A HYDROPHILIC ACRYLATE IMPLANT FOR SCLERAL BUCKLING:

Technique and Clinical Experience

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Abstract: A new hydrophilic acrylate implant developed for scleral buckling was used in 51 patients: as an accessory meridional piece under a solid silicone buckle in 25 and as a main buckling element in 26 (intrasclerally in 15 and episclerally in 11). Clinical observations six to 18 months after implantation showed the implants to be well tolerated in all cases. There was no infection, rejection, extrusion of the implant, or erosion of the eye coats. In two patients who had reoperations, smooth fibrous tissue encapsulating the implant including the scleral bed was present. Our observations indicate that this new material has all the characteristics of an ideal implant for scleral buckling. RETINA 1:281–286, 1981

Refojo and co-workers developed and described a new scleral buckling material made of methyl acrylate and 2-hydroxyethyl acrylate.[1,2] Laboratory studies in rabbits showed this material, called the Refojo implant (or MAI), to be inert and well tolerated in the anterior chamber, vitreous cavity, and orbit.[1] Long-term observations in rabbits (F.I. Tolentino, MD, M.F. Refojo, DSc, M. Lahav, MD, and L.H.S. Liu, MD, unpublished observations) show that the Refojo implant is an effective intrascleral or episcleral buckling material.

We report herein our experience with the Refojo implant in human eyes.

Patients, Materials, and Methods

The experimental use of the Refojo implant in human eyes was approved by the Subcommittee on Human Studies of the Massachusetts Eye and Ear Infirmary. All patients gave their informed consent. The Refojo implant was used only in uncomplicated cases of rhegmatogenous retinal detachment. Patients with glaucoma or serious systemic disorders and those over 75 years old were excluded. Patients who had follow-up examinations less than six months after implantation were excluded from this report. The longest follow-up period was 18 months.

The implant was supplied in a glass vial with isotonic sodium chloride by the Polymer Chemistry Laboratory of the Eye Research Institute of Retina Foundation. The vial was sealed with silicone rubber septa and an aluminum cap, and sterilized by steam autoclave for 20 minutes at 121 C.

The Refojo implant was available in three consistencies: soft, medium, and hard. The soft material matched the Lincoff silicone sponge in consistency, the medium implant had a consistency between that of the Lincoff sponge and that of a solid silicone implant, and the hard implant matched a solid silicone implant. The implants were oval or round in cross section. The oval implants were 2 to 4 mm thick and 5 to 9 mm wide; the round implants were available in diameters

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ranging from 5 to 9 mm. Both types of implants were made in lengths of 30 to 100 mm.

Before the implant was used for surgery, the sealed glass vial was steam-autoclaved for 10 minutes in the operating room and then allowed to cool. The implant was removed from the container with forceps and soaked in a solution containing polymyxin B sulfate (400,000 units in 8 ml distilled water mixed with 150 ml normal saline solution) from the beginning of surgery until implantation.

In 25 cases, the implant was used as an accessory meridional implant placed beneath the solid silicone material that had been previously implanted as an equatorial buckle. In most instances, the objective of adding a meridional implant was to augment the height of the buckle because the retinal break had developed a fishmouth. In some cases, the aim was to extend the buckling effect posteriorly to cover a retinal break located behind a previously placed buckle. In 26 cases, the implant was used as the main scleral buckling element, either intrasclerally or episclerally (Table 1).

