; the initial removal was primarily performed years earlier or by surgeons who were not familiar with the brittle nature of degraded MIRAgel. Two examples of postremoval swollen hydrogel explants are shown in Figure 5. In 326 cases, the surgeon's operating time could be determined from the electronic data; on the basis of these data, the median surgery time was 21 minutes (range, 6–106 minutes).

After 4 cases with phthisis bulbi or previous enucleation/evisceration were excluded, intraoperative scleral perforation was calculated and found to be present in 30 of 463 eyes (6.5%); all 30 of these eyes had a silicone encircling band. Both the presence of an active ocular infection (odds ratio [OR], 2.8; 95% confidence interval, 1.3–6.0; $P = 0.008$) and a history of more than 1 preceding retinal detachment procedure (OR, 3.4; 95% confidence interval, 1.5–7.5; $P = 0.004$) were significantly associated with a higher risk of scleral perforation during the removal procedure. In most cases, we were unable to determine whether the perforation was full-thickness erosion (covered by the explant) or a perforation caused by manipulation over a partially eroded area during surgery. We found no significant correlation between the duration of time that the MIRAgel explant was in the eye and the risk of intraoperative scleral perforation ($P = 0.35$), even after we corrected for differences in duration in eyes that underwent multiple sessions of MIRAgel placement ($P = 0.27$) or multiple sessions of MIRAgel removal ($P = 0.49$). The risk of scleral perforation was not significantly correlated with the size of the explant in clock hours ($P = 0.28$), high myopia (defined as >6 diopters; $P = 0.29$), or radial versus segmental orientation ($P = 0.38$). Of the 30 eyes with scleral perforation, 10 subsequently developed a retinal redetachment; in these cases, the retina was reattached using pars plana vitrectomy, often with silicone oil tamponade, with varying degrees of success with respect to anatomy and visual acuity. Visual acuity was ≥20/40 (Snellen) in 5 of the 10 eyes before MIRAgel removal, and final visual acuity after retinal detachment surgery varied from 20/80 to light perception only. Of the 20 eyes that had scleral perforation but not retinal redetachment, only 3 eyes had visual acuity of ≥20/40 (Snellen) before MIRAgel removal; visual acuity was unchanged in 1 eye, whereas the other 2 eyes lost 1 and 4 Snellen lines.

The mean follow-up period after removal of the explant was 7 months (range, 1 day to 260 months). For their follow-up care, the patients were seen at Radboud University Medical Center or by the referring ophthalmologist. After we excluded 34 eyes that had visual acuity <1/60 at presentation, we found that 6.7% of the remaining eyes (29/433) had a retinal redetachment. This risk was reduced to 4.4% (19/433 eyes) after we excluded the 10 eyes that experienced intraoperative scleral perforation. After retinal redetachment surgery, 15 of these 19 eyes had a decline in visual acuity that was ≤2 Snellen lines. A multivariate regression analysis revealed that none of the factors studied was significantly associated with an increased risk of retinal detachment in the absence of scleral perforation.

Next, we evaluated the risk that receiving a MIRAgel explant can lead to serious complications that ultimately necessitate removal of the explant by determining the total number of MIRAgel explants that were implanted in patients at Radboud University Medical Center from 1986 to 1997. Although this

