The Initial Complication Rate of Phacoemulsification in India

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Purpose. This study was designed to investigate the feasibility of teaching experienced surgeons to perform phacoemulsification in India, a cataract-endemic area. Complications occurring during surgery and the first postoperative day were documented and evaluated.

Methods. During a 1-month period, at the Aravind Eye Hospital in Madurai, India, the first 100 consecutive cataract operations performed by each of three experienced surgeons (a total of 300 cases), using phacoemulsification were prospectively evaluated. Multiple logistic regression was used to identify factors associated with intraoperative and postoperative complications.

Results. The mean age of patients was 57.4 ± 9.3 years. The median best corrected preoperative visual acuity was 20/80. Mean surgical and phacoemulsification times were 15.8 ± 3.7 minutes and 2.2 ± 1.5 minutes, respectively. Complications occurred in 65 (21.7%) eyes. The most common was a rent in the posterior capsule, occurring in 40 (13.3%) eyes. There were significant variations in complication rate and in surgical time among the surgeons. The risk of experiencing a complication decreased as the number of phacoemulsifications performed increased. An increased risk of complications was associated with worse preoperative visual acuity and increasing patient age.

Conclusions. With each successive case, the chances of experiencing a complication decreased 1%. Acceptable results were obtained within 1 month of performing the first phacoemulsification. Invest Ophthalmol Vis Sci. 1997;38:2331–2337.

The elimination of global blindness is a complex and daunting problem. The number of treatable cataract-blind throughout the world is increasing, particularly in developing nations. According to the World Health Organization's definition of blindness (best corrected acuity less than 20/400 in the better-seeing eye), there are an estimated 5 million cataract-blind in India, 2 million in China, and at least 3 million in Africa; and the numbers are increasing.1-10 Despite the treatable nature of the disease, new cases of cataract blindness develop in approximately 3.8 million people in India annually, whereas the number of cataract operations performed approaches only 2 million.1 Thus, the number of persons for whom sight is restored through cataract surgery is only approximately one half of those newly blind from cataract.

Techniques for cataract surgery in the developing world have changed dramatically during the last decade. For years, intracapsular cataract surgery was the procedure of choice,5 and less than a decade ago it was considered impractical to perform large-scale extracapsular cataract extraction or posterior chamber intraocular lens implantation.5 Technology and surgical skills have increased with the development of extracapsular cataract extraction.11-17 Sophisticated factories now manufacture intraocular lenses in India, Africa, Nepal, and China.18 These low-cost, high-quality intraocular lenses are available to patients who can not afford the costs of surgery or of an intraocular lens. As a result, extracapsular cataract extraction with intraocular lens implantation has become widely used in many parts of the developing world.

The use of phacoemulsification, however, is rela-
tively new in these areas. It requires not only an operating microscope and constant electrical power, but also a large initial capital outlay for equipment and continued capital outlays for certain consumables (hand pieces and tubing). The skills needed to learn phacoemulsification may be more advanced than those needed to perform extracapsular cataract surgery. In the more developed nations, phacoemulsification is currently taught during residency training, with constant supervision and monitoring by experienced instructors—a type of personal instruction that is rarely available in the less developed nations. Additionally, phacoemulsification is more difficult to master than conventional extracapsular cataract surgery, because it requires coordination of hands and feet simultaneously.

However, several features of phacoemulsification give it the potential for obtaining better results than have been produced by extracapsular cataract extraction in the developing world. The smaller incisions used in phacoemulsification require less suture material, which is expensive and in short supply in many regions. In addition, the risk of serious vision loss related to perioperative trauma may be less with smaller cataract incisions. Shorter rehabilitation time, less astigmatism, and the decreased need for suture removal may result in reduced need for postoperative care. Phacoemulsification can be considered worthwhile if it can be done quickly and safely, and if it has a short learning curve.

To begin to determine the feasibility of using phacoemulsification in the setting of a developing country, we performed the following prospective study to evaluate the immediate complications after phacoemulsification among three experienced extracapsular cataract surgeons. The study’s goals were to quantify the risk of surgical complications for these surgeons during each surgeon’s initial 100 cases, to identify factors associated with an increase in risk, to estimate the time required to perform the procedure, and to determine whether adequate surgical results could be obtained after only 100 surgical cases. We made no attempt to evaluate final visual acuity in the patients or the relationship between initial complications and long-term visual acuity.

