



Original Research Article

Comparative study of outcome of capsulorhexis by assisted capsulorhexis device versus manual capsulorhexis in cataract surgery

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ARTICLE INFO

Article history:

Received 02-11-2019

Accepted 15-01-2020

Available online 16-06-2020

Keywords:

SICS- small incision cataract surgery

ABSTRACT

Context: Cataract is the major cause of treatable blindness in India (62.6%). Quality cataract surgery is basic need of the cataract blind patient. Phacoemulsification and SICS are routine surgery performed for cataract in developing countries. Continuous Curvilinear Capsulorhexis is the most important pre-requisite for successful outcome of cataract surgery.

Aim: To evaluate early outcome of assisted capsulorhexis versus manual capsulorhexis in cataract surgery.

Materials and Methods: This descriptive observational study was carried out during January 2017 to October 2018 with purposive sampling of 100 cases.

Results: Mean age of the study population was 60±9.1 in which 84% patients had immature cataract, while 16% patients had mature cataract. The cases operated by phacoemulsification surgery using manual technique 76% had regular shape of CCC and with assisted technique 84% had regular shape of CCC. Among patients operated with SICS using manual technique, 16% cases had regular shape of CCC and with use of assisted capsulorhexis device, 80% had regular shaped CCC. A statistically significant association was found between assisted technique and centration of the CCC (p=0.00001).

Conclusion: The assisted capsulorhexis device (VERUS) was found to be effective in achieving optimal size, circularity and centration of CCC during cataract surgery.

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1. Introduction

Cataract is the world's leading cause of blindness with around 20 million people blind due to cataract. It is a major cause of severe visual impairment leading to bilateral blindness. In developing countries 50–90% of all blindness in people who are above 50 years of age is caused by cataracts.¹

Quality cataract surgery is basic need of the cataract blind patient. Phacoemulsification and SICS are routine surgery performed for cataract in developing country. Continuous Curvilinear Capsulorhexis is the most important pre-requisite for successful outcome of cataract surgery. A CCC perfect in consistency in terms of size and shape can guide us to manage nucleus easily during the cataract surgery and gives better refractive outcomes after cataract

surgery.

Making of the capsulorhexis, according to senior ophthalmologists, is typically the step that causes the most anxiety for both the resident and the surgeon supervising the training. It is a difficult skill to master and takes a lot of time and fine ness to achieve consistency. Even experienced surgeons who have done thousands of capsulorhexis procedures are frequently off target on centration and sizing.²

Accurate CCC in terms of diameter and centration is required in manual SICS and Phacoemulsification surgery for guiding to manage nucleus easily during cataract surgery, IOL implantation in complicated surgery, newer and advanced IOL implantation like Multifocal, Toric and Accommodative lenses, training institute where teaching and learning for new surgeons. Manual CCC has many disadvantages like improper size and shape, Argentina flag sign in mature cataract, extension of CCC towards

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periphery, zonulolysis. That will lead to difficulty, in putting IOL in bag, in the decantation of IOL, capsular phimosis syndrome etc. Manual capsulorhexis has a long learning curve making the most important step of cataract surgery a difficult one for those under training.

More recently, femtosecond lasers have been used to create an opening in the anterior capsule with the possible benefit of more circular and precisely sized openings compared to that of the manual technique.^{3–5} Although it appears that femtosecond lasers achieve reproducibility of the capsule size, its high cost and concerns regarding tensile strength has led to modest adoption across the globe.³

To overcome the difficulties related to centration and optimum size of continuous curvilinear capsulorhexis (CCC), Dr. Kahook invented an assisted capsulorhexis (VERUS) device. It is a ring made up of medical-grade silicone, with an internal hole that has a diameter of 5.0 and 5.5 mm. After paracentesis followed by filling the anterior chamber with viscoelastic substance and from 2 mm clear corneal incision an assisted capsulorhexis (VERUS) device is inserted and then putting viscoelastic substance over it to adhere with anterior lens capsule and make the capsulorhexis as normally performed.

Manual capsulorhexis has its own disadvantages, so we want to carry out study to evaluate outcome of assisted capsulorhexis versus manual capsulorhexis in cataract surgery. Present study aims to assess the usefulness of assisted capsulorhexis device in learning curve of performing capsulorhexis in cataract surgery.

2. Materials and Methods

2.1. Study design

Descriptive observational study.

2.2. Sample size

Purposive sampling technique was used with a sample size of 100 patients who underwent cataract extraction at Ophthalmology department in a tertiary level government hospital during January 2017 to October 2018.

2.3. Inclusion criteria

All Immature and Mature cataracts in patient above 18 years and who gave consent for participation in the study.

2.4. Exclusion criteria

Subluxated lens, Phacodonesis, Hypermature cataract, Traumatic cataract, Paediatric cataract.

2.5. Data collection methods

Detailed History was taken to determine the inclusion and exclusion parameter and to record various demographic

data.

