

Interim study results

## Better results seen with femtosecond laser channel creation

### Best-corrected visual acuity greatly enhanced for patients with prescription inserts

By Cheryl Guttman

Reviewed by Yaron S. Rabinowitz, MD

**Editor's Note:** On Jan. 4, the FDA granted Addition Technology Inc. the use of the term "corneal implants" to describe its prescription inserts (Intacs). The recognition positions the product as a therapeutic device, the company said in a prepared statement. Yaron S. Rabinowitz, MD, delivered this presentation prior to the FDA's designation.

Chicago—Implantation of microthin prescription inserts (Intacs, Addition Technology) for the treatment of keratoconus appears to result in better visual outcomes when the femtosecond laser (IntraLase FS, IntraLase) is used for channel creation instead of a mechanical device, said Yaron S. Rabinowitz, MD. He spoke during the refractive surgery subspecialty day meeting sponsored by the International Society of Refractive Surgery of the American Academy of Ophthalmology.



Dr. Rabinowitz

Dr. Rabinowitz compared results from 6 months of follow-up in a group of 20 eyes that underwent surgery using the femtosecond laser for channel creation with 1-year data

from a series of 10 eyes that had the channels created with a mechanical spreader. All of the patients undergoing the surgery were contact lens-intolerant.

The analyses showed a slightly greater flattening effect in the mechanical spreader group, whereas differences in improvements in spherical equivalent (SE), uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), and proportions of eyes achieving contact lens or spectacle tolerance were in favor of the femtosecond laser.

"Certainty of depth of placement is a big advantage of the femtosecond laser, and it is also very friendly to surgeons and patients alike. Further follow-up is needed to deter-

mine how the 12-month outcomes of the femtosecond laser procedure compare with the mechanical technique," said Dr. Rabinowitz, director of ophthalmology research, Cedars Sinai Medical Center, Los Angeles.

He began using the femtosecond laser to create the channels for the microthin prescription inserts in January 2004. The results from the comparative study showed the average reduction in K readings was 2.51 D for the mechanical spreader group and 2.37 D for the femtosecond laser eyes. However, mean SE improved by 3.27 D in the femtosecond laser group versus only 2.57 D in the mechanical device group. In addition, UCVA improved slightly more in the femtosecond laser group compared with the mechanical device group, 3.72 versus 3.6 lines.

#### Dramatic effect on BCVA

The most dramatic difference was in BCVA, which improved by 3.54 lines in eyes with femtosecond laser-created channels versus by 1.75 lines in the mechanical device group. In addition, 17 (85%) of the patients were contact lens or glasses tolerant in the femtosecond laser group versus 14 (70%) in the mechanical group. One patient in the laser group had the inserts removed because of an infection.

Similar results were achieved favoring the femtosecond laser in SE, UCVA, and BCVA outcomes when they were compared with outcomes for a combined series of eyes that underwent channel creation with a mechanical spreader. That pooled analysis was composed of patients of Dr. Rabinowitz plus eyes operated on by Joseph Colin, MD, and Charalambos Siganos, MD. Mean increase in BCVA for the mechanical spreader group in the pooled analysis was 2.03 lines.

#### Treatment plan

Dr. Rabinowitz noted he began using the microthin prescription inserts to treat eyes with keratoconus after Dr. Colin published his 1-year results for 10 eyes in *Ophthalmology* in 2001. He stated that patients who undergo this procedure have a little more advanced

disease, but those with mild to moderate keratoconus still do best, and patients with central scarring and central K readings in excess of 57 D should be excluded.

"Our primary goal is to take a patient from contact lens intolerance to tolerance and so prevent the need for corneal transplantation. There are secondary goals, which are to allow transition from rigid to soft toric lenses or to allow for improved acuity with spectacles only," he explained.

Patients who are offered this procedure must be counseled carefully about the potential outcomes so that they have realistic expectations.

"They need to understand that they will still be dependent on visual aids, there is no evidence this procedure retards keratoconus progression, and that they may not achieve any benefit at all. In general, our patients, however, have been very happy with the vision they achieve with glasses or contact lenses and most are contact lens tolerant," he said.

When using the femtosecond laser, the center of the pupil is marked and the cut is centered around that point. The entry site is determined by the topography with a goal to insert the microthin prescription inserts to bisect the thinnest area of the cornea. Segment thickness is chosen according to the SE and desired effect, and the entry wounds are sutured with 10-0 nylon.

The entry cut is made temporally to a depth of 400  $\mu$ m (maximum possible for the laser) and measuring 1.4 mm long and 1.0 mm wide. The laser is set to create a 0.4-mm channel that is 0.05 mm wider than the insert itself.  $\odot$ T

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