**METHODS**

The Aravind Eye Hospital is a large, modern, urban institution in the Tamil Nadu state of southern India. Approximately 80,000 cataract operations are performed in the hospital annually. The study involved three senior, highly skilled surgeons from this institution, each having previously performed more than 20,000 extracapsular cataract extractions, with the implantation of posterior chamber intraocular lenses. The training in phacoemulsification before the study began was identical for all three surgeons. Each had seen instructional videos, attended courses, and practiced parts of the technique on animal eyes. The first 100 patients undergoing phacoemulsification by each of the surgeons had a preoperative evaluation that included a comprehensive eye examination, a measurement of best corrected Snellen visual acuity, a dilated lens and fundus examination, and the recording of demographic information. In each patient the surgeons selected eyes in which they believed phacoemulsification was appropriate. The technique was attempted only in eyes with a fair red reflex, or in eyes with mature cataracts that were thought to have soft nuclei. Eyes with glaucoma, pseudoexfoliation, or prior ocular surgery were not selected for phacoemulsification during the course of the study. All 300 cases were performed within a 1-month period, using the same brand of phacoemulsification machine. Institutional human experimentation committee approval was granted and informed consent was obtained from each patient. The study followed the tenets of the Declaration of Helsinki.

Pupils were widely dilated before surgery, and peribulbar anesthesia was used without neuroleptic agents. All incisions were made with a 5.5-mm scleral tunnel. Various viscoelastics from many countries, depending on availability, were used. The surgical technique included continuous-tear capsulorrhexis, using a bent needle or utrata forceps, hydrodissection, and bimanual divide-and-conquer nucleus removal. Sutures were not used to close the wound. Depending on availability, a one-piece or a three-piece polymethylmethacrylate posterior chamber intraocular lens was implanted in all eyes.

At the time of surgery, the following information was recorded: time from initial incision to injection of postoperative antibiotics, phacoemulsification time (normalized for phacoemulsification power), total surgical time (including incision, cortical removal, and closure), and occurrence of intraoperative complication. Patients were examined on the first postoperative day, and the following information was recorded: uncorrected visual acuity (refraction was not performed at that time), the presence and grade of corneal edema, superficial punctate keratopathy, anterior segment flare and cells, vitreous hemorrhage, iris prolapse, hyphema, or choroidal detachment. The severity of corneal edema, superficial punctate keratopathy, and anterior segment flare and cells were graded as none, mild, moderate, or severe.

Univariate comparison among surgeons of surgical time and phacoemulsification time was obtained by one-way analysis of variance and the global F-test for equality of means. Comparison of unadjusted complication rates was achieved by Fisher’s exact test from
TABLE 1. Surgical Time and Phacoemulsification Time (Normalized for Phacoemulsification Power) for Each Surgeon (Mean ± Standard Deviation)

<table>
<thead>
<tr>
<th>Surgeon</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical time (min)</td>
<td>18.1 ± 3.8</td>
<td>14.5 ± 3.1</td>
<td>15.1 ± 3.3</td>
<td>&lt;0.00005</td>
</tr>
<tr>
<td>Phacoemulsification time (min)</td>
<td>2.6 ± 1.3</td>
<td>1.6 ± 0.7</td>
<td>2.3 ± 2.0</td>
<td>&lt;0.00005</td>
</tr>
</tbody>
</table>

3 × 2 contingency tables. Multivariate analysis of surgical and phacoemulsification time was done by least squares linear regression, with time as the outcome to evaluate differences among surgeons, as well as potential associations with patient age, increased number of phacoemulsifications performed, and severity of cataract using preoperative visual acuity in logMAR (−log[Snellen fraction]) scale as a surrogate. In this conversion, a doubling of the visual angle was assumed for each decreasing step of visual acuity (counting fingers, hand movements, and light perception) below the lowest recordable Snellen acuity of 20/400.

