

Lisbon 2005

The surgical correction of presbyopia: Accommodation, pseudo-accommodation or multifocality ?

Surgical innovations inch ever closer to solving the presbyopic challenge

**Dermot McGrath
in Lisbon**

THE surgical correction of presbyopia remains one of ophthalmology's greatest challenges. Continuing rapid evolution in technology, however, brings promise for the future availability of better methods for restoring accommodation, according to a number of vision scientists speaking at a special symposium on the topic during the XXIII Congress of the ESCRS.

“There is great interest and excitement in this field of research at the moment and we are seeing some very interesting approaches coming on stream which hold great promise for future treatment of presbyopia,”

David Spalton MD

“It is undoubtedly the final frontier of cataract and refractive surgery. There is great interest and excitement in this field of research at the moment and we are seeing some very interesting approaches coming on stream which hold great promise for future treatment of presbyopia,” said David Spalton FRCS, FRCOphth, who co-chaired the symposium.

Dr Spalton said it was important to remember that there is more to near vision than just accommodation and that clinicians should be aware of other factors that might have a bearing on outcomes such as IOL-related factors, pupillary miosis and monovision in pseudo-accommodation, contrast and illumination, testing conditions and patient subjectivity.

“It is vital that we have a critical assessment of near vision. We need to know what psychophysical tests we should be doing and because they are subjective it is

important that we have placebo controls. Equally important is that we need to have objective measurements in these patients of dioptric change and IOL position. If we believe an IOL is moving we need to be able to measure that,” he said.

Dr Spalton said that clinicians also needed to bear in mind the effect of capsular bag fibrosis, the role of lens epithelial cells and the effect of YAG capsulotomy on their presbyopic patients.

“Are we going to have to destroy the lens epithelial cells in order to be able to restore accommodation, and if we do that, what are the consequences going to be in maintaining the capsular bag? Can we maintain the capsular bag without viable cells in it? We are making a lot of progress, in the challenge of restoring accommodation with surgery, but there is still much to be done,” he said.

Will true accommodating IOLs deliver on their promise?

In a review of some of the current and future approaches for the surgical treatment of presbyopia, Samuel Masket MD said that there were many interesting developments coming on stream, including “true accommodating intraocular lenses” which he believes provide the most promising treatment modality for the near future.

“True accommodating IOLs are the hope for and the wave of the future as they are physiologic and will likely have fewer optical side effects compared to pseudo-accommodating IOLs. Single lens, rigid optic IOLs with flexible haptics have been the first of these devices to reach the marketplace but they are limited in their accommodative function,” he said.

While much progress has been made, Dr Masket said there were still many outstanding issues that needed to be resolved in the field of presbyopic research.

“We still do not have a uniform way of measuring accommodation. There is still considerable debate over whether true versus pseudo-accommodation is the best approach, which technique will give us the best reading ease and speed and what allows patients to use and maintain accommodative reserve. There are also issues of quality of vision and higher order aberrations and which approach will deliver consistently high quality of vision to our patients,” he said.

Looking at new pseudo-accommodative materials coming on stream, Dr Masket said

that the AcuFocus corneal inlay (AcuFocus Inc) demonstrated the type of innovation in the field. The AcuFocus is an ultra-thin device placed in a LASIK bed and is based upon a small optical aperture or “pin hole” effect.

“This is a plano optic that increases depth of focus but does not reduce distance visual acuity. The polymer is biocompatible and is micro-perforated to allow for nutrient flow to the cornea. It has an overall diameter of 3.8mm and a current inner aperture of 1.6mm. It is implanted monocularly in the non-dominant eye and early results with this technique are very encouraging,” he said.

Turning to intraocular lens-based pseudoaccommodation, Dr Masket said that while diffractive multifocal lenses such as the ReSTOR and Tecnis and refractive multifocal IOLs such as the Array and ReZoom had become well established, the real breakthrough designs may lie just over the horizon.

Dr Masket pointed to Dr Lee Nordan's “vision membrane” as a case in point. This angle-supported hydrophobic foldable acrylic is well tolerated by ocular tissues and goes through a 2.5mm incision, said Dr Masket. He said that it uses a patented multi-order diffractive optics (MOD) concept to increase depth of focus and provides +2.0 D of pseudo-accommodation.

