A Prospective Randomized Clinical Trial of Phacoemulsification vs Manual Sutureless Small-Incision Extracapsular Cataract Surgery in Nepal

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PURPOSE: To compare the efficacy and visual results of phacoemulsification vs manual sutureless small-incision extracapsular cataract surgery (SICS) for the treatment of cataracts in Nepal.

DESIGN: Prospective, randomized comparison of 108 consecutive patients with visually significant cataracts.

METHODS: SETTINGS: Outreach microsurgical eye clinic. PATIENTS: One hundred eight consecutive patients with cataracts were assigned randomly to receive either phacoemulsification or SICS. INTERVENTION: Cataract surgery with implantation of intraocular lens. MAIN OUTCOME MEASURES: Operative time, surgical complications, uncorrected and best-corrected visual acuity (UCVA), astigmatism, and central corneal thickness (CCT).

RESULTS: Both surgical techniques achieved excellent surgical outcomes with low complication rates. On postoperative day 1, the groups had comparable uncorrected visual acuity (UCVA) \( P = 0.185 \) and the SICS group had less corneal edema \( P = 0.0039 \). At six months, 89% of the SICS patients had UCVA of 20/60 or better and 98% had a best-corrected visual acuity (BCVA) of 20/60 or better vs 85% of patients with UCVA of 20/60 or better and 98% of patients with BCVA of 20/60 or better at six months in the phaco group \( P = 0.30 \). Surgical time for SICS was much shorter than that for phacoemulsification \( P < 0.0001 \).

CONCLUSION: Both phacoemulsification and SICS achieved excellent visual outcomes with low complication rates. SICS is significantly faster, less expensive, and less technology dependent than phacoemulsification. SICS may be the more appropriate surgical procedure for the treatment of advanced cataracts in the developing world. (Am J Ophthalmol 2007;143:32–38. © 2007 by Elsevier Inc. All rights reserved.)

APPROXIMATELY 18 MILLION PEOPLE WORLDWIDE are blind from bilateral mature cataracts. Despite what modern technology has done to advance the treatment of cataracts, the greatest challenge in our field continues to be the large and increasing backlog of cataract blindness in developing countries. In North America and Europe, the focus of cataract research has been directed at exciting, but expensive, new intraocular lens (IOL) and phacoemulsification technology. The best centers in the developing world are adopting this technology slowly, allowing those who can afford it to receive phacoemulsification and foldable IOL surgery. Meanwhile, millions of underprivileged people in developing nations with reversible blindness from mature cataracts go untreated.

Reducing the growing backlog of cataract blindness is a formidable challenge. If services continue to be skewed toward only the wealthiest members of poor countries, then the number of people who will be blind from cataracts will double by the year 2020. Phacoemulsification machines are expensive to purchase and maintain, and they add relatively high costs of surgical consumables. Foldable IOLs are cost-prohibitive for poor populations. The extensive surgical training that is required for phacoemulsification is unrealistic in health care systems with severe shortages of ophthalmologists. Finally, the brunescent hard cataracts that are typical of underserved populations make phacoemulsification significantly more difficult, time consuming, and prone to complication.

Several centers have reported significant success with high volume, low technology, low cost, sutureless small
incision extracapsular cataract surgery (manual SICS). Other studies have shown that manual SICS is clearly more cost effective than the alternatives, which includes large incision extracapsular cataract extraction. Gogate and associates recently reported six-week results from a series of 400 patients in which manual SICS was compared with phacoemulsification. Both surgical methods were shown to be safe and effective.

The Aravind Eye Hospital network reported on a retrospective study of sutureless, manual SICS when performed in an extremely high-volume setting. They reviewed the records of approximately 600 patients, which represented the surgical output of three surgeons during two randomly selected operative days. Before operation, 90% of the patients had vision of better than or equal to 20/240. Despite an average surgical time of 3.75 minutes per case, the surgical complication rate was low, with less than a 1% rate of vitreous loss. By six-weeks after operation, 95% of the patients had achieved a best-corrected visual acuity (BCVA) of better than or equal to 20/60.

