Innovations in Ophthalmology

The Ganesh–Grewal cystitome maker – A step in standardizing cataract surgery

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A well-centered, adequately sized continuous curvilinear capsulorhexis (CCC) is a prerequisite for successful cataract surgery. A perfect capsulorhexis ensures safe and effective performance of various steps of surgery as well as a correctly positioned intraocular lens (IOL) with optimal rotational stability. Ganesh and Grewal (GG) cystitome maker is a step toward standardizing the creation of a cystitome to reduce variations and complications associated with the crucial step of CCC in cataract surgery. We conducted a study to measure the repeatability and precision of cystitomes made by the GG cystitome maker versus those made manually with a needle holder. The results showed that the cystitomes made with GG cystitome maker had a lesser degree of variation. This indicates a more repeatable cystitome, which will inadvertently help in reducing the error caused by the instrument in making a good CCC during cataract surgery.

Key words: Capsulorhexis, continuous curvilinear capsulorhexis, cystitome, needle rhexis, phacoemulsification

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A well-centered, adequately sized continuous curvilinear capsulorhexis (CCC) is a prerequisite for successful cataract surgery. Capsulorhexis, as described by Gimbel and Neuhann, is a circular, central, curvilinear opening in the anterior capsule created with a subincisional needle puncture and then completed with arcuate shearing taken in clockwise and anticlockwise directions.[1] This has now evolved to a technique where a puncture is made in the anterior capsule, a single flap is lifted, and the CCC is completed unidirectionally. A perfect capsulorhexis ensures safe and effective performance of various steps of surgery as well as a correctly positioned IOL with optimal rotational stability.[2]

Various instruments and techniques have been developed to facilitate the creation of a perfect CCC. These include the cystitome, Utrata capsulorhexis forceps, micro capsulorhexis forceps, bimanual capsulorhexis method, and two-staged capsulorhexis method. Several mechanized systems including the femto-laser technology and Zepto precision pulse capsulotomy have also been developed to facilitate CCC.[3-7] Despite the numerous advances, results of cataract surgery, however, still vary the world over. In cataract surgery, it is important that the surgical steps are accurate and reproducible among different surgeons to optimize clinical outcomes. Hence, standardizing intraoperative surgical techniques, such as creation of CCC, will minimize the risk of complications and is the key to yield consistent results.

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Ganesh and Grewal (GG) cystitome maker is a step toward standardizing the creation of a cystitome to reduce variations and complications associated with the crucial step of CCC in cataract surgery.

A study was conducted to compare the repeatability and precision of cystitomes made using the GG cystitome maker versus those made manually using a needle holder. The size and angulation of the GG cystitome were analyzed and compared to those made manually using a needle holder in a laboratory setting.

For validation, surgeon satisfaction scores have been taken from two surgeons with varying degrees of surgical skills. Their satisfaction regarding the quality of capsulotomy and comfort of use with GG cystitomes versus manual cystitomes was assessed.

Study Methodology

The reproducibility of cystitomes made using the GG cystitome maker and manually created cystitomes for capsulotomy during phacoemulsification were evaluated.

Specifications of the GG cystitome maker: The GG cystitome maker (Epsilon Surgicals, Chino, CA, USA) is a hand-held device similar to a pair of locking pliers designed to create

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standardized cystitomes. It is based on the specifications of the Irrigating Cystitome 25-Gauge Angled Reverse Cutting Tip, Alcon #8065425120 (Alcon, Fort worth, TX, USA) The method of using the GG cystitome maker has been shown in the Video 1 and Fig. 1.

Institutional ethics committee approval was obtained, and the study was conducted as per the tenets of Declaration of Helsinki. The study was registered with Clinical Trials Registry of India (CTRI) with CTRI no. CTRI/2022/07/044241, and informed consent was obtained from all patients participating in the study.

The study was conducted in two parts. The first part of the study assessed the repeatability and precision of making cystitomes similar to a standard cystitome (Alcon cystitome) through a laboratory study. A total of 100 cystitomes (50 each for GG cystitome group and manual group) were created using 26½ G needles by an experienced operation theater assistant, who was well versed with the techniques of making cystitomes with both the GG cystitome maker and a needle holder. These cystitomes were evaluated using a scaled slide under a binocular compound microscope with a fixed magnification to measure the length of the tip in millimeters. To measure the angle of the cystitome, digital photographs of the cystitome were taken using an I-phone camera at a fixed magnification. These photographs were subjected to an online measurement software (protractor overlay) to measure the angle between the tip and the shaft of the cystitome and the angle between the shaft and the hub. The measurement value of the cystitome tip and the angulation of the bends were compared between both the cystitome groups, as well as with the measurements of the Irrigating Cystitome 25-Gauge Angled Reverse Cutting Tip, Alcon #8065425120 (Alcon Surgicals), which has a tip length of 0.5 mm and the angle between the tip and shaft of 90°.

