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De Mul Zegger

L9001753/NG

KOPIE

HEDEN de achtste juli
tweeduizendnegen, ten verzoeke van:

Mr. Jan Hendrik Sassen, wonende te Nijmegen, te dezer zake woonplaats kiezende te Malden, gemeente Heumen, aan de Promenade 2 (Postbus 48, 6580 AA) ten kantore van mr I.P.C. Sindram, die door mijn requirant tot advocaat wordt gesteld om als zodanig voor hem in na te melden geding zal optreden;

HEB IK: Juul Jeanne Bernadette van Putten, als toegevoegd kandidaat gerechtsdeurwaarder werkzaam ten kantore van Petrus Johannes Lambertus Gerardus van Krijl, als gerechtsdeurwaarder gevestigd te Nijmegen, kantoorhoudende en beiden mitsdien ten deze woonplaats hebbende te Nijmegen aan de Wijchenseweg 118;

GEDAGVAARD:

de stichting
Stichting Katholieke Universiteit (UMC St. Radboud), statutair gevestigd te Nijmegen, aan (6525HP) Comeniuslaan 4 aldaar aan dat adres mijn exploit doende, sprekende met en afschrift dezes latende aan: mevr. B. Maat, aldaar werkzaam;

OM:
op woensdag
negenentwintig juli tweeduizennegen (2009), des voormiddags te 10.00 uur niet in persoon doch vertegenwoordigd door een advocaat te verschijnen ter terechtzitting van de Rechtbank te Arnhem, alsdan aldaar gehouden wordende in het paleis van justitie aan de Walburgstraat 2-4 te Arnhem

MET DE UITDRUKKELIJKE VERMELDING:

dat indien gedaagde niet op de voorgenoemde wijze in het geding verschijnt en de voorgeschreven termijnen en formaliteiten in acht zijn genomen, de rechtbank tegen gedaagde verstek zal verlenen en de hierna te formuleren vordering zal toewijzen, tenzij deze hem onrechtmatig of ongegrond voorkomt

TENEINDE alsdan en aldaar namens mijn requirant als eiser te horen eis doen en concluderen

I. De feiten:

I.1.
Eiser is op 6 juli 1992 door prof. dr. A.F. Deutman, die als medisch oogspecialist destijds verbonden was aan het door gedaagde gedreven Academisch Ziekenhuis Nijmegen St. Radboud (verder: "het ziekenhuis"), geopereerd aan een netvliesscheur in zijn rechteroog.

I.2.
Deze operatie had visuele beperkingen, onder meer dubbelzien, tot blijvend gevolg. Na een periode van algehele arbeidsongeschiktheid na de operatie resteerde uiteindelijk een arbeidsongeschiktheid van eiser als advocaat van 50%.

I.3.
De operatie bestond o.m. uit het aanbrengen van een cerclagebandje om het oog en van een plombe ter afdichting van de netvliesscheur.

I.4.
Om wat voor soort plombe het ging, een silicone of een hydrogel plombe, is niet in het operatieverslag vermeld en ook niet aan eiser meegedeeld.
Sinds augustus 2006 weet eiser dat het hier een zgn. MIRAgel plombe betrof, die gebleken is in een aantal gevallen na een aantal jaren van chemische samenstelling te veranderen, te zwellen, te defragmenteren en zowel het oog uit als in te groeien, met alle gevolgen van dien in het geval dat een en ander niet tijdig wordt onderkend en behandeld door de medische behandelaar(s).

I.5.
Al in januari 1992 blijkt in de medische literatuur te zijn gewaarschuwd voor de hiervoor genoemde complicaties.
De plombe blijkt ook vanwege zijn gebreken al in 1995 uit de markt te zijn genomen.
In 1997 is in de medische literatuur het eerste concrete geval gemeld van complicaties als gevolg van de MIRAgel plombe.
Vervolgens zijn in de jaren 1999 t/m 2003 meerdere publicaties in de medische literatuur verschenen over deze complicaties. Steeds is aanbevolen om patiënten over lange termijn te volgen in verband met deze mogelijke complicaties. Aanbevolen is ook om de plombe bij eerste herkenning van de complicaties te verwijderen om erger te voorkomen, juist vanwege de gevolgen van de zwelling en de moeilijke verwijdering ingeval van zwelling en defragmentering.

I.6.
Eind 2002, begin 2003 kreeg eiser klachten aan zijn rechter oog, die hij medio augustus 2003 (per fax) aan prof. Deutman voorlegde met het verzoek hem te zien.
Eiser werd echter door prof. Deutman naar andere oogartsen doorverwezen, die op de klachten geen antwoord konden geven.
Op 13 november 2003 heeft prof.dr J.R.M. Cruysberg – naar wie eiser door prof. Deutman was doorverwezen – bij eiser een geringe uitstulping van de plombe geconstateerd en in eisers medisch

dossier aangetekend ("geringe prominentie explant") zonder enig ander ingrijpen dan het met water doorspuiten van een zijns inziens verstopt traanbuisje.
Pas toen eiser zich op 17 maart 2005 wegens acute klachten meldde bij de spoedarts van de afdeling oogheelkunde, werd hem door de arts meegedeeld dat de plombe doende was uit het oog te zwellen en dat hij daarvoor geopereerd diende te worden.
Prof.dr J.E.E. Keunen, de opvolger van prof. Deutman, besloot echter in dat stadium niet in te grijpen en de ontwikkelingen af te wachten.

I.7.
Eerst in augustus 2006, toen de plombe daadwerkelijk uit het oog kwam te steken en het materiaal direct tegen het ooglid aanschuurde, is operatief ingegrepen en is de helft van de plombe verwijderd kunnen worden.
Vier weken later veroorzaakte de andere helft, die ook naar binnen was gezwollen, een nieuw netvliesdefect, waaraan eiser acuut geopereerd is moeten worden.
Na de laatste operatieve behandeling eind mei 2007 is het gezichtsvermogen van eisers rechteroog nog maar 20% en is zijn dubbelzien toegenomen.
Zijn blijvende arbeidsongeschiktheid is 80-100%.

II. De grondslagen van de vordering.

Eiser stelt in de eerste plaats dat het ziekenhuis ex art. 6: 185 jo. art. 6:187 lid 3 BW aansprakelijk is voor de schade van eiser veroorzaakt door een gebrek in de bij eiser toegepaste plombe. Het ziekenhuis c.q. prof. Deutman heeft de plombe uit Amerika in Nederland ingevoerd en vervolgens bij eiser toegepast c.q. verstrekt in het kader van diens medische behandeling.

Eiser stelt in de tweede plaats dat de aan het ziekenhuis verbonden medische hulpverleners jegens eiser niet de zorg hebben betracht, die een redelijk bekwaam en redelijk handelend hulpverlener behoort te verlenen en voorts jegens eiser niet de informatieplicht, het toestemmingsvereiste en de dossierplicht hebben nageleefd, waaraan de medische hulpverlener zich behoort te houden.

a. Informatieplicht
De medisch hulpverlener behoort de patiënt op duidelijke wijze in te lichten over de voorgestelde behandeling en over de ontwikkelingen omtrent de behandeling (vgl. art. 7:448 lid 1 BW).
Bij het uitvoeren van deze informatieverplichting behoort de hulpverlener zich te laten leiden door hetgeen de patiënt redelijkerwijze dient te weten ten aanzien van de behandeling die hij noodzakelijk acht en van de uit te voeren verrichtingen (vgl. art. 7:448 lid 2 en sub a BW), de te verwachten gevolgen en risico's daarvan voor de gezondheid van de patiënt (vgl. art. 7:448 lid 2 en sub b BW), andere methoden van behandeling die in aanmerking komen (vgl. art. 7:448 lid 2 en sub c BW) en de staat van en de vooruitzichten met betrekking tot diens gezondheid voor wat betreft het terrein van de behandeling (vgl. art. 7:448 lid 2 en sub d BW).
Deze informatieverplichting was reeds voor 1995, toen de Wet Geneeskundige Behandeling Overeenkomst werd ingevoerd, in de rechtspraak ontwikkeld.

Het feit dat een behandelmethode nog niet algemeen wetenschappelijk is aanvaard, moet aan de patiënt worden meegedeeld (Sluiters/Biesaart, De geneeskundige behandelingsovereenkomst, 2e druk, blz. 24 sub 4.4 met verwijzing naar CMT 23 januari 1992, TvGR 1993/22).
Prof. Deutman heeft de MIRAgel plombe (als 'het nieuwste van het nieuwste', aldus de spoedarts tegenover eiser op 17 maart 2005) bij eiser toegepast zonder hem tevoren dienaangaande te informeren en met hem overleg te plegen, in het bijzonder is niet met hem overlegd of mogelijk een ander, minder risicovolle plombe zou kunnen worden toegepast – waartoe in de periode tussen de ziekenhuisopname op 2 juli 1992 en de operatie op 6 juli 1992 alle gelegenheid bestond.
Al een half jaar voordien was in de medische literatuur, een artikel van Marin ea van januari 1992, gewaarschuwd voor mogelijke risico's op lange termijn van de plombe, bestaande uit zwelling van de plombe naar binnen in het oog en naar buiten uit het oog, en is de aanbeveling gedaan om patiënten met het oog op die risico's te volgen.
Prof. Deutman heeft eiser niet geïnformeerd omtrent deze risico's op lange termijn van de plombe, ofschoon deze risico's direct van belang waren voor eisers gezondheid.
Eiser is ook na het bij hem aangebracht zijn van de plombe niet geïnformeerd over deze plombe en de mogelijk daaraan verbonden risico's en hij is ook niet gevolgd met het oog op eventuele verwezenlijking van deze risico's.
Ook niet nadat de plombe vanwege de risico's ervan in 1995 door de producent MIRA Inc. uit de handel genomen werd.
Evenmin toen in 1997 het eerste concrete geval van complicaties als gevolg van de plombe in de medische literatuur werd beschreven en werd gewezen op de noodzaak om mogelijke defragmentering en zwelling te voorkomen.
En ook niet toen in de medische literatuur steeds meer publicaties verschenen, waarin werd aanbevolen om patiënten op lange termijn te volgen en in te grijpen om erger te voorkomen.

b. Toestemmingsvereiste
Voor verrichtingen ter uitvoering van een behandelingsovereenkomst (anno 1992: overeenkomst van opdracht) is de toestemming van de patiënt vereist (vgl. art. 7:450 lid 1 BW).
De WGBO bracht voor wat betreft het toestemmingsvereiste geen wezenlijke verandering ten opzichte van de voorafgaande jurisprudentie.
Prof. Deutman heeft eiser niet om toestemming gevraagd voor toepassing van de MIRAgel plombe en eiser heeft mitsdien ook geen toestemming daarvoor verleend.
Eiser zou zeker niet met de toepassing bij hem van deze zo risicovolle plombe hebben ingestemd, tenzij geen enkel alternatief voorhanden was, hetgeen onaannemelijk is gelet op de beschikbaarheid van silicone plombes en hetgeen eiser ook bij gebreke van wetenschap moet betwisten.

c. Dossierplicht
De hulpverlener richt een dossier in met betrekking tot de behandeling van de patiënt. Hij houdt in het dossier aantekening van de gegevens omtrent de ten aanzien van de patiënt uitgevoerde verrichtingen, voor zover dit voor een goede hulpverlening aan hem noodzakelijk is. (vgl. art. 7:454 lid 1 BW). Dit artikel bevat in grote lijnen de codificatie van eerdere rechtspraak.
In eisers medisch dossier is niet aangetekend, noch in het operatieverslag van 6 juli 1992 noch anderszins, dat de toegepaste plombe een MIRAgel plombe was met de mogelijk daaraan op termijn verbonden risico's van zwelling en defragmentering.

Denkbaar zou zijn geweest een aantekening in de trant van: "Miragel plombe toegepast. Mogelijk risico's op lange termijn (zwelling en defragmentering). Zie Marin ea, Arch Ophthalmol 1992;110:86-8. Patiënt op lange termijn volgen als aanbevolen".
Het nalaten te voldoen aan de informatie- en dossierplicht heeft de herkenning van de verwezenlijking van de aan de plombe verbonden risico's bij eiser niet alleen voor eiser zelf onmogelijk gemaakt – zo constateerde hij zelf in 2003 een bultje op zijn oog en informeerde prof. Cruysberg daarover maar kon bij gebreke van adequate informatie in het geheel niet bevroeden wat gaande was – maar heeft ongetwijfeld ook de diagnose bemoeilijkt voor opvolgende medische behandelaren die niet vertrouwd waren met de MIRAgel-plombe en de daaraan verbonden problematiek – hiervoor blijkt in de medische literatuur ook te zijn gewaarschuwd –, met ernstige vertraging in herkenning en behandeling als gevolg.

d. De zorg van een goed hulpverlener
De hulpverlener moet bij zijn werkzaamheden de zorg van een goed hulpverlener in acht nemen en handelt daarbij in overeenstemming met de op hem rustende verantwoordelijkheid, voortvloeiende uit de voor hulpverleners geldende professionele standaard (art. 7:453 BW).
Deze norm, de zorg van de redelijk bekwame en redelijk handelende vakgenoot in de omstandigheden van het geval, gold ingevolge de jurisprudentie van de HR ook reeds in de periode van 1992 tot 1995, toen de WGBO werd ingevoerd.
Van het ziekenhuis, als academisch centrum, had mogen worden verwacht dat de aan haar afdeling oogheelkunde verbonden medische specialisten na de toepassing bij eiser – en andere patiënten – van de potentieel risicovolle plombe de verdere ontwikkelingen dienaangaande niet alleen bij de patiënt zelf maar ook in de medische literatuur nauwgezet zouden hebben gevolgd.
In een artikel van Oshitari ea van april 2003 is geconcludeerd dat de Miragel plombes gemakkelijk verwijderd kunnen worden vóór chemische verandering. Chirurgen dienden zich bewust te zijn van de complicaties en patiënten dienden regelmatig onderzocht te worden en gewaarschuwd voor mogelijke problemen. Ingeval van zwelling diende de plombe te worden verwijderd.
Zo ook concludeerden Kearney e.a. in een artikel van januari 2004 dat vroegtijdige herkenning ernstige complicaties van uitgestelde verwijdering kon voorkomen.
In 2007 bevestigden Roldan-Pallares ea in hun artikel dat dadelijke verwijdering ingeval van klachten in overweging dient te worden genomen ter vermijding van toenemende complicaties.
Eisers behandeling door de medische hulpverleners van afdeling oogheelkunde van het ziekenhuis verschilt geheel van deze aanbevelingen.
Toen in 2003 de aan de MIRAgel plombe verbonden risico's zich bij eiser begonnen te manifesteren in de vorm van een zwelling uit eisers geopereerde oog, is zulks niet eens door de toenmalige behandelaar prof. Cruysberg onderkend en herkend als signaal dat de MIRAgel plombe begonnen was te zwellen, ook al was een dergelijke zwelling bij herhaling in de medische literatuur beschreven. Wel is de zwelling op eisers oog opgemerkt en in het medisch dossier aangetekend (onderzoek prof. Cruysberg op 13 nov. 2003: "geringe prominentie explant") maar werd slechts een traanbuisje met water doorgespoten.
Niet is dadelijk en adequaat ingegrepen door middel van gehele of gedeeltelijke verwijdering van de plombe zoals bij herhaling in de medische literatuur is aanbevolen om verdere zwelling met defragmentering en toenemende moeilijkheidsgraad van operatieve verwijdering te voorkomen.

Indien prof. Cruysberg de problematiek wel heeft herkend, is diens behandeling niet die welke een redelijk bekwaam en redelijk handelend hulpverlener zou hebben betaamd. Bovendien heeft hij dan zijn informatieplicht jegens eiser niet nageleefd.
Toen in maart 2005 eindelijk bij eiser werd geconstateerd dat de MIRAgel plombe doende was het oog uit te zwellen, besloot de toenmalige behandelaar prof. Keunen niet in te grijpen maar een afwachtende houding in te nemen, in weerwil van de aanbevelingen in de medische literatuur om de plombe te verwijderen teneinde erger te voorkomen.
Besloten is pas tot verwijdering van de plombe op het moment dat dit wel moest gebeuren omdat de plombe daadwerkelijk uit het oog naar buiten kwam. Slechts de helft van de plombe kon nog verwijderd worden. Vier weken later veroorzaakte de andere helft een nieuw netvliesdefect.

e. algeheel tekortschieten in zorgplicht
Door na te laten eiser te informeren omtrent de mogelijke risico's van de MIRAgel plombe, door deze plombe bij hem toe te passen zonder zijn toestemming, door van deze toepassing geen melding te maken in eisers medisch dossier, door hem niet te volgen met het oog op mogelijke toekomstige aan de plombe verbonden complicaties, door het optreden van deze complicaties niet tijdig te diagnosticeren en door niet tijdig in te grijpen toen de diagnose werd gesteld dat de plombe doende was te zwellen, hebben de aan het ziekenhuis verbonden hulpverleners jegens eiser niet gehandeld als goed hulpverleners, mede gelet op de uit de medische literatuur blijkende professionele standaard.

III. Aansprakelijkstelling en verweer van het ziekenhuis

Het ziekenhuis is namens eiser aansprakelijk gesteld bij aangetekend schrijven van 3 september 2007.
Het ziekenhuis heeft – bij monde van zijn verzekeraar Achmea – de aansprakelijkheid bestreden.

Voor wat betreft de eerste aansprakelijkheidsgrond, de productenaansprakelijkheid, stelt Achmea, dat het ziekenhuis de MIRAgel plombe niet heeft ingevoerd in de EER met als doel het beroeps- of bedrijfsmatig verder te verhandelen, zodat zijn aansprakelijkheid niet dezelfde is als die van een producent.
Voorts beroept Achmea zich op de vervaltermijn van 10 jaar ex art. 6:191 lid 2 BW, omdat de bewuste MIRAgel plombe reeds meer dan 10 jaar geleden in het verkeer is gebracht.
Voor wat betreft de overige aansprakelijkheidsgronden beroept het ziekenhuis zich op een advies van Medas (Medisch adviseurs schaderegelingen), van wie mevr. C. Hutchison, arts, Register Geneeskundig Adviseur, eisers medisch dossier heeft beoordeeld en een literatuuronderzoek heeft uitgevoerd.
Volgens Medas is door de aan het ziekenhuis verbonden oogartsen gehandeld conform de standaard van de beroepsgroep en is er geen sprake geweest van onzorgvuldig handelen dan wel nalaten.
De stand van de wetenschap was in 1992 nog niet van dien aard dat men wist dat aan het gebruik van MIRAgel plombes grotere risico's waren verbonden dan aan het gebruik van andere plombes.
Wel was toen net een aantal patiënten beschreven met lange termijn complicaties, maar alleen als deze complicaties veelvuldig voorkomen, moet de patiënt hierover geïnformeerd worden.

Het gebruik van de hydrogel plombe is niet als verwijtbaar te bestempelen.
Ook is niet verwijtbaar dat eiser niet is geïnformeerd over mogelijke complicaties op lange termijn.
Pas in 1995 werd het product van de markt gehaald.
Verder is eiser regelmatig gecontroleerd en is er geen sprake van ondeugdelijke nazorg.
In 1994 is wel op een gegeven moment overwogen om de plombe te verwijderen maar hiervan is afgezien.
In november 2003 is n.a.v. eisers klachten een gering promineren van de plombe gezien.
In maart 2005 wordt een prominente plombe gezien die goed bedekt is.
Pas in juni 2006 zijn de hechtingen van de MIRAgel plombe naar buiten gekomen en in augustus 2006 is er sprake van een spontane protrusie van de plombe.
Op 20 augustus is de plombe partieel verwijderd.
Eisers klachten kunnen teruggevoerd op klachten die regulier voor kunnen komen na een operatie na een netvliesloslating waarbij altijd een cerclage en plombe worden gebruikt, aldus (kort samengevat) Medas, mevr. Hutchison.

IV. Nadere toelichting op de feiten

Ter ontzenuwing van het verweer van het ziekenhuis, wordt hierna de problematiek van de MIRAgel plombe geschetst aan de hand van enerzijds de in de medische literatuur verschenen publicaties en anderzijds de verschillende stadia van eisers medische behandeling.

IV.1. De MIRAgel plombe

De MIRAgel-plombe, die bij eiser is gebruikt om de netvliesscheur af te dichten, is vervaardigd door MIRA Inc., Massachussets, USA.
Deze plombe werd in de 80er en begin 90er jaren wijd en zijd gebruikt, doch is gebleken in een aantal gevallen na een jaar of tien van chemische samenstelling te veranderen, te zwellen (tot wel 4 x zo groot), te fragmenteren en uit te treden. Vanwege dit defect is het product in 1995 uit de handel genomen.
Al in juni 2001, ruim voordat eisers klachten in 2003 aanvingen, is deze MIRAgel problematiek kernachtig beschreven in een artikel van Lane e.a.(**prod. 4**) [1]:

> One of the objectives of retinal reattachment surgery is to relieve significant vitreous traction on the detached retina by indenting the sclera (buckling) to mechanically support the areas under traction. Silicone rubber bands are commonly placed circumferentially around the episcleral surface of the globe with grooved pieces of silicone rubber or sponge placed beneath the band, if necessary, to achieve a buckle of greater height.
> Episcleral bands composed of MAI, a hydrophilic polymer (copoly[methyl acrylate-2-hydroxyethyl acrylate]) cross-linked with ethylene diacrylate, were introduced in the early 1980s as a superior product

[1] Lane ea, Imaging of Hydrogel Episcleral Buckle Fragmentation as a Late Complication After Retina! Reattachment Surgery, AJNR Am J Neuroradio/ 2001;22:1199-1202.

to bands composed of solid silicone rubber or silicone sponges for producing scleral buckles (1, 2). The softness and elasticity of this hydrogel substance were thought to guard against the scleral erosions occasionally seen with solid silicone rubber. As with silicone sponge, this gelatinlike polymer had the ability to absorb antibiotics; however, unlike sponge, its inherent lack of dead space theoretically made it less prone to infection. Enthusiasm over its use began to wane in the early 1990s owing to the unanticipated instability of the product in vivo (3, 4). An increasing number of reports of swelling and fragmentation of this buckling material, producing orbital discomfort and diplopia 7 to 10 years after implantation, led to its discontinuation in 1995. We report the imaging features of this late complication in five patients treated for retinal detachment with scleral buckle procedures using MIRAgel (Mira, Waltham, MA) encircling bands.

IV.2. Medische literatuur januari 1992

Ten tijde van eisers operatie op 6 juli 1992 was uit de medische literatuur bekend dat bij de genoemde MAI plombe op lange termijn complicaties waren opgetreden, bestaande uit zwelling en defragmentering, en dat de MIRAgel plombe dezelfde chemische samenstelling bezat als de MAI plombe, zodat in de betrokken publicatie gewaarschuwd werd voor mogelijke dezelfde complicaties als bij de MAI plombe waren gesignaleerd, met de aanbeveling patiënten, bij wie de plombe was toegepast op lange termijn te volgen met het oog op die complicaties.

Marin e.a. hadden namelijk in een artikel van januari 1992.(**prod. 5**) [2] lange-termijn-complicaties beschreven van de "MAI hydrogel intrascleral buckling implant", die 7-11 jaar na de operatie optraden. Geadviseerd werd om periodieke lange termijn controles te houden bij patiënten die met de MAI implant waren geopereerd.
Direct al in het abstract van het artikel wordt gewaarschuwd m.b.t. de MIRAgel implant:

> Seven cases in which long-term complications developed from swelling of the MAI 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 composition as the MAI implant, may require similar precautions.

In het artikel zelf wordt de MAI implant beschreven:

> The MAI implant, also known as the Refojo implant, is a synthetic, hydrophilic scleral buckling material introduced in de late 1970s.[1-2] MAI is made of poly(methyl acrylate-co-2-hydroxyethyl acrylate) cross-linked with ethylene driacrylate with 15% water. The material is soft, elastic, and smooth and can be heat sterilized.

[2] Marin ea, Long term complications of the MAI hydrogel intrascleral buckling implant, Arch Ophthalmol 1992;110:86-8

The MAI 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 complication in seven patients treated at Retina Associates, Boston, Mass.
(...)

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.

Randy Hasslinger, director of Research and Development at MIRA Inc., Waltham, Mass. reageerde in hetzelfde nummer van Arch Ophthalmol- Voll110, January 1992, als volgt:

To the Editor .-We at MIRA Inc, Waltham, Mass, have had the opportunity to support the investigation of MAl hydrogel implants described in this issue of the ARCHIVES. We performed the micro-Fourier transform infrared spectroscopic analysis that compared the clinical specimen from case 3 with production lots of hydrogel implants of different ages.
The spectroscopic analysis revealed that the clinical specimen had a polymeric structure significantly different from that of the production lots, but this does not imply that the clinical specimen degr3997Xade vivo. The clinical specimen was synthesized from a laboratory batch process that predated the production lots. These laboratory batches were experimental and known to contain variable levels of components that would account for the differences described by the spectra. Polymers most resistant to degradation are prepared with careful control for extent of polymerization, level of impurities, and ratio of components. Furthermore, a hydrogel sample from the same laboratory batch was not available to serve as a control in the analysis. The original structure of the clinical specimen could not be confirmed.
To date, there have been no patients with MIRAgel implants who have developed the complications described in the report by Marin et al. MIRAgel continues to be manufactured according to goodmanufacturing practice guidelines for strict formulation and processing controls.
MIRA Inc concurs with the authors for lifetime annual follow-up of scleral buckling procedures regardless of tbe buckle material used.

Marin et al. reageerden in een naschrift als volgt:

> *In Reply.*-We concur with Mr Hasslinger that because we were unable to obtain unused MAI polymer implants of the same vintage as the polymer implants retrieved from the patients, we cannot be sure that the hydrolysis observed in the retrieved implants was not a phenomenon characteristic of these early MAl samples. The polymer implants retrieved from the patients were made before MIRA Inc obtained the license from the Eye Research Institute to make MIRAgel. However; MAl polymer made by the same procedure as the retrieved implants, and the currently available MIRAgel implants have the same chemical composition, as is demonstrated by the identical micro-Fourier transform infrared spectra. In fact, there are no data available to us to support Mr Hasslinger's remark that the early MAI "laboratory batches were experimental and known to contain variable levels of components that would account for the differences described by the spectra." Sterile MAI implants stored in saline solution in the laboratory for several years maintained their original hydration and chemical structure. The changes were only observed in retrieved intrascleral MAl implants.

Het artikel van Marin ea, de reactie van Hasslinger en het naschrift van Marin ea markeren de stand van de uit de medische literatuur bekende medische wetenschap ten tijde van eisers operatie op 6 juli 1992.
Hoewel MIRA Inc. de zorg om mogelijke lange termijn complicaties van de MIRAgel plombe trachtte te bezweren, waren zowel Marin ea als Hasslinger eenstemmig over de noodzaak om patienten te volgen met het oog op mogelijke complicaties.
Het volgen van patiënten brengt uiteraard ook mee hen te informeren omtrent de noodzaak van dit volgen.

De opvatting van het ziekenhuis c.q. Medas' opvatting dat het niet nodig is geweest om eiser omtrent de toepassing van de MIRAgel plombe en de mogelijke lange termijn risico's te informeren, kan reeds op grond van deze publicatie van Marin ea geen stand houden en wordt ook door de hierna nog te noemen publicaties in de medische literatuur ontkracht.

IV.3. Eisers behandeling van 1992 tot 2003

Eiser, geboren op 16 september 1944, is sinds 1970 advocaat en heeft zich gespecialiseerd in het belastingrecht. I.v.m. zijn bijziendheid was hij aanvankelijk onder behandeling van prof. Van den Heuvel, later van diens opvolger prof. dr. A.F. Deutman.

Op 30 juni 1992 heeft eiser telefonisch klachten, namelijk een soort belemmering in het rechter oog, voorgelegd aan de secretaresse van prof. Deutman, destijds verbonden aan het Academisch Ziekenhuis Nijmegen St. Radboud. Zij overlegde met prof. Deutman en een afspraak werd gemaakt voor 8 juli 1992. Aangezien op 2 juli 1992 de belemmering een soort halve maan was geworden, heeft eiser gevraagd om spoedcontrole. Die middag heeft Prof. Deutman eiser onderzocht en een netvliesscheur in eisers rechteroog geconstateerd. In eisers bijzijn kreeg de secretaresse een uitbrander omdat zij eiser niet direct had laten komen, hoewel zij aan prof. Deutman precies had verteld hetgeen eiser haar had verteld, zo zei zij later tegen eiser.

Op 6 juli 1992 heeft prof. Deutman eiser onder volledige narcose geopereerd.
De operatie bestond o.m. uit het aanbrengen van een cerclagebandje om het oog en het aanbrengen van een plombe ter afdichting van de scheur.
In het operatieverslag van 6 juli 1992 is niet vermeld wat voor soort plombe is aangebracht. Ook aan eiser is dienaangaande geen informatie verstrekt – hetgeen zijdens het ziekenhuis (Medas) ook wordt erkend.

Eiser werd op 8 juli 1992 uit het ziekenhuis ontslagen en verkeerde in de veronderstelling dat met zo'n twee maanden volledig herstel zou intreden. Nog vóór de operatie had prof. Deutman eiser gezegd dat hij een op 9 juli 1992 bepaald pleidooi zou kunnen houden – maar kennelijk was dat een grapje, want het pleidooi moest wel degelijk uitgesteld worden.

De operatie had instabiel dubbelzien tot gevolg. In rust stond eisers rechteroog op ca 30 graden en hij moest de hele dag moeite doen om de ogen bij elkaar te krijgen.
Zijn klachten heeft hij bij herhaling aan prof. Deutman voorgelegd, schriftelijk omdat de korte spreekuren van prof. Deutman daarvoor veel te weinig tijd bleken te bieden.
N.a.v. een fax van eiser van 11 januari 1993 schreef prof. Deutman hem bij brief van 12 januari 1993 o.m. het volgende:

> Uw klachten en beperkingen zijn mij geheel en al duidelijk. Een probleem is dat zij niet uitsluitend op oogheelkundig gebied liggen al is de oogsituatie wel het ontsporend moment geweest.
> Soms kan een cerclagebandje zoals u om uw rechteroog heeft een bepaalde hoofdpijn geven die veelal geleidelijk verdwijnt. In uw geval lijkt de pijn anders van karakter te zijn maar het kan toch zeker zo zijn dat geleidelijk aan de situatie verbetert. (...)
> Ik hoop dat de gehele situatie zich nog ten goede zal keren en wens u veel sterkte.

Enige tijd later bleek aan eiser dat prof. Deutman bij brief van 11 januari 1993 aan de medisch adviseur van De Amersfoortse o.m. het volgende had geschreven:

> Wat mij betreft bestaan er geen beperkingen en die zijn ook niet opgelegd. De prognose lijkt oogheelkundig goed. Patient zelf klaagt wel over hoofdpijn bij intensief werken en hij zou inmiddels een functie bij de rechterlijke macht prefereren boven de meer stress creërende advocatuur.
> Zuiver technisch is de toestand oogheelkundig bezien goed maar men ziet wel eens meer een geestelijke decompensatie optreden die moeilijk te beïnvloeden is.

De Amersfoortse beëindigde op grond van deze brief de arbeidsongeschiktheidsuitkeringen aan eiser.

Daarop door eiser aangesproken ter gelegenheid van een controle op 26 april 1993 gaf prof. Deutman wat onthutst te kennen dat zijn brief aan De Amersfoortse niet zo bedoeld was. Prof. Deutman herzag zijn standpunt en bevestigde bij brief van 17 mei 1993 alsnog eisers klachten aan De Amersfoortse, onder aantekening dat – anders dan hij op 11 januari 1993 in het algemeen had gesuggereerd - hij geen grond had bij eiser in enig opzicht het optreden van geestelijke decompensatie aan te nemen.

Bovendien ging prof. Deutman nu uitgebreid naar eisers ogen kijken met inschakeling van zijn collega dr. Cruysberg (afdeling orthoptie). Het dubbelzien had immers na 3 tot 6 maanden over moeten zijn.

Inmiddels was eiser door een bevriend medisch specialist in contact gebracht met dr. A.M. Verbeek, ook verbonden aan de afdeling oogheelkunde, die hem op 11 mei 1993 telefonisch nader informeerde als volgt:

> Eiser is hoog bijziend. Het netvlies is aan de periferie zwak en degeneratief. De kwaliteit van het oogvocht is ook niet zo best. Wat hem is overkomen, is niet echt goed te voorzien. Het oogvochtmembraam kan loslaten op voor het netvlies gunstige wijze, doch ook op ongunstige wijze. Dit laatste is bij eiser gebeurd. Om het oog is een bandje gezet in zijn geval met extra verbreding. In 90/95 procent van de gevallen is er na de operatie geen sprake van dubbelzien. Eiser zit net bij de andere 5/10 procent. Indien het dubbelzien zich voordoet, is het verstandig een paar weken af te wachten. Er kan zich een verkleving van de oogspieren voordoen. Bij eiser is veel te lang gewacht. Hij heeft inderdaad gigantische klachten. Het netvlies van het linker en het rechter oog zit thans vaster dan ooit. Eiser heeft storende glasvochttroebelingen, in het linkeroog rustiger dan in het rechter. De ogen zijn in disbalans. Zijn klachten zijn recht toe recht aan te herkennen. Gaat hij werken waarbij hij zich moet inspannen om goed te zien en veel moet lezen, dan ontstaat vermoeidheid en hoofdpijn. Ontspant hij zich, werkt hij bv. een weekend rustig in de tuin, dan treedt ontspanning op en verdwijnt de hoofdpijn. Eiser verkeert bij het zien tengevolge de inspanning door troebelingen en het na de operatie niet meer optimaal in evenwicht zijn van de oogspieren in een constante stress en dat levert inderdaad hoofdpijn op. Het trachten goed te blijven zien levert vermoeidheid op en dat heeft ook tot gevolg dat hij dan meer hinder gaat krijgen van de troebelingen. De
>
> hoofdpijn is daardoor verklaarbaar. Zijn drempel voor de troebelingen zakt. Door de disbalans ontstaat chronische stress.
> Verbeek weet dat eiser op 14 mei 1993 door de afdeling orthoptie wordt gezien. Die afdeling moet thans uitvoerig gaan kijken naar het dubbelzien. Zij moet met een concreet advies kunnen komen.
> Het kan zijn dat het dubbelzien ofwel moet worden opgevangen met een spiercorrectie, hetgeen een nieuwe oogoperatie betekent - waarvan eiser weer zo'n 3 maanden nodig heeft om van bij te komen - ofwel met een prisma in zijn bril.
> Indien de ogen weer in balans zijn, moet worden bezien hoe storend de troebelingen zijn. Kan eiser er mee leren leven ? Zijn de troebelingen te sterk, dan moet operatief worden ingegrepen.
> Een operatie levert altijd risico op - bv. ontstekingen - doch de kans op succes is uitermate groot.
> Voor het vervangen van de lens is Verbeek huiverig. Je krijgt dan een asymetrische ontwikkeling. Links blijft ongewijzigd en rechts zorgt de kunstlens nog slechts voor een kleine correctie. Van dat verschil wordt je stapelgek. Een kunstlens met grote correctie zou moeten worden gebruikt. Tezijnertijd weer te vervangen als het andere oog aan de kunstlens toe is. De ene ingreep na de andere.
> Van belang is dat orthoptie komt met concrete heldere voorstellen. Supervisor van die afdeling is dr.Cruijsberg.

Op 19 augustus 1993 is eiser uitgebreid gezien door dr. Cruysberg, die een nieuw brilrecept verstrekte, waarbij de prismatische werking van de glazen benut ging worden.

Na de brief van prof. Deutman van 17 mei 1993 hervatte De Amersfoortse de arbeidsongeschiktheidsuitkeringen aan eiser. Tevens schakelde de Amersfoortse prof. Bleeker van het Amsterdamse Prinsengracht Ziekenhuis in, die eiser op 22 november 1993 zeer uitgebreid – 2 uur lang – onderzocht. Diens onderzoek bevestigde eisers klachten. De oorzaak van het dubbelzien kon niet worden achterhaald.
De samenvatting en beschouwing van het rapport van prof. Bleeker luiden aldus:

Samenvatting en beschouwing.
Wat in de eerste plaats opvalt bij patiënt is het feit dat hij voor de netvliesloslating reeds moeilijkheden had met glasvochttroebelingen. De troebeling aan de linkerzijde dateert van 1982 na een val met de fiets en resulteerde in een tamelijk concreet klein vlekje, dat vaak zeer storend voor het midden van het beeld heen en weer zweefde. Dankzij het goede gezichtsvermogen aan de rechterzijde kon hij deze storing gemakkelijk overwinnen. April 1992 is in het rechteroog een zeer storende troebeling gekomen in de vorm van een meer vage vitrage, welke hem, tezamen met de vlek voor het linkeroog, het werk zeer heeft bemoeilijkt. Beide troebelingen zijn objectief zonder moeite waarneembaar, waarbij vooral aan de rechterzijde sprake is van een uitgebreide vlek. Kennelijk was deze glasvochtloslating aan de rechterzijde een voorloper van de zich later ontwikkelende netvliesloslating d.d. 2 juli 1992. Prof. Deutman vond een grote scheur en heeft hem meteen geopereerd. Deze operatie is in feite zeer fraai verlopen. De resulterende gezichtsscherpte is bepaald niet slecht. Er zijn geen grote scotomen ontstaan, doch wel bestaat er een aanzienlijke beperking van het gezichtsveld. Na de netvliesoperatie heeft patiënt ernstige bezwaren gehouden. Net als voorheen waren de zwevende troebelingen voor het beeld nog aanwezig, doch nu werd hij tevens geplaagd door een neiging tot dubbelzien. Bij nameten kan objectief gemakkelijk worden aangetoond dat de ogen een uitgesproken neiging tot dubbelzien hebben in alle blikrichtingen. Het minst nog bij kijken naar midden boven en het meest bij kijken in de onderste regionen. Er is sprake van een teveel aan convergentie (tot 30 graden toe) en bovendien een neiging tot hoogstand van het rechteroog. . Patiënt beschikt over een uitstekend fusievermogen om de beelden weer op elkaar te trekken. 's-Morgens vroeg wanneer hij nog fris is, lukt hem dat ook, doch na verloop van tijd geeft de fusie het op ten gevolge van de te hoge inspanning. Neemt hij dan een prismabril, dan gaat het weer een tijdje goed, doch tegen de avond knapt hij af met prismabril en al. Hij ziet dan dubbel en kan niet meer werken, televisiekijken of autorijden. De bevindingen van het onderzoek bevestigen objectief de klachten van patiënt en het baart zelfs enige verwondering dat zijn fusievermogen zo goed is ontwikkeld dat hij de motiliteitsstoornissen een tijdlang kan overbruggen.
De oorzaak van de vlekken in het gezichtsveld en van de gezichtsveldbeperking rechts is zonder moeite aantoonbaar. De oorzaak van deze motiliteitsstoornis is niet gemakkelijk te verklaren. Reeds werd vermeld dat het hier niet betreft een selectieve uitval van een bepaalde spier of spiergroepen. Verondersteld moet worden dat hier sprake is van een passieve bewegingsbeperking ten gevolge van de cerclageoperatie, danwel, van een beschadiging van de spierfuncties ten gevolge van de coagulatieprocedures, die hebben plaatsgevonden in de nabijheid van de inserties van oogspieren. Welke de juiste oorzaak is, valt niet te zeggen. Het feit is daar.

