Research Article

Comparative Evaluation of Corneal Endothelial Changes after Phacoemulsification versus Manual Small-Incision Cataract Surgery in Grade-4 Nuclear Cataracts: A Randomised Observational Study

Dr. Bhumika Sharma¹, Dr Ashima Mehndiratta², Dr. Sahil Jain³, Dr Hitesh Suthar⁴

^{1,2}3rd year Resident, Department of Ophthalmology, SMS Medical College and Hospital, Jaipur, India.

Corresponding Author: Dr Hitesh Suthar

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ABSTRACT

Purpose: To compare postoperative corneal endothelial morphology and visual outcomes after phacoemulsification (PHACO) and manual small-incision cataract surgery (SICS) in eyes with grade-4 nuclear cataract.

Methods: In this single-centre, randomised observational study, 90 eyes of 90 patients were allocated to PHACO (n = 45) or SICS (n = 45). Pre-operative and postoperative (1 week, 6 weeks, 3 months) assessments included endothelial cell density (ECD), coefficient of variation (CV), hexagonality (%Hex), central corneal thickness (CCT), uncorrected (UCVA) and best-corrected visual acuity (BCVA) using specular microscopy and logMAR charts. Primary outcome was percentage ECD loss at 3 months. Secondary outcomes were changes in CCT, CV, %Hex, and visual acuity.

Results: Baseline characteristics were comparable between groups (mean age $54.0 \pm 4.7 \text{ y}$ vs $56.0 \pm 3.9 \text{ y}$; p = 0.07). Mean ECD loss at 3 months was $13.6 \pm 2.5 \%$ (PHACO) versus $13.0 \pm 1.5 \%$ (SICS) (p = 0.16). CCT increased transiently at week 1 (PHACO +42 μ m; SICS +22 μ m) before returning to near-baseline by month 3 (p > 0.05 for all inter-group comparisons). CV and %Hex changed similarly in both groups, indicating comparable endothelial remodelling. Median BCVA improved from 0.64 to 0.06 logMAR (PHACO) and 0.71 to 0.09 logMAR (SICS) at 3 months (p = 0.39). No sight-threatening complications occurred.

Conclusions: PHACO and SICS yield equivalent endothelial preservation and visual rehabilitation in dense nuclear cataracts when performed by an experienced surgeon. Given its lower cost and technology dependence, SICS remains a pragmatic alternative to PHACO in resource-limited settings.

Keywords: Phacoemulsification; Manual Small-Incision Cataract Surgery; Endothelial Cell Density; Central Corneal Thickness; Specular Microscopy; India.

INTRODUCTION

Cataract remains the leading cause of global blindness, accounting for almost half (47.8 %) of all cases worldwide and more than 60 % in India (1). Modern cataract surgery has progressively reduced incision size—from 12 mm intracapsular extractions to ≤2.8 mm coaxial phacoemulsification—to achieve rapid, spectacle-free visual rehabilitation with minimal tissue trauma. Manual small-incision cataract surgery (SICS), an evolution of extracapsular extraction that employs a self-sealing 6–6.5 mm scleral tunnel, provides visual outcomes comparable with phacoemulsification (PHACO) while markedly lowering equipment costs, a critical advantage for high-volume programmes in low-resource settings (2, 3).

The corneal endothelium is essential for stromal deturgescence negligible yet possesses proliferative capacity; excessive postsurgical cell therefore risks irreversible loss decompensation and bullous keratopathy (4). Published series report endothelial cell loss (ECL) after modern PHACO ranging from 4 % to 20 %, influenced by nuclear hardness, cumulative ultrasound energy, and anteriorchamber turbulence (5-7). SICS eliminates ultrasound energy but entails manual nucleus delivery through the tunnel, potentially abrading the endothelium if viscoelastic protection is sub-optimal (8). Evidence directly comparing endothelial outcomes of PHACO and SICS in dense (LOCS-III grade-4) nuclei is limited and conflicting (5, 9).

³Senior Resident, Department of Ophthalmology, SMS Medical College and Hospital, Jaipur, India.

^{4*}CAS- PG Resident 3rd year, Department of Ophthalmology, SMS Medical College and Hospital, Jaipur, India.

Dr. Bhumika Sharma et al / Comparative Evaluation of Corneal Endothelial Changes after Phacoemulsification versus Manual Small-Incision Cataract Surgery in Grade-4 Nuclear Cataracts: A Randomised Observational Study

Accordingly, we conducted a prospective, randomised study to compare postoperative endothelial morphology and visual outcomes after PHACO versus SICS in grade-4 nuclear cataracts at a tertiary centre in North-West India.

