

THE SURGICAL REVERSAL OF

PRESBYOPIA

A NEW PROCEDURE
TO RESTORE
ACCOMMODATION

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THE LOSS OF ACCOMMODATION OCCURRING IN ALL INDIVIDUALS AFTER THE AGE OF 40 HAS BEEN ATTRIBUTED TO THE GRADUAL HARDENING OF THE CRYSTALLINE LENS.

Purpose: TO RESTORE THE NATURAL NEAR ACCOMMODATIVE FOCUSING ABILITY OF ALL PHAKIC INDIVIDUALS WITHOUT ALTERING THE DISTANCE REFRACTIVE ERROR.

Method: BASED ON CLINICAL INVESTIGATION BY DR RONALD A SCHACHAR, IT HAS BEEN ESTABLISHED THAT THE NATURAL LENS OF THE HUMAN EYE CONTINUES TO GROW THROUGHOUT LIFE AND EVENTUALLY ENCROACHES ON THE AREA OF THE ZONULES AND CILIARY MUSCLE COMPLEX REDUCING THEIR ABILITY TO TRANSMIT THE NECESSARY FORCES RESPONSIBLE FOR ACCOMMODATION.

Result: BY INSERTING A SMALL POLYMETHYLMETHACRYLATE (PMMA) SEGMENT WITHIN THE SCLERA OVERLYING THE CILIARY BODY IN EACH OF THE FOUR OBLIQUE QUADRANTS OF THE GLOBE, THE TENSION BETWEEN THE LENS, ZONULES, AND CILIARY MUSCLE IS RE-ESTABLISHED AND NORMAL ACCOMMODATION IS RESTORED.

historical background

Surgical reversal of presbyopia (SRP) can be called the last frontier in the attempt to correct refractive and optical disorders. Modern refractive surgery began approximately 50 years ago when Jose Barraquer of Bogota, Columbia, developed keratomileusis.¹ Other procedures to alter the optical and focusing mechanism of the eye followed. This included radial and astigmatic keratotomy,² hexagonal keratotomy,³ thermokeratoplasty,⁴ automated lamellar keratoplasty,⁵ intrastromal corneal lenses,⁶ epikeratophakia,⁷ intacs,⁸ clear lens extraction,⁹ multifocal intraocular lenses (IOLs),¹⁰ phakic IOLs (including intraocular "contact lenses"),^{11,12} photorefractive keratectomy (PRK),¹³ laser in situ keratomileusis (LASIK),¹⁴ and laser computer-generated multifocal corneal correction.¹⁵

All of them have been used to alter the cornea and/or change the focusing powers of the ocular system. The only methods to date that helped those experiencing presbyopia was the use of monovision, (correcting one eye for near and one eye for distance), using any of the aforementioned techniques of refractive surgery on one eye, or the use of optical devices such as a single contact lens, bifocal lenses, or reading glasses. These were all compensatory. No procedure up to this time has been able to reverse presbyopia and actually restore the natural focusing mechanism. This would be independent of those meth-

ods used at this time to compensate for the loss of the accommodative near-focusing powers of the eye. For the last 150 years, the explanation of the loss of accommodation through Helmholtz's theory has been included in the medical textbooks.¹⁶ It has been described as the lens hardening with aging. This decrease in flexibility of the lens and the loss of elasticity of the lens capsule makes it more difficult for the focusing mechanism to work, so that when the ciliary muscle contracts, the lens, because of its rigidity, can no longer round up to focus more clearly at near. Consequently, some supplemental method of focusing, such as reading glasses or bifocal lenses, is required.

In 1984, the American Academy of Ophthalmology defined presbyopia as "the gradual loss of accommodation resulting from loss of elasticity of the lens capsule and lens substance." Hardening of the lens and lens capsule does not appear to start in all individuals at the same time, nor does it progress at the same rate in all individuals. Presbyopia, however, occurs at the exact same time, $\pm 1\frac{1}{2}$ years, in 100% of the population. In fact, a graph demonstrating the amount of accommodation an individual has from birth through 75 years of age shows a progressive decrease in accommodation with nearly the same amount of decline in accommodative amplitude in everyone (Figure 1). At about 5 years of age, individuals have approximately 16.0

FIGURE 1

Age-related loss of accommodation.