Although these reported outcomes are impressive, the follow-up period was short. In addition, phacoemulsification with a foldable IOL is the procedure of choice in industrialized nations. Therefore, an important question is how sutureless, manual SICS with polymethylmethacrylate (PMMA) IOLs would compare to phacoemulsification with foldable IOLs for a similar population with advanced cataracts.

To compare these two surgical methods, we conducted a prospective randomized trial at an outreach microsurgical eye clinic (OMEC) in Nepal. All patients who were included in the study had advanced cataracts with no evidence of other ocular disease. The patients were assigned randomly to receive either phacoemulsification with a foldable IOL or manual SICS with a rigid PMMA IOL. Patients were followed for six months after operation.

Study variables included operative time, intraoperative and postoperative complications, changes in corneal thickness, uncorrected and best-spectacle corrected visual recovery, and keratometric astigmatism. Follow-up rates were excellent in both groups.

METHODS

• SUBJECTS: In May 2005, 108 consecutive Nepalese OMEC patients with operable cataracts and no other discernable ocular disease were assigned randomly to receive either phacoemulsification or manual SICS. Although no formal institutional review board exists at the Tilganga Eye Center, detailed informed consent was obtained from every subject before enrollment in the study.

• INCLUSION AND EXCLUSION CRITERIA: Initial screening examinations consisted of uncorrected visual acuity (UCVA), pinhole visual acuity, pupil and slit-lamp examination, and intraocular pressure measurement. Patients with decreased visual acuity because of cataracts and no other apparent ocular disease received further testing that consisted of manual keratometry, pachymetry, A-scan and B-scan, finger stick blood glucose measurement, and blood pressure measurement.

• RANDOMIZATION: Patients who were cleared for cataract surgery were assigned randomly by picking a ball from a bag that contained one white ball and one black ball. A white ball assigned the patient to phacoemulsification with a foldable IOL, which was performed by one of the authors (D.C.), who is a clinical professor at the University of California, San Francisco. A black ball assigned the patient to sutureless manual SICS, which was performed by another author (S.R.), director of the Tilganga Eye Center in Nepal. After each random assignment, the following patient was assigned automatically to the alternative procedure. The process was repeated until all 108 patients had been assigned; there were 54 total patients assigned to each procedure.

• INTERVENTION: All patients in both groups underwent dilution with topical tropicamide and phenylephrine and were prepped with Betadine solution. A retrobulbar block was administered, and a balanced weight was applied to soften the eye. The patients were brought to the operating room where they were reprepped with betadine and draped for cataract surgery. Biometry was performed before the operation on all patients with the use of a Javal Schiotz keratometer (Haag-Streit, Bern, Switzerland) and an Alcon biophysics Acuscan (Alcon Laboratories, Inc, Orlando, Florida, USA) for axial length calculations and determination of IOL power.

In the phacoemulsification group, all surgery was performed by Dr David Chang, a leading teacher of phacoemulsification surgery in the United States. Dr Chang has performed more than 10,000 cataract extractions with the phacoemulsification technique, which includes multiple trips to India and Nepal where he has operated on many advanced cataracts. Dr Chang’s surgeries were performed through a temporal clear corneal incision that was fashioned with a diamond keratome. A Zeiss OPMI operating microscope (Carl Zeiss Meditec, Jena, Germany) was used. A capsulorrhesis was performed in every eye, and trypan blue dye was used, if needed, to visualize the capsule. Advanced Medical Optics (AMO) Vitrax (Santa Ana, California, USA), a dispersive viscoelastic, was used for each case. The AMO Sovereign phacoemulsification machine with WhiteStar technology was used to perform a phacoemulsification chop technique in every eye. After cortical clean-up, each eye received a foldable IOL that was injected through the un-enlarged phacoemulsification incision. The AMO Clariflex three-piece silicone IOL (with a truncated Opti-edge) was used, unless the calculated power was not available. In this case, a foldable
hydrogel IOL that was manufactured at the Tilganga Eye Center was used. With the exception of one case of posterior capsule rupture in which the incision was enlarged to remove the nucleus, none of the eyes required sutures.

