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Micro-thin prescription inserts an option for keratoconus

By Julia Talsma

Simple procedure helps reduce higher-order aberrations, allowing patients to see better

Editor's Note: Addition Technology Inc., the manufacturer of Intacs micro-thin prescription inserts for surgical vision correction, announced Aug. 4 that it had received approval from the FDA for a Humanitarian Device Exemption to market the inserts for the treatment of keratoconus. Dr. Rabinowitz's presentation was given earlier this year at the American Society of Cataract and Refractive Surgery meeting.

San Diego—Micro-thin prescription inserts (Intacs, Addition Technology Inc.) can be successfully used to treat patients with keratoconus employing the IntraLase femtosecond laser (IntraLase Corp.), reported Yaron S. Rabinowitz, MD, during the American Society of Cataract and Refractive Surgery annual meeting.

In a small comparative study of this off-label use of the micro-thin prescription inserts, patients who received the inserts after IntraLase creation of the channels had refractive outcomes similar to patients who received the inserts with mechanically made channels, according to Dr. Rabinowitz, director of ophthalmology research, Cedars-Sinai Medical Center, Los Angeles, and clinical professor of ophthalmology, University of California-Los Angeles School of Medicine.

Dr. Rabinowitz completed 12 cases with the channels created mechanically and then another 12 after obtaining the IntraLase laser. He found postoperative uncorrected visual acuity (UCVA) to be similar in each group, achieving a mean improvement of three lines. Best-corrected visual acuity (BCVA) postoperatively was slightly better in the IntraLase group, which achieved a mean improvement of 3.4 lines. The group with mechanically created channels had a mean improvement of only 2.4 lines of BCVA, he noted.

Improvement in sphere postoperatively was slightly better in the group with mechanically created channels than the IntraLase group, with a mean change of 3 D in sphere versus a mean change of 2.17 D in sphere, respectively. The same was true for astigmatism postoperatively, with a mean change of 1.43 D in the mechanical group versus a mean change of 1.22 D in the IntraLase group, Dr. Rabinowitz said.

"The primary goal is to make the patients who are contact lens-intolerant, contact lens-tolerant and to prevent the need for a corneal transplant," Dr. Rabinowitz said.

"In terms of contact lens tolerance, 90% of my patients who underwent IntraLase treatment (to create the channels for the prescription inserts) were contact lens or glasses-tolerant versus 75% of the chanical group," he said.
Other advantages of the IntraLase laser for creation of the channels were fewer epithelial defects, less pain, and quicker visual recovery. It is also possible to guarantee the depth of placement of the prescription inserts with no perforations or erosions. Also, the procedure can be completed more quickly, in about 3 minutes with the laser-cut channels versus 20 minutes with the mechanical method.

"It only takes about 12 seconds to make the circumferential channel (with the laser) and 6 seconds to make the vertical cut," he explained. "We then take patients off the table and put them under the microscope to put in the prescription inserts.

"In addition, patients are more likely to accept the laser versus the blade," Dr. Rabinowitz said. "There is also a lot of potential for intralamellar astigmatic manipulation."

The femtosecond procedure The IntraLase femtosecond laser is set at a 400-μm depth, which is as deep as possible. The entry cut is 1.4 mm long and 1 mm wide. Dr. Rabinowitz makes the cut for the channels either at the temporal or steep axis. He doesn't use sutures.

"The nomogram does require a lot of refinement," Dr. Rabinowitz noted. "The tighter you make the channels, the more effect is produced. The manufacturer recommends 6.6 × 8.8 mm (1-mm width) channels. I recommend starting with 6.6 × 7.6 mm (0.5-mm width) channels and slowly reduce it until you are comfortable with 6.6 × 7.4 mm (0.4-mm width) channels."

He noted that in his first case, using the manufacturer's nomogram for channel size, the patient had almost no change in BCVA. In another case which he employed a narrower channel, the patient's BCVA improved by six lines.

"In one patient I achieved an 8-D effect. It did, however, take me about 30 minutes to get the ring in, so it is a lot of work. But there is a lot of potential for achieving a great effect," Dr. Rabinowitz noted.

For patients with oval cones, Dr. Rabinowitz uses an asymmetric approach, with a 0.3-mm insert superiorly and a 0.35-mm insert inferiorly. For patients with nipple cones, he plans a symmetric technique with a 0.35-mm insert superiorly and inferiorly. These are the options available in the United States, he said.

Two keratoconus cases Dr. Rabinowitz described two cases of mild-to-moderate keratoconus in which the patients were treated with the prescription inserts and IntraLase-created channels. In the first case, a 40-year-old male had best spectacle-corrected visual acuity (BSCVA) of 20/70. One insert was placed in the steepest part of the cone. One day postoperatively, he achieved a BSCVA of 20/20 and had a prescription of +1.50 -1.0 × 160°.

In the second case, a 32-year-old female who was contact lens-intolerant had a visual acuity of 20/70 with a prescription of +1.50 -3.75 × 65°. Dr. Rabinowitz used an asymmetric approach, with a 0.3-mm insert superiorly and a 0.35-mm insert inferiorly. One day postoperatively, the patient could see 20/20 with a +3.50 disposable soft contact lens.

"The reason patients see better is because of the reduction in higher-order aberrations," Dr. Rabinowitz explained. "In the second case, the patient had a higher-order aberration RMS of 2.79 μm preoperatively. Postoperatively, the higher-order aberrations were cut in half (1.39 μm)."

Overall, the inserts with the IntraLase-created channels offer surgeons a quick and simple approach to treating keratoconus in patients who are contact lens-intolerant or who want to improve their BCVA with glasses or contact lenses.

"However, much work is required to refine the nomogram and determine the optimal depth for the incision, its placement, and the width of the channels," Dr. Rabinowitz said.
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Figure 1 Preoperative corneal topography of 40-year-old male with a best spectacle-corrected visual acuity of 20/70.
Figure 2 Postoperative corneal topography after placement of a single micro-thin prescription insert placed in the steepest part of the cone.

Figure 3 At 1 day postoperatively, the patient had a best spectacle-corrected visual acuity of 20/20.
Figure 4 Preoperative corneal topography of a 32-year-old female who was contact lens-intolerant and had a visual acuity of 20/70.

Figure 5 Postoperative corneal topography after placement of a 0.3-mm prescription insert superiorly and a 0.35-mm prescription insert inferiorly.

Figure 6 At 1 day postoperatively, the patient achieved 20/20 with a +3.50 soft disposable contact lens. (Figures courtesy of Yaron S. Rabinowitz, MD)