Will Reversible (Removable) Refractive Surgery Reverse the Way We Do Refractive Surgery?

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IS IT REALLY REVERSIBLE?

In the January/February 2001 issue of the Journal of Refractive Surgery, Asbell and colleagues reported the reversible effect of the intrastromal corneal ring segments (Intacs)\(^1\). They presented compelling evidence to suggest that Intacs can be removed with full reversibility of refractive effect. This is the first corneal refractive surgical procedure to claim reversibility. That claim opens a whole new issue for refractive surgery regarding the reality and importance of reversibility. Glasses and contact lenses are reversible. But can a surgically created change in the shape of the cornea be made unpermanent because the procedure can be reversed? Asbell and colleagues reported a cohort of 34 eyes in which the ring segments were removed and showed that 18 of 21 eyes (86\%) examined at 3 months returned to within ±0.50 D of the original refractive error and regained their original uncorrected and best spectacle-corrected visual acuity. Despite this high percentage of reversibility, not all eyes were fully reversed; Why? Certainly the refractive results of reversibility are quite impressive, but anatomically when the ring segments are placed, adjacent channel deposits and corneal haze can develop, which remain to a lesser degree after the ring segments are removed. Perhaps some of these anatomical changes contribute to the lack of reversibility.

The term "reversibility" may be an overstatement; removability best describes this procedure's feature.

Indeed, a truly reversible refractive surgical procedure is not possible, because once surgery is performed the refractive effect of surgery may be removed, but the surgical event and its anatomical consequences cannot be reversed. Only nonsurgical refractive devices, such as spectacles and contact lenses, can truly be considered reversible.

IS REMOVABILITY IMPORTANT?

In nearly all of the 34 eyes, the reason for ring removal was dissatisfaction of the patient. The overall percentage of removal was nearly 5\% in both phase II and phase III of the US FDA trial and over 2\% of these patients elected ring removal because of visual symptoms of glare and halos. Although these symptoms are not unique to refractive surgery, they emphasize that Intacs can produce visual distortions and optical aberrations. The unique feature of Intacs is that these symptoms can be eliminated by removal of the ring implant, as noted in every case. The reversibility of refractive effect in most eyes is complimented by elimination of the adverse visual symptoms and aberrations, which makes the claim of reversibility with Intacs so important.

Visual symptoms of glare, halos, and other aberrations are often seen after excimer laser refractive surgery with higher corrections and in eyes with a large pupil diameter. This is due to the oblate corneal shape induced by excimer laser ablation for myopia, in contrast to the prolate shape maintained by Intacs. Many of these symptoms are not clinically significant with excimer laser corneal surgery in the low myopia range covered by Intacs. Undercorrection with LASIK can be managed by doing an enhancement procedure. Although an enhancement procedure does not reverse the original surgery, it can improve the correction to the desired outcome and provide an alternative for patients who may be unhappy with their initial surgical outcome. Nevertheless, the unique feature of undoing not
only change in refractive errors but also the symptoms resulting from optical aberrations makes removability an important feature offered by Intacs and not found with laser in situ keratomileusis (LASIK).

WHAT OTHER REFRACTIVE SURGICAL PROCEDURES ARE REMOVABLE?

In a previous issue of the Journal of Refractive Surgery, Menezo described the removal of an iris claw phakic intraocular lens (PIOL) together with an age-related cataract in a patient requiring cataract surgery. This goes right along with the concept of removing an implantable device in order to remove an adverse reaction or vision impairing outcome. The need for explantation may be due to the implantable device or procedure itself or, as in this case, may be unrelated to the refractive surgical procedure, as with age-related cataract. Colin discussed the implications of removing a PIOL in association with cataract surgery and pointed out how PIOL removal may complicate the process. A large incision for IOL explantation, IOL-induced anterior or posterior synechiae, and endothelial decompensation are not reversible.

Intracorneal lens inlays of various types also have the potential for removability. Even implanted living tissue, as with epikeratoplasty, can be removed to support claims of reversibility. Yet again, these are not truly reversible, and in fact, they have not achieved the results required to stand the test of time.

DOES REMOVABILITY MAKE A DIFFERENCE?

Even though Intacs provide removability, does the technology of ring implantation provide enough of a compelling alternative to make Intacs superior to other procedures? At present, LASIK is the dominant refractive surgical procedure worldwide. The percentage of patients receiving 20/20 vision and within ±0.50 D of target is high with LASIK for the correction of low myopia. Although the results with Intacs closely parallel the outcome of LASIK, Intacs corrects only low myopia, which, like PRK and RK, make it suitable for approximately 75% of spherical myopes. Unlike photorefractive keratectomy (PRK) and radial keratotomy (RK), Intacs can only correct myopia without astigmatism. Additionally, Intacs corrections are titratable to only a fixed number of ring thicknesses. At present, only three ring thicknesses are approved by the US FDA. Laser refractive surgery offers greater flexibility and allows a more specific target end point. Although at present enhancement surgery with LASIK is best suited for under- and overcorrection and residual astigmatism, the future may allow for custom laser treatment that will take into account high order optical aberrations and complications such as decentration. This future hope challenges the importance of removability, because the unsatisfied patient may be corrected to their desired refractive outcome or to a better quality of vision by a custom laser enhancement. An accurate enhancement could perhaps be as good as or even better than implant removability—assuming there is enough residual corneal stroma for further laser ablation.

WILL REMOVABILITY CHANGE THE WAY WE DO REFRACTIVE SURGERY?

LASIK has become big business in refractive surgery. Many patients specifically request LASIK surgery when visiting their ophthalmologist/refractive surgeon. The outstanding results that many of these patients experience fuels the incentive for their friends and colleagues to follow the same course. Yet despite the growing success of LASIK, refractive surgery is still in its infancy, with single digit market penetration, so a new, superior refractive surgical procedure could certainly dominate the field as it continues to grow. Because contact lenses are removable prosthetic devices placed on the surface of the cornea, the concept of Intacs as a potentially removable prosthetic device placed inside the cornea provides an identifiable and attractive alternative for patients. Contact lens wearers who are tired of the maintenance and cleaning of contact lenses can simply have Intacs placed inside the cornea, making them free of maintenance and yet have the option for removal. (Indeed, the trade-name, Intacs, is a derivative of contacts.)

The success of Intacs will not depend on their efficacy, safety, and removability, but on the continued refinement and improvements of their major competitor—laser vision correction—especially if custom laser treatments can improve corneal optics with greater accuracy than Intacs. The ease and time required for implantation and explantation will also play a role in the success of Intacs, as will the long-term support of the procedure on the market.
SHOULD THE LASER REFRACTIVE SURGEON OFFER A REMOVABLE PROCEDURE?

Since removability is an important feature, Intacs may be a perfect complement in the practice of the complete refractive surgeon. The successful laser refractive surgeon should certainly consider offering Intacs as an alternative to their patients. The timing for this entry point, however, depends more on whether the surgeon is a leader or follower, a trend setter or a trend opportunist. Since refractive surgery is an evolving field with tremendous growth potential, a wise surgeon should offer a broad spectrum of alternatives that are safe and effective, keeping the best interests of the patients in mind. Intacs, with its merits as reported in previous articles as well as the reversible (removable) features reported in the article by Asbell1 make it a suitable alternative, the full success of which has yet to be determined.

REFERENCES