Factors associated with the occurrence of an intraoperative complication were determined by multivariate logistic regression. An intraoperative complication was defined as having one or more of the following occur during surgery: posterior capsule tear, zonular dehiscence, loss of the nucleus into the posterior segment, intraoperative hyphema, iris prolapse, damage to the iris caused by the phacoemulsification tip, or suprachoroidal hemorrhage. The learning effect on the risk of complication was estimated by including the case sequence number (1 to 100) as a predictor variable in the logistic regression model. Logistic regression was also used to determine the effect of an increased number of prior phacoemulsifications performed on the risk of developing moderate to severe postoperative corneal edema, adjusting for surgeon, the patient’s age, and preoperative visual acuity.

RESULTS

Three hundred eyes of 300 patients were enrolled in the study. The mean patient age was 57.4 ± 9.3 years (range, 28 to 79 years). One hundred sixty-one patients (53.7%) were men. The median preoperative visual acuity was 20/80. Seventy-five eyes (25%) had preoperative acuity between 20/100 and 20/300, and 71 eyes (23.7%) had acuity less than 20/400. There were no differences among the three surgeons in preoperative characteristics.

The time required for cataract surgery is important in a less developed country, because the numerous cataract-blind people dictate that each physician can only spend a limited time with each patient. The mean surgical and phacoemulsification times for each surgeon are shown in Table 1. The results of the multiple linear regression model of surgical time indicate that the expected surgical time, after adjusting for age and preoperative visual acuity, was 3.9 minutes shorter for surgeon 2 compared with that of surgeon 1 throughout the study (P < 0.00005) and that neither of these surgeons showed a significant change in surgical time with increasing experience (P > 0.2). The expected surgical time of surgeon 3 was only 1.2 minutes shorter than that of surgeon 1 during the first 25 cases (P = 0.21) but decreased significantly with experience (P = 0.02) and had declined by 2.8 minutes by case 100. The surgical time increased with patient age, after adjusting for surgeon, increased number of prior phacoemulsifications performed, and differences in preoperative visual acuity (P = 0.0002), with an observed increase of 0.8 minutes per 10-year increase in age.

A similar analysis of phacoemulsification time demonstrated that, after adjusting for age and preoperative visual acuity, surgeon 2 required less time for phacoemulsification than either of the other surgeons (P < 0.00005). There was no significant decline in time with increasing experience for any of the surgeons. A 10-year increase in patient age was associated with a 0.3-minute increase in time required for phacoemulsification, after adjusting for surgeon, increased number of prior phacoemulsifications performed, and preoperative visual acuity (P = 0.002).

A rent in the posterior capsule was the most frequent intraoperative complication, occurring in 40 (13.3%) eyes (Table 2). This did not preclude the placement of a posterior chamber intraocular lens in any eye. The term "iris damage" refers to any inadvertent contact between the phacoemulsification tip and the iris, causing iris disfiguration. This complication occurred in 12 (4%) eyes. Reversible iris prolapse during surgery, possibly related to suboptimal wound construction occurred in 11 (3.7%) eyes. Although neither of these two complications involving the iris was serious, both were included because they are related to surgical skill in manipulating the probe and in wound construction. Only three eyes had either vitreous in the anterior chamber or loss of the nucleus into the vitreous cavity. All of these complications occurred during the first 50 cases of each surgeon. In addition, all cases of zonular dehiscence occurred in the first 50 cases.
TABLE 2. Proportion of Patients With Intraoperative Complications by Surgeon

<table>
<thead>
<tr>
<th>Surgeon</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posterior capsule tear</td>
<td>19</td>
<td>9</td>
<td>12</td>
<td>0.12</td>
</tr>
<tr>
<td>Iris damage</td>
<td>7</td>
<td>3</td>
<td>2</td>
<td>0.25</td>
</tr>
<tr>
<td>Iris prolapse</td>
<td>11</td>
<td>0</td>
<td>0</td>
<td>&lt;0.00005</td>
</tr>
<tr>
<td>Zonular dehiscence</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>&lt;0.00005</td>
</tr>
<tr>
<td>Hyphema</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>—</td>
</tr>
<tr>
<td>Nucleus lost into vitreous</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>—</td>
</tr>
<tr>
<td>Any complication</td>
<td>35</td>
<td>15</td>
<td>14</td>
<td>&lt;0.00005</td>
</tr>
</tbody>
</table>

* Any complication is defined as the occurrence of one or more specific intraoperative complication; N = 300 (100 per surgeon).