Functieverlies en invaliditeit.
(...)
Functieverlies van de gehele persoon 26%. uitsluitend op basis van verlies aan gezichtsvermogen, zonder rekening te houden met het beroep.
Gevraagd naar de arbeidsongeschiktheid van patiënt, dus wel rekening houdend met zijn beroepsomstandigheden als advocaat en procureur, is een arbeidsongeschiktheid ten bedrage van 50% volkomen reëel.

De medisch adviseur schreef vervolgens prof. Deutman dat het onderzoek van prof. Bleeker diens eerdere bevindingen, neergelegd in de brief van 17 mei 1993, bevestigde

Bij fax van 4 oktober 1994 schreef eiser aan prof. Deutman o.m. het volgende:

Na het rapport van Prof.Bleeker van 22 november 1993 moet de conclusie zijn dat Uw operatie van maandagochtend 6 juli 1992 maar gedeeltelijk geslaagd is.

In Uw brief van 11 januari 1993 aan de medisch adviseur van De Amersfoortse hebt U het anders doen voorkomen en laten doorschemeren dat mijn klachten mogelijk meer psychisch zouden zijn bepaald - zie de hierna volgende tweede bladzijde van de brief van de medisch adviseur aan Prof.Bleeker van 5 aug.1993, blz.2.

De conclusies van Prof.Bleeker zijn echter duidelijk:
"Resumerend (...) bestaat hier een foutieve functie van meerdere spieren, welke zich kenmerkt door een grote esoforie en een niet onbelangrijke hoogstand van het rechteroog." (blz.4 rapport),
"Bij nameten kan objectief gemakkelijk worden aangetoond dat de ogen een uitgesproken neiging tot dubbelzien hebben in alle blikrichtingen. Het minst nog bij het kijken naar midden boven en het meest bij kijken in de onderste regionen. Er is sprake van een teveel aan convergentie (tot 30 graden toe) en bovendien een neiging tot hoogstand van het rechteroog." (blz.6),
"De oorzaak van deze motiliteitsstoornis is niet gemakkelijk te verklaren. Reeds werd vermeld dat het hier niet betreft een selectieve uitval van een bepaalde spier of spiergroepen. Verondersteld moet worden dat hier sprake is van een passieve bewegingsbeperking ten gevolge van de cerclage-operatie, danwel, van een beschadiging van de spierfuncties ten gevolge van de coagulatieprocedures, die hebben plaatsgevonden in de nabijheid van de inserties van oogspieren. Welke de juiste oorzaak is, valt niet te zeggen." (blz.7).

Bij de controle van 24 maart j.l. zei U mij dat mogelijk de plombe (?) blokkeerde. Deze zou met slechts geringe kans op lekkage (2 á 3%) kunnen worden weggenomen.
Toen ik hem korte tijd later vroeg naar zijn mening dienaangaande, gaf dr Verbeek blijk van twijfels.

Ik word nog steeds bijzonder belemmerd door het dubbelzien.

6 Dezer kom ik weer op controle bij dr Cruysberg en U.

Ik moge U verzoeken om in overleg met dr Cruysberg en dr Verbeek vast te stellen wat precies mis is gegaan bij de operatie en wat gedaan kan worden tot ongedaanmaking van het dubbelzien met welke kans (percentage) op succes en welke risico's.

Daarop antwoordde prof Deutman eiser bij fax van 5 oktober 1994:

Er is niets mis gegaan bij uw operatie voor netvliesloslating. Postoperatief zien van dubbelbeelden is een vaker voorkomend gebeuren na succesvolle chirurgie. Als een operatie voor netvliesloslating "mis" gaat wordt een oog blind. Dit is in uw geval niet terzake.
De plombe moest gezien de localisatie van het retinadefect vlak naast een oogspier geplaatst worden en dit kan de oorzaak van de motiliteitsproblemen zijn. Het coaguleren met koude (cryocoagulatie) is hier vrijwel zeker niet de oorzaak van.

Op 6 oktober 1994 is eiser opnieuw door prof. Deutman en door dr. Cruysberg gezien. Een operatie werd ontraden. Bij dit mondeling advies is het gebleven. Dr. Cruysberg tekende aan: "m.i. géén operatie". Prof. Deutman tekende aan: "Voorlopig aanzien".

Op 20 oktober 1994 in het begin van de middag – tot dusverre waren alle onderzoeken 's morgens gehouden – heeft dr. Cruysberg nog verschillende prisma's uitgeprobeerd maar het dubbelzien was niet blijvend op te vangen, welke correctie ook werd geprobeerd, en de prisma's brachten geen verbetering boven eisers eigen brillen. Bij vermoeidheid had eiser met dubbelzien te kampen, zo wees het onderzoek uit.

Bij brief van 13 juni 1995 legde eiser zijn nog steeds voortdurende klachten voor aan dr. Verbeek:

Mijn bevindingen zijn: dubbel zien (na iedere sluiting van de oogleden) is regel, niet dubbel zien is uitzondering. 's Ochtends slaag ik er het beste in het dubbelzien te corrigeren. 's Middags ontstaan problemen met lezen. 's Avonds is lezen niet of nauwelijks mogelijk. Na een uur of tien 's avonds is ook TV-kijken nauwelijks meer doenlijk. De prisma-bril houdt het wegzakken van het rechteroog enige tijd tegen, doch niet lang. Met de prismabril kan ik niet goed lezen, als het wegzakken in de loop van de dag eenmaal is begonnen. Rust - wat daaronder te verstaan ? - brengt geen verandering in dit patroon. Sluit ik enige tijd de ogen, bijvoorbeeld na de lunch, dan duurt het circa een kwartier voordat het rechteroog weer geheel uit zijn ruststand kan komen. Lezen na werk in de tuin is slechts incidenteel mogelijk. Dubbelzien treedt bij iedere inspanning op, ook fysieke inspanning. Inspannend is ook iedere situatie, waarin ik genoodzaakt ben gedurende langere tijd (meer dan een uur of twee) het dubbelzien te corrigeren: lezen, besprekingen, autorijden, lopen door een niet bekende omgeving. Het ieder moment verschillende beelden krijgen, werkt ook niet rustgevend: het ene moment zie ik met beide ogen goed, het andere moment zitten de troebelingen voor het rechter oog en zie ik voornamelijk met het linker oog, tenzij de troebeling in dat oog belemmert; weer een volgend moment zie ik met het rechteroog beter dan met het linker. Daarbij gaan tengevolge van het dubbelzien de beelden ook nog eens voortdurend op en neer (splitsen zich).
Forceren van niet dubbelzien heeft geen effect en werkt juist averechts (pijn in de ogen, hoofdpijn, desorientatie tegen misselijkheid aan). Eerst ontspanning - dat iets anders is dan een uur rust - brengt dan soelaas.

Dr Verbeek zag eiser vervolgens op 23 juni 1995 en arrangeerde bij Orthoptie een zgn. Hess onderzoek. Het Hess-scherm wordt gebruikt om de oogbewegingen in verschillende richtingen vast te leggen en wordt vooral gebruikt als er sprake is van dubbelzien.
Dit Hess onderzoek vond plaats op 18 oktober 1995 en bevestigde opnieuw dat prisma's geen beter resultaat opleverden dan eisers eigen brillen.

In de periode van 1996 t/m 2002 is eiser op zijn verzoek periodiek gezien door meerdere artsen van oogheelkunde en door orthoptie.
Steeds is onderzocht of het netvlies nog goed vast lag en gekeken naar eventuele betere refracties (brilsterkten)

IV.4. MIRAgel plombe uit de markt in 1995

Zoals blijkt uit het voormeld citaat uit het artikel van Lane ea uit juni 2001 is de MIRAgel plombe in 1995 vanwege zijn defecten van zwelling en defragmentatie uit de markt genomen. Ook uit onderstaand citaat blijkt dit.

> MIRAgel and its precursor, MAI, are hydrophilic polymers that are permeable to water and other low molecular weight hydrophilic substances. The polymer is copoly(methyl acrylate-2-hydroxyethyl acrylate) cross-linked with ethylene diacrylate. It is softer than silicone rubber and therefore presumably less likely to produce scleral erosion or extrusion. It was initially thought that its ability to absorb and slowly release water-soluble antibiotics would lead to a reduction in infectious complications, offering an advantage over silicone sponges. Early reports supported these assumptions (1, 2). However, long-term follow-up studies (7–11 years) began to reveal complications ranging from bulging to intraocular erosion and migration of the buckle (3, 4, 8). At surgery, the fragmented bands were described as translucent, gellike, and friable. Surgical removal was complicated by a thick, fibrous capsule, which often fixed the swollen implant to Tenon's capsule, limiting the mobility of the globe. Removal of the fragmented implant in its entirety required meticulous technique but provided substantial relief of ocular discomfort and improved mobility, with a low risk of recurrent retinal detachment (12). Infrared spectroscopic analysis of recovered buckle fragments showed chemical alteration of the polymer, with hydrolytic degradation and swelling (3). The chemical alteration in vivo allowed the hydrogel to absorb more water. The implant changed from soft, spongy, opaque, and compact to friable, gellike, and translucent. The MIRAgel product was taken off the market in 1995 subsequent to these reports (personal communication, MIRA, Waltham, MA).

Lane ea besluiten hun artikel met:

> Although the hydrogel product was pulled off the market in 1995, presentations of this late complication may occur for several years to come.

Dit gegeven, het uit de markt genomen zijn vanwege de defecten, blijkt ook uit een artikel van januari 2004 van Kearney e.a. .**(prod. 6)** [3]:

> 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.

Als gebruiker van plombes van MIRA Inc. kan het van de markt genomen zijn van deze plombes onmogelijk onopgemerkt aan prof. Deutman voorbij zijn gegaan.

IV.5. Medische literatuur 1992 - 2003

1997 Hwang ea
In 1997 wordt het eerste geval van de lange termijn complicaties van de MIRAgel plombe in de medische literatuur gepubliceerd.
Hwang ea beschrijven in hun artikel van september 1997.**(prod. 7)** [4] de ontwikkelingsgang van de MAI plombe en de MIRAgel plombe, de aanvankelijk positieve verwachtingen en de latere negatieve ontwikkelingen.

> Materials used for scleral buckling procedures in detachment repair have evolved from absorbable tissues, including autogenous fascia lata and cadaveric sclera or dura mater, to nonabsorbable synthetic agents such as polyethylene tubing, solid silicone rubber, silicone sponges, and hydrogels. Hydrogels are hydrophilic materials formed from 3-dimensional polymer networks. The most widely used hydrogel is co-poly(methylacrylate-2hydroxyethyl acrylate), or MIRAgel (MIRA, Waltham, Mass). The forerunner of MIRAgel, MAI, has the same chemical composition. Hydrogels are permeable to water and low-molecular-weight hydrophilic substances. Their ability to absorb and then slowly release water-soluble antibiotics offers an advantage over silicone. Ho et al[1] reported that the MAI implant was as effective a buckling element as either solid silicone rubber or silicone sponge. He noted that the degree of swelling of the exoplant could be altered by varying its state of hydration, its softness and elasticity were protective against erosion, and it was less prone to infection because of its lack of dead spaces and its ability to absorb, then gradually release antibiotics.
> The apparent effectiveness and safety of MAI hydrogel scleral exoplants was reported by Tolentino et al.[2] who followed up 82 eyes of 79 patients for 6 to 53 months and found no complications of buckle extrusion, erosion, or infection. However, with longer follow-up of 7 to II years, 7 complications of MAI exoplants were documented by Marin and colleagues,[3] Clinical manifestations ranged from benign subconjunctival bulging to in traocular erosion and migration of the exoplant. At the time of surgery, the exoplants were seen to be translucent, gel-like, and friable. Erosion into the vitreous cavity occurred in 1 case and was complicated by difficulty grasping the friable buckle material. Micro-Fourier transform in-

[3] Kearney ea, Complications of hydrogel explants used in scleral buckling surgery, Am J Ophthalmol 2004;137:96-100.
[4] Hwang ea, Hydrogel Exoplant Fragmentation 10 Years After Scleral Buckling Surgery, Arch Ophthalmol, vol.115, sept 1997, p. 12051206

> frared spectroscopic analysis of 2 recovered implants demonstrated hydrolytic degradation of the implant leading to swelling significantly greater than the original polymer. We report the first case, to our knowledge, of scleral buckle extrusion and fragmentation associated with a MIRAgel episcleral exoplant.

Dit geval van complicaties als gevolg van de MIRAgel plombe kon volgens de auteurs geen verrassing opleveren gezien de eerder gerapporteerde 7 gevallen van MAI-complicaties

> This case represents the first reported breakdown of a MIRAgel scleral buckle. Its occurrence should not be surprising,as cases of complications with the MAI exoplant,composed of the same hydrogel material, have been reported in the past. The mechanism of fragmentation and degradation likely resembles that reported with the MAI exoplant; hydrolysis of the material with resultant swelling. The presence of an incomplete capsule surrounding the buckle in our patient may have facilitated access of orbital fluid to the exoplant. Similar to the report by Marin et al,[3] these changes appeared approximately 10 years after exoplant placement.

Hwang ea benadrukken de noodzaak om te anticiperen op mogelijke verbrokkeling en zwelling van de plombe.

> The findings in this patient illustrate the need to anticipate potential friability and swelling of MIRAgel buckle material and to meticulously search for fragments during removal of long-standing exoplants.

Zij zien geen werkelijke voordelen van toepassing van de MAI en MIRAgel plombes in vergelijking met silicone plombes.

> Our observation together with the historical data suggest that there are no real advantages of MIRAgel and MAI over silicone for use as scleral buckling material.

1999 Roldán-Pallarés ea

Roldán-Pallarés ea doen in een artikel uit 1999.**(prod. 8)** [5] de aanbeveling voor periodieke lange termijn controles ook voor patiënten die waren geopereerd met de MIRAgel explant vanwege de mogelijke complicaties van chemische verandering en zwelling.

> **Conclusions:** Periodic long-term folluw-up previously recommended for use of other materials also must be recommended for MIRAgel use because of long-term alterations in its chemical composition and eventual swelling of material.

Het doel van hun studie was:

[5] Roldán-Pallarés ea, Long term complications of silicone and hydrogel explants in retinal reattachment surgery, Arch Ophthalmol 1999;117:197-201

was to compare long-term complications of the 3 materials (silicone sponge [Dow Corning, Midland, Mich], silicone rubber [Dow Corning], and MAI or MIRAgel hydrogel) used more commonly as episcleral buckling elements.

Zij signaleerden o.m. het verschil in verwijdering van silicone rubber explants en MIRAgel explants:

In the group treated with silicone rubber, the explants were removed 1 year after surgery (Table 4). In these patients, the sclera beneath the explants was smooth and clean, indicating compression of the sclera by the explant.
Explants with the MIRAgel removed revealed evident fragmentation of the material and fibrous tissue proliferation around the explant material. Fragmentation of this material after swelling was previously reported [11-14] Negative cultures of the removed MIRAgel explants may be due to long-term antibiotics and/or corticosteroids needed to treat redness, discharge, or chronic infection; or to particular characteristics of MIRAgel. Initially, it was reported as an ideal buckling element, less prone to infection because it lacked dead spaces and could absorb and gradually release antibiotic drugs. [15]

2001 Lane ea

In het hiervoor reeds geciteerde artikel van Lane ea van juni/juli 2001 (prod. 4) is ook de moeilijke verwijdering van de MIRAgel explant geschetst:

At surgery, the fragmented bands were described as translucent, gellike, and friable. Surgical removal was complicated by a thick, fibrous capsule, which often fixed the swollen implant to Tenon's capsule, limiting the mobility of the globe. Removal of the fragmented implant in its entirety required meticulous technique but provided substantial relief of ocular discomfort and improved mobility, with a low risk of recurrent retinal detachment (12).

2002 Braunstein ea

In een artikel van febr. 2002.(**prod. 9**) [6] beschrijven Braunstein en Winnick een patiënt met een sterk gezwollen Miragel exoplant, die 13 jaar later onder het ooglid naar buiten trad – zoals ook bij eiser is gebeurd:

Complications following retinal detachment surgery may necessitate the removal of the scleral buckling element. Some of these complications have been attributed to the type of buckling material used. Scleral buckling material has evolved from autologous fascia lata to nonabsorbable synthetic agents, such as polyethylene, silicone, and hydrogels.

[6] Braunstein ea, Complications of Miragel: Pseudotumor, Arch Ophthalmol 2002;120:228-229.

Hydrogels are composed of a low-molecular-weight hydrophilic material that is water-permeable.[1] Hydrogel scleral buckling elements (Miragel) were introduced in 1979 and marketed to have an advantage over the silicone agents currently being used.[2] The degree of buckle swelling could be varied by altering the state of hydration. The softness and elasticity of Miragel were thought to minimize erosion, and its lack of dead spaces promised to prevent infection by allowing the absorption and gradual release of antibiotics.[3] Long-term complications related to the swelling properties of hydrogel exoplants have been reported. These problems have been attributed to erosion and migration, infection, granuloma formation, and fragmentation of the hydrogel material, resulting in particle retention on removal of the scleral buckling element.[4]
This case represents a complication that can occur as a result of the more than 4-fold volume expansion of the Miragel exoplant during a 13 year period. In this case, the profound increase in size of the exoplant caused restriction of extraocular movement and mimicked a periorbital mass lesion

2002 Taku Kawano

Zo ook beschrijven Taku Kawano ea in een artikel van mei/juni 2002.(**prod. 10**) [7] een patiënt "with extrusion and fragmentation of the MIRAgel episcleral exoplant 11 years after scleral buckling surgery" en bevelen lange termijn controles aan. Het abstract van het artikel vermeldt:

MAl or MIRAgel is a hydrogel developed as a scleral buckling material. We identified upper lid masses and a limitation of supraduction in the left eye of a patient who was associated with extrusion and fragmentation of the MIRAgel episcleral exoplant 11 years after scleral buckling surgery. The material could not be removed completely because of fragmentation. Fragmentation and extrusion of MIRAgel may be rare, but periodic long-term follow-up examinations should be performed after this product has been used.

2003 Oshitari ea

Oshitari e.a. .(**prod. 11**) [8] concluderen in een artikel van april 2003 dat Miragel plombes gemakkelijk verwijderd kunnen worden vóór chemische verandering.

Severe deterioration of hydrogel buckles may occur when they are left in place for 5 years or longer and may cause adverse symptoms and rarely intraocular complications. This deterioration is associated with changes in the microstructural architecture of the hydrogel material.
(...)
Buckle extrusion is not an uncommonly encountered postoperative complication of scleral buckling surgery, especially after explant procedures. Removal of the buckle in these cases is usually relatively

[7] Taku Kawano ea, Case Reports: Extrusion and Fragmentation of Hydrogel Exoplant 11 Years After Scleral Buckling Surgery, Ophthalmic Surgery, Lasers and Imaging Vol. 33 No. 3 May/June 2002
[8] Oshitari ea, Long-term complications of hydrogel buckles, Retina 2003;23:257-61

easy, since the mattress sutures in these eyes are often loose or detached from the sclera such that the buckles can simply be pulled out. Buckles that have eroded inward (buckle intrusion) can also be removed fairly easily, although cutting of scleral mattress sutures may be required.
Hydrogel buckles used as explants can also be removed in a similarly easy manner, if they are removed before structural alterations. However, as we observed in 28 eyes, hydrogel buckles left in place for over 5.5 years resulted in buckle swelling, with associated buckle extrusion or intrusion.
Removed MIRAgel buckles from these eyes were noted to have become translucent, gellike, and extremely friable, in comparison to unused MIRAgel buckles which are transparent, more solid, and elastic. In fact, we encountered much difficulty during attempted removal of the MIRAgel buckles. In most cases, the buckles had already become fragmented or disintegrated immediately upon light traction with forceps.
Removal was often performed in a piecemeal fashion, and a muscle hook was commonly used to fish out buckle debris from the subconjunctivalor sub-Tenon's space. Swollen buckles also inhibited globe rotation intraoperatively and made it difficult to gain access to remaining buckle fragments. A granulomatous reaction was observed surrounding the buckle material in some cases.

Deteriorated MIRAgel has the tendency to absorb a great volume of water and therefore to increase in size. 1 Indeed, in our study, the calculated cross-sectional area of buckles from group A that were visibly altered had increased by an average of 185%. We believe this phenomenon to be related to the microstructural changes we observed by SEM. Swelling of the MIRAgel buckle within the confines of sub-Tenon's space results in tortuosity of the buckle, with subsequent buckle dislocation and extrusion or intrusion. It has been reported that hydrolytic degeneration occurs with hydrogel material and that this process may occur even without physically evident alterations in the buckle. 6 Therefore, even in the absence of gross alterations in appearance of the buckles in group B, we believe that the process of degeneration had already begun, leading to various symptoms in the patients.

De auteurs signaleren het toenemend aantal gevallen met complicaties.

Hwang and Lim reported the first case of this complication 10 years after commercial use of the MIRAgel buckle had begun. 7
Roldan and colleagues also reported the long-term complications of MIRAgel when used as an episcleral buckling element. 3 In the Roldan study, 206 cases were followed for more than 7 years. Of these, five patients eventually underwent buckle removal for granulomatous reaction or chronic infection, but no patients developed buckle extrusion or intraocular erosion.
Marin and colleagues reported seven cases with complications that developed 7 to 11 years after scleral buckling surgery using MAl hydrogel, the precursor of MIRAgel, as an intrascleral implant. 6 These complications ranged from a visible but nontender subconjunctival bulge to intraocular erosion to frank buckle extrusion. The implants were noted to be swollen, altered, translucent, gellike, and friable. Chemical changes of the polymer and hydrophilic degeneration of the material were confirmed spectrographically. Interestingly, Marin and colleagues stated that, in contrast to patients with MAI hydrogel buckles, complications were rarely observed in patients with MIRAgel buckles. 6

Hun indruk is dat de symptomen die patiënten ontwikkelen met hydrogel plombes veel ernstiger zijn dan die van patiënten met silicone plombes.

> The current report represents the largest series of long-term complications of hydrogel buckles to date in the literature. Since we used this material in numerous scleral buckling cases, the number of patients returning to us with various complaints is still increasing. It is our impression that the symptoms patients develop with hydrogel buckles are much more severe than those of patients with silicone sponge or rubber buckles. In fact, one of the patients in our study experienced marked visual loss due to scleral erosion, buckle intrusion, and retinal cyst formation. Although such a severe vision-threatening complication is unusual to date, we have only begun to witness all the possible complications associated with hydrogel buckles. Recently, several Japanese vitreoretinal specialists have noted various complications in patients who received MIRAgel buckles (unpublished data, Drs. Takeshi Hoshino and Miyo Matsumura), and the Japanese Ophthalmologic Society has decided to make an official announcement regarding the seriousness of these complications.

Kortom, chirurgen dienen zich bewust te zijn van de complicaties en patiënten dienen regelmatig onderzocht te worden en gewaarschuwd voor mogelijke problemen. Ingeval van zwelling dient de plombe te worden verwijderd.

> In summary, the long-term complications of hydrogel buckles may be quite severe with potential visual loss. Surgeons must be aware of these possible complications in patients who have received hydrogel buckles during scleral buckling procedures, and these patients should undergo periodic examination and be warned of the possibility of problems. When symptomatic buckle swelling or buckle extrusion occurs or if scleral erosion and buckle intrusion are identified, the hydrogel buckle material should be removed.

2003 Le Rouic ea

In een publicatie in 2003.(**prod. 12**) [9] beschrijven Le Rouic e.a. de verschillen tussen silicone en MIRAgel implants:

> Episcleral buckling is a common technique used for retinal detachment (RD) surgery. In some cases, however, the implant must be removed. [1-15] The two most common reasons for removal are extrusion, associated with or without buckle infection, [1-8, 10, 13] and diplopia. [9, 10, 16-19] These complications have mostly been reported for eyes implanted with silicone sponges or solid silicone. Miragel elements have also been widely used for episcleral indentation. Initial series have reported a good tolerance of this material. [20-21] With a longer follow-up, sporadic cases of late swelling of this material, which appeared fragmented during its surgical removal have been report ed. [11.14.15.22-28] Although the use of Miragel buckling elements has been discontinued, their explantation is subject of concern because of their now established long-term complications. We also had to remove a large number of episcleral Miragel buckles. In this series, we describe the indications for their removal and compare them with the silicone buckles removed during the same period.

[9] Le Rouic ea, Late swelling and removal of miragel buckles: a comparison with silicone indentations. Retina 2003;23:641-6.

De auteurs doen ook de aanbeveling om patiënten voortdurend te volgen en verwijdering van de Miragel-plombe te overwegen bij de eerste tekenen van zwelling om erger te voorkomen:

> After reviewing all these late complications, we think that patients implanted with Miragel buckles intrasclerally or episclerally should undergo a close and long-lasting follow-up, ideally by their eye surgeon, be informed of the potential long-term complications of Miragel elements, which were not known at the time of their RD repair, and be asked to present promptly if they notice ocular motility disturbance or a bulkiness of their indentation. Although it is possible that, after 10 years or more in the eye, Miragel implants invariably swell up, we do not advocate for a systematic removal of well-tolerated buckles, because retinal redetachment and scleral rupture are still potential visualthreatening complications of indentation removal. Conversely, the SB extraction should be considered as soon as the first signs of Miragel swelling occur to avoid a major fragmentation of the buckle, which renders the removal technically difficult or even dangerous to the underlying sclera.
> Although the use of Miragel buckling elements is now discontinued, this type of material is still a subject of concern because of the long-term swelling that will often lead to removal of the buckle. In this series, the mean time from surgery to Miragel buckle elements removal was approximately 8 years. However, our longest follow-up does not exceed 10 years. This example of a late complication of an initially welltolerated material is an invitation to increase our vigilance when following up patients with any type of implant

2003 Li ea

In 2003 waarschuwen ook Li ea.(**prod. 13**) [10] (Liverpool) voor de moeilijke verwijdering van de MIRAgel explants vanwege de desintegratie ervan. Omdat MIRAgel explants op uitgebreide schaal zijn gebruikt dienen afdelingen oogheelkunde zich bewust te zijn van latere complicaties:

> Miragel explants were subsequently withdrawn because of late complications.[1,2,3,4] These include erosion into the globe, extrusion of the explants and progressive diplopia. The material had been shown to be structurally unstable and this led to excessive water absorption, swelling and disintegration.[1] This process must be a very slow one, as typically many of these complications only appear 7–10 years after the initial scleral buckle operation.[1,2,3,4]
> **Comment**
> Using scissors and forceps in the conventional manner, the removal of Miragel may be difficult, as the explants disintegrate when grasped by instruments. In our patient, the explant was associated with massive periocular fibrosis and extensive dissection was required to free the globe from its mechanical restriction. Our case illustrated that the symptoms can be slowly progressive and that some complications tended to be delayed for many years. We may only be starting to see a number of these cases in this country, even though the explants were withdrawn some years ago. Where Miragel explants had been used extensively in the past, eye units should be aware of the possibility of late complications.

[10] Li ea, Miragel explant fragmentation 10 years after scleral buckling surgery, *Eye* (2003) 17, 248–250.

IV.6. Eisers behandeling in 2003

Vanaf de zomer 2002 en gaandeweg in 2003 kreeg eiser steeds meer last van zijn rechteroog.
Op 25 augustus 2003 schreef hij aan prof .Deutman als volgt:

> Is het mogelijk mij op korte termijn te zien ?
> Sinds enige tijd kamp ik in het – in 1992 geopereerde – rechteroog met het verschijnsel van traanvorming, waarbij de traan a.h.w. als een druppel blijft hangen en extra troebeling veroorzaakt. Wel trekt dit vaak weer weg doch ik heb er toch in toenemende mate last van. Bij het lezen valt mij op dat de regels een kromming naar omlaag (dal) laten zien, terwijl het linkeroog normaal horizontale regels ziet.

Omdat prof. Deutman aan het afbouwen was en met pensioen ging, verwees hij eiser naar zijn collega in het St. Radboud Ziekenhuis, prof. Cruysberg, door wie eiser op 26 augustus 2003 werd gezien. Beide ogen werden gedruppeld en het netvlies werd bekeken. Alles zat goed (vast). Op eisers klacht kon niet goed antwoord worden gegeven.

In de periode nadien ging de druppelvorming meer over naar regelmatige traanvorming, zij het dat het traanvocht vettig en plakkerig aanvoelde en ook weer extra (weer wegtrekkende) troebelingen veroorzaakte.
In de loop van dinsdag 30 september 2003 en vooral die avond had eiser daarvan zoveel last, dat hij opnieuw het Radboud heeft gebeld voor een afspraak.
Prof. Deutman verwees eiser via zijn secretaresse – die eiser aanvankelijk op een opengevallen plaats op zijn spreekuur op vrijdag 3 oktober zette – weer naar prof. Cruysberg, die geen tijd had en zo kwam eiser op donderdag 2 oktober terecht bij de oogarts mevr. Smeets. Zij vroeg zich enkele keren af waarom eiser op haar spreekuur was geplaatst, druppelde beide ogen, constateerde dat alles goed (vast) zat, en merkte ten aanzien van het tranen op dat traanvocht nu eenmaal vettig was en zij verder ook niets kon vinden/doen. Het zou waarschijnlijk vanzelf overgaan.
Haar reactie bevredigde reeds niet, omdat het tranen bij het rechteroog anders aanvoelde dan bij het linkeroog en – ook weer anders dan bij het linkeroog het geval was – (tijdelijke) troebelingen veroorzaakte waardoor het zien aanmerkelijk achteruit ging – hetgeen eiser haar uiteraard heeft meegedeeld.

Eiser ondervond nog steeds last van druppelvorming, traanvorming, wazig worden van het rechteroog en dubbelzien in het rechteroog zelf.
Op 8 oktober 2003 heeft eiser zich met deze klachten maar gewend tot zijn huisarts. Deze heeft hem een kuur met acetylcysteine bruistabletten voorgeschreven. Dit hielp in zoverre dat gevolgen van een verkoudheid in juli – slijmvorming – werden verholpen, doch de (afwijkende) traanvorming van het rechteroog bleef, zij het dat het vettige karakter vrijwel verdween.

De traanvorming, soms incidenteel soms doorlopend, in wisselende mate, veroorzaakte evenwel wazigheid en dubbelbeelden in het oog zelf, resulterend in sterkere bijziendheid. Van tijd tot tijd herstelde het oog zich en voelde weer als vanouds aan, doch eiser kon moeilijk aangeven onder welke (gelijke) omstandigheden zich dit voordeed.

Wat eiser op een gegeven moment wel opviel was het (lichte) gevoel van verkleving van het ooglid aan het oog rechtsboven, naar voren kijkend. Ter plaatse bleek onder het ooglid een uitstulping te zitten, kennelijk afkomstig van de operatie uit 1992.
Bij faxbrief van 12 november 2003 bracht eiser prof. Cruysberg hiervan op de hoogte i.v.m. de oogmeting van de volgende dag, 13 november 2003, aangezien de resultaten daarvan wellicht (sterk) negatief beïnvloed konden worden indien zich de traanvorming dan (nog) voordeed.
Prof. Cruysberg meende dat het probleem zat in een verstopt traanbuisje, spoot dit door met water en toonde de uitstulping nog aan een assistent ("kijk, dat is nog van de operatie"), zonder daar verder conclusies uit te trekken. Wel is aangetekend in eisers medisch dossier "geringe prominentie explant (...)".
Verder werd niets ondernomen. Eiser werd niet geïnformeerd over hetgeen er aan de hand was en werd aan zijn lot overgelaten.

IV.7. Medische literatuur 2003 - 2005

In de periode tussen november 2003 en maart 2005 verschijnen dan nog meer publicaties in de medische literatuur over de MIRAgel complicaties.

2004 Kearny ea

Kearney e.a. beschrijven in een artikel van januari 2004 (prod. 6) [11] een groep patiënten met "symptoms of pain, strabismus, sensation of orbital fullness and presence of a subconjuntival mass many years after successful scleral buckling surgery using hydrogel explants" en concluderen dat vroegtijdige herkenning ernstige complicaties van uitgestelde verwijdering kan voorkomen:

> 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 with delayed removal.

Zij waarschuwen er ook voor dat de aard van de plombe vaak onbekend is en de arts de oorzaak van het probleem vaak niet onderkent: :

> 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.

Zij signaleren dat de verwijdering van de plombe moeilijk is:

[11] Kearney ea, Complications of hydrogel explants used in scleral buckling surgery, Am J Ophthalmol 2004;137:96-100.

> 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.

Een derde van de gevallen leidde tot nieuwe netvliesdefecten:

> The incidence of redetachment of the retina after hydrogel buckle removal was high (nearly one third of our cases).

2004 Metz ea

Metz e.a. beschrijven in een artikel van febr. 2004.**(prod. 14)** [12] een patiënt met een MIRAgel scleral buckle, waarvan de complicaties leidde tot blindheid.

> A hydrophilic implant for scleral buckling was developed in 1980. [1] Advantages include softness and elasticity, no dead spaces, ability to gradually absorb and release antibiotics, and stimulating production of a fibrous capsule around the implant. Short-term follow up studies in rabbits showed no clinical or histologic complications.[1,2] Long-term complications of the hydrogel scleral buckle have emerged in the last 10 years.[3-6] These included fragmentation, subconjunctival bulging, intraocular erosion, migration, and restriction of extraocular movement. We recently encountered a patient with progressive restrictive strabismus beginning 8 years after retinal detachment repair with a MIRAgel (hydrogel; MIRA, Uxbridge, MA) scleral buckle. Worsening complaints of diplopia and discomfort led to strabismus surgery. Untreatable retinal detachment resulted in enucleation.

De volgende passage uit hun artikel verklaart mogelijk de opvatting van Medas dat uittreding van de plombe zich bij iedere netvliesscheur operatie kan voordoen:

> Scleral buckling with exoplant material, such as solid silicone and silicone sponge. has been associated complications such as extrusion, pressure necrosis with erosion through the sclera, infection rates reported from 2.7% to 18%,[2] and restrictive strabismus with diplopia during a period several months after surgery. This can occur with any scleral buckling surgery. In an attempt to eliminate or minimize these problems, a hydrogel material was developed by Refojo et al. [1] Favorable qualities of the new material included softness, elasticity, nonabsorbability, absence of dead spaces, ability to be sterilized with heat, and ability to absorb and gradually release antibiotics. Short-term follow up studies in rabbits indicated no clinical or histologic signs of significant toxicity or inflammation.[1-2]

[12] Metz ea, Late-onset progressive strabismus associated with a hydrogel scleral buckle, J AAPOS 2004;8:72-3.

In 1992, Marin [3] reported seven patients in whom long-term complications developed from swelling of the hydrogel buckling implant (MIRAgel) 7 to 11 years after surgery. Hasslinger [7] the director of research and development at MIRA Inc, denied knowledge of any reported complications secondary to the placement of MIRAgel implants. Since then, there have been several reports of long-term problems in patients who have had hydrogel used for scleral buckling repair of their retinal detachments.[3-6,8] The implants were often removed because of excessive scleral indentation and subconjunctival intrusion or extrusion. On removal, the hydrogel appeared friable and swollen with dehiscence of the scleral bed (as in the case of implants), vitreous hemorrhage, and loss of vision in some cases.
A patient reported by Hwang and Lim[4] had limitation of adduction and infraduction with diplopia 8 years after scleral buckling with MIRAgel, and this condition worsened over time. After the scleral buckle was removed, the patient became orthophoric in primary gaze with mild remaining restriction of adduction and infraduction.
Braunstein and Winnick[6] reported a patient with complications 13 years after uneventful scleral buckling procedure using MIRAgel. Diplopia and orbital swelling were noted, and infraduction of the operated eye was limited. These findings mimicked a periorbital mass lesion. During surgery to remove the buckle, the hydrogel material was noted to be 4.5 times its normal size. Removal of the buckle resulted in elimination of diplopia.

De complicaties van zwelling en defragmentering met als gevolg de moeilijke operatieve verwijdering worden echter alleen beschreven bij MIRAgel plombes. In het hiervoor aangehaalde artikel van Oshitari ea wordt ook gesignaleerd dat de symptomen die patiënten ontwikkelen met hydrogel plombes veel ernstiger zijn dan die van patiënten met silicone plombes.

2004 Chung ea

In een artikel van juni 2004 beschrijven Chung ea het eerste Koreaanse geval .(**prod. 15**) [13], een patiënte met een gezwollen en gefragmenteerde Miragel explant, 9 jaar na de netvliesoperatie. Zij roepen de oogartsen op om zich bewust te zijn van de problemen en hun patienten regelmatig te volgen:

> Considering the historical data and the late complications observed in the present case, the hydrogel explants can no longer claim to provide advantages over other conventional scleral buckling materials. The hydrogel explants have been withdrawn from the market since the 1990s. As these complications usually occur 7 to 11 years following the surgery, it is highly recommended for the ophthalmologists who have used hydrogel materials in retinal surgery to be aware of these problems and do regular follow ups for the patients with hydrogel explants.

[13] Chung ea, Diplopia and periorbital mass associated with Miragel buckling explant, Korean J Ophthalmol. 2004 Jun; 18(1):47-51

2004 Mazzoli ea

Mazzoli e.a. maken in een artikel van oktober 2004.(**prod. 16**) [14] gewag van een recente stortvloed ("spate") van meldingen van complicaties van MIRAgel, zij signaleren dat als gevolg van het feit dat MIRAgel midden 90er jaren van de markt werd genomen en de lange termijn, waarop de complicaties zich ontwikkelen, oogartsen helemaal niet meer vertrouwd zijn met het materiaal hydrogel, en zij vermelden ook de moeilijke verwijdering van de verbrokkeling naarmate het materiaal ouder is.

