Comparison of endothelial cell loss after cataract surgery: Phacoemulsification versus manual small-incision cataract surgery

Six-week results of a randomized control trial

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PURPOSE: To compare endothelial cell loss in cataract surgery by phacoemulsification and by manual small-incision cataract surgery (SICS).

SETTINGS: Tertiary care ophthalmic center, India.

METHODS: A complete ophthalmologic examination and endothelial specular microscopy were performed preoperatively and 1 and 6 weeks postoperatively in patients having cataract surgery. The endothelial cell count (ECC) was calculated manually and automatically using an LSM 12000 specular microscope. Patients were randomly allocated to have SICS or phacoemulsification using a random number table. Phacoemulsification was performed using the stop-and-chop technique and SICS, by viscoexpression.

RESULTS: The study evaluated 200 patients, 100 in each group. The mean preoperative ECC by the manual counting method was 2950.7 cells/mm^2 in the phacoemulsification group and 2852.5 cells/mm^2 in the SICS group and by the automated counting method, 3053.7 cells/mm^2 and 2975.3 cells/mm^2, respectively. The difference at 6 weeks was 543.4 cells/mm^2 and 505.9 cells/mm^2, respectively, by the manual method ($P = .44$) and 474.2 cells/mm^2 and 456.1 cells/mm^2, respectively, by the automated method ($P = .98$). The corrected distance visual acuity at 6 weeks was better than 6/18 in 98.5% of eyes in the phacoemulsification group and 97.3% of eyes in the SICS group.

CONCLUSION: There were no clinically or statistically significant differences in ECC loss or visual acuity between phacoemulsification and SICS, although there was a small difference in the astigmatic shift.

Financial Disclosure: No author has a financial or proprietary interest in any material or method mentioned.

J Cataract Refract Surg 2010; 36:247–253 © *2010 ASCRS and ESCRS*

The proponents of manual small-incision cataract surgery (SICS) and phacoemulsification cataract surgery claim equally good results.[1–3] However, SICS costs much less than phacoemulsification.[3–5] There is concern that manual SICS may be more harmful to the endothelium than phacoemulsification because most maneuvering is performed manually in the anterior chamber; in phacoemulsification, the maneuvering is mechanical and performed in the capsular bag, far from the endothelium. Significant loss of endothelium can lead to corneal decompensation and loss of corneal clarity.[6,7]

Some degree of endothelial cell loss is inevitable after any type of cataract surgery.[6,7] Intraoperative and postoperative complications are generally associated with a greater mean cell loss than that in uneventful cases.[8] In uneventful extracapsular cataract extraction (ECCE), the mean cell loss varies from 6% to 17%; however, in complicated cases, cell loss can exceed 40%.[6,7]

Two important factors in maintaining corneal transparency are the number and the integrity of the corneal endothelial cells. The chief function of this endothelial cell monolayer is to remove fluid from the corneal

Published by Elsevier Inc.

0886-3350/10/$—see front matter
doi:10.1016/j.jcrs.2009.09.023

stroma, keeping it optically clear. The mean endothelial cell count (ECC) in a normal adult cornea ranges from 2000 to 2500 cells/mm,[2] and the count continues to decrease with age. Other factors contributing to a decreased ECC include endothelial abnormalities, such as Fuchs dystrophy, corneal guttate, and iridocorneal endothelial syndrome. Another important cause of a decreased ECC is trauma from cataract surgery.

Cataract extraction is one of the most common surgical procedures performed in ophthalmology. It is also one of the most cost-effective interventions in terms of disability-adjusted life years saved and quality of life restored.[9,10] Providing ECCE to 95% of those who need it (95% coverage level) would avert more than 3.5 million disability-adjusted life years per year globally.[10] In India, approximately 5 million cataract surgeries are performed per year; therefore, it is important to determine which technique is safest to the endothelium. A review of the literature showed that no randomized study has been performed to determine this. Therefore, we performed a randomized controlled trial to determine which surgery is safer and better for the endothelium with respect to maintaining corneal transparency after surgery, keeping in mind that SICS is reported to be almost as effective as and more economical than phacoemulsification.[3,4]

