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Scleral Expansion Bands

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Historical Background

Accommodation is defined as a change in the dioptric power of the eye that occurs to project near objects in focus on the retina.[1] Since 1855, the Helmoltz theory[2] has attributed accommodation to a decrease in zonular tension and presbyopia to a loss of elasticity of the crystalline lens. This theory, which has been reinforced by recent experiments, is the most widely accepted theory of the physical mechanism of accommodation,[3] although it has been challenged recently by Schachar et al.[4,5] Schachar's own theory suggests that accommodation occurs from an increase in zonular traction at the lens equator. Under this theory, presbyopia occurs due to the increasing equatorial diameter of the aging lens with a subsequent decrease in the effective working distance of the ciliary muscle. On the basis of his theory, Schachar proposed scleral expansion for the treatment of presbyopia.[4]

Different Theories of Accommodation

The classic Helmholtz mechanism of accommodation states that, during accommodation, the anterior and axial movement of the contracting ciliary muscle results in a relaxation of zonular tension.[2] This allows the lens, surrounded by its elastic capsule, to round up and increase in optical power, with the lens equator moving away from the sclera. The posterior movement of the lens is restricted by the vitreous humor, which results in a decrease in the equatorial diameter. Other theories of accommodation have been proposed by Tscherning,[6] Schachar,[4,5] and Coleman.[7] Although there has been much discussion over these alternative theories, there is considerable credible evidence against them, which further supports the Helmholtz theory.[2]

Schachar[4] first makes a distinction between the anterior, posterior, and equatorial zonules. He believes that, during accommodation, the contraction of the ciliary muscle, directly through the equatorial zonules, pulls the lens equator toward the sclera and increases lens diameter. Simultaneously, the anterior and posterior zonules play supportive roles by relaxing, which cause central steepening and peripheral flattening of the lens, with an increase in its optical power.[4,5] Schachar et al[5] claimed to have demonstrated this phenomenon in monkeys and humans. This theory contradicts Helmholtz's theory. Schachar stated that the effective force the ciliary muscle can apply to the lens equator is reduced with age because the distance between the ciliary muscle and the equator of the lens decreases throughout life due to the increasing equatorial diameter of the aging lens.[4,5] He postulated that expanding the dimensions of the overlying scleral wall by pulling the ciliary muscle away from the equatorial edge of the lens would reverse

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the process of presbyopia and increase accommodative amplitude. Thus, he introduced a new surgery for presbyopia based on scleral expansion.[4]

However, it should be noted that the in vitro measurements of the lens equatorial diameter used to support Schachar's theory may not reflect the in vivo measurements. Using high-resolution magnetic resonance imaging, Strenk et al[8] found that the lens diameter decreased during accommodation, which is in contrast to Schachar's theory. Glasser and Kaufman[3] studied the principle of accommodation in primates when the induced accommodation occurred through stimulation of a surgically implanted midbrain electrode. They applied a topical muscarinic antagonist to achieve pharmacological disaccommodation, and using ultrasound biomicroscopy and goniovideography, they imaged the lens equator and ciliary body movements during accommodation and disaccommodation. In all cases, they observed the movement of the ciliary body and the lens equator away from the sclera during accommodation, which is consistent with the mechanism of accommodation described by Helmholtz[2] but contrary to that proposed by Schachar et al.[5]

Scleral Expansion Bands

Schachar introduced a new surgery for presbyopia based on the use of intrascleral implants positioned at the level of the ciliary body (scleral expansion bands).[4] The aim of this technique was to restore the working distance between the ciliary muscle and the lens equator, which should theoretically, as suggested by Schachar, allow the muscle to work more effectively.

Early Surgical Techniques for Scleral Expansion

Scleral expansion bands are the development of an earlier concept that consisted of a rigid plastic poly(methyl methacrylate) (PMMA) ring that increases the scleral circumference. However, this technique was abandoned due to complications such as anterior segment ischemia and conjunctival erosions. This original ring was replaced by portions of the bands inserted into 4 scleral belt loops.[4]

In 1997, Yang et al[9] reported on 6 patients who underwent scleral expansion using a complete encircling band. Four separate scleral belt loops were made at the 12-, 3-, 6-, and 9-o'clock positions; 4 bands then were inserted into these loops and were ultrasonically fused together. All patients reported an improvement in near vision. Unfortunately, 5 of the 6 patients required removal of the scleral expansion bands 6 months later due to conjunctival erosion in areas where the bands were ultrasonically fused together. The accommodation amplitude of these patients after scleral expansion band removal returned to preoperative values.

To avoid conjunctival erosion and compression of the anterior ciliary body, a new protocol was developed in 1998. Four PMMA bands, which were not connected to each other, were inserted into 4 scleral loops along the 45-degree meridians at the 1:30, 4:30, 7:30, and 10:30 clock positions.