Surgical Technique

Accessory Meridional Piece

The technique of using the Refojo implant as an accessory meridional element beneath a preexisting equatorial solid silicone implant followed that described by Schepens and co-workers.[3-7] Under indirect ophthalmoscopy, the recalcitrant retinal break was localized precisely with a cotton-tip applicator, which was inserted between the prepared scleral bed and the previously placed implant. (Localizing the area with a diathermy electrode is risky because the scleral bed may be thin and could rupture.) The position of the localizing cotton tip was marked with a methylene blue pencil. The sclera in this meridian was dissected posteriorly if the objective of inserting a meridional implant was to cover a retinal break lying posterior to the existing buckle. The flap was not dissected if the break was located well on the buckle and the meridional piece was intended only to increase the buckle height in the area of the retinal break. If dissection of the posterior scleral flap was necessary, the scleral bed in the area of the break was extended about 5 mm posteriorly, or more, depending on the location of the posterior border of the break. The width of the pouch depended upon the width of the retinal break. For a 7-mm-wide, 3-mm-thick meridional implant, a pouch 12 mm wide was required. When a vortex vein was present in the area of the pouch, the vein was closed with diathermy after it exited the sclera. The bed was treated with diathermy or cryoapplications. A Refojo implant was cut, trimmed, and shaped to the size of the pouch (Fig. 1). An additional mattress suture was placed on the scleral flap, in the meridian of the accessory implant, to secure the implant and produce a high buckle.

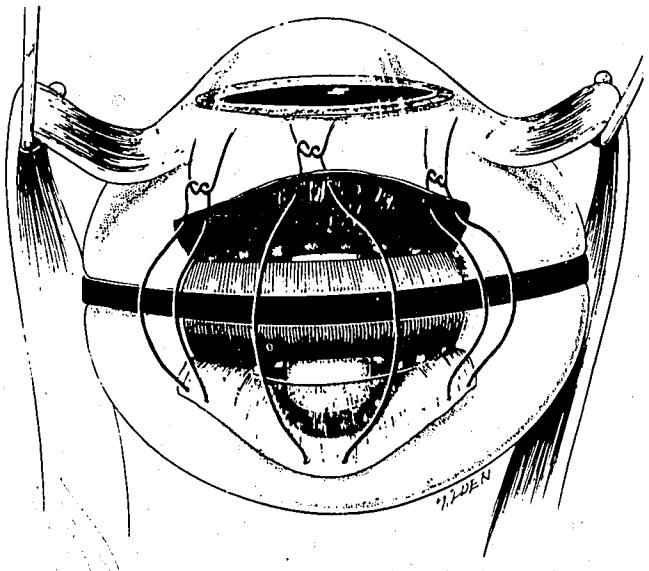

Fig. 1. Refojo material used as meridional implant under equatorial implant. Note pouch created to accommodate meridional piece.

Table 1. Uses of Refojo Implant in Scleral Buckling

Use of Sponge	Number of Cases
Meridional implant under silicone buckle	25
Intrascleral implant without encircling band	8
Intrascleral implant with encircling band	7
Episcleral implant without encircling band	2
Episcleral implant with encircling band	9
Total	51

Intrascleral Implant

The technique of intrascleral buckling with the Refojo implant followed that described previously by Schepens and co-workers.[3-7] The length of the scleral bed and implant depended on the extent of the pathologic changes in the retina and vitreous, and the width on the meridional extent of these changes. As a rule, the width of the scleral bed was equal to the width of the implant plus twice its thickness. For example, an implant 7 mm wide and 2 mm thick required an 11-mm scleral bed. A 3-mm-thick implant, which required a 14-mm bed, was used in eyes that needed a higher

buckle because of severe pathologic changes in the vitreous base. In most cases, a 2-mm-thick implant was used.

When an encircling band was desired, a 2-mm groove was made along the midline of the implant with a sharp blade and scissors. The encircling band was placed over the implant in the usual manner.

When a Refojo implant was used to close retinal breaks requiring a meridional implant, an encircling band was often not required. In this case, a meridional intrascleral trapdoor was created, using the mark for the retinal break as the midline of the scleral bed (Fig. 2A). Two equatorially oriented, 4–0 polyester fiber (Mersilene) sutures were placed through the scleral flaps with a tapered-tip needle. Because the posterior mattress suture was usually more difficult to insert through the scleral flaps than was the anterior one, the posterior mattress suture was inserted first. The scleral bed was treated with cryoapplications or diathermy. We selected diathermy in cases of retinal breaks near the macula, since the chorioretinal lesion from diathermy is smaller and has less tendency to spread to the macula or optic nerve. A Refojo implant of appropriate size was placed in the bed. After closing the scleral flaps tightly, the implant was trimmed to produce smooth edges and to prevent exposure through Tenon's capsule and conjunctiva (Fig. 2B).