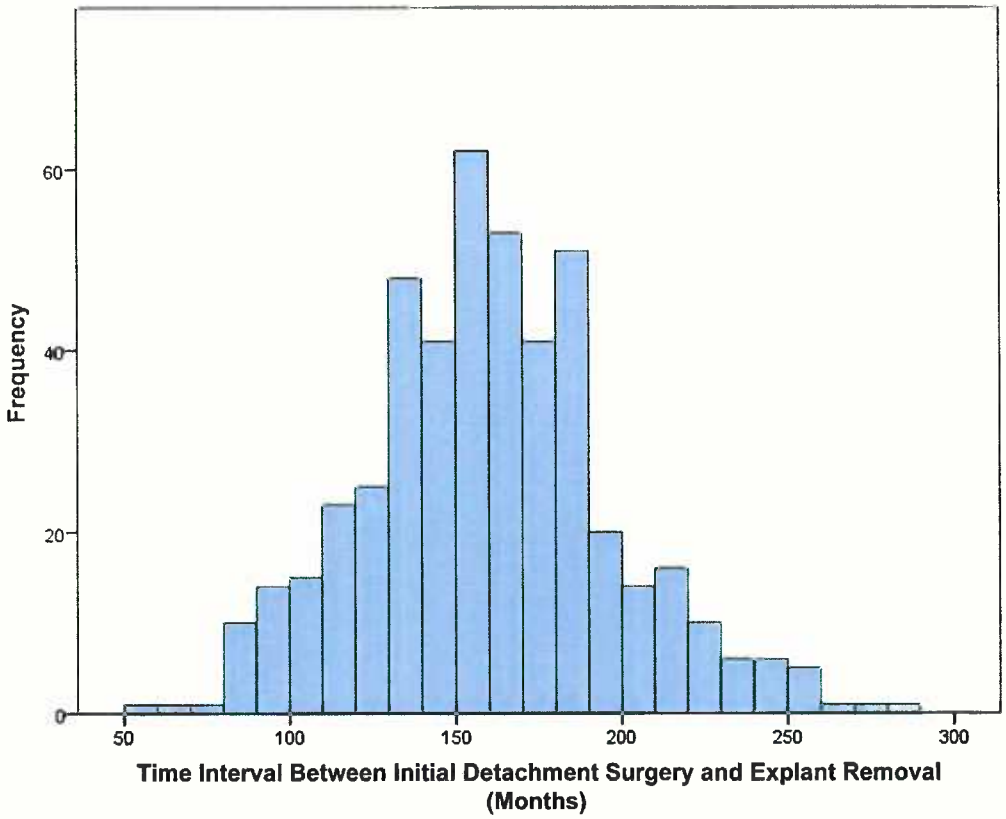

Figure 3. Time interval (in months) between the initial detachment surgery and the removal of the explant.

number could not be determined directly from the surgical data, we determined that a total of 1354 MIRAgel explants were delivered to Radboud University Medical Center from 1986 to 1997. By comparing this number with the number of explants we removed from our own patients (461), it can be concluded that 34% of MIRAgel explants (461/1354) eventually need to be removed because of symptomatic swelling, with an average post-implantation interval of approximately 13 years (159 months; range, 54–284 months).

Discussion

MIRAgel was developed initially as a softer, more pliable material that can slowly release antibiotics, thereby minimizing the scleral erosion and infection that can occur with solid silicone explants. However, after the introduction of MIRAgel in 1985, it took many years before practitioners became aware of the complications associated with hydrolytic degeneration, including progressive swelling of the explant. As early as 1992, Marin et al[2] reported swelling of intrascleral MAI implants, a precursor of the MIRAgel explant.[20] However, it took another 5 years before the first of several reports emerged regarding the symptomatic swelling of MIRAgel.[4–6] By that time, practitioners had been implanting MIRAgel explants for approximately 12 years. Of note, in 1995 the production facilities of the company that made MIRAgel (MIRA Inc) were closed by the Food and Drug Administration because of repeated violations of Good Manufacturing Practice regulations. However, this action was not specifically related to MAI or MIRAgel.[21] Moreover, a formal recall was never issued for MAI or MIRAgel products (personal communication with the Food and Drug Administration, December 10-13, 2010). Although the company closed in the United States, MIRAgel continued to be distributed outside of the United States after 1995, and some surgeons used this material until the year 2000.[16]

In our study, 34% of eyes implanted with MIRAgel developed symptomatic swelling that was serious enough to warrant removal of the explant after a median post-implantation period of 159 months. As highlighted in Figure 2, the cumulative percentage of MIRAgel explants that will need to be removed likely will be even higher in the future. This high percentage is in stark contrast to reported values, in which the explant was removed in

Table 1. Overview of the Most Frequent MIRAgel (MIRA Inc, Waltham, MA) Complications that Necessitated Surgical Removal of the Explant (Calculation Based on 462 Cases)

MIRAgel Complications	No. of Cases (%)
Pain/discomfort	322 (70%)
Cosmetic symptoms	229 (49%)
Eye motility disorders	179 (39%)
Diplopia	133 (29%)
Periocular infection	124 (27%)
Exposure/extrusion of explant	121 (26%)