> Recent findings: (...)
> Initial results appear promising. Tempering the enthusiasm for their use, however - particularly in terms of implanted orbital expanders – is the recent spate of long-term complications reported from previous uses of hydrogels as scleral buckling material.
> (...)
> **Potential drawbacks**
> As with any new material or technique, there can be potential for unintended or unexpected consequences in the long term. The fly in this particular soup is the recent spate of reports of complications of prior hydrogel applications in the orbit, to whit, retinal buckling elements made of MIRAge1 (MIRA, Waltham, MA) and its precursor, MAl, popular products introduced in the late 1970s [27,28•,29••,30•,31••-38]. Reputed advantages of these products were the following: less likelihood for extrusion or erosion because of the material's softness and elasticity: less likelihood of buckle infections because of its lack of dead-air spaces and the fact that it could be saturated in antibiotic solution (which it would gradually release thereafter); the degree of swelling could be controlled by controlling hydration; and, it stimulated the formation of a surrounding pseudocapsule [27,28•,29••.30•]. In fact, most of these claims were borne out clinically, at least in the short-tcrm [29••,35]. Unfortunately, over the long term (l0+ years), complications of late hydrogel breakdown were recognized. attributed to uncontrolled swelling of the material beyond its initial size [28•,29••.31••,33]. In fact, the long time lapse between implantation and development of complications may lead to initial misdiagnosis of the condition, particularly if the patient presents to a clinician unfamiliar with either the prior surgery performed, or the material used [31••]. Indeed, since withdrawal of MIRAgel from the market in the mid 1990s, many novice ophthalmologists are no longer historically familiar with the material at all. There are now reports of buckle extrusions, intraocular erosion and migration, progressive limitation of motility, intraorbital fibrosis and mass effect, pain, foreign body granuloma formation, and inflammatory orbital pseudotumor [27,28•,29••,30•,31••,32-38]. Attempts at removing the material are frustrating, because the hydrogel becomes very friable with age, becomes semisolid, and fragments easily between the forceps. Some advocate using cryo or curettage to help remove the pieces [29••,30•,32].

[14] Mazzoli ea, Use of self-expanding, hydrophilic osmotic expanders (hydrogel) in the reconstruction of congenital clinical anophthalmos, Current Opinion in Ophthalmology. 15(5):426-431, October 2004

2005 Shields ea

Shields ea beschrijven in een artikel van januari 2005.(**prod. 17**) [15] vier patiënten met "uncomplicated retinal detachment surgery 12 to 20 years earlier", bij wie "orbital tumor" vermoed werd. Het bleek hier te gaan om "a swollen MIRAgel implant". Zij concluderen dat patiënten zich vaak geen bijzonderheden van de oogoperatie herinneren en dat de medisch specialist de MIRAgel implant dient te herkennen en voorbereid te zijn op de chirurgie van de verwijdering:

> MIRAgel scleral buckle material can greatly enlarge over a period of 10 years and simulate an orbital tumor or orbital cyst. Patients often do not recall details of the retinal surgery. Caution is advised regarding excision of this material because it is friable and can lead to extensive postoperative inflammation.
> (...)
> MIRAg has subsequently been removed from the market. However, many patients have this implant and are at risk for development of the problems seen in our cases. (...) The orbital surgeon should recognize this implant and be prepared for challenging surgical removal if necessary.

IV.8. Eisers behandeling in 2005 - 2006

Op donderdag 17 maart 2005 had eiser weer zoveel last van het oog dat hij een afspraak heeft gemaakt met de spoed(oog)arts – alle oogartsen bleken aan het congresseren te zijn in Maastricht. Geconstateerd werd dat een hechting bezig was zijn oog uit te groeien (dit betrof niet de voormelde uitstulping !) en op eisers verzoek is die hechting onder plaatselijke verdoving met oogdruppels ietwat naar buiten getrokken en afgeknipt, zodat hij daar geen last meer van had. De ontstane bacteriële infectie werd met zalf bestreden.
Bij die gelegenheid hoorde eiser voor het eerst dat het "uit het oog groeien van de hechting" een bekend probleem was, want prof. Deutman bleek bij de operatie in 1992 het nieuwste van het nieuwste hechtingsmateriaal uit Amerika te hebben gebruikt en dat materiaal bleek na 10 jaar te gaan groeien/uitzetten. De uitstulping was de hoofdhechting (zo begreep eiser) en die was bezig alsmaar uit te zetten.
De aantekening in eisers medisch dossier vermeldt een forse, prominente plombe met infectie rondom.
Voor de (operatieve) verwijdering daarvan diende eiser een afspraak met prof. Deutmans opvolger te maken.

Op 11 april 2005 werd eiser door prof. Keunen gezien die hem Fucithalmic zalf voorschreef tegen bacteriële infecties en zei huiverig te zijn voor operatieve verwijdering van de uitstulping omdat daardoor het dubbelzien zou kunnen toenemen.

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[15] Shields ea, Expanding MIRAgel Scleral Buckle Simulating an Orbital Tumor in Four Cases, Ophthal Plast Reconstructive Surg.;2005,Jan; 21(1),32-34

I.v.m. voortdurende klachten sprak eiser op 10 oktober 2005 opnieuw met prof. Keunen, die echter bleef bij zijn aarzeling om te opereren. Eisers geval was er een van pappen en nahouden, zo zei hij. Het enige nut van de gesprekken was de opmerking van prof. Keunen dat chloorwater goed was om de infecties tegen te gaan, dus spoelde eiser om de zoveel tijd zijn oog even onder het zwemmen 's morgens en dat hielp. Zoals eiser later tegen de ook aan het Radboud verbonden oogarts dr. Vos zei: prof. Keunen papt en ik houd nat.

De stand van zaken in juni 2006 was dat de uitstulping steeds groter en dikker werd – van bobbeltje uitgegroeid tot een soort haaienvin – en dat tezijnertijd. een operatie zou moeten volgen met ongewis resultaat.
Regelmatig ontstonden bacteriële infecties, waarvoor Fucithalmec ooggel werd voorgeschreven, die lang niet altijd hielp. Van tijd tot tijd spoelde eiser een irritatie onder het zwemmen weg. Het bleef behelpen.
Medio juni 2006 ontstond ook nog een conjunctivitis in het linker oog, die oversloeg naar het rechter.

In de hete zomer van 2006 brak – de "hechting" die bleek te zijn – de plombe door. Het materiaal stak daadwerkelijk met een hoek uit de bult op het oog naar buiten en schuurde van binnen uit tegen het ooglid aan.
Vanwege de continue irritatie trok eiser opnieuw aan de bel. Bij brief van 8 augustus 2006 schreef hij aan prof. Keunen o.m. het volgende:

> Bacteriële infecties en onrust heb ik in de afgelopen tijd zoveel mogelijk bestreden met het even "spoelen" van het rechter oog in zwembadwater in mijn chloorbril, dat in mijn ervaring beter en directer werkt dan de fucithalmec ooggel, die u mij in april 2005 als recept gaf.
>
> Na enkele dagen verkoudheid bleek ik op woensdag 14 juni j.l. een conjunctivitis in het linker oog te hebben opgelopen, die de vrijdag daarop oversloeg naar het rechter oog.
> Dr. Vos zag mij op zaterdag 17 juni en schreef Chlooramfenicol voor, dat hielp.
> Wel is het rechteroog sindsdien onrustig gebleven, zodanig dat ik weer de fucithalmec ooggel heb gebruikt, maar het zwembadwater blijkt toch het meest effectief.
>
> Het oog blijft wel een (zeer) lichte vorm van afscheiding houden (anders dan bij de conjunctivitis) en doet soms licht pijn. Ook ervoer ik recent een licht gezwollen ooglid, maar na "spoelen" ging dat weer over.
>
> Als ik goed observeer is de hoofdhechting/plombe (?) in de afgelopen weken daadwerkelijk uit het oog gaan treden, eerst een klein geelwit puntje, daarna zeer geleidelijk groter wordend. Direct om de plombe heen ziet het er roodachtig uit. Door de uitstulping wordt kennelijk het ooglid van binnen geïrriteerd, zodanig dat bij het naar links kijken soms het gevoel ontstaat dat er een beschadiging (gevoel van het oplopen van een schaafwond) optreedt . De hinder is in ieder geval niet gering.

Hoelang moet dit nog blijven doorgaan ?
Is zo langzamerhand niet operatieve verwijdering van de hechting/plombe geïndiceerd ?
Is het niet verstandig dat er op korte termijn naar gekeken wordt ?

Op 11 augustus 2006 werd eiser gezien door prof. Keunen. Hij besloot alsnog te doen opereren. Direct die zelfde dag nog heeft prof. Keunen uit voorzorg zelf het oog gelaserd.

Op 22 augustus 2006 heeft de eveneens aan het Radboud verbonden oogarts dr. Hoyng onder plaatselijke verdoving de plombe voor de helft verwijderd. Verwijdering van het restant bleek te riskant. Zoals eiser beluisterde, was het netvlies ter plaatse zeer dun geworden – aderen waren zichtbaar – en algehele verwijdering van de plombe zou mogelijk een gat in het oog hebben veroorzaakt. Overigens was het oog ontstoken en eiser kreeg uit voorzorg een dubbele oogprik ter verdoving. Bij de gedeeltelijke verwijdering bleek het materiaal ook broos geworden, naar mededeling van dr. Hoyng. Ziekenhuisopname na de operatie was niet nodig.

Bij controle op 24 augustus 2006 zei prof. Keunen tegen eiser dat hij niet meer terug hoefde te komen, zo goed zag het oog er uit ! De overlast moest nu dus afgelopen zijn. De rest van de plombe, die dr. Hoyng niet durfde te verwijderen vanwege risico van beschadiging van het oog, kon tezijnertijd ook nog wel naar buiten komen – vergelijk een wandelende nier (aldus prof. Keunen) – maar dat zouden we dan wel weer zien.
Prof. Keunen bevestigde eiser toen desgevraagd dat de plombe een zgn. MIRAgel-plombe was – eiser had die mogelijkheid kort tevoren vernomen van een bevriend oogarts –, waarvan het materiaal na 10 jaar begint uit te zetten en ook uiteen te vallen. Dat geldt niet alleen voor plombes doch ook voor cerclagebandjes om het oog. Gelukkig bleek het cerclagebandje om eisers oog niet van dit materiaal te zijn. De plombe in eisers oog was gaan zwellen en was afgestoten.

Het dubbelzien bleek na de operatie aanzienlijk verergerd.
Anderzijds, het oog onderging na enkele dagen veranderingen en de sterkte daalde van -15 naar -13 met verandering van cylinder-as (aldus de bevindingen van eisers opticien De Boer).

Leek de ontwikkeling verder goed te gaan bij de controle van 11 september 2006, op zondag 17 september 2006 ontstond een "druppel" in het oog die langzaam groter werd.
Per fax van maandagochtend 18 september bracht eiser prof. Keunen hiervan op de hoogte met de vraag of hier sprake was van een netvliesloslating.
Op deze fax werd niet gereageerd en pas toen eiser zelf in de middag telefonisch contact opnam met de secretaresse van prof. Keunen werd hem de gelegenheid geboden, om als hij dit wilde, dinsdag 19 september 2006 op controle te komen.
Bij die controle bleek alsnog een netvliesdefect te zijn ontstaan. Onmiddellijk ingrijpen was geboden.

Op 20 september 2006 is eiser onder plaatselijke verdoving geopereerd door de eveneens aan het Radboud verbonden oogspecialist Dr. Tilanus als zijnde de beste operateur van de afdeling oogheelkunde.

De operatie geschiedde van binnenuit (vitrectomy), het glasvocht is verwijderd, de opening in het netvlies – direct naast het restant van de plombe, die in de afgelopen jaren enigszins het oog was ingegroeid, zo beluisterde eiser tijdens en direct na de operatie van Dr. Tilanus – is gedicht en vanwege het risico van nieuwe defecten is gevuld - niet met gas maar - met olie 5000.
Ook in het operatieverslag van 19 september 2006 is neergelegd dat de plombe eisers oog in kwam. Ziekenhuisopname was overigens niet nodig.

Voorafgaand aan de operatie van 20 september 2006 is een lensmeting gedaan van beide ogen i.v.m. toekomstige staaroperaties.

Een aantal dagen later trof eiser nog een e-mail aan van zijn secretaresse, waarin zij schreef:

> Ziekenhuis heeft gebeld.
> Prof. Keunen denkt dat het niet dringend is en heeft een afspraak voor je staan op 10 oktober a.s. te 12.30 uur.
> Als jij een andere mening bent toegedaan dan moet je bellen en krijg je een afspraak met een andere arts omdat Keunen niet eerder tijd heeft (bezoek buitenland).

Als eiser dit advies had gevolgd, was hij zijn oog hoogstwaarschijnlijk kwijtgeraakt. Zoals Dr. Tilanus hem later zei: "jouw oog was aan het leeglopen". Dr. Tilanus verzekerde eiser wel dat die ene dag vertraging – hij werd in plaats van op maandag op dinsdag gezien en de woensdag daarop geopereerd – geen verschil heeft uitgemaakt.

Controles door prof. Keunen op 21 en 26 september, 2 en 9 oktober 2006 vielen positief uit.
Op 15 oktober 2006, 2 weken na het stoppen met de oogdruppels (Tobradex) , ontstond evenwel een ontsteking, die met hernieuwd gebruik van deze oogdruppels onderdrukt is kunnen worden.
Vervolgcontroles door prof. Keunen vonden plaats op 19 oktober, 6 november, 11 december 2006 en 22 januari 2007, waarbij prof. Keunen zich telkens optimistisch uitliet.

Op 11 december 2006 is eiser op zijn verzoek tevens door Dr. Tilanus gezien. Zijn benadering bleek bepaald minder optimistisch te zijn dan die van prof. Keunen. Voor wat betreft de verwijdering van de olie stelde hij zich terughoudend op. Hij sloot zeker niet uit dat na verwijdering van de olie en vervanging door kunstmatig glasvocht (water) er opnieuw een defect zou ontstaan, in welk geval weer olie in het oog zou moeten die er dan nooit meer uit zou mogen.

De verwijdering van de olie is door Dr. Tilanus geschied op 29 mei 2007.
Kort tijd later ontstond een grote vochtbel in het oog, die door Dr. Tilanus op 7 juni 2007 door middel van een laserbehandeling met 88 'punten' is "ingedamd" en die dam heeft het tot dusverre gehouden.

Eiser heeft echter als gevolg van de operatieve ingrepen dusdanige visuele beperkingen opgelopen dat hij sedert 22 augustus 2006 80-100% arbeidsongeschikt is en hij zijn beroep als advocaat niet of nauwelijks meer behoorlijk kan uitoefenen.

IV.9. Medische literatuur 2007 - 2009

2007 Roldan-Pallares ea

In een artikel van april 2007 (**prod. 18**) [16] concluderen Roldan-Pallares ea dat dadelijke verwijdering ingeval van klachten in overweging dient te worden genomen ter vermijding van toenemende complicaties.

> **Conclusion:** Prompt removal of MIRAgel explants when discomfort starts should be considered to avoid in creased incidence of complications.

Het heeft er alle schijn van dat de aangehaalde literatuur geheel aan eisers medische behandelaren voorbij is gegaan.
De complicaties van de MIRAgel plombe zijn immers niet dadelijk herkend en er is niet tijdig en adequaat operatief ingegrepen, zoals bij herhaling in de medische literatuur is aanbevolen.

2009 NOG jaarcongres

Op internet is geplaatst het programmaboekje van de 203e jaarvergadering van het Nederlands Oogheelkundig Gezelschap in maart 2009.

*Op blz. 115 (**prod. 19**) wordt de presentatie vermeld van* W. Swart:

> De MIRAgel plombe: blijf er aan denken bij vreemde orbitale zwellingen en een ablatio retinae operatie in het verleden
> SAMENVATTING:
> Bij een patient met een hoogstand van het rechter oog en forse bewegingsbeperking was vroeger een MIRAgel plombe geplaatst.

> De MIRAgel plombe is in het begin van de jaren negentig gebruikt als plombe materiaal ter behandeling van ablatio retinae. In tegenstelling tot ander materiaal ging de plombe na een periode van ca 5 jaar geleidelijke zwellen en van structuur veranderen.

Op blz. 158 (**prod. 20**) wordt de presentatie (**prod. 21**) vermeld van N. Crama en B.J. Klevering (Nijmegen UMC St Radboud):

> Complicaties (bij het verwijderen) van Miragel plombes
> SAMENVATTING:
> Doel: Beschrijven van de complicaties, in het bijzonder de kans op scleraperforatie, bij operatieve verwijdering van gezwollen Miragel plombes.

[16] Roldan-Pallares ea, Hydrolytic Degradation and Long-term Observations, Arch Ophthalmol 2007; Vol. 125 No.4

Methode: Retrospectief statusonderzoek. Resultaten: Bij 17 (5.4%) van totaal 312 patiënten bij wie tussen 1998 en 2008 gezwollen Miragel indentatiemateriaal werd verwijderd, ontstond peroperatief een scleraperforatie.
Een overzicht van mogelijke risicofactoren zal worden gepresenteerd, evenals de kans op een recidief netvliesloslating en overige complicaties. Conclusie: Bij het verwijderen van gezwollen Miragel indentatiemateriaal is er een kans van 5% op een peroperatieve scleraperforatie.

Eiser kan zich niet aan de indruk onttrekken dat de afdeling oogheelkunde van het ziekenhuis op grote schaal destijds de zo risicovolle MIRAgel plombe heeft toegepast zonder daarvan melding te maken in de medische dossiers van de betrokken patiënten, zonder hen daaromtrent behoorlijk te informeren en zonder hun toestemming te vragen. Toen zich kennelijk in 1998 de eerste patiënten meldden met gezwollen MIRAgel materiaal, werden zij wel behandeld, maar bij gebreke van gegevens – er was immers niets geregistreerd – was natuurlijk niet bekend bij welke overige patiënten de MIRAgel plombes ook nog waren toegepast, zodat zij niet konden worden opgeroepen ter controle. Oogheelkunde kon slechts wachten tot patiënten zich meldden met gezwollen MIRAgel materiaal en dan was de verwijdering al (meer) risicovol geworden. Tijdig ingrijpen, zoals bij herhaling in de wereldlitteratuur is aanbevolen om erger te voorkomen, was in die situatie kennelijk niet mogelijk. Daarvoor zou immers vereist zijn geweest dat aantekening was gehouden in de medische dossiers en de patiënten tijdig waren geïnformeerd omtrent de risico's. Vermoedelijk is daarom besloten maar zo min mogelijk ruchtbaarheid aan de zaak te geven en slechts reactief op te treden en te reageren op binnengekomen klachten in plaats van proactief op te treden en eigener beweging de patiënten op te roepen voor informatie en nader onderzoek. De patiënten werd dan maar verteld dat plombes wel vaker door het menselijk lichaam werden afgestoten – zoals aanvankelijk prof. Keunen aan eiser meedeelde in antwoord diens vraag naar de oorzaak van het gebeuren. Dat het om een gebrekkig, onvoldoende lang getest en dus in wezen experimenteel medisch hulpmiddel gaat, is niet gezegd. En als patiënten als eiser dan ook nog door de behandelend arts prof. Deutman, die de plombe heeft aangebracht, ongezien verwezen worden naar collega-oogspecialisten die kennelijk van de MIRAgel problematiek onwetend zijn en bij wie geen lampje gaat branden bij het constateren van vreemde orbitale zwellingen en een ablatio retinae operatie in het verleden, kan natuurlijk van tijdig ingrijpen, hoezeer ook geboden, helemaal geen sprake meer zijn.

V. Nadere toelichting naar aanleiding van het verweer van het ziekenhuis

M.b.t. de eerste aansprakelijkheidsgrond:

Het ziekenhuis voert aan dat hij de MIRAgel plombe niet heeft ingevoerd in de EER met als doel het beroeps- of bedrijfsmatig verder te verhandelen, zodat zijn aansprakelijkheid niet dezelfde is als die van een producent.
Daarmee legt het ziekenhuis evenwel een onjuist criterium aan.

Iedereen die een product in de EG Gemeenschap invoert om dit product te verkopen, te verhuren, te leasen of anderszins te verstrekken in het kader van commerciële activiteiten, wordt beschouwd als een producent in de zin van de Richtlijn en is dan ook op dezelfde voet als deze producent aanspra-

kelijk. De plombe is aan eiser verstrekt door het ziekenhuis in het kader van zijn ondernemingsactiviteiten, namelijk zorgverlening aan, meer speciaal de operatieve behandeling van eiser, mitsdien om commerciële redenen en daarmee zit het ziekenhuis op één lijn met de Amerikaanse fabrikant van de MIRAgel plombe, MIRA Inc.

Voorts beroept het ziekenhuis zich op de vervaltermijn van 10 jaar ex art. 6:191 lid 2 BW, omdat de bewuste MIRAgel plombe reeds meer dan 10 jaar geleden in het verkeer is gebracht.
Dit beroep op de wettelijke vervaltermijn is evenwel onaanvaardbaar naar maatstaven van redelijkheid en billijkheid, omdat de intrinsiek aan het product klevende gebreken, de verandering van chemische samenstelling, zich pas na ommekomst van de vervaltermijn hebben gemanifesteerd en de informatie dat dit product is toegepast ook pas jaren na ommekomst van de vervaltermijn is verstrekt.
Voor wat betreft haar beroep op de wettelijke vervaltermijn van 10 jaar ex art.6:191 lid 2 BW is gewezen op het gegeven dat het product zich in eisers geval kenmerkt door pas na 10 jaar van chemische samenstelling te veranderen en te zwellen. Het is al een oud leerstuk dat dwingend recht opzij gezet kan worden door redelijkheid en billijkheid. In uitzonderingsgevallen kan een beroep op een wettelijke vervaltermijn onaanvaardbaar zijn naar maatstaven van redelijkheid en billijkheid.
Eiser is geopereerd op 6 juli 1992. De vervaltermijn liep af op 6 juli 2002. Eisers klachten traden op eind 2002, begin 2003. In de loop van 2003 heeft hij deze klachten gemeld bij prof. Deutman. Pas op 17 maart 2005 kreeg cliënt te horen dat de plombe bezig was uit te treden en pas in augustus 2006 vernam hij dat het om de MIRAgel plombe ging.

M.b.t. de overige aansprakelijkheidsgronden:

Eisers ervaringen – die daarom ook zo uitgebreid zijn beschreven – laten zien dat eiser door de afdeling oogheelkunde niet is geïnformeerd omtrent de toepassing bij hem van de MIRAgel plombe en de mogelijke complicaties daarvan – zoals in het Medas rapport ook wordt erkend.
Ook laten zij zien dat oogheelkunde hem in het geheel niet heeft gevolgd juist met het oog op deze complicaties, ondanks de herhaalde aanbevelingen in de medische literatuur.
Eisers medisch dossier bevat ook geen enkele verwijzing naar die complicaties.
Dat eiser herhaaldelijk werd gezien geschiedde steeds op zijn verzoek, niet op verzoek van oogheelkunde, en de controles vonden plaats vanwege eisers klachten, die veroorzaakt werden door het dubbelzien, welke klachten door prof. Deutman veel te laat werden onderkend.
Zo ook werden eisers klachten vanwege de MIRAgel plombe in 2003 niet onderkend en werd in november 2003 de uitstulping op het oog wel herkend als een gevolg van de operatie maar niet als signaal dat de plombe doende was te zwellen, uit te treden en dus ook naar binnen te zwellen (!) en te defragmenteren, met alle gevolgen van dien.
Bij het waarnemen van de uitstulping hadden als het ware alle alarmbellen tegelijk behoren af te gaan. In meerdere publicaties in de medische literatuur was immers bij herhaling en met klem geattendeerd op de noodzaak van vroegtijdige herkenning en verwijdering van de plombe om erger, namelijk de toenemende zwelling (tot wel 4 x zo groot) en defragmentering te voorkomen.
Ook de beslissing van prof. Keunen om de verdere ontwikkeling van de plombe maar aan te zien ("pappen en nathouden") wordt niet door de toenmaals bekende literatuur ondersteund. Uit diens

benadering blijkt ook een op niets gebaseerde optimistische inschatting, hetgeen treffend geïllustreerd wordt door zijn mededeling aan eiser 2 dagen na de gedeeltelijke verwijdering van de plombe dat hij niet meer behoefde terug te komen, terwijl 4 weken later een nieuw netvliesdefect ontstond, waarbij prof. Keunen zelfs naliet dadelijk adequaat te reageren op eisers klachten, terwijl eisers oog "aan het leeglopen was".
Eisers behandeling door de afdeling oogheelkunde van het ziekenhuis sluit volstrekt niet aan bij de benaderingswijzen die in de medische literatuur uit ervaring en proefondervindelijk bij herhaling en met klem werden aanbevolen.
Voor deze afwijkende behandeling wordt namens het ziekenhuis geen behoorlijke verklaring gegeven.

In dit verband is merkwaardig, inconsequent en tegenstrijdig dat het Medas rapport wel uit eisers medisch dossier aantekent:
"In november 2003 wordt wederom vermeld dat betrokkene last heeft van het rechteroog waarbij bij onderzoek gering promineren van de plombe wordt gezien. Er is hiervoor geen verdere behandeling ingezet."
maar vervolgens onder 'beschouwing' vermeldt:
"Pas in 2006 als de plombe een spontane protrusie vertoont door de conjunctiva, is operatieve behandeling geïndiceerd.".
Medas miskent dat al in november 2003 de 'spontane protrusie' van de plombe bij eiser waarneembaar was, ook al was die 'prominentie' gering !
De MIRAgel plombe was in 2003 al begonnen te zwellen en had in november 2003 dadelijk operatief verwijderd behoren te worden om verdere zwelling naar buiten en naar binnen in het oog met defragmentering van het materiaal te voorkomen, zoals toen al bij herhaling en met klem in de medische literatuur was aanbevolen.

Medas miskent ook dat de gevolgen van het uittreden van MIRAgel plombes wezenlijk verschillen van die van silicone plombes, namelijk het op lange termijn veranderen van chemische samenstelling, zwelling en defragmentatie met moeilijker operatieve verwijdering naarmate de zwelling en defragmentatie zijn toegenomen.

Reactie het ziekenhuis

Op 20 maart 2009 heeft eisers advocaat het eerste concept van de dagvaarding aan het ziekenhuis toegezonden. De advocaat van Achmea heeft een ruime termijn verzocht voor reactie teneinde een deskundige te kunnen raadplegen doch heeft uiteindelijk volstaan met handhaving van de betwisting van de aansprakelijkheid zonder nadere inhoudelijke onderbouwing.

VI. Causaal verband

Als gevolg van het operatief aanbrengen bij eiser van de MIRAgel plombe, het onthouden van de vereiste nazorg en controle alsmede het niet tijdig verwijderen van de plombe toen de complicaties

zichtbaar werden, is ernstige schade berokkend aan eisers oog, omdat de plombe is gaan zwellen en zowel uit het oog naar buiten is gekomen als het oog naar binnen is gedrongen met een nieuw netvliesdefect als gevolg.
Als gevolg van de zwelling van de plombe is hij in toenemende mate belemmerd geworden in de uitoefening van zijn beroep,
Als gevolg van de operatieve behandelingen hiervan is eisers gezichtsvermogen dusdanig aangetast dat hij sinds de operatie van 22 augustus 2006 100% arbeidsongeschikt is geworden voor het beroep van advocaat-belastingkundige. Sedertdien ontvangt hij van zijn particuliere arbeidsongeschiktheidsverzekeraar De Amersfoortse een 100% arbeidsongeschiktheidsuitkering, waarbij De Amersfoortse zich baseert op de medische informatie, die haar medisch adviseur heeft ingewonnen bij eisers behandelend oogspecialist Dr. Tilanus. In maart 2009 is eiser ook gezien door de verzekeringsarts van het Uwv, die vervolgens medische informatie heeft ingewonnen bij Dr. Tilanus. Op 11 juni 2009 heeft de arbeidsdeskundige van Uwv aan eiser meegedeeld dat in overleg met de verzekeringsarts besloten is eiser per 29 augustus 2006 (dit i.v.m. de wachttijd van 4 weken) in te delen in de arbeidsongeschiktheidsklasse 80-100%, hetgeen bevestigd bij beslissing van Uwv van 27 juni 2009.

VII. Schade

Materiële en immateriële schade

Als gevolg van het operatief aanbrengen bij eiser van de MIRAgel plombe zonder enig overleg met, zonder informatie aan eiser over de risico's die aan deze plombe waren verbonden en zonder eisers toestemming, het onthouden van de vereiste nazorg en controle alsmede het niet tijdig verwijderen van de plombe toen de complicaties zichtbaar werden, het door de plombe veroorzaakte nieuwe netvliesdefect, de operatieve ingrepen en het als gevolg van een en ander ernstig verminderd en aangetast gezichtsvermogen heeft eiser schade geleden, lijdt hij schade en zal hij schade lijden, zowel materieel, in het bijzonder die van gederfde winst en inkomen, als immaterieel, het jarenlang ondervonden ongemak en het ernstig verlies aan gezichtsvermogen.
Eiser was van september 1994 tot 15 april 2007 als fiscaal advocaat verbonden aan het Arnhemse kantoor van CMS Derks Star Busmann. Per 16 april 2007 heeft hij een samenwerkingsovereenkomst met Jaegers & Soons advocaten-belastingkundigen te Nijmegen, aan welk kantoor hij voor zover mogelijk zijn praktijk heeft overgedragen. Deze samenwerkingsovereenkomst is aangegaan in de verwachting dat eiser nog parttime werkzaam zou kunnen zijn en loopt tot 1 april 2010.
In de periode 2001/2003 behaalde hij een gemiddelde bruto jaarwinst van ruim € 16. ...,-. Deze winst is geleidelijk aan verminderd en inmiddels nagenoeg weggevallen.
Ook medisch gezien is nog geen eindtoestand bereikt. Eisers rechteroog gaat langzaam verder achteruit.
Op dit moment is het nog te vroeg om eisers schade definitief vast te stellen en/of te begroten.

Wettelijke rente.
Eiser maakt aanspraak op vergoeding van de wettelijke rente over de hoofdsom en het smartengeld, te rekenen vanaf de datum van verschijning van de schade tot aan de dag van algehele voldoening.

VIII. Bewijsmiddelen

Eiser levert het bewijs van zijn stellingen door het overleggen van de volgende producties, die aan deze dagvaarding zijn gehecht en daarvan deel uit maken..

1. het operatieverslag van 6 juli 1992
2. de aantekening van 13 november 2003 in eisers medisch dossier
3. het operatieverslag van 20 september 2006;

en de hiervoor aangehaalde artikelen (in volgorde van citering)

4. Lane ea, Imaging of Hydrogel Episcleral Buckle Fragmentation as a Late Complication After Retina! Reattachment Surgery, AJNR Am J Neuroradio/ 2001;22:1199-1202.
5. Marin ea, Long term complications of the MAI hydrogel intrascleral buckling implant, Arch Ophthalmol 1992;110:86-8 met weerwoord van Randy Hasslinger, director of Research and Development at MIRA Inc., Waltham, Mass. en reactie van Marin ea
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9. Braunstein ea, Complications of Miragel: Pseudotumor, Arch Ophthalmol 2002;120:228-229.
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11. Oshitari ea, Long-term complications of hydrogel buckles, Retina 2003;23:257-61
12. Le Rouic ea, Late swelling and removal of miragel buckles: a comparison with silicone indentations. Retina 2003;23:641-6.
13. Li ea, Miragel explant fragmentation 10 years after scleral buckling surgery, *Eye* (2003) 17, 248–250.
14. Metz ea, Late-onset progressive strabismus associated with a hydrogel scleral buckle, J AAPOS 2004;8:72-3.
15. Chung ea, Diplopia and periorbital mass associated with Miragel buckling explant, Korean J Ophthalmol. 2004 Jun; 18(1):47-51
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17. Shields ea, Expanding MIRAgel Scleral Buckle Simulating an Orbital Tumor in Four Cases, Ophthal Plast Reconstructive Surg.;2005,Jan; 21(1),32-34

18. Roldan-Pallares ea, Hydrolytic Degradation and Long-term Observations, Arch Ophthalmol 2007; Vol. 125 No.4
19. NOG 2009 programmaboekje blz.115
20. NOG 2009 programmaboekje blz. 158
21. PowerPoint-presentatie Crama, Tilanus en Klevering

EIS:

MITSDIEN het de rechtbank behage bij vonnis, voorzover mogelijk, uitvoerbaar bij voorraad, gedaagde c.q. het ziekenhuis te veroordelen tot vergoeding van alle materiële en immateriële schade die eiser heeft geleden, lijdt en nog zal lijden die veroorzaakt is door de op 6 juli 1992 bij hem in zijn rechteroog aangebrachte en uiteindelijk zowel zijn oog in- als uitgezwollen zijnde en een netvliesdefect veroorzaakt hebbende MIRAgel plombe, welke schade nader dient te worden opgemaakt bij staat en te vereffenen als naar de wet, verhoogd met de wettelijke rente tot aan de dag der algehele voldoening. Een en ander met veroordeling van gedaagde c.q. het ziekenhuis in de kosten van het geding.

De kosten voor mij, deurwaarder, zijn: € 85,98

Het berekende schuldenaarstarief is verhoogd met het tarief van de omzetbelasting, nu eiser(es) de omzetbelasting niet kan verrekenen in de zin van de Wet op de Omzetbelasting 1968 en zulks nadrukkelijk verklaart.

(t.k.) gerechtsdeurwaarder

PRODUCTIE 1

OPERATIE-VERSLAG

J. SASSEN 9152815 A
160944 M PARTIKULIER
BEEKMANSDALSEWG 1 NYMEGEN 080-226915
E. MANUELS Cro 080-552339
16 DEUTMAN ~~P886~~ 6522 KC

datum operatie 6-7-92

OOGHEELKUNDE

diagnose **ABLATIO RETINAE OD**

indicatie (in te vullen door kliniek) cerclage, punctie, explant/plombe, cryo OD

~~Neuesine~~, chlooramfenicol 0,25%, indoptol, fenylefrine 5%, mydriaticum, atropine OD

oogheelkundige voorbereiding

operatie Cerclage, Cryopexy, Radiële plombage

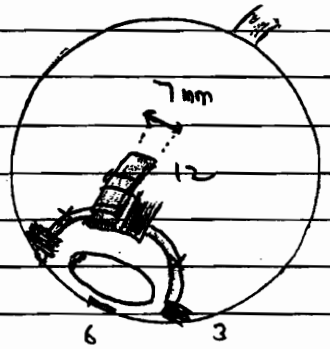
duur

operateur prof Deutman assistent Yes

narcose algeheel operatiezuster

door

VERSLAG OD-OS



1) 360° Peritomy
2) 4 recti isolated
3) 240 band inserted
4) Cryopexy
5) 7 mm radial incised + secured
6) Conjunctival closed ē 160 nylon
7) Optic disc pink + end
& operation - details normal.

opmerkingen - Atropine
- Softacon

nabehandeling - Maxitrol 4x
- Atropine 2x
} OD

hechtingen verwijderen op

SINT RADBOUDZIEKENHUIS NIJMEGEN

16mr28@657 A

PRODUCTIE 2

ZIEKTEBELOOP (poliklinisch)

afd. blad

datum en naam van de arts	
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	Cl.
02.10.03	A/ Tranen OD. In de loop v.d. dag af en toe een traan. Belemmerend voor het zien.
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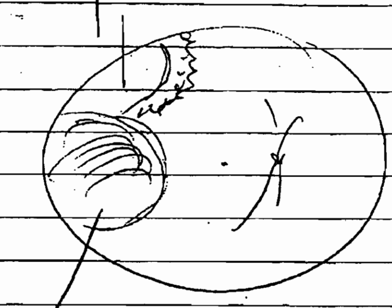
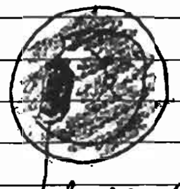
	AOD: AOS:
	ØOD: helder ØOS:
	OD: aanliggend OS: aanliggend.
	→ ? maakt zich zorgen. blepharitis, conjunctivitis ? Neen. Villey! ⊕
	→ ~~[illegible]~~
13.11.03 ØEBO	ORTHOPTIE A/ Subj zicht loopt achteruit door toename byziendheid.
	VOD ec = } zie. 2.10.03.
	VOS ec = }
	30cm. +Δ + tort: ⊕
	+Δ ztort: ⊕ + kl R hyperforie
	SC ztort: R/L
	oogb nr abd bep. OD.
	nL gb. (lidspleet OD<OS)
	nT moeizaam
	nL↑ zelfs R/R.
	n↑n↓ Veoo.
	n↓ >> R/L.
	conv goed.
	wing mgl +Δ: Ø 7ΔRH
NP protes:	Last van tranen OD.
	O/ [illegible] prominentie explant temp boven OD [illegible].
	Angel ⊕ na spuiten.
	Ø OD traanfilm valt 1mm droog

PRODUCTIE 3

datum en naam van de arts	
19-9-6 vos kunnen	plombe + laser
	USG
	OD
	
	A) Sinds 2 dgn vlekken OD
	bolle mobiele ablatio macula aan
CMN AF	
	VOD +chl + myd + St: 0,10
	ATOP: 4
	∅ OD: [illegible]
	∅ OD:
	
	bolle blaas def (–)
	c/ Hoog myoop OD eigen lens abl. ret OD na plombe deels uit hypotonie.
10M.	**Vitrectomie** OD OS (OD circled) — gas ([illegible])
	AN: Tobrexzalf
	oxybuprocaïne, fenylefrine 5% (max 1 drp per keer), tropicamide, acular, atropine 1%, gentamytrex, povidon-jood 5% — [illegible] [illegible] [illegible]
20/9/2006	BIOMETRIE Printer defect. Verslag wordt ingescand.
	Voorbereiding [illegible]. Vitrectomie [illegible] te [illegible] [illegible]. [illegible] [illegible] [illegible] zichtbaar. [illegible] [illegible] [illegible] defect [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] defect [illegible] gelaten. [illegible] [illegible] te plaatsen [illegible] [illegible]. [illegible] 4x Cadg[illegible] [illegible] 4x

IN dossier

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Hoofd Prof. dr J.E.E. Keunen

Dagsupervisie polikliniek
T (024) 361 51 04

Datum 21-09-06

Betreft patiënt Sassen
M
16-09-44

Geachte collega,

Dit is een voorlopige brief, bedoeld om u snel te informeren over een oogheelkundige operatie bij uw bovengenoemde patiënt(e).
Op 20-09-06 vond een vitreoretinale ingreep plaats bij deze patiënt(e) vanwege: ablatio retinae (recidief) van het rechter oog. Deze vitreoretinale ingreep vond plaats onder locale anesthesie.

De volgende operatieve handelingen werden verricht:

- Pars plana vitrectomie

Endolaser: rond defect(en) en periferie (≤180°)
Tamponade: siliconenolie 5000

Bijzonderheden: Op10 uur ver perifeer klein defect en siliconen-materiaal dat subretinaal ligt. Niet verwijderd gezien gevaar groot scleradefect. Terughoudend met olie uit.

Postoperatieve medicatie OD: Tobradex 4 dd en atropine 1% 1 dd

Patiënt(e) zal worden gecontroleerd op onze (poli)kliniek.

