

Visual Outcomes and Astigmatism After Sutureless, Manual Cataract Extraction in Rural China

Study of Cataract Outcomes and Up-Take of Services (SCOUTS) in the Caring Is Hip Project, Report 1

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Objective: To study the visual acuity and astigmatism of persons undergoing cataract extraction by local surgeons in rural China.

Methods: Visual acuity, keratometry, and refraction were measured 10 to 14 months postoperatively for all cataract cases during 4 months in Sanrao, China.

Results: Among 313 eligible subjects, 242 (77%) could be contacted, of whom 176 (73%) were examined. Of those who were examined, mean \pm SD age was 69.3 ± 10.5 years, 66.5% were female, 35 had been operated on bilaterally at Sanrao, and 85.2% had a preoperative presenting visual acuity of 6/60 or worse. Presenting and best-corrected postoperative acuity in the eye that was operated on were 6/18 or better in 83.4% and 95.7%, respectively. Among 27 fel-

low eyes operated on elsewhere, 40.7% had a presenting acuity of 6/18 or better and 40.7% were blind ($P < .001$). Mean \pm SD postoperative astigmatism did not differ between 211 eyes that were operated on (-1.13 ± 0.84 diopters) and 109 eyes that were not (-1.13 ± 1.17 diopters; $P = .27$). Presence of operative complications (8.5%) and older age were associated with worse vision; bilateral surgery was associated with better vision.

Conclusions: These results confirm the effectiveness of skill transfer in this setting, with superior outcomes to most studies in rural Asia and to eyes in this cohort operated on at other facilities.

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CHINA, A COUNTRY WITH nearly 24 000 ophthalmologists,¹ has among the lowest cataract surgical rates in Asia, at 446 cases per million population per year in 2004.² In recent years, approximately 550 000 cataract surgeries have been reported in China annually. This represents 24 cases per ophthalmologist, some 15% of patients requiring operations.² Lack of surgery for cataract remains the leading cause of blindness in population-based surveys.³⁻⁵ Reasons for the low cataract surgical output include the fact that surgical fees often exceed what patients feel they are able to pay,⁶ only half of Chinese ophthalmologists are trained to perform surgery,^{7,8} and physicians are concentrated in cities,⁹ while some 70% of Chinese individuals still dwell in rural areas.

An additional reason for low uptake of cataract surgical services has been poor outcomes, with 2 population-based studies in

rural China reporting a prevalence of postoperative blindness of approximately 50% after cataract surgery.^{5,10} The majority of eyes operated on in both studies had undergone intracapsular cataract extraction, with rates of pseudophakia varying from 6% to 39%. Many patients with aphakia were without spectacle correction.^{5,10}

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In view of these statistics and the enormous number of people involved, there is a need to improve the availability and affordability of cataract surgery associated with a high proportion of good (visual acuity $> 6/18$) visual outcomes. One of us (D.S.C.L.) has initiated Project Vision (the eye care component of Caring is Hip, a medical relief program supported by the Li Ka Shing Foundation), in which eye centers offering quality cataract surgery are established in rural China. Initial program inputs include modern equipment

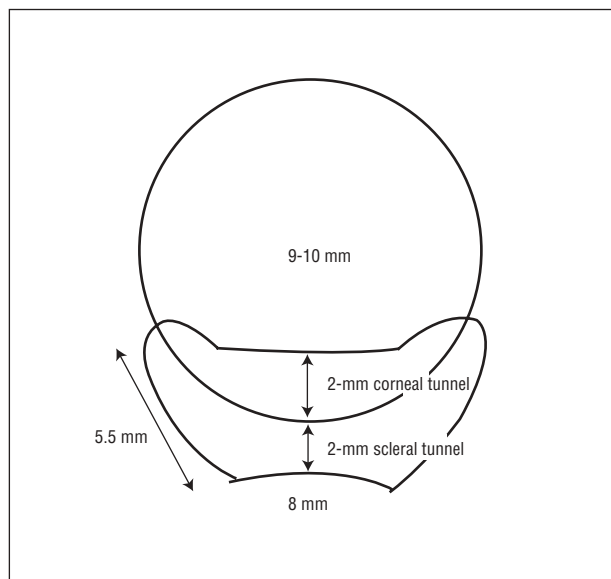


Figure 1. A schematic diagram of the sutureless, large-incision, manual cataract extraction surgical technique.

