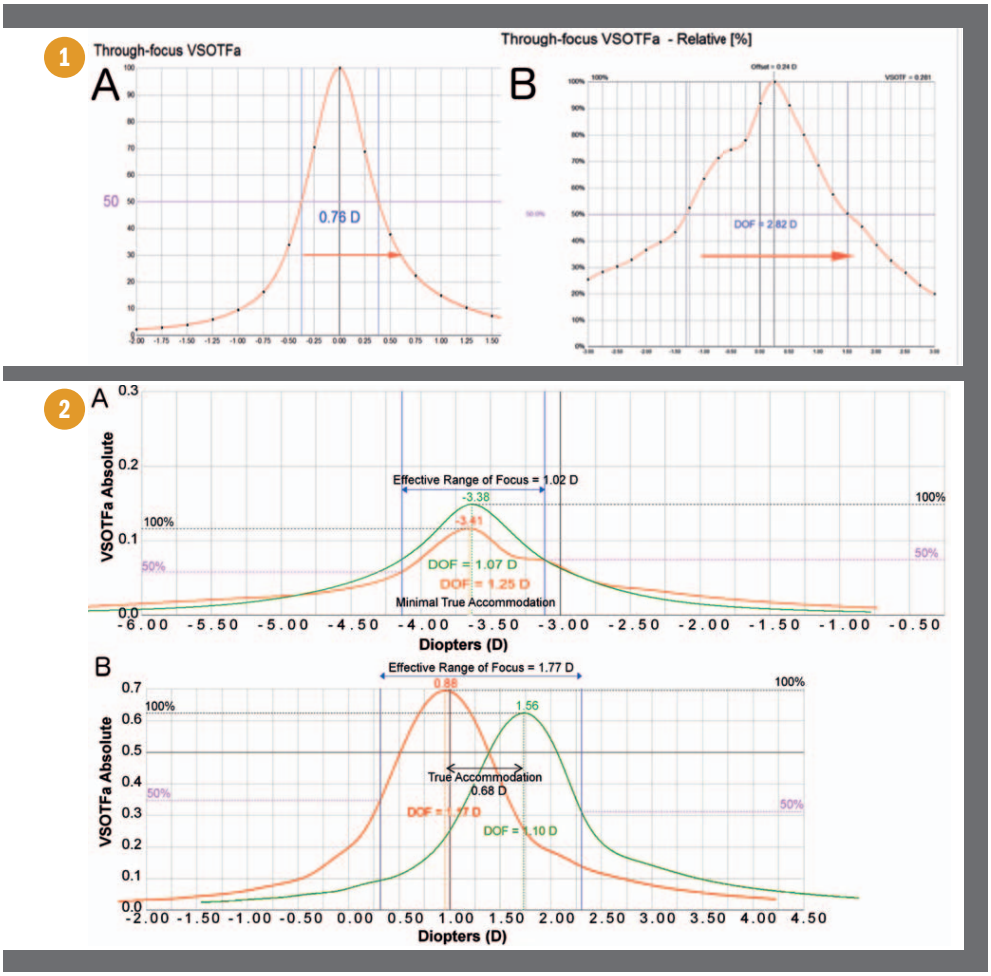


1 Representative figure of the depth of focus (DoF) for a patient eye with A) normal depth of focus and B) extended depth of focus after LaserACE.

2 Representative figure of the effective range of focus (EROF) for a patient eye A) preoperatively and B) 10 years postoperatively after LaserACE. Reprinted with permission from Hipsley A, Hall B, Rocha KM. Scleral surgery for the treatment of presbyopia: Where are we today? *Eye Vis*. 2018;5:4.

(Figures courtesy of AnnMarie Hipsley, DPT, PhD)

TRUE ACCOMMODATION ABILITY PERSISTS OVER LONG TERM

Patients maintain improvement at 10-year follow-up

By Cheryl Guttman Krader; *Reviewed by Karolinne Maia Rocha, MD, PhD*

Patients who undergo laser anterior ciliary excision (LaserACE) maintain long-term improvement in effective visual range of focus that is explained by increases in both true and pseudoaccommodative ability, according to Karolinne M. Rocha, MD, PhD, director, Cornea and Refractive Surgery, Storm Eye Institute, Medical University of South Carolina, Charleston.

Dr. Rocha and colleagues used a ray-tracing aberrometer (iTrace, Tracey Technologies) to obtain an objective evaluation of accommodation in six eyes of three patients who had undergone the LaserACE procedure bilaterally 10 years earlier.

All patients had also been treated with transepithelial PRK using topography-guided, no-touch excimer laser technology (Schwind) to correct hyperopic regression following previous laser vision surgery. Patients ranged in age from 58 to 62 years at the time of the 10-year follow-up.

RAY-TRACING MEASUREMENT

Ray-tracing measurements were obtained at distance and 40 cm. The aberrometer is capable of creating corneal and lenticular maps as well as a difference map, which can demonstrate independent image quality metrics (IQM) for the cornea and lens.

Subjective depth of focus (DoF) was overlaid on the visual Strehl of the optical transfer function (VSOTF) through-focus curve to establish the best IQM threshold value for correlation between subjective and objective DoF.

Effective range of focus (EROF) was determined by measuring the difference in diopters between the near and distance through-focus curves, at 50% of VSOTF. The EROF is the range of focus with acceptable blur, and will be a combination of both the true accommodation and the pseudoaccommodation.

