

# Comparative Clinical Outcomes of Divide and Conquer and Tilt and Tumble Cataract Surgery: A Randomized Controlled Trial

Johan Ursberg<sup>1,2</sup>, Andreas Viberg<sup>3</sup>, Madeleine Zetterberg<sup>1,4</sup>

<sup>1</sup>Department of Clinical Neuroscience, Institute of Neuroscience and Physiology, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden; <sup>2</sup>Aleris Healthcare Sweden, Division of Ophthalmology, Malmö, Sweden; <sup>3</sup>Department of Clinical Sciences, Ophthalmology, Umeå University, Umeå, Sweden; <sup>4</sup>Department of Ophthalmology, Sahlgrenska University Hospital, Mölndal, Sweden

Correspondence: Johan Ursberg, Department of Clinical Neuroscience, Institute of Neuroscience and Physiology the Sahlgrenska Academy, University of Gothenburg, SE-431 80 Mölndal, Gothenburg, Sweden, Tel +46 70 43 90 781, Email johan.ursberg@gu.se

**Purpose:** To compare the clinical performance of the divide and conquer and tilt and tumble techniques in cataract surgery with respect to surgical efficiency, safety and energy usage.

**Setting:** The research was conducted at two private clinics specialized in cataract surgeries located in the southern region of Sweden.

**Design:** The study was a prospective randomized controlled trial.

**Methods:** A total of 535 patients undergoing cataract surgery were randomized to either divide and conquer or tilt and tumble. Primary outcomes included total surgery time, phacoemulsification time, ultrasound time, cumulative dissipated energy (CDE) and intraoperative complications. Postoperative visual acuity, intraocular pressure (IOP) and, for a subset, central retinal thickness (CRT), were assessed at follow up.

**Results:** Tilt and tumble demonstrated significantly shorter operation time, 4.68 compared to 6.50 minutes ( $p < 0.001$ ), phaco time 60 versus 148 seconds ( $p < 0.001$ ) and ultrasound time, 32 versus 40 seconds ( $p < 0.001$ ) compared to divide and conquer. Baseline characteristics, Energy expenditure (CDE), intraoperative complications and postoperative outcomes did not differ significantly between groups.

**Conclusion:** Our results revealed that the tilt and tumble technique is notably swifter and demonstrates comparable safety, energy consumption and postoperative outcome compared to divide and conquer. This sheds light on the potential benefits of the tilt and tumble technique ultimately enhancing patient care.

**Keywords:** phacoemulsification, cataract surgery, tilt and tumble, divide and conquer

## Introduction

The divide and conquer technique in cataract surgery<sup>1</sup> has long been a standard approach in phacoemulsification procedures, demonstrating efficacy and safety in numerous studies.<sup>2–5</sup> It is often the first technique taught to new cataract surgeons and also the most commonly used technique in both America<sup>6</sup> and Europe.<sup>7</sup>

Supracapsular phacoemulsification, such as the tilt and tumble technique,<sup>8</sup> is employed less frequently,<sup>5–7,9</sup> despite being documented as both a rapid and energy-efficient alternative to the more commonly used endocapsular techniques.<sup>8,10,11</sup> Reluctance toward supracapsular approaches is often attributed to concerns regarding capsulorhexis stability, the risk of capsular rupture and potential corneal endothelial damage.<sup>11,12</sup> Although the limited available studies do not demonstrate any disadvantage of supracapsular phacoemulsification compared with endocapsular techniques, most existing evidence is observational.<sup>8,10,11,13</sup> Randomized comparative data directly evaluating these techniques are lacking, representing a relevant clinical and knowledge gap, particularly in the context of the increasing emphasis on surgical efficiency and tissue preservation in modern cataract surgery.

This study presents the findings of a randomized controlled trial (RCT) designed to systematically compare the surgical outcomes of divide and conquer with tilt and tumble in cataract surgery. The focus of the study lies not only on procedural speed and energy consumption but also on safety parameters, as well as postoperative differences. A comprehensive understanding of the relative merits of these two techniques can contribute to informed decision-making in the selection of surgical approaches, ultimately optimizing patient care in cataract surgery.

