Developing Innovations, New Applications in Refractive Laser Surgery

In an interview, Kristian Hohla, PhD, and Mike Riding, two executives of Technolas Perfect Vision, discuss the undertakings of the new joint-venture company.

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— Mike Riding

When Bausch & Lomb (Rochester, New York) and 20/10 Perfect Vision (Heidelberg, Germany) announced the completion of their joint-venture agreement in April, a new refractive surgery company was created—Technolas Perfect Vision (Heidelberg, Germany). The company combines the refractive surgery assets of both businesses and establishes a new ophthalmic business model: a company with global reach focused on laser-based vision correction procedures.

Cataract & Refractive Surgery Today Europe explored the rationale behind the joint venture, the initial undertakings of the company, and its plans for the future in an interview with two principals of the company, Chief Executive Officer Kristian Hohla, PhD, and Chief Commercial Officer Mike Riding. Dr. Hohla was previously Executive President at 20/10 Perfect Vision. He founded Technolas in 1985. Mr. Riding was previously European Vice President, Surgical, at Bausch & Lomb.

Q: What was the impetus behind the formation of the joint venture?

Mike Riding: Bausch & Lomb (B&L) was seeking to expand its interest into femtosecond laser technologies to complement its strong excimer portfolio. At the same time, 20/10 needed a global service and applications infrastructure to support the rollout of its Femtec femtosecond laser and its IntraCOR presbyopia-correction technology; this led to the formation of Technolas Perfect Vision.

Kristian Hohla, PhD: Cooperation and combination is a current trend in this area of technology. Companies are looking for areas of growth. Surgeons want new technologies, not another box, and therefore B&L and 20/10 Perfect Vision decided to combine technologies and move forward with the femtosecond and the excimer laser together.

Mr. Riding: But the coming together of B&L Refractive and 20/10 Perfect Vision was not simply designed to put a flap-cutting femtosecond laser alongside an excimer. Ophthalmology already has that. The coming together was to generate innovations and provide surgeons with new indications.

We are now in a position to leverage our global resources across an increased product portfolio. Our expanded research and development team is able to accelerate development of new laser-based treatments. We will be bringing some exciting new treatments to market quickly. The IntraCOR presbyopia-correcting procedure is only the tip of the iceberg.
All laser companies are now seeking wider applications. You are going to see a radical change in the laser ophthalmic market in the next 5 years.

**FEMTOSECOND TECHNOLOGY AND INTRACOR**

Q: You mentioned that your initial focus will be on techniques for presbyopia correction. Can you talk about how your IntraCOR procedure works?

Mr. Hohla: Previous attempts to perform intrastromal refractive correction involved intrastromal ablation, excavating a lenticle of some type within the stroma. That is not what we are doing with IntraCOR. This procedure relies on redistribution of the internal biomechanical forces in the cornea to create gentle, localized changes in corneal curvature. In IntraCOR, incisions are made within the stroma, perpendicular to the corneal surface, without touching either Bowman’s or Descemet’s membrane. The cut is made in the center of the stroma, perpendicular to the surface of the cornea (Figure 1).

You can imagine that, by staying clear of Bowman’s, you have a greater degree of freedom to design treatments. You can start just below Bowman’s or at the center of the cornea between Descemet’s and the epithelium, so you have control of a variety of parameters. There is no change in corneal thickness because no tissue is taken away from the cornea, so patients with thin corneas can also potentially be treated.

We have patent coverage of this technology, and therefore we are confident that for some time we will be in a competitive position in the marketplace. This is a new paradigm in refractive surgery—a shift away from surface ablation, or rather from ablation at all. With IntraCOR, we are not working against the cornea; we are working with the forces of the cornea.

Mr. Riding: We received the Conformité Européenne (CE) mark for IntraCOR earlier this year, and we are rolling out the procedure now in a controlled way over a 9-month period because we want to monitor its introduction carefully. The first centers began to do commercial IntraCOR procedures in June.

We also want to ensure that we support our users well, so we are training our teams of engineers and application specialists, who currently work on the excimer side, on the femtosecond technology. We have a training program that runs through 2009.

With the CE approval behind us, we have another round of studies under way seeking to broaden the indication. The initial indication is for presbyopia correction in mild hyperopes, and we will seek to progressively expand the range to, for example, emmetropes.

We want people to understand IntraCOR because we believe it has the potential to transform the refractive market. We think patient acceptance will be high.

**TAKE-HOME MESSAGE**

- Technolas Perfect Vision is initially focusing on presbyopia correction. Other undertakings will follow.
- IntraCOR redistributes the internal biomechanical forces in the cornea to create changes in corneal curvature.
- The first commercial IntraCOR procedures began in June in select centers.
because of the simplicity of the procedure. Surgeons involved in the European multicenter study were struck by how easy it was for them to satisfy patients. The effects are almost instantaneous.

