

Roundtable at DOC Ponders Use of Accommodating/Multifocal IOLs

Plenty of attention was placed on multifocal and accommodating IOLs at the recent congress of German Ophthalmic Surgeons (DOC), in Nuremberg, Germany last month. One roundtable discussion asked a panel of distinguished cataract surgeons what their current technique is for restoring accommodation after cataract surgery.

Australian surgeon Graham Barrett, MD, the DOC Ridley Lecturer, told the audience that he believes that accommodating IOL technology is “not there yet.” He added, “I favor monovision — there is a compromise, but you can tweak this with spectacles or contact lenses.” Dr. Barrett’s preferred technique is to perform cataract surgery on the worst eye first, aiming for ± 0.25 D of emmetropia. For the second eye, he lets the patient decide if the eye will be corrected the same — for distance, or for near vision. “I don’t believe you have to correct the dominant eye for distance,” Dr. Barrett told the audience. “There’s no evidence that shows that you have to do it that way.”

German surgeon Ulrich Mester, MD, said he prefers diffractive multifocal IOLs because “patients are independent of glasses.” In his clinical experience, 82% of patients were spectacle free, though he noted that even though newer technology multifocals offer better vision, there are still some patients who are not appropriate candi-

dates. One point about multifocal IOLs does trouble Dr. Mester. “Most patients in my area are not aware of these lenses, so I would like to see more patients be aware of the option of multifocal lenses.”

Professor Thomas Neuhann, moderator of the session, then asked each panelist to give a snapshot of the percentage of patients in whom they implant bifocal IOLs and blue-blocker IOLs. A. Scharrer, MD, reported that he uses multifocal IOLs in 1% of patients and does monovision in 3% to 4% of patients. He told the audience that he uses the blue-blocker IOLs in 100% of cases. On the opposite side of the issue, Rupert Menapace, MD, said he does not use blue-blocker IOLs and will not because there is no proven advantage. Dr. Menapace said he uses a combination of monovision and/or multifocals in a large percentage of his patients. Gerd Auffarth, MD, said he uses the blue-light blocking lenses in 10% to 20% of eyes. He also implants about 10% of his patients with multifocal IOLs. Finally, Dr. Barrett reiterated his preference for monovision, telling the audience that he uses it in 20% of patients now, compared with a multifocal IOL in just 1% of patients. Dr. Barrett added that he now uses the blue-blocker lens in 75% of patients, and would use it more frequently if it were available in all the IOLs he currently implants.

SFO Creates an International Council

The French Society of Ophthalmology (SFO) has created an international council in hopes of expanding its ability to draw attendees from outside of France to its annual meeting. According to Joseph Colin, MD, president of the SFO and cochief medical editor of CATARACT & REFRACTIVE SURGERY TODAY EUROPE, the international council is made up of 45 countries.

Representatives of these countries were invited to participate during a joint session held at the annual meeting. Professor Colin hopes that the positive response from the attendees will encourage a more active role in

future meetings. SFO organizers said attendance for this year’s meeting was approximately 7,000, with 2,000 coming from outside France, including French-speaking African countries.

This year’s conference featured numerous joint symposia with other international societies such as the Franco-Syrian, Franco-Chilean and SFO-European Society of Ophthalmology symposia.

Professor Colin said that the SFO has established new relationships with the American Academy of Ophthalmology that will lead to common projects, including the Franco-American meeting in Paris next year.

The International Council of the SFO will also assist members with obtaining visas for professional travel.

According to SFO reports, there was also an increase in support from industry, as reflected in the number of industry-sponsored lunchtime symposia this year.

As it has in past years, the SFO hosted an information day for the general public on the topics of refractive surgery, low vision, dry eye and glaucoma. The society said this activity has been extremely successful and popular.

Bausch & Lomb Institutes Worldwide Recall of Contact Lens Solution

Global eye care company Bausch & Lomb (Rochester, NY) took the step of recalling its Renu with Moistureloc contact lens solution from the European market last month. The move followed the company's decision to pull the product from the market in the United States and Asia earlier in the spring on reports of unusually high numbers of *Fusarium keratitis*. In making the announcement, B&L Chairman and CEO, Ronald Zarrella cited the safety of their customers as the company's number one concern.

Renu with Moistureloc was launched in late 2004. Mr. Zarrella said in a company statement that its investigation found no evidence of product contamination, tampering, counterfeiting or sterility failure. "That leads us to conclude that some aspect of the Moistureloc formulation may be increasing the relative risk of *Fusarium* infection in unusual circumstances," said Mr. Zarrella.

Both the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), which have been leading the investigation into the outbreak of *Fusarium keratitis* in the United States, supported the recall. The CDC investigation concluded that the Moistureloc formulation was the only product with a statistically significant association with the outbreak.

Just days after taking the action, B&L was forced to issue another statement following media reports that claimed the company withheld details of the initial *Fusarium keratitis* outbreak that occurred in Asia. An FDA report into its investigation of the company's manufacturing facility in South Carolina stated that, "Unspecified keratitis complaints were reported to the company in July 2005 were not reported to the agency." The company strongly denied that the cases were related and said in its statement that the six cases were noninfectious keratitis.

The company has encouraged consumers and eye care

practitioners to switch to Renu Multiplus or Renu Multipurpose. Both of these products have completed different formulations from Renu with Moistureloc and have been given a clean bill of health in the investigation.

