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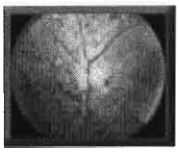

RETINA

## Long-Term Complications of Hydrogel Buckles

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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.

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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 | 9.9 | 904 (round) | Circumferential | 5.5 | 189 |
| 28 | 6.4 | 906 (oval) | Encircling | 6 × 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.

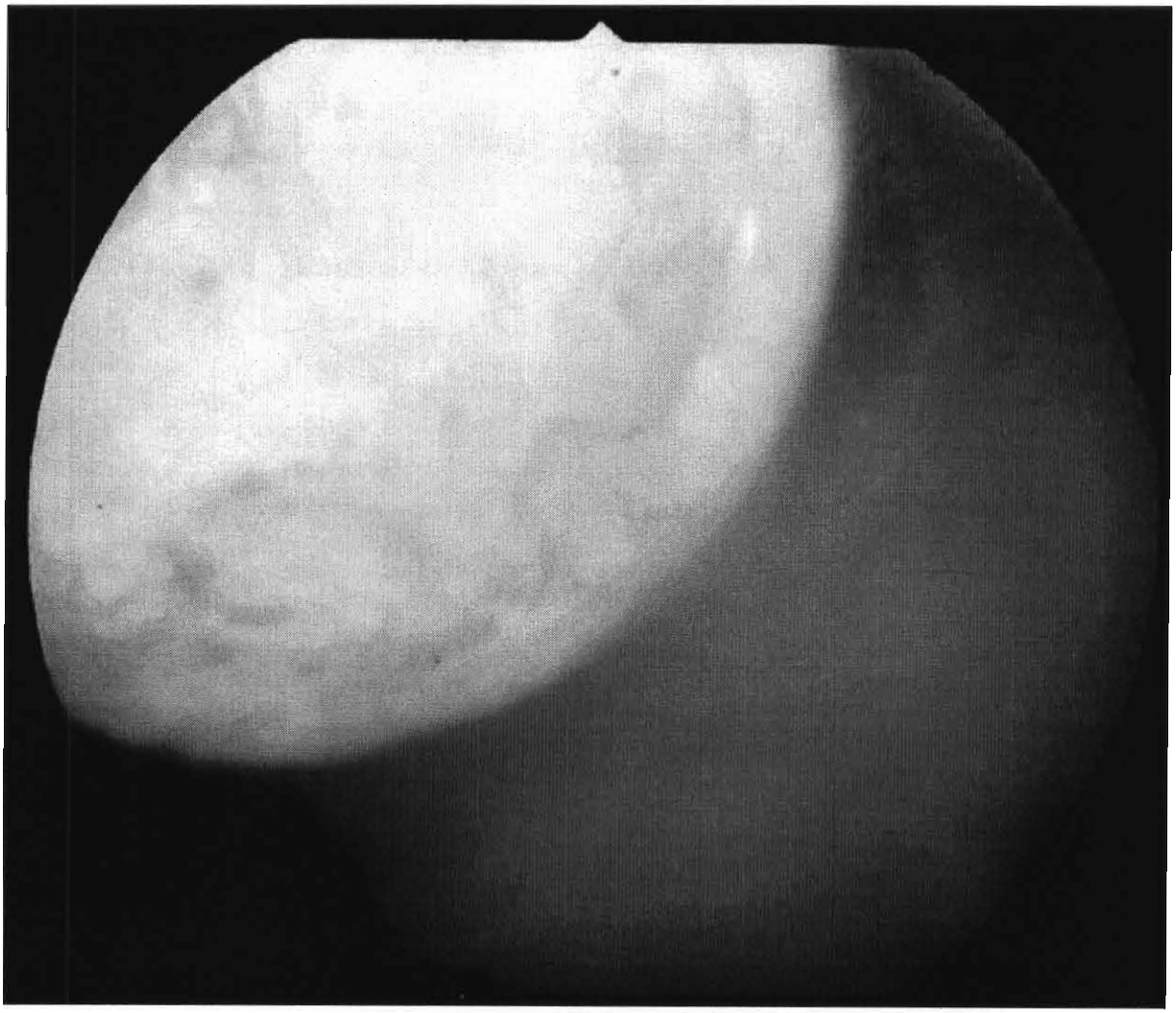

Fig. 1. A MIRAgel buckle is observed eroding into the subretinal space and producing a retinal cyst in the superotemporal quadrant, adjacent to a cryopexy scar.