PATIENTS AND METHODS

This randomized controlled trial compared endothelial cell loss after cataract surgery by phacoemulsification and by manual SICS. Both cataract surgery techniques met the accepted standards worldwide and had been used in many parts of the world for more than a decade. All walk-in patients to the hospital with operable cataract were asked to participate. The study was approved by the Ethical Committee, H.V. Desai Eye Hospital, Pune, India. The patient consent form was designed in accordance with the Helsinki Declaration. It was translated into Marathi (the regional language) by 2 independent translators and translated back into English by another 2 translators to ensure validity. The drafts in both languages were shown to the Ethical Committee for approval. A separate patient information sheet was drafted in Marathi to inform the patients of their rights as well as of the potential risks and benefits of the study. Patients were free to withdraw from the study and were assured that the study would not compromise the quality of their eyecare.

Patients who had ocular comorbidity (eg, acute infection, severe inflammation, preexisting corneal opacity, black cataract, non age-related or complicated cataract), another cause of decreased vision (eg, glaucoma or retinal pathology, pseudoexfoliation), or a preoperative ECC of less than 2000 cells/mm^2 were excluded from the study. Patients who were known to have diabetes and those who were unable or unwilling to provide informed consent were also excluded. Patients with mature cataract, white cataract, or cataract up to grade 4 hardness were included in the study.

The outcome measures were the preoperative and 1-week and 6-week postoperative ECC, the difference in the ECC over time, the corrected distance visual acuity (CDVA) at 1 and 6 weeks, the intraoperative and postoperative complications (up to 6 weeks), and postoperative astigmatism.

Bias and Confounding

To minimize bias, patients were masked to the type of surgery. Health workers interviewing patients were also unaware of the type of surgery the patients were to have. Surgeons were masked to the technique until 10 minutes before surgery. Optometrists and ophthalmologists examining the patient postoperatively were not masked to the type of surgery. A different set of ophthalmologists performed the postoperative follow-up and refractions. Randomization was performed to minimize confounding, especially that which would result if the hardness of cataract, preoperative visual acuity, and surgeon skill were used to assign the type of surgery.

Sample-Size Calculation

The sample-size estimation was based on an 80% power to detect a 20% difference in endothelial cell loss at a 5% level of significance and with a 20% loss to follow-up. The sample size meeting this requirement was 100 for each surgical technique (ie, phacoemulsification and SICS).

Ballots drawn from sealed envelopes at the beginning of the surgery were used to randomly allocate each patient to phacoemulsification or SICS. There were 50 ballots for each of 4 surgeons; 25 ballots were for SICS and 25 for phacoemulsification. The randomization (allocation) schedule for each surgeon was generated using the EpiTable application (Epi Info, Centers for Disease Control) at the International Centre for Advancement and Rural Eye Care, L.V. Prasad Eye Institute, Hyderabad, India. The allocation codes were sealed in sequentially numbered, opaque envelopes and kept by the study coordinator. The envelopes were opened 10 minutes before surgery. The participating surgeons were not involved in the care or opening of the envelopes. If the surgeons performed a different technique or converted from phacoemulsification to SICS, the patients were analyzed on an intent-to-treat basis.

Grading of the cataract was not taken into consideration in the patient allotment to surgical technique. Figure 1 shows the flowchart of the patients through the trial.

Submitted: February 2, 2009.
Final revision submitted: August 11, 2009.
Accepted: September 3, 2009.

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S. Krishnaiah, International Centre for Advancement of Rural Eye Care, L.V. Prasad Eye Institute, Hyderabad, India, randomized the schedule. Swapna Deshpande provided biostatistical assistance. Kuldeep Dole, MSc, MS(Ophth), reviewed the manuscript.

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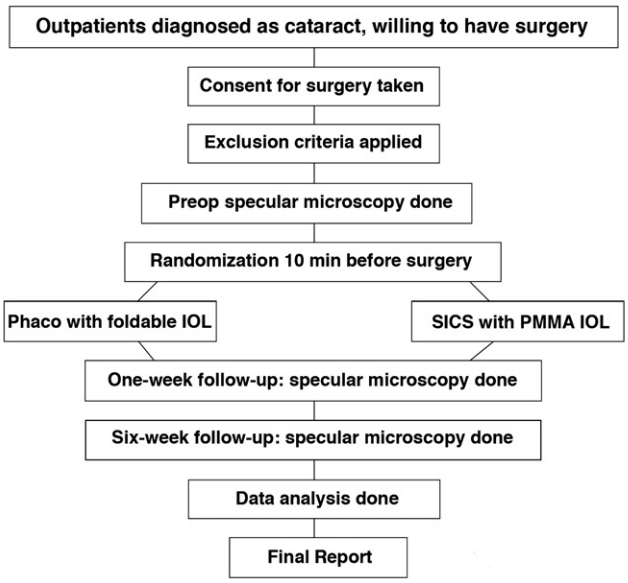

Figure 1. Flowchart of the patients through the methods part of the trial (IOL = intraocular lens; PMMA = poly(methyl methacrylate); SICS = small-incision cataract surgery).