The results of the logistic regression model of the risk of development of an intraoperative complication confirmed the presence of significant differences in risk between surgeons after adjusting for differences in the patient’s age and preoperative visual acuity (Table 3). These results did not relate to case selection. There was no difference in the number of higher risk cases (older patients, vision less than 20/400, and female gender) in the first 50 cases for any surgeon, compared with the case mix in each surgeon’s last 50 cases. The adjusted odds ratio of 0.989 (95% confidence interval [CI; 0.979, 0.999]; P = 0.04) associated with a one-case increase in prior phacoemulsifications performed corresponds to a 65.5% decrease in the odds of a complication occurring in case 100 compared with those in case 1 (Fig. 1). Inclusion of interaction terms in the model indicated that there was no significant difference in the magnitude of the learning effect among surgeons (P = 0.78). In addition to the number of prior phacoemulsifications performed, increasing patient age and worse preoperative visual acuity were independently associated with a greater risk of intraoperative complication. The adjusted odds ratio for a 10-year increase in patient age was 1.38 (95% CI [1.05, 1.75]; P = 0.05). A 1-unit increase in preoperative logMAR, which corresponds to a 10-fold increase in visual angle (20/400 versus 20/40) was associated with an adjusted odds ratio of 1.35 (95% CI [1.05, 1.75]; P = 0.02). Female gender was associated with an increased complication rate but was of borderline statistical significance (P = 0.10). Given the fairly large magnitude of the point estimate (adjusted odds ratio = 1.64), gender was included in the final model.

Central corneal edema was noted on the first postoperative day in 86 (28.8%) eyes and was graded as moderate or severe in 29 (9.7%) eyes (Table 4). An increase in the number of prior phacoemulsifications performed was associated with a decreased risk of this complication after adjusting for surgeon, age, and preoperative visual acuity, with an adjusted odds ratio per case of increased experience of 0.978 (95% CI [0.963, 0.993]; P = 0.003). An association between increasing patient age and moderate to severe corneal edema was found but was of borderline statistical significance (adjusted odds ratio for a 10-year increase in the pa-
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TABLE 4. Proportion of Patients With Postoperative Complications by Surgeon
[N = 300 (100 per Surgeon)]

<table>
<thead>
<tr>
<th>Complication (%)</th>
<th>Surgeon</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Central corneal edema*</td>
<td>14</td>
<td>9</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Hyphema</td>
<td>4</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

* Central corneal edema graded as moderate or severe was considered a complication.

We observed no serious perioperative complications (wound leak, intraocular lens dislocation, endophthalmitis, vitreous hemorrhage, choroidal detachment, or hemorrhage). However, the expected rate is much less than 1%; therefore, it is not unusual that we did not see these complications.

DISCUSSION

This is the first prospective study in a developing nation evaluating the complications associated with the initial experience of phacoemulsification and the ability, through experience, to decrease the rate of complications within a relatively short time. We evaluated phacoemulsifications performed by three high-volume extracapsular cataract surgeons in a developing nation, without guidance from an accomplished assistant. We are able to determine all of the following: quantification of the various risks of complications during this learning phase, detection of factors associated with these complications, evaluation of eyes in which the risk of developing complications is highest, and determination of the chances of each complication decreasing with increasing experience.

It is encouraging to see that all surgeons had fewer complications with increasing experience. The chance of any complication’s occurring decreased by 1% with each additional surgical procedure. Further work is needed to decide whether this rate of improvement continues or is altered with increasing experience.

Many of our results seem intuitively obvious. Some surgeons are better than others. This difference in ability did not directly correlate with the actual time required for surgery or phacoemulsification. Also, ability to decrease required time depends on the surgeon. The decreasing rate of intraocular inflammation and moderate or severe corneal edema with increasing experience appears logical. The skills of manipulating the nucleus away from the posterior capsule, iris, and the corneal endothelium are probably related to increasing skill.

The complication rates that we observed are likely to be related to the surgeons’ overall level of skill and experience. As a result, the individual experiences of surgeons in the developing world who learn this technique would be expected to differ from our results. Given the extensive experience in extracapsular cataract surgery of the three surgeons in the study, our results are probably indicative of the best outcome that could be expected during the learning process. In addition, the rate of decline of the risk of complication may be related to the surgeon’s prior skill and the short time during which the first 100 cases were performed. The complication rate could decline more slowly for surgeons with less extracapsular cataract surgical experience, or for those who learn the procedure during a longer period.

