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Original Article

Ophthalmology Section

Comparison of Corneal Endothelial Cell Loss during Manual Small-incision Cataract Surgery using Visco-expression versus Irrigating Wire Vectis-assisted Nucleus Removal: A Prospective Randomised Study

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ABSTRACT

Introduction: Age-related cataract is the leading cause of curable blindness in India, and Manual Small-Incision Cataract Surgery (MSICS) is a machine-independent and cost-effective alternative to phacoemulsification for handling this significant burden. In every cataract surgery, some endothelial cell loss is inevitable. Therefore, the present study was conducted to compare endothelial cell loss in the two most commonly practiced methods of nucleus delivery in MSICS.

Aim: To compare and analyse endothelial cell loss during MSICS using viscoelastic/viscoexpression-assisted nucleus removal versus irrigating wire vectis-assisted nucleus removal.

Materials and Methods: A prospective randomised interventional study was conducted at the Regional Institute of Ophthalmology, Postgraduate Institute of Medical Sciences (PGIMS) Rohtak, Haryana, India. The study duration was three years, from May 2018 to May 2021. A total of 250 patients with uncomplicated senile cataract over 40 years of age, with nuclear sclerosis of grade 2 or higher and "with the rule" astigmatism, were included in the study. The patients were randomly divided into Group A and Group B (125 each), who underwent MSICS using visco-expression (Group A) versus irrigating wire vectis-assisted (Group B) nucleus removal. Visual Acuity (VA), keratometry, astigmatism, pachymetry, and Endothelial Cell Density (ECD) were recorded in every patient preoperatively and postoperatively on day 1 and day 40. The Shapiro-wilk test was used to assess the normality of the data, and student's t-test was performed to identify significant differences in continuous factors between the two groups. Chi-square test was used to find the association between factors and techniques, with a p-value <0.05 considered statistically significant.

Results: The mean age of the patients was 68.5±9.4 years (range 52-89 years) with a significant male preponderance. The mean LogMAR visual acuity on Postoperative Day (POD)-1 was 0.3±0.1 for Group A, while for Group B, it was 0.5±0.2, showing a statistically significant difference (p=0.004). However, on day 40, visual acuity was comparable in both groups, with Group A (0.1±0.2) and Group B (0.1±0.1), and no significant difference (p=0.09). On POD-1, the percentage change in Endothelial Cell Density (ECD) was 4.2% in Group A and 10.6% in Group B, with a statistically significant difference (p=0.0017). On day 40, it was 2.1% and 4.8% in Group A and Group B, respectively, also showing a statistically significant difference (p=0.003). On postoperative day 40, the mean Surgically Induced Astigmatism (SIA) in Group A and Group B was 0.67±0.24 and 0.74±0.41, respectively, but this difference was statistically insignificant (p=0.074). Intra and postoperative complications such as hyphema, iridodialysis, and corneal oedema were more common in Group B than Group A.

Conclusion: The study concludes that there was a statistically significant endothelial cell loss in the irrigating wire vectis-assisted nucleus delivery method compared to the visco-expression of the nucleus during MSICS. The present method also showed delayed visual rehabilitation and a higher risk of intra and postoperative complications. Therefore, visco-expression of the nucleus should be the preferred method of nucleus delivery in every MSICS where feasible.

Keywords: Cataract extraction, Phacoemulsification, Surgical outcome

INTRODUCTION

Age-related cataract is the primary cause of curable blindness worldwide, accounting for almost 50% of blindness [1]. This burden is even greater in developing countries due to a lack of awareness, late presentation, and limited healthcare facilities. According to a survey conducted by the National Program for Control of Blindness and Visual Impairment (NPCB and VI), cataract is the most common cause of blindness (62.6%), followed by refractive error (19.70%) [2]. According to a survey conducted by the National Statistical Office (NSO) in 2021, the elderly population has drastically increased from 24.71 million in 1961 to 138 million, highlighting the significant burden of cataract in India [3].