## Materials and Methods

All cataract patients scheduled for surgery with the current surgeon (JU) at Aleris Eye Clinics in Helsingborg and Malmö between 1<sup>st</sup> September 2021 and 30<sup>th</sup> June 2022, and who did not meet the exclusion criteria were invited to participate in the study. Out of 536 patients who were approached, only one declined participation.

The exclusion criteria were age below 56 years due to expected particularly soft lenses in this age bracket, which could pose challenges during lens division, thus making the divide and conquer technique less suitable. Patients with an anterior chamber depth (ACD) of 2.3 mm or less were also excluded, as the tilt and tumble technique necessitates a certain chamber volume to mitigate potential harm to the corneal endothelium.<sup>14,15</sup> Patients with cognitive impairment were excluded. Only data from the first eye were included in the study.

The Swedish Ethical Review Authority approved the study (2021–06546-02), which was performed according to the tenets of the Declaration of Helsinki. Study information was given during the preoperative appointment and written consent was obtained before enrollment. The study was registered at ClinicalTrials.gov (NCT05271942).

Approximately 15–20 patients were included per week. Patients were randomized to undergo cataract surgery using either the tilt and tumble technique or the divide and conquer technique in a 1:1 allocation. Randomization was performed on a weekly basis, such that one surgical technique was used for all consecutively scheduled patients during a given week and the alternate technique was used during the following week. The order of the techniques was alternated week by week throughout the study period. All surgeries were performed by the same surgeon (JU), who had performed approximately 1200 procedures with each technique prior to study initiation. Surgeries were conducted at two private clinics using identical equipment and standardized operating room routines. Masking of the surgeon was not possible due to the nature of the surgical techniques. For statistical analysis, patient data were pseudo-anonymized and analyses were performed without access to identifiable patient information.

Preoperatively, best corrected visual acuity (BCVA), intraocular pressure (IOP; air puff Topcon TRK-2P), and ACD were measured. Biometry was conducted using Zeiss IOL Master 700 (Carl Zeiss Jena, Germany). Central retinal thickness (CRT; 3D OCT-1 Maestro 2) was measured on the first 239 patients.

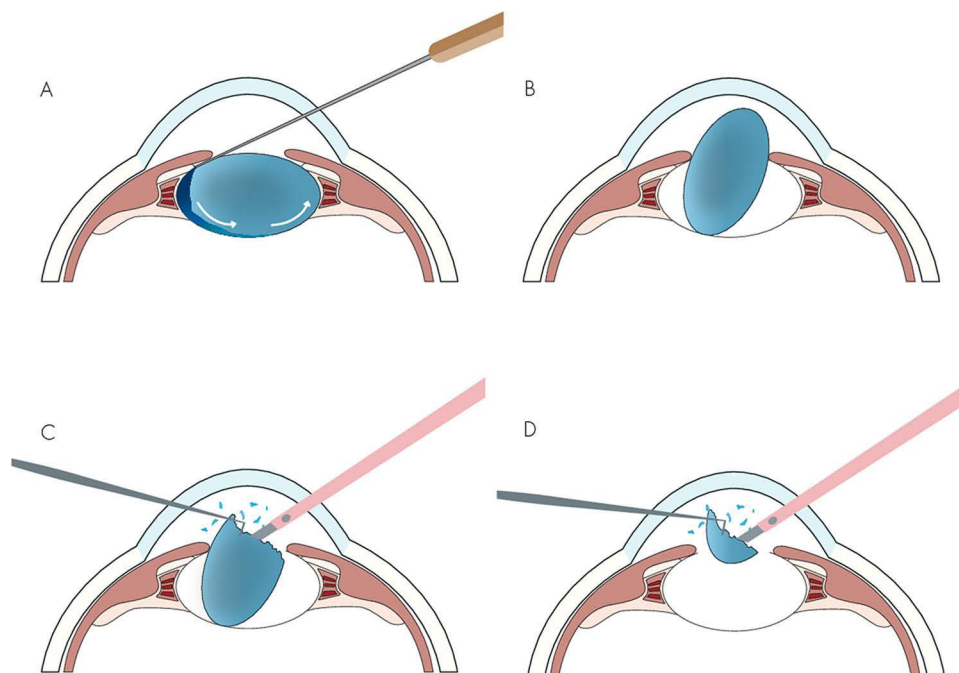
During surgery, time was measured using an athletics stopwatch (Decathlon, France, Kick and Run model no. 4017246) controlled by the surgeon's foot. The stopwatch could record up to four split times, allowing precise measurement of both the phacoemulsification phase and the entire operation. The phacoemulsification machine, Alcon Centurion 3.02 BLD:0109 (Alcon Surgical, Texas, USA), automatically recorded energy and ultrasound time.