Episcleral Implant

The technique originally described by Custodis[8] and modified by Lincoff and co-workers[9,10] was adapted. We used this technique in eyes with thin sclera in which scleral dissection was considered risky and conducive to scleral rupture. In cases of a single retinal break or multiple breaks a quadrant apart, each break was closed with a meridionally positioned episcleral buckle (Fig. 3). An encircling band was placed over the implant.

The anterior and posterior ends of the break were localized on the sclera with a flat localizing diathermy electrode. The borders of the break at its widest part were also marked to assure an adequate buckle. Two 4–0 Mersilene mattress sutures were placed on the sclera, each scleral bite being located 5 mm from the side of the tear. One suture was placed at the anterior end of the break, a second at the posterior end. After treating the break with adequate cryoapplications, a Refojo implant of appropriate size was inserted beneath the sutures over the break. A No. 240 silicone band was placed over the middle portion of the implant, anchored on each side of the implant, and passed around the globe under the recti muscles. It was also anchored in each quadrant with a 4–0 polyester fiber (Dacron) suture mounted on a spatula needle. The ends of the band were tied with a clove hitch of 4–0 Mersilene.

In all episcleral implant cases, subretinal fluid was drained through a sclerotomy in the area with the most fluid. The sclerotomy was closed with a Dacron suture if it was located away from the episcleral implant. The suture was temporarily tied to close the sclerotomy whenever the band was pulled up, or when the scleral mattress sutures over the implant were pulled up and tied. This was done to prevent incarceration of retina in the sclerotomy site during readjustment of the implant or the encircling band. If a vitreous injection

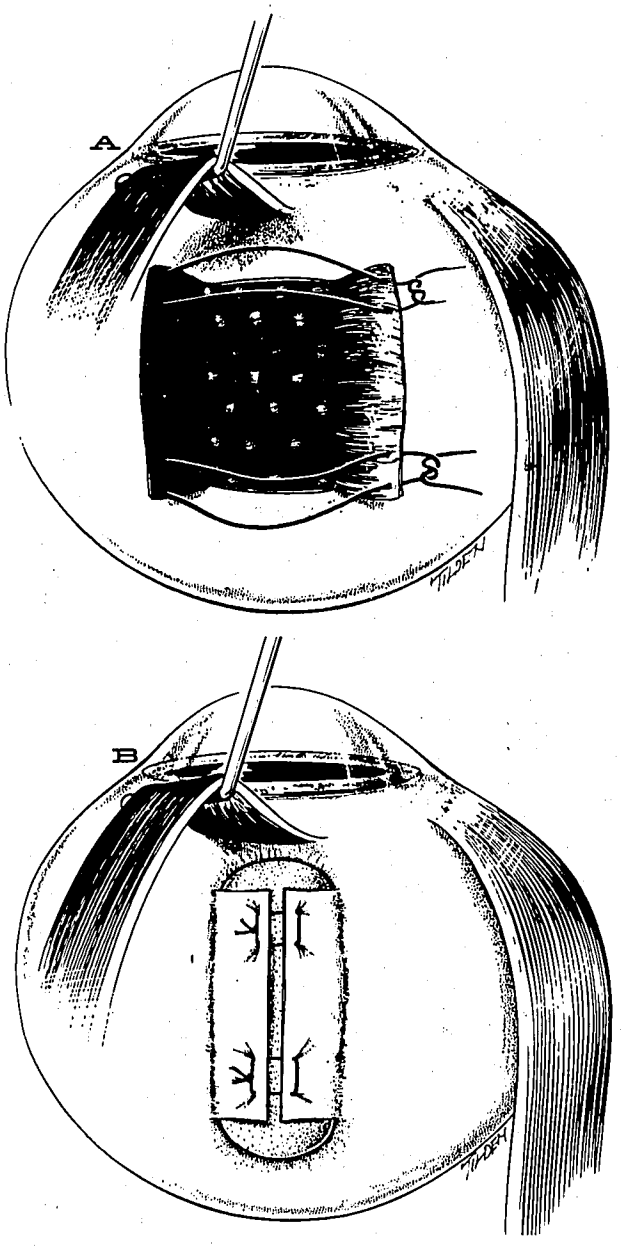

Fig. 2. **A,** Scleral bed treated with diathermy. **B,** Implant in scleral bed. Scleral flaps are closed with sutures.