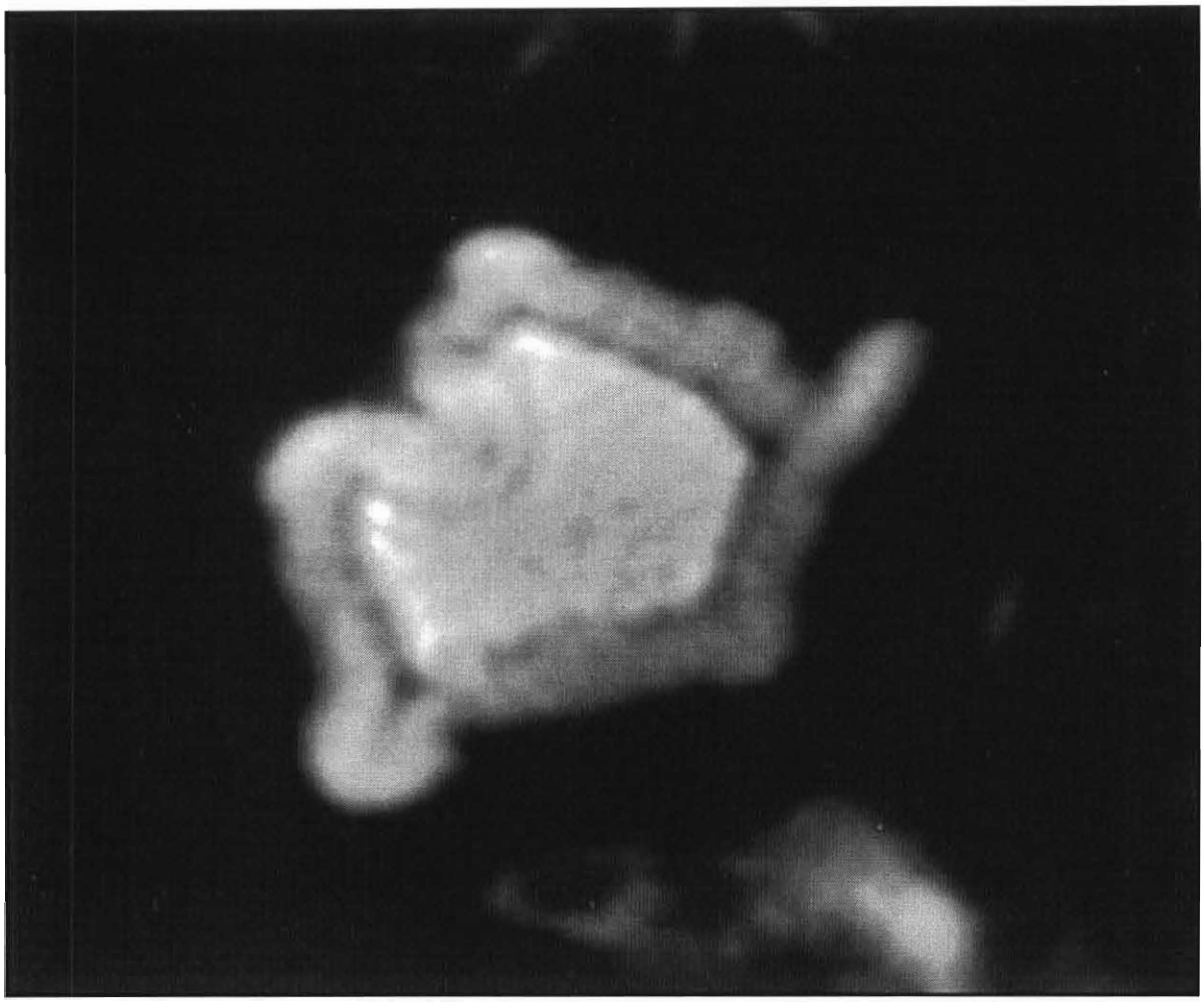

Fig. 2. A T2-weighted magnetic resonance image revealed a high-intensity tortuous mass consistent with a deteriorated buckle.

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).