Worldwide, elective cataract surgery is the most common ophthalmic surgery performed nowadays, and it has rapidly evolved from couching to Intra-capsular Cataract Extraction (ICCE) to conventional Extra-capsular Cataract Extraction (ECCE) to Small-incision Cataract Surgery (SICS) to phacoemulsification to Micro-Incision Cataract Surgery (MICS) to Femto-Laser Cataract Surgery (FLACS) to robotic cataract surgery [4]. With the advent of phacoemulsification, cataract surgery has become a daycare procedure, but due to its long learning curve and expensive equipment, it is limited to large Institutions only [5]. This scenario becomes even more challenging in developing countries with large populations, limited resources, and healthcare facilities. MSICS is an equally effective alternative with a short learning curve, which is more economical and suitable for the significant backlog in third-world countries [6]. Due to a lack of awareness and delayed presentation to the hospital, patients often present with more advanced stages of cataract, and MSICS is a better alternative in such difficult situations, as there is more endothelial cell loss due to the burst of ultrasonic energy used in emulsifying the hard nucleus [7].

The endothelial cell loss during cataract surgery is well-documented in the literature and has always been a matter of concern, as endothelial cells do not regenerate. When the cell count declines below a count of 1000 cells/mm^2, it can lead to decompensated cornea and ultimately result in bullous keratopathy and loss of vision [8]. Previous studies have reported endothelial cell loss ranging from 16-67% in phacoemulsification, with the determining factors being the grade of nucleus sclerosis and the plane of phacoemulsification [9,10]. However, the reported incidence of percentage endothelial cell loss during MSICS is much less than phacoemulsification, ranging from 4-17%. The responsible factors for this are less viscoelastic cover to the endothelium, nucleus prolapse, nucleus delivery, and continuous irrigation and aspiration causing endothelial damage during various stages of MSICS [10,11].

Atraumatic nucleus delivery is the most challenging step in performing a successful MSICS. After prolapsing the nucleus into the anterior chamber, various techniques can be used to deliver the nucleus out of the sclerocorneal tunnel incision, such as irrigating vectis, snare technique, fishhook technique, phaco-fracture technique, hydro-expression technique, Blumenthal technique, and visco-expression technique [4].

Upon detailed literature review, no available study comparing endothelial cell loss in different methods of nucleus delivery was found. With this background, the authors conducted this prospective, randomised interventional study to compare and analyse endothelial cell loss during MSICS using viscoelastic-assisted nucleus removal versus irrigating wire vectis-assisted nucleus delivery.

MATERIALS AND METHODS

A prospective randomised interventional study was conducted at the Regional Institute of Ophthalmology, PGIMS Rohtak, Haryana, India. The study duration was three years, from May 2018 to May 2021. A total of 250 patients undergoing cataract surgery were included in the study after obtaining clearance from the Institutional Ethics Committee and obtaining informed written consent from the patients, in accordance with the Declaration of Helsinki. The sample size was calculated using a convenient sampling method, and the patients were randomly divided into two groups, Group A and Group B (125 each), who underwent MSICS using visco-expression (Group A) versus irrigating wire vectis (Group B) nucleus removal.

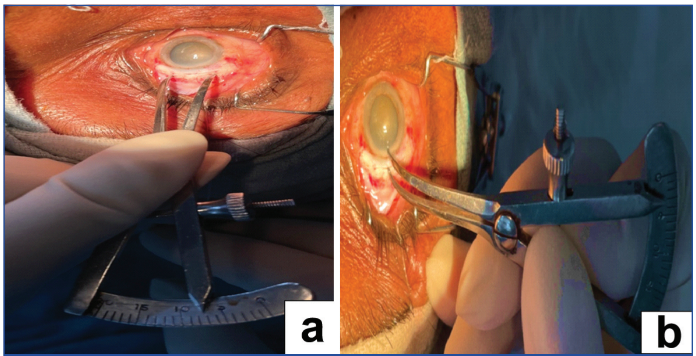
Inclusion criteria: Patients with uncomplicated senile cataract over 40 years of age, with nuclear sclerosis of Grade 2 to Grade 4 and "with the rule" astigmatism, were included in the study.

Exclusion criteria: Patients with "against the rule" astigmatism, complicated cataract cases, nuclear sclerosis of Grade 5, any pre-existing corneal pathology, pre-existing astigmatism >2D, Central Corneal Thickness (CCT) <450 microns or >600 microns, preoperative decompensated cornea with <1500 cells/mm^2, non dilating pupil, Anterior Chamber Depth (ACD) <2.5 mm, and those who were not willing to participate in the study were excluded.

