Scleral spacing procedure – the answer to presbyopia?

Barrie Soloway MD

AN alternative presbyopia treatment known as scleral spacing (PresView™ Scleral Spacing Procedure/Refocus Group, Inc.) appears to provide long-lasting improvements in near vision without affecting distance vision in select patients, its developers report.

“We think the safety and effectiveness has really been evidenced by the FDA’s rapid and unqualified acceptance of our surgery and our ability to move on to phase III trials over the summer of 2005. Those surgeries can now be done bilaterally,” said Barrie Soloway, MD, assistant professor of ophthalmology at the New York Eye and Ear Infirmary in New York City, New York. Dr Soloway is also the medical director of Refocus Group, the maker of the scleral implants used in the procedure.

“We think the safety and effectiveness has really been evidenced by the FDA’s rapid and unqualified acceptance of our surgery and our ability to move on to phase III trials over the summer of 2005” DF
Barrie Soloway MD

An FDA phase II study in the US enrolled 53 patients and 28 controls between the ages of 50 and 60 years with a near vision (UCVA Sloan) of 20/63 or worse without glasses and a best-corrected distance vision (DCVA) of 20/20. To qualify for the study, the patients also needed at least a +1.25 D add to achieve an uncorrected near visual acuity of 20/25, refraction between +0.75 D and -0.50 D and a corrected visual acuity for distance of 20/20. All participants had their natural lenses and had not undergone prior refractive eye surgery.

The older style implants tended to rotate and subluxate easily. The current implant is ‘remarkably stable’ from a rotation point of view, and the subluxation rate is greatly improved but not 100% solved” Barrie Soloway MD

When asked which patients might benefit most from the procedure, he said, “I tend to like the mild hyperopes in the FDA clinical trials because we need to check their near acuity with their distance correction and they still seem to have some accommodative reserve. The myope has a disadvantage here because the distance correction that is required to be used in the clinical trials is going to hinder the results but since they typically do not wear them in the real world, they are generally also pleased with their results.”

In response to questions about adverse events and how long the procedure effect lasted, Dr Soloway said that there were no unexpected adverse events and that the patients who completed the two-year follow-up in the Phase III FDA trial retained the effects very well.

New design reduces complications
Several changes have been made to the implant’s design and there remain some problems. The older style implants tended to rotate and subluxate easily. The current implant is “remarkably stable” from a rotation point of view, and the subluxation rate is greatly improved but not 100% solved, said Dr Soloway.

In 1992, surgeons sutured the first scleral band onto the sclera over the ciliary body. The patient experienced several complications, among them conjunctival erosion and anterior ischemia. In response, the product’s maker the Refocus Group created four separate bands to avoid these complications.

In addition, the company also improved the implants’ effectiveness by flattening the curved design, which prevents the rotation that occurred in earlier devices, according to Dr Soloway.

The Phase I trial established SSP’s safety between 2000 and 2002. Between 2001 and 2004, the company developed the so-called PresView drive to create an automated scleratome that would cut more uniform lamellar scleral tunnels. The new scleratome also sped up the surgery and produced more reproducibility, he noted.

“Our current direction of the study has moved away from the reasons for decline of accommodation. Why it’s working, I’m not really sure, but the fact that so many patients are happy without glasses speaks for itself” Barrie Soloway MD

Scleral expansion implants try to affect the tension between the lens and the supporting zonules to restore accommodation. The underlying theory behind this approach calls into question a 150-year-old theory of what causes presbyopia, Dr Soloway explained.

Accommodation debate continues
In the mid-1900s German physicist Hermann Helmholtz theorised that presbyopia occurs because the crystalline lens, just like aging skin, loses elasticity with age, which affects the lens’s ability to smoothly accommodate near and distance vision.

Helmholtz’s theory of the lens’s slow deterioration has been accepted by the ophthalmic community probably because of its intuitive logic and Helmholtz’s scientific
genius demonstrated by his invention of the ophthalmoscope and groundbreaking theories on colour vision and motion perception.

But in 1994, eye surgeon Ronald Schachar MD, PhD theorised that the lens's flexibility does not deteriorate with time but instead continues to grow concentrically like an onion. Dr Schachar proceeded to publish a plethora of papers delivering evidence for his theory (Schachar R et al; Br J Ophthalm; July 2006). (Chien C et al; Compr Ther; Summer/Fall 2003; 29 (2-3):167-75), (Schachar R; Invest Ophthalmol Vis Sci; August 2004; 45 (8); 2691-5). According to this theory, the lens's growth shrinks the space between the ciliary muscle and the lens, which then progressively reduces the muscle's ability to accommodate.

Dr Schachar was also involved in the early development of the SSP procedure. He founded PresbyCorp, the company now known as Refocus, but he is no longer involved with the company.

In theory, SSP is supposed to expand the space between the ciliary muscle and the lens so the lens can smoothly contract and expand to accommodate vision. So far however, there has not been any objective evidence in the form of biometry that demonstrates that SSP actually accomplishes this.

SSP's underlying theory and the accompanying debate are secondary to the trial's impressive results, according to Dr Soloway.

“O ur current direction of the study has moved away from the reasons for decline of accommodation.W hy it's working, I'm not really sure, but the fact that so many patients are happy without glasses speaks for itself,” he said during a discussion following his presentation in San Francisco.

**Controversy surrounding procedure**

The scleral spacing procedure continues to generate controversy in the world of clinical ophthalmology. The procedure is very invasive, whereas other procedures such as refractive lens exchange with multifocal intraocular lenses such as the ReSTOR (Alcon) and Tecnis MF (AMO) produce consistent predictable results for patients with presbyopia, said Richard Packard MD, Prince Charles Eye Unit, Windsor, UK, in an interview with EuroTimes.

“The procedure remains controversial, and I remain sceptical,” John Vukich MD, surgical director of the Davis Duehr Dean Center for refractive surgery in Madison, Wiscons in, told EuroTimes.

Anterior segment ischaemia, inflammation and irritation have all been associated with the procedure from previous case reports and anecdotal evidence, he noted. In addition, sometimes the implant can be seen in the sclera because it is slightly raised, which can have cosmetic consequences, he said.

“The eyes are one of the most notable features of a person and even minor changes are easy to notice,” he said.

However, it would be wonderful if all of these issues were improved upon and scleral spacing would turn out to be the answer to presbyopia, he commented. Other procedures like intraocular lenses first met much scepticism but are now widely accepted by the ophthalmic community, he explained.

“We'd love for something to work; we're looking for an answer,” said Dr Vukich.

Based on the previously reported adverse events with previous methods of scleral spacing a high burden of proof will have to be met to convince the ophthalmic community at large that the means justify the ends, he added.

John Vukich MD

“We need to be convinced. At this point, there is not enough information to make really sound decisions,” he said.

In terms of Dr Schachar's theory on accommodation, the most convincing data has confirmed and established Helmholtz's theory as the correct one, according to Dr Vukich.

“The data builds a much stronger case for Helmholtz to be correct. There really is no longer a debate for most ophthalmologists, we've moved beyond that,” he said.

Dr Soloway is the medical director of Refocus, the maker of the scleral implants used in the procedure. In addition, the Refocus group is also working on trans-conjunctival SSP, which would speed up surgical time and recuperation.

The PresView procedure is still considered experimental in the US and Canada. It has recently received marketing approval in the EU.

bds@ihateglasses.com
r.schachar@presbycorp.com
javukich@facstaff.wisc.edu
mail@eyequack-vossnet.co.uk