

Capsule sealing system may reduce PCO after cataract surgery

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in Paris



Gerd Auffarth

THE PerfectCapsule™ System (Milvella) is effective in providing a temporary yet complete seal of the capsule bag and may provide a new means of preventing PCO, according to the preliminary results of a European multicentre study, presented at the XXII Congress of the ESCRS.

“We used the PerfectCapsule System to successfully seal off capsulorhexis of less than 5.0 mm. It was effective for the selective application of osmotic substances in the capsular bag without endangering the surrounding tissue, and helped prevent posterior capsule opacification (PCO),” confirmed Gerd Auffarth MD, University of Heidelberg, Germany, one of three European eye centres that participated in the trial.

The investigation’s first early postoperative results revealed no corneal endothelial cell damage, no change of pachymetry, stable development of visual acuity, and a tendency towards less fibrotic reactions with sealed capsule irrigation (SCI), the researchers showed.

In an ongoing, prospective randomised, double-masked, intra-individual trial, the investigators operated using SCI with the PerfectCapsule System in 32 patients: eight patients (16 eyes) who underwent clear lens extractions and 24 patients (48 eyes) who underwent cataract extractions.

The surgery involved topical anaesthesia (lidocaine gel), a 2.8 mm clear cornea incision, 5.0 mm - 4.5 mm capsulorhexis, phacoemulsification, and cortical cleanup. The surgeon enlarged the clear cornea incision to 3.2 mm - 3.5 mm and injected a small amount of viscoelastic.

The surgeon then inserted the PerfectCapsule System and positioned it in one eye of the patient. He applied vacuum and tested for complete seal with stained BSS. He irrigated the eye with sterile deionised water (osmotic agent) for 120 seconds and after a second injection of viscoelastic behind the capsule, he released the vacuum, removed the PerfectCapsule System, and implanted

the IOL.

The study involved the implantation of the same IOL in both eyes of the patient, either acrylic (16 cases in the Crete study centre), hydrophilic (28 cases in the Heidelberg study centre) and silicone IOLs (20 in the Berlin study centre), placing the same lens into the fellow eye without irrigation, as a means of intra-individual comparison.

Although the study results were encouraging, some ophthalmic surgeons expressed concern regarding the anterior chamber depth, as highly myopic eyes with deep anterior chambers might make sealing off of the capsule bag more difficult. They suggested that this patient group be carefully considered when evaluating exclusion criteria. Dr Auffarth agreed, noting that in his experience, sealing with the PerfectCapsule System was imperfect in this patient subset because at times the length of the irrigation line was too short.

He also acknowledged criticism regarding the use of stained BSS and the PerfectCapsule System in one eye only, instead of in both, with the only other variable being deionised water. He said that the study was designed to compare the use of the system using SCI in one eye with standard cataract surgery in the other, and not the effects of deionised water.

SCI consists of a foldable silicone sealing device with an overall diameter of 7.0 mm and an inner diameter of 5.0 mm, which can be applied on the anterior capsule with a capsulorhexis of 5.0 mm. The device has an irrigation line and an aspiration line onto which the vacuum can be applied. After sealing of the capsule, the internal capsular bag can be selectively irrigated with different substances.

Manfred Tetz MD, Eye Centre Spreebogen, Berlin, Germany, who participated in the trial, explained that the irrigation time for the in-the-bag cellular cleansing was set at 120 sec. Initial animal experiments and data from a pilot human study both suggest that an irrigation time of at least two minutes would be necessary to disrupt all lens epithelial cell membranes, due to the osmotic effect of deionised sterile water, he said.

SCI could be used in all 32 patients

without complications and the endothelial cell count and corneal pachymetry did not differ from the control eyes, he said. The development of visual acuity over a three-month period was also similar in both groups.