and intensive training of local village doctors. The program is designed to create sustainable cataract services at rural government hospitals in China by instituting a system of affordable surgical fees (currently \$90, about 10%-20% of prevailing rates). The first center was established in 2004; currently 5 centers are in operation, with more than 5000 cataract operations completed.

The choice of cataract surgical technique is critical to the success of the program. Requirements include low cost (eg, without the initial investment and recurrent costs of phacoemulsification), ease of skill transfer, and quality of outcomes. One of us (D.S.C.L., assisted by S.K.R.) adapted sutureless, large-incision, manual cataract extraction (SLIMCE) based on modifications of existing manual cataract techniques. Principal features include a large incision (8 mm) to reduce the risk of endothelial trauma during nucleus delivery, a long tunnel (4 mm) to ensure a self-sealing of the wound, and a posteriorly placed temporal incision to reduce corneal astigmatism.¹¹

The Study of Cataract Outcomes and Up-Take of Services (SCOUTS) is an intensive study of visual and refractive outcomes, comorbidities, and uptake of postoperative services in approximately 300 persons undergoing SLIMCE surgery by 2 recently trained, local, nonophthalmologist physicians in Guangdong, China. This cohort of patients consisted largely of rural-dwelling persons able to pay modest fees for cataract surgery. The current report provides data on visual outcomes and corneal astigmatism as an indicator of the success of skill transfer in this setting.

METHODS

Two local physicians who had not previously performed eye surgery underwent 6 months of intensive training in SLIMCE surgery with placement of an intraocular lens (IOL), provided by The Chinese University of Hong Kong and the Joint Shantou International Eye Center (JSIEC). The Li Ka Shing Foundation furnished equipment and supplies for cataract surgery.

All training and subsequent surgeries took place at the Sanrao Hospital, a government-run, village-level facility in Sanrao, China. All study procedures were approved by the institutional review board of the JSIEC, which serves as a parent hospital for the Sanrao facility. Informed consent was obtained from all study subjects, and the Declaration of Helsinki was followed throughout the study.

All patients undergoing cataract surgery at Sanrao received a preoperative examination, with measurement of visual acuity and dilation of the pupil. Intraocular lens power was calculated for a postoperative target refraction of -0.5 diopter (D) on the basis of axial length (SW-2000S; Tianjin Suwei, Tianjin, China), keratometric (KR-8800; Topcon Optical [H.K.] Limited, Hong Kong, China) measurements, and the SRK/T formula. Data recorded for all patients included age, sex, preoperative presenting acuity, IOL power, and presenting acuity on the first postoperative day.

The 2 surgeons began to perform independent surgery on August 8, 2005. All patients undergoing surgery in at least 1 eye between this date and December 31, 2005, were contacted by telephone and invited to return to the Sanrao Hospital for an examination and questionnaires, which were administered between October 16 and 21, 2006, 10 to 14 months after surgery. Data for patients undergoing surgery in the second eye after December 31, 2005, were also included in the study data set. However, eyes operated on previous to the surgeons becoming independent on August 8, 2005, were not included. Data on laterality of surgery (unilateral vs bilateral) are only available for subjects who were examined and not for the subjects who underwent only telephone interview or those who could not be contacted. Having had at least 1 eye operated on for cataract at Sanrao between the period of August 8 and December 31, 2005, was the only study eligibility criterion.

