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Tittle Comparative evaluation of Endothelial cells count in patients undergoing SICS(Small Incision Cataract Surgery) and phacoemulsification post operatively

Author:Dr ANKITA SRIVASTAVA , Dr R N KUSHAWAHA ,Dr PERWEZ KHAN, Dr PARUL SINGH

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INTRODUCTION

Vision 2020: the Right to Sight, a joint initiative of the World Health Organization (WHO) and the International Agency for the Prevention of Blindness (IAPB) aims to eliminate avoidable blindness in the world by the year 2020 [1]. It is estimated that over 90% of the world's visually impaired live in developing countries, where blindness is associated with considerable disability, resulting in major economic and social consequences [2].

Cataract is the leading cause of treatable blindness in the world [3]. Advances in the science and techniques for cataract extraction make this procedure one of the most successful and common surgical procedures in medicine[4]Smallincision cataract surgery (SICS) became a good alternative for surgeons who did not have access to a phacoemulsification machine. Phacoemulsification technique reduced the size of incision further and foldable IOL came into use [5].

In the western world, phacoemulsification is the gold standard for cataract surgery[6]. Small incision cataract surgery (SICS) is widely practiced in India and other Asian countries. Manual small incision cataract surgery (SICS) in which the nucleus was prolapsed through a self-sealing sclerocorneal tunnel was developed in the United States and Israel and later popularized in India. As it was found to be safer, more effective and cheaper than ECCE, it became popular in India and forms the major proportion of the cataract surgeries done in south Asia[7].

Cataract is the leading cause of treatable blindness worldwide and 75% of people with cataracts live in developing countries where blindness is associated with considerable disability, and major economic and social consequences[8].

Of the total estimated 38 million blind people in the world, 9–12 million are in India [9]. Estimates report that 50%–80% of these people are blind because of cataract [10]. In addition to the backlog, an additional 3.8 million become blind each year because of cataract [11].

Manual small incision cataract surgery (SICS) has become an established surgical alternative to phacoemulsification. Phacoemulsification is the preferred technique in the developed world and tertiary centers of developing countries [12].

Age-related cataracts are a common condition and one of the most important causes of blindness [13]. Due to improvements in medical technology and surgical instruments, phacoemulsification has now become a mainstream treatment for cataracts. Cataract surgery has gradually evolved from blindness prevention surgery to refractive surgery, with the aim of not only restoring vision but also improving visual quality and quality of life. The choice of surgical incision plays a crucial role in the efficacy of surgery, as the incision damages the surrounding tissues and affects the surgical approach. The size of microincisional phacoemulsification surgery (MICS) incisions ranges from 1.8 mm to 2.8 mm, whereas standard-incision phacoemulsification surgery (SICS) incisions range from5.0 mm to 6.0 mm [14]As the field of cataract surgery has trended towards minimally invasive approaches in recent years, some scholars now hold the view that smaller incisions contribute to less surgically induced astigmatism (SIA) [15] and hasten healing of the incision, thus leading to faster post-surgical recovery [16].

Diet, smoking,[17] and exposure to ultraviolet light[18] are thought to be risk factors in the development of age-related cataract. In addition, some people may have a genetic predisposition to development of age-related cataract [19]. Oxidative stress is also thought to be a factor in cataract development [20].

Cataract remains a major cause of visual impairment in India, and free, hospital based cataract surgery camps continue to be held to deal with the problem [21].

India accounts for about one-third of the world's blindness. Cataract is the leading cause of blindness and cataract surgery is by far the most commonly performed procedure[22].

The mean endothelial count (ECC) in the normal adult cornea ranges from 2000 to3000 cells/mm2, and the count continues to decrease with age. Previous cross-sectional studies have shown the normal attrition rate of corneal endothelial cells is 0.3-0.5% per year [23]

India accounts for about one-third of the world's blindness. Cataract is the leadinMorphological stability and functional integrity of the corneal endothelium are necessary to maintain long-term corneal transparency after cataract surgery. Endothelial cell loss and corneal decompensation after cataract surgery is well-documented. All surgical procedures that involve entry into the anterior chamber damage a proportion of endothelial cells intraoperative corneal manipulation. After endothelial cell loss, the adjacent cells enlarge and slide over to maintain endothelial cell continuity, which is observed as a change in the endothelial cell density and morphology. Moderate damage to the endothelium during surgery can also lead to a transient increase in corneal thickness. Endothelial cell density and function can be assessed clinically using specular microscopy and pachymetry [24].

In normal population to assess the response of the endothelium to cataract surgery, studies have shown a decrease in the endothelial density over a 3-month period postoperatively, with an increase in the coefficient of variation and decrease in the percentage of hexagonal cells [25]

.In India, approximately 5 million cataract surgeries are performed per year; therefore, it is important to determine the safest surgical technique for the endothelium. There is a paucity of data from India on the effect of small-incision cataract surgery (SICS) and phacoemulsification on the corneal endothelium (morphological and functional) to assess the postoperative endothelial cell loss and change in endothelial morphology over a short period of time between the two commonly performed cataract techniques [26].

The current study is being undertaken for the evaluation and assessment of endothelial cell count loss in the two most commonly performed surgeries for cataract in India, namely, phacoemulsification and small incision cataract surgery (SICS).

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.The damage to the corneal endothelium leads to corneal endothelial cell loss which if severe can eventually lead to the development of corneal edema.

Successful cataract surgery depends on the good endothelial count pre operatively and post operatively. This observation of corneal endothelium by specular reflection date back to the early past of 20th century by Vogt demonstrated the first direct visualisation of corneal endothelial cells using principle of specular microscopy in 1918 using S/L bio microscope. We hope that this corneal endothelial study helps us to chose an ideal technique for extraction of cataractous lens in order to get a good visual rehabilitation in 2 immediate post operative period as mentioned by our pioneer - our ultimate goal.