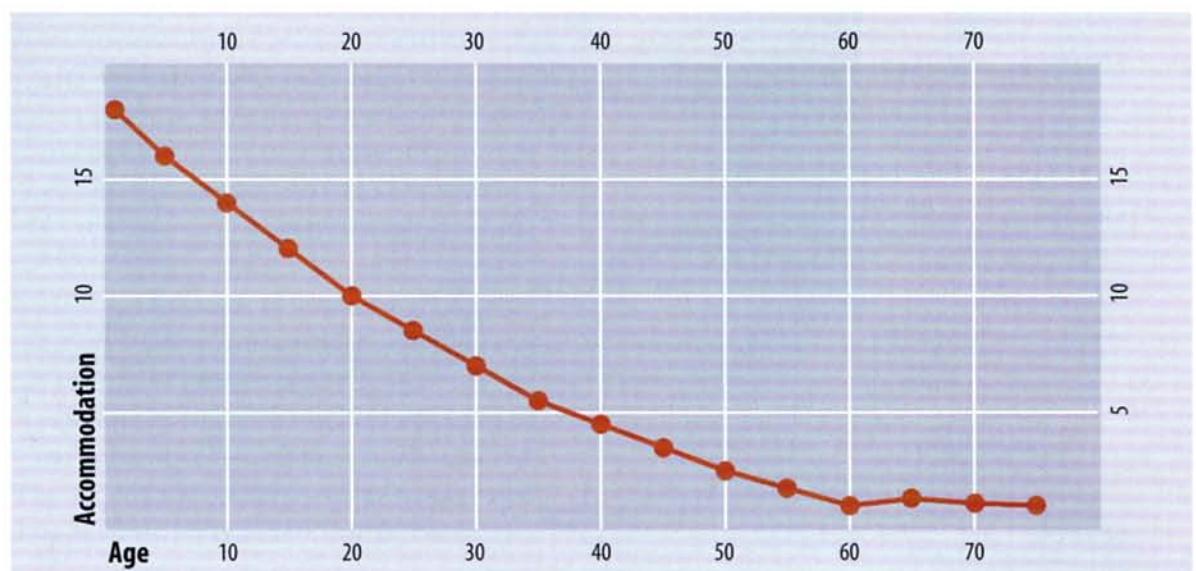


Table 1: Comparing the accommodation theory

	Helmholtz	Schachar	Actual
Lens hardness	Increases with age	Independent of age	Independent of age
Hyperopic shift	No	Yes	Yes
Spherical aberration	Increases with accommodation	Decreases with accommodation	Decreases with accommodation
Gravity	Should change focus	Does not change focus	Does not change focus

diopters (D) of accommodation. By the time they reach age 45, they have less than 4.0 D of accommodation; by 55, only 2.0 D; at 65, only 1.0 D; and by age 75, they have no accommodation whatsoever. As a result of Schachar's theory, the American Academy of Ophthalmology has revised their definition of presbyopia to "that condition in which impaired near vision results from the decreased amplitude of accommodation that normally occurs with age."

The anatomical structures responsible for accommodation include the ciliary muscle, the lens, and the zonules. Helmholtz's theory states that as the ciliary body contracts for accommodation, it constricts inwardly, relaxing the zonules, and allows the crystalline lens to become more convex for focusing at near. The relaxation of the zonules causes the lens to "round up" and bring the near objects into focus more easily.

Challenging Helmholtz's theory

With relaxed zonules in accommodation, the lens should be subject to the forces of gravity "falling" anteriorly when the person is in the prone position or looking down, and "falling" posteriorly when they are lying supine or looking up. This does not occur. Helmholtz's theory of accommodation also should result in an increase of spherical aberration, since a more uniformly spherical lens creates a greater separa-

tion between peripheral and central point of focus. On the contrary, it has been shown to actually decrease. If Helmholtz's theory that accommodation occurs with relaxed zonules thus increasing lens power was accurate, a myopic shift would occur as the progressive increase in lens mass encroaches the zonule-ciliary muscle with aging. Actually, a hyperopic shift in refraction occurs with age. These phenomena are all consistent with Schachar's theory (Table 1).

Another explanation for the onset of presbyopia has been described by Ronald A Schachar.¹⁷ This appears to be more logical and can be tested by careful scientific investigation. In reality, the loss of accommodation appears to occur because the lens continues to grow throughout life. Therefore, at approximately 40 years of age, the size of the crystalline lens begins to compromise the space of the lens-zonule-ciliary muscle complex. As the lens encroaches upon this area, the zonules become lax and the physical force of the ciliary muscle contraction cannot be transmitted to the lens in order to allow the lens to change shape.