SURGICAL TECHNIQUE

Surgery was performed under sterile conditions after retrobulbar anesthesia. A temporal peritomy was performed and a half-scleral thickness, temporal, corneoscleral tunnel was fashioned, 8 mm in width and 4 mm in length (**Figure 1**). A continuous-tear capsulorrhexis was carried out after staining with locally sourced trypan blue. The lens nucleus was mobilized by gentle rotation under viscoelastic (also locally available) and removed intact through the tunnel incision with the aid of an anterior chamber maintainer and lens vectis. Cortical cleanup was carried out with a Simcoe cannula, and a rigid polymethyl methacrylate IOL (Model KC60BN; Alcon Laboratories, Fort Worth, Texas) was placed in the capsular bag. The corneoscleral wound was left unsutured, and 2.5 mg of dexamethasone disodium phosphate and gentamicin sulfate aqueous solution were administered by subconjunctival injection. Surgical time was not recorded as a variable in this study because our principal emphasis was on the quality of outcomes.

POSTOPERATIVE OCULAR EXAMINATION

All eligible patients underwent measurement of distance and near visual acuity in each eye without correction and with habitual refraction, if available. Automatic refraction (KR-8800) with subjective refinement by an ophthalmologist was carried out at near and distance in each eye. Distance visual acuity was measured using an illuminated tumbling E Snellen chart at a distance of 6 m, and near visual acuity was measured at 33 cm with a handheld chart. Intraocular pressure (AT550; Leica Microsystems GmbH, Wetzlar, Germany) and corneal curvature (KR-8800) were measured. A slitlamp examination (YZ5F1; Suzhou Liuliu, Suzhou, China), including indentation goni-

oscopy by a fellowship-trained glaucoma specialist (N.G.C.), was carried out, and both pupils were dilated (after yttrium aluminum garnet [YAG] laser iridotomy if the angle was felt to be closed in 1 or more quadrants). Examination of the lens/IOL and fundus with a 90-D lens and indirect ophthalmoscopy with a 20-D lens were carried out in both eyes. Evidence of the following complications was recorded by the examiner: abnormalities of wound architecture, presence of an irregular pupil, iris adherent to the wound, vitreous visible in the anterior chamber, decentration of the IOL, visible capsular rent, or cystoid macular edema. Patients with visual acuity at near or distance improving by 2 or more lines on refraction were offered prescriptions that could be filled at an optical shop nearby. Those thought by the examining ophthalmologist to have visually significant posterior capsular opacification were offered YAG capsulotomy (Visulas YAG III; Carl Zeiss Far East Co Ltd, Kowloon, Hong Kong, China) on the spot.

“Presenting visual acuity” was defined as the visual acuity without spectacles or with the patient’s own habitual refraction, whichever was better. “Best-corrected visual acuity” was defined as the visual acuity after refraction and/or YAG capsulotomy (measured the next day) if indicated.

STATISTICAL METHODS

Corneal astigmatism measurements underwent squared transformation to correct skewness. Generalized estimating equations (GEE) models were used to assess the association between potential predictors and each of the outcome variables: postoperative presenting visual acuity, postoperative best-corrected visual acuity, and corneal astigmatism. The GEE models accounted for intracorrelated data from subjects with bilateral surgery. The PROC GENMOD (Release 9.1; SAS Institute, Cary, North Carolina) was used to fit GEE models. All statistical tests were 2-sided and a P value $< .05$ was considered statistically significant.

RESULTS

Among 313 eligible subjects, 242 (77%) could be contacted by telephone; 176 (73%) of those contacted were examined (**Figure 2**). Examined subjects had a mean \pm SD age of 69.3 ± 10.5 years, 117 (66.5%) were female, and 150 (85.2%) had been blind (presenting visual acuity $\leq 6/60$) in the first eye operated on prior to surgery (**Table 1**). Examined and contacted patients did not differ significantly from those who could not be contacted with regard to age, sex, preoperative presenting visual acuity, or day 1 postoperative presenting visual acuity in the eye that was operated on (Table 1).