Dr Masket said he believed that IOL-based true accommodation based on the Helmholtz theory offers a particularly promising avenue for future product development. Among other new concepts of accommodating lenses currently under development, Dr Masket cited:

- The PowerVision, a dynamic optic with fixed haptics using

fluidics. Upon accommodative stimulation, fluid is pumped reversibly, altering the radius of curvature and affecting an increase in IOL power for near vision purposes.

- Medennium Smart IOL, a single-piece hydrophobic acrylic optic with thermodynamic properties that is pliable for accommodation.
- Accommodating injectable materials, currently under development by AMO.
- The NuLens accommodating IOL, a multi-piece optic with fixed optics that incorporates a piston-like concept for accommodation.
- LiquiLens, a dual liquid, gravity-dependent IOL.
- Visiogen's Synchrony lens, a dual-lens telescopic IOL.

Pseudo-accommodation – What's Coming Next?

CORNEAL BASED SURGERY

AcuFocus Corneal Inlay

- Ultra-thin device placed in Lasik bed
- Based on small optical aperture effect – “pin hole”
- Plano optic that increases depth of focus but does not reduce distance VA



Phakic Pseudo-accommodative IOLs

Angle Supported

“Vision Membrane”

- Developed by Lee Nordan
- Anterior Chamber – angle supported, thin, vaulted
- Hydrophobic foldable acrylic
- Patented Multi-Order Diffractive Optics – MOD
- Increases depth of focus – there is no add, but provides +2 D pseudo-accommodation



Courtesy of Samuel Masket MD

Reading charts for near visual function

The best means of assessing near visual function was discussed in detail by Professor Wolfgang Radner MD, who recommended that ophthalmologists should include reading performance tests as part of their assessment procedures.

"A lot of previous studies have shown that distance acuity, which is a single optotype test, underestimates the full functional impairment to a significant degree," he said.

In collaboration with linguists, psychologists and computer scientists, Dr Radner and his fellow researchers have developed a new type of reading chart for the simultaneous evaluation of reading acuity and reading speed. Using the Radner Reading Charts, a reading acuity score (LogRAD-score) can be calculated considering reading errors in words of different length while reading speed can also be determined at the same time.

Dr Radner said that such standardised reading charts provide clinically relevant, reliable and reproducible results both for patients with normal eyesight as well as those with visual impairment.

"The standardised modern reading test system offers detailed information about near visual function. The more information we can obtain about our patients' abilities, the better it is for research, particularly when we are thinking about restoring accommodation. Single optotypes cannot show the full functional impairment without the risk of misinformation, so I would recommend that clinicians introduce these tests as a standard part of their assessment protocols," he said.

Limited success with focus-shift IOLs

The clinical performance of accommodative IOLs that work on the basis of the focus shift principle invariably involves a trade-off between questionable accommodation and compromised capsular bag performance, according to Oliver Findl, MD.

Dr Findl said that studies that rely on psychophysical measures to show that accommodative lenses work are inherently unreliable due to other variables that are not taken into account. These variables include factors such as the patient's pupil size, astigmatism and corneal multifocality, as well as the motivation of patient and examiner.

"Measuring the movement of the IOL optic is the only reliable method of assessing whether an accommodating IOL actually works," said Dr Findl.

In a series of controlled trials, Dr Findl and co-workers evaluated the optic movement of two accommodative IOLs – the 1CU (HumanOptics AG) and Crystalens (Eyeonics, Inc) – using the Carl Zeiss Meditec IOL Master. This system uses non-contact

partial coherence interferometry (PCI) to measure anterior chamber depth with precision within a range of a few microns, Dr Findl said.

The studies found that the 1CU lens shifted only slightly and that the anterior movement is equivalent to a mean refractive change of about 0.50 D. The amount of movement also varied substantially between patients, he said.

For the Crystalens AT-45, Dr Findl's team actually recorded a slight backward movement of the optic under pilocarpine ciliary muscle contraction. They also found that near distance visual acuity with distance correction was not better than the age-matched control group implanted with standard IOLs.

"On the positive side, the capsular bag performance of this small optic IOL (Crystalens) was found to be quite good with no edge glare or haloes. We did find quite a high PCO YAG capsulotomy rate after two years, which was higher than what we are used to from other standard IOLs on the market," he said.

Dr Findl concluded that lenses based on the focus shift principle would probably be superseded in the near future by dual optic IOLs and especially bag refilling, which he believed offered a more promising approach to the problem of restoring accommodation in presbyopic patients.