The main objective of the current study was to assess the corneal endothelial cell count pre and post cataract surgeries at Department of Ophthalmology LLRH Hospital Kanpur. The study has evaluated and quantified the corneal endothelial cell loss related to this commonest intraocular surgery at LLRH Hospital kanpur. Therefore, the study has raised awareness to the surgeons on the importance of pre and post operative evaluation of patients for cataract surgery which is going to contribute towards the efforts of the hospital on improving the quality of cataract surgery on individual basis.

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REVIEW OF LITERATURE

1. Ammous Iet al : 2017 Jun.

Did a study on Phacoemulsification versus manual small incision cataract surgery: Anatomic and functional results and concluded that both SICS and PHACO give excellent results, both anatomical and refractive.

However, SICS appears to be more advantageous than PHACO in terms of speed, cost, and independence from technology, and appears to be better suited to dense cataracts and mass surgery

2 .Maggon R et al : 2017 Dec.

Their study emphasised on relation of pupillay dilatation on endothelial cell loss outcome after phaco emulsification and concluded that Phacoemulsification done in eyes with maximal pupillary dilatation of <5 mm causes a greater EC loss and results in thicker corneas postoperatively as compared to eyes with pupillary dilatation of >5 mm at the end of one month.

3.Kaur T et al : 2016 Oct.

Did a comparative study on endothelial cell loss in SICS vs Phacoemulsification and found average decrease of 17.17% in group which underwent SICS as compared to 19.53% in phacoemulsification in their follow up study.

4.Gogate P et al: 2015 Jul-Sep.

Did a Meta-analysis to Compare the Safety and Efficacy of Manual Small Incision Cataract Surgery and Phacoemulsification and concluded that Manual SICS and phacoemulsification do not differ significantly in endothelial cell loss and complication rates in uveitic eyes. However, increased anterior chamber manoeuvring due to additional procedures may lead to significantly higher endothelial cell loss.

The outcome of their meta-analysis indicated there is no difference between phacoemulsification and SICS for BCVA and UCVA of 6/18 and 6/60. Endothelial cell loss and intraoperative and postoperative complications were similar between procedures. SICSresulted in statistically greater astigmatism and UCVA of 6/9 or worse, however, near UCVA was better.

5.Jagani SN et al :2015.

Did a comparative study of endothelial cell loss and found more cell loss in phaco group as compared to SICS at three month period but was not statistically significant

6.Sunil Ganekal et al :2014 Jan-Mar.

Did a study on Comparison of Morphological and Functional Endothelial Cell Changes after Cataract Surgery: Phacoemulsification Versus Manual Small-Incision Cataract Surgery and concluded that in India, approximately 5 million cataract surgeries are performed per year; therefore, it is important to determine the safest surgical technique for the endothelium. There is a paucity of data from India on the effect of small-incision cataract surgery (SICS) and phacoemulsification on the corneal endothelium (morphological and functional) was performed to assess the postoperative endothelial cell loss and change in endothelial morphology over a short period of time between the two commonly performed cataract techniques.

7.Reshma Balan K et al : 2012.

SICS group showed comparable endothelial cell loss with the Phacoemulsification group(p=0.084). The mean endothelial cell loss in SICS group showed lesser corneal endothelial cell loss than Phacoemulsification in all study intervals.However this was not statistically significant.Diabetics in the combined data(SICS+Phacoemulsification)showed statistically significant corneal endothelial cell loss than the non-diabetic group(t=2.13,p=<0.05).

8.Thakur SK, Dan A et al : 2011 July-December

Did a study on Endothelial cell loss after small incision cataract surgery and concluded that there is 15.83 % reduction in endothelial cell count after SICS with PC IOL implantation, which is comparable with other modes of cataract surgery like extra-capsular cataract extraction and phacoemulsification.

9.Gogate P, Ambardekar P et al : 2010 Feb .

Did a study on Comparison of endothelial cell loss after cataract surgery: phacoemulsification versus manual small-incision cataract surgery: six-week results of a randomized control trial and concluded that there were no clinically or statistically significant differences in ECC loss or visual acuity between phacoemulsification and SICS.

10.Rao SK et al: 2000

Did a study on corneal endothelial cell density and morphology in the Indian population and compared it with data available for American

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and Japanese populatin and found that endothelial cell density in Indian eyes is less than the value described for Japanese ans American population.

AIM/OBJECTIVES

To determine the corneal endothelial cell loss after manual small incision and phacoemulsification cataract surgery.

Study design

A hospital based prospective Observational study that followed tenets of Declaration of Helsinki and was approved by Ethics Committee of GSVM Medical College Kanpur.Written informed consent was obtained from each participant.

Inclusion criteria

All adult consenting patients with grade 1 to 4 Nuclear sclerotic cataract, Posterior subscapular cataract,Cortical cataract who underwent either manual small incision cataract surgery or phacoemulsification both males and females in the group under 15 years,15 to 45 years,more than 45 years were included.

Exclusion criteria

- Unwilling patients
- Patients with history of previous intraocular surgery
- Ocular trauma
- Acute or Chronic Ocular Infection
- Significant corneal opacification
- Corneal dystrophy
- Uveitis
- Posterior capsule rent
- Vitreous loss during surgery were excluded

Sampling and Sample size

Convenient sampling was used. All consenting patients with cataracts undergoing either manual small incision cataract surgery or phacoemulsification at LLRH Hospital during the study period were included.

PROCEDURE

All adult patients who were diagnosed to have cataract and planned for cataract surgery during the study period were informed about the study.

A thorough history was taken followed by a general and systemic examination which was performed by the investigator.

