Results of Sutureless Manual Small Incision Cataract Surgery in a Low-Income Population

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Abstract:

Purpose: To analyze the results, intraoperative complications and reoperations of sutureless manual small incision cataract surgery (mSICS).

Setting: Visualiza Clinic, Guatemala, Guatemala.

Design: retrospective cohort study

Methods: This study comprised 2296 consecutive mSICS performed during 2017. Results, complications and reoperations were tabulated and analyzed.

Results: The median of preoperative best corrected visual acuity (BCVA) was .84 logMar (.47, 1.8) (6/43 or 20/140 Snellen), it improved to .17 logMar (.09, .3) (6/9 or 20/30 Snellen) (p<0.001). The overall complication rate was 3.12%. When excluding patients with preoperative known zonular weakness, the complication rate was 1.72%. The most common complication was posterior capsule rupture (1.5%). Reoperation rate was 3.51%, the most common indication was wound exploration due to hypotony or shallow anterior chamber (0.9%).

Conclusions: In hands of experienced surgeons, mSICS is a high volume, low cost, high quality procedure, making it a very good alternative in terms of cost-effectiveness.

Keywords: small incision cataract surgery, intraoperative complications, reoperations.

Background

Although phacoemulsification is considered the standard of care for cataract surgery, a less expensive technique in terms of capital equipment investment, equipment maintenance, and disposable costs per case seems like the best option in developing countries with low-income populations, where a growing backlog of blindness due to cataract has resulted from insufficient health-care access and resources.

Sutureless manual small incision cataract surgery (mSICS) may be faster and better suited for the advanced mature cataracts that typify underserved populations. It is considered a high volume, low cost, high quality procedure, making it a very good alternative in terms of cost-effectiveness.

Outcomes of mSICS have been reported in numerous studies mainly from India and Nepal, however these had small populations. There is no data available regarding Latin-American countries. According to several publications, mSICS outcomes in terms of visual rehabilitation and complications are comparable to phacoemulsification outcomes. Therefore, we decided to collect data from patients than underwent mSICS at the same surgical facility during 2017. We assessed the outcomes in terms of best corrected visual acuity (BCVA), surgical complications and reoperations. Comparing them with the results from other populations as well as with the ones published from phacoemulsification (gold standard).

Methods

Study Design

Single center, retrospective cohort study of 1279 eyes that underwent mSICS. All procedures were performed during 2017 by 7 surgeons with an experience that ranged from 1 to 15 years. Every eye had a visual impairing cataract with no other visual impairing condition. A/B scan was performed prior to surgery. Ultrasound immersion biometry or optical biometry was performed prior to surgery. SRK/T was the formula used for intraocular lens (IOL) calculation. Clinical variables extracted were age, sex, eye, incision site, intraoperative complications, reoperations, preoperative and postoperative BCVA and sphere.

Because some visual acuities were expressed in non-numerical terms, they were assigned a rank/value in logMar scale for their analysis. Then they were converted to decimal scale for classification and comparison with other publications (appendix A).

Levels of visual impairment before surgery were categorized using the World Health Organization (WHO) International Classification of Diseases 11 from 2018 as follows:

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Appendix A. Visual acuity, assigned values for statistical analysis.

<table>
<thead>
<tr>
<th>Snellen</th>
<th>Decimal</th>
<th>LogMar</th>
</tr>
</thead>
<tbody>
<tr>
<td>20/20</td>
<td>6/6 (1)</td>
<td>0.00</td>
</tr>
<tr>
<td>20/25</td>
<td>6/7.5 (0.8)</td>
<td>0.09</td>
</tr>
<tr>
<td>20/30</td>
<td>6/9 (0.66)</td>
<td>0.17</td>
</tr>
<tr>
<td>20/40</td>
<td>6/12 (0.5)</td>
<td>0.30</td>
</tr>
<tr>
<td>20/50</td>
<td>6/15 (0.4)</td>
<td>0.39</td>
</tr>
<tr>
<td>20/60</td>
<td>6/18 (0.33)</td>
<td>0.47</td>
</tr>
<tr>
<td>20/70</td>
<td>6/21 (0.28)</td>
<td>0.54</td>
</tr>
<tr>
<td>20/80</td>
<td>6/24 (0.25)</td>
<td>0.60</td>
</tr>
<tr>
<td>20/100</td>
<td>6/30 (0.2)</td>
<td>0.69</td>
</tr>
<tr>
<td>20/140</td>
<td>6/43 (0.14)</td>
<td>0.84</td>
</tr>
<tr>
<td>20/200</td>
<td>6/60 (0.1)</td>
<td>1.00</td>
</tr>
<tr>
<td>20/400</td>
<td>6/120 (0.3)</td>
<td>1.30</td>
</tr>
<tr>
<td>CD</td>
<td>&gt;0.3</td>
<td>1.80</td>
</tr>
<tr>
<td>MM</td>
<td>&gt;0.3</td>
<td>1.90</td>
</tr>
<tr>
<td>PL</td>
<td>&gt;0.3</td>
<td>2.00</td>
</tr>
<tr>
<td>NPL</td>
<td>&gt;0.3</td>
<td>2.50</td>
</tr>
</tbody>
</table>

