

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 procedure¹⁰ 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 buckles¹² 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 intravitreal 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 ($\leq 180^\circ$)*

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 ($\leq 270^\circ$) 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 ($\leq 270^\circ$) 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.

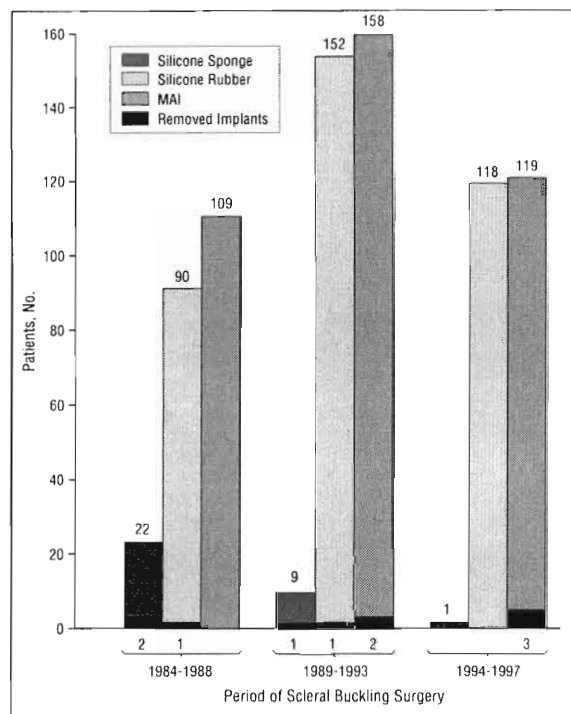
Table 4. Data on Patients With Removed Implants

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	<i>Staphylococcus aureus</i>
53/M	Radial, silicone sponge (round, 5 mm)	2 mo; extrusion	2.5 mo	<i>Escherichia coli</i>
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	<i>Staphylococcus epidermis</i>
63/M	Meridional, silicone rubber (77G) + 240 silicone band (360°)	13 mo; discharge, granuloma	15 mo	<i>S epidermis</i>
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	<i>S epidermis</i>
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 sur-

gery; 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 ($\leq 270^\circ$) 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 authors³⁻⁶ 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 reported³⁻⁶; 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 ($\leq 180^\circ$) 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 authors¹⁻⁶ 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 al¹⁰ 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 Lim¹¹ 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 Schepens¹⁷ 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.