Patients were explained about the study their Distant and near visual acuity with Snellen's vision chart was recorded. Anterior segment examination was done with Appasamy AIA 11 slit lamp to record their cataract grading. Detailed posterior segment examination Keratometry was performed using manual keratometry. A-scan and Anterior chamber depth measurement with Echorule Biomedix a scan biometry of both manual and device assisted capsulorhexis used routinely and choice of procedure selected as per operating surgeon's preference. There are two groups of patients which were observed.

2.6. Manual technique

In this technique, CCC is made with 26G $\frac{1}{2}$ inch needle through the side port

2.7. Assisted technique

In this technique, CCC was made with Assisted CCC device in a method as mentioned earlier. Intra operative measurement of CCC size, shape and centration was done with the use of capsulorhexis marker. On the next day, size of CCC, its shape, centration is recorded after dilatation of pupil.

2.8. Data management and analysis

Data entry was done into Excel sheet and data analysis was done by Epi info version 6.04 software.

3. Results & Discussion

The mean age of the study population was 60 ± 9.1 and maximum number of cases were from the age group of 60–69 years (46%).

Out of 100 cataract patients, 84% patients had immature cataract, while 16% patients had mature cataract.

Total 50 patients were operated using phacoemulsification and 50 patients were operated for small incision cataract surgery (SICS) and in equal number of patients capsulorhexis was done using manual and assisted technique.

As per Table 1, CCC was performed using two different techniques, one is manual capsulorhexis technique and other one is assisted technique with (VERUS) device. In phacoemulsification surgery with manual technique, size of 5.0 mm was achieved in 48% cases and 5.5 mm was achieved in 24% cases, while in SICS 5.0 mm was achieved in 32% cases and 5.5 mm was achieved in 48% cases.

On the other hand, in phacoemulsification surgery with assisted technique, size of 5.0 mm was achieved in 60% cases and 5.5 mm was achieved in 32% cases, While in SICS with assisted technique, size of 5 mm was achieved in 20% cases and size of 5.5 mm was achieved in 72% cases.

As per Table 2, the chance of CCC size 5.5mm ($p=0.1137$) was twice in assisted technique as compared to manual technique. Although the difference was not found to be statistically significant, it was clinically meaningful. The size of 5.0 and 5.5 mm was 76% in manual technique while 92% in assisted technique.

As per Table 3, the cases operated by phacoemulsification surgery using manual technique 76% had regular shape of CCC and with assisted technique 84% had regular shape of CCC. Among patients operated with SICS using manual technique, 16% cases had regular shape of CCC and with use of assisted capsulorhexis device, 80% had regular shaped CCC.

The association between shape of CCC and type of technique was found using Chi square test. A significant association was found between assisted technique and regular shape of the CCC ($p=0.0001$, odds ratio=5.252). The Odds ratio was 5 indicating that regular shape was five times more common in assisted technique in comparison to manual technique.

As per Table 4, a statistically significant association was found between assisted technique and centration of the CCC ($p=0.00001$).

More than four fifth (84%) patients had immature cataract, while 16% patients had mature cataract. The higher number of patients with immature grade of cataract in this study can be probably explained by the awareness among patients regarding the symptoms of cataract like diminution of vision and complications of mature cataract and hence seek early medical care.

Madhuchanchlani et al. conducted a study on total 792 eyes of 412 patients evaluated for cataract in which 596 were cortical and 196 were nuclear. Out of cortical 428 (71.81%) were immature and 168 (28.18%) were mature.⁶

K. Kanthamani et al. conducted a study in which 302(58.06%) had senile immature cataract and 195(37.5%) had mature cataract and 23(4.42%) cases were hyper mature cataract.⁷

Rathnakumar K. et al. conducted a study in which cortical immature cataract was seen in 105(52.5%) cases, mature cataract in 34(17) and hyper mature cataracts in 24(12%) cases.⁸

CCC was performed using two different techniques, one is Manual capsulorhexis technique and other one is assisted technique with (VERUS) device. In phacoemulsification surgery with manual technique, size of 5.0 mm was achieved in 48% cases and 5.5 mm was achieved in 24% cases, while in SICS 5.0 mm was achieved in 32% cases and 5.5 mm was achieved in 48% cases (Table 1).

Though chance of CCC size 5.5mm ($p=0.1137$) was twice in assisted technique as compared to manual technique, the difference was not found to be statistically significant, it was clinically meaningful (Table 2).

In study conducted by Kahook M et al., a comparison between mean deviation from target diameter of manual CCC cases ($420\pm 230\mu\text{m}$) and assisted device capsulotomy procedure ($80\pm 50\mu\text{m}$) was statistically significant.⁹

In this tertiary care centre, phacoemulsification is generally being used by senior surgeons so shape or regularity was nearly same for manual and assisted technique. SICS is generally performed by trainee doctors. so assisted technique was better among trainee doctors.

In this study out of the 50 patients operated with manual technique, 46% cases had regular shape of CCC and 54% cases had irregular shaped CCC. Out of 50 patients operated with assisted technique, 82% had regular shaped CCC and 18% had irregular shaped CCC (Table 3).