Met collegiale hoogachting,

Dr M.A.D. Tilanus

Chef de policlinique
Dr. B.J. Klevering 361 51 04
Chef de clinique
Dr. M.A.D. Tilanus 361 44 48

Stafleden
Prof.dr.J.R.M. Cruysberg 361 44 48
Dr. C.B. Hoyng 361 44 48
Dr B.J. Klevering 361 44 48

Dr. T. Theelen 361 44 48
Dr. D.F. Schaling 361 44 48

Mol. Celbiologisch Lab
Dr. J.J.M. Janssen 361 44 51
Beheer
J.C. Hennink 361 51 05

Patient

Naam: Sassen
M/V: M
Geb. dat.: 16-09-44
Reg. nr.: 9152815

OPERATIEVERSLAG 20-09-06

ablatio retinae (recidief) OD

Algemeen

Operateur: Dr M.A.D. Tilanus
Arts-assistent: Dr S.L. Go
Operatieduur: 60 minuten
Anesthesie: locaal

Intraoculaire handelingen

- Pars plana vitrectomie

- Kleurstof: triamcinolon
- Perfluorcarbon: DK-line
- Endolaser: rond defect(en) en periferie (≤180°)

Observaties

PVR graad: B

- Tamponade: siliconenolie 5000

Bijzonderheden: *Op10 uur ver perifeer klein defect en siliconen-materiaal dat subretinaal ligt. Niet verwijderd gezien gevaar groot scleradefect. Terughoudend met olie uit.*

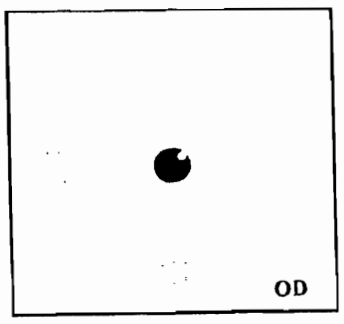
Tekeningen

Preoperatief

OD

Postoperatief

OD



Postoperatief beleid

Medicatie OD: Tobradex 4 dd en atropine 1% 1 dd
Houding: geen

Controle: 1 dag

PRODUCTIE 4

AJNR Am J Neuroradiol 22:1199–1202, June/July 2001

Case Report

Imaging of Hydrogel Episcleral Buckle Fragmentation as a Late Complication After Retinal Reattachment Surgery

John I. Lane, James G. Randall, Norbert G. Campeau, Paul K. Overland, Colin A. McCannel, and Thomas A. Matsko

Summary: Hydrogel encircling bands were introduced in the early 1980s as a product that was superior to bands composed of silicone rubber or silicone sponge for the surgical treatment of retinal detachment. Late complications consisting of orbital swelling and diplopia requiring band removal began to be reported in the early 1990s. Pathologic studies of these expanded fragments of hydrogel material after removal showed in vivo hydrolysis with foreign body reaction and dystrophic calcification. We report the imaging findings in five patients in whom this late complication developed. Hydrogel fragmentation has a characteristic imaging appearance consisting of a circumferential orbital mass associated with rim enhancement. This appearance should prompt inquiries regarding previous scleral buckle procedures with hydrogel bands. Familiarity with this appearance will avoid misinterpretation and unwarranted biopsy before band removal.

One of the objectives of retinal reattachment surgery is to relieve significant vitreous traction on the detached retina by indenting the sclera (buckling) to mechanically support the areas under traction. Silicone rubber bands are commonly placed circumferentially around the episcleral surface of the globe with grooved pieces of silicone rubber or sponge placed beneath the band, if necessary, to achieve a buckle of greater height.

Episcleral bands composed of MAI, a hydrophilic polymer (copoly[methyl acrylate-2-hydroxyethyl acrylate]) cross-linked with ethylene diacrylate, were introduced in the early 1980s as a superior product to bands composed of solid silicone rubber or silicone sponges for producing scleral buckles (1, 2). The softness and elasticity of this hydrogel substance were thought to guard against the scleral erosions occasionally seen with solid silicone rubber. As with silicone sponge, this gelatinlike polymer had the ability to absorb antibiotics; however, unlike sponge, its inherent lack of dead space theoretically made it less prone to infection. Enthusiasm over its use began to wane in the early 1990s owing to the unanticipated instability of the product in vivo (3, 4). An increasing number of reports of swelling and fragmentation of this buckling material, producing orbital discomfort and diplopia 7 to 10 years after implantation, led to its discontinuation in 1995. We report the imaging features of this late complication in five patients treated for retinal detachment with scleral buckle procedures using MIRAgel (Mira, Waltham, MA) encircling bands.

Received November 9, 2000; accepted after revision February 9, 2001.

From the Departments of Radiology (J.I.L., N.G.C.) and Ophthalmology (C.A.M.), Mayo Clinic, Rochester, MN; and the Rocky Mountain Eye and Ear Center, Missoula, MT (J.G.R., P.K.O.); and Opthalmology (T.H.M.), Great Falls, MT.

Address reprint requests to John I. Lane, MD, Department of Radiology, Mayo Clinic, Rochester, MN 55905.

Case Reports

Imaging was performed in five patients with diplopia and orbital discomfort as part of an orbital mass workup between April 1998 and October 1999. All patients had originally undergone procedures between 1987 and 1990 for rhegmatogenous retinal detachment using a MIRAgel encircling band sutured to the sclera in all four quadrants with satisfactory apposition of the detached retina flap. Imaging studies were obtained before band removal. Demographic and clinical data pertaining to these five patients are presented in the Table 1. At the time of presentation, clinical examination showed restricted eye motion associated with varying degrees of extrusion of the buckle beneath the upper or lower lid ipsilaterally (Fig 1A). Intraoperative descriptions of the buckle material consistently noted fragmentation of the buckle material, which was often encased by granulation tissue, making complete removal of the hydrogel band difficult. In case 2, the surgeon elected to leave a portion of the implant behind to avoid an increased risk of globe rupture. Pathologic samples were limited to the fragmented buckle in four of five patients (Fig 1B). One patient (case 1) had undergone a biopsy before removal to exclude orbital tumor suggested by the radiologist. The specimen showed foreign body reaction and dystrophic calcification. Cultures were negative in all cases.

Imaging features of the hydrolyzed bands are listed in the Table. All four patients who underwent MR imaging were studied on 1.5-T scanners. MR examinations were performed as dedicated orbital studies to include axial and coronal T1-weighted (500/15/1 [TR/TE/excitation]) and T2-weighted (2000/80/1) sequences, with contrast-enhanced T1-weighted studies obtained in three of the patients. All examinations showed a lobulated, circumferential mass encircling the globe. Thin-section, high-resolution CT scans in the axial and coronal planes were obtained in three of the five patients. In cases 2 and 3, CT scans showed chunklike areas of calcification within the mass (Fig 2). Additionally, in case 1, there was evidence of calcification within the pathologic specimen, which corresponded to focal areas of hypointensity on MR images (CT was not obtained in this case). In all patients for whom MR studies were available, there was an identical appearance of a markedly expanded buckle that was isointense with muscle on T1-weighted images and hyperintense on T2-weighted images (Figs 3 and 4). Contrast-enhanced images, which were avail-

Hydrogel fragmentation: clinical and imaging data

Case No.	Age (y)/Sex	Interval between Surgery and Presentation	Presenting Symptoms	CT Findings	MR Findings	Surgical Findings	Pathologic Findings
1	62/M	9	Progressive orbital swelling, restricted gaze, O.S.	NA	T2 hyperintense; T1 isointense; peripherally enhancing	Expanded, fragmented buckle material partially adherent to episcleral tissue	Fibrosis with calcification, foreign body reaction (biopsy)
2	71/F	10	Swelling beneath upper lid, O.S.	Circumferential soft tissue mass surrounding globe, partially calcified	T2 hyperintense; T1 isointense; peripherally enhancing	Expanded, fragmented buckle material, partially removed	Multiple elongated segments of rubbery, white synthetic material (gross only)
3	60/F	7	Diplopia, pressure, and pain, O.D.	Circumferential soft tissue mass surrounding globe, partially calcified	NA	Expanded, fragmented buckle material	Multiple elongated segments of rubber, white synthetic material (gross only)
4	67/F	8	Pain and orbital pressure, restricted motion, O.S.	NA	T2 hyperintense; T1 isointense	Expanded, fragmented buckle material	Multiple elongated segments of rubbery, white synthetic material (gross only)
5	67/F	8	Intermittent diplopia	Circumferential soft tissue mass surrounding globe	T2 hyperintense; T1 isointense; peripherally enhancing	Expanded, fragmented buckle material	Multiple elongated segments of rubber, white synthetic material (gross only)

Note.—O.S. indicates left eye; O.D., right eye; NA, not applicable.

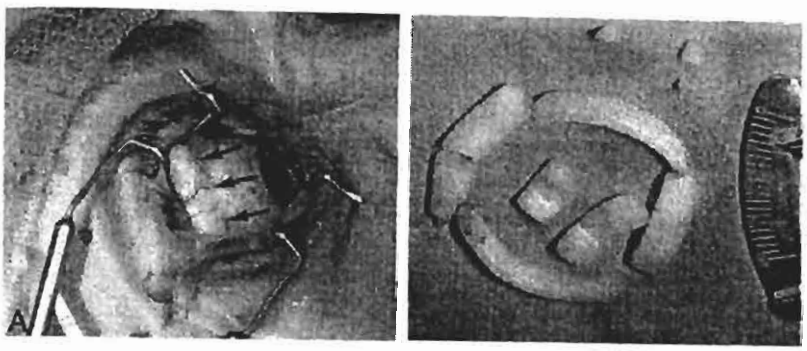


FIG 1. Case 4. *A*, Intraoperative photograph shows extruded, swollen band surrounding right eye (*arrows*). *B*, Surgical specimen shows expanded fragments of the hydrolyzed buckle material.

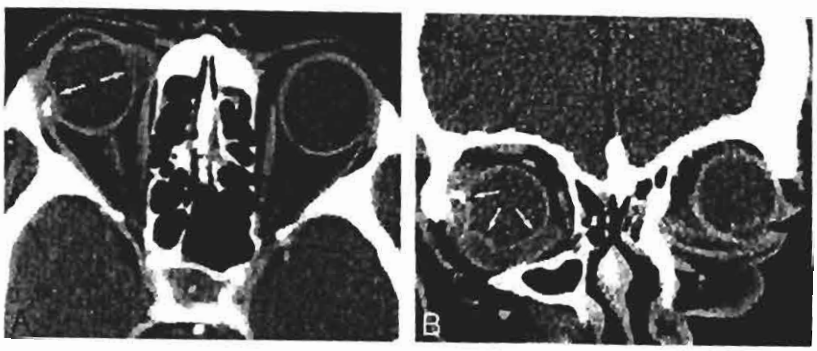


FIG 2. Case 3. *A* and *B*, Contrast-enhanced axial (*A*) and coronal (*B*) CT scans show circumferential soft tissue mass surrounding the globe with focal, dystrophic calcification and a peripherally enhancing rim (*arrows*).

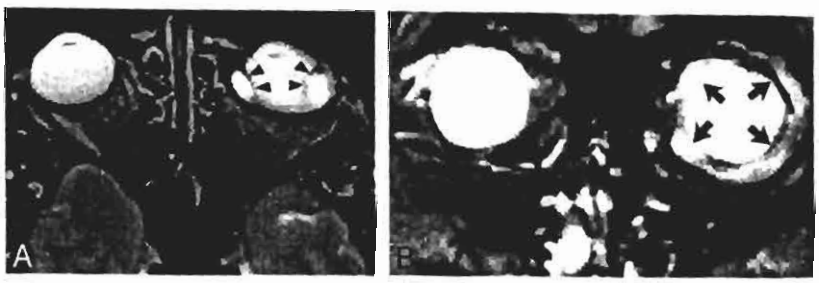


FIG 3. *A* and *B*, T2-weighted axial (*A*, case 2) and coronal (*B*, case 4) MR images (2000/80/1) show circumferential, hyperintense mass (*arrowheads, arrows*) surrounding the globe. Increased T2 signal reflects increased water content and swelling of hydrolyzed buckle material.

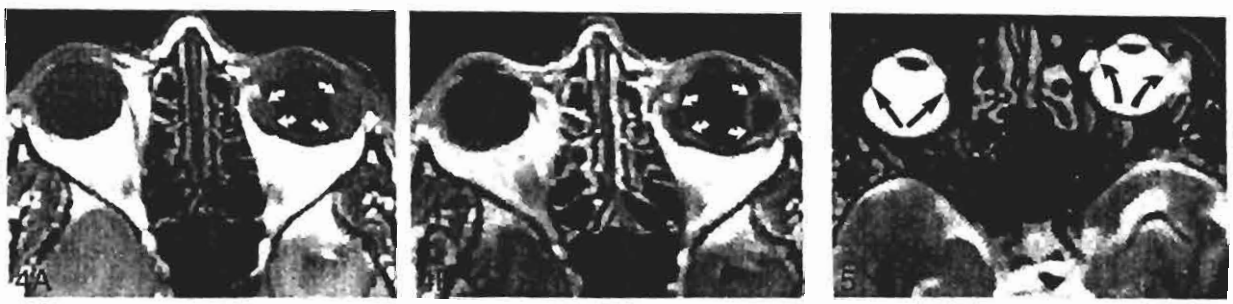


FIG 4. Case 2.

A and *B*, Noncontrast (*A*) and contrast-enhanced (*B*) T1-weighted axial images (500/15/1) show soft tissue mass isointense with muscle, with peripheral rim of enhancement (*arrows*) corresponding to thick, fibrous capsule and foreign body reaction seen at pathologic examination.

FIG 5. Case 1. T2-weighted axial image (2000/80/1) shows normal profile of an uncomplicated encircling silicone band in the right orbit (*straight arrows*) as compared with hydrolyzed, fragmented hydrogel buckle in the left orbit (*curved arrows*). An uncomplicated hydrogel band would be expected to have a similar profile to that of the silicone band.

able in three of the four patients examined with MR imaging and in two of the three patients examined with CT, exhibited a characteristic pattern of rim enhancement (Figs 2B and 4B). One patient (case 5) had previously undergone an uncomplicated scleral buckle procedure using a silicone rubber band involving the contralateral globe 1 year before the ipsilateral procedure in which the hydrogel band was used. Comparison with the uncomplicated globe underscored the marked swelling of the hydrogel band, which initially had an identical profile to that of the silicone band (Fig 5).

Discussion

Complications arising from scleral buckle procedures, which include postoperative extrusion or infection of the buckle material, have been reported to develop in 1.3% to 24.4% of patients (5–8). Although the literature contains several descriptions of the radiologic appearance of surgical materials used in scleral buckle procedures (9–11), to our knowledge this is the first report of the CT or MR appearance of orbital complications following use of these materials. All cases involved procedures in which the buckle was produced using a MIRAgel encircling band. MIRAgel and its precursor, MAI, are hydrophilic polymers that are permeable to water and other low molecular weight hydrophilic substances. The polymer is copoly(methyl acrylate-2-hydroxyethyl acrylate) cross-linked with ethylene diacrylate. It is softer than silicone rubber and therefore presumably less likely to produce scleral erosion or extrusion. It was initially thought that its ability to absorb and slowly release water-soluble antibiotics would lead to a reduction in infectious complications, offering an advantage over silicone sponges. Early reports supported these assumptions (1, 2). However, long-term follow-up studies (7–11 years) began to reveal complications ranging from bulging to intraocular erosion and migration of the buckle (3, 4, 8). At surgery, the fragmented bands were described as translucent, gellike, and friable. Surgical removal was complicated by a thick, fibrous capsule, which often fixed the swollen implant to Tenon's capsule, limiting the mobility of the globe. Removal of the fragmented implant in its entirety required meticulous technique but provided substantial relief of ocular discomfort and improved mobility, with a low risk of recurrent retinal detachment (12). Infrared spectroscopic analysis of recovered buckle fragments showed chemical alteration of the polymer, with hydrolytic degradation and swelling (3). The chemical alteration in vivo allowed the hydrogel to absorb more water. The implant changed from soft, spongy, opaque, and compact to friable, gellike, and translucent. The MIRAgel product was taken off the market in 1995 subsequent to these reports (personal communication, MIRA, Waltham, MA).

The appearance on imaging studies correlates well with the surgical and pathologic findings, reflecting the increase in its state of hydration. The T2 signal characteristics of the encircling band are consistent with the swelling and expansion of the buckle material observed intraoperatively with a marked increase in volume and T2 signal intensity. Previously published pathologic reports have described a surrounding fibrous capsule that corresponds to the enhancing rim observed in those patients who received contrast material (4). CT findings in cases 2 and 3 confirmed previously reported histologic evidence of calcification associated with changes of chronic inflammation documented in pathologic reports (13). The surgical and pathologic observations in case 1 were notable for dystrophic calcification as well, but were not clearly detectable on MR studies.

The observation of a ringlike soft tissue mass encircling the globe, which is isointense with vitreous on T2-weighted images, isointense with muscle on T1-weighted images, and shows rim enhancement, should prompt inquiries into the patient's previous surgical history. Dystrophic calcification is best delineated by CT. Documentation of the exact construct of the buckle material should be obtained from the treating ophthalmologist. Differential diagnostic considerations would include orbital abscess, but the circumferential morphology would be unusual, as would the lack of other clinical manifestations, such as fistula formation. An infiltrative orbital neoplasm, such as lymphoma, might also be considered in the absence of a relevant surgical history, but the T2 signal characteristics, ring enhancement, and the presence of dystrophic calcification would be inconsistent with this diagnosis. A complete surgical history, however, will aid in arriving at the correct diagnosis. Recognition of this characteristic appearance will help avoid unnecessary biopsy. Although the hydrogel product was pulled off the market in 1995, presentations of this late complication may occur for several years to come.

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PRODUCTIE 5

Long-term Complications of the MAI Hydrogel Intrascleral Buckling Implant

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• **Seven cases in which long-term complications developed from swelling of the MAI 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 MAI implant, may require similar precautions.**

***(Arch Ophtha/mo/.* 1992;110:86-88)**

The MAI implant, also known as the Refojo implant, is a synthetic, hydrophilic scleral buckling material introduced in the late 1970s.[1,2] MAI 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 MAI 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.

Accepted for publication May 20, 1991.

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REPORT OF CASES

MAI Implants as a Primary Intrascleral Buckle

CASE I.-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 MAI 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.

MAI 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 MAI 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 MAI 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 MAI 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.

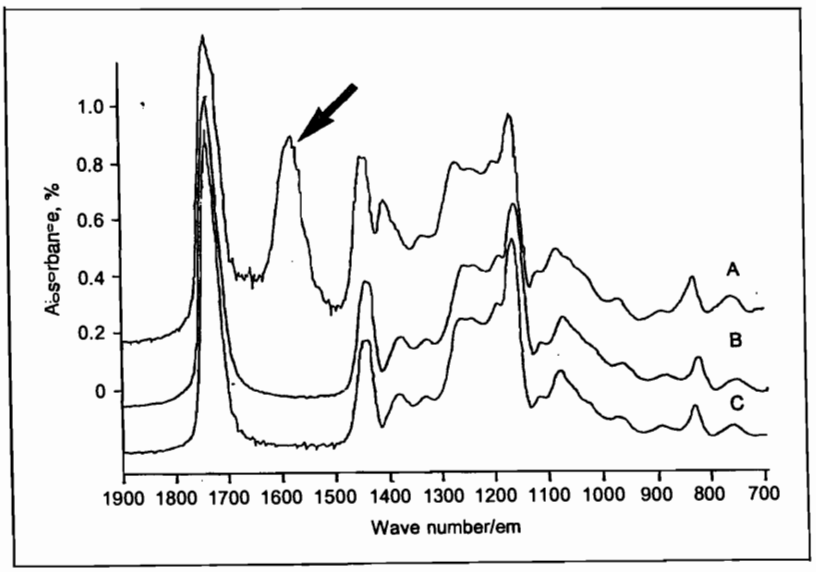
The patient was unavailable for follow-up for 10 years and returned because of an eroding buckle. On examination, visual acuity was counting fingers. Indirect ophthalmoscopy revealed a prominent inferior subretinal implant obscming the disc as well as a superiorly eroding buckle. The eroding inferior 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. lDtrasonography 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 MAI 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 MAI 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 MAI implant samples, The analysis involved using an infrared (IR) detector to

yield an IR spectrum dependent on the atomic composition, structure, and thickness of a given sample. With this technique, the MAI 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 IR spectrographic recordings among the retention stock samples of MIRAgel and MAI 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 MAI 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 MAI 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 MAI 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[8]; 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.s 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[5] erosion is sometimes observed under episcleral silicone sponges held in place by scleral sutures. Because of the physical properties of the MAI 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 MAI 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.

This study was supported in part by the Emily Bishara Hatem Ophthalmic Research Fund (Dr 'Iblentino) and NIH grant EY00327 (Dr Refojo).

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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Correspondence

Long-term Complications ofthe MAl HydrogelIntrascleral Buckling Implant

To the Editor.-We at MIRA Inc, Waltham, Mass, have had the opportunity to support the investigation ofMAl hydrogel implants described in this issue of the ARCHIVES.[1] We performed the micro-Fourier transform infrared spectroscopic analysis that compared the clinical specimen from case 3 with production lots ofhydrogel implants of different ages.

See also p 86.

The spectroscopic analysis revealed that the clinical specimen had a polymeric structure significantly different from that of the production lots, but this does not imply that the clinical specimen degraded in vivo. The clinical specimen was synthesized from a laboratory batch process that predated the production lots. These laboratory batches were experimental and !mown to contain variable levels of components that would account for the differences described by the spectra. Polymers most resistant to degradation are prepared with careful control for extent of polymerization, level of impurities, and ratio of components. Furthermore, a hydrogel sample from the same laboratory batch was not available to serve as a control in the analysis. The original structure of the clinical specimen could not be confirmed.

To date, there have been no patients with MIRAgel implants who have developed the complications described in the report by Marin et al. MIRAgel continues to be manufactured according to good manufacturing practice guidelines for strict formulation and processing controls.

MIRA Inc concurs with the authors for lifetime annual follow-up of scleral buckling procedures regardless of tbe buckle material used.

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Mr Hasslinger is the director of Research and Development at MIRA Inc, Waltham, Mass.

1. Marin JF, Thlentino Fl, Refojo MF, Schepens CL. Long-term complications of the MAl hydrogel intrascleral buckling implant. *Arch Ophthalmol.* 1992;86-88.

In Reply.-We concur with Mr Hasslinger that because we were unable to obtain unused MAl polymer implants of the same vintage as the polymer implants retrieved from the patients, we cannot be sure that the hydrolysis observed in the retrieved implants was not a phenomenon characteristic ofthese early MAl samples. The polymer implants retrieved from the patients were made before MIRA Inc obtained the license from the Eye Research Institute to make MIRAgel. However, MAl polymer, made by the same procedure as the retrieved implants, and the currently available MIRAgel implants have the same chemical composition, as is demonstrated by the identical micro-Fourier transform infrared spectra.

In fact, there are no data available to us to support Mr Hasslinger's remark that the early MAl "laboratory batches were experimental and !mown to contain variable levels of components that would account for the differences described by the spectra." Sterile MAl implants stored in saline solution in the laboratory for several years maintained their original hydration and chemical structure. The changes were only observed in retrieved intrasc leral MAl implants.

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Corneal Welding Using Hydrogen Fluoride Lasers

To the Editol:-Welding, or fusion, of tissues using laser energy was first described by Jain and Gorisch.[1,2] The process involves some heat rise and apparently involves dissociation and reassociation of collagen fibrils without causing complete protein denaturation. Attempts to weld corneal or other ocular tissues have not met with success to date.[3,4]

We report the fusion of corneal stroma in porcine cadaver eyes using two special wavelengths of the laser. The fusion occurred without the use of adhesional or accessory proteins and exhibited mechanical strength dependent on the depth of the fusion. Scleral tissue was also welded, although without the high degree of strength demonstrated by a corneal weld. To our !mowledge, this is the first report of welding in corneal or scleral tissue in which significant mechanical strength was exhibited.

Porcine eyes were obtained within 6 hours of slaughter. Epithelium was debrided by scraping it with a Bard-Parker surgical blade. A full-thic!mess incision was made in a 7-mm arc directly across the central cornea for experimental purposes.

Helios continuous-wave hydrogen fluoride (HF) chemical lasers were used to produce the welds. One wavelength was the HF fundamental10P2 vibrational rotational transition at 2.5788 μm and 30 mW. The other wavelength was the HF overtone 20P6 vibrational rotational transition at 1.3404 μm and 320 mW.[5] The welding spot size was 0.2 mm in diameter, and was moved at a rate of 1 mm per minute across the incision. The entire incision was closed in 7 minutes, forming a leakproof seal. The HF fundamental laser produced a weld that was visible as a thin line of approximately 100 μm in depth from the surface of the cornea, while the HF overtone laser produced a weld that was much deeper, approximately 300 μm.

The welded globes were slowly filled and pressurized with

PRODUCTIE 6

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.

Accepted for publication July 22, 2003.
InternetAdvance publication at ajo.com July 23, 2003.
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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

0002-9394/04/$30.00
doi:10.1016/S0002-9394(03)00873-0

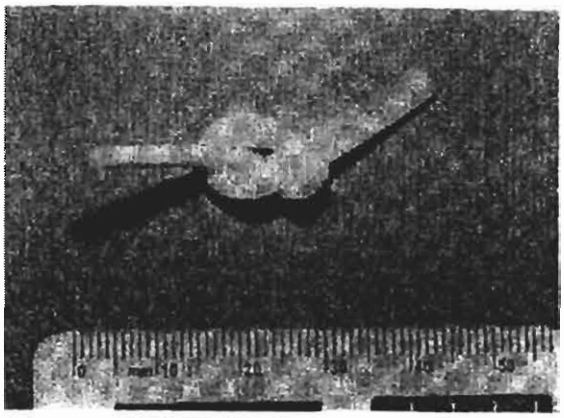

FIGURE 1. An oval hydrogel explant. Note that it appears soft and pliable.

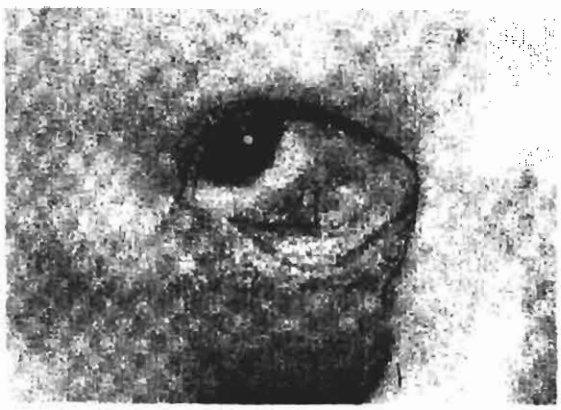

FIGURE 2. Right eye of patient with visible subconjunctival mass, resembling an inclusion cyst.

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.

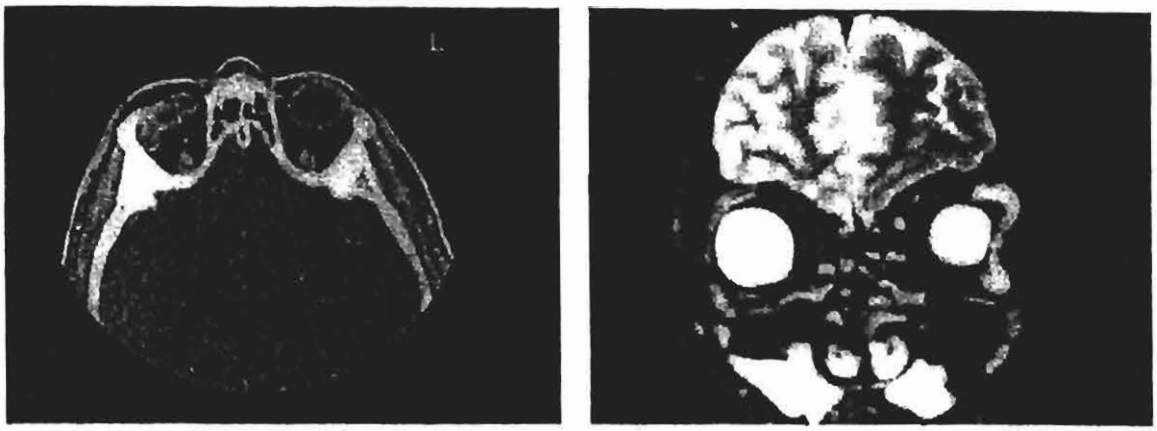

FIGURE 5. (Left panel) Computed tomography scan showing a hydrogel explant in the anterior orbit of the right eye. (Right panel) Magnetic resonance image of the left orbit shows an expanded hydrogel explant.

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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PRODUCTIE 7

Cyclodialysis occurred in our patient because the implant was apparently placed unintentionally into the supraciliary space. This maneuver disinserted the ciliary body from the scleral spur in a fashion similar to that performed intentionally in the past using a spatula for the treatment of glaucoma. The internal pars plana incision may have been smaller than its external scleral counterpart and contributed to the capture of the implant by the pars plana epithelium. To possibly prevent this complication, care must be made to ensure that the pars plana incision is as long as the external scleral incision. The wound can be slightly gaped to confirm this. In addition, the implant should fit easily into the wound with minimal resistance. If unusual resistance is encountered, the wound should be reevaluated.

Our patient had no adverse consequences from the cyclodialysis cleft. This may be owing to the mechanism in which the cleft was formed and its anatomy. The full-thickness incision of the pars plana with subsequent inflammation and healing may have caused the cleft to be nonfunctional. Cyclodialysis formation, although rare, is a complication that can occur with the placement of a ganciclovir implant.

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This work was supported in part by an unrestricted grant from Research to Prevent Blindness Inc, New York, NY

The authors do not have a financial interest in any device or technique described in this report.

Dr *Lewis is a Heed Foundation Fellow for 1996-1997.*

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Hydrogel Exoplant Fragmentation 10 Years After Scleral Buckling Surgery

Materials used for scleral buckling procedures in retinal detachment repair have evolved from absorbable tissues, including autogenous fascia lata and cadaveric sclera or dura mater, to nonabsorbable synthetic agents such as polyethylene tubing, solid silicone rubber, silicone sponges, and hydrogels. Hydrogels are hydrophilic materials formed from 3-dimensional polymer networks. The most widely used hydrogel is co-poly(methylacrylate-2-hydroxyethyl acrylate), or MIRAgel (MIRA, Waltham, Mass). The forerunner of MIRAgel, MA1, has the same chemical composition. Hydrogels are permeable to water and low-molecular-weight hydrophilic substances. Their ability to absorb and then slowly release water-soluble antibiotics offers an advantage over silicone. Ho et al[1] reported that the MA1 implant was as effective a buckling element as either solid silicone rubber or silicone sponge. He noted that the degree of swelling of the exoplant could be altered by varying its state of hydration, its softness and elasticity were protective against erosion, and it was less prone to infection because of its lack of dead spaces and its ability to absorb, then gradually release antibiotics.

The apparent effectiveness and safety of MA1 hydrogel scleral exoplants was reported by Tolentino et al[2] who followed up 82 eyes of 79 patients for 6 to 53 months and found no complications of buckle extrusion, erosion, or infection. However, with longer follow-up of 7 to 11 years, 7 complications of MAr exoplants were documented by Marin and colleagues[3] Clinical manifestations ranged from benign subconjunctival bulging to intraocular erosion and migration of the exoplant. At the time of surgery, the exoplants were seen to be translucent, gel-like, and friable. Erosion into the vitreous cavity occurred in 1 case and was complicated by difficulty grasping the friable buckle material. Micro-Fourier transform infrared spectroscopic analysis of 2 recovered implants demonstrated hydrolytic degradation of the implant leading to swelling significantly greater than the original polymer. We report the first case, to our knowledge, of scleral buckle extrusion and fragmentation associated with a MIRAgel episcleral exoplant.

Report of a Case. A 53-year-old man with high myopia was referred in August 1996 for evaluation of an extruding scleral buckle in the right lower eyelid. In 1986, he had undergone a scleral buckling procedure for a macula-on rhegmatogenous retinal detachment of the right eye. The patient had undergone placement of an encircling 4-mm MIRAgel buckle with a radial silicone sponge at the 10-o'clock position. The retina was attached postoperatively. However, limitation of adduction and infraduction in the right eye developed in 1988 and progressively worsened over time. In 1996, the patient was referred because of significant discomfort and diplopia on primary gaze and downgaze.

On presentation, his visual acuity was *20/20* OD Motility examination findings revealed complete loss of adduction and infraduction, and mild limitation of supraduction in the right eye. The scleral buckle was easily palpable through the right lower eyelid. Indirect ophthalmoscopy of the right eye revealed cryotherapy scars superotemporally, the retinal break well-supported on a high scleral buckle. The patient was informed of the risk for postoperative retinal redetachment, but chose to proceed with surgery to remove the buckle.

At the time of removal of the scleral buckle, the MIRAgel buckle material was partially encapsulated, extremely friable, and fragmented. Prior to any manipulation, the exoplant was seen to be severed at points of contact with the residual scleral buckling sutures. Frag-

Fragments of hydrogel scleral buckle material removed from orbit.

ments of the MIRAgel buckle were lodged within the incomplete fibrous capsule and within the Tenon capsule. Careful inspection was required to ensure that all fragments were removed from the orbital soft tissues **(Figure).** The retina remained attached postoperatively, and the visual acuity stabilized at *20/20* OD at 3 months. The patient became onhophoric in plimary gaze, with mild remaining restriction of adduction and infraduction in the right eye.

Comment.·This case represents the first reported breakdown of a MIRAgel scleral buckle. Its occurrence should not be surprising, as 7 cases of complications with the MAI exoplant, composed of the same hydrogel material, have been reported in the past. The mechanism of fragmentation and degradation likely resembles that reported with the MAI exoplant; hydrolysis of the material with resultant swelling. The presence of an incomplete capsule surrounding the buckle in our patient may have facilitated access of orbital fluid to the exoplant. Similar to the report by Marin et al,[3] these changes appeared approximately 10 years after exoplant placement. The findings in this patient illustrate the need to anticipate potential friability and swelling of MIRAgel buckle material and to meticulously search for fragments during removal of long-standing exoplants. Our observation together with the historical data suggest that there are no real advantages of MIRAgel and MAI over silicone for use as scleral buckling material.

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Lalanoprosl and Hyperplgmenlalion of Eyelashes

Latanoprost (Xalatan, Pharmacia Upjohn Co, Kalamazoo, Mich) is the first new class of antiglaucoma medication introduced in 20 years. Initial reports about its ocular hypotensive effects seem to be promising, but it has an intriguing side effect of increasing iris pigmentation. On a theoretical basis, hyperpigmentation of periocular structures also might be expected. To our knowledge, this may be the first reported case of increased pigmeniallon of eyelashes from topical lalanoprost.

Report of a Case. During the course of 6 years, a 65-year-old woman with open-angle glaucoma developed allergy and/or intolerance to topical β-blockers, pilocarpine hydrochloride, dorzolamide hydrochloride, and apraclonidine hydrochloride. Argon laser trabeculoplasty provided only transient control of the intraocular pressure (IOP). Because of progressing disc changes and visual field changes in her left eye, she was enrolled in the Latanoprost Compassionate Use Study (Hartford Hospital, Hartford, Conn) The pretreatment protocol included a comprehensive ocular examination, disc and iris photographs, visual fields, and a signed consent form approved by the Hartford Hospital institutional review board.

Her pretreatment visual acuity was *20/20* OU and her IOP was 19 mm Hg OD and 27 mm Hg OS. Pertinent ocular findings included a cup-disc ratio of 0.5 OD and 0.8 OS. The color of the irides were light gray with a light brown pigmented pupillary margin. The visual field was normal in the right eye and there were scattered spots of depression in the inferior arcuate region of the left eye. Treatment with topical 0.005% latanoprost, 1 drop (~20 *μL)* at 8 PM every evening, was started in her left eye on May 15, 1996. On her 1-month visit on June 18, 1996, her IOP was 20 mm Hg OD and 1[illegible] mm Hg OS. Results from the visual acuity and ocular examination were completely unchanged, except she had one in-turned eyelash on her left lower eyelid. The offending eyelash was epilated. On her 2-month visit on July 16, 1996, the IOP was 28 mm Hg OD and 17 mm Hg OS and the ocular examination results were unchanged On her 3-month visit on August 21, 1996, her IOP was 20 mm Hg OD and 15 mm Hg OS. Results of her ocular examination were again unchanged but she had another in-turned eyelash on her left [illegible]

PRODUCTIE 8

Long-term Complications of Silicone and Hydrogel Explants in Retinal Reattachment Surgery

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Objective: To compare long-term complications of silicone sponge, silicone rubber, and MIRAgel used as episcleral buckling elements.

Methods: Medical reports were reviewed of 805 patients with cryotherapy and episcleral buckle for rhegmatogenous retinal detachment who were operated on by 1 of us (M.R.-P.) between March 1984 and December 1997. Average follow-up was 76 months. Symptoms and signs of infection or rejection were considered. Care was taken in buckling element removal, considering the material used for scleral buckling (detailed operative note), duration of the buckle, cause of removal, and culture of the removed element.

Results: A total of 757 patients were included in the study. Removal of the implant was necessary in 10 patients (1.3%). Silicone sponge (3 [9%] of 32 patients) was more frequently removed than was silicone rubber (2 [0.6%] of 360 patients) or MIRAgel (5 [1.3%] of 386 patients). Silicone sponge needed to be removed a short time after surgery, showing symptoms of acute infection and positive cultures. Silicone rubber was removed 1 year after surgery with symptoms of chronic infection and positive cultures, and MIRAgel implants were removed after long-term follow-up (7-10 years), showing positive cultures in only 20%.

Conclusion: Periodic long-term follow-up previously recommended for use of other materials also must be recommended for MIRAgel use because of long-term alterations in its chemical composition and eventual swelling of material.

Arch Ophthalmol. 1999;117:197-201

COMPLICATIONS after retinal detachment surgery that lead to removal of the scleral buckling element have been reported.[1,2] Postoperative extrusion or infection with exposure of the scleral buckling material has been more common[3,4] with use of silicone sponge explants (2.7%-18.0%) than with use of hard silicone explants (0.2%-1.4%).[5,6] These complications also are more common for patients with explants than for those with implants.[5]

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Hydrogel implants (originally MAI and then commercialized as MIRAgel [MIRA, Waltham, Mass]) seemed to be the ideal implant material[7,8] when observed 6 to 53 months after surgery.[9] Recently, long-term (7-11 years after surgery) complications have been reported in 8.5% of patients after an intrascleral buckling procedure[10] and in 1 patient after episcleral buckle,[11] related to the swelling properties of the hydrophilic implant.

The aim of our study was to compare long-term complications of the 3 materials (silicone sponge [Dow Corning, Midland, Mich], silicone rubber [Dow Corning], and MAI or MIRAgel hydrogel) used more commonly as episcleral buckling elements.

RESULTS

Medical reports were reviewed of 757 patients with episcleral buckle for rhegmatogenous retinal detachment who were operated on. Average patient age was 56 years (range, 14-81 years). Average follow-up was 76 months (range, 8 months to 12 years).

Silicone sponge was used as the segmental-localized buckle material in 32 patients (7 radial and 25 meridional) (Table 1 and the **Figure**). After April 1994, only 1 of these explants was used. The eye developed redness and tenderness 4 months after surgery, and 6 months after surgery it continues corticosteroid and antibiotic drug treatment. Three silicone sponge buckles (9%) needed removal a short time

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PATIENTS AND METHODS

Medical reports were reviewed of patients with cryotherapy and episcleral buckles[12] for rhegmatogenous retinal detachment who were operated on at the Hospital Clinico San Carlos, Madrid, Spain, by 1 of us (M.R.-P.) between March 1984 and December 1997.