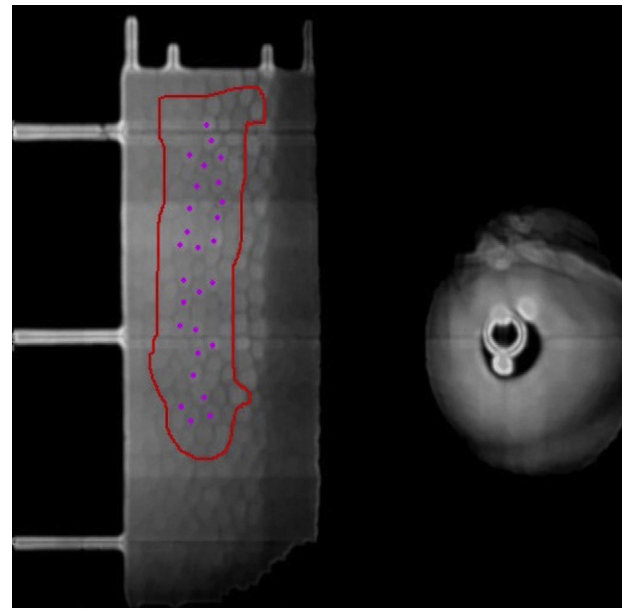

Figure 2. Endothelial cell count using the manual variable-frame method.

Specular Microscopy

The endothelial cell count was performed using an LSM 12000 specular microscope (Bio-Optics), a noncontact device that photographs the endothelium. For the examination, the patient was seated at the appropriate height with his or her chin resting on the chin rest of the instrument. A white dot filter was used with a medium-width light beam. A joystick was used to focus the bright circular reticle on the center of the pupil to take the endothelial photograph from the center of the cornea. The vertical light beam was aligned adjacent to the reticle, and a foot switch was used to begin recording the photographs. The best of 9 photographs was chosen for analysis. If clear photographs were not obtained, the procedure was repeated.

The endothelial cells were counted using a manual variable-frame technique (Figure 2) and by automated counting of cells by the software of the specular microscope (Figure 3). In the variable-frame method, 1 observer counted at least 50 cells to obtain the cell count. In the automated counting method, 1 observer marked the area of interest and the software program counted the cells.

Surgical Technique

Manual Small Incision

After a peribulbar block of 5 cc of lidocaine hydrochloride 2% with (1:20 000) adrenaline was administered, the surgical area was painted and draped and the lids were separated using a wire speculum. A bridle suture was then passed through the superior rectus.

A fornix-based conjunctival flap was made at the superior limbus, and bleeders were cauterized with ballpoint cautery. A 6.0 mm incision was made on the sclera 1.5 mm from the superior limbus. A sclerocorneal tunnel was created with a stainless steel crescent knife. A side port was made at 3 or 9 o'clock based on the surgeon's preference. Hydroxypropyl methylcellulose (HPMC) 2% was injected to fill the anterior chamber. A 26-gauge bent capsulotomy needle was used to create a continuous curvilinear capsulorhexis (CCC). An entry was made through the tunnel using a 3.2 mm keratome. The tunnel was then extended using an extension blade.