All information was recorded on a structured questionarre.

Ocular examination was performed starting with visual acuity using Snellen's chart/illiterate echart. Slit lamp bio-microscope(Carl ZeisssSL 130 Germany) was used for examination of the anterior segment of the eye including the eyelids, conjunctiva, cornea, anterior chamber, iris, pupil, lens and anterior vitreous. Intraocular pressure measurement was done by using a Goldmann Applanation Tonometer.

Patients were allocated to either manual small incision cataract surgery group or Phacoemulsification. .

Corneal endothelial cell count assessment was determined by use of a non contact specular microscope(CEM 530 NIDEK CO.LTD), the machine which was available at the department at the time of study which gives reliable and reproducible values for endothelial cell density at high magnification The machine enumerates the number of endothelial cells, allowing an objective assessment of the patient's endothelium which guides the physician to make a mutual decision.

It is useful for the selection of eyes for intraocular surgery in general and foreseeing the prognosis in cases of donor corneas. The photographs were taken a day before surgery and were repeated on day one and one month after cataract surgery.

Examination of the posterior segment was done by slit lamp bio-microscope using 90D volk aspheric lenses preoperatively for patients who did not have dense or bilateral cataracts and post operatively for all patients after dilatation of both pupils using tropicamide and phenylephrine eye drops.

Manual small incision cataract surgeries and phacoemulsification were performed by surgeon equally well versed in both the surgeries.

Patients were subsequently followed up on first day post op,second week and fourth Week

Details of phacoemulsification Surgery Steps

A clear corneal groove of 2.8 to 3.2 mm was made with 15 no blade from Superotemporaly in right or Superonasaly in left eye. By depressing the portions of the lips of the groove, the point of the keratome or crescent was slid into the external incision 2.5 mm in the clear cornea. At this point, AC entry was carried out with 2.8 or 3.2 mm keratome and a side port was made with a side port blade of 15°. Corneal tunnel was triplanar and had self-sealing property.

A side port entry was made 2–3 clock hours away from the primary incision. Viscoelastic was injected through the side port to form the AC. A capsulotomy was carried out by Continuos curvilinear capsulorhexis(CCC) technique with 26 gauge bent needle. At this point, AC entry was made with a keratome 3.2 mm. Hydrodissection was performed with ringer lactate solution. Phacoprobe inserted through the sclera-corneal tunnel. Nucleus was removed by phacoemulsification with stop and chop technique. The remaining cortical matter was aspirated using a classical simcoe cannula. Viscoelastic(HPMC) was injected in the AC and the inner opening of the tunnel was extended parallel to limbus up to periphery using the 5.5 mm blunt-tip keratome. A 6.0 mm optic,Foldable Acrylic, IOL was implanted in the bag in all cases. Viscoelastic was washed off and AC was formed with ringer lactate.

Side port and main port hydration was performed. Conjunctiva and Tenon's capsule were reposited to cover the wound and cauterized. Subconjunctival gentamycin (20 mg) and dexamethasone (2 mg) injection were given. Eye drop preservative free moxifloxacin 0.3% was instilled in the conjunctival sac. Eye patch was applied.

Details of Manual small incision cataract surgery Steps

A fornix based conjunctival flap was made superiorly with corneoscleral scissors and hemostasis was achieved with wet field bipolar cautery.

A 6 mm Frown incision was made on the sclera from 11 o' clock to 2 o' clock with a 15 no. blade 2 mm posterior to the corneal vascular arcade. A sclero-corneal tunnel was constructed using a crescent knife and dissection continued 1.0mm to1.5 mm into clear cornea .

Side port was made using side port ,anterior capsule was stained using tryptan dye and washed followed by injection of hydroxymethyl cellulose viscoelastic and CCC was made.

Anterior chamber was entered from the anterior limit of sclera-corneal tunnel using a 3.2 mm entry keratome. The inner opening of tunnel was extended parallel to limbus up to periphery the same 3.2 mm blunt-tip keratome. Hydrodissection and hydrodelineation wasperformed. Nucleus prolapsed into AC and delivered using viscoexpression or with the help of irrigating wire vectis. Cortical matter was aspirated using a classical simcoe cannula. A 6.0 mm optic, PMMA or Foldable IOL of appropriate power was implanted in the bag in all cases. Viscoelastic was thoroughly washed off and AC was formed with ringer lactate. Side port opening was sealed by stromal hydration. Conjunctiva and Tenon's capsule were reposited to cover the wound and cauterized. Subconjunctival gentamycin (20 mg) and dexamethasone (2 mg) injection were given. Antibiotic oinmentand eye patch was applied.

RATIONALE OF THE STUDY

This was the first study to be conducted at GSVM Medical college LLRH Hospital Kanpur. Therefore, it has provided baseline data for future studies related to pre and post operative corneal endothelial cell count. The study had also raised awareness to the surgeons on the importance of pre and post operative evaluation of patients for cataract surgery. This is going to contribute towards the efforts of the hospital on improving the quality of cataract surgery.