Only single procedures (805 patients) were considered, without other intraocular or combined surgery. The included 757 patients had complete reattachment of the retina 6 months after surgery. The excluded 39 detached eyes did not show symptoms or signs of implant rejection, and combined surgeries were considered to reattach the retina (exclusion criteria). Nine patients were lost during follow-up. Only patients with up-to-date follow-up information and signed informed consent forms were included in the study.

No preoperative local antibiotic drugs were used. The operative technique was a modified Custodis operation, using cryopexy to the edges of the breaks and an explant compressed over full-thickness sclera.[12] The materials used were silicone sponge, solid silicone rubber, and MIRAgel. Different material sizes and lengths were used, as were different surgical procedures (segmental-localized indentation, segmental indentation associated with cerclage, and broad indentation for 360°) (**Table 1**, **Table 2**, and **Table 3**). When cerclage was required, a 240 solid silicone band was used. In some patients, drainage of the subretinal fluid or intravitreous balanced salt solution or air injection was performed. Gentamicin sulfate was used to soak the buckling elements before implantation and for injection into the Tenon space after closure, following the procedure of McPherson and Moura.[13] Systemic antibiotic drugs were used after surgery for 6 days, and local antibiotic drugs were used for 3 weeks.

Patients made follow-up office visits 1, 3, 6, 12, 24, and 36 months after surgery and then annually or biannually. At each follow-up visit, the patient was questioned about pain, ocular redness, and ocular discharge. Anterior segment examination included inspection of the conjunctiva overlying the area of the explant; intraocular muscle movements; palpation of the globe for tenderness; tonometry; and slitlamp examination of the cornea, anterior chamber, crystalline lens, and anterior vitreous. The posterior segment was evaluated by direct and indirect ophthalmoscopy to determine the status of the retina and optic disc (atrophy) and the height of the buckle.

A total of 757 patients were included in the study. Silicone sponge was used as the buckling element in 32 patients (all segmental-localized), silicone rubber was used in 360 patients (11 segmental-localized, 193 segmental with cerclage, and 156 broad indentation for 360°), and MIRAgel was used in 386 patients (77 segmental-localized, 101 segmental with cerclage, 21 as additional "side-by-side" element for fishmouth phenomenon, and 187 broad indentation for 360°) (Tables 1-3).

A segmental-localized buckle was considered when a buckle with meridional extension of 180° or less was performed. Different materials and orientations were used (Table 1). When a cerclage is required, we use a 240 silicone rubber band, and usually the associated segmental buckle of the different materials is 270° of extension or less. We say broad indentation for 360° when the buckling element (different materials) has 360° of extension and may be used isolated (usually MIRAgel, not grooved) or associated (grooved silicone rubber or MIRAgel) with a cerclage (240 silicone rubber band) (Tables 1-3).

Average follow-up was 76 months (range, 8 months to 12 years). Symptoms (pain, discomfort, redness, and discharge) and signs (inflammatory reaction, subconjunctival bulge, secretion, fistula, granuloma, wound dehiscence, infection, migration of the explant, extrusion, intrusion, tenderness, unilateral gaze deviation, and ocular movements alteration) of infection and rejection were considered at each follow-up visit and by telephone at the end of the study for all included patients.

Scleral buckling element removal, considering the material used for scleral buckling (detailed operative note), duration of the buckle, cause of removal, and culture of the removed element are given in **Table 4**.

Table 1. Quantity and Material of Episcleral Buckles: Segmental-Localized Indentation (≤180°)*

Implant Characteristics			Patients With Implants Removed, No. (%)	
Material	Patients, No.	Orientation/ Patients, No.	By Orientation	By Material
Silicone sponge	32	Radial/7	2 (29)	...
		Meridional/25	1 (4)	3 (9)
Silicone rubber	11	Meridional/11	...	...
MAI	77	Radial/12	...	...
		Meridional/65	1 (1)	1 (1)
Total	120	Radial/19	4 (3)	4 (3)
		Meridional/101		

*Ellipses indicate not applicable.

after surgery (2-3 months) because of symptoms of acute infection (1.0-2.5 months after surgery) and positive cultures (Table 4). When we consider the orientation of the explant, of the 7 radial sponges, 2 had to be removed shortly after implantation (28.6% of this type of orientation) (Table 1). In all patients, the retina remained attached after removal of the explant.

Solid silicone rubber was used as the main buckle element in 360 patients (11 segmental-localized, 193 under a 240 silicone band of cerclage, and 156 as 360° broad-indentation buckle also under a 240 silicone band) (Tables 1-3). Of these patients, 2 had buckles that needed to be removed (0.6%). This material had been regularly used during follow-up (Figure). Patients with removed buckles started showing signs of discharge, redness, and granuloma 10 to 13 months after surgery, and cultures of the removed implants were all positive (Table 4). Considering the type of surgery, both patients with removal had a 77G implant (≤270°) under a 240 silicone band for cerclage (2 [1.2%] of 172 patients undergoing this type of surgery). If we also include patients operated on with an additional "side-by-side" meridional MAI explant necessary for fishmouth phenomenon (Table 2), then the percentage of removal

Table 2. Quantity and Material of Episcleral Buckles: Segmental Indentation (≤270°) and Cerclage (240 Silicone Band)*

Implant Characteristics			Patients With Implants Removed, No. (%)	
Material	Patients, No.	Orientation/Patients, No.	By Orientation	By Material
Silicone sponge	0	...	...	...
Silicone rubber	193	Meridional/172	2 (1.16)	2 (1.03)
		Additional MAI "side-by-side" meridional (fishmouth)/21	...	...
MAI	101	Meridional/101	3 (2.9)	3 (2.9)
Total	294	Meridional/294	5 (1.7)	5 (1.7)

*Ellipses indicate not applicable.

Table 3. Quantity and Material of Episcleral Buckles: Broad Indentation for 360° (360°)*

Implant Characteristics			Patients With Implant Removed, No. (%)	
Material	Patient, No.	Orientation/Patients, No.	By Orientation	By Material
Silicone sponge	0	...	...	...
Silicone rubber (360°) + 240 silicone band (360°)	156	Meridional/156	...	...
MAI (360°) + 240 silicone band	92	Meridional/92	1 (1)	1 (1)
MAI (360°)	95	Meridional/95	...	...
Total	343	Meridional/343	1 (0.3)	1 (0.3)

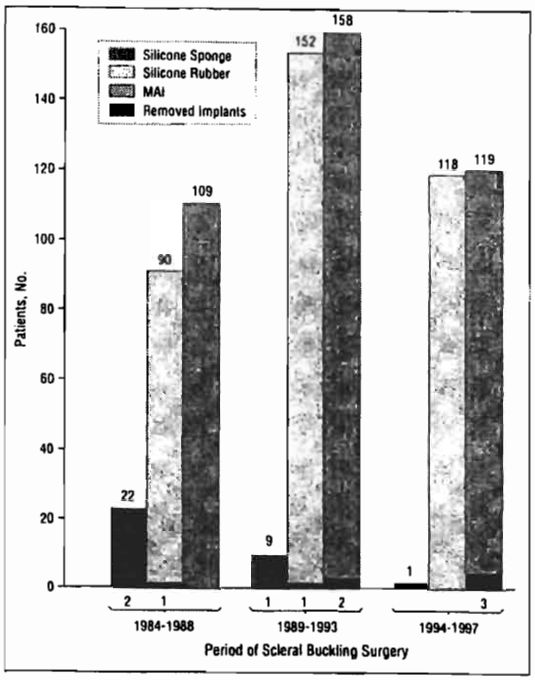
*Ellipses indicate not applicable.

Table 4. Data on Patients With Removed Implants

Patient Age, y/Sex	Implant Used	Average Time to Onset of Symptoms/Signs	Interval to Surgery Removal	Cultures
42/F	Radial, silicone sponge (round, 5 mm)	2.5 mo; exposure, fistula	3 mo	*Staphylococcus aureus*
53/M	Radial, silicone sponge (round, 5 mm)	2 mo; extrusion	2.5 mo	*Escherichia coli*
23/M	Meridional, silicone sponge (round, 3 mm)	1 mo; exposure, fistula	2 mo	No growth
41/F	Meridional, MIRAgel (medium oval)	7 y; discharge, extrusion	7.3 y	No growth
62/M	Meridional, silicone rubber (77G) + 240 silicone band (360°)	10 mo; discharge, granuloma	13 mo	*Staphylococcus epidermis*
63/M	Meridional, silicone rubber (77G) + 240 silicone band (360°)	13 mo; discharge, granuloma	15 mo	*S epidermis*
21/F	Meridional, MIRAgel (large grooved) + 240 silicone band (360°)	7 y; anterior migration lateral rectus palsy	7.2 y	No growth
46/F	Meridional, MIRAgel (medium grooved) + 240 silicone band (360°)	8.5 y; subconjunctival mass, discharge	8.8 y	No report
59/M	Meridional, MIRAgel (large grooved) + 240 silicone band (360°)	9.2 y; discharge, extrusion	9.2 y	*S epidermis*
56/F	Meridional 360°, MIRAgel (medium grooved) + 240 silicone band (360°)	10 y; discharge, extrusion	10.5 y	No growth

was 1.0%. The 2 patients with silicone rubber needed removal more than 1 year after surgery (Table 4). The retina remained attached after explant removal in both patients.

MIRAgel was used in 386 patients regularly during follow-up (Figure) (77 segmental-localized, 101 under a 240 silicone band of cerclage, 21 "side-by-side" meridional and posterior to the main rubber silicone implant to resolve a fishmouth phenomenon, and 187 as 360° broad indentation buckle [92 patients under a 240 silicone band and 95 patients without a silicone band]) (Tables 1-3). Two hundred six of these patients using hydrogel were followed up for 7 years or longer after surgery; at the end of the study, 8 patients (3.9%) reported redness or subconjunctival mass. Removal was necessary in 5 (1.3%) of 386 patients taking MIRAgel, and in 5 (2.4%) of 206 patients taking MIRAgel for 7 or more years: 1 segmental-meridional (1/65 [1.5%]), 3 meridional (≤270°) under a 240 silicone band for cerclage (3/101 [3.0%]), and 1 broad-meridional for 360° under a 240 silicone band (1/92 [1.1%]) (Tables 1-4). Symptoms and signs of granuloma and chronic infection appeared in these 5 patients after long-term follow-up (7-10 years), but cultures were positive in only 1 of them (patient 9) (Table 4). No other complications were found related to this explant material. After



Episcleral buckling surgeries performed between March 1984 and December 1997, considering the materials (silicone sponge, silicone rubber, and MIRAgel [MAI]) used and implants removed.

explant removal, the retina remained attached in 4 patients. Only 1 patient with removal developed vitreous hemorrhage and new retinal detachment. At the end of the study, 2 additional patients using hydrogel (1 segmental-meridional and the other 360° meridional under a 240 silicone band) showed subconjunctival mass and redness and started treatment with antibiotic drugs and corticosteroids; both patients had surgery 6 years earlier.

COMMENT

Only 10 (1.3%) of 757 implants reviewed in the study needed to be removed. We agree with other authors[3-6] that silicone sponge needs to be removed more frequently (9.3% in our findings) than solid silicone rubber (0.6%) or MIRAgel (1.3%) explants. Our percentages of removal of silicone sponge and silicone rubber correlate well with percentages previously reported[3-6]; no previous data about the long-term follow-up and rate of removal of the MIRAgel explant have been found in the literature. Although we have a small number of patients, silicone sponges used for segmental-localized procedures (≤180°) and with radial orientation showed the highest removal rate (28.6%) (Table 1), probably because short explants with radial orientation had more probabilities to erode Tenon and conjunctiva during normal ocular movements. However, it is difficult to know which is the first cause of the problem—inadequate scleral or conjunctival suturing or infection. Either exposure of the implant may be followed by secondary infection, or acute infection of the implant may produce secondary exposure. In either case, most authors[1-6] agree that acute infection occurs more frequently with use of silicone sponges. Fistula and exposure is a common finding in those patients,[4] with a soft and discolored sclera beneath the removed implant.

In the group treated with silicone rubber, the explants were removed 1 year after surgery (Table 4). In these patients, the sclera beneath the explants was smooth and clean, indicating compression of the sclera by the explant. Explants with the MIRAgel removed revealed evident fragmentation of the material and fibrous tissue proliferation around the explant material. Fragmentation of this material after swelling was previously reported.[11,14] Negative cultures of the removed MIRAgel explants may be due to long-term antibiotics and/or corticosteroids needed to treat redness, discharge, or chronic infection; or to particular characteristics of MIRAgel. Initially, it was reported as an ideal buckling element, less prone to infection because it lacked dead spaces and could absorb and gradually release antibiotic drugs.[15]

Problems ranging from subconjunctival bulge to intraocular erosion and migration of the implant have been reported in 7 patients after intrascleral buckling with MAI hydrogel,[10] the laboratory precursor of the commercial MIRAgel. Clinical complications appeared 7 to 10 years after surgery, and chemical changes related to swelling of the implant were demonstrated.[10] However, Marin et al[10] stated that they have used MIRAgel as an episcleral implant in a large number of patients since 1986 and have not observed complications. We followed up 206 patients with MIRAgel as an episcleral buckling material for more than 7 years after surgery, and only 5 of these patients needed removal, 1 of them showing positive culture (Table 4). Three more patients with this follow-up also showed redness and required periodic antibiotic drug and corticosteroid treatment.

In 1997, Hwang and Lim[11] reported the first case of scleral buckle extrusion and fragmentation associated with use of a MIRAgel episcleral explant. They illustrated the need to anticipate potential friability and swelling of MIRAgel buckle material and to meticulously search for fragments during removal.

However, erosion is not unique to the hydrogel implant and has characterized all the implants used to date.[16] That is why Schepens[17] defended that the expected short- or long-term complications of the implants justify lifetime yearly follow-up after all scleral buckling implantations.

Because of the physical properties of the MIRAgel material (MAI),[8] it was thought initially to be a better buckling element.[7-9] We followed up 206 patients with hydrogel explants (53.4% of all patients with hydrogel) for 7 years or more after surgery, and no important complications were found. Signs of granuloma and chronic infection appeared in 8 of these patients (3.9%), and 5 of them needed removal. No other complications were detected related to use of this material episclerally. However, we think that long-term alterations in chemical com-

position and eventual increase in swelling of the material justify a high recommendation for the need for periodic follow-up, as with all use of scleral buckling materials.

Accepted for publication October 15, 1998.

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From the Archives of the ARCHIVES

A look at the past . . .

The favorable but incomplete results of partial resection or cutting through the cervical sympathetic in Graves's disease have led Jounesco to undertake its complete bilateral resection. An incision through the skin beginning at the mastoid process and following the margin of the sterno-cleido-mastoid to the clavicle, gives access to the jugular vein which is ligated in two places and divided. The exposing of the posterior margin of the sterno-cleido-mastoid necessitates cutting the branches of the cervical plexus. The trunk of the cervical sympathetic must be sought for in the middle of the region of operation. The isolated nerve trunk serves as a guide for finding the upper, middle, and lower cervical ganglia. In three of his six operations the author was forced to omit the resection of the lower ganglion. The removal of the upper ganglion immediately brings about contraction of the pupil and congestion of one half the face and secretion of saliva and tears. These symptoms soon pass off and the results of the operation are trivial. Among the six patients two had Basedow's disease. The resection of the sympathetic led in both cases to the disappearance of the exophthalmus, with decrease in size of the thyroid and a slight lessening of the frequency of the pulse.

Reference: Progress of ophthalmology. *Arch Ophthalmol.* 1897;26:618-619.

PRODUCTIE 9

PHOTO ESSAY

Complications of Miragel

Pseudotumor

A 38-YEAR-OLD patient with myopia and an inferior temporal retinal detachment and multiple peripheral retinal holes in his right eye underwent an uneventful scleral buckling procedure using an encircling 907 (3×5 mm) Miragel (MIRA, Walthem, Mass) exoplant. Postoperatively, the retina was attached and central visual acuity was 20/20 OD.

Thirteen years later, the patient returned with double vision and a nonpainful, noninflamed right infraorbital swelling. A firm cylindrical mass protruded beneath the lateral aspect of the right lower eyelid (**Figure 1**). The retina was attached and visual acuity was 20/30 OD. The patient claimed that during the past few years, a hard mass lesion had developed under his right lower eyelid, causing progressive double vision.

On examination, inferior gaze in his right eye was limited. A firm, nontender, noninflamed mass could be palpated beneath the lower eyelid. Magnetic resonance imaging demonstrated the extent of enlargement of the encircling Miragel element (**Figure 2**). Using subconjunctival anesthesia, the buckling element was removed. The procedure was tedious because of fragmentation of the hydrogel material. Postoperatively, immediate cosmetic improvement was noted and diplopia was no longer experienced.

A comparison of the removed buckle with a new identically sized Miragel buckle demonstrated that the implanted buckle had swelled to 4.34 times its original cross-sectional area (**Figure 3**). The inferior temporal bulging of the Miragel buckle noted

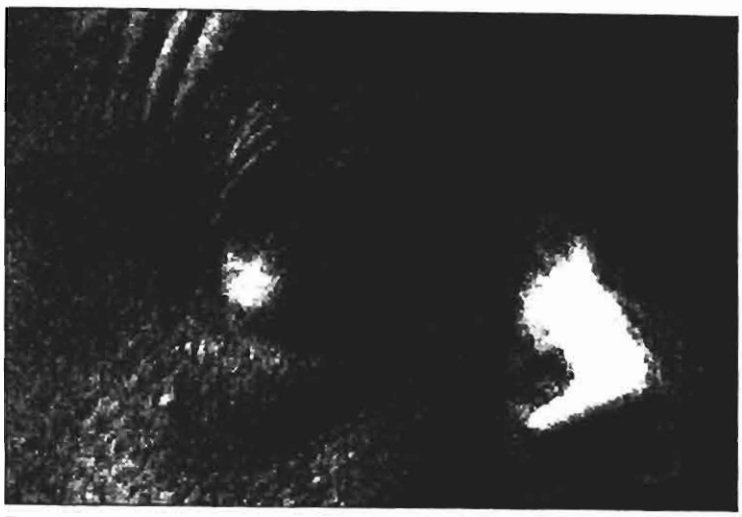

Figure 1. Side profile of patient with a 15-mm firm, nonmotile, nonpainful right infraorbital protrusion.

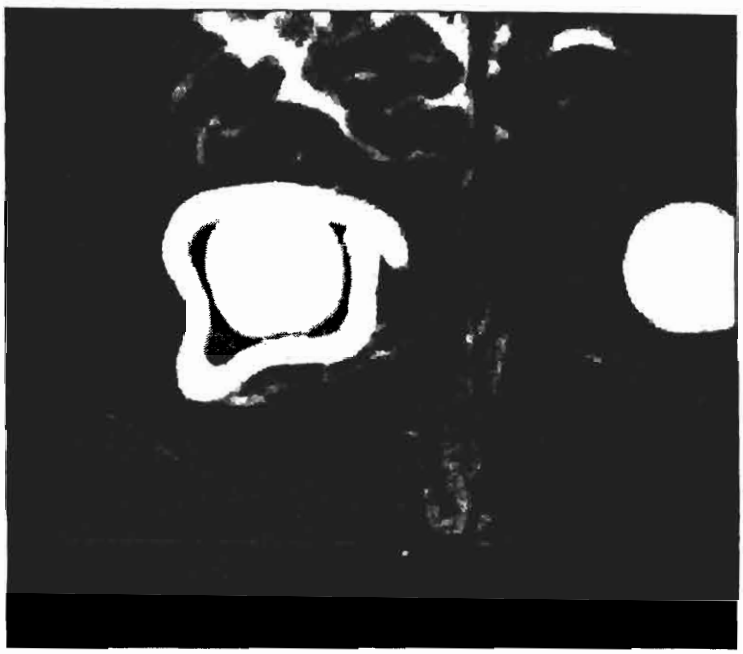

Figure 2. Coronal magnetic resonance image demonstrating Miragel element enlargement as the cause of the inferotemporal bulge.

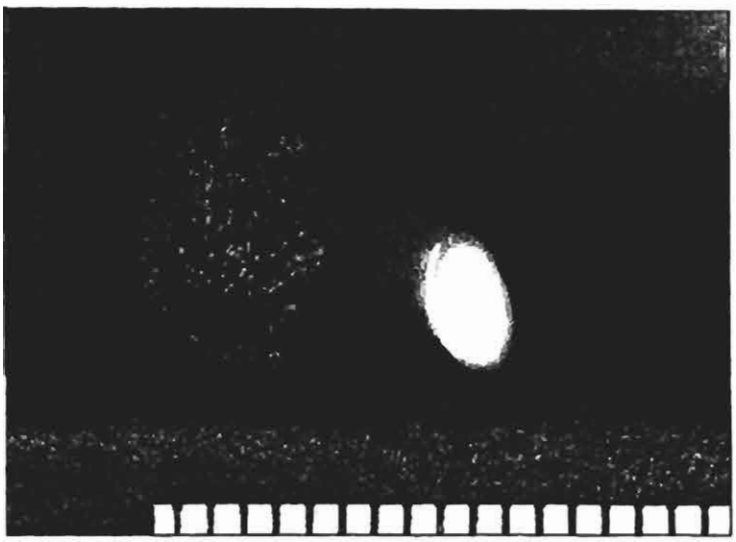

Figure 3. A cross-sectional comparison of a 5 × 3-mm Miragel exoplant prior to use (right) and a 9.7 × 6.7-mm exoplant removed 13 years later (left).

on magnetic resonance imaging indicates that there had also been an increase in the length of the element. This significant increase in volume might explain the patient's diplopia.

COMMENT

Complications following retinal detachment surgery may necessitate the removal of the scleral buckling element. Some of these complications have been attributed to the type of buckling material used. Scleral buckling material has evolved from autologous fascia lata to nonabsorbable synthetic agents, such as polyethylene, silicone, and hydrogels.

Hydrogels are composed of a low-molecular-weight hydrophilic material that is water-permeable.[1] Hydrogel scleral buckling elements (Miragel) were introduced in 1979 and marketed to have an advantage over the silicone agents currently being used.[2] The degree of buckle swelling could be varied by altering the state of hydration. The softness and elasticity of Miragel were thought to minimize erosion, and its lack of dead spaces promised to prevent infection by allowing the absorption and gradual release of antibiotics.[3] Long-term complications related to the swelling properties of hydrogel exoplants have been reported. These problems have been attributed to erosion and migration, infection, granuloma formation, and fragmentation of the hydrogel material, resulting in particle retention on removal of the scleral buckling element.[4]

This case represents a complication that can occur as a result of the more than 4-fold volume expansion of the Miragel exoplant during a 13-year period. In this case, the profound increase in size of the exoplant caused restriction of extraocular movement and mimicked a periorbital mass lesion.

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PRODUCTIE 10

CASE REPORTS

Extrusion and Fragmentation of Hydrogel Exoplant 11 Years After Scleral Buckling Surgery

Ophthalmic Surgery, Lasers and Imaging Vol. 33 No. 3 May/June 2002

Taku Kawano, MD; Motoaki Doi, MD; Masataka Miyamura, MD; Koji Esaki, MD; Mikio Sasoh, MD; Yukitaka Uji, MD

ABSTRACT

MAI or MIRAgel is a hydrogel developed as a scleral buckling material. We identified upper lid masses and a limitation of supraduction in the left eye of a patient who was associated with extrusion and fragmentation of the MIRAgel episcleral exoplant 11 years after scleral buckling surgery. The material could not be removed completely because of fragmentation. Fragmentation and extrusion of MIRAgel may be rare, but periodic long-term follow-up examinations should be performed after this product has been used. [*Ophthalmol Surg Lasers* 2002;33:240-242]

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Accepted for publication December 20, 2001.

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PRODUCTIE 11

Full Text

Wolters Kluwer Health | Lippincott Williams & Wilkins

RETIN

Long-Term Complications of Hydrogel Buckles

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ISSN: 0275-004X
Accession: 00006982-200304000-00025

Issue: Volume 23(2), April 2003, pp 257-261
Publication Type: [BRIEF REPORTS]

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This paper was presented in part at the 18th Annual Meeting of the Vitreous Society in Cancun, Mexico, January 7-11, 2001.

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None of the authors have a proprietary interest in this study.

Keywords: hydrogel, retinal detachment surgery, scleral buckle, surgical complication

Abstract

Purpose: To investigate long-term complications of hydrogel buckles used in scleral buckling surgery for retinal detachment.

Methods: Clinical records of 31 patients who underwent scleral buckle removal between April 1998 and April 2001 were reviewed. Removed buckles were examined by scanning electron microscopy (SEM).

Results: Nineteen patients were men and 12 were women, with a mean age of 43 years. Initial scleral buckling surgery using hydrogel buckles had been performed between February 1988 and October 1995. Patients presented at a mean of 8.5 years postoperatively with complaints of symptoms such as foreign body sensation and diplopia, prompting buckle removal. Buckles from 28 eyes, left in place for 5.8 years or more, were discolored, friable, and swollen. Buckles from three eyes, left in place for 5.5 years or less, appeared grossly unaltered. One eye with buckle swelling associated with a large retinal cyst underwent buckle removal and vitrectomy. SEM of deteriorated buckles showed distortion of micropores when compared to grossly unaltered buckles and unused controls.

Conclusions: Severe deterioration of hydrogel buckles may occur when they are left in place for 5 years or longer and may cause adverse symptoms and rarely intraocular complications. This deterioration is associated with changes in the microstructural architecture of the hydrogel material.

The MAI buckle, also known as the Refojo implant, is a synthetic hydrophilic scleral buckling material introduced in the 1970s. MAI is made of polymethyl acrylate-co2-hydroxyethyl acrylate cross-linked with ethylene diacrylate with 15% water, and it is the precursor of the present-day MIRAgel buckle (MIRA, Waltham, MA), which has the same basic chemical composition. Due to its softness and elasticity, the MIRAgel buckle was touted as being easy to handle and useful in creating a smooth scleral indentation. 1,2

We utilized MIRAgel in explant scleral buckling surgery from 1987 until 1996, when its distribution was voluntarily stopped by the manufacturer. However, complications have recently been reported in patients who received MIRAgel buckles that appear to be related to swelling properties of the hydrophilic material. 3 Over a 3-year period, we removed MIRAgel buckles from 31 eyes of 31 patients who developed various symptoms, such as foreign body sensation and diplopia, and report our findings here.

Patients and Methods

Medical records were reviewed for 31 patients who had undergone initial explant scleral buckling surgery for retinal detachment using MIRAgel at the Kyorin Eye Center or affiliated institutions, and who subsequently required buckle removal between April 1998 and April 2001. The time interval between scleral buckling surgery and buckle removal and the symptoms and signs that led to buckle removal were noted. The size of removed buckle material was measured intraoperatively. Selected samples were examined by scanning electron microscopy (SEM) as follows. Buckle samples were desalinized by overnight immersion in distilled water and then dried at room temperature. After critical point drying, specimens were coated with gold and examined with a scanning electron microscope (JSM-5600LV, JEOL, Tokyo, Japan). Unused MIRAgel buckles were used as controls.

Results

All patients in this study had undergone initial scleral buckling surgery for rhegmatogenous retinal detachment, with or without proliferative vitreoretinopathy, between February 1988 and October 1995. The results are summarized in Table 1. Nineteen of the patients were men and 12 were women, with a mean age of 43 years. The mean time interval between initial scleral buckling surgery and subsequent buckle removal was 8.6 years. Cases were divided into two groups according to the appearance of the removed buckle material upon gross examination intraoperatively.

Table 1. Results of Patients who have Undergone Initial Scleral Buckling Surgery for Retinal Detachment

Group/Patient No.	Interval,* yr	Buckle Type†	Placement	Diameter, mm‡	Increase in Size,§ %
Group A					
1	12	904 (round)	Radial	5	156
2	9.9	904 (round)	Encircling	5	156
3	10.8	904 (round)	Circumferential	5	156
4	10.3	904 (round)	Radial	5.5	189
5	9.8	904 (round)	Encircling	5	156
6	8.4	904 (round)	Encircling	5	156
7	9.5	904 (round)	Encircling	6	225
8	8.9	904 (round)	Circumferential	5	156
9	10.1	904 (round)	Circumferential	6	225
10	9.9	904 (round)	Radial	5	156
11	9.9	906 (oval)	Encircling	8 × 5	267
12	7.3	904 (round)	Encircling	5	156
13	9.9	906 (oval)	Encircling	6.5 × 4	173
14	8.1	904 (round)	Circumferential	5	156
15	9.3	906 (oval)	Circumferential	6 × 8	320
16	7.8	904 (round)	Radial	5	156
17	7.3	904 (round)	Radial	4.5	127
18	6.9	906 (oval)	Encircling	6 × 5	200
19	5.8	904 (round)	Radial	4.5	127
20	7.8	906 (oval)	Encircling	7.6 × 4	203
21	9.1	906 (oval)	Encircling	8 × 4	213
22	9.1	907 (oval)	Encircling	8 × 9	175
23	10.3	904 (round)	Encircling	5	156
24	10.8	906 (oval)	Circumferential	6.5 × 7	303
25	10.8	906 (oval)	Circumferential	6 × 5	200
26	8.9	904 (round)	Encircling	5	156
27	8.9	904 (round)	Circumferential	5.5	189
28	6.4	906 (oval)	Encircling	8 × 4.5	180
Group B					
29	4.5	906 (oval)	Encircling	5 × 3	100
30	5.5	906 (oval)	Encircling	5 × 3	100
31	2.8	904 (round)	Encircling	4	100

* Interval between initial scleral buckling surgery and buckle removal.
† MIRA gel® buckle catalog number.
‡ Diameter measured intraoperatively on buckle removal.
§ Calculated increase in the cross-sectional area of the removed buckle compared to an unused buckle.

Table 1. Results of Patients who have Undergone Initial Scleral Buckling Surgery for Retinal Detachment* Interval between initial scleral buckling surgery and buckle removal.† MIRA gel® buckle catalog number.‡ Diameter measured intraoperatively on buckle removal.§ Calculated increase in the cross-sectional area of the removed buckle compared to an unused buckle.

Group A consisted of buckles removed from 28 eyes that were noted to be swollen, altered to a brownish hue, translucent, and extremely friable or already fragmented. Surgical records showed that the types of MIRAgel buckles used in this group were the number 904 (4 mm cylinder) in 18 eyes, the number 906 (3 × 5 mm oval) in nine eyes, and the number 907 (5.5 × 7.5 mm oval) in one eye. The time interval between scleral buckling surgery and buckle removal for group A eyes ranged from 5.8 years to 12.0 years (mean, 9.1 years). On average, the calculated cross-sectional area of buckles removed from group A had expanded by 185%.

Group B consisted of buckles removed from three eyes that showed no alterations by gross examination when compared to unused MIRAgel buckles. The types of buckles used were the number 906 in two eyes and the number 904 in one eye. The time interval between scleral buckling surgery and buckle removal ranged from 2.8 years to 5.5 years (mean, 4.3 years). The cross-sectional area of buckles removed from group B had not changed from the original size.

The reasons for surgical buckle removal included foreign body sensation (23 eyes in group A, one eye in group B), limitation of ocular motility with or without diplopia (16 eyes in group A, one eye in group B), and ocular pain (one eye in each group). Overall, symptoms were more severe in group A eyes and were associated in all eyes with objective findings such as conjunctival bulge, buckle extrusion, and swelling of the buckle by magnetic resonance imaging (MRI).

Case Report

A 36-year-old man (Patient 7) presented in September 1997 with a complaint of decreased vision in the right eye associated with abnormal eye movement. On examination, his visual acuity was 20/50 in his right eye and 20/20 in his left eye, and he had normal intraocular pressures. Dilated fundus examination of the right eye revealed a very high and broad encircling buckle with the retina attached. In addition, a retinal cyst was observed at the level of the buckle in the superotemporal quadrant, adjacent to a cryopexy scar (Figure 1). T2-weighted MRI revealed a high-intensity tortuous mass consistent with a deteriorated scleral buckle (Figure 2). Review of his records showed that the patient had undergone explant scleral buckling surgery using a number 904 MIRAgel element in May 1990, 9.5 years earlier.

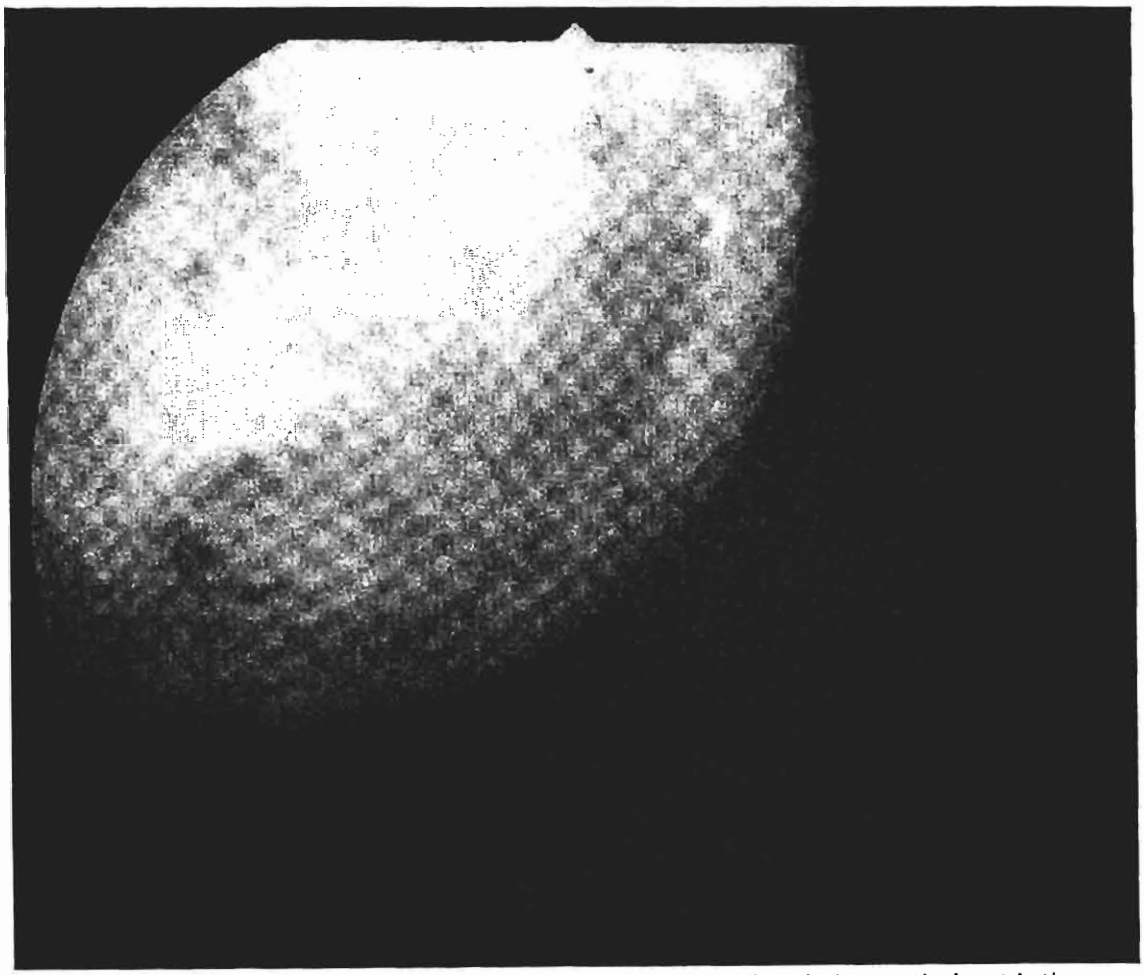

Fig. 1. A MIRAgel buckle is observed eroding into the subretinal space and producing a retinal cyst in the superotemporal quadrant, adjacent to a cryopexy scar.

Fig. 2. A T2-weighted magnetic resonance image revealed a high-intensity tortuous mass consistent with a deteriorated buckle.

The patient was initially followed without intervention. However, over the following 2 years, the retinal cyst gradually expanded to block the central visual axis and prompted buckle removal in November 1999. Intraoperatively, severe erosion of the sclera and uvea beneath the buckle material in the temporal quadrant was noted, with retina incarcerated in the scleral defect. As the buckle was being removed, the retinal cyst collapsed with subsequent formation of a retinal tear. Vitrectomy, gas tamponade, and endolaser photocoagulation around the retinal tear was then performed. Postoperatively, retinal detachment recurred with the development of proliferative vitreoretinopathy. Four additional intraocular procedures, including silicone oil tamponade, were required before the retina could be successfully reattached. Two years after the final surgical procedure, the best-corrected visual acuity was 20/400.

Scanning Electron Microscopy Findings

Buckling material removed from eight eyes was examined by SEM. After immersion in distilled water during sample preparation, buckles from group A were noted to increase further in size. Similar immersion in distilled water of buckles from group B and unused MIRAgel controls did not result in swelling. SEM showed a smooth surface and uniformly sized micropores in control samples and in removed buckles from group B (Figure 3A). In contrast, the surface of deteriorated buckles from group A were uneven, with micropores that were distorted in shape and irregular in size (Figure 3B).

