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) (range)	80	52.4 ± 12.0 (31–70)	61.2 ± 10.2 (38–77)	58.7 ± 12.8 (31–80)
Gender	1 M	7 M, 3 F	7 M, 5 F	15 M, 8 F
Mean duration of buckling ± SD (mo) (range)	84	7.4 ± 6.5 (1–18)	12.8 ± 10.2 (1–31)	13.6 ± 17.7 (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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