Surgical Technique for Scleral Expansion Bands

The principle of this surgery is to insert 4 arcuate segments into scleral loops located in 4 quadrants. The limbus is marked at the 12-o'clock position and at each 45-degree meridian. A small amount of subconjunctival anesthetic is injected at the 12- and 6-o'clock positions to elevate the conjunctiva and produce a surgical plane for dissection. Then, limbal conjunctival peritomy is performed from the 10:30 to 1:30 clock positions with a vertical relaxing incision at 12 o'clock. A similar peritomy is done at the 4:30 to 7:30 clock positions with a vertical incision at 6 o'clock. Following a blunt dissection to expose the scleral surface, a marker is used to place an arc 3.5 mm from the limbus that is centered on each 45-degree axis. The opening of the superficial sclera is performed using a calibrated guarded diamond knife. A scleral tunnel is then made using a specific lamella diamond knife to delaminate the sclera. Next, the PMMA segment is inserted into the scleral belt loop (Figure 25-1). An important surgical step is to ensure that the 2 ends of the segment protrude outside and that the segment is not tilted laterally to push on the plain sclera, pull up the scleral loop, and so induce the expansion effect. This procedure is repeated in each of the 4 oblique quadrants of the eye, and the conjunctiva is carefully closed. Finally, 1% to 2% pilocarpine drops are instilled to rule out anterior segment ischemia. In addition, 20% mannitol is given intravenously within 30 minutes before the end of the last implantation to avoid malignant glaucoma.

Postoperatively, patients must use a topical antibiotic-corticosteroid 4 times a day for 15 days. The patient is also advised to perform frequent eye exercises for the rehabilitation of the ciliary muscle.

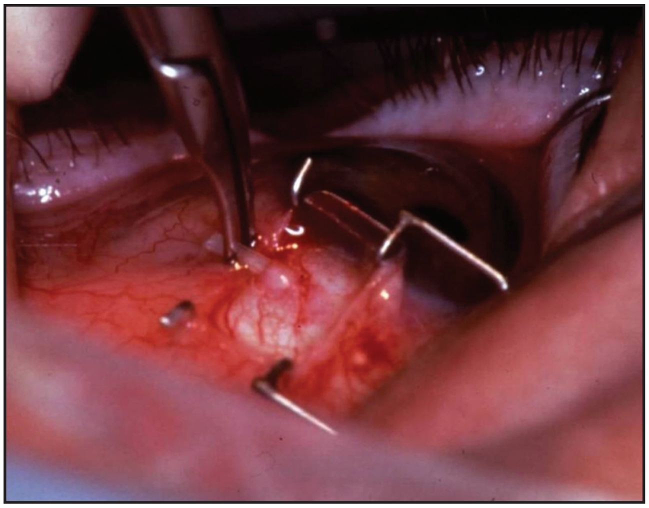

Figure 25-1. An intraoperative view of the implantation of a scleral expansion band.

Clinical Results

The scleral expansion segments are supposed to stretch the sclera and consequently pull on the adjacent ciliary muscle, thus restoring an appropriate tension in the zonule.[4] Despite considerable interest aroused by the scleral expansion theory, it has failed to find a significant confirmation in practice. The accommodation results seem to be inconsistent and not predictable.[10,11] Mathews[10] used an infrared optometer to perform objective dynamic accommodative measurements on 3 postoperative scleral expansion patients and reported no evidence of accommodation. Similar results were obtained by Ostrin et al,[12] who investigated objective measurements of accommodation in scleral expansion band patients. They reported a complete absence of objective accommodative amplitudes, which was similar to age-matched control patients.

In 2001, we reported on 4 patients who underwent implantation of scleral expansion bands in one eye and on 2 patients who had bilateral implantation.[11] In all patients, there was no change in distance vision. However, near visual acuity and subjective perception of accommodation amplitude improved in only 3 eyes 6 months following surgery, but all eyes returned to preoperative values within 1 year. In the remaining 5 eyes, no implant-related changes were observed. Another study of 29 patients reported a modest improvement in near vision in approximately half the patients, as well as an improvement in the contralateral unoperated eye using subjective testing methods.[13] The high variability and increase in near visual acuity of the unoperated eye were attributed to the subjective nature of the testing and point to a possible placebo effect.

