IOLs and the Future: Refractive Index Shaping
We recently conducted the first in-vivo study evaluating the Perfect Lens LLC femtosecond laser system for IOL power adjustment, based on RIS, with promising results. Our research found this new technology, which can be applied to any commercially available hydrophobic or hydrophilic acrylic IOL, to be both effective and biocompatible based on two weeks of post-treatment observations.

Using green light (520 nm), the laser operates with energy levels that are below the threshold for ablation or cuts—allowing patients to be treated using topical anesthesia only. In 23 seconds, it changes lens power through a laser-induced chemical reaction in a targeted area of the IOL, producing an increase in hydrophilicity and a decrease in the refractive index. Simultaneous to these changes, the laser builds an RIS lens within the targeted area.

We performed IOL laser power adjustment two weeks after implantation in one eye. Our measurements showed the change in refractive power was consistent and produced a remarkable degree of accuracy, within 0.1 diopter of the target.

A slit-lamp examination showed that small gas bubbles formed behind the lens, but these disappeared within a few hours. We also observed no postoperative inflammation or toxicity in the treated eyes, and postoperative outcomes as well as histopathological exams were similar to the non-treated eyes.

**Nick Mamalis, MD, and Liliana Werner, MD, PhD, co-directors of the Intermountain Ocular Research Center**

Imagine being able to precisely adjust the power of your patient’s intraocular lens (IOL) multiple times after implantation, using only a laser that produces no ablation or cuts.

New research from the Intermountain Ocular Research Center at the John A. Moran Eye Center suggests the concept, known as refractive index shaping (RIS), could soon become a reality that makes explantation surgery a thing of the past.
This technology could be used to adjust IOL dioptic power in response to surgical errors, IOL tilt, IOL decentration, or a change in the physical characteristics of the eye. Another remarkable benefit: the same IOL can be adjusted multiple times, with each adjustment only changing a very thin layer within the IOL optic substance. Premium functions can be added to the lens as well, and later removed, if necessary. A multifocal pattern, for example, could be canceled by applying a pattern with opposite characteristics.

What’s the next step in testing? While we found no evidence of glistenings (multiple microvacuoles) or inflammation in our research, we will conduct a second, six-month biocompatibility study specifically looking for any sign of glistenings or long-term inflammation before potential clinical trials.

STUDY: “Biocompatibility of Intraocular Lens Power Adjustment Using a Femtosecond Laser,” Journal of Cataract and Refractive Surgery, August 2017. Liliana Werner, MD, PhD; Jason Ludlow, MD; Jason Nguyen, MD; Joah Aliancy, MD; Larry Ha, BS; Bryan Masino, BS; Sean Enright, BS; Ray K. Alley, BS; Ruth Sahler, MSc; Nick Mamalis, MD.
IOL Dislocation—To Refix or Explant?

Lens dislocation is a rare but serious complication. Moran cataract and glaucoma specialist, Alan S. Crandall, MD, is one of the few physicians in the country to perform adult lens dislocation and explantation surgery and the only physician performing pediatric lens dislocation surgery in the Mountain West.

The question for Crandall is always whether to try to work with the existing IOL or to explant and exchange it.

Case Presentation  Alan S. Crandall, MD

I had a 74-year-old man who presented with double and decreasing vision in his left eye. He had cataract surgery approximately 15 years previously and no history of trauma. His uncorrected visual acuity was 20/200, the posterior capsule was open, the pupil didn’t dilate well, but his retina was normal. The slit-lamp exam revealed a displaced three-piece IOL with a dense Soemmering ring. With this presentation, the patient most likely had pseudoexfoliation syndrome.

I came to surgery prepared with several options ready to go because I prefer to make the decision to refix or to explant and exchange the IOL during the actual surgery, based on a number of factors:

1. If the lens is structurally fine with no scratches or defects from a laser, then I try to use that IOL and fixate it to the sclera.
2. If a capsular tension ring (CTR) is in place, I use a lasso technique that uses a 9–0 Prolene suture. This approach saves time, is relatively easy to perform, and minimally invasive. It can also be done without a CTR, which was the situation in this case.
3. There are several other techniques to use the existing lens if the bag appears too weak for suturing. One is to remove the bag and the Soemmering ring, which often is not easy and may require manual extraction. Next, the lens can be iris fixated, glued to the sclera, or addressed with the Yamane IOL fixation technique—no glue, no flaps—which is what I now use.
4. If I need to explant the lens, I try to cut the implant to pass through a small incision, then fixate a micro incision lens to the sclera with a suture. One could also consider a standard anterior chamber lens if no glaucoma exists.

Whatever the case presents, I can’t emphasize enough that it is critical to plan carefully and have the necessary tools available to ensure an excellent outcome.

Alan S. Crandall, MD, is Senior Vice Chair of the Department of Ophthalmology and Visual Sciences, Director of Moran’s Glaucoma and Cataract Division, Senior Medical Director of Moran’s Global Outreach Division, and the John E. and Marva M. Warnock Presidential Endowed Chair in Global Ophthalmology.
The Moran Eye Center is one of a few centers in the country where children can receive prosthetic lens surgery.

Specialists Alan S. Crandall, MD; Leah Owen, MD, PhD; Marielle Young, MD; and Julia Byrd, MD, recently performed a study in which they analyzed a technique to attach a prosthetic lens to the eye wall in children.