Figure 1: (a) GG cystitome maker. (b) 26½ G needle bent by GG cystitome maker to make a cystitome. GG = Ganesh–Grewal

In the second part of the study, the cystitomes were evaluated by obtaining a satisfaction score at the end of each surgery from two cataract surgeons with varying degrees of surgical skill.

A total of 100 eyes satisfying the eligibility criteria were recruited in the study. Phacoemulsification with implantation of a foldable posterior chamber intraocular lens (IOL) was performed by a two cataract surgeons. One of the surgeons was a beginner surgeon and the other was an experienced surgeon, both with a fairly good degree of surgical skill.

Both the operating surgeons operated 50 nonconsecutive eyes each, satisfying the eligibility criteria for the study, which are as follows.

Inclusion criteria: Patients of either sex, aged between 40 and 75 years, diagnosed with nuclear or corticonuclear cataract of grade I–IV according to the Lens Opacity Classification System III (LOCS III) scale, suitable to undergo phacoemulsification with foldable IOL implantation within an IOL power range of + 16–+24 D, and willing and able to understand/sign a written informed consent document were included.

Exclusion criteria: LOCS III nuclear sclerosis grade 4+; complex cases of cataract such as mature and intumescent, Morgagnian, posterior polar, phacomorphic glaucoma, uveitic cataracts, traumatic and subluxated cataracts; cataracts with subcapsular fibrosis, very thin/friable capsules, and pseudoexfoliation; poorly dilating pupils or patients on alpha-adrenergic antagonists for benign prostrate hyperplasia (BPH) requiring pupil expansion devices intraoperatively; corneal diseases such as keratoconus, pellucid marginal degeneration, leukomatous corneal scars, corneal degeneration; planned multiple procedures at the time of surgery or during the course of the study (e.g. Laser in situ keratomileusis (LASIK), Limbal relaxing incisions (LRI), etc.); previous intraocular or corneal surgery of any kind.

All surgeries were performed under topical or local anesthesia, depending upon the case and surgeon's preference, using a temporal approach. For both the surgeons, eyes were randomized using computer-generated random tables to achieve capsulotomy using a cystitome made by either the GG cystitome maker or a needle holder. A 2.8-mm clear corneal incision was made, followed by a CCC of 5–5.5 mm using a cystitome made by either the GG cystitome maker or a needle holder, as per the randomization protocol. After hydro-dissection, the nucleus was divided and emulsified, followed by implantation of a foldable IOL in the bag.

At the end of the surgical procedure, the following grading system were presented to both the operating surgeons to assess their satisfaction regarding the quality of capsulotomies made by using cystitomes belonging to both the study groups.

Satisfaction grade 1: Poor/unacceptable; included poor capsulotomy achieved with major deviations in size, shape, and centration. Surgeon faced issues during initiation and continuation, leading to capsular extension/tears or complicating the subsequent course of the surgery. Warranting a change in the cystitome or need for a capsulorhexis forceps to complete capsulotomy

Satisfaction grade 2: Fair; included capsulotomy associated with moderate but acceptable deviations in size (too small or too large), shape (irregular, but continuous), and

centration (eccentric). Surgeon faced difficulty in using the cystitome, but change of cystitome was not warranted and the course of surgery was not altered.

Satisfaction grade 3: Excellent; included perfect capsulotomy achieved in terms of size (5–5.5 mm), shape (perfectly circular), and centration (well centered). Surgeon did not face any difficulty in initiation and continuation of capsulotomy.

The process was double blinded.

Statistical analysis

Analysis was performed using data analysis tool pack available in Microsoft Excel. The mean and standard deviation of each measurement (tip length, the angle between the tip and the shaft of the cystitome, and the angle between the shaft and the hub) and the average satisfaction scores of surgeons for the two groups of cystitomes were calculated and compared using independent *t*-tests. The *t*-tests were performed to calculate any significant differences between the observations and the standard, and within each group of cystitomes made by the two different tools. The coefficient of variation (CV) was calculated and expressed as a percentage of the standard deviation and the overall mean. CV was calculated for repeatability for each observation and repeatability for all measurements combined. A *P* value less than 0.05 was considered statistically significant.