In the United States, the Refocus Group (Dallas, TX) has developed the patented PresView System, which incorporates preoperative ultrasound mapping for precise implant location. The phase I trial, sponsored by the Food and Drug Administration (FDA), was completed between 2000 and 2002 and demonstrated the safety of the implants on 29 eyes of 29 patients over 2 years. Approximately 59% of patients gained 3 lines or more of near vision. However, the accommodation results have varied among the study centers, with such inconsistency largely unexplained. Repeatability of the scleral pocket's incisional depth may play a role and is being evaluated. Another thought is that the scleral band depression creates a multifocal crystalline lens surface that provides variable degrees of pseudoaccommodation. Phase II of the trial had been initiated and included 150 patients. PresView scleral implant patients had up to 7 lines of improvement, and the median patient had 3 lines of improvement at 6 months. The study has tracked results with the iTrace wavefront aberrometer (Tracey Technologies, Houston, TX) for objective measurement of accommodation, and the Visante coherence tomographer (Carl Zeiss Meditec, Jena, Germany) for optimal placement (position and depth) of the implants. Phase III trials of the PresView scleral implant procedure began in 2005. Implants are inserted with the help of an automated sclerotome (PresView sclerotome), which has made the surgery easier. These clinical trials are ongoing.

Complications

These scleral surgical procedures are prone to complications. Singh and Chalfin[14] reported a case of mild iritis developing after scleral expansion segment surgery that seemed to be characteristic of anterior segment ischemia. One case of scleral thinning has been reported, similar to that observed with scleral buckles,[14] and one case of endophthalmitis resulting from a break in sterile procedure. Other minor complications are frequent and include conjunctival redness (Figure 25-2), subconjunctival hemorrhage, scleral expansion segment rotation or extrusion, conjunctival erosion, and increased intraocular pressure. No cases of malignant glaucoma have been reported using the 4 scleral expansion bands, but it is theoretically possible that segments may increase posterior pressure, resulting in aqueous misdirection.[15] Intravenous mannitol should be administered to avoid malignant glaucoma.

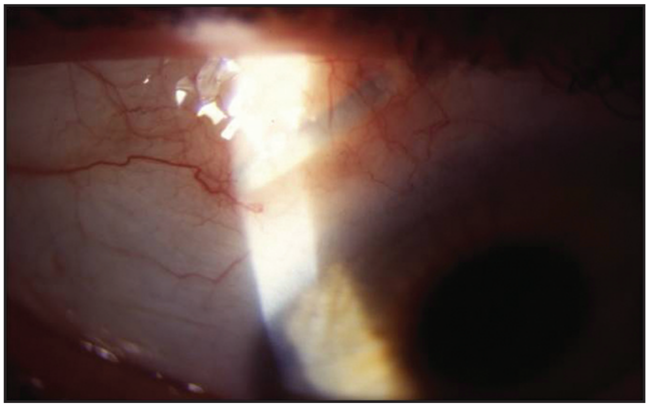

Figure 25-2. Conjunctival hyperemia close to a scleral expansion band.

Anterior Ciliary Sclerotomy

Another method used for surgical reversal of presbyopia is anterior ciliary sclerotomy. This method was first described by Thornton and Shear[16] who used radial incisions in the sclera to create an expansion of the scleral diameter to obtain more room for the lens-zonular complex. They theorized that providing more space for the lens and lenticular zonules may place more resting tension on the equatorial zonules, thus allowing for increased tension to develop during muscle contraction. The procedure is hypothesized to restore accommodative amplitude in presbyopic patients.

The anterior ciliary sclerotomy procedure was performed by Fukasaku and Marron[17] and consisted of 8 radial incisions of the conjunctiva and sclera overlying the ciliary body in each of the oblique quadrants. To avoid excessive conjunctival bleeding, they included limbal peritomies. They reported a good initial effect from anterior ciliary sclerotomy with a mean increase in accommodative amplitude of 2.20 D. However, the effect of surgery was found to be short-lasting, as 1 year after the procedure the amplitude increase was only 0.80 D. The authors attributed the loss of effect to healing of the sclera and therefore modified the technique with an additional implantation of silicone plugs in the incisions sutured in place in a criss-cross fashion to prevent scleral healing. They reported that the silicone plugs reduced this regression, with a mean accommodative amplitude gain of 1.50 D at 12 months, in addition to significantly lowering the intraocular pressure.

Summary

Scleral approaches for restoring accommodation are based on ill-conceived, revisionist notions of the mechanisms of accommodation and presbyopia. Schachar et al[4,5] attributed presbyopia to a progressive growth in the lens equatorial diameter and not to the increase in stiffness of the lens, which had been widely documented. Disregarding the ill-founded theories of accommodation and presbyopia on which these scleral approaches may be based, surgical expansion of the sclera cannot restore the accommodative ability to the presbyopic lens and, therefore, cannot restore accommodation in human presbyopia. Nonetheless, we cannot ignore the fact that some patients, who have undergone scleral expansion, had improvement of near vision. Thus, further studies with carefully controlled, prospective, multicenter trials using repeatable and objective means to measure accommodation are required to validate these procedures.

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