Results at 18 months were presented this spring at the American Society of Cataract and Refractive Surgery (ASCRS) meeting.1

Q: Will the femtosecond laser used for IntraCOR also be capable of cutting LASIK flaps and other applications?

Mr. Hohla: Yes. Our femtosecond technology is a broad application system now. The Femtec laser can create LASIK flaps; make cuts for therapeutic applications, such as keratoplasty procedures; and now, with IntraCOR, we have the means to alter the cornea's refractive power. In addition to the presbyopic treatment, which I think is the most fascinating indication, we are also working on hyperopia and myopia applications. All these refractive changes will be accomplished without opening the eye. Basically it could be done in a living room.

Mr. Riding: Once you have the hardware of the femtosecond laser, it is a matter of changing the software to carry out these various procedures. But all femtosecond lasers are not created equal; they deliver the laser pulse in different ways. It depends on what you want it to do. If you just want a flap-cutting laser, you would use a different beam profile and a different patient interface from one that would be able to perform deeper cuts within the eye, down through and even behind the cornea. Surgeons tend to generalize about femtosecond lasers, but there are differences.

**EXCIMER TECHNOLOGY AND PRESBY-LASIK**

Q: In addition to IntraCOR, you have an excimer-based presbyopia solution, which should be available beginning in 2010.

Mr. Hohla: That is a binocular hyperprolate approach, a presbyopic treatment for patients also undergoing LASIK. The optical zone of the cornea is divided into concentric outer and inner segments, with one used for near and the other for distance vision. This so-called presby-LASIK approach has been explored by a number of investigators, not only with our laser but with other lasers.2 We are now...
in the process of conducting a multicenter clinical study for CE mark approval of our approach.

Mr. Riding: The concept of presby-LASIK has been around for some time. There have been several approaches available in the ophthalmic market in the past few years, but none has been widely adopted. To be honest, we also have made previous attempts to master the technology.

The precision of modern diagnostics and the accuracy with which we can ablate the cornea today are phenomenal, compared with 5 or 10 years ago, and this has opened the door to success. We now see the possibility of a robust and predictable presby-LASIK treatment.

Mr. Hohla: We really want to manifest ourselves as the company offering a range of corneal refractive options for presbyopia correction. With the availability of IntraCOR and presby-LASIK side by side, we hope to offer a continuum of correction. We envision IntraCOR as primarily for low hyperopes, emmetropes, and low myopes, with at most 2.00 to 3.00 D of refractive error in either direction. For correction of 3.00 D and above, presby-LASIK will probably be preferable.

Mr. Riding: But the key market is the near emmetrope who is going to be satisfied by IntraCOR.

THE REFRACTIVE SURGERY MARKET AND THE FUTURE

Q: Your mention of market brings to mind the fact that you launched this venture in some of the toughest economic times in living memory. How do you hope to address this?

Mr. Riding: An important aspect is the market segment we will be serving with these presbyopia-correcting technologies. We will no longer be seeking the 20- to 40-year-old refractive patient. These procedures will be of interest to the more affluent baby boomer generation (ie, 45- to 60-year-olds) who have the funds to pay for procedures such as this—and the motivation, because they are frustrated with their reading glasses.

The economic slowdown has reduced the number of refractive procedures by approximately 20% worldwide and is restricting the ability of refractive centers to invest in new equipment. Offering better equipment is not enough in itself; we need to help clinics increase turnover by delivering new treatments and new indications. Our customers see these presbyopia procedures as transformational for their practices.

Q: How has the transition from two companies to one gone, and what do you foresee for the company beyond the procedures we have discussed?

Mr. Riding: The transition has gone better than we could have hoped. Combining advanced technologies, expert commercial execution, and a clear business strategy has been motivational for our people. In the background, we have enjoyed a lot of administrative support from B&L, which has assisted greatly.

We have several other treatments under development that we cannot disclose at this time. It is suffice to say that laser-based ophthalmic surgery has a bright future. That said, we must be careful not to overcommit ourselves. We have no shortage of exciting ideas, but we need to match our development priorities to commercial needs.

Customer acceptance of the new company has been gratifying. As you know, Kristian founded Technolas in 1985; the name has widespread recognition, with a reputation for leading-edge technology and clinical innovation. Internationally, the Technolas laser has had a large share of the market, especially in Europe and Asia, at first on its own and then under the B&L aegis. We want people to recognize the Technolas name and see us as a company that will bring new laser-based treatments to ophthalmology.

Mr. Hohla: Refractive laser companies tend to put too much emphasis on introducing new boxes. In most cases, unfortunately, this means added cost to the surgeon, often without added value. We see Technolas Perfect Vision as a treatment company, introducing new treatments that will expand refractive practices by attracting new, premium patients.

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