The divide and conquer technique commence with the creation of a longitudinal groove in the cataractous lens, a Haefliger chopper was engaged in the side-port incision to stabilize the eye while the initial grooves were created. Subsequently, a second groove is sculpted perpendicular to the initial one. The phaco probe, together with the auxiliary instrument, is then used to separate the nucleus into four quadrants by pushing the instruments apart in the grooves, each subsequently phacoemulsified individually.<sup>1</sup>

The tilt and tumble technique (Figure 1) is a modified form of supracapsular phacoemulsification. It uses hydrodissection, where a cannula elevates the capsular rim, to release and tilt the nucleus partly out of the bag. Gentle irrigation generates a fluid wave beneath the capsular space, leading to nuclear pole tilting. Subsequent engagement and emulsification of the prolapsed pole are performed using the phaco probe. The remaining nucleus is then tumbled out and emulsified in a similar manner.<sup>5,8</sup>

The surgeon targeted a 5 mm capsulorhexis, considering that the rhexis should fully overlap the optics of the lens. The Alcon Centurion machine with Kelman 45° tip was used on all surgeries, the settings are described in Table 1.

Patients returned for a follow-up visit when the second eye was scheduled for surgery. During the follow-up, BCVA and IOP were measured as well as CRT for a subset of the participants (n=232). If any of the research participants



**Figure 1** (A) Gradual and consistent hydrodissection separates the nucleus from the capsular bag. The white arrow indicates the direction of BSS flow during hydrodissection. (B) The nucleus is tilted above the capsular rim, partially emerging from the bag. (C) The nucleus is positioned for direct phacoemulsification using chop technique. (D) The nucleus is progressively emulsified while maintaining the phaco probe at the iris plane.

experienced postoperative macular edema ( $n=2$ ), they were treated and monitored separately outside the study protocol. Patients lost to follow-up were 4.3% ( $n=23$ ).

## Statistical Procedures

A power-analysis was conducted prior to the study based on Cumulative Dissipated Energy (CDE) and phaco time for a small group of patients that were not included in the study. The preliminary data yielded effect sizes (Cohen's  $d$ ) of 0.67 (CDE) and 2.7 (phaco time). Using G\*Power software 3.1.9.7. (Heinrich Heine Universität Düsseldorf, Germany), a power of 80% and  $p<0.05$ , the required sample size was estimated to be  $n=74$  for CDE and  $n=8$  for phaco time. In order to include several additional parameters and also to perform multiple regression, the study aimed at recruiting 250 patients in each group.

For categorical variables, Pearson's chi-square tests or Fisher's exact test were employed to assess associations and differences in proportions (%) between the two groups. Continuous variables were described by mean and standard deviation (SD) or as median, interquartile range (IQR) and range when appropriate. Statistical significance was tested using independent samples  $T$ -test when the data was normally distributed and Mann-Whitney  $U$ -test when the data

**Table 1** Phacoemulsification System Settings Used During Cataract Surgery. Settings Were Predefined and Identical Throughout the Study Period

Mode	Technique	IOP (mmHg)	Vacuum (mmHg)	Aspiration Flow (cc/min)	Longitudinal (%)	Torsional (%)
Sculpt*	Divide and Conquer	70	120	26	0	60
Chop	Both	70	525	36	5	70
Epinucleus	Both	55	380	30	0	50
Cortex	Both	55	500	36	–	–
Polish	Both	55	20	10	–	–
Visco	Both	55	650	50	–	–

**Notes:** \* Sculpt mode was used only for divide-and-conquer procedures. IOP = intraocular pressure. Aspiration flow is expressed in cc/min. Longitudinal and torsional values represent percentage ultrasound power.

lacked a normal distribution. Multiple regression analysis of predictors was performed with total surgery time, phaco time, ultrasound time and energy as dependent variables and the following variables as covariates: age, gender, preoperative BCVA, ACD, laterality and surgical technique. P-value of less than 0.05 was considered significant and statistical analyses were performed using SPSS version 28.0.1.1 (IBM, U.S.A).