Study Procedure

After obtaining a detailed history, a standard preoperative protocol was followed for every patient, including assessing the best-corrected visual acuity with a Snellen chart, lacrimal sac syringing, measuring Intraocular Pressure (IOP) using Non Contact Tonometry (NCT), conducting a detailed Slit Lamp Examination (SLE) for anterior segment evaluation, including grading of nuclear sclerosis using the Emery and Little nuclear hardness classification, and performing Indirect Ophthalmoscopy (IDO) for posterior segment evaluation. Preoperative CCT and ECD were calculated using specular microscopy (SP-3000P; Topcon, USA). Manual keratometry (Bausch and Lomb) was performed before the surgery by the same person to avoid any interobserver variation. Intraocular Lens (IOL) power was calculated using the SRK T formula with A-scan measurements. Subsequently, based on the assigned group, patients underwent cataract extraction with intraocular lens implantation. Postoperatively, all patients were followed-up on postoperative day 1 and day 40, and visual acuity, CCT, ECD, and SIA (Surgical Induced Astigmatism) were assessed. To avoid any bias, all surgeries were performed by a single operating surgeon, who was informed about the assigned group by the assisting resident on the operation table before commencing the surgery. All doctors involved in assessing the postoperative parameters were masked regarding the patient group.

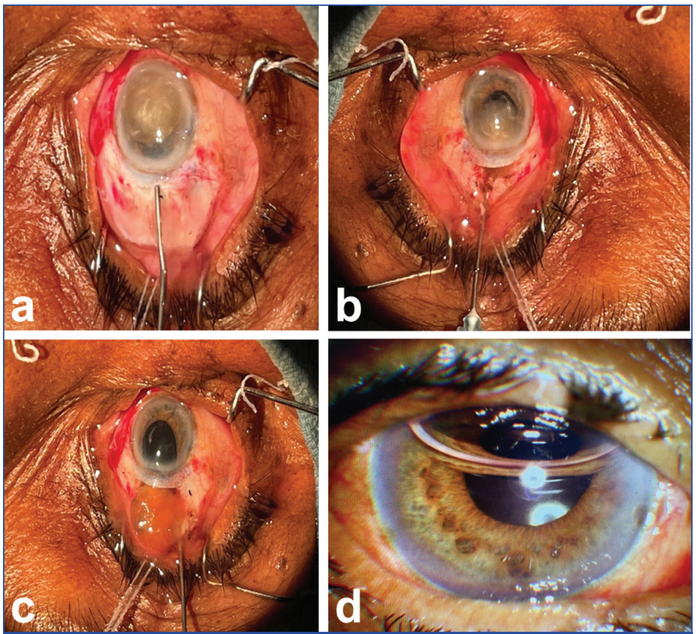
Surgical technique: Preoperatively, all patients were prescribed 0.5% moxifloxacin eye drops and 0.4% ketorolac eye drops to be used every six hours for three days before surgery in the eye to be operated on. On the day of surgery, the pupil was dilated using 0.8% tropicamide and 5% phenylephrine drops. All surgeries were performed by the same surgeon under peribulbar block anesthesia. After cleaning and draping the eye under aseptic conditions, a superior rectus bridle suture was applied, followed by a conjunctival peritomy from 10-2 o'clock. Wet field cautery was used to achieve a smooth and clean bed for the scleral incision. To ensure accuracy, the distance of the scleral incision from the limbus and the length of the incision were marked in every case using a calliper. In each case, a 7 mm scleral incision was made 2 mm away from the superior limbus, followed by the creation of a self-sealing, triplanar sclero-corneal tunnel using a sterile disposable 2.8 mm crescent blade. The tunnel extended into the clear cornea for 1.5 mm [Table/Fig-1a,b].