TABLE AND GRAPHS

Table 1

	Group 1	Group 2	
Total patients	**45**	**52**	**97**
male	**24**	**27**	**52.57%**
female	**21**	**25**	**47.42%**

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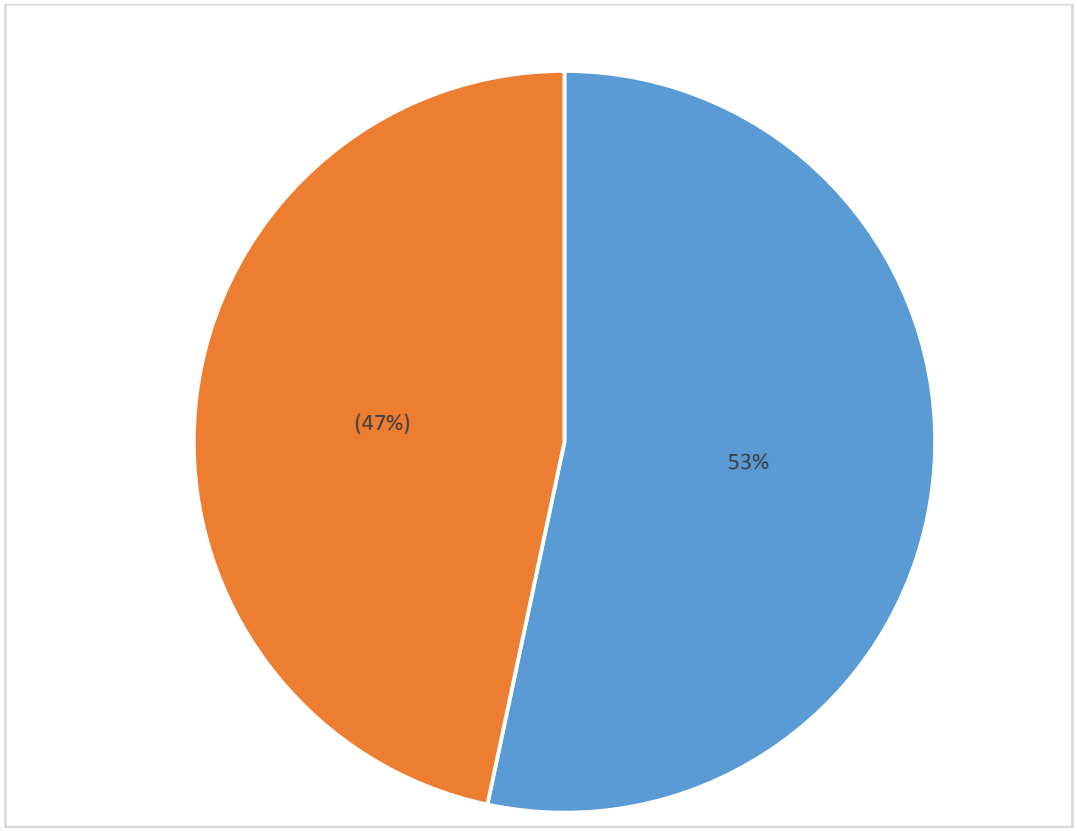
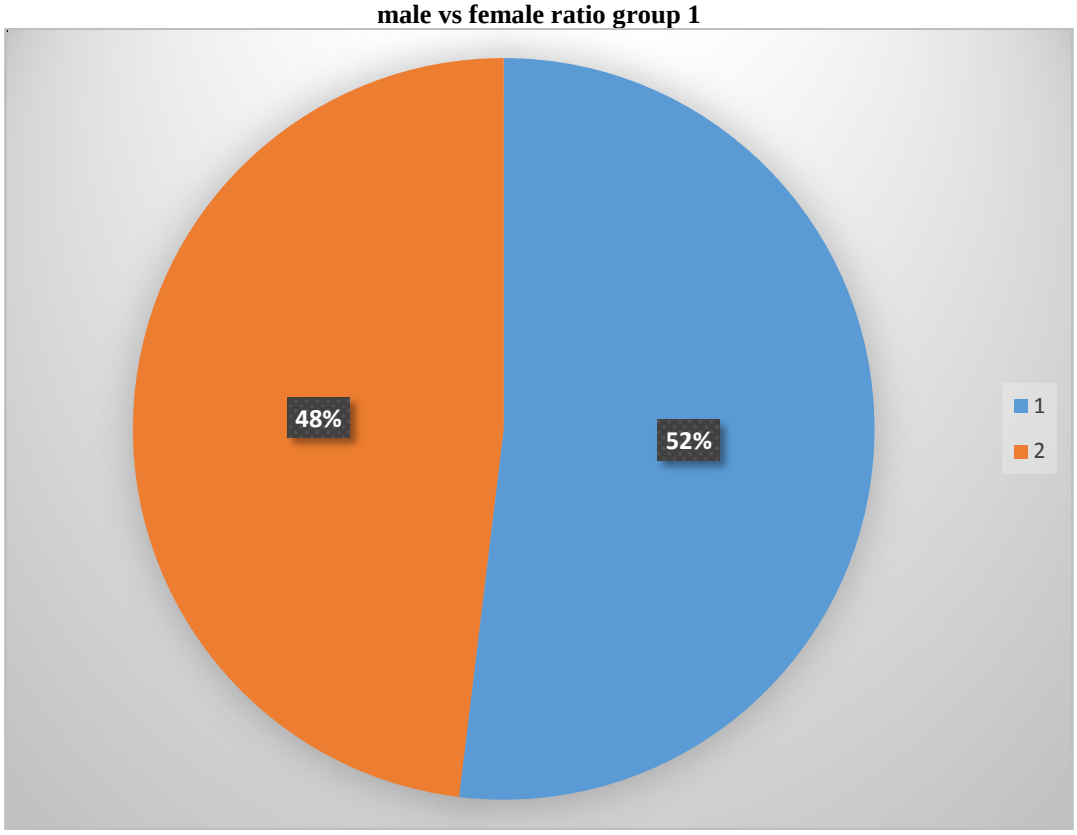


male vs female ratio group 1



Male vs female in group 2

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Table 2 Pre vs Post op Endothelial cell comparison in Group 1(cells/mm^2)

	First day post op	First week post op	Second week post op	Fourth week post op
Mean pre op endothelial cell count	2951.77	2951.77	2951.77	2951.77
SD	92.63	92.63	92.63	92.63
Mean post op endothelial cell count	2851.08	2759.39	2597.46	2559.86
SD	197.28	169.70	289.20	322.44