Update: UK Refractive Surgery Regulation

Legislation introduced into the British House of Commons to regulate the practice of refractive laser surgery has apparently stalled out. The bill, first introduced more than 1 year ago, was due to have a second reading last month. But, no action took place.

The bill, introduced following a series of hearings in 2004 and 2005, would require refractive surgeons to be registered. It also proposed a cooling-off period between when a consumer consents to have refractive laser surgery and when the surgery takes place. A surgeon who performs surgery without being registered would have faced fines and penalties.

Although it seems unlikely that the House of Commons will take action on the bill, the Royal College of Ophthalmologists (RCO) is pressing ahead with an accreditation process for refractive surgeons. The RCO is also in the process of developing guidelines for general practitioners and optometrists. As part of this, the RCO released updated guidelines in April for consumers on refractive surgery.

RCO Opposes Government Restrictions on Foreign Docs

The RCO is challenging a UK government plan that makes it more difficult for physicians from outside the European Union (EU) to come to the United Kingdom to practice medicine.

From July, any public hospital will have to prove that a vacant position cannot be filled by a *home-grown* doctor before it can hire someone from outside the EU. According to the RCO, this change puts an end to the current permit-free training arrangement that is now in place for overseas doctors.

"We believe that the new appointment procedure is discriminatory and unfair," said Mr. Nick Astbury, the immediate past president of the RCO and chairman of its International Committee. "The abolition of permit-free training means the best applicant will no longer be appointed, as nationality will be a deciding factor."

Over the past 5 years, the RCO has helped to place

62 ophthalmologists from developing countries in the UK to help further their training. Mr. Astbury believes that by making it more difficult for overseas doctors to do additional training in the United Kingdom, this could impact medical care in developing countries.

"In Africa, there is one ophthalmologist per 1 million people, compared with 50 per million in Europe," said Mr. Puvana Chandra, a UK ophthalmologist who chaired a session on international ophthalmology during the RCO's annual meeting last month in Manchester. "We do have an international obligation to train health care professionals in the developing world."

Wavelight: Celebrating 10 Years of Innovation

Wavelight (Sterling, Va), a subsidiary of Wavelight Technologie AG (Erlangen, Germany) announced its 10-year anniversary as an ophthalmic medical device manufacturer of laser systems for the ophthalmology and aesthetic industries.

Wavelight has achieved a market capitalization of more than €80 million and established successful subsidiaries in the United States, Spain and France. The company was founded in 1996 by Max Reindl. Working with Professor Theo Seiler and his team of engineers, Wavelight developed the Wavefront Optimized Allegretto Wave, a high-speed flying spot excimer laser designed to maintain the natural aspheric shape of the cornea following refractive surgery. The Allegretto Wave was approved by the FDA in October 2003; over 650 systems are available worldwide.

Wavelight was the first European manufacturer to achieve approval for a refractive laser system, and it has been granted the widest approval ranges to date. This May, the FDA approved the Allegretto Wave for the treatment of mixed astigmatism.

"Wavelight's goal from the beginning has been to pioneer the most innovative and advanced technology for optimizing the optics in the eye," said Mr. Reindl, in a news release. "The Allegretto Wave is designed to protect quality of vision while also providing a new level of safety for physician and patient."

Wavelight announced earlier this year that it plans to dedicate resources to ophthalmic market segment. The company has now spun-off its aesthetic division (a fully owned subsidiary of Wavelight Aesthetic GmbH). "Devoting all our efforts to ophthalmology further strengthens Wavelight's position ... not only in the field of refractive laser surgery, but in other areas

aimed at improving the optics of the eye for the anterior segment," said Mr. Reindl. "Our research and engineering assets are addressing new technologies, as shown by our introduction of microkeratomers and IOLs in our European markets."

Preloaded Aspheric IOL Receives CE Mark Approval

STAAR Surgical Company (Monrovia, Calif) announced it has received Conformité Européenne (CE) Mark approval for its preloaded aspheric silicone IOL (KS-3Ai). The approval will allow STAAR to market the aspheric silicone IOL for use in cataract surgery in 21 countries where the CE Mark is accepted.

This product is the latest development in the first line of preloaded IOLs, which were introduced into international markets in 2003 through STAAR's affiliate, STAAR AG (Switzerland). Like all of STAAR's preloaded IOLs, the KS-3Ai includes the lens, cartridge and injector body in a single, disposable presterilized unit, offering ease, safety and convenience to the surgeon and providing a consistent and controlled sterile pathway directly into the eye, according to a company news release.

The KS-3Ai is the world's first preloaded IOL injection system to offer an aspheric optic design, which has a more complex surface profile designed to eliminate spherical aberrations and reduce the other optical aberrations that can occur in conventional spherical lenses. The refined aspheric lens is delivered through an incision size <3 mm. The preloaded aspheric silicone IOL also features a square edge, which is preferred by many surgeons.

"The launch of the preloaded aspheric IOL builds on our unique preloaded feature and allows us to broaden our reach into the fast-growing aspheric silicone market," said David Bailey, president and CEO of STAAR Surgical, in a news release. "Aspheric lenses are quickly becoming the standard of care and we believe the features of our easy-to-use preloaded delivery system will allow us to gain market share in this growing segment. Our preloaded silicone IOL has grown significantly in international markets. We have seen very strong interest from both doctors and distributors in our new aspheric model."

The lens was officially launched in May, during the Italian Association of Cataract and Refractive Surgery/Italian Society of Ophthalmology Joint (ISRS/SOI) Annual Meeting, in Rome. STAAR began distribution during the first week of June. ■