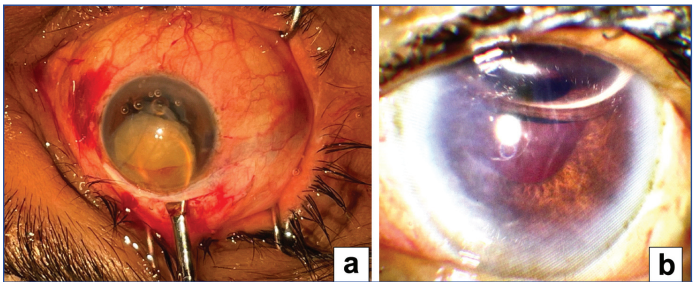
[Table/Fig-1]: (a): 7 mm straight scleral incision given; (b): 3 mm distance from limbus.

A side port was created using a straight Micro Vitreo-Retinal blade (MVR blade) at the 9 o'clock position, through which a 7-8 mm Continuous Curvilinear Capsulorrhexis (CCC) was performed in every case using a 26 G cystitome under viscoelastic cover after staining the capsule with trypan blue dye. Then, a 2.8 mm sterile disposable keratome was used to enter the anterior chamber through the sclero-corneal tunnel. The internal wound was enlarged with a crescent to approximately 8-10 mm in length to accommodate a larger nucleus if necessary. Hydro-dissection was then performed to prolapse one pole of the nucleus into the anterior chamber, followed by rotation of the nucleus with a sinskey hook to completely prolapse it into the anterior chamber. Nucleus delivery was then performed according to the group assigned to the patient, either by visco-expression using 2% Hydroxy Propyl Methy Cellulose (HPMC) APPAVISC PFS [Table/Fig-2] or by the irrigating wire vectis method [Table/Fig-3]. This was followed by cortical wash using a two-way irrigation-aspiration Simcoe cannula and intraocular lens implantation. The viscoelastic was washed out with ringer lactate, and side port hydration was performed to reform the anterior chamber. After giving a subconjunctival injection, the tunnel was covered with conjunctiva, followed by wet field cautery.

Postoperatively, all patients were prescribed 0.5% moxifloxacin eye drops four times a day, 0.5% Carboxymethylcellulose (CMC) three times a day, and 1% prednisolone acetate drops six times a day in tapering doses for 40 days.



[Table/Fig-2]: (a-c) Viscoexpression of hard sclerotic nucleus through a 7 mm sclero-corneal tunnel; (d): POD-1 anterior segment picture showing clear cornea with visible fundal glow.



[Table/Fig-3]: (a) Irrigating wire vectis assisted nucleus delivery through a 7 mm sclerocorneal tunnel; (b) POD-1 anterior segment picture showing central keratitis with few descemet membrane folds.

During the postoperative day 1 and day 40 visits, visual acuity, CCT, and ECD were measured. SIA was calculated on day 40 for each patient using SIA calculator version 2.1 [12]. CCT readings were taken when cell borders were well-defined on the monitor. ECD was evaluated by freezing the scan and manually counting 70 cells. Pachymetry and ECD readings were performed three times, and the mean value was recorded.

STATISTICAL ANALYSIS

The data was collected and analysed statistically using Statistical Packages for Social Sciences (SPSS) version 28.0 software. Descriptive statistics such as frequencies and percentages were used for categorical parameters. SIA was calculated in each case using SIA Calculator version 2.1 [13]. For continuous parametric data, mean and Standard Deviations (SDs) were used, while median and Interquartile Ranges (IQRs) were used for non parametric data. The Shapiro-wilk test was used to assess the normality of the data, and Student's t-test was performed to determine any significant differences in continuous factors between the two groups. Chi-square test was conducted to examine the association between factors and techniques, with a p-value <0.05 considered statistically significant.

RESULTS

The present study was conducted on 250 cases of uncomplicated senile cataract with nuclear sclerosis grade 2 or higher who completed a six-week follow-up. The patients had a mean age of 68.5±9.4 years (range 52-89 years), with a significant male preponderance {Male to Female (M;F) ratio 2:1}. The majority of patients belonged to the age group of 60-69 years (40%), followed by 70-79 years (28%). The main factors responsible for delayed presentation were female gender, rural background, and illiteracy. There was no statistical difference between the two groups in various parameters such as presenting Best Corrected Visual Acuity (BCVA), nuclear sclerosis grading, preoperative CCT, ECD, and mean keratometry readings, indicating that both groups were comparable in every aspect [Table/Fig-4].