Among 176 examined patients, 109 had only one eye operated on by the 2 Sanrao surgeons, 32 had one eye operated on by the 2 Sanrao surgeons and the other eye operated on by others (5 fellow eyes were operated on by Sanrao surgeons not participating in the study and 27 were operated on locally outside the Sanrao facility), and 35 had both eyes operated on by the 2 Sanrao surgeons. Thus, a total of 211 eyes operated on by the 2 recently trained Sanrao surgeons were examined and are considered in the following analyses.

Presenting postoperative visual acuity in the eye that was operated on was 6/18 or better in 83.4% (176 of 211) and 6/60 or worse in 3.3% (7 of 211) of the study eyes. For the 27 eyes operated on elsewhere, the correspond-

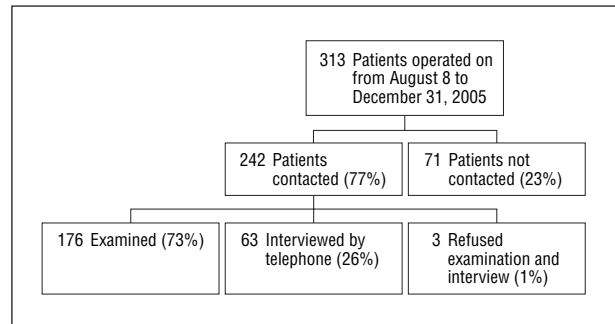


Figure 2. Persons contacted and examined among a cohort of 313 patients operated on for cataract in Sanrao, China.

ing figures were 40.7% (11 of 27) and 40.7% (11 of 27) ($P < .001$, χ^2 test). Two hundred two of 211 study eyes (95.7%) had best-corrected acuity of 6/18 or better, and 4 (1.9%) had an acuity of 6/60 or worse.

Evidence of operative complications (see “Methods” section for complete list) was present in 8.5% (18 of 211) of eyes operated on at Sanrao (7.3% for surgeon A and 9.8% for surgeon B; $P = .69$). The prevalence of complications among 27 eyes operated on elsewhere was 15 of 27 (55.6%; $P < .001$, χ^2 test).

The mean radius of corneal curvature and mean corneal astigmatism did not differ significantly ($P = .20$) between 211 eyes that were operated on and 109 eyes that were not (excluding eyes operated on outside the study) (**Table 2**). However, there was a statistically significant ($P < .001$, χ^2 test) trend toward with-the-rule astigmatism in eyes that were operated on (Table 2).

In GEE models of factors potentially predictive of presenting distance visual acuity among 211 eyes that were operated on, older age ($P < .001$), evidence of operative complications ($P = .04$), higher spherical equivalent (absolute value) ($P < .001$), and astigmatism ($P < .001$) were associated with worse presenting visual acuity (**Table 3**). Sex, laterality of surgery (unilateral vs bilateral), surgeon, preoperative visual acuity, and operative date (as an indicator of surgeon experience) were not associated with presenting visual acuity in this model.

In the model for best-corrected visual acuity in the eye that was operated on, older age ($P = .002$) and intraoperative complications ($P = .057$, borderline) were associated with worse outcomes and bilateral surgery, with better outcomes ($P = .02$) (Table 3).

Surgeon A ($P = .005$) was associated with less postoperative astigmatism among eyes that were operated on and pterygium, with more astigmatism; laterality, age, operation date, and surgical complications were not significantly associated with the amount of astigmatism (**Table 4**).

