Will the femtosecond laser revolutionize corneal surgery?

On a quest to improve precision and success of corneal surgery

Roger Steinert, MD[a] and Melvin Sarayba, MD[b]

[a] University of California, USA

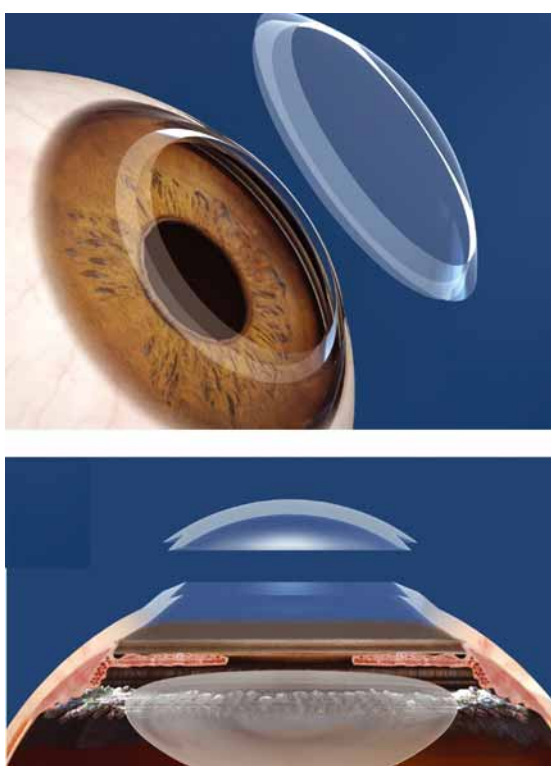
[b] IntraLase Corp., USA

It seems many technologies are developed for one application but then become effectively applied for another. With laser technology there is an old witticism that "the laser is a solution looking for a problem!" This has proven to be the case with the femtosecond laser. First conceived for cutting vitreous membranes, then developed as a very successful tool for flap creation in LASIK, the femtosecond laser is now proving to be the single biggest innovation in corneal surgery in more than 30 years.

Corneal surgery has largely remained unchanged since the early 1970s when operating microscopes and 10-0 nylon sutures were introduced. Since that time, we've learned more about managing the induced astigmatism of penetrating keratoplasty (PKP) with corneal topography to guide us in suture manipulation, but the surgical techniques haven't changed much. In an era of outpatient microsurgery with less invasive procedures and faster rehabilitation in cataract, vitreoretinal, and glaucoma surgery, PKP still has slow recovery of vision with high amounts of regular and irregular astigmatism.

Certainly there have been attempts to move the techniques forward. Barraquer first described a shaped PKP in the 1950s to make corneal transplants more effective. The idea was abandoned, however, because the technique was cumbersome. In 2003, Busin resurrected the idea of a "Top Hat" shaped corneal graft using more modern surgical trephines. His studies found that using this configuration meant quicker wound healing, less wound leakage and less induced astigmatism. Still, the technique was technically challenging to perform manually and failed to garner many advocates.

Today, it's a different story. We have the first opportunity in years to move corneal transplantation forward. By harnessing the precision and flexibility of the femtosecond laser, we are able to create an almost infinite variety of cuts that can enable us to improve the precision and success of corneal surgery. These innovations will allow corneal surgeons to speed recovery, make a secure incision and provide a better quality of vision to our patients.



- Hermatic wound seal
- Angled edge provides smooth transition between host and donor

***Figure 1:** IntraLase laser.*

Evolution of the femtosecond laser

In the spring of 2004, we started working in the laboratory here at the University of California, Irvine, USA to determine if it was feasible to use the IntraLase FS femtosecond laser in corneal surgery. Part of this involved looking at different cut patterns that could be used to fashion the donor cornea. This work resulted in the development of hardware and software changes to the femtosecond laser to make these cuts and the creation of IntraLase-enabled keratoplasty.

Following FDA clearance in September 2005, Frank Price, MD, in Indianapolis, performed the first human surgery in November of the same year using the "Top Hat" configuration. Shortly after this, William Culbertson, MD and other corneal surgeons at Bascom Palmer Eye Institute began working with this modified laser, treating a variety of corneal diseases. Early in 2006, the clinical investigation expanded to Europe where it was first evaluated by Lucio Buratto, MD (Italy), Rudy Nuijts, MD (The Netherlands) and Professor Thomas Neuhann (Germany). To date more than 100 procedures have been performed globally with a