Parameters	Group A (n=125)	Group B (n=125)	Overall (N=250)	p-value
Mean age (in years)	65.6±5.4	70.4±6.8	68.5±9.4	0.74
Background				
Rural	86	82	168	0.08
Urban	39	43	82	
Education				
Illiterate	22	24	46	0.96
Primary	20	19	39	
High school	28	30	58	
Secondary school	22	17	39	
Graduate	17	20	37	
Postgraduate	16	15	31	
Presenting BCVA				
LogMAR VA (Mean±SD)	0.6±0.2	0.8±0.3	0.72±0.4	0.067
Nuclear sclerosis				
NS2	32	34	66	0.0746
NS3	46	52	98	
NS4	28	24	52	
NS5	19	15	34	
Mean IOP (NCT)	14.56±2.34	15.42±3.32	14.78±2.87	0.089
Fundus				
WNL	35	36	71	0.678
Dull FR	18	24	42	
Hazy media	45	39	84	
Tessellated fundus	12	14	26	
Vitreous deg.	12	8	20	
ARMD	3	4	7	
Mean ACD	2.82±0.56	2.97±0.65	2.89±0.76	0.79
Mean axial length	23.6±1.4	22.9±1.7	23.2±1.6	0.069
Mean CCT	485.2±17.8	487.6±18.1	486.4±18.0	0.74
Mean preoperative endothelial cell density	2298.4±198.3	2302.9±212.6	2260.7±206.5	0.96
Mean KV	44.96±0.746	45.04±0.672	44.98±0.87	0.861
Mean KH	44.61±0.534	44.84±0.368	44.72±0.94	0.762

[Table/Fig-4]: Demographic and clinical parameters in Group A and B.
Test applied: Chi-square test; BCVA: Best corrected visual acuity; NS: Nuclear sclerosis; FR: Foveal reflex; ARMD: Age related macular dystrophy; ACD: Anterior chamber depth; CCT: Central corneal thickness
Kh (horizontal component); Kv (vertical component)

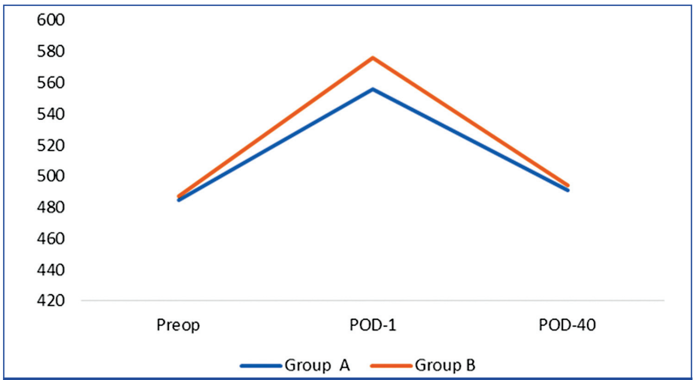
The mean LogMAR visual acuity on postoperative day 1 for Group A was 0.3±0.1, while for Group B it was 0.5±0.2. This difference was statistically significant (p=0.004). However, on day 40, the mean LogMAR visual acuity in both groups was comparable: Group A - 0.1±0.2, Group B - 0.1±0.1, with no statistically significant difference (p=0.09). On postoperative day 40, the mean SIA in Group A and B was 0.67±0.24 and 0.74±0.41, respectively, and this difference was statistically insignificant (p=0.074) [Table/Fig-5].

Preoperatively, the mean CCT in Group A and B was 485.2±17.8 and 487.6±18.1, respectively, which was comparable in both groups with no significant difference (p=0.74). On postoperative day 1, mean CCT increased in both groups: 556.3±22.8 microns in Group A and 576.6±25.6 microns in Group B, with a mean percentage change in CCT of 14.7% in Group A and 18.4% in

	Group A (Visco-expression)	Group B (Wire vectis)	p-value
Parameters	0.6±0.2	0.8±0.3	0.067
POD-1	0.3±0.1	0.5±0.2	0.004
POD-40	0.1±0.2	0.1±0.1	0.09

