Original Article

Corneal endothelial changes following cataract surgery in hard nuclear cataract: Randomized trial comparing phacoemulsification to manual small-incision cataract surgery

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Purpose: To evaluate and compare endothelial cell changes in phacoemulsification and manual small-incision cataract surgery (MSICS) in patients with uncomplicated senile cataracts. **Methods:** This was a prospective, tertiary care hospital-based, randomized, double-blinded interventional study. In total, 152 patients with an uncomplicated senile cataract of nuclear grade III and above were recruited. Exclusion criteria included patients with preoperative endothelial cell density (ECD) less than 1500 cells/mm^3, a history of previous ocular surgery, any other coexisting ocular disease, and intraoperative or postoperative surgical complications. Preoperative and postoperative values of ECD and central corneal thickness (CCT) were measured, analyzed, and correlated with various factors. **Results:** Patients were randomized into two interventional groups-MSICS and phacoemulsification. Factors associated with significant drop in postoperative ECD following phacoemulsification were patients with advanced age ($P = 0.01$), higher grades of cataract ($P = 0.01$), and longer effective phacoemulsification time ($P = 0.007$). Shallow anterior chamber depth (ACD) was strongly associated with greater ECD loss in both groups ($P < 0.0001$). A threshold value of 2.86 mm of ACD was defined for minimal endothelial cell loss following phacoemulsification. CCT was observed to slightly increase postoperatively in both groups but was insignificant ($P > 0.05$). **Conclusion:** Both MSICS and phacoemulsification have similar postoperative visual outcomes. An increase in postoperative CCT is insignificant following surgery. Greater postoperative ECD loss is associated with phacoemulsification with advanced age, hard nuclear cataracts, and longer effective phacoemulsification time. ACD can be used as an essential parameter preoperatively to determine the choice of surgical technique between MSICS and phacoemulsification.

Key words: Central corneal thickness, endothelial cell density, manual small-incision cataract surgery, phacoemulsification

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Cataract is the most common curable cause of diminished visual acuity worldwide.[1] Its extraction is one of the most common surgical procedures performed in ophthalmology and is the most cost-effective procedure second only to vaccination. The main objective of modern cataract surgery is to achieve a better unaided visual acuity with rapid postsurgical recovery and minimal complications. There is a paucity of data from India for comparison between endothelial loss in phacoemulsification and manual small-incision cataract surgery (MSICS) in harder nuclear-grade cataracts. It is imperative to determine the surgical technique to be performed in such cases for optimal results. The current study is designed to analogize endothelial cell loss in phacoemulsification and MSICS in harder nuclear cataracts (more than LOCS grade III).

Methods

The current project was a tertiary care hospital-based, prospective, randomized, interventional, parallel-group study conducted in a tertiary care center for 6 months. Both patients and the investigator were blinded (double blinding).

The study adhered to the tenets of the Declaration of Helsinki and was approved by the Institutional Ethics Committee. The project followed CONSORT (Consolidated Standards of Reporting Trials) 2010 guidelines [Fig. 1] and was registered in the Clinical Trials Registry of India (CTRI) before the recruitment of patients. Written informed consent was obtained from all patients.

The aim of the study was to evaluate and compare endothelial cell loss in MSICS and phacoemulsification in patients with an uncomplicated harder senile cataract of nuclear grade III-V (Lens Opacities Classification System III). Exclusion criteria included patients with an endothelial cell density (ECD) of less than 1500 cells/mm^3, a history of previous ocular surgery, any other coexisting ocular disease, and intraoperative or postoperative surgical complications.

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A total of 152 patients were encompassed in the study after calculating the sample size using the Charan–Biswas formula. The patients underwent randomization by computer-generated random number allocation into two interventional groups-MSICS (Group A) and phacoemulsification (Group B) [Fig. 1].

Work-up protocol

A detailed history was taken and a routine ophthalmological examination was done of each patient. ECD and central corneal thickness (CCT) were measured using a specular microscope (NIDEK Model CEM-530).