An important means of reducing the risk to patients during the learning phase of phacoemulsification is appropriate patient selection. We have identified several factors that are associated with an increased risk of complication (Table 3). A strong association was found between the risk of complication and decreasing visual acuity. Higher patient age was also found to be a significant risk factor for intraoperative complication, independent of its association with decreased visual acuity. Age-related alteration in ocular tissues—the lens capsule independent of cataract density, for example—may account for this observation. Regardless of the mechanism of this effect, it appears that the risks associated with phacoemulsification in this and possibly other regions of the developing world can be reduced by selecting younger patients for the procedure, particularly during the learning phase. A deficiency of our study is the failure to classify cataracts according to grade or severity. Such classification is important, because it would help to determine better which types of cataracts are likely to be more difficult for phacoemulsification.

Although not statistically significant, there may be a trend for women to have more complications than men (P = 0.1). This observation has not been previously reported and could be an outlier, or it may be that there are nutritional or metabolic factors related to gender that could make phacoemulsification more difficult in women.

The complication rates observed were acceptable enough to consider further evaluation of phacoemulsification as a safe alternative to conventional extra-
capsular cataract extraction in the developing world, at least in settings comparable to that described in this study—particularly true, given the rapid decline in the observed risk of complication during the first 100 cases. Appropriate patient selection, taking patient age and cataract density as risk factors for intraoperative complications, can reduce the occurrence of adverse outcomes during the learning phase.

Our study has some limitations. It was not designed to answer the questions of speed of visual rehabilitation or long-term success—it dealt only with complications detected during surgery or on the first postoperative day. We do not know whether the initial complications we report correlate with a long-term decrease in visual acuity. However, many of the complications are minor and are unlikely to result in marked visual loss. The results obtained in our study may or may not be generalizable to other groups learning phacoemulsification, to less experienced surgeons, to other surgeons with prior experience in phacoemulsification, or in other geographic regions. The availability of a tutor\(^{17,18,19,22}\) (a faculty member who helps a resident during a case) might also influence the types and number of intraoperative complications.

We did not attempt to compare prospectively the complications associated with phacoemulsification and traditional extracapsular cataract surgery. The current results may be viewed in the context of the existing complication rate of extracapsular surgery in developing countries\(^{11-16,29}\) and the complication rate of phacoemulsification in the hands of experienced surgeons in the United States.\(^{24-26}\) The patients who underwent cataract surgery in the current study are relatively young (but similar to the age at surgery in other developing nations). The median best corrected preoperative visual acuity was 20/80, with 25% of eyes having visual acuity of 20/400 or worse. Obviously, patients with better preoperative visual acuity were preselected for phacoemulsification rather than extracapsular surgery because more than one half the eyes undergoing extracapsular cataract surgery in another study had count-fingers or worse visual acuity.\(^{15}\) However, the preoperative visual acuity in the current study was worse than that seen in the national study of cataract surgery outcomes in the United States.\(^{24,25}\)

As would be expected, our complication rate was higher than that in the United States study.\(^{24,25}\) In that our surgeons were learning, the phacoemulsification procedure. But the rate was lower than that in another recent study involving one surgeon’s initial experience with phacoemulsification in India.\(^{17}\)

Results in our pilot study suggest that phacoemulsification can be learned relatively quickly in such developing nations as India. We must express many reservations. First, the cost effectiveness of phacoemulsification must be proved. In developing nations, there are limited fiscal resources available for health care. Studies comparing the direct and indirect costs of high-volume phacoemulsification and conventional extracapsular cataract surgery are needed.

Additional utilization studies are needed to evaluate the allocation of physicians and paramedical professionals during phacoemulsification. Health-care planners should realize that not all cataracts can be attacked using phacoemulsification nor should all surgeons be advised to perform the procedure.

We raise ethical questions of how best to train surgeons in developing nations in newer surgical techniques. It would be ideal to have a tutor present at the time of surgery and to have the use of an extensive video library for better training. Practice surgery in animals might also be a better way to learn. However, these training tools are rarely available in less developed nations. We are currently developing training programs to resolve these problems and, we hope, to minimize complications during the initial training period.

**Key Words**
cataract, complications, lens, phacoemulsification, posterior capsule, surgery

**References**


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