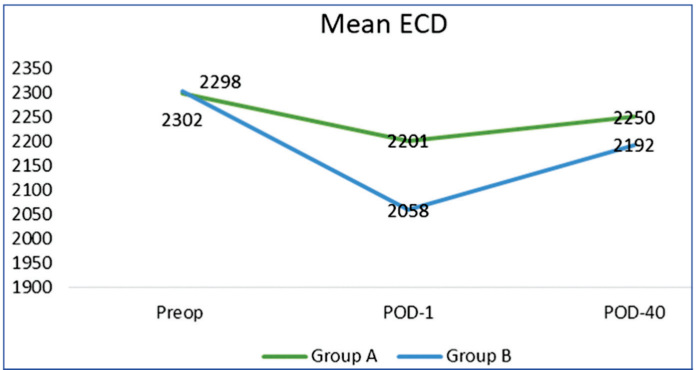
[Table/Fig-5]: Preoperative, Postoperative day (POD) 1 and day 40 change in visual acuity in Group A and B.
Test applied: Chi-square test

Group B. This difference was statistically significant (p=0.02). On postoperative day 40, the mean CCT in Group A and B was 491.8±15.6 and 494.12±16.7, respectively, and this difference was not significant (p=0.09) (Chi-square test) [Table/Fig-6].



[Table/Fig-6]: Digital line graph showing change in CCT in Group A and B on POD-1 and POD-40.

Preoperatively, the mean ECD in Group A and B was 2298.4±198.3 and 2302.9±212.6, respectively, which was comparable in both groups with no significant difference (p=0.96). On postoperative day 1, mean ECD reduced in both groups: 2201.83±118.8 in Group A and 2058.6±115.6 in Group B, with a mean percentage change in ECD of 4.2% in Group A and 10.6% in Group B. This difference was statistically significant (p=0.0017). On postoperative day 40, the mean ECD in Group A and B was 2250.13±125.6 and 2192.40±116.7, respectively, with mean percentage changes of 2.1% and 4.8% in Group A and B, respectively. There was a statistically significant difference on the Chi-square test (p=0.003) [Table/Fig-7].

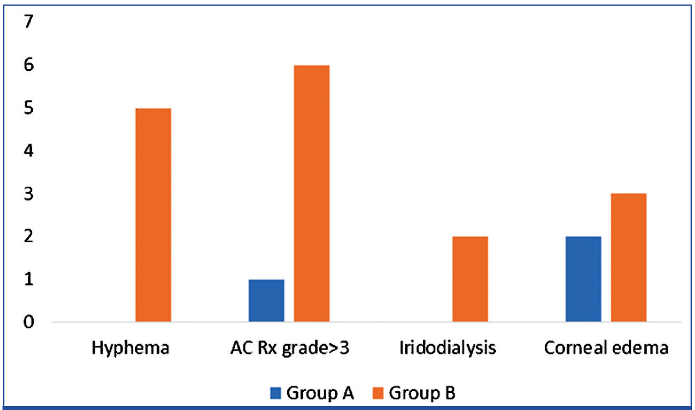


[Table/Fig-7]: Digital line graph depicting the changes in Endothelial Cell Density (ECD) on POD-1 and POD-40 compared to preoperative ECD in Group A and B.

The intra and immediate postoperative complications, such as hyphema, anterior chamber inflammatory reaction, iridodialysis, and corneal oedema, were more common in the irrigating wire vectis nucleus delivery method than in the visco-expression method of nucleus delivery. The complication rate in Group A was 2.4% (3/125), while it was 12.8% (16/125) in Group B, with a statistically significant difference (p=0.0004) when applying the Chi-square test [Table/Fig-8].

DISCUSSION

Cataract is the leading cause of global blindness, and manual small incision cataract surgery is a cost-effective surgical modality for



[Table/Fig-8]: Bar chart depicting complication rate in Group A and B.

addressing the large number of cataract patients [14]. To achieve a good postoperative visual outcome, a transparent and clear cornea is essential for obtaining a clear image on the macula. The endothelial cell monolayer is an extremely important structure that helps maintain the cornea's dehydrated state, serving both as a barrier and a pump function [15].