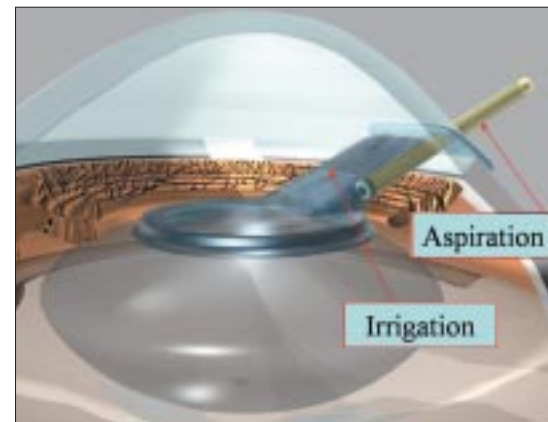


Manfred Tetz

Dr Tetz noted that PCO is an important longterm complication of modern cataract surgery, resulting from standard cataract surgery, paediatric cataract surgery, clear lens extraction, presbyopic lens exchange, and the implantation of special IOL-Types (accommodative IOLs).

“By the standardisation of modern small incision lens surgery and the improvement of phacoemulsification, cataract surgery and clear lens extraction have become highly sophisticated routine treatments. However, postoperatively one common problem still is the occurrence of PCO. The SCI system using the Perfect Capsule Device efficiently provided a closed system for irrigation of the posterior capsule with sterile water and the preliminary results show a promising effect on PCO reduction,” Dr Tetz observed.

He noted that the retro-illumination photographs (taken in three month intervals) of the capsule bag and IOL highlighted a relevant difference between the SCI and control eyes. The photographs showed a higher incidence of fibrosis and anterior capsule whitening in the control group compared to the SCI group. The slit-lamp exam also revealed some remaining cells along the optic margin, however.



The PerfectCapsule system completely seals off the capsulorhexis allowing selective application of osmotic substance without endangering surrounding tissue.

Dr Tetz noted that the sealing properties of the device worked perfectly for all 32 eyes, allowing a selective irrigation of the capsule sac. The preliminary results recorded the outcome of surgeries up to 12 months in most cases. These revealed a significant reduction in capsule fibrosis and contraction in the treated eyes, compared to the control fellow eyes. All 64 eyes had clear corneas during follow-up.

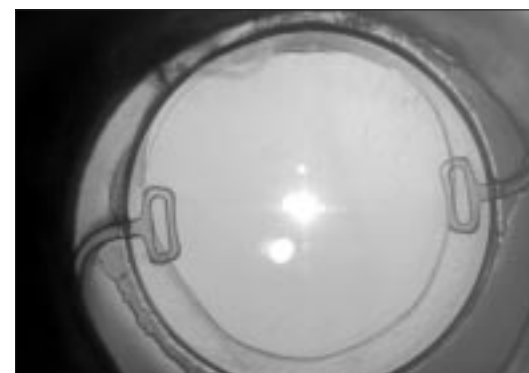
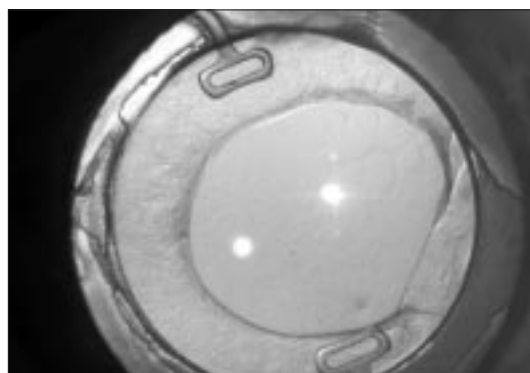
He reported that the time of surgery with the use of the device was extended by 3-5 minutes. No additional corneal incisions were necessary.

Although PCO prevention may be achieved through the application of pharmacological agents, some drawbacks include damage to the surrounding tissues, difficulty in selectively targeting the lens epithelial cells, difficulty in completely removing the substance, and the duration of necessary exposure time is difficult to evaluate, Dr Tetz observed.

The investigators noted the need for long-term follow-up of at least another 18 months to show whether simple substances such as sterile deionised water were in fact suitable for capsular bag cleaning and to determine the optimum exposure time.

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Retroillumination photographs taken at 12 months follow-up of an eye that underwent conventional phaco (on left) and the patient's fellow eye that underwent phaco with the PerfectCapsule system (on right).