Laser scleral microporation proposed as accommodation restoration therapy

Visual axis untouched, meaning patients can benefit from future corneal, cataract surgeries

By Laird Harrison; *Reviewed by Sunil Shah, MBBS, FRCOphth, FRCS, FBCLA, and AnnMarie Hipsley, DPT, PhD*

LASER SCLERAL microporation appears promising as a treatment for presbyopia in emmetropic subjects, according to Sunil Shah, MBBS, FRCOphth, FRCS, FBCLA.

Unlike most treatments for presbyopia, the technique restores some natural ability to accommodate along with some extended depth of focus (EDOF) by increasing compliance in the sclera, said Dr. Shah, professor, Aston University, Birmingham, UK.

The procedure—in which a laser creates tiny micropores in the sclera—is an advanced iteration of a technique pioneered a decade ago, laser anterior ciliary excision (LaserACE). In a preliminary trial of the new approach, subjects gained a median 4.5 lines of near and intermediate visual acuity.

The technique is based on new understanding of the etiology of presbyopia and the biomechanical mechanisms involved in accommodation. While most attention in the past has focused on changes in the lens, recent discoveries have highlighted the role of other structures, including the sclera and choroid.

All ocular tissues stiffen or lose elasticity as the eye ages just like many other connective tissues in the body. Age-related changes in the eye result largely from the steady increase in crosslinks or bonds between polymer chains in the collagen and elastin that form the fibrils and microfibrils in the sclera, Dr. Shah said.

DIVING DEEPER

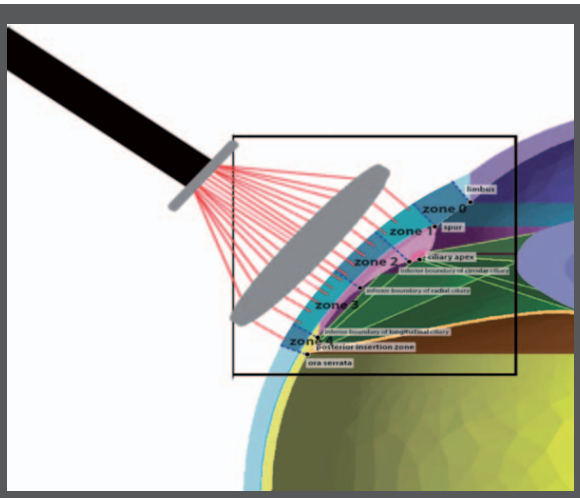
In her published manuscript, "VisioDynamics Theory: A Biomechanical Model for the Aging Ocular Organ" (Jaypee Books, 2003), AnnMarie Hipsley, DPT, PhD, described an age-related progressive "sclerosclerosis" which decreases scleral compliance in response to forces applied during accommodation, thus reducing accommodative efficiency.

Some researchers have estimated that extralenticular structures could account for up to 2 D of accommodation, and the aging of the structures might result in 1 to 2 D of lost accommodation.

Current treatments compensate for the lost accommodation rather than restoring it. Whether induced by manipulating multifocality, monovision, or depth of focus by using laser refractive procedures or created with contact lenses, all of these procedures may decrease binocularity, stereopsis, and uncorrected distance visual acuity.

Although monovision is the most popular treatment alternative to reading glasses, most people with presbyopia cannot tolerate it, Dr. Shah said.

Likewise, corneal presbyopic correction—an attempt to create a bifocal or multifocal cornea—can also result in loss of binocularity, stereopsis, or distance vision.



(FIGURE 1) Schematic representation of the laser scleral microporation procedure over the five critical anatomical zones of physiological and biomechanical importance.

In laser scleral microporation, an Er:Yag laser uses 225-µm spots to create a 5- x 5-mm matrix of micropores in a variety of densities and number that are 225 µm in diameter in four oblique quadrants of the eye.

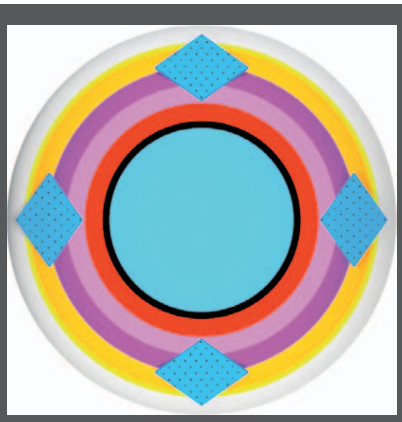
According to Dr. Hipsley's postulate, the creation of the micropore matrix over five key critical zones of biomechanical and physiological importance improve the compliance of the sclera in these regions to yield to accommodative forces from the ciliary muscles and extralenticular anatomy, thus restoring the efficiency of the accommodation mechanism.

take-home

- **With laser scleral microporation, a laser creates tiny micropores in the sclera. In a preliminary trial, subjects gained a median 4.5 lines of near and intermediate visual acuity.**

In a trial of 12 patients, mean monocular uncorrected visual acuities at near (40 cm), intermediate (60 cm), and distance (4 m) improved from +0.65 logMAR, +0.54 logMAR, and +0.20 logMAR, respectively, preoperatively, to +0.27 logMAR, +0.15 logMAR (p = 0.0087), and +0.11 logMAR, respectively, at 1 month postoperatively.