Hydrodissection was performed using Ringer lactate solution. The anterior chamber was refilled with HPMC 2% and the nucleus rotated and tumbled into the anterior chamber with a Sinskey hook. The ophthalmic viscosurgical device (OVD) was again injected below as well as above the nucleus to protect the endothelium. The nucleus was then delivered by viscoexpression. The remaining cortical matter was

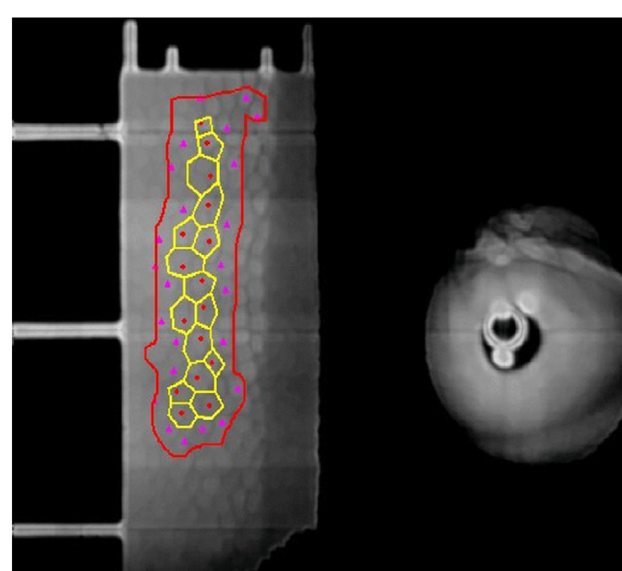

Figure 3. Endothelial cell count obtained by automated counting using the specular microscope's software.

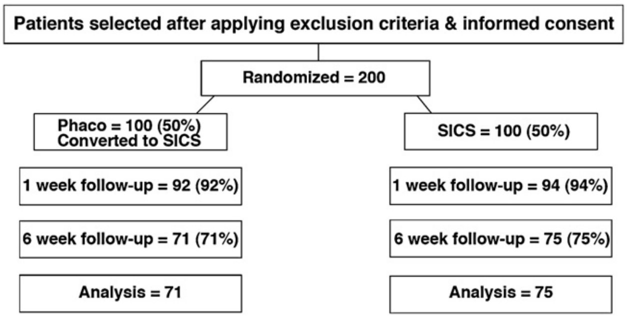

Figure 4. Flowchart of the patients through the results part of the trial (SICS = small-incision cataract surgery).

removed with an irrigation/aspiration (I/A) cannula. The posterior capsular bag was filled with OVD, after which a poly(methyl methacrylate) posterior chamber intraocular lens (IOL) was implanted in the capsular bag. The anterior chamber was then meticulously irrigated to remove the OVD. A subconjunctival injection (0.3 mL) of 10 mg gentamicin and 2 mg dexamethasone was given and antibiotic eye ointment instilled. The eye was then patched.

Phacoemulsification A 3.0 mm clear corneal incision was made on the steeper meridian with a blade. A corneal tunnel was then dissected with a keratome. Two side ports were made at 3 o'clock and 9 o'clock. Sodium hyaluronate 1% was injected through a side port. A CCC was made with a 26-gauge bent capsulotomy needle. An entry was then made through the tunnel using a keratome.

Hydrodissection and hydrodelineation were performed using Ringer lactate solution. The OVD was then injected and the nucleus stabilized with the chopper. Sculpting of the nucleus was done up to 90% depth with the phaco tip. The nucleus was thus fragmented and removed by the stop-and-chop technique. The rest of the cortical matter was removed using an I/A handpiece. The posterior capsular bag was then filled with OVD, and a foldable hydrophilic acrylic posterior chamber IOL was inserted in the capsular bag with a lens injector. The anterior chamber was meticulously irrigated to remove the OVD. A subconjunctival injection (0.3 mL) of 10 mg gentamicin and 2 mg dexamethasone was given and the eye patched after antibiotic eye ointment was instilled.

RESULTS

Two hundred patients were randomized; 100 patients had phacoemulsification and 100 patients, SICS (Figure 4). Ninety-five patients (47.5%) were men. The mean age was 63.7 years ± 8.7 (SD) in the phacoemulsification group and 62.7 ± 10.9 years in the SICS group. There were no statistically significant differences in demographic variables (eg, age, sex) between the 2 groups.

Table 1 shows the mean ECC and endothelial cell loss over time. There was no statistically significant difference in endothelial cell loss between the phacoemulsification group and the SICS group using the manual counting method ($P = .06$) or using the automated counting method ($P = .22$).