## Results

### Baseline Characteristics

No significant disparities were seen between the groups regarding baseline characteristics, including gender, age, preoperative BCVA, IOP, CRT, and ACD (Table 2). In the divide and conquer group, the gender distribution leaned at 56.3% women, while in the tilt and tumble group, it stood at 58.0% women ( $p=0.73$ ). The mean age was 75.2 and 74.3 years, respectively ( $p=0.11$ ). Preoperative BCVA medians were approx. 0.4 logarithm of the minimum angle of resolution (logMAR) in both groups ( $p=0.29$ ). Other measurements, like preoperative IOP, CRT and ACD, showed no statistically significant differences between the two groups (Table 2). Right eyes appeared to dominate in both cohorts, with 60.2% in the divide and conquer group and 60.9% in the tilt and tumble group ( $p=0.86$ ).

### Intraoperative Outcomes

Intraoperatively, a clear difference was apparent between the groups concerning total operation time, phaco time, ultrasound time, and energy expenditure in single parameter analyses (Table 3 and Figure 2). The overall duration of the surgical procedure revealed a significant difference, with a median of 6.50 (IQR=5.75–7.18) minutes for the divide and conquer technique and 4.68 (IQR=4.18–5.33) minutes for the tilt and tumble approach ( $p<0.001$ ). The critical factor influencing this disparity was the phaco time—the duration that the phaco tip was inside the eye (Figure 3). In the divide and conquer group, the median phaco time was 148 (IQR=124–179) seconds, compared to 60 (IQR=49–81) seconds observed in the tilt and tumble group ( $p<0.001$ ).

**Table 2** Baseline Characteristics of Study Cohort Randomized to Two Different Cataract Surgery Techniques

Variable	Divide and Conquer	Tilt and Tumble	P-value
Subjects	n=261	n=274	
1. Women, n (%)	147 (56.3)	159 (58.0)	0.73 <sup>†</sup>
2. Men, n (%)	114 (43.7)	115 (42.0)	
Age of patient at surgery, years	n=261	n=274	
1. Mean (SD)	75.2 (6.2)	74.3 (6.5)	0.11 <sup>‡</sup>
Preop BCVA, LogMAR	n=261	n=273	
1. Mean (SD)	0.42 (0.22)	0.44 (0.25)	0.30 <sup>‡</sup>
Preop IOP, mmHg	n=261	n=274	
1. Mean (SD)	18.2 (3.4)	18.7 (3.4)	0.10 <sup>‡</sup>
Preop CRT, $\mu$ m	n=119	n=120	
1. Mean (SD)	246.5 (30.0)	245.4 (26.5)	0.77 <sup>‡</sup>
ACD, mm	n=261	n=274	
1. Mean (SD)	3.11 (0.34)	3.15 (0.34)	0.38 <sup>‡</sup>
Laterality	n=261	n=274	
1. Left, n (%)	104 (39.8)	107 (39.1)	0.86 <sup>†</sup>
2. Right, n (%)	157 (60.2)	167 (60.9)	

