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Original Research Article

A Comparative Study of Pre & Post Operative Specular Microscopy Counts of Cataract Surgery Patients- Phacoemulsification Vs Manual Small Incision Cataract Surgery in a Tertiary Care Hospital

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Abstract

Introduction: The definitive treatment of cataract is surgical removal of the opacified lens. The damage to the corneal endothelium during surgery leads to corneal endothelial cell loss which if severe can eventually lead to corneal oedema. The study was conducted in our hospital for the assessment of the corneal endothelium preoperatively and post operatively in cataract surgery patients as it would help to provide baseline information for future studies and it would contribute towards improvement of quality of care at our hospital.

Methodology: This was a randomized prospective comparative longitudinal study of 200 eyes, who underwent cataract surgery by Phacoemulsification (Group A) and Manual Small Incision Cataract Surgery (Group B) with Posterior chamber intraocular lens (PCIOL) implantation. Each group had 100 cases selected by convenience sampling method. Endothelial cell count was measured on a non-contact photographing specular microscope, Tomey EM -3000. Endothelial cell count was measured preoperatively and postoperatively on day 1, day 7, 1 month, 3 months.

Data master sheets were used to process and analyze collected data by using tables and figures using the Microsoft Excel 2013 software. The statistical software used was Graphpad InStat 4.0 . Demographic variables were presented using descriptive statistics like ratios, proportions and percentages. Unpaired t- test and One way ANOVA test were used to compare variables in 2 groups respectively.

Results: The loss of endothelial cells (%) on Day 1, Day 7, 1 Month and 3 Months in Phacoemulsification group was 9.9%, 11.8%, 13.7% and 13.9% respectively, depicting a small range of loss of cells between 9.9% to 13.9%. In the Small Incision Cataract Surgery group it was 10.7%, 12.7%, 14.6% and 14.8% respectively with a relatively larger range from 10.7% to 14.8%.

Conclusion: At 3 months postoperative period there was no clinically or statistically significant difference in endothelial cell loss between Phacoemulsification and Manual Small Incision Cataract Surgery.

Keywords: Endothelial cells , Phacoemulsification, Small incision cataract surgery.