Similarly, mean binocular uncorrected visual acuities at near (40 cm), intermediate (60 cm), and distance (4 m) improved from +0.6 logMAR, +0.47 logMAR, and +0.19 logMAR, respectively, preoperatively, to +0.14 logMAR, +0.08 logMAR, and -0.04 logMAR, respectively,



(FIGURE 2) Microporations in four oblique quadrants over the five critical anatomical zones of physiological and biomechanical importance.
(Images courtesy of AnnMarie Hipsley, DPT, PhD)

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LASER SCLERAL

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at 1 month postoperatively. No patients experienced complications that decreased best-corrected visual acuity or quality of vision, he said.

"It's topical anesthesia, and they barely feel anything because you're only doing a very tiny microporation," Dr. Shah said. "They don't have any problem at all, and very little discomfort afterward either."

Some evidence suggests decreasing ocular rigidity may affect the development of glaucoma and age-related macular degeneration as well as presbyopia. With the loss of elasticity, the sclera puts compression and loading stresses on underlying structures, and can affect blood flow through the sclera and optic nerve, according to Dr. Hipsley.

An earlier iteration of the procedure (LaserACE) has shown a statistically significant reduction in IOP from a mean of 13.56 mm Hg at baseline to 11.74 mm Hg after 2 years, she said.

Investigations of the effects of laser scleral microporation on intraocular pressure are ongoing.

The improvements appear long-lasting. In a study on macaque monkeys, the researchers found cellular infiltration at the margin of the micropores at 1 month, Dr. Hipsley noted.

The inflammatory response subsided after that. The researchers noted coagulative necrosis at the margins of the micropores.

"Overtime, the inflammatory response receded leaving clear histological evidence, however, that the healed micropore was not as dense as the surrounding untreated sclera," Dr. Hipsley said.

Researchers also reported that scleral fibroblasts migrated and proliferated into the mircopores. Collagen treatment reduced this response in the early period after the procedure.

So far, these changes do not appear to cause a reversal of the effects of the microporation. The researchers are still collecting longer-term data with this version of the procedure. But they have followed for over 10 years patients who underwent a preceding similar scleral procedure, LaserACE.

These patients have continued to enjoy reduced presbyopia, Dr. Shah said.

"The 10-year data we've got shows it doesn't come back," he said. "There is some progression with age as would be expected, but you don't get a complete loss of effect. We need longer-term data with the new system."

The newer system—laser scleral microporation—is faster and easier because it treats four quadrants in 14 seconds each, employing a scanning technology. LaserACE was performed with a fiberoptic handheld probe and performed only 1 spot at a time.

An advantage to laser scleral microporation compared with other presbyopia treatments is that the visual axis remains untouched. This means patients can benefit from future corneal or cataract procedures, such as receiving enhancements to LASIK or accommodative IOLs, the researchers noted. ■

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This article was adapted from Dr. Shah's presentation at the 2018 meeting of the American Society of Cataract and Refractive Surgery. He is a consultant to AceVision.

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OCULAR SURFACE

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while reducing markers of inflammation and ocular surface disease index score by 12 weeks.[1]

At least two mechanisms have been proposed—the breakdown of omega-3 fatty acids results in anti-inflammatory molecules and/or the use of omega-3 fatty acids alters the composition of meibomian gland secretions such that they no longer induce blockade of the glands.[1] Either mechanism (or both) increases meibomian gland secretions that reduces tear film evaporation.[2] Getting neutraceuticals on board prior to surgery maximizes the potential for the tear film to respond to the surgical insult and heal properly.

Additional measures may be added as needed. We typically start with artificial tears and oral neutraceuticals, with discretionary use of cyclosporine or a similar topical therapy based on severity. If MGD is suspected, we offer a certain treatment (LipiFlow, TearScience).

Some colleagues may contend that each option adds expense in the form of co-payments or out-of-pocket expenditures that might make patients hesitant to move forward. It has been our experience, however, that patients appreciate knowing how they can maximize outcomes and improve healing, with the ancillary benefit of tacitly letting them know we will take steps to ensure they are happy with results.

CONCLUSION

Optimizing the ocular surface prior to refractive surgery is not intended to be a panacea. Whether a patient is set to undergo PRK, LASIK, or even newer options like SMILE, the procedure will disrupt the corneal nerve plexus. Transient dryness is almost an inevitability, and if it is not mentioned prior to surgery, it becomes more problematic.

At the same time, with safe/effective treatments at surgeons' disposal, both cost and convenience become the most relevant barriers to taking action. These can be overcome through proper education about what clinicians are recommending and the science behind the options.

Technology in modern refractive surgery is better then ever, and likewise, results are more predictable and accurate than ever. As surgeons look to further refine outcomes and ensure patient happiness, the subtle change to being more proactive about managing the ocular surface perioperatively represents an important step in achieving the goals that patients want. ■

References

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