Cataract extraction and hydrophobic acrylic intraocular lens implantation (IOL) were performed by either MSICS or phacoemulsification as described by Gupta *et al*.[2]

Adequate preoperative pupillary dilatation was achieved by topical administration of tropicamide 0.8% and phenylephrine 5% eye drops and flurbiprofen 0.03% eye drops. The eyelids and periocular area were painted with 7% povidone–iodine solution twice and the patient was draped. Once fully draped, a self-retaining speculum was used to retract the eyelids, and one drop of 5% povidone–iodine was instilled in the conjunctival cul-de-sac before initiating the surgery.

Phacoemulsification was carried out under topical anesthesia using 5% proparacaine. MSICS was performed after giving a local peribulbar anesthetic block using 2% lignocaine and 0.5% bupivacaine.

Phacoemulsification

All steps and aseptic precautions were followed as mentioned above before the surgery was initiated. A clear corneal incision of 2.8 mm was made, and the site depended on the preoperative corneal astigmatism. The entry into the anterior chamber was carried out with keratome and a side port was made using a lance tip.

Then, 2% hydroxy propyl methyl cellulose was injected into the anterior chamber and continuous curvilinear capsulorhexis (CCC) was done using capsulorhexis forceps. Hydrodissection and/or hydrodelineation were performed using Ringer's lactate solution.

The nucleus was checked if freely mobile and removed by phacoemulsification using the direct chop technique (Alcon Infiniti Ozil Vision System, Alcon Laboratories, USA). The cortical matter was aspirated using the irrigation and aspiration mode. An anterior chamber was filled with 2% hydroxypropyl methylcellulose and IOL was injected using the cartridge and injector system. The viscoelastic substance was washed out, the incision site was checked for leakage, and the edges were hydrated if needed. The effective phacoemulsification time (EPT) was documented after the completion of each case.

Manual small-incision cataract surgery

The surgery was started after waiting for about 1 min of delivering the peribulbar block. No superior rectus suture was taken. A fornix-based conjunctival flap was made to expose the sclera. Conjunctival vessels were cauterized and a corneoscleral tunnel was designed. The length of the incision varied from 6 to 8 mm, depending on the surgeon's assessment of the nucleus size.

Then, 2% hydroxypropyl methylcellulose was injected into the anterior chamber and continuous curvilinear capsulorhexis was done using capsulorhexis forceps. Hydrodissection was performed using Ringer's lactate solution to separate the cortex from the lens capsule. The nucleus was prolapsed out of the capsular bag after making sure that the capsulorhexis was large enough with respect to the nucleus size. The nucleus was delivered after the chamber was inflated with 2% hydroxy propyl methyl cellulose, and the nucleus was extracted with the fishhook technique.

The nucleus was brought out of the tunnel with the support of forceps holding the anterior lip of the tunnel to prevent the upward rotation of the globe. The cortex was aspirated using a Simcoe cannula, and then, with the chamber filled with 2% hydroxy propyl methyl cellulose, IOL was implanted in the bag. The viscoelastic substance was washed out and the tunnel was inspected for integrity by looking for any leakage. At the end of the surgery, a subconjunctival injection of dexamethasone and gentamycin was given (0.25 mL each). There was no need to suture the conjunctiva or cauterize it to bring it back, as the ballooning caused by the subconjunctival injection made it come anterior and drape the exposed sclera. After the surgery, the eye was patched for 4 h.

All patients were examined on the next day of surgery and subsequent follow-ups were done at 1 week and 6 weeks postoperatively.

Statistical tests

Medcalc version 19.1 software application was used for statistical analysis. The Chi-square test was used to compare qualitative variables and an independent test to compare quantitative variables of parametric data. A comparison of the preoperative and postoperative best-corrected visual acuity (BCVA), ECD, and CCT was done utilizing Wilcoxon paired sample test. Spearman correlation (rho coefficient) was used to find the correlation between variables and endothelial cell loss. P value <0.05 was considered to be statistically significant (95% confidence interval [CI]).

Results

There were a total of 152 patients in our study who were randomized into two interventional groups. Group A included 27 (17.7%) patients who underwent MSICS and Group B comprised 125 (82.2%) patients who underwent phacoemulsification.