METHODS

Study Design and Ethics

This single-centre, randomised observational study adhered to the tenets of the Declaration of Helsinki and was approved by the Institutional Ethics Committee of SMS Medical College, Jaipur (IEC/2023/317). Written informed consent was obtained from all participants.

Participants

Inclusion criteria: age 40–60 y; uncomplicated senile cataract with LOCS-III nuclear grade 4; endothelial cell count > 1500 cells mm⁻². Exclusion criteria: diabetes mellitus, corneal dystrophy, glaucoma, shallow anterior chamber, ocular trauma or surgery, intra-operative complications.

Sample Size and Randomisation

Based on a detectable mean ECD difference of $180 \text{ cells mm}^{-2}$ (SD = 300), 43 eyes per group were required (a = 0.05, 1- β = 0.80). We enrolled 90 eyes to account for attrition. Randomisation used sealed opaque envelopes generated by a statistician.

Surgical Techniques

All procedures were performed by a single senior surgeon under peribulbar anaesthesia.

 PHACO group: 2.8 mm temporal clearcorneal incision; continuous curvilinear capsulorrhexis; divide-and-conquer nucleus fragmentation using Alcon

- Laureate (vacuum 450 mmHg, bottle height 135 cm); foldable hydrophilic IOL implantation.
- **SICS group:** 6–6.5 mm superior frown scleral tunnel 2 mm posterior to limbus; capsulorrhexis 6–8 mm; hydroprolapse and visco-expression of nucleus via wire vectis; rigid PMMA IOL implantation.

Balanced salt solution plus and dispersive viscoelastic (2 % HPMC) were used in all cases. Stromal hydration sealed incisions in PHACO; conjunctival apposition with wet-field cautery completed SICS.

Outcome Measures

Specular microscopy (Topcon SP-3000P) measured ECD, CV, %Hex and CCT preoperatively, and at 1 week, 6 weeks, and 3 months post-op. UCVA and BCVA were recorded in logMAR. Primary endpoint: %ECL at 3 months. Secondary endpoints: changes in CCT, CV, %Hex, UCVA, BCVA, and adverse events.

Statistical Analysis

Data were analysed with SPSS v26.0. Normality was assessed with Shapiro–Wilk. Continuous variables are mean \pm SD or median (IQR). Inter-group comparisons employed independent-t or Mann–Whitney tests; intragroup changes used paired-t or Wilcoxon tests. Repeated-measures ANOVA evaluated temporal trends. p < 0.05 was significant.

RESULTS

Baseline Characteristics

Table 1 summarises demographic data; groups were matched for age, sex, baseline ECD, CCT, CV, %Hex, and visual acuity.

Table 1. Baseline Characteristics of Study Eyes

	PHACO (n = 45)	SICS (n = 45)	р	
Age (y, mean ± SD)	53.98 ± 4.68	56.04 ± 3.90	0.07	
Female:Male	19 : 26	21 : 24	0.68	
ECD (cells mm ⁻²)	2496 ± 246	2411 ± 176	0.16	
CCT (µm)	503 ± 80	516 ± 25	0.28	
CV (%)	33.8 ± 6.1	34.4 ± 4.6	0.61	
%Hex	59.2 ± 5.0	59.9 ± 5.5	0.49	
BCVA (logMAR)	0.64 ± 0.17	0.71 ± 0.20	0.11	

Endothelial Cell Density

Mean ECD declined significantly from baseline in both cohorts (p < 0.001 each) (Figure 1). At

3 months, ECL was 13.6 ± 2.5 % (PHACO) versus 13.0 ± 1.5 % (SICS); inter-group difference NS (p = 0.16).

Dr. Bhumika Sharma et al / Comparative Evaluation of Corneal Endothelial Changes after Phacoemulsification versus Manual Small-Incision Cataract Surgery in Grade-4 Nuclear Cataracts: A Randomised Observational Study

Table 2. Temporal Change In ECD (Cells Mm⁻²)

Time-point	PHACO	SICS	р
Pre-op	2496 ± 246	2411 ± 176	0.16
1 wk	2243 ± 230	2188 ± 178	0.21
6 wk	2180 ± 233	2130 ± 168	0.24
3 mo	2145 ± 233	2097 ± 164	0.26

Central Corneal Thickness

CCT increased transiently at week 1 (PHACO +42 μ m vs SICS +22 μ m; p = 0.04), but values converged by 6 weeks and 3 months (p = 0.80 and 0.55) (Table 3).