Results

In the laboratory part of the study, 100 cystitomes were analyzed to assess the repeatability and precision of making cystitomes using the GG cystitome maker compared to making them manually.

From Table 1, we can infer that the GG cystitome group had a lesser CV for tip length, angle between the tip and the shaft, and angle between the shaft and the hub when compared to the manual group. The GG cystitome group also had a smaller range compared to the manual group in all the parameters. On comparing the GG cystitome to the manual group, the length of the tip in both groups proved to be statistically insignificant ($P = 0.135176$). However, the angles were statistically significant ($P < 0.00001$ for both the angle between the tip and the shaft and the angle between the shaft and the hub), with the GG cystitome being better in the one-tailed *t*-test.

On comparing the GG cystitome group and the manual group with the standard Alcon Irrigating Cystitome 25-Gauge Angled Reverse Cutting Tip, there was a statistically significant difference in both groups when compared to the standard for measurements of tip length and angle between the tip and the shaft ($P < 0.00001$). Table 2 shows the surgeon satisfaction scores for GG cystitome maker and manual cystitome.

In the second part of the study where the surgeon satisfaction score was assessed for 100 eyes, it was found that both the surgeons had a minimum score of 1 and a maximum score of 3 in both the GG cystitome maker and manual groups.

On comparing the satisfaction scores between the two surgeons, there was no statistically significant difference in either the GG cystitome group or the manual group at $P < 0.05\%$, with $P = 0.55768$ in the GG group and $P = 0.327268$ in the manual group.

Discussion

The GG cystitome maker has been designed to standardize the dimensions of cystitomes required for the crucial step of capsulorhexis in cataract surgery. We observed that the repeatability and precision of making cystitomes using the GG cystitome maker were much better than those made manually with a needle holder by an experienced operation theater

Table 1: Measurements of GG cystitome and manual cystitome

Measurements		GG cystitome	Manual cystitome	*P*
Tip length	Average±SD (mm)	0.372±0.071	0.345±0.104	*P*=0.135176
	Range (mm)	0.2–0.5	0.15–0.65	
	SD (mm)	0.071	0.104	
	COV (%)	19.23	30.32	
Angle between the tip and the shaft	Average±SD (°)	126±5.11	114±7.43	*P*<0.00001
	Range (°)	115–137	99–133	
	SD (°)	5.11	7.43	
	COV (%)	4.03	6.48	
Angle between the shaft and the hub	Average±SD (°)	144±4.17	123±5.39	*P*<0.00001
	Range (°)	136–155	110–137	
	SD (°)	4.17	5.39	
	COV (%)	2.88	4.37	

GG=Ganesh–Grewal, SD=standard deviation, COV=Coefficient of Variation

Table 2: Surgeon satisfaction scores for GG cystitome and manual cystitome

Satisfaction score	Surgeon 1		Surgeon 2	
	GG cystitome	Manual cystitome	GG cystitome	Manual cystitome
Average	2.52	2.52	2.8	2.68
P	*P*=1.00; hence, no statistically significant difference		*P*=0.343518; hence, no statistically significant difference	

GG=Ganesh–Grewal

assistant. Also, using the specialized GG cystitome will help prevent damage to the needle holder used to make cystitomes.

The surgeon satisfaction scores between the GG cystitome maker and the manually made cystitomes were similar, which could be attributed to the surgeons being skilled enough to adapt to minor changes in the cystitome, as well the assistant bending the cystitomes for the manual group being very experienced.

However, the range and degree of variation of all dimensions was lower in the cystitomes made with the GG cystitome maker than those made manually with the needle holder, suggesting a better repeatability. The dimensions of cystitomes made with the GG cystitome maker also tended to be closer to the dimensions of the Irrigating Cystitome 25-Gauge Angled Reverse Cutting Tip, Alcon #8065425120 (Alcon Surgicals).

Standardizing the dimensions of a cystitome will help in getting a reliable and repeatable capsulorhexis. Using the GG cystitome maker to do so will help reduce reliance on the experience of the ophthalmic assistant to make cystitomes using a needle holder.

Conclusion

The GG cystitome maker helps in producing repeatable and precise cystitomes. This will help in standardizing the CCC step in cataract surgery by reducing the error from the instrument used in this step.

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Conflicts of interest

Dr. Sri Ganesh is the inventor of the GG cystitome maker, but has no financial interest.

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