The mean age of the patients in our study group was 62 ± 9 years. There were 85 (56%) males and 67 (44%) females in the study. The majority of the patients (69.7%) were of nuclear III grade cataracts in both the study groups. There was no statistical difference in the demographic parameters ($P = 0.05$).

Mann–Whitney independent test was applied on BCVA, ECD, and CCT. Comparative analysis of the study variables is tabulated in Table 1.

The postoperative ECD loss was statistically significant ($P = 0.0071$) with greater loss observed in Group B (334.3 ± 253.2) compared to Group A (201.2 ± 158.2) [Fig. 2].

In Group B, factors associated with a significant drop in postoperative ECD were patients with advanced

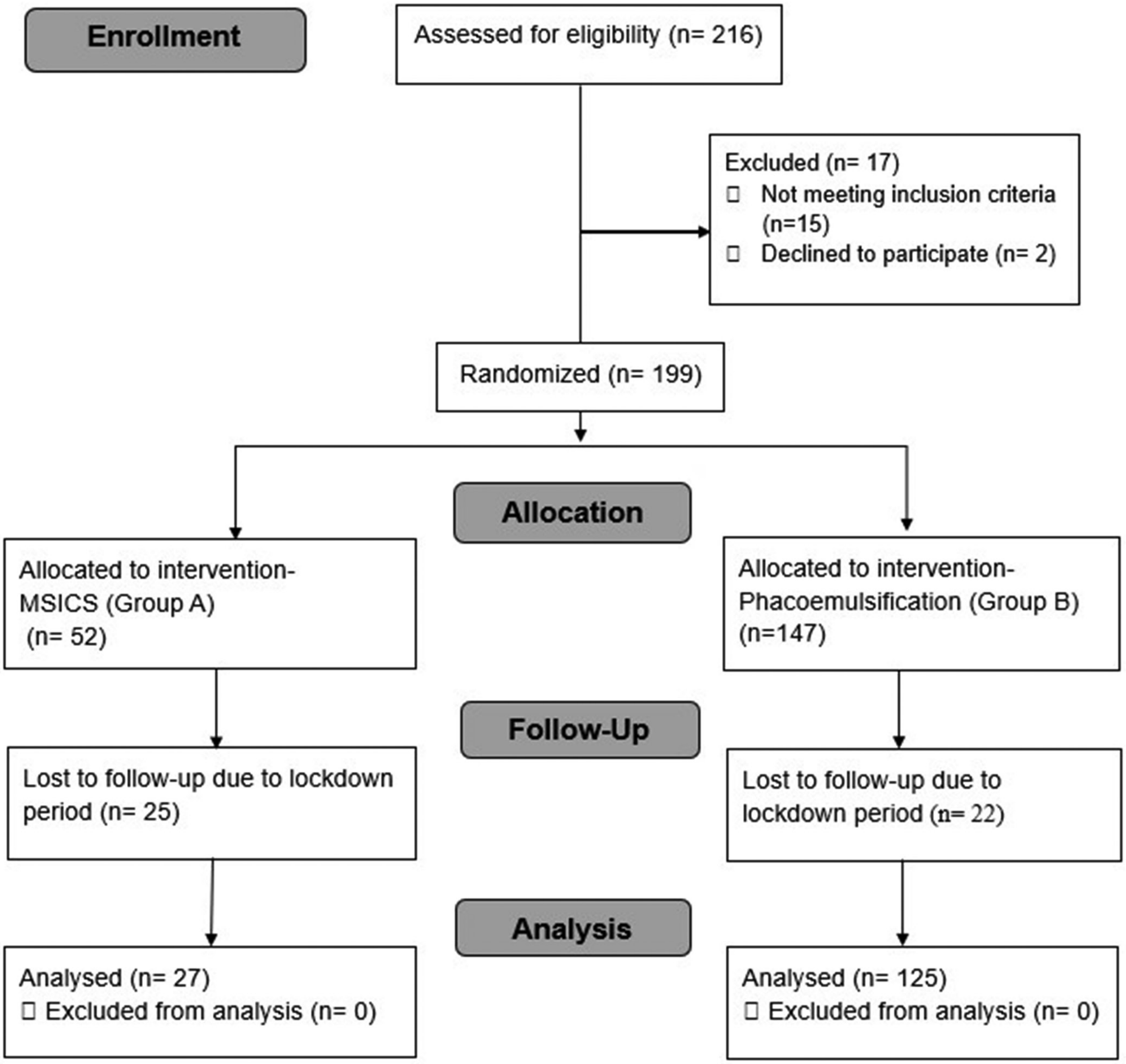

Figure 1: Study protocol as per the CONSORT 2010 guidelines

age ($P = 0.01$) [Fig. 3], higher grades of cataract ($P = 0.01$) [Fig. 4], and longer effective phacoemulsification time (EPT) ($P = 0.007$) [Fig. 5].

Shallow anterior chamber depth (ACD) was observed to cause a significant loss in postoperative ECD in both the study groups ($P < 0.0001$) [Figs. 6 and 7]. A receiver operating characteristic (ROC) curve was plotted for ACD with 95% CI [Fig. 8]. The ROC curve had a sensitivity of 100% and specificity of 71.43%. The area under the ROC curve (AUC) was 0.8, which was statistically significant ($P = 0.044$).

Axial length showed no effect on postoperative ECD in either of the study groups. In the present study, there was no significant correlation seen between ACD and axial length in either of the groups ($P = 0.09$).