Manual sutureless small incision extracapsular cataract extraction was performed by our previously described technique with the use of a temporal approach. After a limited peritomy and light wetfield cautery, a 6 to 7 mm scleral tunnel incision was created with a crescent blade, starting 1.5 to 2.0 mm behind the limbus. This incision was widened to approximately 9 mm as it was carried forward 1.0 to 1.5 mm into clear cornea. A bent 27-gauge needle was used to create a V-shaped capsulotomy. A 3.0 mm metal keratome blade was used to open the entire internal lip of the tunnel incision. An irrigating simcoe cannula that was designed especially with a 21-gauge infusion and a corrugated concave edge was used to hydrodissect, loosen, and float the nucleus into the mouth of the tunneled incision, through which it was then expressed. All cortical material was removed with the simcoe cannula. A single-piece PMMA IOL was inserted into the capsular bag. The base of the anterior capsule flap was transected with a long Vannas scissor, and the flap was removed with the aspirating cannula. A watertight wound was confirmed by reinflating the eye with balanced salt solution. No sutures were placed, and the conjunctiva was apposed with cautery.

All patients in both groups received the same postoperative medication regimen, beginning with topical ciprofloxacin and dexamethasone and a sterile dressing at the conclusion of surgery. After operation, all patients received a combination ciprofloxacin and dexamethasone eye drop every two hours, beginning on the first postoperative day and then five times per day for the next week. The drop usage was then tapered and continued three times per day for a total of five weeks.

● MEASUREMENT OF SURGICAL TIME: Three separate time trials were conducted. For each time trial, the surgeons performed five consecutive cataract extractions using their assigned technique in immediate succession. Elapsed running time was recorded, starting from the end of the preceding case and continuing through the completion of the next five consecutive cases. The total running time was divided by five to determine the average case time, which included both operating and turnover time. For the remainder of the study, both surgeons began cases simultaneously, with the manual SICS table waiting for the phacoemulsification table to begin each case.

● FOLLOW-UP AND END POINTS: Patients were monitored on postoperative days 1 and 5, weeks 3 and 6, and postoperative months 3 and 6. Parameters that were measured were UCVA and BCVA, keratometry, and central corneal thickness (CCT). All postoperative visual acuities and refractions were obtained by ophthalmic assistants who were masked to the treatment group and had not been involved in the preoperative portion of the study. Patients were then examined at the slit-lamp by a physician.

● COST ANALYSIS: At the conclusion of the trial, data on cost of equipment and consumables for each technique were collected and analyzed.

### RESULTS

BASELINE CHARACTERISTICS OF THE 54 PATIENTS IN THE PHACOEMULSIFICATION AND 54 PATIENTS IN THE MANUAL SICS GROUPS WERE COMPARABLE (Table). The sample size of 108 was the number of patients who met the inclusion criteria and who opted to participate in the study during one site visit (G.T., S.R., D.C.). Preoperative visual acuity was similar in both groups. In the phacoemulsification group, 12 of 54 patients (22.2%) had an uncorrected acuity of hand motions or worse, compared with 13 of 54 patients (24.1%) in the SICS group ($P = .819$). The average visual acuity of the 42 remaining patients in the phacoemulsification group was 20/300. The average visual acuity of the remaining 41 patients in the SICS groups was 20/353 ($P = .681$).
Approximately one half of the phacoemulsification cases required trypan blue dye to visualize the anterior capsule. Intraoperative or postoperative complications were rare in both groups. There were no cases of posterior capsule rupture in the manual SICS group. In the phacoemulsification group, there was one instance of a radial tear in the capsulorrhexis because of poor corneal visibility. Surgery was completed successfully in this eye with capsular bag implantation of a foldable IOL. The fragments were then removed through an enlarged incision with a lens loop. After a bimanual pars plana anterior vitrectomy, the IOL was placed in the sulcus with capsulorrhexis capture of the optic. The incision was closed with simple interrupted 10-0 nylon sutures. This patient did not require any further surgical intervention, and her BCVA was 20/30 at the six-month follow-up visit.