Introduction

Age related Cataract is believed to be the main cause of reversible blindness worldwide and in developing countries [1]. The prevalence of cataract increases with age and is slightly higher in women [2]. Lens opacities are found in more than 70% of all people more than 75 years of age [2]. A cataract is a clouding of the lens of the eye that may lead to loss of vision. Cataracts result from many conditions, the most common cause is the natural aging process due to degenerative changes on the specific lens proteins within the lens which are altered leading to gradual clouding of the lens. Other causes include eye injury, chronic eye diseases and other systemic diseases, such as diabetes mellitus [3]. Cataract surgery is the most common major eye surgery [4]. The aim of cataract surgery is to prevent blindness by restoring normal vision [5] as well as improving the quality of life. Extracapsular cataract extraction is performed to remove the cataractous nucleus and cortex, and today phacoemulsification technique tends to become an ideal vision rehabilitation technique with a view to ensuring patients' quality of life. Every cataract extraction even in experienced hands and modern techniques involves some corneal manipulation and endothelial damage. Severe damage leads to late corneal decompensation, which has been reported to occur in about 1% of cataract extractions [6]. The damage to the corneal endothelium leads to corneal endothelial cell loss which if severe can eventually lead to the development of corneal oedema [7]. This leads to the loss of corneal transparency and poor visual outcome post cataract surgery. Corneal transparency is regulated by a corneal endothelial pump that can be interfered by surgical trauma. The corneal endothelium is the innermost layer of the cornea made up of hexagonal cell monolayer that does not divide significantly i.e. does not regenerate when damaged. The corneal endothelial layer possesses the ability to pump water out of the corneal stroma against an osmotic gradient since it contains an active Na^+/K^+ pump [7,8,9]. Its cell count varies from 3500 – 4000 cells/mm^2 in infancy to about 2400 to 3200 cells/mm^2 in adults [10]. Studies have shown that, for the cornea endothelium to perform the function of maintaining corneal clarity it must consist of healthy cells above a minimum cell density which is reported to range from 400 – 700 cells/mm^2 . If the average cell count per square millimeter falls below this limit, it is likely that stromal oedema and bullous keratopathy will result following cataract surgery [7,9,10,11]. Deturgescence (dehydrated state) of corneal endothelial stroma can be monitored by measurement of corneal endothelial cell counts [12]. Some amount of endothelial cell loss invariably occurs in all types of cataract surgery but the amount of endothelial cell loss varies with surgical technique [13]. Loss or damage of endothelial cells leads to an increase in corneal thickness (oedema) which may ultimately induce corneal decompensation and loss of vision [14]. Corneal endothelial cell density reduction may be a result of a number of factors. Cataract extraction has been reported by several studies to be one of the factors contributing to the reduction of corneal endothelial cell density. The mechanisms are related to surgical manipulation by the surgeons resulting in corneal endothelial damage and consequently leading to corneal endothelial cell loss [15,16]. Other factors leading to corneal endothelial cell loss include, (a) Aging process [9,17] as in most individuals the cell density decreases from birth to death due to the senile degenerative changes of the corneal endothelium, (b) Glaucoma, elevated intraocular pressure result in the gradual loss of endothelial cells and a progressive loss in endothelial function which is said to be not the direct result of high pressure but rather due to some metabolic disturbance, such as prolonged low oxygen concentration in the aqueous humor [18], (c) Intraocular inflammation is said to be another factor contributing to endothelial cell loss, in the most advanced cases the inflammatory cells dislodge individual endothelial cells and cause them to float free in the aqueous humor [19], (d) Posterior annular keratopathy, occurring after blunt corneal trauma in humans, represents a contusion injury and consists of disrupted and swollen endothelial cells [20,21] and (e) Fuchs' endothelial dystrophy [10]. Hence, preoperative assessment of corneal endothelium as well as ruling out the existence of such conditions is important for the surgery to be successful. The main objective of the current study was to assess the corneal endothelial cell count pre and post cataract surgeries.

Aims and Objectives

Primary Objective: To estimate the specular microscopy counts before and after cataract surgery by Phacoemulsification and Manual Small Incision Cataract Surgery.

Secondary Objective: To estimate the endothelial cell loss after cataract surgery by Phacoemulsification and Manual Small Incision Cataract Surgery.

Tertiary Objective: To compare the endothelial cell loss after cataract surgery by Phacoemulsification vs. Manual Small Incision Cataract Surgery.

Materials and Methods:-

The study was conducted in Department of Ophthalmology, Lokmanya Tilak Municipal Medical College, Sion, Mumbai. It was single centre, randomized prospective comparative longitudinal study of 200 eyes, who underwent cataract surgery by Phacoemulsification (Group A) and Manual Small Incision Cataract Surgery (Group B) with Posterior chamber intraocular lens (PCIOL) implantation. Each group had 100 cases selected by convenience sampling method. The sample-size estimation was based on an 80% power to detect a 20% difference in endothelial cell loss at a 5% level of significance and with a 20% loss to follow-up.

Approval was obtained from the Institutional Ethics Committee- Human Research before commencement of the study. All patients' information was kept confidentially.

The Specular Microscopy : Endothelial cell count was measured on a non-contact photographing specular microscope, Tomey EM -3000. This microscope captures a seven point area of 0.25 mm x 0.54 mm with one central and 6 peripheral points (2, 4, 6, 8, 10, and 12-o'clock positions on a 0.6 mm arc) of capture via auto or manual modes. Fixed frame analysis method was used to capture the central area of cornea. It measures corneal thickness upto an accuracy of +/-10 um. It automatically computes the data stating the number of cells, cell density (average cell area), standard deviation of cell area, coefficient of variation of cell area and the minimum and maximum cell areas, also a histogram of the polymegathism and pleomorphism. A series of 15 serial photographs were taken and the best image amongst the 15 was displayed and used for which was the computations. Endothelial cell count was measured preoperatively and postoperatively on day 1, day 7, 1 month, 3 months from January 2016 to November 2017.