**Note:** <sup>†</sup> Chi-Square test or Fisher's Exact test <sup>‡</sup> Independent samples T-test.

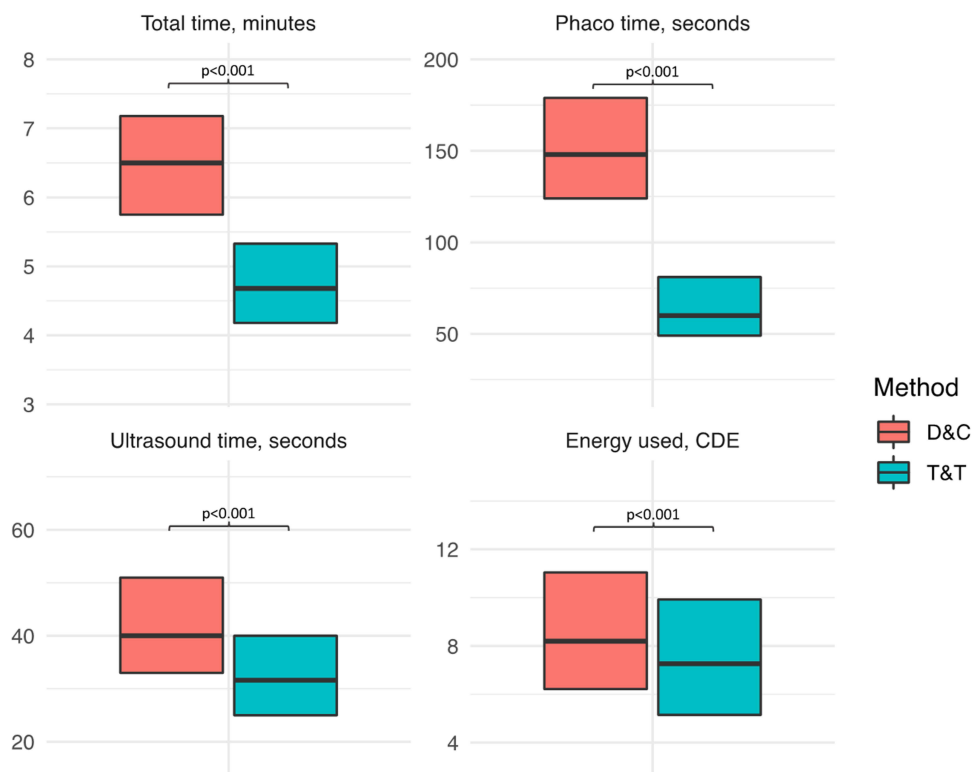
**Abbreviations:** BCVA, Best Corrected Visual Acuity; logMAR, logarithm of the minimum angle of resolution; IOP, Intra Ocular Pressure; CRT, Central Retinal Thickness; ACD, Anterior Chamber Depth.

**Table 3** Intraoperative Parameters of the Study Cohort

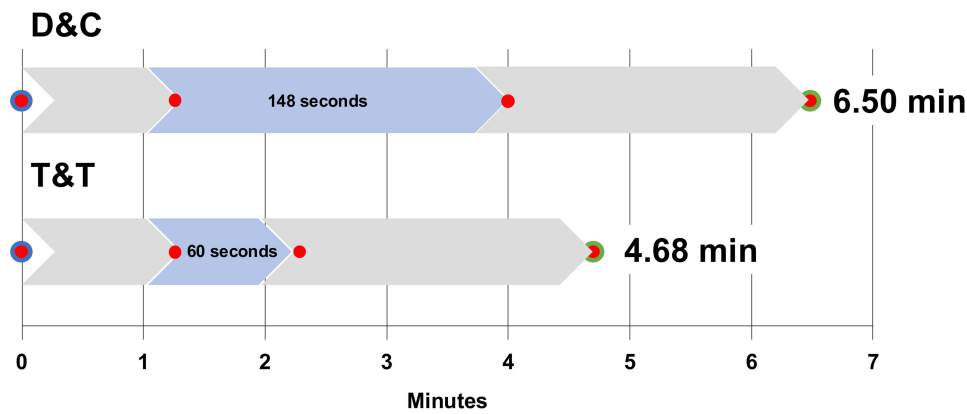
Variable	Divide and Conquer	Tilt and Tumble	P-value
Total surgery time, minutes I. Median (range)	n=261 6.50 (4.6–15.0)	n=274 4.68 (3.2–14.1)	<0.001 <sup>†</sup>
Phacotime, seconds I. Median (range)	n=256 148 (56–592)	n=274 60.0 (19–335)	<0.001 <sup>†</sup>
Ultrasound, seconds I. Median (range)	n=259 40.0 (17.9–140.0)	n=273 31.6 (7.5–214)	<0.001 <sup>†</sup>
Energy used, CDE I. Median (range)	n=261 8.20 (3.1–39.6)	n=274 7.27 (1.3–44.64)	<0.001 <sup>†</sup>
Capsular staining, n (%) I. Yes	n=261 0 (0.0)	n=274 1 (0.4)	1.0 <sup>#</sup>
Posterior capsule rupture, n (%) I. Yes	n=261 1 (0.4)	n=274 1 (0.4)	1.0 <sup>#</sup>
Rhexis tear, n (%) I. Yes	n=261 0 (0.0)	n=274 1 (0.4)	1.0 <sup>#</sup>