Are two optics better than one?

Looking at the promise of dual optic accommodating IOLs in more detail, Burkhard Dick MD, PhD told the symposium that the second-generation Visiogen Synchrony dual-optic lens shows increased safety, better predictability and improved functionality over earlier models of the IOL.

Dr Dick explained that the IOL has incorporated a number of key design changes to address concerns noted with the first generation.

"Posterior stabilisers have been improved to ensure proper position, to compensate for size variations in the capsular bag and to prevent decentration of the lens. The haptic design has also been improved, the spring forces have been optimised and there are displacement limiters to prevent contact with delicate ocular tissues and prevent lens adhesion," he said.

The IOL also includes fluid channels in the anterior portion to facilitate fluid exchange from the anterior chamber to the interface between the two optics, as well as to help support the anterior capsule, he said.

To facilitate implantation, the new Synchrony IOL is pre-loaded into a specially designed injector system, allowing for controlled release of the two optics, said Dr Dick. He noted that a



David J. Spalton



Samuel Masket



Oliver Findl



Burkhard Dick



David Allen



Stephen S. Lane



Jorge Alio

prospective, multicentre trial of the new Synchrony IOL is ongoing and initial results have been very encouraging.

Of 29 eyes implanted with the lens, 86% achieved uncorrected distance visual acuity of 20/40 or better at three months and 79% achieved uncorrected near distance visual acuity of 20/40 or better. While the postoperative spherical equivalent had turned out slightly hyperopic, Dr Dick said that the results were nevertheless much closer to what investigators had wanted to attain compared to results with the earlier version of the lens, he said.

As well as emphasising the importance of careful biometry preoperatively, Dr Dick stressed that rigorous intraoperative cleanup was mandatory in order to achieve optimal results with this lens. He also noted that capsular fibrosis and posterior capsule opacification seem to be less of a problem with the new version of the IOL.

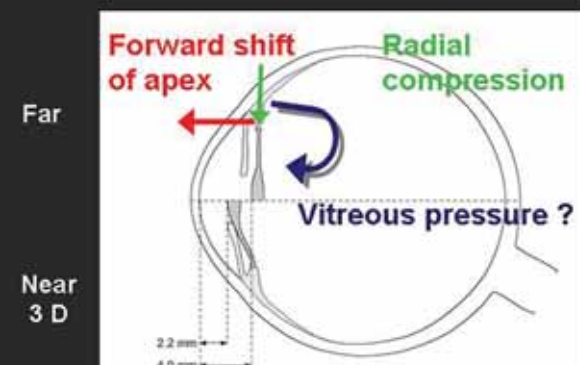
"While we certainly need a longer follow-up to confirm these findings, results thus far with this IOL are encouraging. The refractive outcomes were stable, PCO was less of an issue and the design changes have led to better safety, predictability and perhaps improved functionality. There were no additional surgical interventions required and I see a clear improvement over previous lens refractive modalities," Dr Dick said.

Surgical technique and patient selection emphasised

Excellent surgical technique and meticulous patient selection are among the most important factors to be borne in mind when implanting multifocal IOLs, according to David Allen FRCOphth.

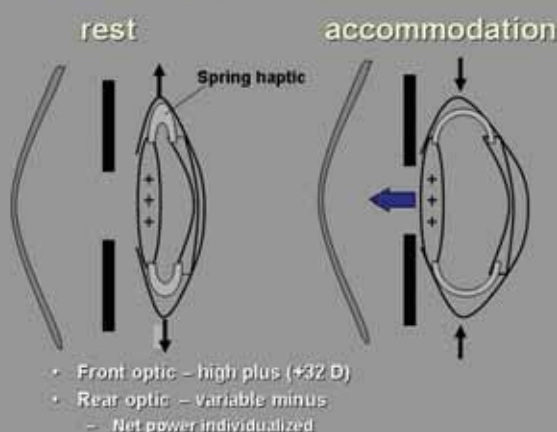
"We need to get to a situation where we are leaving the patients uncorrected with little or no astigmatism, so it does require excellent surgical techniques to achieve good results. I think the latest generation of multifocal lenses, particularly those based on a diffractive platform, give impressive

Focus-Shift Principle



Courtesy of Oliver Findl, MD

Functional Hypothesis: Dual-optic AIOL



Courtesy of Burkhard Dick, MD

Courtesy of Wolfgang Radner, MD

Radner Reading Charts

Sentence Optotypes

comparable in terms of:

- lexical difficulty
- syntactical structure
- position and length of words

Radner W et al. Klin Monatsbl Augenheilkd 213: 174-181
Radner W et al. Graefes Arch Clin Exp Ophthalmol 240: 451-7

results with unaided reading and spectacle independence," he said.