CD: counting fingers, MM: hand movement, PL: light perception, NPL: no light perception

- Mild – presenting visual acuity worse than 6/12 (20/40 Snellen)
- Moderate – presenting visual acuity worse than 6/18 (20/60 Snellen)
- Severe – presenting visual acuity worse than 6/60 (20/200 Snellen)
- Blindness – presenting visual acuity worse than 3/60 (20/400 Snellen)

Exclusion Criteria

Patients with any other preoperative vision impairing pathology (moderate – severe non-proliferative diabetic retinopathy, proliferative diabetic retinopathy, age related macular degeneration, other retinal conditions, severe glaucoma, corneal scarring, amblyopia, etc.) Patients who failed to complete at least a 1-month follow-up. Patients who underwent combined procedures (cataract + cyclodialysis). Patients with known history of prior ocular surgery (strabismus, keratoplasty, glaucoma surgery, retina surgery).

Surgical Technique

After sedation administered by an anesthesiologist and peribulbar anesthesia application (1:1 mix of 1% lidocaine, 0.75% bupivacaine + 150 units of hyaluronidase), patients were prepped/draped in the normal fashion. A lid speculum was placed in the eye, a 6mm fornix-based peritomy was performed, followed by light wetfield diathermy on episcleral vessels. When this was completed, a 5.5 – 6mm frown scleral incision with a diamond blade or a 15° scalpel was created starting 1 - 2mm behind the limbus. Figure 1. (Location of both peritomy and scleral incision was decided by the surgeon according to the preoperative keratometry). This incision was carried forward with a crescent blade until the limbus was reached advancing it 1 – 1.5mm into clear cornea. Figure 2. A paracentesis with a 3.2mm keratome blade was performed. In some cases, surgeons used trypan blue to dye the anterior capsule, then the anterior chamber was filled with viscoelastic. Subsequently, the entire internal lip of the tunnel incision was opened in a valved fashion with the 3.2mm keratome blade. Figure 3. Following this, a capsular rhexis using a cystotome was performed. Figure 4. Hydrodissection and cataract luxation to the anterior chamber for posterior cataract extraction using an irrigation vectis was made. Figures 5-6. All cortical material was removed using a 21 simcoe cannula. Figure 7. Then a single piece polymethylmethacrylate (PMMA) lens was introduced in the capsular bag. Figure 8. Finally, the viscoelastic was removed, the paracentesis hydrated, and the main wound checked for any leakage. The conjunctiva was closed using either diathermy or a 10-0 nylon suture. All eyes were shielded once the procedure was finished.
Intraoperative complications were categorized using the Oxford Cataract Treatment Evaluation Team (OCTET) definitions.\(^9\) (appendix B).

**Postoperative Care**

Every patient used combined ciprofloxacin 0.3% + dexamethasone 0.1% or combined tobramycin 0.3% + dexamethasone 0.1% drops every 1 or 2 hours while awake for seven days, then tapered slowly for 1 month unless inflammation did not resolve. Follow-up visits at day 1, 1 week and 1 month were scheduled.

A complete ophthalmologic evaluation was performed including BCVA, IOP measurement with Goldmann tonometer, slit lamp examination and fundoscopy at the 1-month follow-up.

Surgery outcomes in terms of BCVA were categorized using the WHO definition as follows:\(^8\)
- Good – better than 6/18 (20/60 Snellen)
- Borderline – 6/24 (20/100 Snellen) better than 6/60 (20/200 Snellen)
- Poor – worse than 6/60 (20/200 Snellen)

**Statistical Analysis**

Descriptive analysis was made for all the continuous variables. The normally distributed variables are presented with mean and standard deviation (SD), the ones that were not normally distributed are presented with median and interquartile range (IQR). For all the categorical variables we present frequencies and proportions. According to data distribution, paired t-test or non-parametric Kruskal-Wallis test were used to compare continuous variables. Statistical analysis was based on a two-sided significance level. Missing data was handled with available data method. Analysis were made using STATA version 14.2 (StataCorp LLC, Tx, EE. UU.).

**Results**

mSICS was performed in 2296 eyes during 2017. After exclusion criteria application 1279 cases were analyzed. Ultrasound immersion biometry was performed in 84.42% of cases and the remaining 15.57% were made with optical biometry. In 99.3% of the cases SRK/T was the formula used for IOL calculation. Demographic characteristics are presented on Table 1.

Preoperatively 76.7% of patients had at least a moderate visual impairment according to the WHO definition (BCVA worse than 6/18) 29.8% where considered blind (BCVA worse than 3/60). After surgery 96.4% of patients had a good outcome as defined by the WHO (BCVA better than 6/18).

Mean difference of preoperative and postoperative BCVA was 0.81 logMar (95% CI .78 - .84) (p<0.001). The mean postoperative sphere was -0.03 diopters.

In this series, incision was performed superiorly in 64.26% of patients, oblique localization was made in 16.26% of patients and 19.46% had a temporal approach. Results, complications and reoperations according to the incision site are presented in Table 2.