Preoperative workup: On presentation, an informed consent form was filled by each patient before the patient was included in the study. A detailed history was obtained from patients/relatives. Questions were asked in order to rule out systemic disorders associated with cataract. A detailed history was followed by a thorough ophthalmic evaluation comprising of 1. Visual acuity (Best Corrected Visual Acuity BCVA) 2. Ocular Examination. 3. Intraocular Tension. 4. Lacrimal Sac Patency. 5. Slit Lamp Examination. 6. Auto Refractometry. 7. Keratometry. 8. A-Scan. 9. Direct/Indirect Ophthalmoscopy . 10. Specular Microscopy (Model - TOMEY EM-3000). 11. B scan (where indicated). 12. Optical Coherence Tomography (OCT) optic disc and macula (where indicated).

Inclusion Criteria: 1. Patients above the age of 40 years 2. Grade I–III nuclear cataract, PSC (posterior subcapsular cataract) and cortical cataract 3. Patients undergoing Phacoemulsification and Manual Small-incision Cataract Surgery without significant intraoperative complications (like posterior capsular rent, zonular dialysis, vitreous loss , Descemet's detachment).

Exclusion Criteria: 1. Complicated cataract 2. Black cataract 3. Traumatic cataract 4. Cataract associated with glaucoma 5. Uveitis 6. Corneal Pathology 7. Acute infection of eyes 8. Eyes which had undergone previous ocular surgery.

Randomisation Technique: Ballots drawn from sealed envelopes at the beginning of the surgery were used to randomly allocate each patient to Phacoemulsification or Small Incision Cataract Surgery (SICS). There were 100 ballots for each of 2 surgeons; 50 ballots were for group A phacoemulsification and 50 for group B SICS. The allocation codes were sealed in sequentially numbered, opaque envelopes and kept by the study coordinator. The envelopes were opened 10 minutes before surgery. The participating surgeons were not involved in the care or opening of the envelopes.

Procedures:

Patients were allocated to either Manual small incision cataract surgery group or Phacoemulsification group according to the grade of cataracts they presented with. Grading of nuclear cataract was done using WHO – simplified cataract grading system (2002) whereby cataracts grade 1 up to grade 3 were included.

All the operations were carried out by two of the senior most faculties at our hospital under local peribulbar anaesthesia. Under all aseptic precautions the eye to be operated was painted with 10 % Povidone iodine (for skin) and was draped. Eyelids were retracted with wire speculum and one drop of 5% Povidone iodine was instilled in the conjunctival cul-de-sac.

Group A comprised of 100 eyes who underwent cataract surgery by Phacoemulsification with PCIOL (Posterior chamber intraocular lens) implantation. A clear corneal groove of 2.8 mm was made with 15 No. blade at 11 o'clock. By depressing the portions of the lips of the groove, the point of the keratome was slid into the anterior chamber (AC). Two side ports were made with a side port blade of 15° at 9 and 2 o' clock. Corneal tunnel was triplanar and had self-sealing property. After entering the anterior chamber, viscoelastic was injected in AC. Continuous curvilinear capsulorrhexis (CCC) was done with 26 gauge bent needle. Hydrodissection and hydrodelineation was performed using ringer lactate solution and a 23 G hydrocannula. The nucleus was freely rotated and removed by phacoemulsification on a peristaltic based vacuum phacoemulsification system with stop and chop technique. The cortical matter was aspirated using a Simcoe cannula. Viscoelastic was injected in the AC and the internal lip of the wound was extended with the keratome upto 3 mm. A foldable acrylic IOL was implanted in the bag in all cases using an injector. Viscoelastic was washed off and AC was formed with ringer lactate solution. Main incision site and side port opening were sealed by stromal hydration. The corneal lip hydration helped in self-sealing of the wound. Subconjunctival injection of Gentamycin (20 mg) and Dexamethasone (2 mg) was injected . Eye ointment Chloramphenicol was instilled in conjunctival sac. Eye pad was applied.