COMMENT

More than 85% of the eyes in this study were blind prior to surgery, and nearly 96% had best-corrected visual acuity of 6/18 or better, a visual outcome identified by the World Health Organization as indicative of “good” results for cataract surgery. The corresponding figure for presenting postoperative visual acuity was 83% with vi-

Table 1. Characteristics of the Cohort of 313 Persons Operated On for Cataract in Rural China^a

Characteristic	No. (%)				P Value
	All (n = 313)	Examined (n = 176)	Interviewed But Not Examined (n = 63)	Failed to Contact or Refused Interview (n = 74)	
Age, y, mean ± SD	69.8 ± 10.3	69.3 ± 10.5	71.3 ± 9.3	70.4 ± 10.5	.32 ^b
Sex					
F	198 (63.3)	117 (66.5)	36 (57.1)	45 (60.8)	.37 ^c
M	115 (36.7)	59 (33.5)	27 (42.9)	29 (39.2)	
Preoperative visual acuity					
≤ 6/60	275 (87.9)	150 (85.2)	58 (92.1)	67 (90.5)	.21 ^d
> 6/60- < 6/18	30 (9.6)	18 (10.2)	5 (7.9)	7 (9.5)	
≥ 6/18	8 (2.6)	8 (4.5)	0	0	
Postoperative visual acuity (day 1)					
≤ 6/60	5 (1.6)	2 (1.1)	0	3 (4.1)	.40 ^d
> 6/60- < 6/18	20 (6.4)	11 (6.3)	3 (4.8)	6 (8.1)	
≥ 6/18	287 (92.0)	163 (92.6)	59 (95.2)	65 (87.8)	

^aVisual results refer to the first eye operated on in the case of subjects operated on bilaterally.

^bOne-way analysis of variance.

^cPearson χ^2 test.

^dFisher exact test.

Table 2. Distribution of Corneal Astigmatism an Average of 1 Year After Surgery in 176 Patients in Rural China^a

Characteristic	Eyes Operated On (n = 211)	Eyes Not Operated On (n = 109)	P Value ^b
Radius of corneal curvature, D, mean ± SE	44.7 ± 1.7	44.6 ± 1.7	.60
Corneal astigmatism, D, mean ± SD	-1.13 ± 0.84	-1.13 ± 1.17	.27
Axis of corneal astigmatism, ^c No. (%)			
0-30 or 150-180 (with the rule)	123 (58.3)	32 (29.4)	
31-59 or 121-149 (oblique)	41 (19.4)	16 (14.7)	
60-120 (against the rule)	47 (22.3)	61 (56.0)	< .001 ^c

^aEyes operated on by surgeons other than the 2 participating physicians from Sanrao, China, are excluded from this analysis.

^bP values of the comparisons between eyes operated on and eyes not operated on were assessed using generalized estimating equations modeling.

^c"Against the rule" vs "with the rule."

visual acuity of 6/18 or better. Among 35 eyes that were operated on in this cohort with presenting visual acuity of 6/18 or worse, 3 (8.6%) could be improved to 6/18 or better by YAG capsulotomy, and 26 of 35 (74.3%) were improved with refraction.¹²

These results are on par with figures for postoperative visual acuity from large studies in Sweden,¹³ the United States,¹⁴ and the United Kingdom.¹⁵ Our results are also comparable with the best surgical outcomes reported from urban centers in Asia, such as Aravind Eye Hospital¹⁶ in southern India, which found best-corrected visual acuity of 6/12 or better in 96% of patients after extracapsular cataract extraction.

However, more than 60% of Asia's population, nearly 40% of the world's people,¹⁷ dwell in rural areas. A number of studies have now reported poor outcomes from ru-

ral cataract surgery in Bangladesh,¹⁸ Pakistan,¹⁹ China,¹⁰ and India.²⁰⁻²³ The proportion of patients blind (visual acuity < 6/60) after surgery has ranged from 28% to 53%,^{10,18-20,23} with good visual results (presenting visual acuity ≥ 6/18 or 6/12) seen in only 15% to 35%.^{10,18-20} Among the patients we observed who had been operated on at other local centers, only 41% had good presenting vision and 41% were blind at presentation. Stratifying by location, 73% of patients operated on in rural areas were blind in the eye that was operated on, as compared with 0% of eyes operated on in urban areas (data not shown).