Both groups achieved excellent visual results (Figures 1 to 4). The two groups showed no statistically significant difference in UCVA or BCVA at the six-month follow-up examination. Eighty-nine percent of the manual SICS group had better than or equal to 20/60 UCVA, compared with 85% of the phacoemulsification group at the six-month follow-up visit (Mantel Haenszel Chi-square test, modified Ridit score; \( P = .30 \)). Ninety-eight percent of both the manual SICS group and the phacoemulsification group attained BCVA of better than or equal to 20/60 at six months.
the six-month follow-up visit. Initial visual recovery was better in the patients who underwent manual SICS, with 50% of the patients seeing better than or equal to 20/30 uncorrected on postoperative day 1 vs 30% in the phacoemulsification group (two-sided Wilcoxon two sample test; P < .028). This difference equalized by three weeks. At six months, logarithm of minimal angle of resolution analysis of final refracted visual acuity showed the phacoemulsification group being slightly better, with 94% of the patients seeing better than or equal to 20/30 vs 89% in the manual SICS cohort (Mantel Haenszel Chi-square test, modified Ridit score; P = .028). At six months, UCVA was better than or equal to 20/30 in 54% of the phacoemulsification group vs 32% for the manual SICS group (P = .295).

Postoperative corneal edema was determined individually by calculation of the difference between pre- and postoperative CCT measurements. The differences were then averaged within each group. On postoperative day 1, the phacoemulsification group had an average increase of 70 μm in CCT vs 9 μm in the manual SICS cohort. Edema decreased by day 5 to 29 μm and 4 μm in the phacoemulsification and manual SICS groups, respectively. By postoperative week 3, CCT had returned to baseline in both groups.

Clinical grading of posterior capsular opacification (PCO) varied significantly between groups. At the six-month follow-up visit, 26 of 46 patients (56.5%) in the manual SICS group vs 41 of 48 patients (85.4%) in the phacoemulsification group had no PCO (P = .203). Of the remaining 20 patients in the manual SICS group, 12 patients were graded as 1+ PCO, and eight patients were graded as 2+ PCO. In the phacoemulsification group, seven patients were graded as having 1+ PCO, and no patients were found to have 2+ PCO.

At the final examination, there was no statistical difference in keratometric astigmatism between the two groups. The average keratometric astigmatism was 0.88D in the manual SICS group and 0.70D in the phacoemulsification group (P = .12). A vector analysis was not performed. Because only averaged keratometric data were recorded before the operation for each patient, further analysis was not performed on astigmatic change.

Time trials significantly favored the manual SICS group over the phacoemulsification group, with average case-plus-turnover times of 9.0 minutes for manual SICS vs 15.5 minutes for phacoemulsification (Wilcoxon rank sum test; P < .0001).

The per-case cost of surgical consumables was much greater for phacoemulsification at 70 US dollars (USD) vs 15 USD for manual SICS. The increased cost per case included the more expensive foldable acrylic IOL at a cost of 52 USD, compared with the 5 USD one-piece PMMA lens for manual SICS. Phacoemulsification tips, sleeves, test chambers, large volumes of infusion fluid, and trypan blue dye were also used exclusively for the phacoemulsification technique.

The surgical equipment that was required for phacoemulsification was also much more costly than the equipment that was used for SICS. An AMO sovereign with Whitestar technology was obtained at a cost of 70,000 USD, and a high-quality operating microscope (Visu 210; Zeiss), at a cost of 52,000 USD, was used. The manual SICS cases, in contrast, were performed under a Zeiss 1FR operative microscope that cost 9,200 USD. Finally, phacoemulsification requires a constant source of reliable electricity and maintenance by trained personnel.

**DISCUSSION**

**BOTH PHACOEMLSIFICATION AND SICS ACHIEVED EXCELLENT VISUAL OUTCOMES IN OUR PROSPECTIVE RANDOMIZED STUDY OF 108 EYES WITH ADVANCED CATARACTS IN A NEPALESE OMEC.** Both groups had a low complication rate, with only one case of posterior capsule rupture with vitreous loss (in the phacoemulsification group). There were 17 cases of transient hyphema; all but one case occurred in the manual SICS cohort. Vision on postoperative day 1 was better with manual SICS. This correlated with the greater increase in corneal thickness in the phacoemulsification group. Although phacoemulsification times were not recorded and endothelial cell counts were not measured in this study, the increased corneal edema that was seen in the phacoemulsification group is understandable, given the advanced nuclear cataracts in this patient population. All of the corneas in both groups were clear by three weeks after surgery and had returned to their baseline CCT.