Table 2 shows the CDVA before and after cataract surgery. The CDVA at 6 weeks was better than 6/18 in 98.5% of eyes in the phacoemulsification group and 97.3% of eyes in the SICS group

Five phacoemulsification cases were converted to SICS; however, the cases were analyzed an on intent-to-treat basis. In 3 eyes, the case was converted due to zonular dialysis; 2 of these eyes had an anterior chamber IOL and 1 had a posterior chamber IOL. In 2 eyes, the case was converted due to a posterior capsule tear; in 1 of the eyes, a posterior capsule rupture occurred while the IOL was being injected into the eye; the haptic broke, and an anterior chamber IOL was implanted.

Posterior capsule tears occurred in 6 eyes in the phacoemulsification group and 4 eyes in the SICS group. In these eyes, the mean endothelial cell loss was 22.1% at 1 week and 25.9% at 6 weeks in the phacoemulsification group and 11.4% and 25.9%, respectively, in the SICS group.

Table 1. Comparison of endothelial cells loss.

	Mean ECC (Cells/mm^2)			Mean Cell Loss, n (%)*	
		Postop		Postop	
Method/Group	Preop	1 Wk	6 Wk	1 Wk	6 Wk
Manual*					
Phaco	2950.7	2475.5	2407.3	475.2 (16.1)	543.4 (18.4)
SICS	2852.5	2502.2	2346.6	350.3 (12.2)	505.9 (17.7)
Automated†					
Phaco	3053.7	2649.6	2579.5	404.1 (13.2)	474.2 (15.5)
SICS	2975.3	2643.4	2519.2	331.9 (11.1)	456.1 (15.3)

ECC = endothelial cell count
*$P = .06$ at 1 week; $P = .44$ at 6 weeks
†$P = .22$ at 1 week; $P = .98$ at 6 weeks

Table 2. Corrected distance visual acuity over time.

	Phaco Group, n (%)			SICS Group, n (%)		
		Postop			Postop	
Visual Acuity	Preop (n = 100)	1 Wk (n = 92)	6 Wk (n = 71)	Preop (n = 100)	1 Wk (n = 94)	6 Wk (n = 75)
PL/PR–2/60	12 (12.0)	0 (0)	0 (0)	23 (23.0)	2 (2.1)	0 (0)
3/60–5/60	13 (13.0)	0 (0)	0 (0)	12 (12.0)	0 (0)	0 (0)
6/60–6/24	47 (47.0)	3 (3.3)	1 (1.5)	43 (43.0)	4 (4.3)	2 (2.7)
6/18–6/6	28 (28.0)	89 (96.7)	70 (98.5)	22 (22.0)	88 (93.6)	73 (97.3)

PL = light perception; PR = projection of light; SICS = small-incision cataract surgery

Both groups had 7 cases of corneal edema (ie, >5 Descemet folds). In these cases, the mean cell loss was 22.9% at 1 week and 26.8% at 6 weeks in the phacoemulsification group and 17.3% and 19.7%, respectively, in the SICS group.

Other complications included CCC extension in 2 eyes in the phacoemulsification group and in 1 eye in the SICS group, iridodialysis of 1 clock hour in 1 eye in the SICS group, retained cortex in 4 eyes in the phacoemulsification group and 5 eyes in the SICS group, cortex in the vitreous in 1 eye in each group, and a decentered IOL in 1 eye in the phacoemulsification group.

DISCUSSION

Phacoemulsification has been shown to be safe for the corneal endothelium.[2,11,12] The results in our study show that manual SICS is as safe for the corneal endothelium as phacoemulsification, is almost as effective,[1] and is much more economical.[4,5] These factors indicate that SICS can be an alternative to phacoemulsification in areas in which surgeons proficient in phacoemulsification and phaco machines are not available.

A study comparing phacoemulsification and conventional ECCE[2] found a 10% reduction in endothelial cells in both groups. In a study comparing endothelial cell loss after conventional ECCE, manual SICS, and phacoemulsification,[11] the ECC decreased by 4.72%, 4.21%, and 5.41%, respectively, with no significant differences between the 3 groups. Another study[12] evaluated endothelial cell damage after phacoemulsification and planned ECCE with different capsulotomy techniques. The mean cell loss was 11.8% in the phacoemulsification group, 12.8% in the ECCE group in which a CCC was used, and 10.1% in the ECCE group in which a letterbox capsulotomy was used. In our study, the mean cell loss 6 weeks postoperatively was 15.5% in the phacoemulsification group and 15.3% in the SICS group; there was no statistically significant difference between the 2 groups. The higher cell loss in our study is probably because cases of harder cataracts were not completely excluded. The lower loss of endothelial cells in complicated cases in the SICS group may have been due to easier maneuverability, especially of hard cataracts, through the larger incision used in the technique.