The correlation between increase in postoperative CCT was found to be insignificant with advancing age (Group A: $P = 0.63$; Group B: $P = 0.12$), hardness of cataract grade (Group A: $P = 0.84$; Group B: $P = 0.61$), ACD (Group A: $P = 0.06$; Group B: $P = 0.42$), or axial length (Group A: $P = 0.8$; Group B: $P = 0.1$). The correlation between EPT and change in postoperative CCT in Group B was also insignificant ($P = 0.83$).

Discussion

In our study, both techniques yielded favorably good and approximate visual outcomes in terms of mean BCVA at 6 weeks ($P = 0.09$) [Group A: 0.3 ± 0.2 and Group B: 0.2 ± 0.1]. The results were concurrent with earlier reports in the literature, which showed identical visual outcomes in both surgical techniques.[3-6]

Table 1: Comparative analysis of study variables

Study variable	Group A (MSICS)	Group B (Phacoemulsification)	*P*
Mean pre-op BCVA (logMAR)	1.6±0.8	1.2±0.7	**0.02**
Mean post-op BCVA (logMAR)	0.3±0.2	0.2±0.1	0.09
Mean pre-op ECD (in cells/mm²)	2743.18±329.18	2757.2±284.2	0.83
Mean post-op ECD (in cells/mm²)	2541.9±286.7	2422.8±298.9	**0.04**
Mean reduction in ECD	201.2±158.2	334.3±253.2	**0.007**
Mean pre-op CCT (in microns)	537.6±35.1	525.3±32.7	0.08
Mean post-op CCT (in microns)	553.9±25.8	546.0±23.2	0.27
Mean increase in CCT	16.2±14.2	21.7±20.9	0.28

Significant values highlighted in red

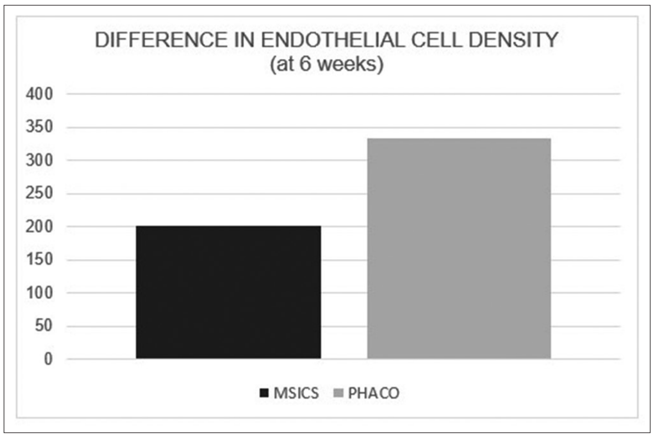

Figure 2: Bar graph depicting postoperative ECD reduction (at 6 weeks) in MSICS versus phacoemulsification