**Note:** Phacotime refers to the overall duration during which the phaco tip is inside the eye. Ultrasound signifies the total duration of ultrasound usage. CDE = Cumulative Dissipated Energy. <sup>#</sup> Chi-Square test (Fisher’s Exact test) <sup>†</sup> Mann–Whitney U-test.

Ultrasound time and cumulative dissipated energy (CDE) also displayed noteworthy differences, with median values of 40.0 (IQR=33-51) versus 31.6 (IQR=25-40) seconds ( $p<0.001$ ) and 8.20 (IQR=6.22–11.04) versus 7.27 (IQR=5.15–9.92) ( $p<0.001$ ), respectively (Table 3 and Figure 2).



**Figure 2** Boxplots with total surgery time in minutes, phacoemulsification time in seconds, ultrasound time in seconds and energy usage in CDE. D&C = divide and conquer technique. T&T = tilt and tumble technique. Mann–Whitney U-test was used for statistical analysis.



**Figure 3** The timeline illustrates the median total surgery time and median phacoemulsification time (light-blue area) for the techniques used. Surgery starts at the blue circle and ends at the green circle. The red dot marks initiation of the stopwatch, enabling split-time recordings for each activation.  
**Abbreviations:** D&C, divide and conquer; T&T, tilt and tumble.

Capsule staining occurred once in the tilt and tumble group (Table 3). Both groups experienced one capsule rupture each, with an additional incident of rhexis tear in the tilt and tumble group, identified post-phacoemulsification. Fortunately, the lens could be safely placed in the bag, and the surgery concluded routinely.

### Postoperative Outcomes

No substantial disparities emerged in visual improvement, with average logMAR improvements of  $-0.36$  and  $-0.37$ , respectively ( $p=0.67$ ) (Table 4). The average decrease in IOP was marginal at  $-1$  mmHg in the divide and conquer group and  $-0.6$  in the tilt and tumble group, with no statistically significant difference ( $p=0.14$ ). Mean CRT postoperatively increased marginally by  $2.6 \mu\text{m}$  ( $\text{SD}=10.6$ ) in the divide and conquer group and  $4.3 \mu\text{m}$  ( $\text{SD}=10.5$ ) in the tilt and tumble

**Table 4** Postoperative Outcomes of Parameters

Variable	Divide and Conquer	Tilt and Tumble	P-value
Postoperative BCVA, logMAR I. Mean (SD)	n=250 0.053 (0.093)	n=262 0.069 (0.094)	0.02 <sup>‡</sup>
BCVA difference, logMAR I. Mean (SD)	n=250 -0.360 (0.214)	n=261 -0.369 (0.253)	0.67 <sup>‡</sup>
Postoperative IOP, mmHg I. Mean (SD)	n=249 17.1 (3.5)	n=262 18.1 (4.0)	0.003 <sup>‡</sup>
IOP difference, mmHg I. Mean (SD)	n=249 -1.03 (2.97)	n=262 -0.62 (3.42)	0.14 <sup>‡</sup>
Postoperative CRT, $\mu\text{m}$ I. Mean (SD)	n=116 249.6 (34.0)	n=116 249.2 (28.8)	0.91 <sup>‡</sup>
Postoperative CRT difference, $\mu\text{m}$ I. Mean (SD)	n=116 2.63 (10.6)	n=116 4.3 (10.5)	0.24 <sup>‡</sup>
CRT increase $\geq 10\%$ , n (%) I. Yes	n=116 3 (2.6)	n=116 2 (1.7)	1.00 <sup>#</sup>
Days to follow up, days I. Mean (SD)	n=249 20.4 (12.5)	n=260 20.1 (12.8)	0.81 <sup>‡</sup>