Group B comprised of 100 eyes who underwent cataract surgery by Manual Small Incision Cataract Surgery with PCIOL implantation.. A bridle suture was passed through the superior rectus. A fornix based conjunctival flap was made superiorly with corneoscleral scissors and hemostasis was achieved with wet field bipolar cautery. A 6 mm straight 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 mm into clear cornea. 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 CCC technique with 26 gauge bent needle. At this point, AC entry was made with a keratome of 3.2 mm. Hydrodissection was performed with ringer lactate solution using a 23 G cannula. Nucleus was prolapsed into AC and delivered using visco expression. Cortical matter was aspirated using a Simcoe cannula. A foldable acrylic IOL was implanted in the bag. Viscoelastic was 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. Eye ointment Chloramphenicol was instilled in conjunctival sac. Eye pad was applied.

Data management and analysis: Data master sheets were used to process and analyze collected data by using tables using the Microsoft Excel 2013 software. The statistical software used was Graph pad In Stat 4.0. Demographic variables were presented using descriptive statistics like ratios, proportions and percentages. Unpaired t- test and One way ANOVA test were used to compare variables in 2 groups respectively.

Postoperative follow up: Patients were evaluated post-operatively on day 1, day 7, 1 month and 3 months. At each visit - best corrected visual acuity, ocular examination, intraocular tension, slit lamp examination, auto refractometry, direct/indirect ophthalmoscopy (where indicated) and specular microscopy, B scan and OCT optic disc and macula (where indicated) were done.

Observations and results:

Male patients numbers were as follows: Phacoemulsification 55, Small incision cataract surgery 59. Female patients were as follows: Phacoemulsification 45, Small incision cataract surgery 41.

Distribution of patients as per age groups is shown in Table 1.

Table 1: Distribution of Patients as Per Age Groups

Age groups	Phacoemulsification	SICS
40-50 years	19	17
51-60 years	27	29
61-70 years	38	35
>=71 years	16	19
Total	100	100

Preoperative specular endothelial cell counts (Cells /mm^2) in patients of both groups were compared. The two-tailed p value was 0.5463, considered not significant. Pre-operative specular endothelial cell counts (per mm^2) were therefore comparable in both groups of patients. (Table 2)

Table 2: Preoperative Specular Endothelial Cell Counts (Cells /Mm^2) in Patients of Both Groups

Time relation with surgery	**Specular counts for Phaco (Mean+/-SD)**	**Specular counts for SICS (Mean +/- SD)**	**p Value**
Preoperative period	2618 +/- 188	2597 +/- 202	0.5463

Mean Specular endothelial cell counts (Cells/mm^2) in patients undergoing phacoemulsification surgery are shown in Table 3.

Table 3: Mean Specular Endothelial Cell Counts (Cells/mm^2) in Patients undergoing Phacoemulsification Surgery

Time relation with surgery	Specular counts (Mean+/-SD)
Preoperative period	2618+/-188
Day 1 post-operative	2358+/-197
Day 7 post-operative	2308+/-200
1 Month post-operative	2259+/- 199
3 Months post-operative	2253 +/- 199

Mean Specular endothelial cell counts (Cells/mm^2) in patients undergoing SICS are shown in Table 4**.**

Table 4: Mean Specular Endothelial Cell Counts (Cells/mm^2) in Patients Undergoing SICS

Time relation with surgery	**Specular counts (Mean+/-SD)**
Preoperative period	2597+/-202
Day 1 post-operative	2318+/-213
Day 7 post-operative	2266 +/- 214
1 Month post-operative	2219 +/- 214
3 Months post-operative	2212 +/- 210

The two-tailed p Value is > 0.05 in all four groups of PHACO v/s SICS of Specular Endothelial Cell Counts (per mm^2) on Post-Operative Day1, Day 7, 1 Month & 3 Months and hence considered not significant. Post-Operative Specular Endothelial Cell Counts (per mm^2) are therefore comparable in both the groups of patients (Table 5).