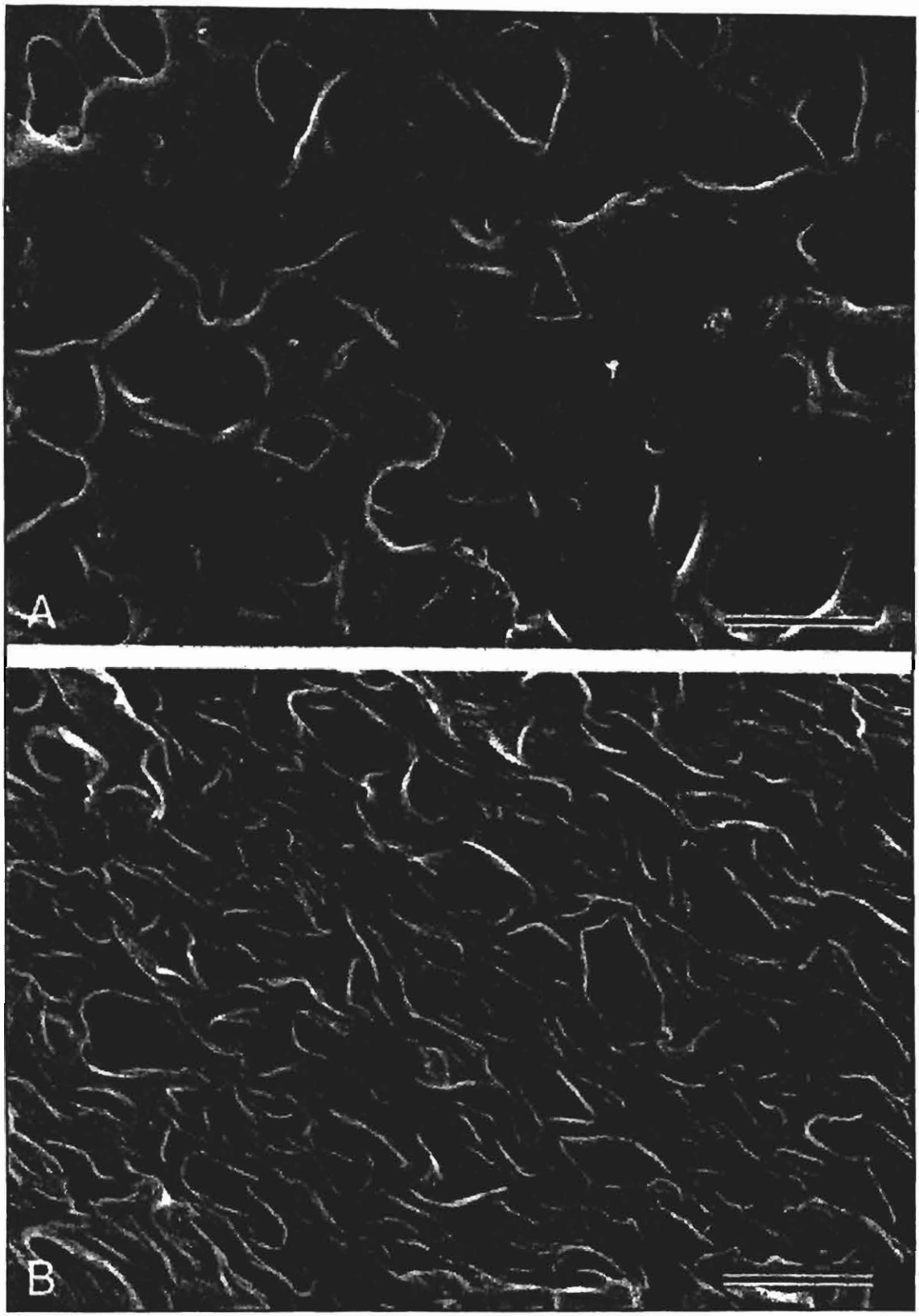

Fig. 3. A, Scanning electron microscopy showed a smooth surface and uniformly sized micropores in control samples. B, In contrast, the surface of a deteriorated buckle was uneven, with micropores that were distorted in shape and irregular in size (bar = 5 µm).

Discussion

Several features of hydrogel material have been touted as being beneficial for use in scleral buckling surgery. Softness and elasticity were said to protect against scleral erosion. 2,4 A relative lack of "dead space" and the ability to absorb and then gradually release antibiotics were also believed to make this buckle less prone to infection. 4,5 However, before the halt in its distribution in 1996, we had been utilizing MIRAgel buckles mainly for their ease in handling and their ability to create a smooth scleral indentation.

Buckle extrusion is not an uncommonly encountered postoperative complication of scleral buckling surgery, especially after explant procedures. Removal of the buckle in these cases is usually relatively easy, since the mattress sutures in these eyes are often loose or detached from the sclera such that the buckles can simply be pulled out. Buckles that have eroded inward (buckle intrusion) can also be removed fairly easily, although cutting of scleral mattress sutures may be required. Hydrogel buckles used as explants can also be removed in a similarly easy manner, if they are removed before structural alterations. However, as we observed in 28 eyes, hydrogel buckles left in place for over 5.5 years resulted in buckle swelling, with associated buckle extrusion or intrusion. Removed MIRAgel buckles from these eyes were noted to have become translucent, gellike, and extremely friable, in comparison to unused MIRAgel buckles which are transparent, more solid, and elastic. In fact, we encountered much difficulty during attempted removal of the MIRAgel buckles. In most cases, the buckles had already become fragmented or disintegrated immediately upon light traction with forceps. Removal was often performed in a piecemeal fashion, and a muscle hook was commonly used to fish out buckle debris from the subconjunctival or sub-Tenon's space. Swollen buckles also inhibited globe rotation intraoperatively and made it difficult to gain access to remaining buckle fragments. A granulomatous reaction was observed surrounding the buckle material in some cases.

Deteriorated MIRAgel has the tendency to absorb a great volume of water and therefore to increase in size. 1 Indeed, in our study, the calculated cross-sectional area of buckles from group A that were visibly altered had increased by an average of 185%. We believe this phenomenon to be related to the microstructural changes we observed by SEM. Swelling of the MIRAgel buckle within the confines of sub-Tenon's space results in tortuosity of the buckle, with subsequent buckle dislocation and extrusion or intrusion. It has been reported that hydrolytic degeneration occurs with hydrogel material and that this process may occur even without physically evident alterations in the buckle. 6 Therefore, even in the absence of gross alterations in appearance of the buckles in group B, we believe that the process of degeneration had already begun, leading to various symptoms in the patients.

Hwang and Lim reported the first case of this complication 10 years after commercial use of the MIRAgel buckle had begun. 7 Roldan and colleagues also reported the long-term complications of MIRAgel when used as an episcleral buckling element. 3 In the Roldan study, 206 cases were followed for more than 7 years. Of these, five patients eventually underwent buckle removal for granulomatous reaction or chronic infection, but no patients developed buckle extrusion or intraocular erosion. Marin and colleagues reported seven cases with complications that developed 7 to 11 years after scleral buckling surgery using MAI hydrogel, the precursor of MIRAgel, as an intrascleral implant. 6 These complications ranged from a visible but nontender subconjunctival bulge to intraocular erosion to frank buckle extrusion. The implants were noted to be swollen, altered, translucent, gellike, and friable. Chemical changes of the polymer and hydrophilic degeneration of the material were confirmed spectrographically. Interestingly, Marin and colleagues stated that, in contrast to patients with MAI hydrogel buckles, complications were rarely observed in patients with MIRAgel buckles. 6

The current report represents the largest series of long-term complications of hydrogel buckles to date in the literature. Since we used this material in numerous scleral buckling cases, the number of patients returning to us with various complaints is still increasing. It is our impression that the symptoms patients develop with hydrogel buckles are much more severe than those of patients with silicone sponge or rubber buckles. In fact, one of the patients in our study experienced marked visual loss due to scleral erosion, buckle intrusion, and retinal cyst formation. Although such a severe vision-threatening complication is unusual to date, we have only begun to witness all the possible complications associated with hydrogel buckles. Recently, several Japanese vitreoretinal specialists have noted various complications in patients who received MIRAgel buckles (unpublished data, Drs. Takeshi Hoshino and Miyo Matsumura), and the Japanese Ophthalmologic Society has decided to make an official

announcement regarding the seriousness of these complications.

In summary, the long-term complications of hydrogel buckles may be quite severe with potential visual loss. Surgeons must be aware of these possible complications in patients who have received hydrogel buckles during scleral buckling procedures, and these patients should undergo periodic examination and be warned of the possibility of problems. When symptomatic buckle swelling or buckle extrusion occurs or if scleral erosion and buckle intrusion are identified, the hydrogel buckle material should be removed.

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Key words: hydrogel; retinal detachment surgery; scleral buckle; surgical complication

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PRODUCTIE 12

LATE SWELLING AND REMOVAL OF MIRAGEL BUCKLES

A Comparison With Silicone Indentations

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Background: To describe the indications for removal of Miragel episcleral buckles and to compare them with removed silicone sponges and solid silicone indentations.

Methods: Retrospective analysis of the charts of patients successfully treated for retinal detachment in whom the episcleral buckle was removed after surgery, with a minimal follow-up of 6 months.

Results: In a series of 90 eyes of 90 patients, including 38 cases of Miragel elements, 25 cases of solid silicone, and 27 cases of silicone sponge removal, the duration of indentation before removal was significantly longer with Miragel (91.9 months) than with solid silicone (10.6 months) and silicone sponges (18.6 months). In eyes treated with Miragel elements, swelling of the material with progressive limitation of ocular motility and protrusion of the buckle beneath the eyelids indicated its removal in 34 (89.5%) eyes. Infection of the buckle and erosion of the conjunctiva with an exposed indentation were significantly more common with silicone buckles. Overall, scleral perforation occurred in four (4.4%) eyes, and retinal redetachment occurred in eight (8.8%) eyes.

Conclusion: Late swelling of Miragel buckling elements represents a common indication for buckle removal, significantly different from silicone indentations.

RETINA 23:641–646, 2003

Episcleral buckling is a common technique used for retinal detachment (RD) surgery. In some cases, however, the implant must be removed.[1–15] The two most common reasons for removal are extrusion, associated with or without buckle infection,[1–8,10,13] and diplopia.[9,10,16–19] These complications have mostly been reported for eyes implanted with silicone sponges or solid silicone. Miragel elements have also been widely used for episcleral indentation. Initial series have reported a good tolerance of this material.[20,21] With a longer follow-up, sporadic cases of late swelling of this material, which appeared fragmented during its surgical removal, have been reported.[11,14,15,22–28] Although the use of Miragel buckling elements has been discontinued, their explantation is a subject of concern because of their now established long-term complications. We also had to remove a large number of episcleral Miragel buckles. In this series, we describe the indications for their removal and compare them with the silicone buckles removed during the same period.

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The authors have no proprietary or financial interests in this article.

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Methods

We reviewed the charts of patients who underwent episcleral buckling removal between January 1996 and December 1999 in a single institution. We se-

Table 1. Patient Demographics

Characteristic	Miragel (n = 38)	Solid Silicone (n = 25)	Silicone Sponge (n = 27)	All (n = 90)
Mean age at removal ± SD (yr) (range)*	49.2 ± 19.2 (21–76)	58.2 ± 17.2 (31–84)	59.9 ± 14.1 (31–87)	54.8 ± 17.7 (21–87)
Gender				
Male (%)	22 (57.9)	19 (76)	16 (59.3)	57 (63.3)
Female (%)†	16 (42.1)	6 (24)	11 (40.7)	33 (36.7)
High myopia (%)†	11 (26.3)	6 (24)	5 (18.5)	22 (24.2)

* Statistically significant difference between Miragel buckles and silicone sponges ($P < 0.05$, unpaired student t-test).
† No statistically significant difference among the three groups.
SD = standard deviation.

lected the charts of patients treated with an episcleral Miragel buckling element, solid silicone, or silicone sponge indentation for a primary rhegmatogenous RD, a complete retinal attachment at the time of scleral buckle (SB) removal, and a follow-up of at least 6 months after explantation.

The collected data included patient demographic characteristics, ocular history, presenting features of the affected eye at the time of RD, analysis of the operative records of the reattachment surgeries and of the buckling removal surgery, duration of the buckling, reasons for explantation, and reported intraoperative and postoperative complications after removal. For phakic eyes, high myopia was defined as higher than −5 diopters. For pseudophakic eyes, patients with a posterior chamber intraocular lens of less than +17 diopters or an anterior chamber intraocular lens of less than +14 diopters were considered high myopes when no refractive data before cataract surgery was available.

The results were compared according to the type of material used for SB (i.e., Miragel, silicone sponge, or solid silicone).

The chi-square test and the unpaired student's t-test were used to compare each group with the two others. Statistical significance was defined as $P < 0.05$.

Results

From January 1996 to December 1999, we treated 1,552 primary RDs by external approach using only episcleral solid silicone buckles or silicone sponges. Episcleral Miragel buckle elements had been used from October 1989 to March 1995. We could not retrospectively assess the exact number of each kind of buckle implanted.

Patient Characteristics Before Scleral Buckling Removal

Of the 90 eyes of 90 patients included in this study, the removed episcleral material was Miragel in 38 (42.2%) patients, solid silicone in 25 (27.8%) patients, and silicone sponge in 27 (30%) patients. The indentation was encircling in 15 (60%) patients of the solid silicone group. No multiple buckling elements were observed in this series.

Patient characteristics are described in Table 1. The patients' mean age at SB removal was significantly lower in the Miragel group than in the silicone sponge group ($P = 0.01$) and tended also to be lower in the solid silicone group ($P = 0.058$).

Buckling element characteristics, functional symptoms, and reasons for removal are presented in Table 2. Thirty (57.7%) silicone buckles and one (2.6%) Miragel element were removed within the first year after their implantation. The rate of removal during the first year of implantation was significantly lower in the Miragel group than in the two others ($P < 0.0001$). The mean interval from implantation to removal was also significantly longer for Miragel elements than for solid silicone ($P < 0.0001$) or silicone sponges ($P < 0.0001$).

Significant pain was more frequent in the solid silicone group than in the silicone sponge ($P = 0.03$) or Miragel ($P = 0.005$) groups.

The rate of extrusion was significantly lower in the Miragel group than in the two others ($P < 0.001$). Similarly, an exposition of the implant, with erosion of the surrounding fibrous capsule and conjunctiva, was significantly less frequent in the Miragel group than in the solid silicone ($P < 0.0001$) or silicone sponge ($P = 0.002$) groups. No significant difference existed between the two different types of silicone buckle ($P = 0.17$).

Persistent diplopia, without any other symptom of buckling intolerance, led to SB removal in seven (7.7%) eyes.

For the 38 removed Miragel implants, an excessive swelling of the material indicated an explantation in 34 (89.5%) eyes. In these cases, patients showed a progressive limitation of ocular motility associated with a protrusion of the buckle beneath the eyelids and

Table 2. Clinical Data Before Buckling Removal and Reasons for Removal

	Miragel	Solid Silicone	Silicone Sponge	All
No. patients	38	25	27	90
Mean duration of buckling ± SD (mo)*	91.9 ± 29.7	10.6 ± 7.9	18.6 ± 20.0	47.4 ± 44.5
Encircling or ≥180° (%)	17 (44.7)	24 (96)	3 (11.1)	44 (48.9)
<180° (%)	16 (42.1)	1 (4)	20 (74.1)	37 (41.1)
Radial (%)	5 (13.2)	0	4 (14.8)	9 (10)
Functional symptoms and clinical data observed before removal				
Ocular inflammation (%)†	3 (7.9)	2 (8)	2 (7.4)	7 (7.7)
Ocular pain (%)‡	3 (7.9)	9 (36)	3 (11.1)	15 (16.5)
Exposed buckle (%)§	3 (7.9)	15 (60)	11 (40.7)	29 (32.2)
Reason for removal				
Diplopia (%)†	1 (2.6)	3 (12)	3 (11.1)	7 (7.7)
Swelling of the buckle (%)§	34 (89.5)	0	0	34 (37.8)
Extrusion (%)§	1 (2.6)	21 (84)	22 (81)	44 (89)
Granuloma (%)†	2 (5.3)	1 (4)	2 (7.4)	5 (5.5)

* Statistically significant difference between Miragel buckles and silicone sponges and between Miragel buckles and solid silicone buckles ($P < 0.05$, unpaired student t-test).

† No statistically significant difference among the three groups.

‡ Statistically significant difference between solid silicone buckles and Miragel buckles and between solid silicone buckles and silicone sponges ($P < 0.05$, chi-square).

§ Statistically significant difference between Miragel buckles and silicone sponges and between Miragel buckles and solid silicone buckles ($P < 0.05$, chi-square).

SD = standard deviation.

a mild conjunctival redness and thinning, several years after surgery. Other reasons for Miragel buckle removal are presented in Table 2. In almost every case of Miragel buckle removal, the episcleral implant had a gellike consistency and a high tendency for fragmentation, preventing it from being grasped by forceps.

Intraoperative and Postoperative Characteristics

All the implants removed for an extrusion were sent for bacteriologic analysis. A microbiologic culture was performed on 16 (47.1%) cases of Miragel swelling. Characteristics of patients with bacterial growth on the removed buckles are described in Table 3. In all, 17 (45%) Miragel buckle elements, 21 (84%) solid silicone buckles, and 22 (81%) silicone sponges had a bacteriologic analysis. A positive culture of the analyzed SB was obtained in 23 (38%) of the 60 implants sent for culture. Bacterial growth was significantly less frequent on Miragel buckles (one case, 5.9%) than on solid silicone (10 cases, 47.6%; $P < 0.01$) or silicone sponges (12 cases, 54.5%; $P < 0.01$). *Staph-*

Table 3. Characteristics of Patients With Bacterial Growth on the Removed Buckles

	Miragel	Solid Silicone	Silicone Sponge	All
No. patients	1	10	12	23
Mean age ± SD (yr)	80	52.4 ± 12.0	61.2 ± 10.2	58.7 ± 12.8
(range)		(31–70)	(38–77)	(31–80)
Gender	1 M	7 M, 3 F	7 M, 5 F	15 M, 8 F
Mean duration of buckling ± SD (mo)	84	7.4 ± 6.5	12.8 ± 10.2	13.6 ± 17.7
(range)		(1–18)	(1–31)	(1–84)
Ocular inflammation (%)	1	2 (20)	2 (16.7)	5 (21.8)
Results of culture				
S. aureus (%)	0	4 (40)	5 (41.7)	9 (39.1)
S. epidermidis (%)	0	3 (30)	4 (33.3)	7 (30.4)
P. aeruginosa (%)	1	0	0	1 (4.3)
M. catarrhalis (%)	0	0	1 (8.3)	1 (4.3)
P. mirabilis (%)	0	2 (20)	0	2 (8.7)
S. β-hemolyticus (%)	0	1 (10)	1 (8.3)	2 (8.7)
S. para-sanguis (%)	0	0	1 (8.3)	1 (4.3)

SD = standard deviation.

Table 4. Intraoperative and Postoperative Data

	Miragel	Solid Silicone	Silicone Sponge	All
No patients	38	25	27	90
Scleral necrosis (%)*	2 (5.3)	6 (24)	0	8 (8.8)
Scleral rupture during removal (%)†	2 (5.3)	2 (8)	0	4 (4.4)
Strabismus surgery (%)†	4 (10.6)	1 (4)	2 (7.4)	7 (7.7)
Strabismus, medical treatment (%)†	2 (5.3)	3 (12)	1 (3.7)	6 (6.6)
New retinal tear (%)†	0	0	2 (7.4)	2 (2.2)
Redetachment (%)†	2 (5.3)	4 (16)	2 (7.4)	8 (8.8)

* Statistically significant difference between solid silicone buckles and Miragel buckles and between solid silicone buckles and silicone sponges ($P < 0.05$, chi-square).
† No statistically significant difference among the three groups.

ylococcus aureus and *Staphylococcus epidermidis* were the most common agents.

Intraoperative and postoperative data are presented in Table 4. Scleral necrosis or thinning was observed in eight (8.8%) cases, six of which were noted during solid silicone removal. It was significantly more frequent in the solid silicone group than in the silicone sponge ($P = 0.007$) or Miragel ($P = 0.03$) groups.

Four (4.4%) cases of scleral rupture occurred during removal, all in the bed of the indentation.

In 13 (14.4%) eyes, a persistent complaint of diplopia or binocular disturbance was reported. These conditions necessitated prismatic correction or orthoptic reeducation in six (6.6%) cases and strabismus surgery in seven (7.7%) cases.

During postremoval follow-up, a new retinal tear was observed in two eyes. The tears were treated by laser photocoagulation.

Eight (8.8%) eyes developed retinal redetachment after SB removal. All occurred within 9 weeks of the buckling removal. In one case, the patient refused any further RD surgery. In the other seven cases, a successful retinal reattachment was obtained at the end of follow-up.

After univariate analysis, placement of the buckle for 1 month or less ($P < 0.001$), extent of the initial RD greater than two quadrants ($P = 0.03$), realization of a vitrectomy ($P = 0.048$), and ocular inflammation at the time of SB removal ($P = 0.001$) were significantly associated with RD recurrence. None of the 14 eyes in which circumferential laser photocoagulation was performed after initial RD repair presented with redetachment after SB removal ($P = 0.2$).

Discussion

Although we discontinued using Miragel buckles elements in 1995, they were still largely removed between 1996 and 1999, representing 42% of all the buckles removed in this series. Progressive swelling of the material was the reason for removal in nearly 90% of cases. Eyes with removed Miragel buckles had significantly different characteristics than eyes with episcleral silicone implants. Removal of silicone episcleral implants was often performed early after its placement, with 58% of the removed silicone buckles placed for 1 year or less. These results are concordant with previous series, in which 48% to 96% of episcleral implant removals were performed within the first year of RD surgery.[4,5,7,10] Conversely, Miragel elements were implanted for a significantly longer time before removal, except for one case removed less than 1 year after RD repair. However, we could not detect the early cases of Miragel buckle removal because the period of collection of the data started in January 1996 and we discontinued using this material in March 1995.

Extrusion of the buckle, with or without infection, was the main indication for removal of silicone implants, which is also concordant with previous studies.[1,7,10] In most of these cases, it was difficult to determine the mechanism leading to extrusion: primary infection, mechanical irritation of the surrounding tissue, or inadequate suture of the implant contributing to tissue loss and subsequent infection. Among the removed silicone implants, we observed a bacterial growth in 40% of cases, whereas only one Miragel implant had a positive culture. This difference was statistically significant.

Miragel buckles were largely used in the 1980s and early 1990s. It was initially suggested that this material was well tolerated and less prone to infection because of its microporous surface, and it was also thought, at that time, to be a better buckling element.[20,21] After 7 to 13 years of follow-up, sporadic cases of intrascleral and episcleral Miragel removal as a result of the late swelling of the material have been

reported leading to a restriction of ocular movements causing diplopia and progressive protrusion of the implant beneath the eyelids, which could mimic an orbital tumor.[11,14,25–28] In these cases, fragmentation of the buckling material was observed, rendering the removal technically difficult. We also met difficulties in grasping this fragmented material. Cryoextraction of the buckle seemed to be the best technique for explantation.[28] The swelling and fragmentation of this material seems to be the consequence of a peripheral degradation of the implant associated with a foreign body giant cell granuloma.[22–24] To our knowledge, only one series of 13 eyes has addressed the characteristics and the outcome of patients needing episcleral Miragel buckle elements removal.[25] In our series, Miragel elements were implanted for a longer time than episcleral silicone sponges or solid silicone implants and had a significantly lower rate of extrusion, exposition of the indentation, and bacteriologically proven buckle infection. With a maximal follow-up of 10 years, the mean time from RD surgery to removal was approximately 8 years, which is similar to the duration observed by Gribomont.[25] Although we were not able to assess the rate of removal of Miragel elements after a definite duration of implantation because of variable follow-up patterns, our results seem to be different from those of the series by Roldan-Pallares et al,[15] which reported a 2.4% rate of Miragel implants removal, with a follow-up of 7 years or more. After reviewing all these late complications, we think that patients implanted with Miragel buckles intrasclerally or episclerally should undergo a close and long-lasting follow-up, ideally by their eye surgeon, be informed of the potential long-term complications of Miragel elements, which were not known at the time of their RD repair, and be asked to present promptly if they notice ocular motility disturbance or a bulkiness of their indentation. Although it is possible that, after 10 years or more in the eye, Miragel implants invariably swell up, we do not advocate for a systematic removal of well-tolerated buckles, because retinal redetachment and scleral rupture are still potential visual-threatening complications of indentation removal. Conversely, the SB extraction should be considered as soon as the first signs of Miragel swelling occur to avoid a major fragmentation of the buckle, which renders the removal technically difficult or even dangerous to the underlying sclera.

Although the use of Miragel buckling elements is now discontinued, this type of material is still a subject of concern because of the long-term swelling that will often lead to removal of the buckle. In this series, the mean time from surgery to Miragel buckle elements removal was approximately 8 years. However, our longest follow-up does not exceed 10 years. This example of a late complication of an initially well-tolerated material is an invitation to increase our vigilance when following up patients with any type of implant.

Key words: episcleral buckle, Miragel, retinal detachment.

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PRODUCTIE 13

Eye

Letter to the Journal

Eye (2003) 17, 248–250. doi:10.1038/sj.eye.6700260

Miragel explant fragmentation 10 years after scleral buckling surgery

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Sir,

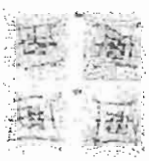
Long-term complications are known to be associated with hydrogel explants.[1,2,3,4] We would like to present a patient with severely restricted eye movements 10 years following the use of Miragel explant (from MIRA, 87 Rumford Avenue, Waltham, MA 02454, USA).

Case report

A 66-year-old man had two scleral buckling surgeries for a right rhegmatogenous retinal detachment 10 years previously. He was referred for increasing binocular diplopia over the past 12 months.

On examination, his visual acuity was 6/18 OD and 6/12 OS. There was a large swelling over the superotemporal aspect of the right globe. On palpation, it was not possible to reach the posterior extent of this swelling. The eye was hypotropic and esotropic, and the extraocular movements were limited in all directions, especially abduction and elevation. Orthoptic assessment showed the deviation to be 8Δ esotropia, 4Δ L/R and 20Δ of excyclotorsion (see Lee's Chart, **Figure 1a**).

Figure 1.



(a) Preop Lee's chart showing severely restricted extraocular movements. (b) Postop Lee's chart showing marked improvement in movements.

Full figure and legend (399K)

A provisional diagnosis of mechanical restriction was made, and we decided to explore and remove the surgical explant in the first instance.

At surgery, forced duction tests confirmed the diagnosis of mechanical restriction. It was found that the explant was covered by a thick fibrous capsule, and when the explant was exposed, it had a straw-colour, opalescent and gel-like appearance. It was not possible to purchase the explant with forceps as the material was extremely friable and tended to disintegrate. Eventually, we found that the best way to remove the surgical explant was to do so in a piece-meal fashion using a curette (see **Figure 2**). After the explant was removed, further excision and dissection of the fibrous tissue were carried out until the forced duction test gave satisfactory eye movements in all directions.

Figure 2.

Fragmentation of Miragel explant.

Full figure and legend (157K)

Two months postoperatively, the extraocular movements were almost full, and repeated orthoptic assessment showed that the excyclotorsion was reduced to 8 prism dioptres with minimal exotropia and hypotropia. The patient was then able to fuse images with the help of a Fresnel prism to correct the exotropia (see Lee's chart, **Figure 1b**).

Hydrogel explants were first introduced in 1979, but were later withdrawn in the 1990s. The initial enthusiasm for the use of this type of explant was for the following reasons:[5,6] (1) The explants were soft and elastic and considered less likely to erode through the conjunctiva. (2) The explant did not contain any dead space, and this was thought to be important in minimising the risk of infection. (3) The explants could absorb and release antibiotics slowly. (4) The swelling from hydration could increase buckle height in the immediate postoperative period.

Miragel explants were subsequently withdrawn because of late complications.[1,2,3,4] These include erosion into the globe, extrusion of the explants and progressive diplopia. The material had been shown to be structurally unstable and this led to excessive water absorption, swelling and disintegration.[1] This process must be a very slow one, as typically many of these complications only appear 7–10 years after the initial scleral buckle operation.[1,2,3,4]

Comment

Using scissors and forceps in the conventional manner, the removal of Miragel may be difficult, as the explants disintegrate when grasped by instruments. In our patient, the explant was associated with massive periocular fibrosis and extensive dissection was required to free the globe from its mechanical restriction. Our case illustrated that the symptoms can be slowly progressive and that some complications tended to be delayed for many years. We may only be starting to see a number of these cases in this country, even though the explants were withdrawn some years ago. Where Miragel explants had been used extensively in the past, eye units should be aware of the possibility of late complications.

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Eye ISSN 0950-222X | EISSN 1476-5454

PRODUCTIE 14

Late-Onset Progressive Strabismus Associated With a Hydrogel Scleral Buckle

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A hydrophilic implant for scleral buckling was developed in 1980.[1] Advantages include softness and elasticity, no dead spaces, ability to gradually absorb and release antibiotics, and stimulating production of a fibrous capsule around the implant. Short-term follow up studies in rabbits showed no clinical or histologic complications.[1,2] Long-term complications of the hydrogel scleral buckle have emerged in the last 10 years.[3-6] These included fragmentation, subconjunctival bulging, intraocular erosion, migration, and restriction of extraocular movement. We recently encountered a patient with progressive restrictive strabismus beginning 8 years after retinal detachment repair with a MIRAgel (hydrogel; MIRA, Uxbridge, MA) scleral buckle. Worsening complaints of diplopia and discomfort led to strabismus surgery. Untreatable retinal detachment resulted in enucleation.

CASE REPORT

An 80-year-old man presented with complaints of binocular diagonal diplopia and ocular discomfort for several months. History included an uncomplicated cataract extraction bilaterally, with an intraocular lens implantation in each eye, 10 years previously and a retinal detachment repair in the right eye with a MIRAgel scleral buckle 8 years previously.

Visual acuity was 20/50 in the right eye and 20/25 in the left eye. He measured 6 PD of right hypertropia and 4 PD of right exotropia at distance and near fixation. Ocular rotations showed overaction of the right inferior oblique muscle and mild underaction of the right superior oblique muscle with no other limitations. The head-tilt test was mildly positive to the right without cyclotorsion. Ocular tensions were normal bilaterally as was the slit-lamp examination. Dilated fundus examination indicated that the retina was attached in each eye with indentation from the scleral buckle. The patient was treated with a small vertical and horizontal prism correction in his glasses with subjective fusion.

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J AAPOS 2004;8:72-73.

1091-8531/2004/$35.00 + 0
doi:10.1016/j.jaapos.2003.09.014

One year later, diplopia had returned. The exotropia remained unchanged, but the right hypertropia had increased to 8 PD in primary gaze and 10 PD in left gaze. Overaction of the right inferior oblique was moderate, and moderate limitation in downgaze of the right eye was observed for the first time. The vertical prism correction in the glasses was increased slightly, and the patient noted subjective fusion.

The diplopia recurred again 1 year later, and the right hypertropia was now 22 PD. Depression of the right eye below the midline was not possible The right inferior oblique overaction was marked with 30 PD right hypertropia in left gaze. On dilated fundus examination, intrusion of the scleral buckle was not noted. Surgical correction was recommended.

During surgery, the forced-duction test showed marked restriction to downgaze of the right eye. Attempts to expose the muscles resulted in observation of a large encapsulated scleral exoplant. After opening the capsule, the MIRAgel buckle appeared translucent and swollen to four to five times normal size. Maneuvers to remove the buckle resulted in fragmentation to the slightest touch.

Continued dissection to remove the exoplant resulted in the appearance of a thinned area of sclera with choroidal exposure and leaking liquid vitreous. No retinal prolapse or detachment was noted. The overlying segment of buckle was replaced to act as a tamponade, and the overlying Tenon's capsule and conjunctival tissue were closed securely.

The following day. the patient was evaluated by his retinal surgeon who found a "kissing" choroidal detachment in the right eye. Treatment, including reoperation to close the scleral perforation, was unsuccessful. Several months later, the right eye was enucleated.

DISCUSSION

Scleral buckling with exoplant material, such as solid silicone and silicone sponge, has been associated complications such as extrusion, pressure necrosis with erosion through the sclera, infection rates reported from 2.7% to 18%,[2] and restrictive strabismus with diplopia during a period several months after surgery. This can occur with any scleral buckling surgery. In an attempt to eliminate or minimize these problems, a hydrogel material was developed by Refojo et al.[1] Favorable qualities of the new material included softness, elasticity, nonabsorbability, absence of dead spaces, ability to be sterilized with heat, and ability to absorb and gradually release antibiotics. Short-

term follow up studies in rabbits indicated no clinical or histologic signs of significant toxicity or inflammation.[1,2]

In 1992, Marin[3] reported seven patients in whom long-term complications developed from swelling of the hydrogel buckling implant (MIRAgel) 7 to 11 years after surgery. Hasslinger,[7] the director of research and development at MIRA Inc, denied knowledge of any reported complications secondary to the placement of MIRAgel implants. Since then, there have been several reports of long-term problems in patients who have had hydrogel used for scleral buckling repair of their retinal detachments.[3-6,8] The implants were often removed because of excessive scleral indentation and subconjunctival intrusion or extrusion. On removal, the hydrogel appeared friable and swollen with dehiscence of the scleral bed (as in the case of implants), vitreous hemorrhage, and loss of vision in some cases.

A patient reported by Hwang and Lim[4] had limitation of adduction and infraduction with diplopia 8 years after scleral buckling with MIRAgel, and this condition worsened over time. After the scleral buckle was removed, the patient became orthophoric in primary gaze with mild remaining restriction of adduction and infraduction.

Braunstein and Winnick[6] reported a patient with complications 13 years after uneventful scleral buckling procedure using MIRAgel. Diplopia and orbital swelling were noted, and infraduction of the operated eye was limited. These findings mimicked a periorbital mass lesion. During surgery to remove the buckle, the hydrogel material was noted to be 4.5 times its normal size. Removal of the buckle resulted in elimination of diplopia.

Our case report patient did well for 8 years after retinal detachment repair. He then presented with increasing horizontal and vertical diplopia as well as increasing restrictions to ocular motility. We now know that hydrogel implants are often well tolerated for a number of years, but they have the potential to cause late problems. Special care must be taken in attempting to remove these implants because the surgery is difficult and tedious, the material fragments easily, and scleral erosion and perforation have been noted as in the case of our patient. In some cases, it may be best to leave the implant in place rather than put the eye at additional risk. This decision depends on the effect of the scleral buckle and the situation. If surgery becomes unavoidable, the strabismologist should consider obtaining the assistance of a retinal surgeon. It seems advisable to have banked sclera, tissue, glue, etc, available in these types of surgeries in case there is a need to close any sclera defects encountered.

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PRODUCTIE 15

Korean J Ophthalmol
Vol. 18:47-51, 2004

Diplopia and Periorbital Mass Associated with Miragel Buckling Explant

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A 28-year-old female presented with a palpable mass lesion on the superonasal aspect of her right globe and she had a progressive diplopia. She had a scleral encircling surgery with a Miragel explant (MIRA, Waltham, Mass, USA) for the tractional retinal detachment associated with pars planitis 9 years previously. On examination, she revealed restricted eye movements of her right eye. The magnetic resonance imaging documented a swelling of the Miragel explant that mimicked a periorbital mass lesion. The Miragel explant was removed and fragmentation of the explant was found intraoperatively. The removed Miragel explant was examined by a scanning electron microscopy, and this demonstrated a disintergrated and swollen structural composition of the Miragel explant. Postoperatively, her extraocular movement was almost restored and the retina remained well attached. Alterations in the structural composition of the Miragel explant results in an excessive swelling that causes a restriction of the extraocular movement, and this can mimick a periorbital mass lesion.

Key words: diplopia, fragmentation, Miragel explant, pseoudotumor, scleral buckling

INTRODUCTION

Hydrogels that are used in retinal reattachment surgery are hydrophilic materials formed by a 3-dimensional polymer network. Miragel (MIRA, Waltham, Mass, USA) is a soft, elastic and smooth material, and it is one of the most widely used hydrogels. It consists of co-poly (methylacrylate-2-hydroxyethy acrylate) cross-linked with ethylene diacrylate and 15% water. It was first introduced in the late 1970s and initially, it was thought to offer several advantages over the silicone materials that were then used.[1,2] It was soft, elastic and considered less likely erode through the conjunctiva. The material did not contain any dead space and it could absorb and slowly release antibiotics; this minimized the risk of infection. However, the explant was withdrawn from the market in the 1990s because of the late complications occurring 7 to 11 years after the surgery.[3-6] These problems include erosion into the globe, extrusion of the explants, formation of a periorbital mass and a progressive diplopia.

In this paper, we report a case of the development of a progressive diplopia associated with restricted extraocular movement and the presence of a pseudotumor 9 years following the use of a Miragel explant. This case presents the first Miragel-associated, long-term complications reported in Korea.

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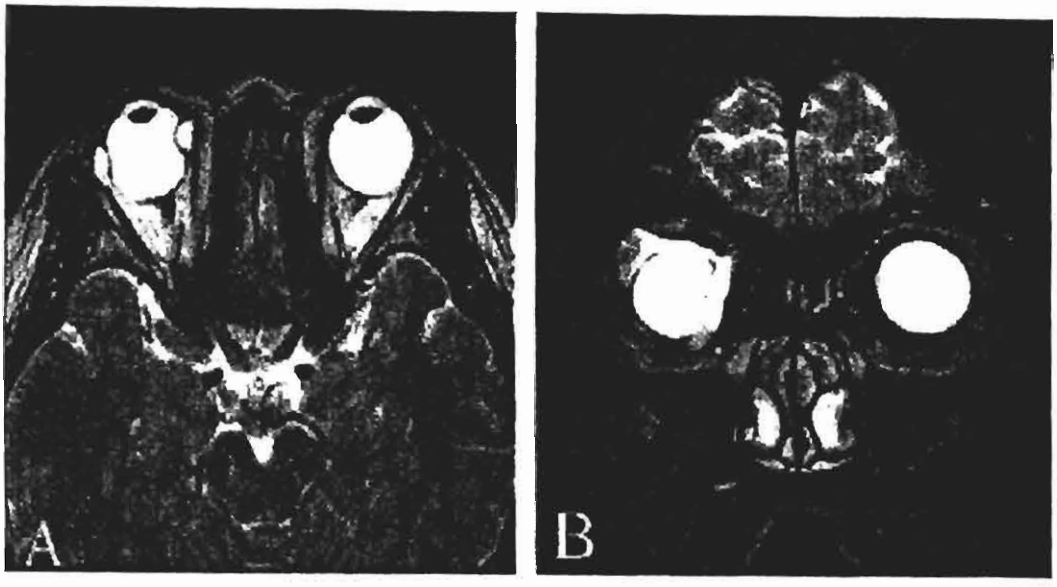

Fig. 1A,B. The magnetic resonance imaging documents the enlargement of the encircling Miragel explant. Sagittal view (A), Coronal view (B).

CASE REPORT

A 28-year-old female visited my clinic with a palpable mass lesion on the superonasal aspect of her right globe, and she had a progressive diplopia over past few years. She had received scleral encircling surgery with a 3.3*5.5 mm Miragel explant (MIRA, Waltham, Mass, USA) for the tractional retinal detachment associated with pars planitis 9 years previously.

On examination, her visual acuity was 20/30 OD and 20/20 OS and the retina was well attached. The protruding mass lesion was palpable beneath the superonasal aspect of her right upper lid. The magnetic resonance imaging revealed an enlargement of the Miragel explant; this implied that the mass lesion was caused by the extrusion of the explant. (Fig.1 A,B) The extraocular movement of her right eye was severely restricted in all directions, especially upon adduction and elevation. (Fig. 2A) The progressive diplopia and limited extraocular movement were thought be caused by the mechanical restriction associated with Miragel explant and so, we decided to remove the explant.

At surgery, the Miragel material was found to be encapsulated with a thick fibrous capsule and it was extremely friable and tending to disintergrate when we tried to hold it with forceps. (Fig. 3) A tedious and complete removal of the encircling material was done, along with the dissection and removal of the fibrous capsule on the explant.

The removed Miragel material demonstrated that the buckle had swollen up to 2.06 times its original size. Scanning electron microscopy revealed a deteriorated material with micropores; the explant was distorted in shape and irregular in size.(Fig. 4 A,B)

At 1 month postoperatively, the retina remained well attached and the patient's visual acuity was 20/25 OD. The follow up Hess screen test documented a much-improved extraocular movement (Fig. 2B), and also, a cosmetic improvement was achieved.