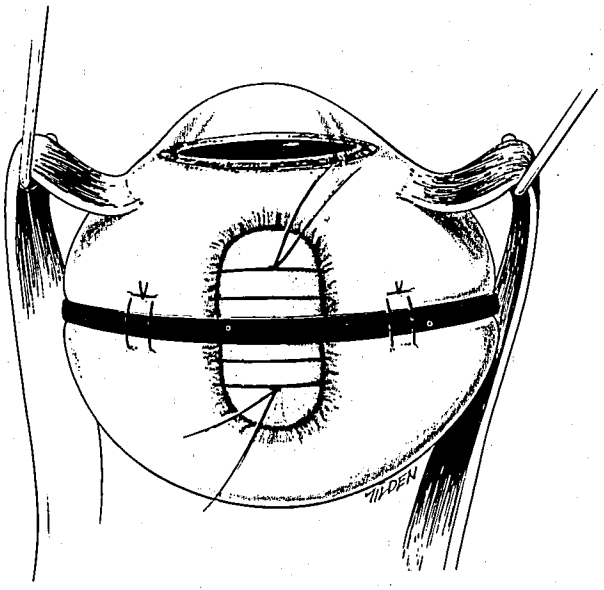

Fig. 3. Episcleral Refojo implant held with mattress sutures and No. 240 silicone band.

was required because a retinal break failed to close, a sclerochoroidal perforation was made in the area of the retinal break to allow fluid vitreous to drain and to provide room for an air injection into the vitreous cavity.

The fundus was checked, and when the implant was correctly positioned the mattress sutures were permanently tied. The band was pulled snugly to produce an intraocular pressure of about 20 mm Hg. Intravenous acetazolamide (Diamox) in doses ranging from 500 to 1000 mg was given if the final intraocular pressure was over 30 mm Hg. The implant was trimmed to produce smooth edges. Excess ends of the band were cut short.

The Refojo implant was used as an episcleral equatorial implant following the technique described by Lincoff and co-workers.[9] A round implant was selected for small peripheral holes not requiring an encircling band; an oval one for retinal tears requiring an encircling element. In cases requiring a 360° episcleral buckle, a 3-mm oval implant was inserted under each rectus muscle. The implant was anchored to the sclera with two mattress sutures in each quadrant. The anterior scleral bite was placed near the ora serrata and the posterior one behind the equator. Subretinal fluid was drained through a sclerotomy in an area with highly elevated retina. No mattress sutures were required as long as the sclerotomy was under the implant. Both ends of the implant were pulled tight. When the implant position had been found satisfactory, the implant ends were tied together with two pairs of 4–0 Mersilene clove hitch tying sutures (Fig. 4).

An encircling element was added when an equatorial implant encompassed less than 360 degrees. Placed in a groove created along the middle of the equatorial implant, it helped keep the buckle height stable in case some mattress sutures gave way.