Predictors of poor outcomes in the earlier studies included refractive error and uncorrected aphakia (the most important cause in studies that gave specific data,^{10,18,19,21,22} ranging from 53%-60%^{18,19} of eyes blind after cataract surgery), ocular comorbidities (28%-29%),^{18,19} surgical complications^{10,18-20} (12%-21%),^{18,19} and rural residence.²⁰ All of these problems are more frequent in rural areas because of inadequate training, poor access to refractive services, and the difficulty in achieving good follow-up.

Reasons for superior outcomes obtained by local surgeons operating under prevailing conditions in local facilities in the current study, as pointed out in early studies by Ruit et al,²⁴ may include the use of modern equipment and materials, including IOLs biometrically selected on the basis of axial length and keratometry, and a high-quality operating microscope (Leica 841; Leica Microsystems GmbH, Wetzlar, Germany). Of equal importance was the successful skill transfer to nonophthalmologists, the result of an intensive training program involving practice surgery on 100 animal eyes, assisting a senior surgeon on 100 cases, and direct supervision by senior surgeons on 100 additional cases. The entire operative team, including physicians and nurses, received a combination of on-site instruction and regular visits to an international facility, the JSIEC in nearby Shantou, for practical training in areas such as sterilization technique. Though the initial inputs required were substantial, the program is currently self-

Table 3. Potential Predictors of Postoperative Presenting Visual Acuity and Best-Corrected Visual Acuity Among 211 Eyes Operated On for Cataract in Rural China

Independent Variable	β Value	Standard Error	P Value
Postoperative Presenting Visual Acuity			
Male sex	0.0436	0.0356	.22
Age	-0.0065	0.0017	<.001
Surgeon	-0.0316	0.0353	.37
Operation date	0.0004	0.0003	.30
Bilateral surgery	0.0417	0.0315	.19
Intraoperative complications	-0.1084	0.0521	.04
Preoperative visual acuity (> 6/60 vs \leq 6/60)	0.0266	0.0399	.504
Refraction (spherical equivalent)	-0.1043	0.0256	<.001
Corneal astigmatism	0.3588	0.0772	<.001
Postoperative Best-Corrected Visual Acuity			
Male sex	0.0995	0.0555	.07
Age	-0.0102	0.0033	.002
Surgeon	-0.0379	0.0545	.49
Operation date	0.0003	0.0005	.54
Bilateral surgery	0.1170	0.0510	.02
Intraoperative complications	-0.1711	0.0898	.057
Preoperative visual acuity (> 6/60 vs \leq 6/60)	0.0743	0.0697	.29

sustaining through funds obtained from low-cost surgery, in part through the use of the SLIMCE technique, which does not generate the recurring costs of phacoemulsification surgery. Social marketing resulting from these excellent results clearly played an important role in the uptake of surgery; as reported elsewhere (N.G.C., S.K.R., K.C., W.W., Shaofang Lin, MD, Shaomian Chen, MD, L. J. Chen, MD, K. Liu, MD, I. C. Hu, MD, and D.S.C.L., unpublished data, August 8, 2005-October 21, 2006), 85% of subjects operated on at Sanrao had a close friend or relative operated on at the same facility.

The 8.5% prevalence of surgical complication in our study was approximately half that reported in other studies from rural Asia.^{18,19} The 2 surgeons in the current study had carried out 100 cases under supervision prior to operating independently, whereas some other series in Asia report higher complication rates for surgeons at an earlier phase of training, while still operating under supervision.²⁵ However, even in the current setting, the presence of complications was still associated with worse presenting and best-corrected visual acuity. This underscores the need to keep operative complications at the lowest possible level through intensive training and surgeon feedback. Higher spherical equivalent refractive error was also associated with worse presenting vision. We are currently analyzing refractive, visual, and visual function outcomes in the SCOUTS cohort to attempt to identify an optimum postoperative target refraction for this rural population.