DISCUSSION

Scleral buckling material evolves from the autologous fascia lata to attach to the non-absorbable synthetic agents, such as polyethylene, silicone, and hydrogels. The hydrogels, including Miragel, were

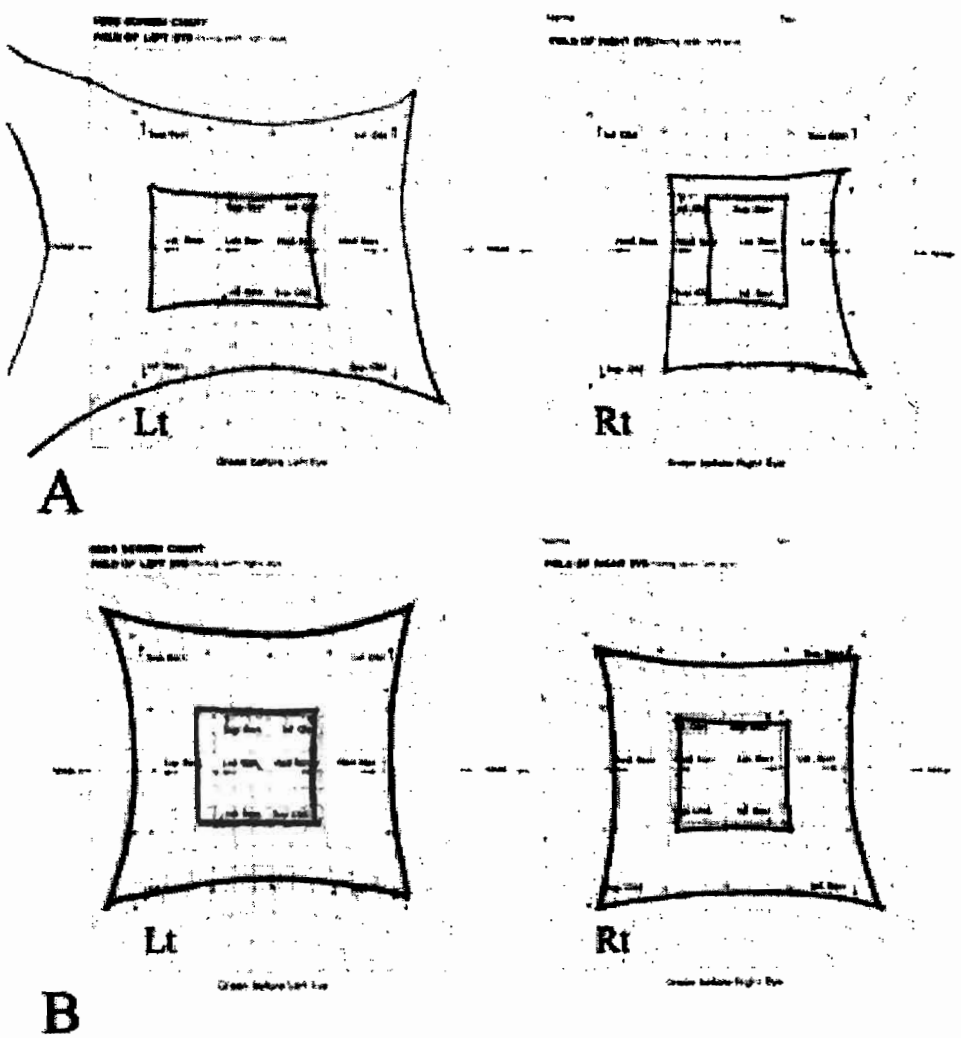

Fig. 2. A preoperative Hess screen test showing a severely restricted extaocular movement in her right eye (A). A postoperative Hess screen test showing the marked improvement in eye movements (B).

initially thought to be ideal substitutes for the other synthetic material because their structural and chemical characteristics. The explant was as effective in buckling as solid silicone rubber and silicone sponge. Altering the state of hydration could vary the degree of swelling and this increased the buckling height in the immediate postoperative period. Hydrogels were soft, elastic and considered less likely to erode through the conjunctiva. In addition, the material was assumed to be less prone to infection because it did not contain any dead space and it could absorb and slowly release water-absorbable antibiotics.[1,2] However, the long-term complications of the Miragel material began to emerge 7 to 11 years following the surgery.[3-6] The complications included erosion into the globe, extrusion of the explants and a progressive diplopia. The material has shown to be structurally unstable and this leads

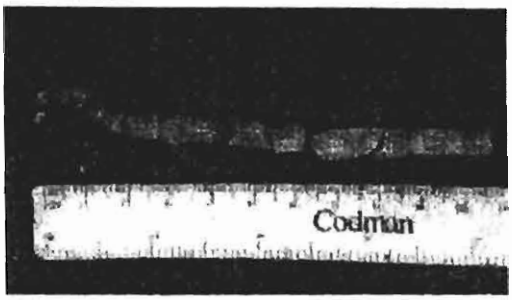

Fig. 3. The Miragel explant shows extreme friability and a tendency to disintegrate into fragments intraoperatively.

to excessive water absorption, swelling and disintergration.[2-4] These complications necessitated the removal of buckling material. At surgery, the explants were seen as translucent and gel-like materials that were extremely friable, and this made it hard to remove them with a conventional method of using scissors and forceps. This resulted in a particle retention on removal of the scleral buckling element. According to the report by Marin, the alteration of the material is associated with a deterioration of its chemical composition.[2] Micro-Fourier transform infrared spectroscopic analysis of recovered implants demonstrated the hydrolytic degradation of the implant; this led to a swelling greater than the original polymer.[3] In our present case, the Miragel explant that was removed from the patient had swollen to 2.06 times its original volume. This resulted in a restriction in extraocular movement and the formation of a mass-like lesion.

Considering the historical data and the late complications observed in the present case, the hydrogel explants can no longer claim to provide advantages over other conventional scleral buckling materials. The hydrogel explants have been withdrawn from the market since the 1990s. As these complications usually occur 7 to 11 years following the surgery, it is highly recommended for the ophthalmologists who have used hydrogel materials in retinal surgery to be aware of these problems and do regular follow

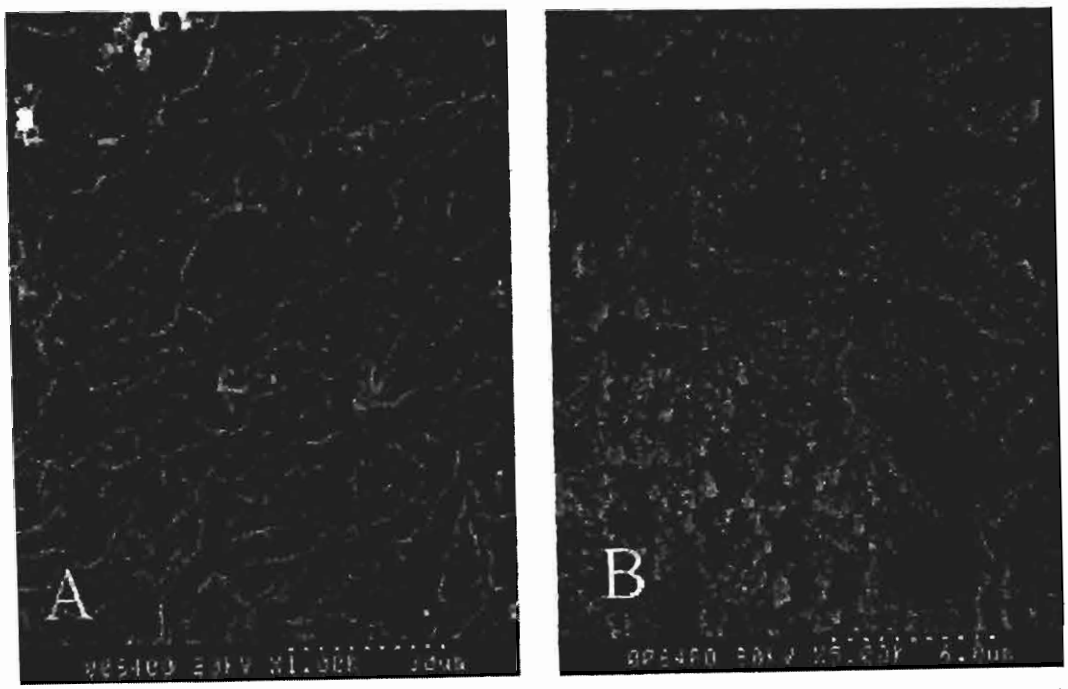

Fig. 4A, B. The removed Miragel material demonstrated a structural deterioration with micropores, a distorted shape and an irregularity in size upon scanning electron microscopy (A: × 1000, B: × 5000).

ups for the patients with hydrogel explants.

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PRODUCTIE 16

Use of self-expanding, hydrophilic osmotic expanders (hydrogel) in the reconstruction of congenital clinical anophthalmos

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Purpose of review

Rehabilitation of the congenitally anophthalmic orbit is frustrating to both the parents and physician. Traditional methods involve using progressively enlarging static acrylic conformers to expand the conjunctival socket, followed by placement of conventional static spherical orbital implants, dermis-fat grafts, or inflatable balloon expanders for orbital enlargement. Limitations of these methods typically result in less-than-optimal cosmetic outcomes, with retardation of bony orbital and overlying soft tissue growth adversely affecting midfacial growth and symmetry. Recent advances in tissue expansion technology may offer additional, novel alternatives to conventional therapies.

Recent findings

Hydrogel tissue expanders were recently adapted for use in congenital anophthalmia. The expanders are placed in their dry, contracted states, and expand gradually to their full size via osmosis of surrounding tissue fluid, with up to a 10-fold increase in volume. Offering the benefit of predictable and controllable self-expansion, hydrogel expanders may offer yet another alternative or adjunctive therapy to the early rehabilitation of the contracted socket. Separate appliances are used for conjunctival and orbital reconstruction. Initial results appear promising. Tempering the enthusiasm for their use, however–particularly in terms of implanted orbital expanders–is the recent spate of long-term complications reported from previous uses of hydrogels as scleral buckling material.

Summary

Self-expanding hydrogel tissue expanders appear to offer an intriguing reconstructive alternative to the frustrating condition of congenital anophthalmia. Long-term safety of the material as an orbital implant has not yet been demonstrated, but early results are promising.

Keywords

congenital clinical anophthalmia and microphthalmia, orbital expansion and reconstruction, conjunctival reconstruction, microblepharon, micro-orbita, hydrogel tissue expanders

Curr Opin Ophthalmol 15:426–431. © 2004 Lippincott Williams & Wilkins.

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The opinions expressed herein are those of the authors, and do not reflect those of the Army or the Department of Defense.

Current Opinion in Ophthalmology 2004, 15:426–431

1040-8738

Introduction

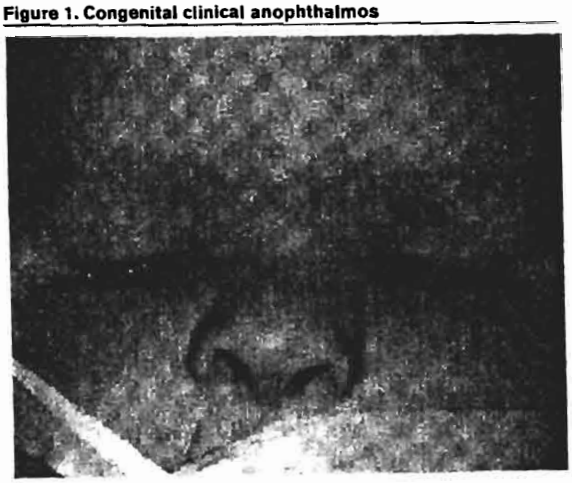
Although decidedly uncommon, congenital anophthalmia and microphthalmia are among the most frequently encountered ocular malformations [1–3]. True congenital anophthalmia is an exceedingly rare condition wherein the optic vesicle fails to develop *in utero*. More commonly, one finds some vestige of ocular tissues that failed to develop properly early on, termed extreme microphthalmos, abortive microphthalmos, or blind microphthalmos. Practically, of course, this distinction is largely academic and matters little to the patient, the parent, or the physician, as the clinical picture is the same regardless of etiology, that being a shrunken bony orbital skeleton (micro-orbitism) and contracted overlying soft tissues (microblepharon). The clinical condition is often referred to as clinical congenital anophthalmia. Reconstruction must begin promptly after birth (within weeks), and requires an intense commitment of time, energy, and resources by the parents, the physician, and the ocularist [4,5]. Reconstruction of these tiny orbits poses significant challenges, as retardation of bony orbital growth leads to retarded growth of the entire hemiface (or midface, in the case of bilateral anophthalmia) and secondary hypoplasia of the maxilla and mandible [6]. The resulting asymmetry is cosmetically and functionally disappointing, despite the best of intentions and efforts. Reconstruction is aimed at expansion first of the conjunctival sac, and subsequently the bony orbit [7,8]. Traditional methods include the initial use of progressively bigger static acrylic conformers to enlarge the conjunctival socket and lids, followed by the placement of conventional solid spherical orbital implants, dermis-fat grafts, or inflatable tissue expanders for orbital expan-

sion. Craniofacial surgery for surgical orbital enlargement may be required at a later stage. Recently, self-expanding hydrogel tissue expansion technology has been applied to this condition [9,10•,11], a development that has been received with equal amounts of enthusiasm and caution. Although used successfully in Europe for several years, the devices have only recently become available in the United States [9–15]. This article will briefly review traditional methods of reconstruction as well as the evolving role of hydrogel expanders in the early treatment of clinical congenital anophthalmia.

Clinical characteristics of congenital anophthalmia

Studies report the incidence of congenital anophthalmia as approximately 0.2 to 0.6 per 10,000 births [1,2]. Clinical anophthalmia can result from primary genetic disorders, maternal exposure to environmental teratogens, or in association with other developmental abnormalities [1–3]. Lacking the globe not only retards growth of the socket and overlying soft tissues, but retards the development of the entire hemiface, affecting the growth of the maxilla, maxillary sinus, and mandible [6]. The distance between the lid fissure and brow is also reduced, creating a compressed appearance of the midface [4] (Fig. 1). The hypoplasia is most marked when the child is congenitally anophthalmic, but less dramatic retardation can also result when a normal eye is removed in early infancy. Although the lids are normally developed structurally, the fissures are severely phimotic both horizontally and vertically. Additionally, the conjunctival sac and fornices are severely contracted and shrunken, in contradistinction to acquired anophthalmia, in which the lids and conjunctiva are more age-proportionally appropriate [4,8].

Figure 1. Congenital clinical anophthalmos



Newborn girl with bilateral congenital clinical anophthalmos. In addition to hollow, sunken orbits, she also demonstrates the microblepharon and midfacial hypoplasia that are characteristic of this condition. (Photo courtesy of Dr. Asa D. Morton, MD, San Diego, CA).

Current therapies: lid expansion

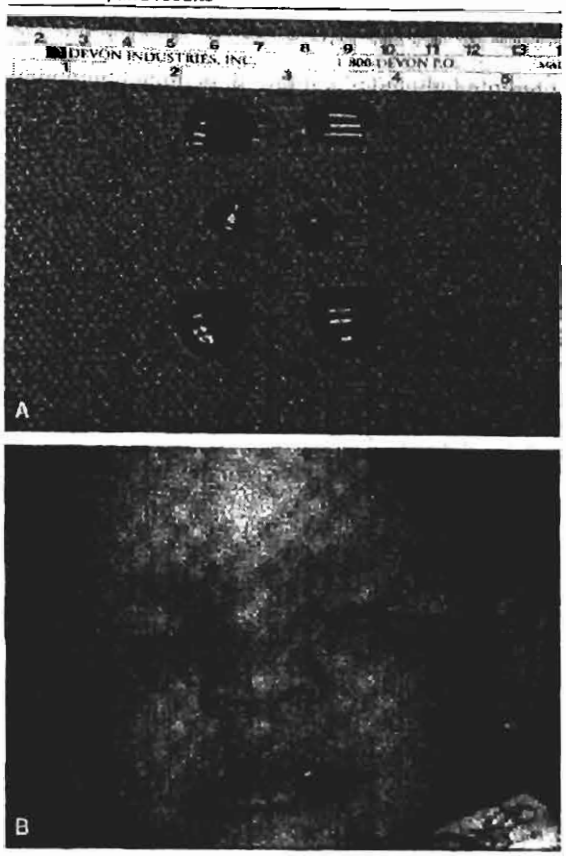
Reconstruction efforts are focused in several directions simultaneously: 1) expansion of the lid dimensions, both horizontally and vertically; 2) expansion of the conjunctival sac and formation of normal fornices; and 3) expansion of the bony orbit [8]. Initial efforts are necessarily directed at expansion of the lid fissure, because the severe phimosis effectively denies access to the orbit. It is axiomatic that soft tissue drapes to the underlying musculoskeletal structures: loss of bone or deep soft tissue leads to contraction and shrinkage of the overlying tissues, while mass effects lead to distention and expansion of those same overlying tissues—this is, of course, the genesis of the microblepharon in this condition, and the principle by which tissue expanders work in the first place. Traditionally, the lids and conjunctiva are expanded with a series of progressively enlarging acrylic conformers (Fig. 2). This effort requires significant dedication and time investment on the parts of the family, the physician, and the ocularist, because the management requires frequent office visits and multiple examinations under anesthesia.

While the lids are expanded via anteriorly directed pressure, the conjunctiva and fornix are expanded via posterior and radially directed pressure, and therein lies several rubs: each conformer has to be incrementally larger than the previous, but not so much larger that it is painful or impossible to place in the cul de sac. However, if it is too easily placed, it may be too small to have dramatic effect on lid dimensions. At the same time, the conformer has to be bulky enough to exert sufficient posterior pressure to induce conjunctival expansion, but not so bulky as to extrude from socket, while still exerting enough anterior pressure to effect lid growth: what one gains in posterior pressure is often lost in anterior pressure, and *vice versa*. For that reason, some surgeons elect to insert bulky appliances under anesthesia and place temporary suture tarsorrhaphies (which can sometimes cheesewire through the lids over time) [16,17]. Additionally, progressively enlarging conformers are nonetheless static, and will force the soft tissues to mold to their shapes. Therefore, the conjunctival space often adopts a dumbbell, spherical, or acorn-shape, with inadequate forniceal depth [8,16]. Clearly, current therapies leave much to be desired.

Current therapies: orbital expansion

Once the lids are opened adequately to afford orbital access, the bony skeleton is addressed. Again, traditionally, conventional solid orbital spheres are used, although the contracted bony orbit severely limits the size of implant able to be placed, ending in uniformly disappointing results. Again, the trade-off appears: small implants

Figure 2. Therapy for anophthalmos with enlarging conformers, and results



(A) Traditional therapy initially includes a series of progressively enlarging conformers. In this figure, the middle conformers represent the patient's initial socket impressions, which were subsequently replaced by the upper, and then the lower series of conformers (Photo courtesy of Dr. Asa D. Morton, MD, San Diego, CA). (B) After several months, the orbits still show marked growth delay that is characteristic of clinical anophthalmia. Note the persistent lid phimosis and compression of all midfacial dimensions.

yield negligible results; large implants risk extrusion. Repeated implant exchanges require numerous anesthesias and surgical traumas until the skull has matured [13].

Because of this, some surgeons use inflatable balloon tissue expanders, implanted via bicoronal flap and surgical orbitotomy [4,11,13,14]. The balloon is inflated with saline via an exteriorized injection/inflation port placed distally from the orbit. The balloon is inflated routinely, either in the office or at home [11–13]. Inflation pressures can sometimes reach 150 to 200 mm Hg, which can be uncomfortable for the patient and the parents (and ultimately the physician) [11,16,17]. To minimize inflation pressure spikes, one group of researchers developed a pulsatile orbital expander that transmits steady carotid pulsations to the orbit [18]. These devices all carry risks of tissue ischemia, infection, and extrusion [11]. Perhaps not surprisingly, although inflatable orbital expanders are effective, ophthalmologists do not commonly use them.

The ideal expander

An ideal expander would have several characteristics: it would be easily placed through a small access site; would gradually enlarge over a relatively short time, yet be well tolerated over the long term; would avoid uncomfortable inflation spikes; would be resistant to infection, extrusion, or inflator complications; and would require minimal intervention, manipulation, or revision.

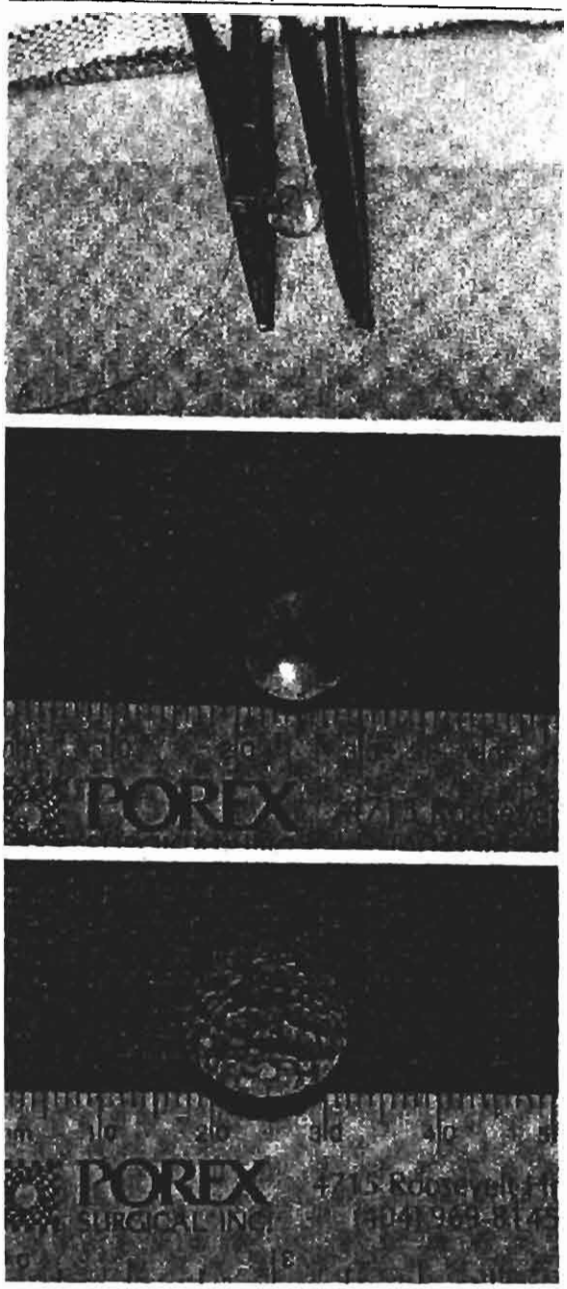
Katowitz *et al.* [7,8] showed promising results in this regard using dermis-fat grafts as orbital implants. Being a vascular tissue that grows with the child, dermis-fat grafts can exert enough orbital pressure and volume to expand both the lids and socket. In some cases, the growth was so exuberant that the dermis-fat grafts had to be debulked to avoid overexpansion. Best success was achieved when the dermis-fat graft was placed before 3 years of age [7,8]. Because of the familiarity of the procedure and the low risks of complications, this procedure is gaining broad acceptance.

Reedy *et al.* [19] attempted to determine the optimal orbital pressure required of an orbital expander to stimulate normal orbital growth. In a well-crafted and controlled study on newborn Yorkshire piglets, they demonstrated that near normal orbital pressures (20 mm Hg in this study) resulted in near normal orbital volumes, that less than normal pressures resulted in reduced orbital growth, and that greater than normal pressures resulted in larger orbital volumes. Normal adult human orbital pressures have been separately shown to be approximately 3 to 6 mm Hg [20–22], so direct application of Reedy's pressures to the human may not be valid. On the other hand, it may be that the smaller infant orbit is more equivalent to that of the piglet and requires a higher pressure for normal growth.

Hydrogel orbital expanders

After several years of use in Europe, a new hydrogel orbital expander—which appears to meet many of the requirements of the ideal expander—has been recently introduced and marketed in the United States (Osmed GmbH, Illmenau, Germany, distributed in the United States by IOP, Inc., Costa Mesa, CA). Hydrogels are highly hydrophilic polymers that expand by osmotically imbibing water (or in the case of implanted expanders, tissue fluids). They are commonly used to make soft contact lenses and some intraocular lenses [9,10•,11,14,15,23,24]. The amount and rate of expansion can be engineered and very precisely controlled. These characteristics, coupled with the ability to craft the anhydrous material into any desired shape and size [23,24], make it an attractive material to consider in reconstructing congenital anophthalmic sock-

Figure 3. Osmotic hydrogel expanders



(A) Hemispheric shape is for lid and conjunctival expansion. Demonstration of surgical technique of loose retention sutures to allow for expansion of the device while in the conjunctival sac. (Photo courtesy of Dr. John D. Ng, MD, Portland, OR). (B) Spherical shapes are for orbital implantation and expansion. The figure demonstrates the 5-mL sphere in its contracted, anhydrous shape. (C) Within a few hours of hydration (in this instance, in water), expansion is already well under way.

ets and orbits. Over the last several years, a variety of hydrogel materials have been used in general plastic and orbital surgery for tissue expansion [9–15,23–25••,26], as well as for retinal scleral buckling elements [27]. The current product is a copolymer of vinyl pyrrolidone and methylmethacrylate [23–25••], whereas prior ophthalmic and retinal hydrogels were crosslinks of different materials [11–13,27].

Two ophthalmic appliances are available: one, a hemisphere designed for conjunctival expansion; and the other, a sphere intended for bony orbital expansion (Fig. 3). Both are inserted in the dry, shrunken, anhydrous state, and expand gradually over several weeks to their fully inflated sizes, roughly a 10-fold increase in volume. The hemisphere is placed into the conjunctival sac, much as a regular conformer, and held in place with fornix reconstruction sutures tied externally (loosely, to allow for expansion). One surmises that these sutures not only help hold the conformer in place against extrusion, but also enhance radial expansion of the conjunctival fornices. Normal tear secretion gradually swells the conformer to maximum size within a few weeks, as it exerts a constant hydrostatic pressure of 20 to 30 mm Hg. A suture tarsorrhaphy is recommended to help maximize anterior and posterior pressure while minimizing the likelihood of extrusion as the conformer expands. Maximum expansion is achieved within 30 days, although the conformer can be retained for 2 to 3 months [11]. Once maximum socket expansion is realized, a conventional prosthesis can be placed [11].

The orbital expander is spherical. Its anhydrous size is roughly one tenth the expanded volume. Surgically, it can be placed intraorbitally through a small lateral soft-tissue incision, avoiding the need for the central conjunctival incision that is required for conventional spheres and dermis-fat grafts, thereby decreasing the chances for anterior wound breakdown and extrusion. Similarly, this avoids the need for bicoronal flap and lateral orbitotomy as required for balloon expander insertion and removal. Additionally, because the hydrogel implants are self-inflating, there is no need for subfascial tracts or remote injection ports, with less risk of inflator-related complications [11]. The orbital expander exerts a constant pressure of about 20 to 25 mm Hg. As mentioned previously, whether that pressure is appropriate for human infants is, at this writing, a matter of conjecture. Regardless, it appears that even the actively expanding sphere is better tolerated than the high-pressure spikes associated with inflatable balloons [9,10•,11,14,16,17].

Potential drawbacks

As with any new material or technique, there can be potential for unintended or unexpected consequences in the long term. The fly in this particular soup is the recent spate of reports of complications of prior hydrogel appli-

cations in the orbit, to whit, retinal buckling elements made of MIRAgel (MIRA, Waltham, MA) and its precursor, MAI, popular products introduced in the late 1970s [27,28•,29••,30•,31••–38]. Reputed advantages of these products were the following: less likelihood for extrusion or erosion because of the material's softness and elasticity; less likelihood of buckle infections because of its lack of dead-air spaces and the fact that it could be saturated in antibiotic solution (which it would gradually release thereafter); the degree of swelling could be controlled by controlling hydration; and, it stimulated the formation of a surrounding pseudocapsule [27,28•,29••,30•]. In fact, most of these claims were borne out clinically, at least in the short-term [29••,35]. Unfortunately, over the long term (10+ years), complications of late hydrogel breakdown were recognized, attributed to uncontrolled swelling of the material beyond its initial size [28•,29••,31••,33]. In fact, the long time lapse between implantation and development of complications may lead to initial misdiagnosis of the condition, particularly if the patient presents to a clinician unfamiliar with either the prior surgery performed, or the material used [31••]. Indeed, since withdrawal of MIRAgel from the market in the mid 1990s, many novice ophthalmologists are no longer historically familiar with the material at all. There are now reports of buckle extrusions, intraocular erosion and migration, progressive limitation of motility, intraorbital fibrosis and mass effect, pain, foreign body granuloma formation, and inflammatory orbital pseudotumor [27,28•,29••,30•,31••,32–38]. Attempts at removing the material are frustrating, because the hydrogel becomes very friable with age, becomes semisolid, and fragments easily between the forceps. Some advocate using cryo or curettage to help remove the pieces [29••,30•,32].

It is this point that gives us pause when it comes to contemplating placing the hydrogel orbital sphere for an extended period, and tempers our eagerness to clamor aboard the wagon quickly. Admittedly, the current hydrogel polymers are different from MAI/ MIRAgel—different base compounds, different cross-linking, different polymerization characteristics—and hydrogel intraocular lenses appear to be tolerated differently from MAI/ MIRAgel [9,10•,11–15,21–24]. Additionally, the rate of extrusion of the MAI/ MIRAgel elements is significantly lower than for silicone buckling elements [28•,29••]. Nevertheless, one wonders what the effect of any hydrogel implant would be in the extreme long term—how well tolerated will the material be over the course of an 80-year lifetime? Obviously, as with any new idea or invention, time will tell. Perhaps a reasonable approach would be to use the hydrogel orbital expander as an initial, temporary step towards reconstruction, allowing it to remain for 5 to 7 years before replacing it with another hydrogel implant, a conventional implant, or a dermis-fat graft.

We could not find any reports of orbital implants being removed. Other hydrogel tissue expanders are covered in a soft, silicone wrap that helps maintain the shape and to control the expansion of the material [25••,26]: the orbital implant is not so encased. When similar hydrogel expanders were removed from elsewhere on the body, there was no comment on the difficulty of removal or of fragmentation of the material, but in those cases, the tissue expanders were removed within weeks of implantation. Nonetheless, despite the chemical differences between the Osmed and MAI/ MIRAgel implants, one cannot help but assume that they would share some characteristics, especially of long-term fragility and friability. Time will tell. However, the concept of a self-expanding orbital implant that can be placed early in the course of clinical congenital anophthalmia is certainly appealing.

Conclusion

Reconstructing congenitally anophthalmic sockets and orbits poses significant difficulties and obstacles that often result in universal frustration and disappointment for all concerned. Current expansion modalities all suffer from significant limitations. Although use of dermis-fat grafts continues to gain popularity among ophthalmologists, a new generation of self-inflating hydrogel tissue expanders is now available that significantly expands our options. The potential for controlled, gentle expansion of the lids, conjunctiva, and orbit with these devices is intriguing and exciting. Prior experience with hydrogel retinal implants should temper initial enthusiasm for long-term use of the implanted orbital expander, but initial reports are encouraging.

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PRODUCTIE 17

Ophthalmic Plastic and Reconstructive Surgery
Vol. 21, No. 1, pp 32–38

Expanding MIRAgel Scleral Buckle Simulating an Orbital Tumor in Four Cases

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Purpose: To describe four patients with an enlarging orbital mass from a swollen MIRAgel scleral buckle that simulated an orbital neoplasm.

Methods: In a retrospective, single-center case series at the Ocular Oncology Service at Wills Eye Hospital of Thomas Jefferson University, 4 eyes of 4 patients were referred for evaluation and treatment of a suspected orbital tumor.

Results: The initial presenting features were orbital mass (case 1), strabismus (case 2), and conjunctival mass with orbital extension (cases 3 and 4). Each patient vaguely recalled previous uncomplicated retinal detachment surgery 12 to 20 years earlier. Confirmation of the buckling implant material was made with the retina surgeon in 3 cases. A nontender, forniceal conjunctival mass, deep to the Tenon fascia and appearing as a translucent firm elevation was seen in all 4 cases. Axial CT (case 1) revealed a circumscribed anterior temporal orbital mass, believed to be a large inclusion cyst, 4 times thicker than the nasal scleral buckle. Ocular ultrasonography depicted an echolucent mass in the episcleral region (cases 3 and 4) that was 2 times thicker than the nasal scleral buckle (case 3). Excision was attempted in case 1, but only piecemeal removal was achieved, leading to extensive postoperative inflammation and decreased vision. The other 3 cases were followed conservatively without excision because they were each recognized to be a swollen MIRAgel implant and not an orbital tumor.

Conclusions: MIRAgel scleral buckle material can greatly enlarge over a period of 10 years and simulate an orbital tumor or orbital cyst. Patients often do not recall details of the retinal surgery. Caution is advised regarding excision of this material because it is friable and can lead to extensive postoperative inflammation.

Several materials have been used as scleral buckling elements, including silicone sponge, silicone rubber, and hydrogel. The hydrogel implant (commercial name MIRAgel, Waltham, Massachusetts) was a popular scleral buckle in the 1980s and early 1990s, as it was marketed as a soft, flexible implant with physical properties allowing it to swell slowly over time, improving the buckling effect, lacking dead space, and minimizing infection.[1–4]

Complications of MIRAgel have been reported. A study of 757 eyes with a scleral buckle followed for a mean of 6 years revealed that removal of the element was necessary in 9% of those with silicone sponge, 1% of silicone rubber, and 1% of MIRAgel.[5] However, most authors have noted that extrusion or complications of MIRAgel happen after 10 years' follow-up, and, more importantly, that removal of MIRAgel is challenging because it typically undergoes fragmentation and can lead to serious periocular inflammation.[5–15] In 1997, Hwang and Lim[10] reported the first case of MIRAgel

Accepted July 21, 2004.
Supported by the Eye Tumor Research Foundation, Philadelphia, Pennsylvania (C.L.S.), the Macula Foundation, New York, New York (C.L.S.), the Rosenthal Award of the Macula Society (C.L.S.), and the Paul Kayser International Award of Merit in Retina Research, Houston Texas, U.S.A. (J.A.S.).
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DOI: 10.1097/01.IOP.0000148409.31127.F5

scleral buckle extrusion and emphasized the long-term friability of this material, leading to fragmentation at the time of removal.

In this report we describe 4 patients who were referred to us with an enlarging orbital mass, presumed to be a malignancy. All 4 patients vaguely recalled retinal detachment surgery 12 to 20 years earlier without postoperative problems. None of the patients had any information regarding the surgical technique or scleral buckling element. We suspected MIRAgel implant in 3 patients and avoided surgery, but 1 patient underwent orbital exploration for presumed orbital cyst, and piecemeal removal of the "friable soft mass" was necessary, leading to extensive postoperative inflammation. We caution the orbital surgeon to recognize this implant and anticipate postoperative clinical challenges if this implant is partially removed or disturbed.

CASE REPORTS

A summary of the 4 cases is listed in the Table.

Case 1

In 2003, an 82-year-old man noted the onset of a lump on the temporal side of the right eye for 2 weeks. His local ophthalmologist diagnosed orbital tumor and referred the patient for treatment. He reported no trauma, pain, or knowledge of a foreign body. He recalled cataract surgery OD in 1984 followed by retinal detachment surgery in 1988. On examination, visual acuity was 20/50 OD and 20/25 OS. There was no diplopia or proptosis. Ocular motility was 30% limited in abduction OD. In the temporal conjunctival fornix, there was a translucent mass with overlying intact white Tenon fascia and prominent conjunctival vessels (Fig. 1). The firm mass measured 20 mm vertically and 15 mm horizontally. On ophthalmoscopy, the retina was flat and scleral buckling effect was noted.

Axial CT revealed a circumscribed epibulbar mass in the right lacrimal gland fossa indenting the globe and showing density similar to brain tissue in its lateral aspect but similar to a cyst in its medial aspect. On CT, the temporal "mass" was 4 times thicker than the nasal portion of the buckle. Our initial diagnosis was chronic postoperative inclusion cyst, and surgical excision was advised.

At surgery, the mass was exposed through a conjunctival approach and found to be a swollen foreign body that had folded on itself, consistent with MIRAgel buckle. The temporal mass was friable and removed

Clinical features of four patients with expanding MIRAgel scleral buckle that simulated orbital tumor

Case No.	Patient: Age/race/sex	Interval (y) between MIRAgel implant and orbital mass	Tumor features: Main finding	Conjunctival location quadrant	Location depth	Color	Diameter of mass (mm)	Texture palpation	Conjunctival vessels	Imaging: Ultrasonography	Computed tomography	Magnetic resonance imaging	Treatment	Follow-up (mo)
1	82/W/M	15	Lump	T	Deep to Tenon fascia	White-translucent	20	Smooth firm	Dilated	ND	Circ mass	ND	Excbx	Inflammation (10)
2	79/W/F	13	Esotropia	ST	Deep to Tenon fascia	White-translucent	20	Smooth firm	Dilated	ND	Circ mass	ND	Obs	Stable (6)
3	46/B/M	12	Lump	ST	Deep to Tenon fascia	White-translucent	10	Smooth firm	Dilated	Hollow mass with shadowing	ND	ND	Obs	Stable (3)
4	38/W/M	20	Lump	SN	Deep to Tenon fascia	Blue-gray translucent	12	Smooth firm	Dilated	Hollow mass with shadowing	ND	ND	Obs	No follow-up

W indicates white; B, black; F, female; M, male; T, temporal; ST, superotemporal; SN, superonasal; circ, circumscribed; Obs, observation; ND, not done; Excbx, excisional biopsy.