**Note:** <sup>‡</sup> Independent samples T-test <sup>#</sup> Chi-Square test (Fisher’s Exact test).

**Abbreviations:** BCVA, Best Corrected Visual Acuity; logMAR, logarithm of the minimum angle of resolution; IOP, Intra Ocular Pressure; CRT, Central Retinal Thickness; BCVA Difference, BCVA postop-BCVA preop; IOP Difference, IOP postop-IOP preop; CRT Difference, CRT postop-CRT preop.

cases, with no statistically significant group differences. The average time to follow-up visits stood at 20 days (SD=13) for both groups.

## Multivariate Analysis

When adjusting for confounders in the multiple regression model, the tilt and tumble technique was associated with shorter total surgery time (Beta =  $-0.57$ , R square =  $0.40$ ,  $p < 0.001$ ), phaco time (Beta =  $-0.68$ , R square =  $0.53$ ,  $p < 0.001$ ), and ultrasound time (Beta =  $-0.23$ , R square =  $0.26$ ,  $p < 0.001$ ). No statistically significant association between surgical method and energy expenditure (CDE) was seen (Beta =  $-0.09$ , R square =  $0.21$ ,  $p = 0.14$ ). The multiple regression analyses for the association between surgical method and total operation time, phaco time, ultrasound time, and energy expenditure are shown in [Supplementary Tables 1–4](#).

## Discussion

The present study sought to investigate and evaluate the effectiveness and safety of the tilt and tumble technique in cataract surgery. While supracapsular phacoemulsification is acknowledged for its efficiency<sup>13,16</sup> it is not as widely employed as other methods.<sup>6,7</sup> This prompts questions about its safety, energy consumption, speed, and applicability to various cases.

Previous research has compared divide and conquer with various chop techniques, demonstrating both lower energy consumption and faster surgery with different chop methods compared to divide and conquer.<sup>2–4</sup> However, no study has deeply compared tilt and tumble with any other method.

Divide and conquer, a technique ingrained in the repertoire of most cataract surgeons, played a pivotal role in our study as a benchmark for evaluating the tilt and tumble technique. For many, it serves as the initial stepping stone into the world of cataract surgery.<sup>1,17</sup> The surgeon (JU), on whom the study is based, had performed approximately the same number of operations with each technique (about 1200 each) at the start of the study and was proficient in both. This was seen as a significant advantage for the study's design.

The results revealed that the tilt and tumble technique is notably swifter than the reference method, with a median total surgery time of 6.50 minutes in the divide and conquer group compared to 4.68 minutes in the tilt and tumble group. Additionally, the tilt and tumble approach demonstrated comparable safety, as it did not show increased intraoperative complications related to posterior capsule rupture or radial tear of the rhexis, nor a postoperative central retinal thickness increase exceeding 10%. Importantly, the tilt and tumble method does not exhibit higher energy consumption than the divide and conquer technique. Furthermore, there was no significant difference in postoperative best-corrected visual acuity (BCVA) improvement.

Our previous register-based study did not show any difference between preferred surgical method and capsule rupture frequency.<sup>5</sup> It was not possible to draw conclusions regarding differences in capsule rupture frequency between the groups in this RCT due to the low event rate ( $< 0.4\%$ ) in both groups. One possible approach may involve incorporating information about the surgical technique into a cataract registry. This would give access to extensive volumes and various levels of surgical experience. Standardizing energy measurements for different phaco machines in such a registry could further assess which technique is the most gentle for the eye.