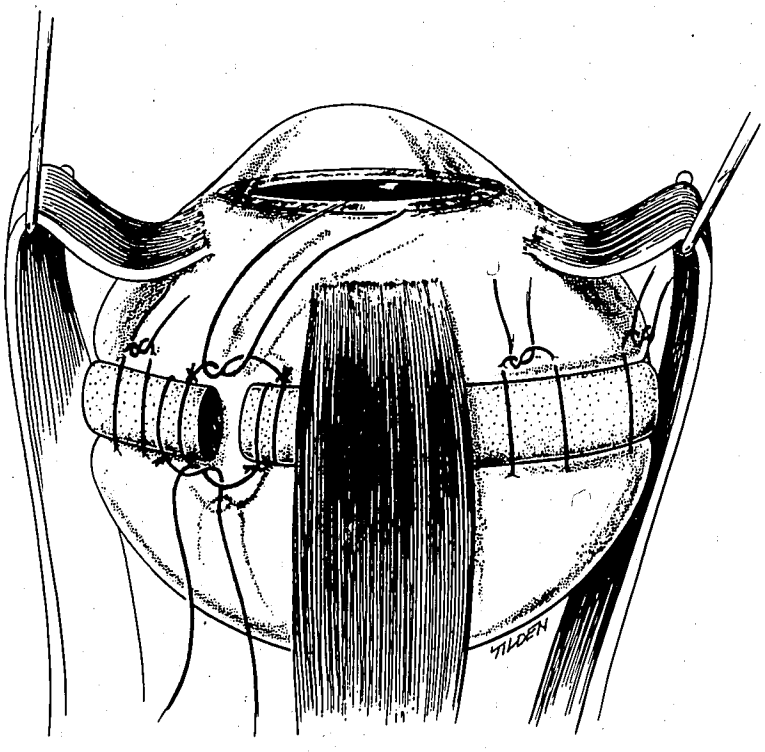

Fig. 4. Refojo material used as 360° episcleral implant. Ends of implant are pulled together and tied with pair of sutures at each end.

Observations

Intraoperative

The soft and medium implants were found most useful and practical. For example, the medium implant (with hardness between that of a Lincoff sponge and that of solid silicone) provided a high and effective meridional buckle under a silicone implant to abort fishmouthing of a retinal break. Because it has some degree of stiffness, the medium implant was suitable as a radial buckle for posteriorly located retinal breaks. When the scleral sutures were pulled up snugly, the posterior end of the meridional implant indented the posterior sclera beyond the location of the posterior mattress suture. The soft implant appeared ideal for equatorial intrascleral or episcleral buckles. There was no difficulty in cutting the soft or medium implants to any size or shape. They were easily trimmed with scissors to the desired thickness.

Since the new implant has a very smooth surface, it is slippery when handled with a wet glove. This problem was minimized by handling the implant with heavy-duty serrated utility forceps or a small mosquito clamp. This feature is actually an advantage, because when a meridional piece was inserted beneath a solid silicone implant, the implant's slipperiness facilitated its insertion and adjustment in the area of the retinal break. The elasticity of the Refojo implant makes it resistant to tearing with forceps or cutting by scleral sutures. The scleral mattress sutures tied over an episcleral implant indented it effectively and secured it very firmly against the scleral surface. When the Refojo implant was used as an equatorial episcleral implant, it was easily adjusted, even under a snugly placed scleral suture. Holding the implant with forceps on each side of a scleral suture reduced its diameter, thus facilitating readjustment of the implant under a tight mattress suture.

Postoperative

The eyes were checked daily for five to seven days while the patient was in the hospital. Thereafter, they were examined 3, 6, 12, 26, and 52 weeks after surgery. These examinations included checking the external appearance of the eye, a test of muscle balance, intraocular pressure measurement, slit-lamp examination of the anterior segment, and direct and indirect ophthalmoscopy.

There were no unusual findings externally during the early or late postoperative periods. The anterior chamber reaction was minimal in all eyes; in no case was it greater than that observed with the Lincoff sponge or a solid silicone implant. Exposure of the implant was not observed.

Elevation in the area of the implant remained stable in all eyes (Fig. 5). The location of the buckle was permanent. Neither erosion of the eye walls nor migration of the implant into the eye was observed. Infection did not develop in any eye. Mild choroidal detachment developed in the peripheral fundus of two eyes but subsided spontaneously without medical or surgical intervention.