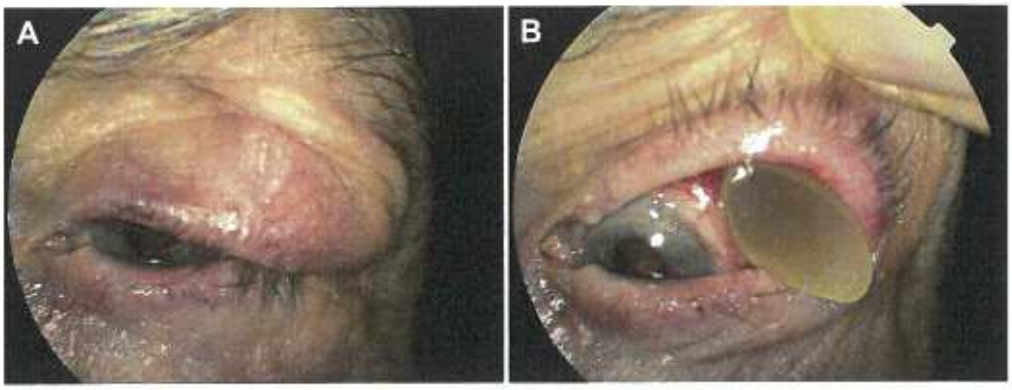

Figure 4. Approximately 20 years after undergoing retinal detachment surgery with a radial hydrogel explant, an 84-year-old man presented with ptosis **(A)**, conjunctival erosion, and conjunctivitis **(B)**.

7.6% of eyes that had a MIRAgel explant for up to 11 years.[16] This difference in removal rates primarily is due to the relatively long follow-up period in our study and clearly indicates that the MIRAgel material can cause severe complications even after an extremely prolonged symptom-free period. The distribution of explant orientation (segmental or radial) in our study group reflects our hospital's general practice of placing episcleral explants, which indicates that the amount of swelling does not seem to be influenced significantly by the orientation of the explant.

The symptoms that led to the surgical removal of MIRAgel explants in our series are consistent with previous reports. The most commonly reported symptoms were pain or discomfort (in 70% of cases), cosmetic problems (49%), eye motility disorders (39%), diplopia (29%), periocular infection (27%), and extrusion of the explant (26%).[8,12,16] Most patients experienced a combination of these symptoms.

It can be difficult to completely remove a swollen MIRAgel explant, because these explants can become friable as the result of degradation of the hydrogel material.[7] The average time needed to completely remove such explants (21 minutes) is longer than the time needed to extract a silicone explant; the additional time arises from the fact that a swollen hydrogel explant often comes apart when manipulated (e.g., pulled in an attempt to remove the explant). To adequately remove the entire explant, the overlying conjunctiva should be opened over the entire length of the explant. In addition, the capsule that has formed around the MIRAgel explant must be opened in both the radial and circumferential directions to maximize visibility and optimize mobilization of the explant. To minimize the risk of scleral tears, all sutures should be cut before removal of the explant. However, in our experience, nonabsorbable Mersilene sutures are found primarily in the surrounding capsule and are no longer attached to the sclera; presumably, gradual swelling of the explant causes the sutures to tear away from the sclera. If a silicone encircling band is present, it must be cut before the swollen explant can be manipulated gently from the sclera and removed from its capsule, thereby minimizing fragmentation of the explant and scleral pressure. The sclera should be inspected thoroughly, and in case of a perforation a patch of donor sclera can be used to restore the integrity of the eyeball. Several other techniques have been suggested to facilitate removal of a swollen explant, including extracting the explant using a cryoprobe and shrinking a swollen MIRAgel explant using boric acid.[3,22,23] In our experience, the cryoprobe technique is particularly useful for removing radially oriented explants.[24] In our patients, we refrained from using boric acid in light of the risk of inducing intraocular damage in cases in which the sclera is thin or has eroded.