An essential inquiry concerning the tilt and tumble technique pertains to its impact on the cornea. As the lens is flipped upward, standing on its edge in close proximity to the corneal endothelium, and with phacoemulsification typically occurring at or above the pupil plane, evaluating the effect on the endothelium during tilt and tumble surgery holds significant interest. Previous studies employing similar techniques have assessed parameters such as endothelial cell count and corneal thickness,<sup>12</sup> the influence of bevel position on corneal endothelium,<sup>18,19</sup> variations in corneal effects based on different techniques,<sup>20–22</sup> and various intraoperative factors affecting the cornea.<sup>15,23,24</sup> These studies show that the degree of cataract, operation time, chamber depth, and postoperative edema are predictors of ECL, but do not show a clear consensus regarding the choice of technique and ECL.

## Clinical Implications

The findings of the present study suggest that the tilt and tumble technique may be particularly advantageous in clinical settings where surgical efficiency is prioritized, such as high-volume cataract units, without compromising safety or postoperative outcomes. The markedly shorter phacoemulsification time and total surgical duration observed with tilt and tumble may be clinically relevant for patients who have difficulty tolerating prolonged procedures, including those with back pain, tremor, anxiety, dementia or movement disorders.

While cataract density was not formally graded, the absence of increased energy use or complication rates suggests that tilt and tumble may be suitable to a broad spectrum of routine cataract cases. However, in eyes with dense nuclei, shallow anterior chambers, or compromised corneal endothelium, careful case selection remains important, as supracapsular nucleus manipulation brings the phacoemulsification plane closer to the corneal endothelium. In such cases, surgeon experience and meticulous fluidics control are likely to be critical.

Importantly, the comparable postoperative visual outcomes and safety profiles observed between techniques indicate that tilt and tumble represents a viable alternative to divide and conquer in routine cataract surgery, allowing surgeons to tailor technique selection to individual patient characteristics and clinical priorities.

## Strengths and Limitations

The study's exclusive reliance on a single surgeon both fortified and constrained our findings. On one hand, it provided a clear depiction of only one surgeon navigating both methods and encountering complications. On the other hand, the streamlined approach allowed isolation of the phacoemulsification moment, minimizing biases introduced by other factors. Scrutinizing phacoemulsification time in comparison to total operation time revealed that this factor singularly accounted for the time disparity between the groups. Another strength lay in the identical clinical setting, staffed by highly experienced nurses dedicated to cataract surgery in both locations, facilitating a nuanced understanding of method differentiators. This allowed us to purify what distinguishes the methods, as other factors that could introduce bias were standardized to the greatest extent possible.

However, several limitations should be acknowledged. First, the study did not include assessments of corneal endothelial cell density or corneal thickness. Given that divide and conquer and tilt and tumble techniques differ in nucleus manipulation and ultrasound delivery, endothelial cell loss represents a clinically relevant safety outcome that could not be evaluated. Future studies incorporating specular microscopy are therefore warranted to more fully assess corneal endothelial effects.

Second, the duration of postoperative follow-up was relatively short and not strictly standardized. While follow-up timing was similar between groups and sufficient for comparative analysis, longer-term follow-up would be valuable to assess continued endothelial recovery, resolution of corneal edema and visual stabilization.

Finally, the single-surgeon design limits the generalizability of the findings. Surgical outcomes may be influenced by operator-dependent factors and the results may not be directly transferable to surgeons with different levels of experience or alternative surgical preferences. Multicenter, multi-surgeon studies would therefore be useful to confirm the reproducibility of these findings across a broader clinical context.

## Conclusion

In conclusion, the tilt and tumble technique was associated with shorter surgical and phacoemulsification times while demonstrating comparable safety, energy use and postoperative outcomes to divide and conquer in this randomized study. These findings suggest that tilt and tumble represent a clinically relevant alternative for routine cataract surgery, although further studies are warranted to confirm its applicability across broader surgical settings and patient populations.

## Data Sharing Statement

The individual de-identified participant data that support the findings of this study are not publicly available due to ethical and privacy considerations. However, relevant data may be made available from the corresponding author upon reasonable request and following assessment of the intended use and applicable ethical approvals. No additional study documents will be made available. Data will be available from the time of publication and for a period of five years thereafter.

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## Disclosure

The authors report no conflicts of interest in this work.

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