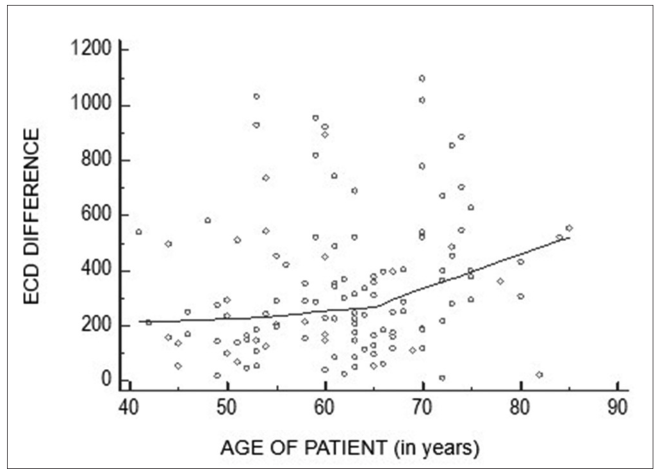

Figure 3: Scatter dot diagram showing correlation of advanced age with postoperative ECD loss (at 6 weeks) in Group B

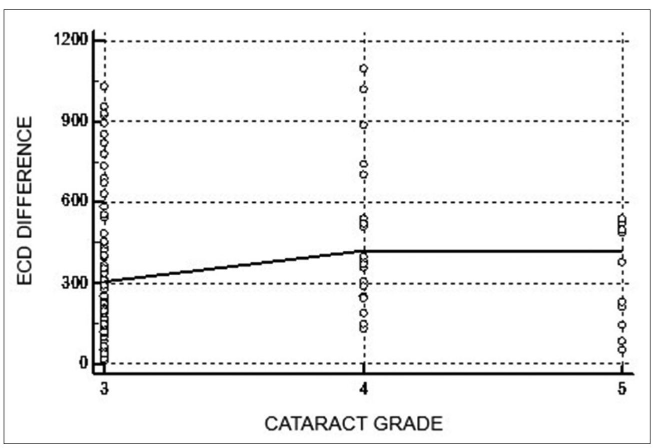

Figure 4: Scatter dot diagram showing correlation of grade of nuclear cataract with postoperative ECD loss (at 6 weeks) in Group B

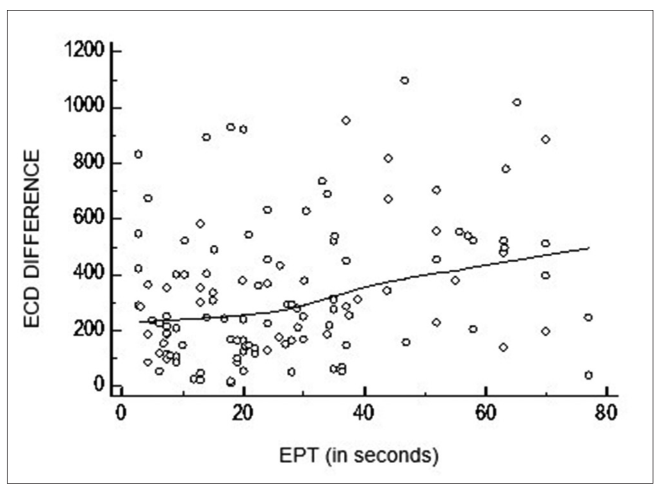

Figure 5: Scatter dot diagram showing correlation of EPT with postoperative ECD loss (at 6 weeks) in Group B

Several studies have quoted insignificant differences in postoperative ECD following both techniques.[7-10] The earlier studies had only included softer grades of cataract in their study population, which henceforth caused negligible corneal endothelial alteration.

However, in our study, patients with only harder grades of nuclear cataract (grade III and above) were included. There was a significant postoperative ECD loss in both surgical techniques after 6 weeks of surgery ($P < 0.0001$). The difference in ECD loss was greater in phacoemulsification (12 ± 8.2%) compared to MSICS (7.1 ± 5.2%), which was statistically significant ($P = 0.0071$). The reduction in postoperative ECD had a linear correlation with advancing age ($P = 0.01$) and harder cataract grade ($P = 0.0183$) in patients who underwent phacoemulsification, which was in accordance with previous studies.[11,12] However, there was no relation observed in Group A with age ($P = 0.3$) or cataract grade ($P = 0.8$).