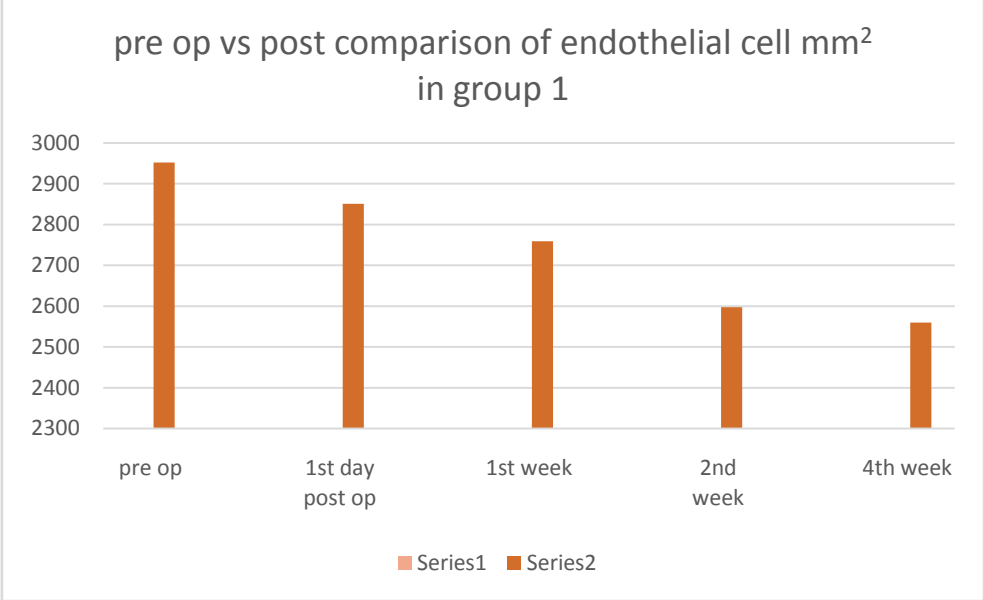

Table 3 Goup 1 First day pre vs post op comparison(cells/mm^2)

	Pre op value	Pre op value	t	p value	Inference
Mean	2951.77	2851.08	4.11	<0.001	Highly significant
SD	92.63	197.28			

Table 4 Group 1 pre vs post op comparison 1st week(cells/mm^2)

	Pre op value	Post op value	t	P value	Inference
Mean	2951.77	2759.39	15.86	<0.001	Highly signficant
SD	92.63	169.7			

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Table 5 Group 1 pre vs post op comparison 2nd week(cells/mm$^{2)}$

	Pre op value	Post op value	t	P value	Inference
Mean	2951.77	2759.39	15.86	<0.001	Highly signficant
SD	92.63	169.7			

Table 6 Group 1 pre vs post op comparison 4th week(cells/mm^2)

	Pre op value	Post op value	t	P value	Inference
Mean	2951.77	2559.86	10.09	<0.001	Highly signficant
SD	92.63	322.44			

Table 7 Pre vs Post op Endothelial cell comparison in Group 2 (cells/mm^2)

	First day post op	**First week post op**	**Second week post op**	**Second week post op**
Mean pre op endothelial cell count	2880.29	2880.29	2880.29	2880.29
SD	172.43	172.43	172.43	172.43
Mean post op endothelial cell count	2696.08	2612.82	2473.27	2418.94
SD	216.11	226.86	227.72	232.53

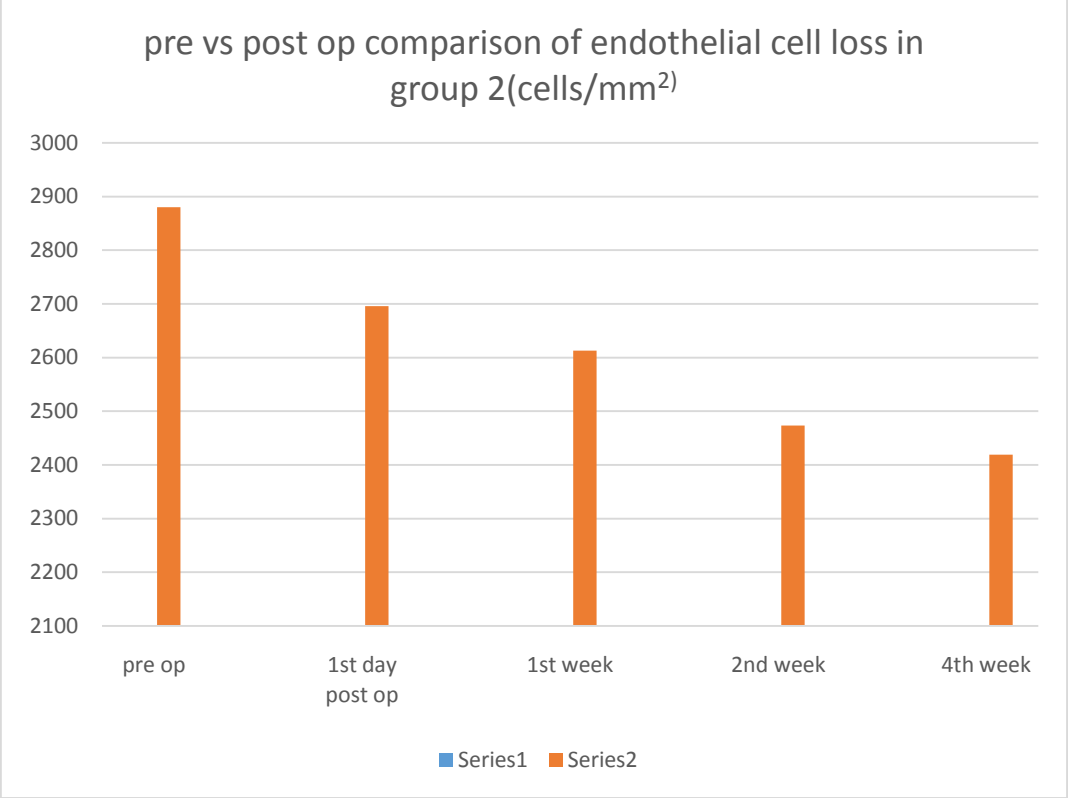

Table 8 Goup 2 First day pre vs post op comparison(cells/mm$^{2)}$

	Pre op value	**Post op value**	**t**	**p value**	**Inference**
Mean	2880.29	2696.8	9.13	<0.001	**Highly**