The endothelial cell loss during cataract surgery is well-documented in the literature and is a matter of concern for operating surgeons. To compensate for cell loss, adjacent cells will enlarge and migrate to cover the defect, as endothelial cells cannot regenerate like epithelial cells. In the Indian population, the average endothelial cell count is approximately 2527±337 cells/mm^2. If this count falls below 500 cells/mm^2, it can lead to corneal decompensation, resulting in a significant reduction in visual acuity [16]. Factors responsible for accentuated endothelial cell loss during surgery include non-dilating pupil, hard cataract, lack of proper viscoelastic cover to the endothelium, increased time spent in irrigation and aspiration, shallow anterior chamber, longer duration of surgery, nucleus delivery during MSICS, and high ultrasonic energy during phacoemulsification [17].

To the best of the authors' knowledge, no study has compared endothelial cell loss during nucleus delivery using the two most common techniques, namely visco-expression and irrigating wire vectis-assisted nucleus removal, in MSICS. In the current Indian scenario, MSICS is widely performed as it is significantly faster, less expensive, and not dependent on machines. This randomised interventional study included 250 patients to gain better insight into endothelial cell loss post-MSICS. The patients were randomly divided into two groups, ensuring comparability in all parameters to avoid potential bias.

In the present study, it was observed that patients with female gender, rural background, and low educational qualification presented late to the hospital with poor presenting visual acuity and more advanced cataract. This finding is consistent with a study conducted by Karve S and Pimprikar S, which concluded that rural patients tend to present late to the hospital due to a lack of awareness [18].

The mean SIA in both groups was comparable, with no statistically significant difference, indicating that the nucleus delivery technique has no effect on SIA. On postoperative day 1, visual acuity was better in the visco-expression group than in the irrigating wire vectis group. However, on POD 40, visual acuity in both groups was comparable, with no statistically significant difference. This suggests that patients who underwent visco-expression of the nucleus during MSICS experience early visual rehabilitation compared to those who underwent irrigating wire vectis-assisted nucleus delivery. However, the final visual outcome is not affected by the different nucleus delivery techniques. This finding is consistent with the results of Morya AK et al., who concluded that the final visual outcome was similar across different nucleus delivery modes in MSICS [19].

On postoperative day 1, the mean CCT was significantly higher in the irrigating wire vectis group (Group B) compared to the visco-expression group (Group A), indicating that irrigating wire vectis-assisted nucleus delivery causes more corneal oedema than the visco-expression method. However, on postoperative day 40, the mean CCT was slightly higher compared to preoperative values in both groups, and the difference between the two groups was statistically insignificant. These findings are consistent with the results of several studies that concluded that CCT returns close to preoperative values at the end of one month [19-21].

The mean ECD was reduced in both groups, which is similar to the results reported by Thakur SK et al., [8]. In the present study, the endothelial cell loss was comparatively lower in the visco-expression technique of nucleus delivery than in the irrigating wire vectis method. This can be attributed to better endothelial protection and the avoidance of any rubbing of the nucleus with the corneal endothelium. In present study, there were no cases of failure in nucleus visco-expression, which can be attributed to the expertise of a single surgeon and the use of a uniform triplanar sclero-corneal tunnel with a large internal opening. The complication rate was also higher in the wire vectis method, with a higher incidence of iridodialysis, corneal oedema, hyphema, and postoperative anterior chamber reaction.

Limitation(s)

The major limitation of the present study was the short follow-up period of only six weeks. Additionally, other morphological endothelial parameters, such as the coefficient of variation and standard deviation, were not compared in the study. However, the study was prospective in nature, with a large sample size and computer-based randomisation to avoid any selection bias. To the best of the authors' knowledge, this is the first large-scale study highlighting the surgically induced astigmatism, pachymetry, and endothelial cell changes during different nucleus delivery methods in manual small incision cataract surgery.

CONCLUSION(S)

The present study highlights a statistically significant endothelial cell loss with irrigating wire vectis-assisted nucleus delivery compared to visco-expression of the nucleus during MSICS, as observed during the short six-week follow-up. However, the CCT and SIA were unaffected in both groups. To achieve successful and smooth visco-expression of nuclei of all grades through a 7mm sclero-corneal incision, the construction of a uniform triplanar tunnel with a large internal opening is a prerequisite.

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