The World Health Organization defines visual impairment as vision worse than 20/60. With the use of this standard of better than or equal to 20/60, both techniques were extremely successful at restoring functional vision. Most importantly, both surgical methods were equally successful at achieving unaided visual acuity of better than or equal to 20/60. In

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**FIGURE 4.** Best-corrected visual acuity (BCVA) by functional level at six months after operation. Stratified into groups with visual acuity of 20/20, better than or equal to 20/30, and better than or equal to 20/60 in the phacoemulsification group (Phaco; black) vs the manual sutureless small incision extracapsular cataract surgery (SICS; gray) group.
remote developing world settings, it is often difficult for poor patients to obtain refractions or corrective spectacles after cataract surgery. The same is true for obtaining replacement lenses if their spectacles break or become scratched. Therefore, good uncorrected vision is particularly important in this population. In our manual SICS cohort, 91% of the patients achieved this level of uncorrected vision on postoperative day 1, and 89% of the patients achieved this level at six months after the operation. In the phacoemulsification group, 78% of the patients saw better than or equal to 20/60 on the first day and increased to 85% at six months. Western studies have reported better initial UCVAs after phacoemulsification. However, the cataracts in this study were more advanced than those reported in these Western studies. With best spectacle correction, all but one patient in each group saw better than or equal to 20/60 at six months.

Our manual SICS results for both corrected and uncorrected vision are slightly better than previously reported series. We have found that induced astigmatism has been reduced by adopting a temporal approach for manual SICS surgery. This has resulted in significantly better uncorrected visual acuities in our experience. We previously performed a prospective controlled trial at the Til-ganga Eye Center on patients who were bilaterally blind in both eyes from mature cataracts (unpublished data). These patients received manual SICS surgery by the same surgeon (S.R.), but with a temporal incision on one eye and a superior incision on the other. The temporal incision was superior in terms of induced astigmatism and uncorrected vision.

At six months, vision outcomes were better in the phacoemulsification group, with more patients having better than or equal to 20/30 vision both with and without correction. The phacoemulsification group had 54% of the patients seeing better than or equal to 20/30 without correction and 94% with correction vs 32% unaided and 89% of the patients with spectacles seeing better than or equal to 20/30 in the manual SICS eyes. Although only 85% of the patients returned for their six-month examination, this trend was already apparent at week 3 when, with nearly 100% follow-up, 35% of the phacoemulsification group saw better than or equal to 20/30 without correction vs 31% of the patients who underwent manual SICS. Ninety-four percent of the phacoemulsification eyes refracted to better than or equal to 20/30 against 81% of the manual SICS cohort at three weeks.

There are several possible reasons for the better visual acuities in the phacoemulsification group compared with the manual SICS group. The most likely explanation may be the greater rate of posterior capsule opacification in the manual SICS group. A foldable silicone IOL with a truncated edge that is placed in the capsular bag with an overlapping capsulorrhexis would be expected to have a lower incidence of PCO compared with a one-piece PMMA IOL with a rounded edge and a discontinuous anterior capsulotomy. In addition, the use of cortical cleaving hydrodissection with a capsulorrhexis may have better facilitated thorough cortical clean-up in the phacoemulsification group. One patient in the manual SICS group returned for his six-month visit with 20/60 best-corrected acuity and significant posterior capsular opacity. After yttrium-aluminum-garnet (YAG) capsulotomy, the vision improved to 20/30. This was the only YAG capsulotomy to be performed in either group during the six-month study period. The capsulorrhexis in the phacoemulsification group also insured 100% in the bag placement of the IOL. The V capsulotomy that was used in the manual SICS technique left a few of the IOLs partially or completely in the sulcus on follow-up examination. However, at the six-month follow-up visit, none of the lenses were noted to be decentred. Although the difference in average keratometric astigmatism between the two groups was very small at 0.18D, the astigmatism that is induced by the 6.5-mm scleral tunnel may play a role in some of the patients who underwent manual SICS having slightly inferior vision. We did not obtain data that would allow us to perform vector analysis of the induced astigmatism. Finally, the iris manipulation that is required with manual SICS to prolapse these large nuclei into the anterior chamber may have resulted in greater inflammatory and cystoid macular edema, compared with the phacoemulsification group. We did not perform fluorescein angiography or ocular coherence tomography to confirm this hypothesis. Although every study patient in both groups was treated with topical steroid for five weeks, none of the patients received topical nonsteroidal anti-inflammatory medications, which might have reduced the overall incidence of cystoid macular edema. Future studies are needed to investigate these possibilities.