In our study of 467 cases, the prevalence of intraoperative scleral perforation was 6.5%. We analyzed any possible risk factors that can be assessed preoperatively to adequately inform the patient and to help the surgeon prepare for this complication. Our analysis revealed 2 risk factors that were significantly associated with a higher

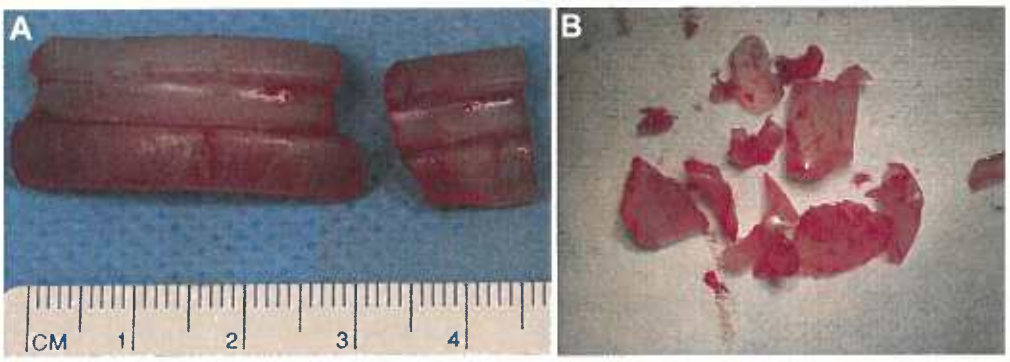

Figure 5. Two examples of postremoval swollen hydrogel explants. Note the increase in volume **(A)** and brittle nature **(B)** of the material.

risk for scleral perforation during removal: multiple (i.e., ≥2) previous retinal procedures (OR, 3.4) and the presence of an active periocular infection (OR, 2.8). Despite the increased risk of scleral perforation, in cases with an active periocular infection, prompt surgical removal is likely the best decision, because postponing surgical removal does not decrease the risk of intraoperative scleral perforation, and bacteria are extremely difficult to eradicate from an inflamed environment such as the MIRAgel material. Of note, neither high myopia nor longer duration of the MIRAgel explant increased the risk of intraoperative scleral perforation.

In our series, a silicone encircling band was present in all cases that experienced intraoperative scleral perforation; in contrast, previous studies reported that scleral perforation can occur both in cases with and without a silicone encircling band.[7,8,16,25] In principle, a silicone encircling band can cause increased scleral pressure when the underlying MIRAgel swells; however, we do not currently know whether—and to what extent—this increased pressure contributes to scleral erosion. Prophylactic removal in the absence of symptoms is generally not advised, particularly given that we found no significant correlation between the duration of the MIRAgel and the risk of scleral perforation. Removal of the explant in asymptomatic cases also is not advised in cases in which intrusion is already present; however, in the event of extensive intrusion, in which the explant erodes into the visual axis and blocks vision, the surgeon may consider removing the internal part of the explant through vitreous surgery using ultrasonic fragmentation.[3,26]

Redetachment of the retina is a serious complication that can arise after removal of the explant. In our case series, the rate of redetachment (excluding cases with scleral perforation) was 4.4%, which is considerably lower than in most previous studies, which reported rates as high as 34%.[9–16] The low prevalence in our series may be the result of meticulous preoperative evaluation and the use of an additional laser when scarring in the area of the retinal tears was deemed insufficient. In addition, the interval between explant placement and explant removal was relatively long in our series, in which the shortest interval was 54 months; this is important because the risk of redetachment is high when the explant is removed relatively soon after placement.[12,27] Our analysis of retinal redetachment revealed no significant correlation between the interval and the risk of postremoval retinal redetachment, suggesting that after an initial period of time, the likelihood of retinal redetachment does not decrease further. In addition, the relatively short follow-up period after removal of the MIRAgel explant in some cases may have led to an underestimation of the rate of retinal redetachment; however, this underestimation is likely to be small, given that our clinic is a regional tertiary referral center.

In conclusion, the percentage of MIRAgel explants that develop symptomatic swelling is considerably higher than previously reported, and this swelling can occur many years after the primary detachment surgery. Our large case series reveals that 11% of patients develop intraoperative scleral perforation or postoperative retinal redetachment associated with surgical removal of the explant. This relatively high rate of serious complications argues against the prophylactic removal of a swollen MIRAgel explant. With respect to symptomatic patients, our results provide a better preoperative analysis of the risks and benefits involved in removing an explant in a given patient.

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Abbreviations and Acronyms:
OR = odds ratio.