A new explanation for presbyopia

The textbooks have informed us that the change in shape of the crystalline lens is due to the relaxation of the anterior and posterior zonules allowing the elasticity of the lens capsule to mold the

lens to a rounder shape, a greater anterior-posterior thickness, and a steeper central curvature. Schachar's theory states that as the ciliary body contracts for accommodation, it expands outwardly, thus pulling the equatorial zonules and tightening the lens capsule, causing the central area to be more convex for focusing at near. As this occurs, the peripheral portion of the lens flattens. In this way, the stretch of the equatorial zonules on the equator of the lens causes flattening of the peripheral portion of the lens and allows rounding up of the central portion, thus allowing near objects to be focused more clearly (Figure 2).

The mechanism of action of Schachar's theory is that the accommodation decreases with age because the crystalline lens grows concentrically, approaching the ciliary body at a rate of 20 μm per year. This resulting decrease in the space between the ciliary body and the lens decreases the tension of the zonules attached to the ciliary muscle, causing the decline in amplitude of accommodation with age. Schachar, however, has demonstrated that it is the central equatorial zonules that are responsible for the accommodative changes of presbyopia. The contraction of the ciliary muscle results in an outward movement toward the sclera, increasing the tension on the equatorial zonules while simultaneously relaxing the anterior and posterior zonules.

Restoring accommodation

By re-establishing the tension between the ciliary muscle-equatorial zonule-lens complex, accommodation can be restored. The force can be directly transmitted from the ciliary muscle to the zonules and then to the lens. Schachar's theory explains that the force of contraction of the ciliary muscle on the central equatorial zonules results in flattening of the peripheral portion of the lens and rounding up of the central portion of the lens, increasing the curvature of both the anterior and posterior lens surface.¹⁸ This allows one to focus at near using one's own natural mechanism of accommodation. Schachar has conducted studies that show that accommodation is not affected by patient's position, eg, prone or supine.¹⁹

Recent investigations on primate eyes²⁰ which tend to dispute Schachar's explanation of accommodation lacked reference points in some measurements and did not include some results in the raw data which supported Schachar's theory.

The hardness of the crystalline lens does not always increase in a predictable fashion. Ophthalmic surgeons performing cataract surgery have noted that the cataractous lenses are often soft, even in patients in their 70s, 80s, and 90s. Even patients with hard nuclei have a very soft cortex that could potentially change shape if tension could be applied to the lens equator.

Current treatment modalities for presbyopia

Modifications and Compensations

1. readers
2. bifocals, both spectacle and bifocal contact lenses
3. monovision, using either contact lenses or refractive surgery
 - a. LASIK
 - b. PRK
 - c. RK/AK
 - d. LTK
 - e. ICL
 - f. Phakic ACIOL
4. SRP
 - a. scleral expansion band (SEB) segments

SRP is a new surgical method of allowing the ciliary body to expand and stretch outwardly, increasing the distance between the lens equator and the ciliary muscle. This appears to restore the accommodation.

Surgical theory

How can this tension of the lens-zonule-ciliary muscle be re-established? If the space between the lens and sclera could be expanded to place the equatorial zonules on stretch when the ciliary muscle contracts, natural accommodation could be restored.

This could be accomplished surgically if the sclera could be "lifted" away from the anatomical site of the ciliary muscle. An attempt to place a

360° SEB embedded 0.3 mm in the wall of the sclera 2.75 mm from the limbus overlying the ciliary muscle resulted in measurements of 10.0 to 15.0 D of accommodation in patients in their mid-to-late 60s.²¹ Because of the compromise of the anterior ciliary blood supply, several of these patients developed anterior segment ischemia.