A high prevalence of significant postoperative astigmatism has been reported in cataract operations involving larger surgical wounds, including intracapsular cataract extraction (≥ 2 D of astigmatism in 14%-58%),²⁶ extracapsular cataract extraction (mean 1.6-3.5 D depending on technique and time after surgery),²⁷⁻²⁹ and sutureless, manual cataract extraction (2.07 D at ap-

Table 4. Potential Predictors of Postoperative Corneal Astigmatism Among 211 Eyes Operated On for Cataract in Rural China

Independent Variable	β Value	Standard Error	P Value
Male sex	0.0393	0.0326	.23
Age	0.0007	0.0016	.68
Surgeon	0.0896	0.0308	.004
Operation date	-0.0003	0.0003	.29
Bilateral surgery	-0.0202	0.0295	.49
Intraoperative complications	0.0028	0.0589	.96
Preoperative visual acuity (> 6/60 vs \leq 6/60)	0.0404	0.0416	.33
Pterygium	0.1211	0.0599	.04

proximately 1 year)³⁰ when compared with phacoemulsification with a 3-mm or smaller wound. Other authors have reported astigmatism in the range of 1 D with sutureless, manual cataract extraction surgery,^{31,32} but generally using wounds of 5 to 6 mm, as opposed to the 8 mm used in our protocol.

The mean \pm SD postoperative astigmatism of 1.13 \pm 0.84 D in the current study did not differ significantly from that observed in eyes that were not operated on. The magnitude of astigmatism was comparable with that previously reported for Chinese eyes undergoing phacoemulsification with a 3.2-mm wound (1.29 D).³³ This may be in part because of our use of a posterior, temporal scleral wound. There was a shift toward with-the-rule astigmatism in eyes operated on in this study. However, recent results appear to suggest that the visual impact of astigmatism does not differ significantly with the axis.³⁴ Residual astigmatism was still significantly associated with worse presenting visual acuity in the eye that was operated on. The presence of a significant 0.34-D difference in the residual astigmatism between the 2 surgeons in our study suggests further reduction in postoperative astigmatism may be possible with SLIMCE.

The results of the SCOUTS study must be understood within the context of study limitations. Although the astigmatism for the eyes operated on and not operated on in this study did not differ significantly in magnitude, data on preoperative astigmatism were not available, and thus, it is not possible to use vector analysis, the preferred method for gauging the impact of surgery on astigmatism.³⁵ Nonetheless, from the standpoint of patient visual outcomes, the fact that postoperative astigmatism was low in this cohort is a meaningful result. Preoperative and postoperative endothelial cell counts would also have provided a useful index of surgery-associated corneal trauma but could not be accomplished because of limited resources.

The proportion of patients contacted and examined was not 100%. Thus, it is possible that the examined patients were not fully representative of all persons operated on at Sanrao. It is encouraging that examined and interviewed patients did not differ significantly from those who could not be contacted with regard to age, sex, preoperative presenting visual acuity, or day 1 postoperative presenting visual acuity in the eye that was operated on. The fact remains, however, that the study was

not population based, and application of these results to the population as a whole is likely not appropriate.

Though the results presented herein confirm the success of skill transfer in this setting, they are to some extent dependent on the 2 surgeons involved. It is certainly possible that a randomized controlled design where patients underwent surgery by the 2 trained surgeons or by other local doctors would have provided even stronger direct evidence of the efficacy of our training. However, the very significant difference in the rate of poor outcomes between the trained surgeons and those generally operating in the community, a fact of which we were aware at the outset of the study, would likely have posed insurmountable ethical barriers to such an approach. Generalizability of these results to other programs in rural Asia must necessarily be open to question. Neither doctor had previously performed ocular surgery prior to initiating training. However, both were physicians, and our results are not representative of non-physician surgeons. Similar training has now been completed by rural doctors at 4 other sites in China and is ongoing at 2 additional sites. An intensive prospective assessment of surgical outcomes is under way.

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