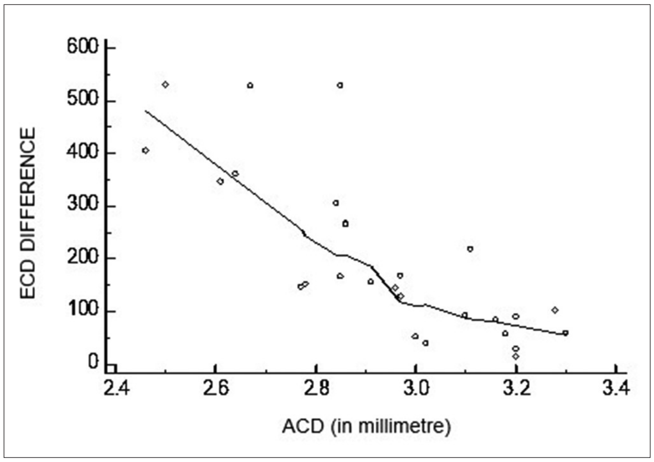

Figure 6: Scatter dot diagram showing correlation of ACD with postoperative ECD loss (at 6 weeks) in Group A

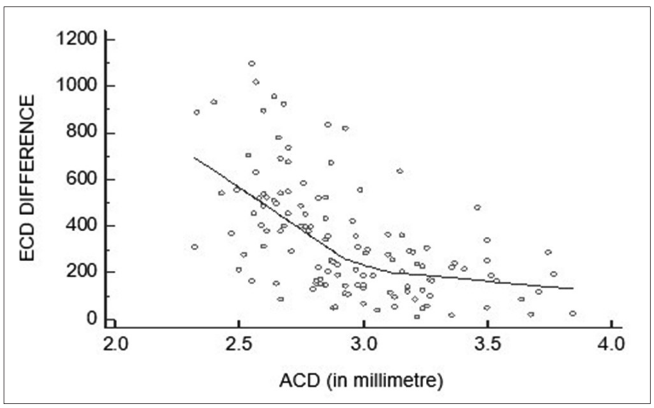

Figure 7: Scatter dot diagram showing correlation of ACD with postoperative ECD loss (at 6 weeks) in Group B

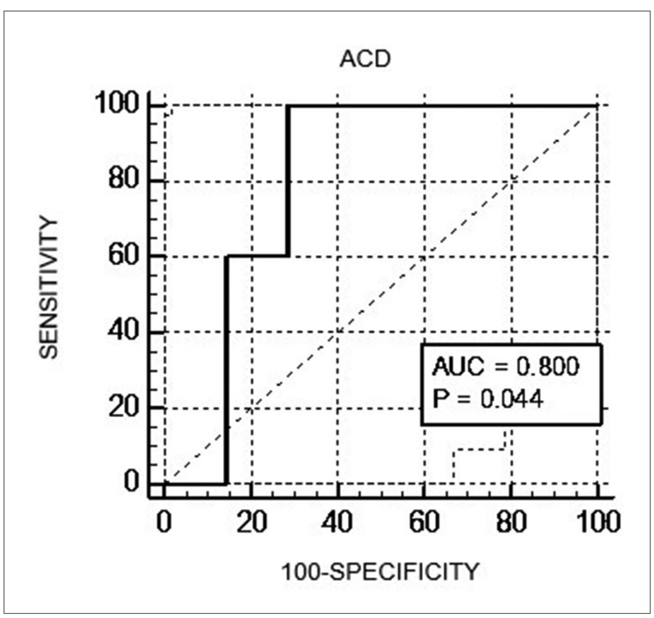

Figure 8: Graph showing receiver operating characteristic (ROC) curve analysis of anterior chamber depth (ACD)

The postoperative endothelial count was substantially reduced in cases with longer EPT and the correlation was statistically significant ($P = 0.0077$), and the results were consistent with the previous studies conducted to find the correlation between ECD loss and EPT.[13]