After several design changes, a technique for placement of four separate PMMA “SEB” segments has been established without any subsequent occurrence of anterior segment ischemia. These segments provide the “lift” over the ciliary muscle-zonule-lens “complex” which re-establishes the tension necessary to permit the equatorial zonules, upon contraction of the ciliary

Contraindications

1. previous cataract extraction
2. scleromalacia
3. previous trabeculectomy
4. coagulopathies
5. collagen-vascular diseases
6. impending rapidly developing cataracts
7. poorly controlled advanced glaucoma

Relative Contraindications

1. if LASIK is required (preferable to perform this first, but reverse order is acceptable)
2. monocular patient
3. age > 70 years
4. severe keratoconjunctivitis sicca

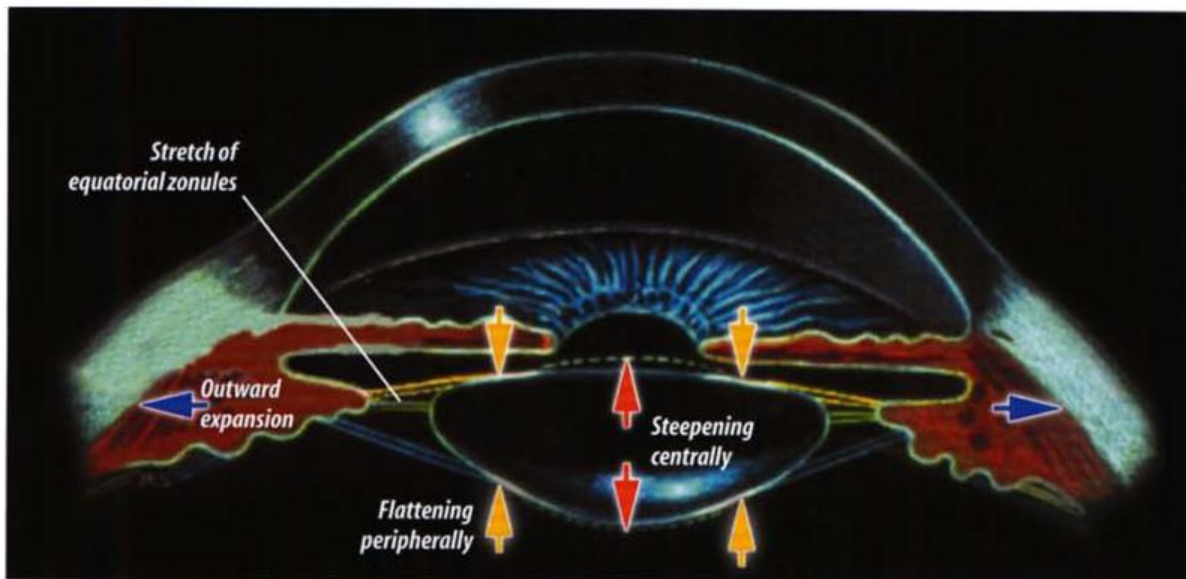


FIGURE 2

Equatorial zonular stretching causes central steepening (red arrows) and peripheral flattening (yellow arrows) of crystalline lens.

muscle, to transmit sufficient force to flatten the periphery and steepen the central portion of the lens to allow clear focus at near. In this manner, accommodation is restored.

Patient selection for SRP

The criteria for selecting the ideal patient for SRP surgery includes the following:

Indications

1. 40 to 70 years of age
2. no refractive error at distance
3. binocular vision
4. age < 40, if slight hyperopia (< +1.00 D) is causing difficulty in near-work requirements

5. diabetes, insulin dependent
6. hyperopia > +1.00 D; LASIK can decrease the hyperopia prior to SRP surgery

Surgical technique

The lamellar diamond knife that creates the scleral tunnel is 5.0 mm in length and 150 μm in thickness. The scleral belt loop is 4.0 mm in length, 900 μm in width, and 0.3 mm in depth. The tunnel is located 2.75 mm posterior to the limbus in the diagonal quadrants. The insertion of the lamellar diamond knife should be at the full depth of the 0.3-mm vertical incision depth and should be advanced slowly and steadily to exit after 4.0 mm of excursion from the entrance

site. Care should be taken not to move the knife intermittently to cause either superior or inferior cuts through the tunnel or to go beyond the exit site and create an “undercut.” The lamellar knife should be pushed steadily without rotating the tip so that the scleral belt loop is no wider than the 900 μm width of the blade.