In study conducted by Lee J et al., proper capsulorhexis was obtained in 60 eyes (67%) in the manual technique group and 81 eyes (86%) in the assisted technique group. In their study they found that introduction of an open ring shaped guider CCC became more larger and circular. The rate of acquiring proper capsulorhexis was higher in the assisted technique group than manual technique group.¹⁰

In study conducted by Kahook M et al., circularity in the guided group (0.84 ± 0.03) was significantly greater than that of free hand group (0.69 ± 0.17 , $p=0.036$).¹¹

In study conducted by Dick HB et al., intraoperatively the horizontal diameter of CCC was within the normal reference range in 92% of eyes in group 1 and 27% in group 2. The vertical diameter was within normal reference range in 83% and 21% respectively.¹²

A statistically significant association was found between assisted technique and centration of the CCC ($p=0.00001$) (Table 4).

In study conducted by Kahook M et al., the capsulotomy centration with assisted capsulorhexis (VERUS) device was within $80 \pm 32 \mu\text{m}$ of intended positioning of relative to pupil compared to manual CCC centration $110 \pm 58 \mu\text{m}$, which was also statistically significant in favour of assisted capsulorhexis (VERUS) device ($p<0.006$). The results of present study in terms of size, shape and centration of CCC are comparable to results obtained in study conducted by Kahook M et al. The verus ophthalmic caliper was found to be effective at improving size, circularity, and centration of the CCC and there was no postoperative anterior chamber reaction when compared to manual procedures performed without VERUS guidance.

In study conducted by Lee J et al., the area of capsulotomy was larger in the guided group 21.55 ± 0.87 mm than that of free hand group 20.34 ± 2.96 mm, $p<0.001$). Circularity in the guided group 0.84 ± 0.03 was significantly greater than that of free hand group 0.69 ± 0.17 , ($p=0.036$).

Table 1: Distribution of study population according to the Size of CCC

Size(mm)	Manual		Assisted	
	Phacoemulsification(no. of patients)n=25 No (%)	SICS(no. of patients)n=25 No (%)	Phacoemulsification(no. of patients)n=25 No (%)	SICS (no. of patients)n=25 No (%)
4.0	3 (12.0)	Nil	Nil	1 (4.0)
4.5	4 (16.0)	1 (4.0)	2 (8.0)	1 (4.0)
5.0	12 (48.)	8 (32.0)	15 (60.0)	5 (20.0)
5.5	6 (24.0)	12 (48.0)	8 (32.0)	18 (72.0)
6	Nil	4 (16.0)	Nil	Nil

Table 2: Distribution of study population according to size of CCC, manual technique and assisted technique

Size(mm)	Manual(no. of patients)n=50 No (%)	Assisted(no. of patients)n=50 No (%)	Odds ratio	χ^2 Chi square value	P value
4.0	3 (6.0)	1 (2.0)	3.095	1.031	0.3674
4.5	5 (10.0)	3 (6.0)	1.731	0.538	0.4918
5.0	20 (40.0)	20 (40.0)	1.0000	0	1.0000
5.5	18 (36.0)	26 (52.0)	0.5227	2.571	0.1137
6.0	4 (8.0)	Nil			

Table 3: Distribution of study population according to shape, manual technique and assisted technique.

Shape	Manual			Assisted		
	Phacoemulsification (no. of patients)n=25 No (%)	SICS (no. of patients)n=25 No (%)	Total	Phacoemulsification(no. of patients)n=25 No (%)	SICS (no. of patients)n=25 No (%)	Total
Regular	19 (76.0)	4 (16.0)	23	21 (84.0)	20 (80.0)	41
Irregular	6 (24.0)	21 (84.0)	27	4 (16.0)	5 (20.0)	9

Table 4: Comparison of centration of CCC (Manual vs Assisted)

	Manual(no. of patients)n=50 No (%)	Assisted(no. of patients)n=50 No (%)	Odds ratio	χ^2 Chi square	p value
Decentration	16 (32.0)	9 (18.0)	2.127	2.587	0.1143
Centration	20 (40.0)	41 (82.0)	0.1495	18.35	0.00001
Extension	14 (28.0)	Nil			

4. Conclusion

The assisted capsulorhexis device (VERUS) was very helpful to trainee doctors for mastering the art of making CCC, there by shortening the learning curve. In comparison to manual CCC, assisted capsulorhexis device was also useful for senior surgeon to achieve optimal CCC which in turn leads to better visual outcome in refractive cataract surgery. The assisted capsulorhexis device (VERUS) was found to be effective in achieving optimal size, circularity and centration of CCC during cataract surgery.

5. Source of Funding

None.

6. Conflict of Interest

None.

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Cite this article: Patel KJ, Chaudhari BR. Comparative study of outcome of capsulorhexis by assisted capsulorhexis device versus manual capsulorhexis in cataract surgery. *Indian J Clin Exp Ophthalmol* 2020;6(2):217-221.