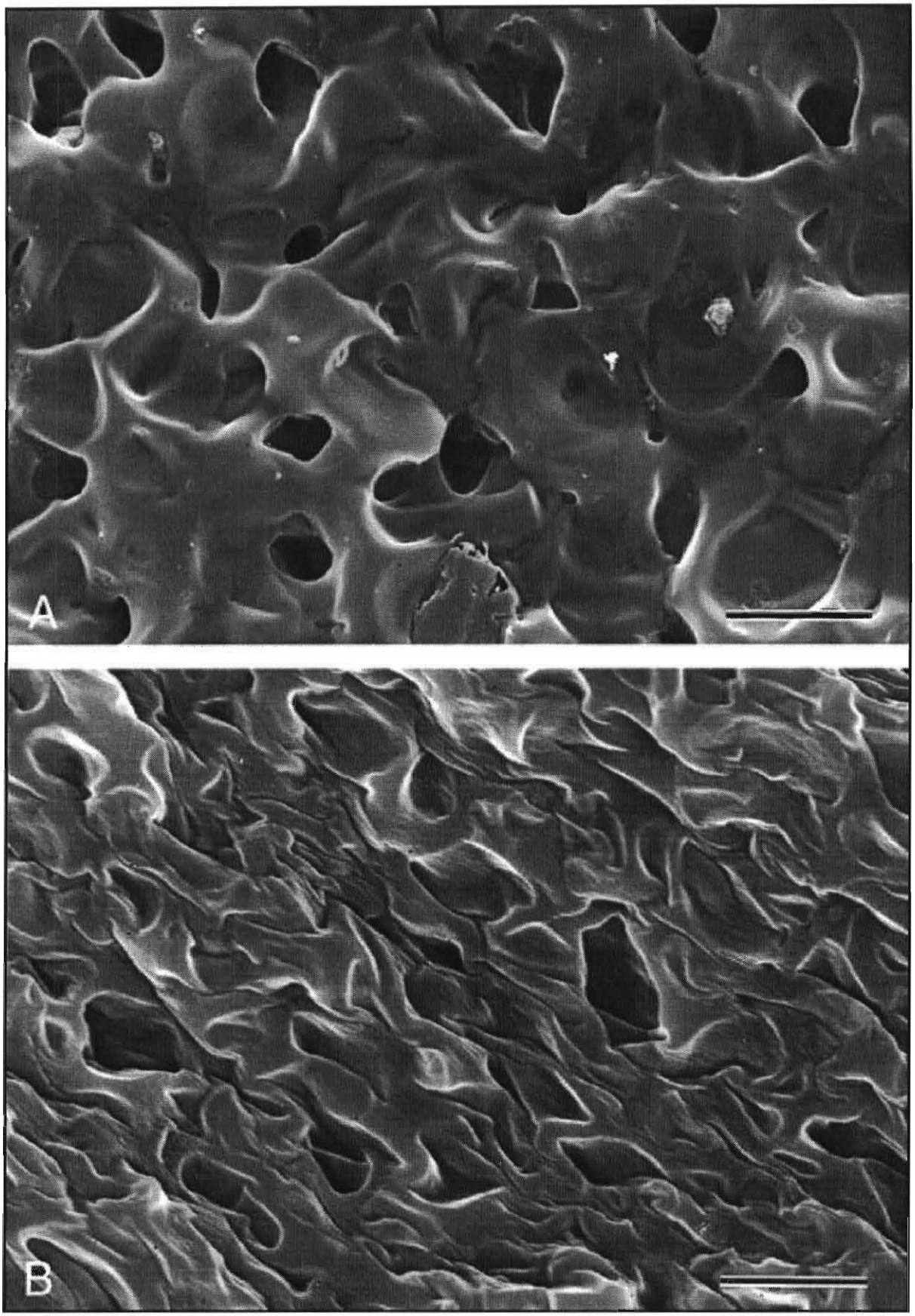


Fig. 3. **A**, Scanning electron microscopy showed a smooth surface and uniformly sized micropores in control samples. **B**, In contrast, the surface of a deteriorated buckle was uneven, with micropores that were distorted in shape and irregular in size (bar = 5 μm).

## 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.

## References

1. Refojo MF, Leong FL. Poly(methyl acrylate-co-hydroxyethyl acrylate) hydrogel implant material of strength and softness. J Biomed Mater Res 1981; 15: 497-509. [Context Link]

2. Tolentino FI, Refojo MF, Schepens CL. A hydrophilic acrylate implant for scleral buckling: technique and clinical experience. Retina 1981; 1: 281-286. **Ovid Full Text** | [Context Link]

3. Roldan-Pallares M, del Castillo Sanz JL, Awad-El Susi S, Refojo MF. Long-term complications of silicone and hydrogel explants in retinal reattachment surgery. Arch Ophthalmol 1999; 117: 197-201. **ExternalResolverBasic** | [Context Link]

4. Ho PC, Chan IM, Refojo MF, Tolentino FI. The MAI hydrophilic implant for scleral buckling: a review. Ophthalmic Surg 1984; 15: 511-515. **ExternalResolverBasic** | [Context Link]

5. Refojo MF, Natchiar G, Liu H, Lahav M, Tolentino FI. New hydrophilic implant for scleral buckling. Ann Ophthalmol 1980; 12: 88-92. [Context Link]

6. Marin JF, Tolentino FI, Refojo MF, Schepens CL. Long-term complications of the MAI hydrogel intrascleral buckling implant. Arch Ophthalmol 1992; 110: 86-88. **ExternalResolverBasic** | [Context Link]

7. Hwang KI, Lim JI. Hydrogel exoplant fragmentation 10 years after scleral buckling surgery. Arch Ophthalmol 1997; 115: 1205-1206. **ExternalResolverBasic** | [Context Link]

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