The sequence of events is to: make a peritomy from 3:30 to 8:30 o'clock and 9:30 to 2:30 o'clock with a vertical incision at 6:00 and 12:00 o'clock toward the fornix; mark two points 2.75 mm posterior to the limbus and 4.0 mm apart; place two parallel sclerotomy incisions 0.3 mm in depth and 4.0 mm apart; create the scleral tunnel with the lamellar diamond blade; and insert the

Results of SRP surgery

Postoperative treatment

1. liberal use of artificial tears
2. TobraDex ophthalmic drops four times daily for one week
3. frequent “exercising” in viewing small print at close distances

Symptoms

1. patient experiences a mild brow ache for the first 24 hours
2. accommodative scleral myalgia (a brow ache when attempting to focus on fine detail at near)



SEB segments through the tunnel. Finally, the conjunctiva is closed (Figure 3).

At the conclusion of the procedure, 1% or 2% pilocarpine drops are instilled into each eye to observe pupillary constriction. The presence of anterior segment ischemia would result in alteration or absence of pupil constriction and repositioning or removal of the SEB may be indicated. To suppress significant potential postoperative elevation of intraocular pressure (IOP), 500 mm of 20% mannitol is given at the end of the surgical procedure.

3. intermittent blurry vision for distance and near. Generally secondary to alteration of the tear film layer (two to three weeks)
4. photosensitivity (one to two weeks)
5. subconjunctival hemorrhage (two to three weeks)
6. hyperemia—localized over SEB segments (three to eight weeks)

Complications

1. anterior segment ischemia
 - a. iris sector dilation
 - b. Descemet’s fold—grayish look
 - c. trace of flare and cells
 - d. very low IOPs

FIGURE 3

The four major steps of SRP surgery.

- e. nausea
2. conjunctival erosion overlying SEB
3. SEB segment rotation
4. SEB segment extrusion

Patient responsibility

Following SRP surgery, the most significant and important follow-through for the patient is to perform near vision "exercises." A frequent maneuver of trying to read the smallest print at the closest distance will help restore the strength of the focusing mechanism. In doing this, patients will note a cramping sensation of the eye. Because the focusing mechanism has not been utilized for many years, the muscle resists constant stimulation, resulting in a "myalgia of accommodation." This is almost like an accommodative spasm of the muscle itself. With continued exercise, however, this disappears, the focusing mechanism becomes stronger, and the ability to focus on small objects for prolonged periods of time is re-established.

Surgical effect on IOP

In addition to improvement of accommodative amplitude following SRP surgery, another phenomenon has been observed. In the presbyopic patients who have had open-angle glaucoma, the untreated IOP has decreased by approximately 10 mmHg following SRP surgery. Since the ciliary muscle is attached to the area of the scleral spur and the trabecular meshwork, outward expansion of the sclera over this area may open the angle and the pore size of the trabecular meshwork, creating an increase in aqueous outflow. More research is required in this area before this procedure can be considered a potential cure for open-angle glaucoma.

Conclusion

We now have an exciting new reversible surgical procedure that can restore the natural near accommodative focusing ability of all phakic individuals experiencing presbyopia, without altering the distance refractive error. The evolution of refractive surgery has given ophthalmologists the capability to correct nearly all varia-

tions and powers of myopia, hyperopia, and astigmatism. Most of this new technology has been developed in the last half of the 1900s. As we begin the new century, we finally have the last piece of the puzzle to correct virtually all refractive disorders.

It is now not only possible, but very probable, that before the end of this century, few, if any, phakic individuals will be wearing "prosthetic" optical devices.

About the author

Robert H Marmer obtained his undergraduate degree at Ohio State University, and his medical degree, with honors, from the University Autonoma de Guadalajara. After an internship in Houston, Texas, he practiced Family Medicine in San Diego, California. Upon completion of his residency program at the Mayo Clinic, Marmer spent time as a professor of ophthalmology lecturing to students at Ahmadubello University in Kaduna and Zaria, Nigeria, West Africa. In September 1975, he established the Marmer Medical Eye Center in Atlanta, Georgia.

Marmer was among the first of US physicians to travel to Russia to learn about the refractive surgery procedure from the world-renowned surgeon, Dr Svyatoslav Fyodorov, who was instrumental in perfecting Radial Keratotomy (RK). He was the first surgeon to introduce and perform RK surgery in Georgia. He is one of only two ophthalmologists in the United States trained in performing Hyperopic Thermal Keratoplasty for farsightedness. Marmer has the privilege of being the official team ophthalmologist for the NBA Atlanta Hawks for over 15 years and he also served as the official team ophthalmologist for the IHL Atlanta Knights since their inaugural season.

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