“The early lenses had much poorer design and that was partly because we did not understand some of the aberrations and side effects that they generated.”

David Allen FRCOphth

Dr Allen cited the ReSTOR lens as a case in point, with some studies showing that over 85% of patients implanted with this IOL attain complete spectacle independence.

Analysing the reasons why multifocal lenses never really achieved widespread acceptance despite their relatively long history, Dr Allen pointed to problems of visual symptoms and night vision difficulties associated with early multifocals.

“The early lenses had much poorer design and that was partly because we did not understand some of the aberrations and side effects that they generated. Nor did we fully understand the type of patient selection that was important and we also did not really have the ability to achieve good, precise biometry and secure in-the-bag placement with accurate outcomes,” he said.

Turning to problems associated with the use of multifocal lenses in mesopic conditions, Dr Allen said that manufacturers have adopted some interesting strategies to counteract such difficulties. The different optical zones on the ReZoom IOL, for instance, have been modified and rebalanced in order to send a smaller amount of light to the (out of focus) near image in mesopic conditions than its predecessor the Array. Similarly, the introduction of different types of diffractive lens designs such as the Tecnis and ReSTOR has helped to improve image quality and deliver better contrast sensitivity function in nighttime conditions.

Monovision – low tech but effective

The pros and cons of monovision as a tried-and-tested approach to treating presbyopia were discussed by Stephen Lane MD, who said that monovision, in the right surgical hands, still has much to offer the presbyopic patient.

“There is no doubt that monovision seems somewhat low-tech compared to some of the new techniques and concepts that are coming on stream today, but I think if used correctly it still represents a viable opportunity to be used for the benefit of our patients,” he said.

Dr Lane defined monovision as the optical correction of distance vision in one eye and intermediate or near vision in the fellow eye in order to compensate for the loss of the accommodative capacity in presbyopia or pseudophakia.

“The mechanism involves the concept of interocular blur suppression which means the ability to suppress the blurred image

from one eye so that it does not interfere with the image from the in-focus eye,” he said.

Dr Lane said that studies have shown that successful monovision contact lens wearers have two orders of magnitude greater interocular blur suppression than unsuccessful wearers. Blur suppression has also been shown to be less effective in dim illumination.

Among factors influencing the success of monovision, Dr Lane also stressed the role played by ocular dominance. When the dominant eye has been corrected for distance visual acuity, the overall monovision success rate is around 75%. Yet Dr Lane emphasised the importance of the constant interocular suppression of blur in obtaining good outcomes.

“In alternating dominance patients – that is those patients who do not really have a significant sighting difference between one eye and the other – they have constant interocular blur suppression and therefore a very high rate of monovision acceptance. If there was a way of testing for this predictably, it would not be necessary to do contact lens trials ahead of time and we could already pre-select good candidates for the procedure,” he said.

“In alternating dominance patients – that is those patients who do not really have a significant sighting difference between one eye and the other – they have constant interocular blur suppression and therefore a very high rate of monovision acceptance.”

Stephen Lane MD

Another key factor in monovision success, he said, was the ability of patients to overcome visual compromises that are part-and-parcel of the procedure. Such compromises include a reduction in binocular visual acuity, stereopsis and reduced contrast sensitivity, he said.

Dr Lane said that the published literature showed an overall success rate of about 75% for monovision procedures, regardless of how the monovision was achieved. He noted, however, that the results were skewed somewhat by the fact that the studies rarely differentiated between those who had rejected monovision because of blur suppression difficulty and those who had simply been intolerant of contact lens wear.

“Many of these reported failures might actually be nothing to do with monovision itself,” he said.

To properly assess which patients might be good candidates for monovision, Dr Lane suggests a three-week contact lens simulation, restricting the difference to 1.5 D and ensuring the patient is well informed about the limitations of the procedure.

“Informed consent really has to include the fact that the goal is distance and intermediate ranges, with reading spectacles needed for the fine details as the advancing age of the patient occurs,” he said.