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SD	172.43	216.11			**significant**

Table 9 **Goup 2 First week pre vs post op comparison(cells/mm$^{2)}$**

	Pre op value	**Post op value**	**t**	**P value**	**Inference**
Mean	2880.29	2612.8	11.96	<0.001	**Highly significant**
SD	172.43	226.86			

Table 10Goup 2 Second week pre vs post op comparison(cells/mm$^{2)}$

	Pre op value	Post op value	t	p value	Inference
Mean	2880.29	2473.27	15.69	<0.001	Highly significant
SD	172.43	227.72			

Table 11 Goup 2 Fourth week pre vs post op comparison(cells/mm$^{2)}$

	Pre op value	**Post op value**	**t**	**P value**	**Inference**
Mean	2880.29	2418.94	15.82	**<0.001**	**Highly significant**
SD	172.43	232.53			

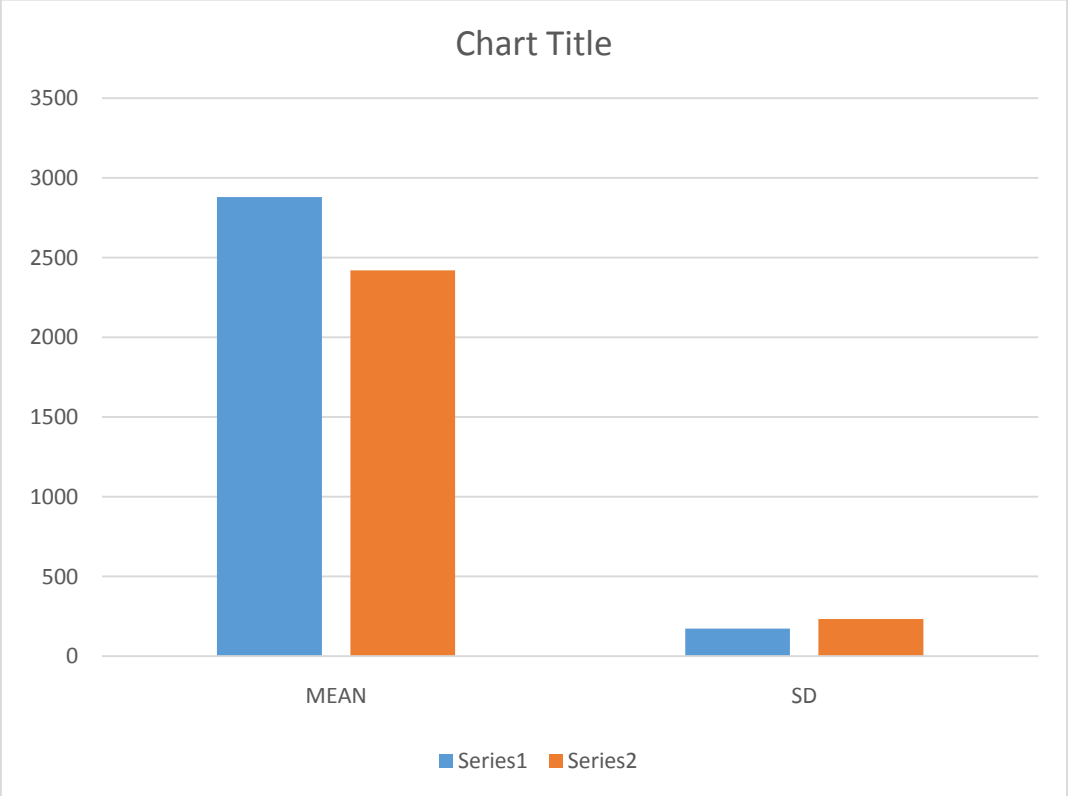

Table 12 Significance relationship between group 1 and group 2

	t	**P value**	**singnificance**
First day	4.68	**<0.001**	**Highly significant**
First week	3.37	**<0.001**	**Highly significant**
Second week	2.64	**<0.001**	**Highly significant**
Fourth week	2.55	**<0.001**	**Highly significant**