Surgical speed and efficiency are paramount in the developing world because surgical cataract capacity is limited by the shortage of experienced ophthalmic surgeons. Visual recovery rates aside, manual SICS proved to be a much faster surgical technique than phacoemulsification for the advanced cataracts typical of our Nepalese OMEC population. Thanks to experienced assistants and the use of multiple sterile instrument sets, case turnover time was equally fast for both techniques.

As previously mentioned, Venkatesh and associates reported outcomes from a high-volume manual SICS study at the Aravind Eye Hospital system in which three surgeons performed >600 surgeries, with an average time of <4 minutes per case, including turnover time. This was accomplished by having the surgeon alternate between two operating tables. While the surgeon was operating on one table, turnover time was minimized by prepping the next patient on the adjacent table. The surgical outcomes and complication rates reported in this group of 600 patients was excellent.

The surgeon who performed manual SICS (S.R.) from our study typically averages 8 to 10 cases per hour using a single long operating table. The surgeon is seated in the middle and operates from a temporal approach on every
eye. To expedite turnover, patients who require right eye surgery alternate with those who need left eye surgery. In this way, consecutive patients can be placed simultaneously on the table, with their legs pointed away from each other. As soon as one patient sits up after surgery, the next patient immediately lays down with his or her head on the same operating pillow. In this way, the surgeon never changes location from one case to the next. Using the identical operating table configuration and a slight variation of the manual SICS technique, another of the authors (G.T.) has been able to perform >150 cases in one nine-hour stretch, which is an average of 17 cases per hour. This ability to perform manual SICS rapidly and with high daily volumes is critical for maximizing surgical efficiency and productivity in a developing world setting.

Manual SICS is far less expensive to perform than phacoemulsification. Added to the large capital expense of the phacoemulsification machine are the per case costs of consumables (phacoemulsification tips, sleeves, and tubing) and ongoing maintenance. Phacoemulsification also requires a dependable source of electricity, which is not always available in remote locations, such as rural Nepal. In contrast, the only expensive equipment that is necessary to perform manual SICS is an operating microscope, which can be powered by a battery or small diesel generator. Finally, high-quality PMMA lenses that are manufactured in Nepal or India are roughly one-tenth the cost of foldable IOLs that are imported from the United States. The use of locally produced IOLs, viscoelastics, and pharmaceuticals has lowered the cost of manual SICS surgery at the Tilganga Eye Center to <20 USD per case.

In conclusion, in the hands of experienced surgeons, both phacoemulsification and manual SICS achieved excellent visual outcomes, with low complication rates in patients with advanced cataracts who were examined at a rural Nepalese OMEC. Manual SICS was a faster and less expensive technique than phacoemulsification. For this reason, we believe that manual SICS is the more appropriate technique for addressing the large and growing backlog of blinding cataracts in the developing world.5,6

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REFERENCES


Biosketch

Sanduk Ruit, MD, is the director of the Tilganga Eye Center in Kathmandu, Nepal and co-director of the Himalayan Cataract Project, which strives to eradicate preventable and treatable blindness in the developing world through education and establishing effective infrastructure for quality eye care. Dr Ruit has personally performed over 40,000 cataract surgeries and has been an innovator of small incision sutureless extracapsular cataract surgery. He also performs more than 500 phacoemulsification surgeries per year.
Biosketch

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