Second generation PresbyLASIK has much to offer

Ongoing advances in laser-based surgical techniques have given clinicians sophisticated new tools for the treatment of presbyopia that hold genuine promise for the future, according to Jorge Alio MD.

Dr Alio defined presbyLASIK as an umbrella term for the group of LASIK techniques that aim to increase depth of field in the presbyopic eye by creating in both eyes a central, peripheral or transitional area for near vision restoration.”

He differentiated between first-generation presbyLASIK procedures –

based only on refractive data – and second-generation presbyLASIK, a more sophisticated approach that draws on data from wavefront and corneal topography.

First-generation presbyLASIK used three distinct approaches, noted Dr Alio, including transitional bifocality, central hyperpositive multifocal area and peripheral multifocal area. Of these, the central presbyLASIK technique (Presby-One, Technovision) as developed by Dr Chaubard in Nice, France, has proved to be the most popular.

Presenting results from trials performed in his own clinic using a Technolas 217z laser and an adapted version of the Presby-One software, Dr Alio said that 80% of the patients had distance uncorrected vision of 0.8 at six months and 92% could read J4 or better without correction. These results remained stable over time.

Dr Telandro of Cannes, France, has also reported good results using a peripheral presbyLASIK technique, noted Dr Alio, with a patient satisfaction ratio of over 90%. The procedure involves firstly a hyperopic treatment on a wide area, followed by a second myopic treatment at the centre.

“The aim is not bifocality, but a progressive aspheric lens on the cornea,” said Dr Alio.

Further improvement of these outcomes should be obtained in the near future with the arrival of second-generation presbyLASIK procedures incorporating wavefront and corneal topographic data which had already delivered encouraging preliminary results, said Dr Alio.

Summing up, Dr Alio said that ongoing refinement of presbyLASIK techniques would help to answer critical questions often posed in relation to such procedures.

“Firstly these techniques are clearly able to improve near vision up to 1.5 D. While there is still some induction of optical aberrations, these are tolerable for most patients and remain stable over time. The same goes for induction of visual symptoms, which are acceptable as long as near vision is restored. Finally there is the question of what do when the presbyopia increases. There is no definite answer to this question at the moment, but probably a combination of monovision with presbyLASIK will provide these patients with spectacle independence when they become fully presbyopic,” he said.

*David J. Spalton FRCS, FRCOphth
St. Thomas' Hospital, UK
spalton@eyeppractice.fsnet.co.uk*

*Samuel Masket MD
avcmasket@aol.com*

*Jules Stein MD
Eye Institute UCLA, Los Angeles, USA*

*Wolfgang Radner MD
University of Vienna School of Medicine, Austria
wolfgang.radner@univie.ac.at*

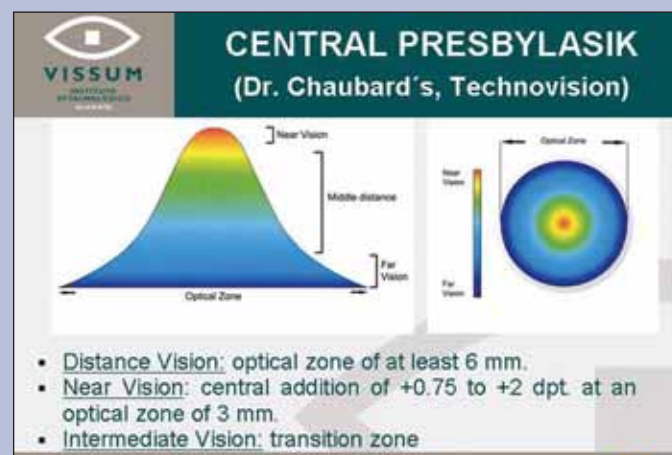
*Oliver Findl MD
Medical University of Vienna, Austria
oliver.findl@medunivien.ac.at*

*Burkhard Dick MD
Johannes Gutenberg-University, Mainz, Germany
bdick@mail.uni-mainz.de*

*David Allen FRCOphth
Sunderland Eye Infirmary, UK
David.Allen@chs.northy.nhs.uk*

*Stephen S. Lane MD
University of Minnesota, USA
sslane@associatedeyecare.com*

*Jorge Alio MD, PhD
Instituto Oftalmologico de Alicante, Spain
jalio@ofitalio.com*



Courtesy of Jorge Alio MD, PhD