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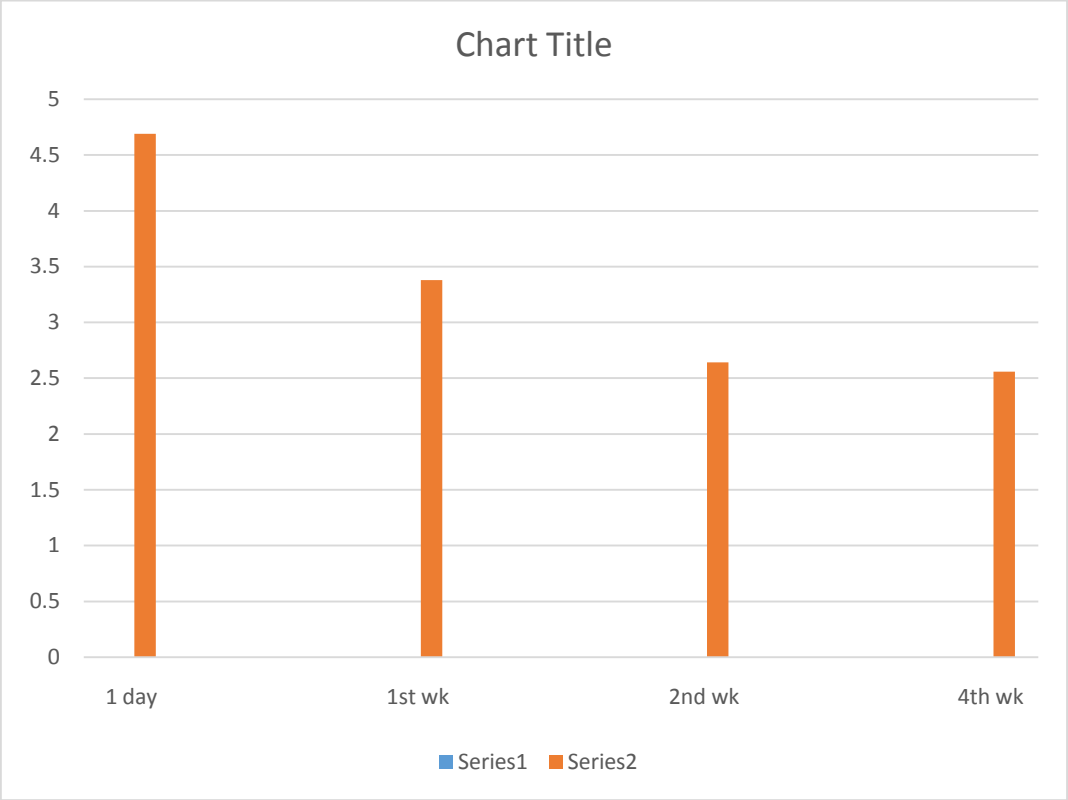

Statistical Analysis

The continuos variables were presented as mean+/- standard deviation and pair t test was used to compare differences between pre and post endothelial cell count.

A p value of less tha0 0.05 was considered statistically significant.

RESULT

In the above study pre operative endothelial cell countwas compared with post operative endothelial cell loss on first day,firstweek,second week and fourth week in both groups and the difference was statistically analysed using paired t test and p value was calculated.

All 97 eyes were assessed by specular microscope had preoperative corneal endothelial cell count ranging from 2100 – 3000 cells/mm^2 which decreased with increasing age (P<0.001).

45 eyes (46.39%) underwent MSICS while 52 eyes (53.60%) underwent phacoemulsification with 51 eyes (52.57%) been for males and 46 eyes (47.42%) for females.

Patients were divided into groups 1 (45 patients) who underwent SICS and 2 (52 patients) who underwent Phacoemulsification.

In Group 1 there was significant loss of endithelialcells(p value<0.001) on 4th week post op(Average loss 346 cell/mm^2) compared to average preop endothelial cell count(2951.77cells/mm$^{2)}$.

In Group 2 there was significant loss of endothelial cells(p<0.001) on 4th week post op(Avg loss 461 cells/mm$^{2)}$ compared to average preop endothelial cell count of 2418cells/mm$^{2)}$

Analysis of the difference in endothelial cell loss both within(p value<0.001) and between the two groups was found to be highly statisticaly significant(p value<0.001).

DISCUSSION

The findings of our study is consistent with the study of **Kaur T et al** where loss was more in group that underwent phaco emulsification as compared to SICS.

Comparative evaluation done by **Balan Reshma et** al showed the mean endothelial cell loss in SICS group showed lesser corneal endothelial cell loss than Phacoemulsification in all study interval.

The study revealed a preoperative statistically significant decrease in corneal endothelial cell count with increasing age (P value

<.001). Previous studies have shown a variation of the corneal endothelial cell count by age.

The corneal endothelial cell count varies from 3500 – 4000 cells/mm^2 in infancy to about 2400 to 3200 cells/mm^2 in adults.

. Further more evidence from literature reveals that as an individual age the corneal endothelial count declines by 30 -50% between the ages of 15 and 75 years. The mechanisms leading to endothelial cell loss with increasing age are not well known though some evidences associated it with aging degenerative changes.

All eyes which were recruited in this study had corneal endothelial count ranging from 2100 to 3000 cells/mm^2 which was above the lower limit which is said to be capable of maintaining the corneal deturgescence. Hence, post operative bullous keratopathy was less likely expected to occur

Results obtained in our study was contradictory to results obtained by **S Ganekal et al**, over 6 weeks there was decrease in cell density of 76.12 cells/mm2 (3.27%) for phacoemulsification and 315.08 cells/mm2 (13.49%) for MSICS. This difference in mean endothelial cell density at 1 week and 6 weeks was statistically significant (P = 0.016). This depicts that in PhacoGroup the mean endothelial cell density at 1 and 6 weeks stabilized and was maintained, whereas the cell density in the MSICS at 1 and 6 weeks was reduced significantly.

The available literatures show enorrmous factors responsible for the corneal endothelial cell loss following cataract surgery. Some of these factors are related to pre-operative selection and evaluation of patients and other majorities are intra-operative factors. One example of the common preoperative factors is the overlooking on the preoperative examination, not performing specular microscopy pre operatively to identify patients with low endothelial count or those with corneal guttata hence the emphasis of this study is to create awareness to clinicians to perform specular microscopy to help quantify endothelial reserve and to aid in risk assessment.

Other factors documented to relate with greater endothelial cell loss in Phacoemulsification has been correlated with cataract incision size and location,density of nucleus, total ultrasound energy used, volume of fluid irrigated into the eye at the time of surgery and individual surgeon techniques a skill and overall duration of surgery.