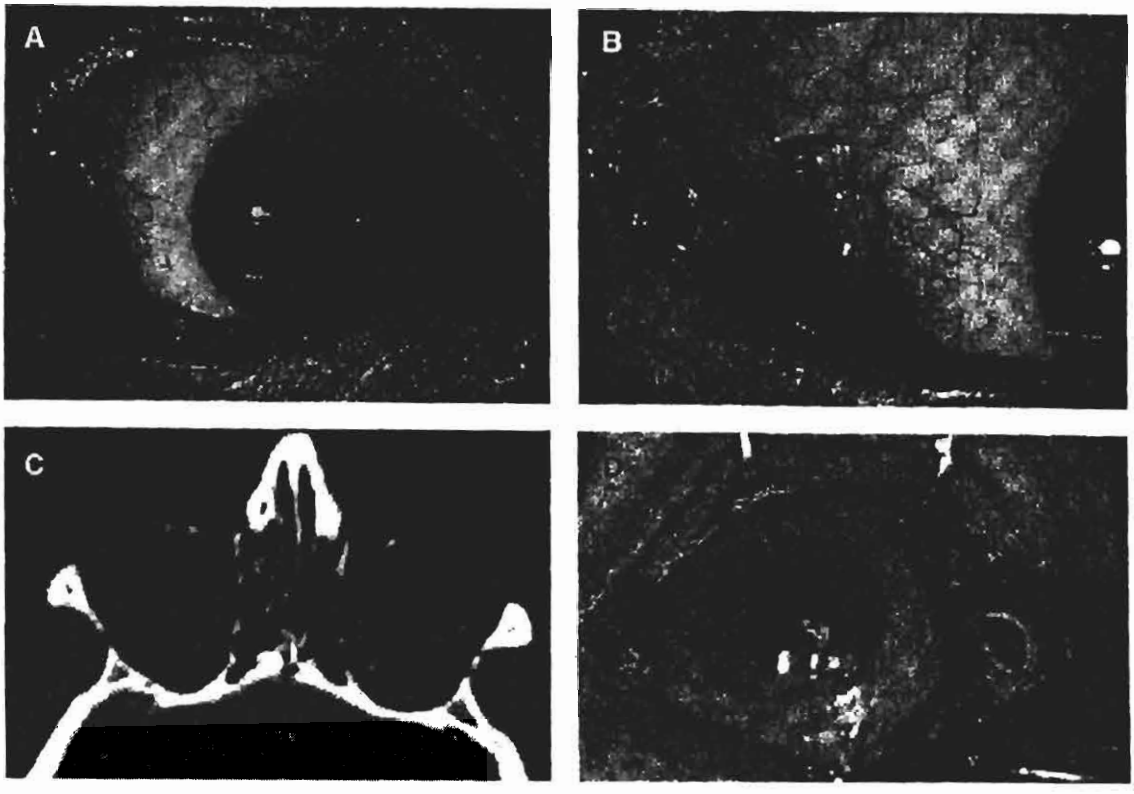

FIG. 1. Case 1. An 82-year-old man had an orbital mass that proved to be a swollen MIRAgel scleral buckle used for retinal detachment repair 15 years earlier. **A**, Mass was palpable through the temporal eyelid; deep conjunctival involvement was noted. **B**, Close-up view of mass reveals translucent material underlying white, fibrous Tenon capsule and prominent vessels. Note that the eye is pushed 10 mm nasally by the mass. This appearance is similar to a large orbital inclusion cyst. **C**, CT shows temporal mass indenting the globe with dense temporal portion and more lucent medial portion. Much smaller nasal portion of scleral buckle is noted at nasal equator of the eye. **D**, At surgery, the mass proved to be a swollen MIRAgel implant that had buckled on itself.

piecemeal, and the remainder of the buckle was left intact. The underlying sclera was thin. After surgery, massive orbital swelling ensued with eyelid edema, corneal striae, keratic precipitates, hypopyon, and poor view of the fundus caused by corneal changes. Systemic and topical antibiotics were instituted for concern for possible endophthalmitis. One month and 4 months later, repeat surgery to remove the remainder of the discohesive buckle was performed. On follow-up, 10 months later, the eye was hypotonous and quiet, with visual acuity of 20/200 as the result of striate keratopathy. The retina was attached.

Case 2

In 2004, a 79-year-old woman with breast cancer was noted to have a mass in the left anterior orbit, near the lacrimal gland fossa and referred with the diagnosis of possible metastatic tumor. She gave a history of long-standing amblyopia and mild esotropia OS from age 2 years, but over the past 6 months, the esotropia had progressively worsened (Fig. 2). In 1991, a retinal detachment OS was repaired with a scleral buckle. On our examination, the visual acuity was 20/60 OD and 20/400 OS. There was 45 prism diopters of left esotropia with only 10% abduction, 20% supraduction, 80% infraduction, and full adduction. In the temporal conjunctival fornix, deep to the Tenon fascia, there was a translucent mass measuring 20 mm vertically and 15 mm horizontally. The mass could be barely palpated for 250° around the globe and was believed to represent a swollen scleral buckle. Axial CT disclosed a mass in the lacrimal gland fossa adherent to the globe. Coronal CT showed the mass partially encircling the globe. The final diagnosis was swollen MIRAgel buckle, and observation was advised.

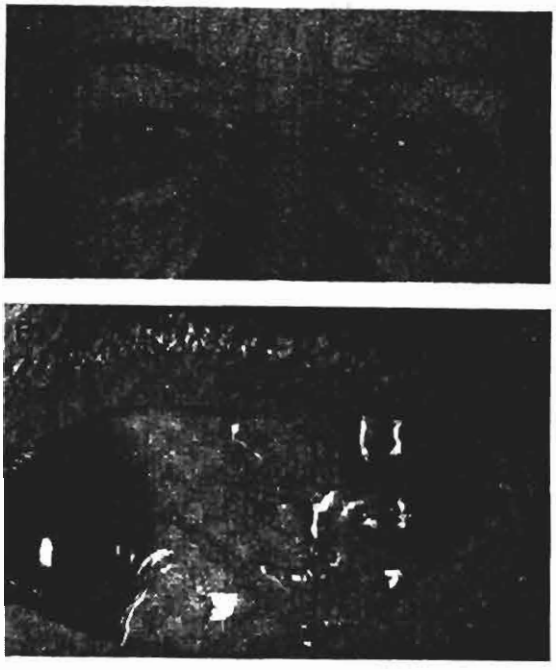

FIG. 2. Case 2. A 79-year-old woman had an orbital mass that proved to be a swollen MIRAgel scleral buckle used for retinal detachment repair 13 years earlier. **A**, Patient presented with worsening left esotropia. **B**, Translucent mass was noted in conjunctival fornix with overlying intact Tenon fascia and prominent conjunctival vessels. Observation was advised.

Phone consultation with the retinal surgeon confirmed the placement of MIRAgel. Follow-up 6 months later showed relatively stable findings.

Case 3

In 2004, a 46-year-old man felt a painless mass superotemporal OD for 1 week. His local ophthalmologist diagnosed orbital-conjunctival tumor and referred the patient for treatment. He denied trauma. He recalled cataract surgery OD in 1992 followed the same year by retinal detachment surgery OD. On examination, visual acuity was 20/100 OD and 20/20 OS. There was no diplopia or proptosis, and ocular motility was intact. The left eye was unremarkable. In the superotemporal fornix of the OD, emanating from the lacrimal gland fossa, was a translucent mass deep to the Tenon fascia and measuring 10 mm in greatest diameter (Fig. 3). The firm mass was noninjected and nontender. Ultrasound confirmed an oval epibulbar mass with scleral indentation and mild shadowing of orbital echoes. By ultrasound, the temporal "mass" was 2 times thicker than the nasal buckle. Ophthalmoscopy of the right eye confirmed flat retina with scleral indentation. The diagnosis was swollen scleral buckle (MIRAgel), and observation was advised. Follow-up of 3 months revealed stable findings.

Case 4

In 2004, a 38-year-old man was noted by his ophthalmologist to have a dark mass deep in the right fornix and extending in the orbit, suggestive of a melanocytic tumor. He recalled trauma to the right eye followed by retinal detachment and repair approximately 20 years earlier. On examination, visual acuity was 20/20, both eyes. There was no proptosis or dysmotility. In the superonasal fornix there was a grey-blue mass deep to the Tenon fascia extending for 30 mm circumferentially and 12 mm in thickness (Fig. 4). The mass was fixed to the globe, and overlying remnants of white sutures remained. Ocular ultrasound disclosed an epibulbar dense mass with orbital shadowing, consistent with scleral buckle. The diagnosis was swollen scleral buckle (MIRAgel), and observation was advised. Phone consultation with the retinal surgeon confirmed the placement of MIRAgel.

DISCUSSION

Orbital foreign body simulating an orbital tumor is uncommon. In an analysis of 1264 consecutive patients with orbital tumors and simulating lesions, only 2 (<1%) proved to have a foreign body, and both were young patients, 17 and 28 years of age.[16] Similarly, foreign body in the conjunctiva simulating tumor was found in only 11 (<1%) of 1,643 consecutive patients with conjunctival tumors.[17] In many instances, patients with orbital or conjunctival foreign body give a history of trauma or surgery with specific details of the foreign material, thus avoiding diagnostic confusion. Additionally, enlargement or "growth" of a foreign body, especially the commonly used silicone scleral buckling element, is distinctly unusual. All 4 patients in this report were suspected by the referring physician to have an orbital tumor as the result of the new onset of the orbital mass. In no case was the patient aware of the specific technique or scleral buckling material used by the retina surgeon at the time of previous retinal detachment surgery.

MIRAgel is a hydrogel (copoly methylacrylate-2-hydroxyethyl acrylate), which is a hydrophilic material formed from 3-dimensional polymer networks.[1] Hydrogels are low-molecular-weight substances that are permeable to water and can absorb and slowly release water-soluble substances such as antibiotics.[3] This elas-

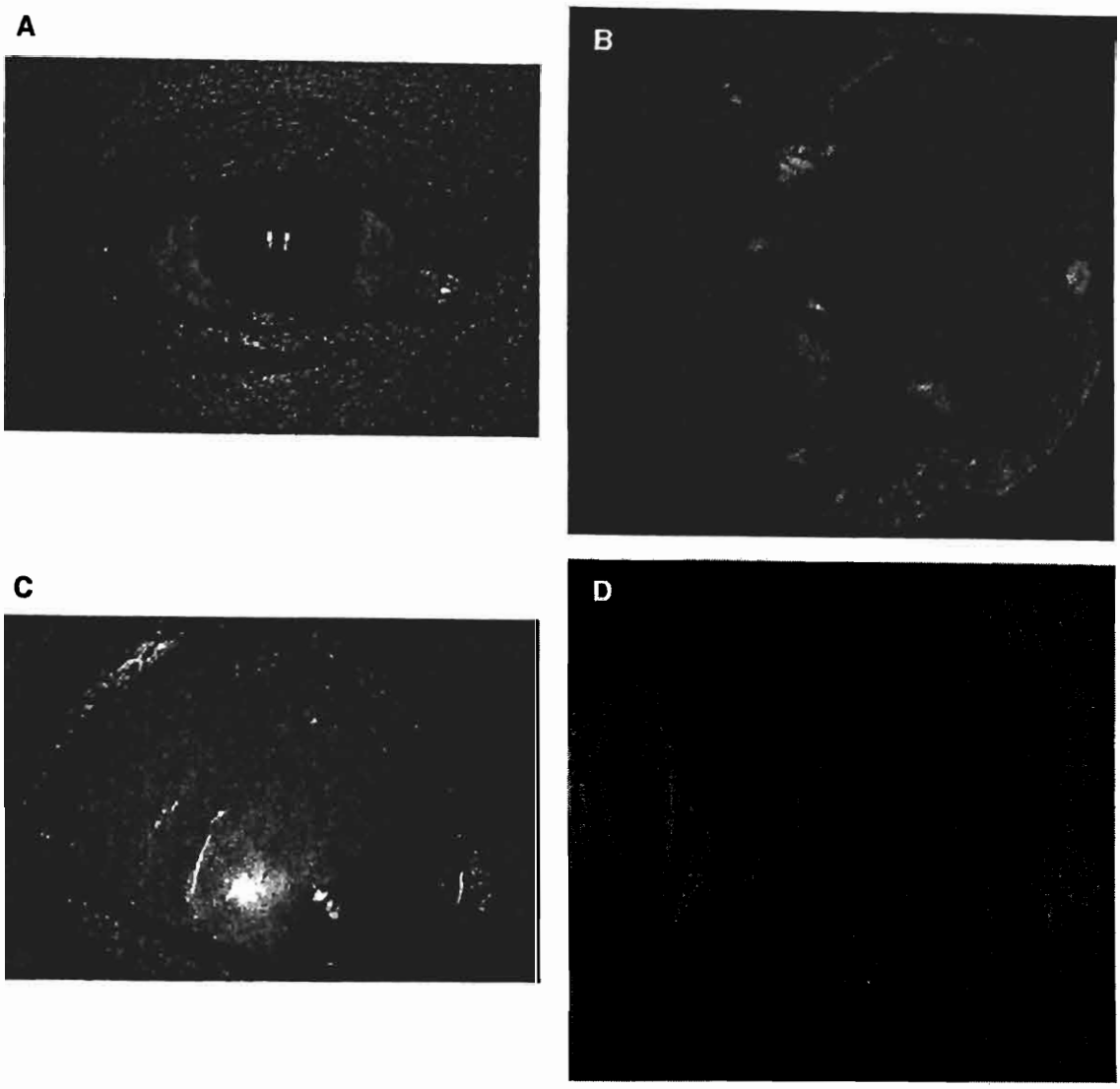

FIG. 3. Case 3. A 46-year-old man had an orbital mass that proved to be a swollen MIRAgel scleral buckle used for retinal detachment repair 12 years earlier. **A**, Patient noted a palpable mass through the eyelid temporally. **B**, Panoramic image shows chorioretinal scars and high scleral buckling effect 12 years after retinal detachment surgery. **C**, Mass was found to be translucent, with overlying prominent conjunctival vessels. Like a circumferential scleral buckle, the large mass appeared to encircle the eye. **D**, Ultrasonography confirmed 6 mm of ocular indentation by echolucent mass with orbital shadowing. This was twice the thickness of the nasal portion of the scleral buckle. Observation was advised.

tic buckling material was shown to be as effective as silicone rubber or sponge and believed to be possibly superior as the result of its low risk for infection. Early related complications in the first 4 to 5 years were reportedly minimal.[3,4] However, long-term observations of hydrogel implants at approximately 7 to 11 years revealed some complications related to extensive swelling of the implant.[7] These included conjunctival bulging, implant migration, and rarely implant erosion in the eye, occasionally with poor visual outcome. Removal of implant material was particularly difficult because fragmentation of the swollen, friable material with piecemeal

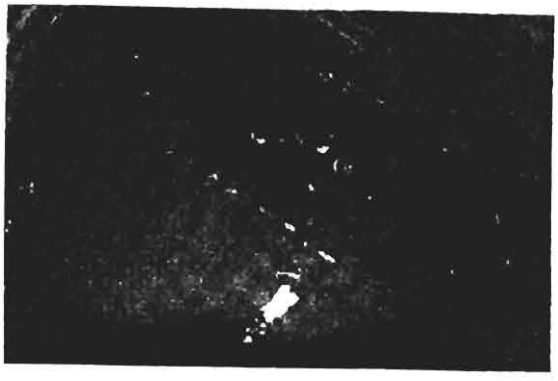

FIG. 4. Case 4. A 38-year-old man had a blue-gray orbital mass extending into the conjunctiva 20 years after retinal detachment surgery. Note white sutures overlying the large buckle.

removal was encountered. In one case, a fragment of hydrogel floated through the eroded sclera in the vitreous cavity.[7]

In 2003, Le Rouic et al.[6] compared complications from various buckling elements and found that MIRAgel complications occurred much later (mean, 92 months) than solid silicone (mean, 11 months) and silicone sponges (mean, 19 months). The progressive swelling of MIRAgel led to limitation of ocular motility, diplopia, ocular pain, ocular inflammation, and protrusion of the buckle beneath the eyelids, necessitating removal in 34 of 38 eyes (90%). The rate of buckle infection was much lower with MIRAgel than other buckling materials. In 2003, Li et al.[13] cautioned that complications of this material could be on the rise because it was used extensively in the past decade, and most complications occur approximately 10 years after placement. Difficult removal should be anticipated.[13]

Swollen MIRAgel can resemble an orbital tumor. In 2002, Braunstein[12] described a patient who had diplopia and an orbital mass 13 years after MIRAgel buckle. On MRI, there was no indentation of the eye and, in fact, the swollen buckle had folded on itself, creating an orbital mass effect. The buckle had expanded 4-fold in volume, and tedious removal was encountered. Case 1 in our series showed similar folding of the buckle on itself secondary to swelling, leading to the appearance of a knuckle. To avoid buckle fragmentation at removal, Le Rouic et al.[18] advised opening the conjunctiva generously and using cryoextraction rather than forceps extraction.

The orbital surgeon should be aware of the orbital complications of retinal detachment surgery. Previous reports on orbital complications from scleral buckles have described clear or hematic orbital cysts.[19–21] From the results in this report, we add the complication of MIRAgel that includes marked late onset swelling of the implant, simulating a solid or cystic tumor. In each of our 4 cases, the patient was referred by an ophthalmologist with a newly diagnosed, enlarging orbital mass. In 3 cases, the mass was visible in the superotemporal orbital region near the lacrimal gland fossa, raising concern for a lacrimal gland tumor. In each case, the mass proved to be swollen MIRAgel implant. MIRAgel has subsequently been removed from the market. However, many patients have this implant and are at risk for development of the problems seen in our cases. It is not known if injection of corticosteroids might minimize the tissue swelling. The orbital surgeon should recognize this implant and be prepared for challenging surgical removal if necessary.

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PRODUCTIE 18

MIRAgel

Hydrolytic Degradation and Long-term Observations

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Objective: To analyze long-term complications of hydrogel (MIRAgel; MIRA Inc, Waltham, Mass) explants.

Design: Institutional clinical study of a retrospective, interventional case series of patients. We included 415 patients with complete reattachment of the retina 6 months after surgery and up-to-date follow-up. Patients underwent ophthalmological examination at each visit (mean follow-up, 187 months), and 6 underwent computed tomography and/or magnetic resonance imaging. Main outcome measures included the MIRAgel explant removal rate, clinical manifestations related to removal, interval from the start of discomfort to removal, mean time from implantation to removal, culture yield of the removed elements, results of histological examination of the capsule surrounding the removed explants (12 cases), and micro-Fourier transform infrared spectroscopic analysis results of 3 recovered explants.

Results: MIRAgel explant removal was necessary in 27 (6.5%) of 415 patients who received MIRAgel material and in 27 (7.6%) of 357 patients who had had it for 7 or more years. Clinical manifestations were related to swelling of the MIRAgel material, with a mean interval of 15 (range, 6-22) months from starting symptoms to removal. The infrared spectroscopic analysis demonstrated the presence of carboxylic groups in 3 recovered explants that had swollen considerably.

Conclusion: Prompt removal of MIRAgel explants when discomfort starts should be considered to avoid increased incidence of complications.

Arch Ophthalmol. 2007;125:511-514

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HYDROGEL IMPLANTS (ORIGINALLY MAI and then commercialized as MIRAgel [MIRA Inc, Waltham, Mass]) initially seemed to be the ideal implant material, with a soft pliable texture and low risk of infection,[1,2] when observed 6 to 53 months after surgery.[3] However, with a longer follow-up of 7 to 11 years, complications have been reported in 8.5% of patients after an intrascleral buckling procedure.[4] Recently, several reports of removal of MIRAgel episcleral buckling material have been published.[5-8] Clinical manifestations ranged[5-8] from benign subconjunctival bulging, pain, strabismus, progressive limitation of ocular motility, protrusion of the buckle beneath the eyelids, and sensation of orbital fullness to pseudotumor[9] for the episcleral buckles or to intraocular erosion and migration into the vitreous for intrascleral procedures.[4,10] After Hwang and Lim[11] reported the first case of scleral buckle extrusion and fragmentation associated with a MIRAgel episcleral explant, other cases have also been published.[12,13]

Fragmentation and peripheral degradation of hydrogel have been described in experimental models.[14] The hydrogel fragments were found next to the inner limit of the surrounding fibrous capsule in human eyes undergoing reoperation; these were often found in association with mononuclear and giant cells, attesting to a foreign-body giant cell granuloma.[15]

Hydrolytic degradation of MAI hydrogel using micro-Fourier transform infrared spectroscopy was demonstrated by the presence of carboxylic groups in 2 recovered implant segments.[4] The polymer implants (MAI) retrieved from these patients[4] were made before MIRA Inc obtained the license to make MIRAgel.[14] Although the MAI hydrogel is the precursor of MIRAgel and both have the same chemical composition, up-to-date hydrolysis of MIRAgel has not been demonstrated.

To further understand the long-term complications of MIRAgel episcleral buckles, we report the clinical outcome of 415 patients after MIRAgel buckling implan-

Table. Characteristics of MIRAgel Buckles and Percentage of Explants Removed

Characteristics of MIRAgel Buckles*	No. of Patients	Orientation/No. of Patients	Removed Explants, No. (%)	
			All Patients	By Orientation
Segmental-localized (≤180°)	90	Radial/18	5 (5.6)	1 (6)
		Circumferential/72		4 (6)
Segmental (≤270°) and cerclage (240 silicone band)	135	Additional "side-by-side"/27	10 (7.4)	0
		Circumferential/108		10 (9)
Broad (360°)	190	Circumferential/95	12 (6.3)	4 (4)
		Circumferential with 240-style silicone band/95		8 (8)
Total	415		27 (6.5)	

*Indicates the removed explants by type and orientation of indentation. MIRAgel is the proprietary name for hydrogel produced by MIRA Inc, Waltham, Mass.

tation for a mean follow-up of 187 months (range, 75 months to 20 years). We evaluated the results of micro-Fourier infrared spectroscopic analysis of the explanted MIRAgel buckles from 3 patients for potential changes in the polymeric explant structure.

METHODS

DESIGN AND SETTING

Herein we describe an interventional consecutive case series of patients with rhegmatogenous retinal detachment who underwent scleral buckling surgery with the MIRAgel explant as a first surgical procedure between March 1, 1984, and December 31, 2000. The patients underwent operation at the Hospital Clínico San Carlos, Madrid, Spain, by one of us (M.R.-P.) with cryotherapy associated with the episcleral buckle.[16] This is a retrospective institutional clinical study.

PATIENT POPULATION

The medical reports were reviewed for 444 patients with retinal detachment in whom MIRAgel was used as unilateral episcleral buckling material. Although only single procedures were considered, 11 patients were excluded because they needed several combined surgeries to reattach the retina (exclusion criteria). Eighteen patients were lost during follow-up. The 415 patients with complete reattachment of the retina 6 months after surgery, up-to-date follow-up information, and signed informed consent forms were included in the study, which was in adherence to the tenets of the Declaration of Helsinki and approved by our institutional research committee.

Patients made follow-up office visits 1, 3, 6, 12, 24, and 36 months after surgery and then annually or biannually. The mean follow-up was 187 months (range, 75 months to 20 years).

OBSERVATION PROCEDURES

Snellen visual acuity, ocular motility, and results of tonometry and slitlamp and fundus examinations were recorded at each visit. Computed tomography and/or magnetic resonance imaging was necessary in 6 patients.

OUTCOME MEASURES

The main outcome measures included the MIRAgel explant removal rate, clinical manifestations related to its removal, interval from the start of discomfort to removal, mean time from implantation to removal, culture yield of the removed elements, results of histological examination of the capsule surrounding the removed explants (12 cases), and results of micro-Fourier transform infrared spectroscopy analysis of 3 recovered explants. The spectrophotometer used to record spectra was a Nicolet Magna-IR 750 (Nicolet Instruments Inc, Warwick, England), with a sampling microscope (IR-Plan Advantage; Spectra-Tech Inc, Oak Ridge, Tenn). The infrared spectra were recorded by accumulation of 240 scans, with a resolution of 4 waves/cm. The postoperative outcome after MIRAgel explant removal was followed up for 6 to 156 (mean follow-up, 84) months.

RESULTS

We reviewed the medical reports of 415 patients who underwent MIRAgel episcleral buckle for rhegmatogenous retinal detachment. The mean patient age was 58 years (range, 16-82 years). MIRAgel was used in the 415 patients regularly during most of the follow-up period (March 1, 1984, through June 30, 2000) but, after June 30, 2000, only 2 of these explants were used. Postoperative follow-up for 357 (86.0%) of 415 patients was 7 years or longer. The **Table** shows the type of surgery performed in these patients.

As of this writing, 38 (9.2%) of the 415 patients reported redness and discharge from the eye that underwent operation. The criteria for buckle removal included morphological and/or functional changes related to swelling of the MIRAgel material.

Removal was necessary in 27 (6.5%) of 415 patients with MIRAgel buckle explants. Clinical manifestations, frequently multiple, in patients with removed explants included redness and discharge in 25 (93%) (cultures yielded *Staphylococcus epidermis* in only 3); extrusion in 6 (22%); subconjunctival mass and/or protrusion of the buckle beneath the eyelids in 19 (70%); strabismus, rectus palsy, limitation of ocular motility, and/or diplopia in 18 (67%); and orbital fullness and/or pseudotumor in 6 (22%).

Considering the type of surgery, 5 (6%) of the 90 segmental-localized explants (≤180°) (1 [6%] of the 18 with radial and 4 [6%] of the 72 with circumferential orientation) were removed. In addition, 10 (7%) of the 135 segmental and cerclage explants (≤270°) (10 [9.3%] of the 108 under a 240-style silicone band of cerclage) were removed. Finally, of the 190 patients with a broad circumferential 360° explant, 12 (6.3%) needed removal (8 [8%] of the 95 under a 240-style silicone band and 4 [4%]

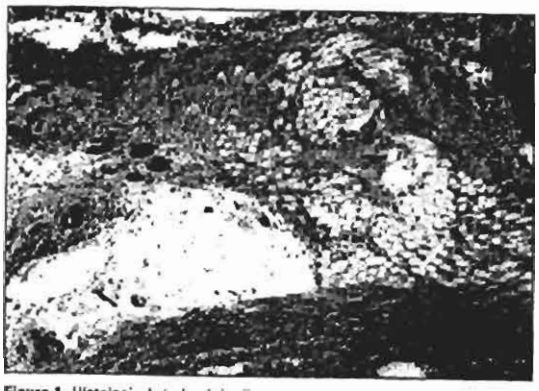

Figure 1. Histological study of the fibrous capsule surrounding hydrogel (MIRAgel; MIRA Inc, Waltham, Mass) explants in a patient with orbital pseudotumor. Giant cell granuloma is seen in relation to the sutures (Masson staining; original magnification ×288).

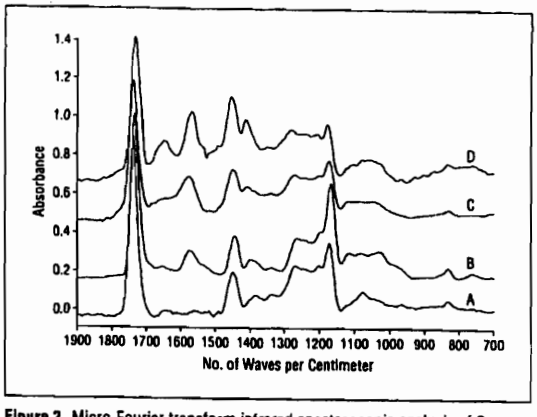

Figure 2. Micro-Fourier transform infrared spectroscopic analysis of 3 recovered hydrogel (MIRAgel; MIRA Inc, Waltham, Mass) segments (B-D) and a MIRAgel stock sample (A). An extra peak appears at about 1560 waves/cm in graphs B, C, and D (with large swelling of the MIRAgel material; C and D corresponded with clinical manifestation of orbital pseudotumor).

of the 95 without cerclage associated) (Table). The mean interval to surgical removal was 9.6 (range, 7.2-11.3) years.

We performed histologic analysis of the fibrous capsule surrounding 12 of the removed explants. Only 3 patients with orbital pseudotumor, all with broad (360°) MIRAgel indentation for more than 10 years, showed giant cell granuloma related to sutures (**Figure 1**).

We performed micro-Fourier transform infrared spectroscopy in 3 recovered MIRAgel segments (**Figure 2**). Hydrolytic degradation was associated with swelling of the material to about 4 times the width and thickness of the original and clinical manifestation of orbital pseudotumor in 2 patients in whom computed tomography (**Figure 3**) was needed for diagnosis. The gellike removed segments from these 2 patients were studied spectroscopically and compared with an original MIRAgel explant and with a less-swollen MIRAgel explant from a patient without clinical manifestation of orbital pseudotumor. Hydrolytic degradation of the material was demonstrated by the presence of the carboxylic groups (Figure 2).

Figure 3. Anteroposterior section of an orbital computed tomogram. A considerably swollen hydrogel (MIRAgel; MIRA Inc, Waltham, Mass) surrounds the eye. The scale indicates centimeters.

After explant removal, the retina remained attached in 23 (85%) of the 27 patients, with no significant changes in visual acuity (mean, 20/60). Usually after removal, diplopia disappeared and the eyes became orthophoric. Redness and discomfort persisted in 6 (22%) of the 27 patients, even after cultures yielded negative results, probably related to residual MIRAgel fragments. Two patients developed vitreous hemorrhage and a new retinal detachment after removal of a meridional MIRAgel explant under a 240-style cerclage silicone band. Two other patients, both with broad indentation (360°) under a 240-style cerclage silicone band, experienced scleral rupture during surgical maneuvers to clean the MIRAgel fragments embedded in the scleral wall, making it thicker and rigid. Finally, 3 of these complicated cases became phthisical. No other complications were found to be related to removal.

COMMENT

For the first time, to our knowledge, considerably swollen MIRAgel explants and clinical manifestations of orbital pseudotumor have been related to hydrolytic degradation of episcleral MIRAgel demonstrated by infrared spectroscopy. Removal of these buckles is a consequence of the explant's progressive degradation and swelling.

At present, removal has been necessary in 27 (6.5%) of 415 patients who received MIRAgel explants, and in 27 (7.6%) of 357 patients who received MIRAgel explants 7 or more years earlier. Eight of these 27 cases have already been reported.[5,17]

It has been suggested in the literature[6-8] that a greater quantity of material used will increase the possibility of removal. In our patients, there was a trend toward a higher removal rate (Table) with an increased quantity of buckling material, and any of the cases with MIRAgel used as an additional and small side-by-side indentation to resolve a fishmouth phenomenon required removal. The association of MIRAgel with a silicone band of cerclage also increased the removal rate in our patients. As first suggested by Marin et al,[4] the sutures may play a role in the physical or functional breakdown of the surrounding fibrous capsule, allowing hydration and swelling of the MIRAgel explant.

In our cases, swelling of the MIRAgel explant combined with progressive limitation of ocular motility and protrusion of the buckle beneath the eyelids frequently indicates the need for MIRAgel removal, as reported by other authors.[6-8] The symptoms usually started with redness and discomfort, and it took a mean of 15 (range, 6-22) months to slowly develop those symptoms related to swelling of the material. Six of our patients had orbital pseudotumor at the initial examination and required computed tomography and/or magnetic resonance imaging for diagnosis. Two of these cases with orbital pseudotumor (the interval from the start of redness and discomfort to removal was 20 and 22 months; the time from implantation to removal of the MIRAgel material, 11.1 and 11.2 years) showed great swelling of the MIRAgel explant related to its hydrolytic degradation.

To our knowledge, this is the first report demonstrating hydrolytic degradation of MIRAgel by the presence of carboxylic groups using micro-Fourier transform infrared spectroscopy. Until now, chemical changes in the polymer were only confirmed spectrographically for the MAI hydrogel intrascleral implants.[4] The presence of carboxylic groups found in our removed explants implies ester hydrolysis. The ionized carboxylic groups result in water absorption and, consequently, the MIRAgel material swelled and became gellike and friable. These characteristics explain the difficulty in grasping and removing MIRAgel fragments—sometimes embedding in the scleral wall, which then became thicker and rigid—and complications related to surgical removal. Persistence of discomfort after MIRAgel retrieval may likely be associated with residual MIRAgel fragments.

After MIRAgel removal, the retina remained attached in 23 (85%) of 27 patients with stabilized visual acuity. In 2 of the cases of pseudotumor and considerable swelling of the MIRAgel material, scleral perforation occurred during removal with intraocular hemorrhage and final retinal redetachment. Retinal redetachment was found in 4 (15%) of 27 patients after MIRAgel material removal. The eyes usually became orthophoric and diplopia disappeared, but redness, discomfort, and ocular motility disturbance persisted in 6 (22%) of the 27 removal cases. We agree with Le Rouic et al[6] that patients should be informed of the possibility of complications related to the surgical removal of episcleral MIRAgel buckles.

Cultures in only 4 of our 27 removed MIRAgel explants yielded positive results. Negative culture findings may be owing to long-term antibiotic and/or corticosteroid therapy that was used to treat redness and discharge, or owing to the particular characteristics of the MIRAgel material. MIRAgel was reported to be an ideal buckling element that was considered less prone to infection because it lacked dead spaces and could absorb and gradually release antibiotic drugs.[5,18]

Hence, MIRAgel buckles resulted in delayed, late complications owing to buckle swelling from hydrolytic degradation and required removal in 6.5% of patients, with a mean follow-up of 187 months. Patients with MIRAgel buckles require long-term follow-up, and removal should be considered once symptoms develop.

Submitted for Publication: April 13, 2006; final revision received July 21, 2006; accepted August 12, 2006.
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Financial Disclosure: None reported.

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PRODUCTIE 19

18.01 PPP F. Sortomme – Keramati, R. J. W. de Keizer

Cornea melting bij Inflammatory Bowel Disease (IBD)

SAMENVATTING:
Doel: Veel oogheelkundige aandoeningen zijn onderdeel van een systeemziekte en zelfs voorbode van een complexer beeld. Een treffende casus is de heer G., een 67-jarige man met recidiverende cornea melting OS.
Methode: Tijdens klinische opname, voor een succesvol verlopen amniontransplantatie met Tissuecol, bleek patiënt ook gewrichtsklachten en bloed bij de ontlasting te hebben. Een algemene analyse werd ingezet in samenwerking met de afdeling Reumatologie, Interne Geneeskunde en Maag- Darm- en Leverziekten. De diagnose luidde diverticulitis en colitis ulcerosa. Conclusie: Een multidisciplinaire aanpak van auto-immunolgische oogheelkundige aandoeningen is soms cruciaal voor een goede zorg.

18.04 QQQ W. Swart

De MIRAgel plombe: blijf er aan denken bij vreemde orbitale zwellingen en een ablatio retinae operatie in het verleden

SAMENVATTING:
Bij een patient met een hoogstand van het rechter oog en forse bewegingsbeperking was vroeger een MIRAgel plombe geplaatst.
De MIRAgel plombe is in het begin van de jaren negentig gebruikt als plombe materiaal ter behandeling van ablatio retinae. In tegenstelling tot ander materiaal ging de plombe na een periode van ca 5 jaar geleidelijke zwellen en van structuur veranderen.

18.07 **Einde**

PRODUCTIE 20

positie van de cerclage, conjunctivale roodheid, status van het netvlies , bedekking van de explants en aantal bezoeken post operatief.
Resultaten: Er was geen statistisch significant verschil tussen de 2 groepen.
Conclusie: Dermabond heeft mogelijk een plaats in ablatiochirurgie, bij geselecteerde patiënten.

11.00 58B N. Crama en B.J. Klevering (Nijmegen UMC St Radboud):

Complicaties (bij het verwijderen) van Miragel plombes

SAMENVATTING:
Doel: Beschrijven van de complicaties, in het bijzonder de kans op scleraperforatie, bij operatieve verwijdering van gezwollen Miragel plombes. Methode: Retrospectief statusonderzoek. Resultaten: Bij 17 (5.4%) van totaal 312 patiënten bij wie tussen 1998 en 2008 gezwollen Miragel indentatiemateriaal werd verwijderd, ontstond peroperatief een scleraperforatie. Een overzicht van mogelijke risicofactoren zal worden gepresenteerd, evenals de kans op een recidief netvliesloslating en overige complicaties. Conclusie: Bij het verwijderen van gezwollen Miragel indentatiemateriaal is er een kans van 5% op een peroperatieve scleraperforatie.

11.10 59B J.C. van Meurs (Rotterdam OZR, Erasmus MC):

Teugelloze cerclage bij vitrectomie voor pseudofake ablatio retinae

SAMENVATTING:
Doel: Vitrectomie met gas, een microchirurgische ingreep, wordt vaker de primaire behandeling bij patienten met pseudofake ablatio retinae. Er zijn argumenten ook dan een cerclage band aan te leggen, meestal een stap zonder microscoop, mogelijk een factor die deze combinatie minder populair maakt. Wij onderzochten een gemodificeerde techniek om een cerclageband vlot onder de microscoop aan te leggen. Methode: Bij 24 patienten met pseudofake ablatio werd een 2 mm cerclage band onder de recti doorgevoerd en geknoopd, waarna de cerclage als spierteugel te gebruiken was bij het plaatsen van sclerale kwadrant hechtingen: teugelloze cerclage. Resultaten: De gemiddelde operatie tijd was 12 minuten (10-16 minuten). Een milde indentatie ter plaatse van de

PRODUCTIE 21

Department of Ophthalmology

UMC St Radboud

REMOVAL OF MIRAGEL® EXPLANTS; COMPLICATIONS

N.Crama
M.A.D. Tilanus
B.J. Klevering

NOG 27 maart 2009

Introduction

- Rhegmatogenous retinal detachment
- Reattachment surgery by scleral buckling
- Different explant materials
  - Silicon sponge
  - Solid silicon
  - Hydrogel (Miragel®)

Miragel

- Introduced in the 80's (used until mid 90's)
- Methylacrylate-2-hydroxyethylacrylate
- Hydrophilic copolymer
- Advantages
  - Influencing swelling (varying hydration)
  - Less erosions (softness and elasticity)
  - Less infection (lack of dead spaces)
  - Absorb and gradually release antibiotics

Miragel disadvantages (1)

- Hydrolytic degeneration of the copolymer causes **alteration** of the material and **extensive swelling**

Figure: Braunstein & Wienck
Arch Ophthalmol 2002;120:228-9

Miragel disadvantages (2)

- Extensive swelling
  - Subconjunctival bulging
  - Cosmetic appearance and ptosis
  - Ocular motility disturbance
  - Conjunctival erosion
  - Scleral erosion

Patients and methods (1)

- Retrospective
- Single centre
- Consecutive case series
- 11 year period (1998-2008)
- Removal of symptomatic swollen Miragel explants
- Symptoms and objectivations
- Complications after removal

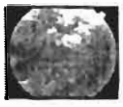
~~Evans et al. Eye 1998~~

Patients and methods (2)

- 336 eyes
- Scleral buckling between 1986-1996
- Original 1 - 12 clock hours (mean 4)
- Silicon encircling band 305
  - Radial 91
  - Meridional 200
  - Combined 39
  - Unspecified 6

Symptoms / objectivations (1)

- Irritation
- Diplopia
- Conjunctivitis
- Scleritis
- Astigmatism
- Ptosis
- Uveitis



Symptoms / objectivations (2)

- 97 transconjunctival extrusion
  - Radial 43 (total 91)
  - Meridional 35 (total 200)
  - Combined 15 (total 39)
  - Unspecified 4 (total 6)
- Removal 17 - 252 months (mean 145)

Miragel removal

- Multiple fragments
- Cryo extraction
- Boric acid

Complications after removal (1)

- Multiple sessions because of incomplete removal (52)

Complications after removal (2)

- Scleral perforation 20/336 (6%)
  - 96 to 252 months (mean 158, median 156)
  - Encircling silicon +
    - 5 radial
    - 8 meridional
    - 6 combined
    - 1 unspecified

Evans et al. Eye 1998

Complications after removal (3)

- Retinal redetachment 18/336 (5%)
  - Spontaneous (14)
  - With scleral perforation (4)

Conclusion / Discussion (1)

- Removal of swollen Miragel material after an average of 12 years (max. 21 years)
- 6% scleral perforation
  - Encircling silicon band
  - Meridional
  - Radial vs Meridional explant
- 5% retinal redetachment

Conclusion / Discussion (2)

- Follow-up
- Risk management
- Patiënt information

Thank you.

~~Evans et al. Eye 1998~~