Table 5: Post-Operative Comparison of Specular Endothelial Cell Counts (Cells /mm^2) in Patients of Both Groups

Time relation with surgery	**Specular Counts for PHACO (Mean ± SD)**	**Specular Counts for SICS (Mean ± SD)**	**p Value**
Day 1 post-operative	2358+/-197	2318+/-213	0.2127
Day 7 post-operative	2308+/-200	2266 +/- 214	0.1875
1 Month post-operative	2259+/- 199	2219 +/- 214	0.4243
3 Months post-operative	2253 +/- 199	2212 +/- 210	0.5765

We also calculated the mean loss of endothelial cells post-operatively compared to the pre-operative counts serially. The loss of endothelial cells (%) on Day 1, Day 7, 1 Month and 3 Months in PHACO Group was 9.9%, 11.8%, 13.7% and 13.9% respectively, depicting a small range of loss of cells between 9.9% to 13.9% while in the SICS Group it was 10.7%, 12.7%, 14.6% and 14.8% respectively with a relatively larger range from 10.7% to 14.8%. As per Table 6 the difference was not significant (Table 6).

Table 6: Comparison of Mean Post-Operative Loss of Endothelial Cell Counts (Cells/mm2)

Time relation with surgery	Mean Loss of Cell Counts for PHACO	Mean Loss of Cell Counts for SICS
Day 1 post-operative	260 (9.9%)	279 (10.7%)
Day 7 post-operative	310 (11.8%)	331 (12.7%)
1 Month post-operative	359 (13.7%)	378 (14.6%)
3 Months post-operative	365 (13.9%)	385 (14.8%)

Discussion

The proponents of Manual small-incision cataract surgery (SICS) and Phacoemulsification cataract surgery (PHACO) claim equally good results. However, SICS costs much less than phacoemulsification. There is concern that manual SICS may be more harmful to the endothelium than phacoemulsification because most manoeuvring is performed manually in the anterior chamber; in phacoemulsification, the manoeuvring is mechanical and performed in the capsular bag, far from the endothelium.

Significant loss of endothelium can lead to corneal decompensation and loss of corneal clarity. Some degree of endothelial cell loss is inevitable after any type of cataract surgery. Intraoperative and postoperative complications are generally associated with a greater mean cell loss than that in uneventful cases. In uneventful cataract extraction, the mean cell loss varies from 6% to 17%; however, in complicated cases, cell loss can exceed 40%. A cell loss resulting in endothelial cell count less than 1000 cells/mm^2, leads to corneal oedema usually irreversible.

There are numerous studies in literature which have compared PHACO with SICS in terms of serial loss of corneal endothelial cells post-operatively. While some studies mention advantages of PHACO over SICS, majority of the studies conclude that the post-operative loss of endothelial cells is comparable after both the types of surgeries.

In our study, n = 100 patients were enrolled randomly into the PHACO Group while n = 100 patients were enrolled in the SICS Group. (Table 1).

Distribution of our patients in both PHACO & SICS groups based on Age Groups were comparable. The 4 age group distributions were 40-50 years, 51-60 years, 61-70 years and more than or equal to 70 years (Table 1).

The baseline pre-operative specular endothelial cell counts (cells/mm^2) were also comparable in both the groups (p = 0.5463) (Table 2).

But when we compared the counts in both the groups (Table 5) it showed that the counts (cells/mm^2) in both the PHACO & SICS groups were comparable post-operatively, similar to the pre-operative counts (Table 2).

In addition, we also compared the Mean Post-Operative Loss of Endothelial Cell Counts (cells/mm^2) (Table 6) in both the groups and it showed that the loss of cell counts(cells/mm^2) compared to baseline were similar in both the groups of patients ranging from a minimum of 260 to a maximum of 365 cells in the PHACO group and from 279 to a maximum of 385 cells in the SICS group.

The loss of cell counts (cells/mm^2) at the various time points in our study showed that patients undergoing PHACO had an approximate cell loss of 9.9-13.9% while patients undergoing SICS had a cell loss of 10.7-14.8%, thus depicting a comparable cell loss.