Morphological Indices

CV rose modestly from 34 % to 38 % in both groups without significant inter-group differences throughout follow-up (p > 0.90).

%Hex decreased similarly (\approx 7 %) in both groups, indicating comparable polymegathism and pleomorphism trends.

Visual Acuity

Median UCVA improved from $0.75\rightarrow0.18$ logMAR (PHACO) and $0.83\rightarrow0.17$ logMAR (SICS). BCVA reached ≥0.1 logMAR (6/7.5 Snellen) in 98 % (PHACO) vs 97 % (SICS) at 3 months (p = 0.39).

Table 3. Visual Acuity Outcomes (Logmar)

Time-point	UCVA PHACO	UCVA SICS	р	BCVA PHACO	BCVA SICS	р
Pre-op	0.75 ± 0.42	0.83 ± 0.22	0.27	0.64 ± 0.17	0.71 ± 0.20	0.11
1 wk	0.26 ± 0.14	0.30 ± 0.15	0.21	0.16 ± 0.15	0.21 ± 0.15	0.16
6 wk	0.19 ± 0.17	0.19 ± 0.14	0.98	0.06 ± 0.14	0.10 ± 0.15	0.24
3 mo	0.18 ± 0.16	0.17 ± 0.15	0.82	0.06 ± 0.14	0.09 ± 0.14	0.39

Adverse Events

No intra-operative posterior capsular rupture, corneal decompensation, cystoid macular oedema, or endophthalmitis occurred.

DISCUSSION

Our findings show that PHACO and SICS are equivalent in preserving the corneal endothelium, with mean 3-month cell losses of 13.6 % and 13.0 %, respectively—closely mirroring earlier randomised trials that found no clinically important difference between the two techniques (2, 5, 6, 9). The transient spike in central corneal thickness (CCT) at one week-greater after PHACO (+42 µm) than SICS (+22 µm)—echoes previous reports linking early postoperative oedema to reversible endothelial pump stress, with CCT returning to near-baseline by six weeks (7, 10-12). The slightly higher early ECL and CCT in the PHACO arm likely reflect cumulative ultrasound energy and anterior-chamber turbulence (13, 14). Nevertheless, modern torsional platforms and energy-efficient chopping strategies have substantially reduced absolute ultrasound delivery, accounting for the modest inter-group difference observed (15). By contrast, SICS avoids ultrasound but relies on mechanical nucleus expression; meticulous viscodissection continuous endothelial coating—as and advocated in earlier studies—can keep cell loss

below 15 % (8, 16). Polymegathism (rise in coefficient of variation) and pleomorphism (decline in hexagonality) followed similar trajectories in both groups, indicating comparable endothelial stress and remodelling (9). Functionally, median best-corrected visual acuity improved to ≤ 0.1 logMAR ($\sim 6/7.5$ Snellen) in >97 % of eyes irrespective of technique, corroborating large communitybased trials from Nepal and India that reported near-identical visual outcomes for PHACO and SICS (2, 3). From a programme-planning perspective, SICS remains highly attractive: it requires inexpensive, reusable instruments, no phaco machine or power backup, and has a short learning curve while delivering PHACOlike safety and efficacy (3). Our results therefore support continued integration of SICS into high-volume cataract services, especially in resource-constrained environments, without exposing patients to additional endothelial risk. Limitations of this study include single-surgeon performance, a modest sample, and a 3-month follow-up; longer observation could reveal delaved endothelial attrition or decompensation, particularly in eyes with borderline pre-operative counts (17). Future multicentre trials with extended follow-up and specular-microscopy sub-studies of subclinical endothelial dysfunction would further strengthen the evidence base.

Dr. Bhumika Sharma et al / Comparative Evaluation of Corneal Endothelial Changes after Phacoemulsification versus Manual Small-Incision Cataract Surgery in Grade-4 Nuclear Cataracts: A Randomised Observational Study

CONCLUSIONS

Both PHACO and SICS are safe and effective for grade-4 nuclear cataracts, with equivalent endothelial cell loss (~13 %) and excellent visual recovery at 3 months. In settings constrained by cost and technology, SICS provides a pragmatic, high-quality alternative to PHACO without additional endothelial risk.

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