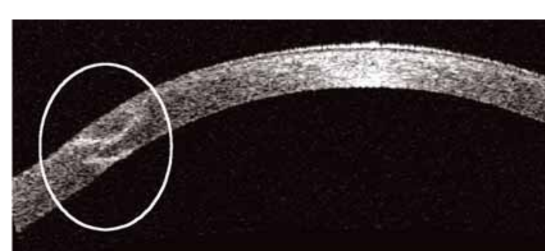


***Figure 2:** The ZigZag shaped incision creates a smooth corneal contour immediately after surgery with less distortion of the corneal optics and less astigmatism. (Image courtesy of Roger F. Steinert, MD)*

variety of shaped incisions all created by the IntraLase FS laser. Meanwhile, work also continued here in Irvine to identify the most optimally shaped incisions for corneal procedures. Currently, we are working with what we call a "ZigZag" pattern (**Figure 1**), which is showing great promise in terms of corneal biomechanics, wound stability and healing and, in the early months, good visual results (**Figure 2**).

Overall, our collective experience has demonstrated an improved connection between the donor and recipient tissue, less induced astigmatism and less need to adjust or cut sutures during the healing process.

A remote-controlled scalpel

The femtosecond laser has the potential to be the ultimate corneal incision device — the possibilities are nearly limitless. Since it is controlled by software, a variety of incisions may be easily programmed. Using the laser also offers important advantages over manual techniques in terms of precision. The laser "scalpel" enables the surgeon to perfectly match the donor and host tissue, again, in a variety of shapes.

The ultimate goal of our current work is to create a corneal incision that is stable, predictable and secure much earlier following transplantation so that the patient may have a faster return to functional vision. The fundamentals of surgical healing and biomechanics dictate that a larger surface area for the incision heals stronger, which is why we think a zigzag incision offers the most promise.

Demoting sutures

While we are not yet talking about a sutureless corneal transplant, the use of the femtosecond laser to create incision patterns that fit together exceptionally well could lead, eventually, to fewer sutures being required, or maybe even a combination of sutures and tissue glue. We are hopeful that our work will stimulate interest in developing better surgical glues that help facilitate wound healing, but also withstand the intraocular pressure. Currently we are unaware of any products that could provide this level of performance. As a first step, we are examining the merits of more shallow sutures, looser sutures and finer sutures, all with the goal of reducing the distortion that detracts from recovery of vision. The high degree of integrity of the zigzag incision allows these variations to be performed safely.

Corneal surgery and postoperative management will always be challenging. However, we believe this technology will encourage surgeons who have abandoned corneal surgery to reconsider. Perhaps this technology will provide the foundation for innovative therapies that could never be realized with the standard, manually created surgical approach. Our next major step is to determine how the femtosecond laser may enable us to incise the host cornea in a laser centre (rather than an operating room) while the donor tissue is prepared with another femtosecond laser at an eye bank. The patient would then report to the operating room for completion of the surgery. This approach would certainly allow more corneal surgeons and their patients to benefit from the large installed base of IntraLase femtosecond lasers globally.

We all want to help our patients see better, faster. Early results with this technology indicate we are moving in the right direction.

The femtosecond laser has the potential to be the ultimate corneal incision device — the possibilities are nearly limitless

IntraLase-enabled keratoplasty clinical investigators

USA

Frank Price, MD, Indianapolis, IN

William Culbertson, MD, Miami, FL

Sonia Yoo, MD, Miami, FL

Eduardo Alfonso, MD, Miami, FL

Roger Steinert, MD, Irvine, CA

Europe

Lucio Burrato, MD, Milan, Italy

Elisabetta Bohm, MD, Milan, Italy

Rudy Nuijts, MD, Maastricht, The Netherlands

Thomas Neuhann, MD, Munich, Germany

Barbara Lege, MD, Munich, Germany

Markus Bauer, MD, Munich, Germany

Emilio Balestrazzi, MD, Rome, Italy

Ciro Tamburelli, MD, Rome, Italy

L. Mosca, MD, Rome, Italy

Sheraz Daya, MD, London, UK

In short...

The femtosecond laser may have found its natural home in corneal surgery. Because it is controlled by software, almost limitless cut patterns can be created. One such example of this is the promising "ZigZag" pattern, which appears to increase wound stability and healing times while also inducing less astigmatism.

AUTHORS

Roger Steinert, MD (pictured) is Vice Chairman of the Department of Ophthalmology at the University of California, Irvine, USA, where he holds joint appointments as Professor of Ophthalmology and Professor of Biomedical Engineering as well as Director of Corneal, Refractive, and Cataract Surgery. **Melvin Sarayba, MD** is Senior Scientific Product Manager at IntraLase Corp. in Irvine, CA, USA.

Article Reprinted from the ©Jan/Feb 2007 issue of

Ophthalmology Times EUROPE

AN ADVANSTAR PUBLICATION

Article Reprint Number: 0721