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BALANS LETSELSCHADE
ADVOCATEN

Productie 2

Scleral buckling biomaterials and implants for retinal detachment surgery

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Abstract

Scleral buckling is a widely used surgical procedure that aims at repairing retinal detachments. Many materials and procedural techniques have been variously proposed and tested in an attempt to find the best combination for providing optimal results to the patient. This review highlights the evolution of scleral buckling implants and chronicles the main advances that have been made in such a context. Specifically, the limitations of the materials and implants fallen in disuse, as well as the advantages of currently adopted devices are critically examined and discussed. Future directions for the research are considered, underlining in particular the great potential carried by the development of accurate mathematical models for describing the postoperative evolution of buckled eye. These analytical models, supported by a comprehensive data set provided by advanced techniques of medical investigations, may become useful tools for helping surgeons to choose, and to design if necessary, the best buckling material and configuration to be used in each specific clinical case.

Keywords: Retina; Scleral buckle; Biocompatibility; Eyeball deformation.

tolerated, thereby demonstrating a good biocompatibility, except for the study of Sheu et al. who reported complications associated to massive strong adhesion [81].

In the early 2000s, silicone bands coated with porous e-PTFE have been tested with quite opposite outcomes. Roldan-Pallares et al. [82] used e-PTFE-coated silicone buckles in 32 patients affected by RRD and reported an excellent material biocompatibility without complications throughout the whole follow-up period (11 months). On the contrary, Mortemousque et al. [83,84] reported massive adhesions between material and surrounding tissue accompanied by local inflammatory reaction; the porous e-PTFE layer was also colonized by inflammatory cells and granulomas with calcium deposits were observed.

5.5. Hydrogels

Since the early 1970s, three type of hydrogels, i.e. poly(glyceryl methacrylate) (PGMA), poly(2-hydroxyethyl acrylate) (PHEA) and poly[methyl methacrylate-*co*-(2-hydroxyethyl methacrylate)] (MAI), have been widely tested in scleral buckling procedures [10,85-91] and MAI has been commercially available under the name of Miragel for several years. Hydrogels, thanks to their softness, ease of shaping and defined swelling under hydration, have been considered for many years as the revolutionary materials in scleral buckling surgery. Some authors also emphasized the potential of hydrogels to act as devices for the *in situ* release of hydrophilic drugs, which could be an additional advantage over solid silicone implants in controlling infections [92]. After the initial enthusiasm, however, many surgeons realized progressively that hydrogel buckles could induce severe mid-term and long-term complications [93-99]. Specifically, PGMA was found to suffer from a lack of tensile strength when swollen and PHEA exhibited a dramatic tendency to fragment after swelling [95]. MAI implants, which could be placed both intrasclerally and episclerally, seemed to offer better bulk features and were found to promote the formation of a strong surrounding capsule of connective tissue [45,47,100,101]; although after 3 weeks from implantation

a mild inflammatory response was generally detected, after 3 months almost no inflammatory cells were found [88]. In spite of their excellent biocompatibility, however, in many cases MAI buckles need to be removed due to foreign body sensation, ocular motility limitations, subconjunctival bulge or pain complained by patients [96,97,99]. These drawbacks were essentially ascribable to hydrogel overexpansion: Oshitari et al. quantified this problem and reported that the cross-sectional area of MAI implant could increase up to 185% due to excessive swelling [97]. In addition, experimental studies carried out in both rabbits and humans demonstrated that MAI implant became surrounded by a capsule of connective tissue, but the inner surface of this capsule was irregular due to the presence of hydrogel debris and foreign body giant cells, which indicated material fragmentation [45,47,100,101]. Therefore, also MAI implants have been progressively fallen in disuse, particularly due to buckle degradation and friability occurring after about 10 years, as reported by several researchers [93,94,98].

5.6. Other non-absorbable buckling materials

Materials different from those described in the previous sections have been occasionally used for permanent buckles manufacturing (Table 1).

In 1937 a cotton gauze pad was used to temporarily indent the eye wall for approximating the retinal layer with the choroid: this is considered the first procedure of scleral buckling, but tissue reactions to the material were not studied [102].

In 1958 Arruga tested nylon braided threads, commercially known as Supramid®, as encircling elements to overcome the drawbacks related to PE tubes [103]. It should be underlined that these threads were not properly used as a "buckle" but rather for suturing the wall of the eye to create a "fold" which then created a buckling effect. Moderate inflammatory reaction was observed by both Arruga [103] and Witschel et al. [104] around the implant, but the material could cause erosion of the underlying sclera, thereby leading to intrusion to the choroid (the so-called "string-syndrome").