Intraoperative complications were categorized using the OCTET definitions. Complications by surgeon can be seen in Table 3.

**Discussion**

Several outcome studies including randomized trials support that mSICS is almost as effective as phacoemulsification and equally safe. But the cost of mSICS is substantially lower. (US$ 15.74 vs US$ 42.10 for phacoemulsification)\(^10\) (US$ 15.0 vs US$ 70.0 for phacoemulsification)\(^6\)

Also, many randomized clinical trials significantly favor mSICS over phacoemulsification in terms of time required per procedure. (Average of 8-9.0 minutes for mSICS vs 15.5 minutes for phacoemulsification)\(^6\)\(^10\)
A good surgical outcome after cataract surgery according to the WHO is a BCVA better than 6/18 (20/60 Snellen). In our study 96.4% of patients had a good outcome as defined by the WHO. These results are similar to those reported by Venkatesh (94.4%), Waghmare (98%), Goate (98.36%) and Ruit (98%).

67.7% of patients in our study had a BCVA better than 6/9 (20/30 Snellen). This compares to the results reported by Waghmare (66%) but is lower than the reports of Goate (85.56%) and Ruit (89%).

In a meta-analysis that included standard extracapsular cataract extraction, phacoemulsification and intracapsular cataract extraction published by Powe et al., the pooled percentage of eyes with postoperative BCVA of 6/12 (20/40 Snellen) or better was 95.5%. In our study 88.11% of patients achieved a BCVA of 6/12 (20/40 Snellen).

In developed countries, phacoemulsification is the standard of care in terms of cataract surgery. When we compare our results with the ones reported of phacoemulsification, (applying the WHO definition for good outcome: BCVA better than 6/18), our 96.4% is similar to the results reported by Goate (98.37%) and Ruit (98%) and is less than the 100% reported by Waghmare.2,5,6

In our study, 67.7% of patients achieved a BCVA of 6/9 (20/30 Snellen) or better, this is lower than the phacoemulsification reports of Goate (77.83%), Waghmare (80%) and Ruit (94%).

The overall complication rate in our study was 3.12% (40 patients); this is higher than the 2.23% reported by Behera, the 1.9% reported by Venkatesh and the 1.01% reported by Aravind. However, we included patients with pseudoexfoliation and known severe zonular dehiscence in our analysis. If we exclude these patients from the analysis (as the three mentioned studies did) our overall complication rate is similar (1.72%).

Posterior capsule rupture in other series ranges from 1.1% to 2.7%. The Cataract National dataset audit from the United Kingdom reported 1.9% of vitreous loss. The Swedish National Cataract database reported a 2.1% rate during an 8-year period. Greenberg et al. reported a 3.5% rate. In our study, the posterior capsule rupture rate was 1.5% this is similar to the report of Venkatesh (1.4%) and is higher when compared to the reports of Behera (0.82%) and Aravind (0.51%).

The rate of iridodialysis in our study was 0.31%; this is higher than the reports of Behera (0.08%) and Aravind (0.03%). Our zonular dialysis rate was 0.31% this is similar to the 0.5% reported by Venkatesh and to the 0.25% reported by Behera, but higher than the 0.09% reported by Aravind. In this study, no cases of postoperative endophthalmitis was found during the follow up.
Of the 40 patients who had any intraoperative complication, 26 (65%) were blind preoperatively with hyper-mature cataracts (according to the WHO definitions). 40% of these patients also had pseudo exfoliation and/or zonular weakness. After complicated surgery, 33 (82.5%) had a good outcome according to the WHO definition (BCVA better than 6/18). 6 (15%) had a borderline outcome (BCVA between 6/24 and 6/60), and only 1 patient had a poor outcome (BCVA worse than 6/60). Macular and optic nerve studies as well as brain magnetic resonance were solicited to this patient however he failed on follow-up. Aravind reported that 89% of patients with mSICS and any kind of intraoperative complication achieved a BCVA of 6/12 or better (20/40 Snellen) in our series only 65% of patients with complicated cataract surgery achieved this outcome. Although this was not statistically significant (p = 0.23), complication rate was slightly higher among patients who had a temporal approach (4.8%) compared to superior (2.7%) and oblique (2.9%) approaches.

The reoperation rate in our series was 3.51% the most common indication was wound exploration due to hypotony or shallow anterior chamber (0.9%) followed by cortical material aspiration (0.78%) and anterior chamber washout due to hyphema (0.78%). IOL exchange accounted for 0.39% (4 patients). We did not find reoperation rates published in the literature. The study of Aravind states that among staff surgeons the rate of reoperations was statistically higher in the mSICS than in the phacoemulsification group (p=0.002) but the re-intervention rate was not found. In this study, no difference in terms of reoperations according to the incision site was found (p= 0.93).

In conclusion, in the hands of experienced surgeons, mSICS is a high volume, high quality procedure that achieves excellent visual outcomes, with low complication rates. It is comparable to phacoemulsification and according to several studies it is faster and less expensive. For these reasons, we believe than mSICS is recommended as an alternative to phacoemulsification and is probably the most appropriate technique for addressing the large and growing backlog of blindness due to cataract in the developing world.

References