These mentioned factors could probably be among the factors responsible for the endothelial cell loss in the current study although a specific study need to be done to find out the responsible factors for the endothelial cell loss at this institution.

Endothelial cell loss if sufficiently severe can cause endothelial cell density to fall below the threshold level needed to maintain corneal transparency. The threshold of endothelial cell density varies considerably amongst individuals. The minimum cell density necessary for adequate function is in the range of 400 - 1000 cells/mm^2.The maintenance of relative stromal dehydration requires this critical number of functioning endothelial cells, without which the cornea becomes edematous and cloudy. The cornea endothelium's chief function is to remove fluid from the cornea stroma allowing the cornea to remain optically clear. Hence, the cornea may remain clear after significant endothelial cell loss if the average cell count per square millimeter does not fall below the range of 400 - 1000 cells/$mm^{2.}$

CONCLUSION

From above study it can be concluded that there occurs significant endothelial cell loss in both group of patients who underwent cataract surgery either SICS or Phacoemulsification.

Maximal cell loss was seen in immediate post op period.Loss was found to be slightly higher in phaco group but the difference of cell loss between two groups was found to steadily decline during fourth week interval.

Hence it can be concluded thal Manual SICS surgery still reamins a safe sugery in hands of experienced surgeon, economical with shorter learning curve especially in set up like ours.

LIMITATIONS OF STUDY

Above study could have been more yielding in terms of outcome if we had a longer study duration, more number of recruited patients and a longer follow up post operatively.

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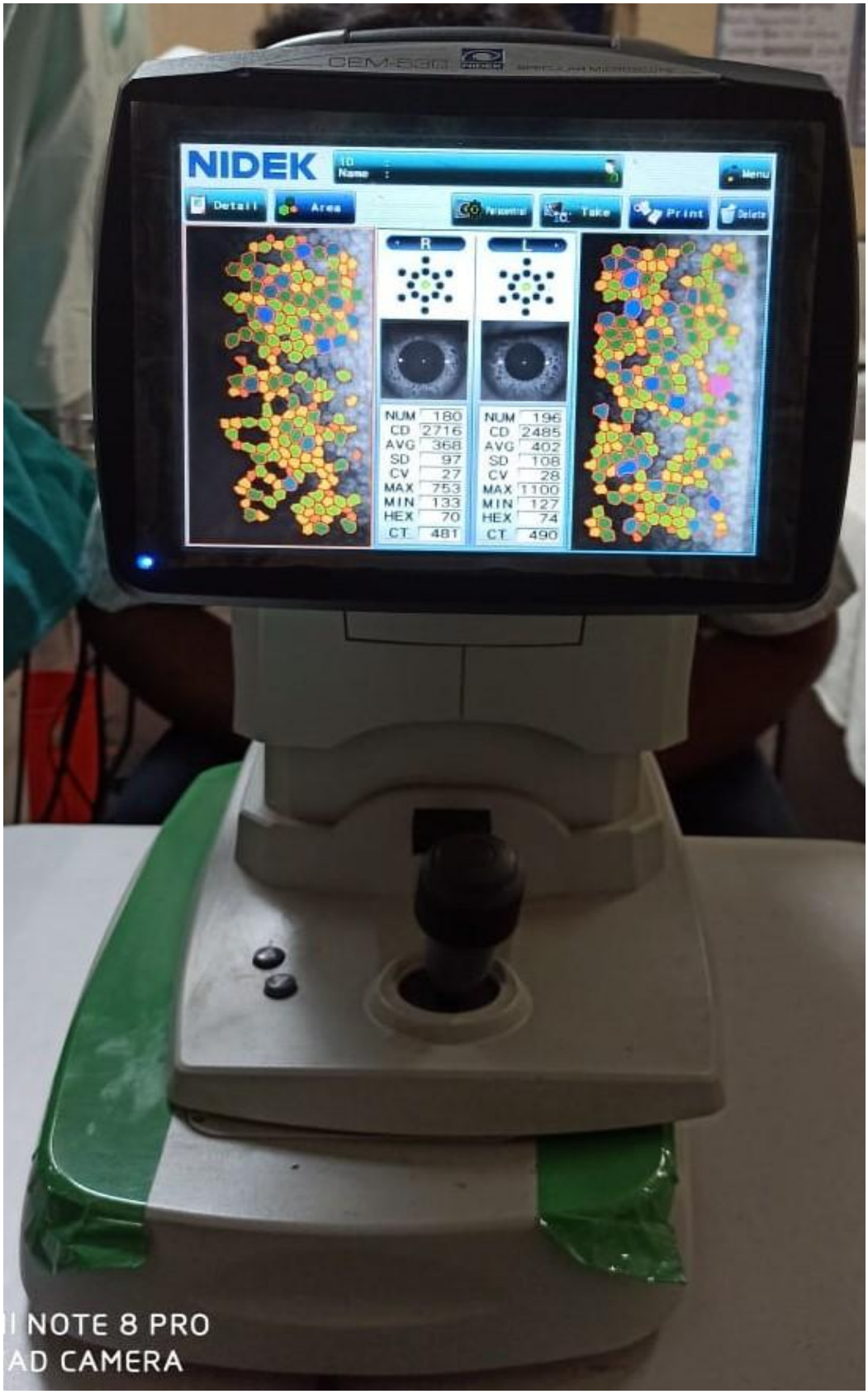

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Working proforma

Case no
Name
Age
Sex
Ward no
Mobile no
Referred By Dr
Clinical history
Past history
Personal History
Family History
General physical examination
Systemic examination
Local examination
1 BCVA
2 Slit lamp examination
3 K**eratometry**
4 Specular Biomicroscopy