A greater cell loss (cells/mm^2) noted in the SICS group as compared to the cell loss (cells/mm^2) in the PHACO group shows a slightly greater chance of endothelial cell damage during SICS, even though not statistically significant. This damage could have been further reduced by using better cohesive viscoelastics rather than the routine dispersive type and using the soft shell technique for hard cataracts.

A study similar to ours was published by Gogate P et al (2010) [22]. The study evaluated 200 patients, 100 in each group. The mean preoperative Endothelial Cell Count (ECC) by the manual counting method was 2950.7 cells/mm^2 in the phacoemulsification group and 2852.5 cells/mm^2 in the SICS group and by the automated counting method, 3053.7 cells/mm^2 and 2975.3 cells/mm^2, respectively. The difference at 6 weeks was 543.4 cells/mm^2 and 505.9 cells/mm^2, respectively, by the manual method (p=0.44) and 474.2 cells/mm^2 and 456.1 cells/mm^2, respectively, by the automated method (p = 0.98). The corrected distance visual acuity at 6 weeks was better than 6/18 in 98.5% of eyes in the phacoemulsification group and 97.3% of eyes in the SICS group.

Compared to this study, our study evaluated the patients in both the groups for 3 months (12 weeks) while Gogate P et al (2010) evaluated their patients for only 6 weeks. But, the difference in cell count in both these studies has shown similar results.

A study comparing the effect of different phacoemulsification techniques on corneal endothelial cells in Denmark (Storr-Paulsen A et al, 2008) [23] found similar 3-months and 1- year results. In our study too, the lack of a statistically significant difference in endothelial cell loss between the 2 techniques at 3 months is likely to continue over time.

Another study similar to the above study in duration is by Ganekal S (2014) [24] in which patients were randomly allocated to undergo phacoemulsification (Group 1, n = 100) or MSICS (Group 2, n = 100). The difference in mean endothelial cell density between groups at 1 week and 6 weeks was statistically significant (P = 0.016). The mean coefficient of variation and mean standard deviation between groups were not statistically significant (P > 0.05, both comparisons).

They concluded that the central corneal thickness, coefficient of variation, and standard deviation were maintained in both groups indicating that the function and morphology of endothelial cells was not affected despite an initial reduction in endothelial cell number in MSICS. Thus, MSICS remains a safe option in the developing world. These findings are similar to the Gogate P et al (2010) study and our findings.

Limitations of study: The shortcoming of this study was that only one technique of PHACO & SICS each was compared; other techniques may give different results. A longer duration of study might give some different findings.

Conclusion:

The specular counts (Cells /mm^2) in the Phacoemulsification group preoperatively were 2618 ± 188 and in the SICS group were 2597 ± 202 . With a p value of 0.5463 the difference was not significant.

The statistical difference in specular counts comparing Phacoemulsification and SICS was 0.2127 on post- operative day 1, 0.1875 on post- operative day 7, 0.4243 on post- operative 1 month, 0.5765 on 3 months post- operative , all of which were not significant.

The loss of endothelial cells (%) on Day 1, Day 7, 1 Month and 3 Months in phacoemulsification group was 9.9%, 11.8%, 13.7% and 13.9% respectively, depicting a small range of loss of cells between 9.9% to 13.9%.

In the SICS group it was 10.7%, 12.7%, 14.6% and 14.8% respectively with a relatively larger range from 10.7% to 14.8%.

Thus, the amount of cell loss in Phacoemulsification and SICS being comparable, both the surgeries give equivalent results.

Manual SICS costs much less than Phacoemulsification. Significant loss of endothelial cell in any cataract surgery can lead to corneal decompensation and loss of corneal clarity. In our study at 3 months postoperative period there was no clinically or statistically significant difference in endothelial cell loss between phacoemulsification and manual SICS. As manual SICS is economical and less dependent on technology than phacoemulsification, it may be the appropriate surgical procedure for treatment of cataract in the developing world. Proper case selection, diligent surgery, and adequate postoperative care are essential to maintain a clear cornea.

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