Leah Owen, MD, PhD

There is no consensus regarding how to surgically manage ectopia lentis (a dislocated natural lens) in children. As a result, these children often are unable to have a prosthetic lens implant and are legally blind without very strong glasses. In adults, the prosthetic lens is safely attached to the eye wall. However, a child’s eye is still growing, and the eye tissue is different than an adult’s eye. The safety, effectiveness, and long-term stability of this technique in children is not clear.

Our group conducted a retrospective analysis of ectopia lentis pediatric patients, average age 6.9 years, who had surgery to attach a prosthetic lens to the eye wall.

We looked at the safety and stability of this surgical technique in children with all conditions causing spontaneous (not traumatic) dislocation of the natural lens. This included children with Marfan’s syndrome, which was the majority of our study population, as well as more rare conditions like homocystinuria, spherophakia, and connective tissue disorders.

Our analysis showed that up to 10 years after surgery was performed, children had significantly improved vision and a very low rate of complications or lens detachment from the eye wall.

To date, this research analyzed the greatest number of eyes and has the longest follow-up of any study. Our hope is that this work will continue to innovate and improve vision for children suffering with ectopia lentis.

RIS—What It Might Mean for Pediatric Lens Implants

When children require IOL implant surgery, we have to “over-power” the lens to allow them to grow into it, but this is not an exact science—we cannot accurately predict how the child’s eye will grow. This can lead to either the need for IOL exchange or extreme myopia. The ability to precisely adjust IOL power as the child’s eye grows would be an exciting, even life-changing development for these patients.
Refractive Index Shaping: The View from a Glaucoma Specialist

The possibility that we may one day, in the case of an unacceptable post-cataract surgery refractive outcome, be able to adjust IOL power with RIS rather than having to explant the IOL is especially exciting to me as a glaucoma specialist.

Here’s why.

Norm Zabriskie, MD

In my experience, the overwhelming majority of patients—I’d say 90 percent—who are unhappy with the result of their cataract surgery have some issue with their IOL. Though it doesn’t happen often, sometimes despite our every effort to select the best IOL power for each case and despite employing the best surgical skills and technologies available, some lenses just don’t deliver the refractive outcome predicted by even the most advanced IOL formulas. Even tenths of a millimeter difference in the effective lens position (ELP) can seriously affect post-operative refraction.

When it comes to the inherently more fragile eyes of my glaucoma patients, I believe there is much more variability in the after-surgery ELP due to a number of factors. Some patients have glaucoma due to trauma, some due to previous surgery, and some have exfoliation syndrome. Any of these conditions can predispose to zonular instability and variable post-operative ELP. Also, the whole population of patients in the narrow-angle and closed-angle classifications, with their shallow anterior chambers, represent a particularly difficult group to accurately predict ELP and thus post-operative refraction. In my experience, the more shallow they are the more difficult to predict the refractive outcome. RIS would be amazingly helpful in this group.

Another potential application in glaucoma patients would be in pseudophakic patients who experience a refractive change due to glaucoma surgery. Again, though not frequent, common glaucoma procedures such as trabeculectomy and tube-shunt surgery can induce post-operative refractive changes. This can be particularly disappointing to both patient and surgeon—to end up with a well-functioning glaucoma procedure but with an adverse visual outcome due to a refractive change.

For a glaucoma surgeon to know that RIS could restore that patient to their baseline refractive state would be fantastic.

Norm Zabriskie, MD, is Moran Eye Center Medical Director and Vice Chairman of Clinical Operations
Notable Surgical Outcomes at Moran

Recent surgical outcomes from calendar year 2016 reflect Moran’s dedication to providing exceptional care while fulfilling its teaching role as part of an academic medical center. Rates below include cases performed with fellows and/or by residents and fellows.

Endophthalmitis
Expressed as a percentage of 6,275 intravitreal injections and 5,674 surgeries.

- Endophthalmitis, 0.06%
- Injection induced 0.02%
- Surgically induced 0.04%
- 99.94% Endophthalmitis free

Complications
Expressed as a percentage of 3,882 cataract extraction procedures.

- Complications, 1.72%
- 98.28% Complications free
- 0.71% — Capsule tear with vitreous loss
- 0.15% — Capsule tear with no vitreous loss
- 0.00% — Endophthalmitis
- 0.86% — Other
Moran Eye Center CEO Randall J Olson, MD, shares his perspective on RIS.

**How could RIS affect patients?**

I see RIS as a real game changer. In cataract patients, it could produce amazingly precise uncorrected vision since lens power would be adjusted after surgery when everything is healed, fixed, and in position. I would imagine that after surgery, a patient might sample a series of glasses allowing them to get a feel for the different types of RIS they can then choose from. And, if a patient isn't happy with what they select, they can have the lens power changed without the additional risks of explantation surgery. RIS might also reduce costs for patients since a common lens can be turned into a premium lens and vice versa.

**What could RIS mean for industry?**

RIS would be an industry disruptor...as significant as the initial development of IOLs themselves.

**Could RIS replace LASIK someday?**

For younger people, the advantage of LASIK is the ability to focus. But once someone is in their 40s, RIS will clearly have great potential with greater precision, and I expect it will predominate.

Randall J Olson, MD, is Professor and Chair of the Department of Ophthalmology and Visual Sciences and CEO of the John A. Moran Eye Center, University of Utah. Olson is a paid consultant for RIS technology owner Perfect Lens, LLC, and is a member of its medical advisory board.