There have been conflicting reports about ACD and axial length influencing postoperative endothelial cell loss. A few past studies have excluded ACD and axial length as influencing factors for postoperative ECD loss where the difference seen following surgery was insignificant ($P > 0.05$).[14-16] However, the anatomical proximity in the shallow anterior chamber rationally plays a role in affecting the endothelium during surgical manipulation. This prudent fact of greater endothelial cell loss has been stated by various authors to be associated with shallow anterior chambers after phacoemulsification.[17-19]

The results of our study confirm that a shallow anterior chamber is a risk factor for greater postoperative ECD loss with a significant positive correlation in both surgical techniques (Group A: $P < 0.0001$; Group B: $P < 0.0001$). The area under the ROC curve (AUC) was 0.8, which was statistically significant ($P = 0.044$). A threshold value of 2.86 mm of ACD was defined by the ROC curve for minimal endothelial cell loss following phacoemulsification. Figs. 6 and 7 illustrate the correlation between ACD and postoperative ECD loss in Groups A and B, respectively. Therefore, it is established that ACD is a suitable and opportune parameter with satisfactory (71.43%) sensitivity, which can be used preoperatively for determining the type of surgical technique.

In our study, axial length did not have any correlation with postoperative ECD reduction in either group (Group A: $P = 0.95$; Group B: $P = 0.99$). It is presumed that eyes with shorter axial length have shallow anterior chambers[20] but a few studies have proven that ACD is not always directly proportional to axial length.[21] Similarly, in our study, we tested axial length against the anterior chamber with no significant correlation found between the two parameters ($P = 0.09$).

CCT was noticed to increase, albeit statistically insignificant ($P = 0.28$), in both the study groups following surgery. Phacoemulsification led to greater postoperative raise (21.7 ± 20.9) compared to MSICS (16.2 ± 14.2) at 6 weeks. There was no significant correlation of postoperative CCT increase with any of the preoperative factors such as age, grade of cataract, ACD, or EPT during surgery ($P > 0.05$).

Despite the significant decrease in ECD, the CCT was maintained in both groups, indicating that the function of the corneal endothelium was not affected. This justifies that both MSICS and phacoemulsification did not induce serious endothelial damage that would have been consequentially reflected as postoperative corneal edema due to severe hampering of the corneal endothelial pump. The findings of our study are analogous to previous studies, which observed a rise in CCT during the immediate postoperative period but restoration of normal values postoperatively.[22,23]

Presently, the choice of surgical technique is mostly dependent on the patient. Technical issues should be addressed instead of a grade of cataract and financial burden to determine the surgical technique. Shallow ACD (< 2.86 mm) is related to greater endothelial cell loss in phacoemulsification, especially in patients with relatively hard nuclear cataract densities. Thus, cataract surgeons should be diligent and pay specific attention to patients with harder nuclear densities and shallow ACD during phacoemulsification surgery.

The main shortcoming of this study was a small sample size owing to incomplete recruitment, unequal randomization, and patients lost to follow-up due to the COVID-19 pandemic and lockdown. Larger sample size can provide much more credibility to the results. Another limitation of our study was that only one technique of phacoemulsification and MSICS was assessed; other techniques may give variable results.

Conclusion

Both phacoemulsification and MSICS are complementary to each other with comparable postoperative visual outcomes. Endothelial cell loss is the inevitable aftermath of cataract extraction surgery. Substantial ECD loss in phacoemulsification is associated with advanced age of patient ($P = 0.01$), hardness of cataractous nucleus ($P = 0.01$), and longer effective phacoemulsification time ($P = 0.007$). Greater postoperative endothelial cell loss is strongly correlated with shallow ACD in both phacoemulsification and MSICS. (Group A: $P = 0.95$; Group B: $P = 0.99$).

ACD can be used as an imperative parameter preoperatively to determine the choice of surgical technique between MSICS and phacoemulsification. An anterior chamber less than 2.86 mm can be used as a cut-off value to decide the surgical technique in harder nuclear density cataracts to minimize endothelial cell loss.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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