The difference was more likely a result of the stop-and-chop technique used for phacoemulsification and the viscoexpression technique used for SICS. In addition, a basic Universal 2 machine (Alcon) was used rather than a newer high-end model. Some surgeons may have performed phacoemulsification in the iris plane and anterior chamber rather than in the bag. Also, white and hard cataracts were not excluded in our study. Before surgery, 60 (30%) of the 200 patients had a preoperative CDVA worse than 6/60 in the operative eye. This is representative of the types of cataract in India and many other developing countries. However, only 1 patient had visual acuity worse than 6/60 postoperatively; 143 (97%) of 146 patients evaluated at 6 weeks had a CDVA better than 6/18. The visual acuity results were similar between the 2 groups.

A major weakness of this study was the short follow-up. However, patients whose data were not available (lost to follow-up, data lost) did not differ from those whose data were available in preoperative variables (age, sex, preoperative acuity, cataract type, operating surgeon), intraoperative variables (type of surgery, surgery time, complications), or 1-week follow-up outcome measures. This indicates that patients attending the follow-ups were representative of the whole sample. A prospective study from the United States evaluating the long-term (5 year) safety of phakic IOLs[13] found that the rate of endothelial cell loss decreased over time. This agrees with findings in shorter studies,[13,14] which report a higher rate of endothelial cell loss than longer studies but a decrease with time. Endothelial cell loss is more likely related to corneal endothelial cell remodeling after the trauma of surgery than to ongoing age-related cell loss.[15] The increase in cells as time increases after surgery may be the result of endothelial cell renewal by corneal stem cells.[16] A study comparing the effect of different phacoemulsification techniques on corneal endothelial cells in Denmark[14] found similar 3-month and 1-year results. In our study, the lack of a statistically significant difference in endothelial cell loss between the 2 techniques at 1 week and 6 weeks is likely to continue over time.

Another shortcoming of this study us that only 1 technique of phacoemulsification and 1 technique of SICS were compared; other techniques may give different results. In addition, stainless steel blades instead of diamond knives were used for phacoemulsification and sodium hyaluronate 1.4% (Healon GV) was not used. An OVD with higher retention may have resulted in less endothelial cell loss.

The major reasons to use OVDs in cataract surgery are to prevent endothelial cell loss, deepen the anterior chamber, mechanically protect against surgical trauma, absorb ultrasound energy, and coat the IOL.[17] Thus, the safety of the endothelium was similar in our study, despite sodium hyaluronate (manufactured in India) being used for phacoemulsification and HPMC being used for SICS. A study in Italy[18] compared HPMC, Healon (sodium hyaluronate 1.0%), Healon GV, and sodium hyaluronate 3.0%–chondroitin sulfate 4.0% (Viscoat) in phacoemulsification and found no significant difference in the postoperative mean endothelial cell loss between the 4 OVDs. Although a newer OVD with higher retention may have caused less endothelial cell loss in our study, the loss would have been the same for either technique.[19–21]

A study in Italy[22] compared endothelial cell damage between scleral tunnel incisions and clear corneal tunnel incisions. The study concluded that scleral tunnels led to less postoperative endothelial cell damage than clear corneal tunnels. Because SICS was performed through the scleral tunnel incision, it may have caused less endothelial cell loss than phacoemulsification performed through a clear corneal tunnel incision. Thus, there was no difference in safety between SICS and phacoemulsification. Proper case selection, diligent surgery, and adequate postoperative care are essential to maintain a clear cornea.

The internal validity of the study was that 5 cases of phacoemulsification converted to SICS were analyzed on an intent-to-treat basis and hard and white cataracts were not completely excluded. The external validity was that the 4 surgeons were trained at different institutes and each had performed more than 5000 SICS procedures (experience >6 years) and more than 1500 phacoemulsification procedures (experience >6 years), a volume comparable to that of most ophthalmologists. For an OVD, HPMC was used in SICS (it is less expensive and locally produced) and sodium hyaluronate was used in phacoemulsification because that is the most common practice in India.

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