The data showed that mean DoF increased from 0.65 D prior to LaserACE to 1.49 D at 10 years post-treatment. At 10 years post-LaserACE, mean EROF was 1.56 D.

"True accommodation is determined using ray-tracing aberrometry by measuring the spherical equivalent of the difference between distance and near refractions," Dr. Rocha said.

"In two separate control groups, we showed that young subjects have a true accommodative ability of approximately 2.65 D whereas untreated presbyopes have little to no true accommodation," she added.

Continues on page 32 : ***Accommodation***

Scleral implants help improve near VA

In a subsample study, patients had positive results at 24 months

By Vanessa Caceres; *Reviewed by Frank Bucci, MD*

THE USE OF SCLERAL IMPLANTS helped lead to a clinically significant improvement in near visual acuity (VA) in a single-site, subsample study, said Frank Bucci, MD.

The study focused on an investigational implant system (VisAbility Micro-Insert System, Refocus Group), which uses a docking station that "locks" with a four-point fixation. The scleratome docks into position, and two-piece interlocking micro-inserts are inserted.

Some benefits of the presbyopia treatment include continuously good vision without the use of monovision or a multifocal solution, said Dr. Bucci, of Bucci Laser Vision Institute, Wilkes Barre, PA.

Near vision for patients continues to improve over time, but the inserts are removable if needed.

Targeted for use in presbyopic patients, the micro-insert system is designed to lift the sclera and the underlying ciliary muscles. This increases the space between the crystalline lens and the ciliary muscle, and it tightens the zonules that hold the lens in place, according to the company's website.

The tension on the zonules helps the ciliary muscles to change the shape of the lens and to help restore accommodation and improve uncorrected near vision.

In the main FDA clinical trial with the implant system, 360 subjects at 13 separate sites were included. All were between 45 and 60 years old and had distance-corrected near visual acuity (DCNVA) and uncorrected near visual acuity (UCNVA) of 20/50 to 20/80 and were followed for 24 months.

The trial's primary endpoint was DCNVA of 20/40 Snellen equivalent or better at 40 cm and at least 10 letters of improvement in DCNVA in the primary eye.

For the subsample study reported on by Dr. Bucci, a total of 20 eyes from a single site were chosen. The mean manifest refraction spherical equivalent was +0.22 D (range, –0.5 D to +0.5 D). There was a mean baseline DCNVA of 20/60.6 and a binocular mean of 20/48.6.

Compared with baseline, the mean improvement in letters read was +18.8, +20.2, +20.3, and +22.3 letters for DCNVA at 6, 12, 18, and 24 months, respectively, Dr. Bucci said.

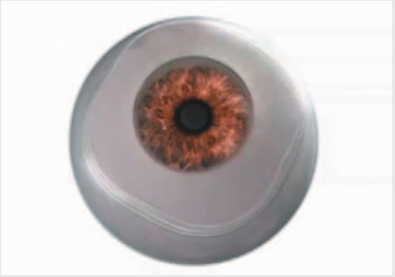
Researchers found an even stronger improvement in mean UCNVA letters read: +21.2, +22.2, +22.7, and +24.0 letters, also at 6, 12, 18, and 24 months, respectively.

An uncorrected distance visual acuity of at least 20/20 was maintained in each eye, and 75% of subjects had improved at least one line of acuity during all follow-ups. No serious ocular adverse events occurred.

"The results of this subsample evaluation of patients at a single center suggest that the [micro-inserts] may provide clinically significant improvement in near visual acuity, both with and without distance correction," Dr. Bucci said. ■

take-home

- **In a subsample study, scleral implants that targeted better near visual acuity had successful results at 24 months.**



Micro-Insert Procedure

STEP 1: Place the docking station
STEP 2: Create the scleral tunnel
STEP 3: Place the micro-insert using shuttle/tubing
STEP 4: Lock the micro-inserts in place

(Photo courtesy of Refocus Group)

FRANK BUCCI, MD
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The VisAbility Micro-Insert System is not yet approved in the United States; it holds a CE mark and is available in the European Union. This article was adapted from Dr. Bucci's presentation at the 2018 meeting of the American Society of Cataract and Refractive Surgery. Dr. Bucci is a consultant with the Refocus Group and is a clinical investigator with the VisAbility Trial.

ACCOMMODATION

(Continued from page 31)

The ray-tracing technology was also used to measure changes in higher-order aberrations (HOAs) with shift from focus from distance to near. The data analysis showed a mean change in total HOAs of 0.6 µm.

"As expected, this change was due to a shift toward negative spherical aberration with accommodation, and there were no significant changes in other higher-order aberrations," Dr. Rocha said.

LaserACE surgery aims to improve natural dynamic accommodative forces. It is performed using a 2.94-um Er:YAG laser (VisioLite, Ace Vision Group) to create an array of micropores in four oblique quadrants in the sclera over the ciliary muscle in three physiologically critical zones.

DIVING DEEPER

"We are still trying to understand the complete mechanism of action of LaserACE as a treatment for presbyopia, but we do know that it results in reduction in ocular rigidity and a change in the biomechanics of the accommodative system," Dr. Rocha said.

"Because the procedure is not done on the visual axis, the patients in this study were able to undergo laser correction for their hyperopic regression," she added. ■

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LaserACE is not yet FDA approved or available in the United States. It is currently in clinical trials only in select areas outside of the United States. This article was adapted from Dr. Rocha's presentation at the 2018 meeting of the American Society of Cataract and Refractive Surgery. Dr. Rocha is a consultant to Ace Vision Group.