Reoperations

Two eyes had reoperations owing to the development of massive preretinal retraction in one eye and a new retinal break in the other. In the first operation in these cases, the Refojo implant had been used as a meridional piece under a solid silicone implant in a scleral bed that had been treated with diathermy. In one eye, the reoperation occurred four weeks after the implant was inserted. In this case, examination of the implant in situ disclosed no changes in its color or consistency. The sclera beneath the Refojo implant

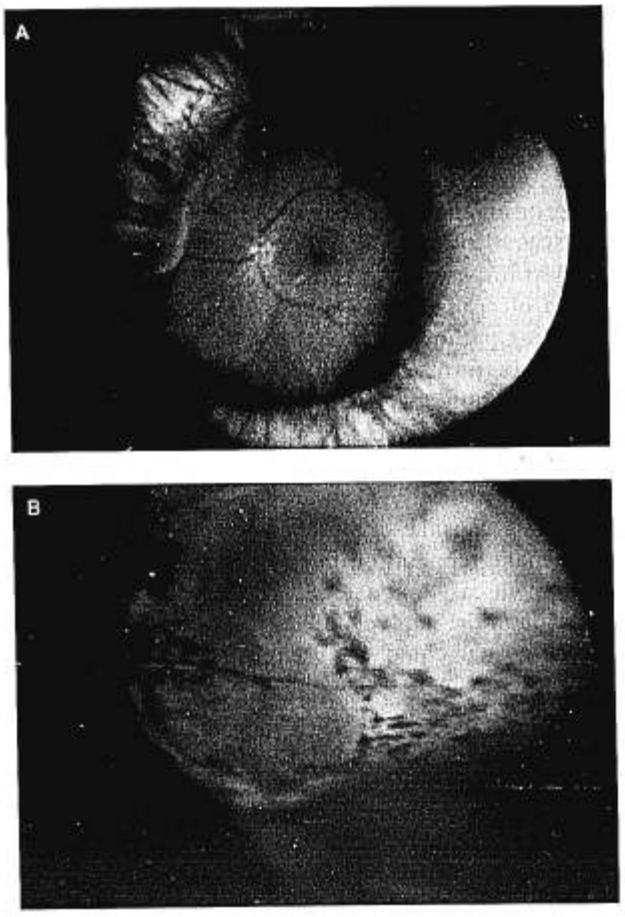

Fig. 5. Fundus photographs of Refojo implant 14 months after scleral buckling. **A,** *top,* wide-angle photograph of equatorial intrascleral implant. **B,** *bottom,* fundus view of buckling caused by meridional episcleral implant.

showed a thin layer of fibrous tissue that made the diathermy marks in the area indistinct. The scleral bed under the adjacent solid silicone did not show a similar fibrous tissue layer, probably because its development was delayed. In the second case, the implant had remained in the scleral bed for four months. A translucent encapsulating fibrous tissue was noted on the scleral surface of the implant. The surface of the implant in contact with the silicone did not show this fibrous capsule. A layer of clear fluid was observed between the capsule and the implant. The inner surface of the capsule was smooth. The capsule was thickest under the implant and was continuous with a similar, but thinner, fibrous capsule under the solid silicone implant.

Discussion

The goal of this study was not to compare the Refojo implant with other available materials for scleral buckling but rather to determine whether it was tolerated by human ocular tissue. This study shows that the implant is well tolerated in human eyes, thus confirming earlier observations in laboratory animals.[1]

This new material appears to have the features of an ideal scleral buckling material. First, it is soft and elastic, properties that help to prevent erosion of the sclera or conjunctiva when the material is implanted intrasclerally or episclerally. It may be an ideal material for scleral buckling in children. Second, it is devoid of dead spaces, which reduces the risk of its harboring pathogenic organisms. This allows its safe use as an intrascleral implant. Third, when it is soaked in antibiotic, the implant absorbs and retains it, which further reduces the risk of infection.[1] Fourth, the material produces a fibrous capsule over the scleral bed as early as four weeks after implantation. This capsule strengthens the scleral bed and could make reoperation in cases of recurrent retinal detachment easy and safe.

Although the implants used in this study were pilot samples, they could be used in a wide range of applications as a scleral buckling material: intrasclerally or episclerally, with or without an encircling band, equatorially or radially. Although long-term observations in more cases are required, we feel that continued use of this new implant for scleral buckling is justified, based on our present observations. The clinical application of this hydrophilic acrylate material is presently limited to scleral buckling. As more clinical experience is gained, we foresee wider clinical applications of the material not only in ophthalmic surgery but also in other surgical specialties.

Key words: acrylic hydrogels, implants, retinal detachment, scleral buckling.

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