



Comparison of Three-Dimensional Surgical System Versus Binocular Microscope for Clear Corneal Incision in Cataract Surgery

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ABSTRACT

Introduction: To compare surgical outcomes of 2.2 mm clear corneal incision (CCI) between a three-dimensional (3D) visualization system and traditional binocular microscope (BM) for phacoemulsification and intraocular lens implantation surgery.

Methods: In this randomized controlled clinical study, 60 eyes with age-related cataracts were divided into two groups receiving cataract surgery using either a 3D vision system ($n = 30$ eyes) (3D group) or a binocular microscope ($n = 30$ eyes) (BM group). We recorded and statistically analyzed surgical parameters and pre- and postoperative ocular parameters. Primary

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outcomes included the change in endothelial cell density (ECD) and CCI architecture, and secondary outcomes comprised other ocular parameters and surgical parameters. All procedures complied with the tenets of the Declaration of Helsinki.

Results: Of the 60 eyes randomly assigned between January 5, 2021, and May 9, 2021, 55 (26 eyes in the 3D group and 29 eyes in the BM group) were analyzed. The ECD loss rate was 8.1% in the 3D group and 12.3% in the BM group, but the difference was not statistically significant. Local detachment of Descemet's membrane was seen in 50% (13 eyes, 3D group) and 51.6% (15 eyes, BM group), wound gaping at the endothelial side in 15.4% (four eyes, 3D group) and 10.3% (four eyes, BM group), gaping at the epithelial side in 11.5% (three eyes, 3D group) and 6.9% (two eyes, BM group), and misalignment of the incision in 3.4% (one eye, BM group) 1 day after surgery. These abnormalities improved with time. There was no difference between the 3D group and BM group in terms of other ocular parameters or surgical parameters before and after surgery.

Conclusions: Using the 3D surgical system for phacoemulsification and IOL implantation surgery seems to result in similar ECD and CCI conditions as using a conventional binocular microscope.

Trial Registration: The protocol was registered on ClinicalTrials.gov (NCT04839250).

Keywords: 3D surgical system; Cataract; Clear corneal incision

Key Summary Points

Why carry out this study?

The 3D surgical system is a promising technique for carrying out more efficient and comfortable cataract surgery.

The safety and efficiency of the 3D system has been confirmed in previous studies. However, whether the 3D system is non-inferior to traditional binocular microscope with regard to clear corneal incision remains unclear.

What was learned from the study?

There was no difference between the 3D system and traditional system in surgical parameters and surgical outcomes including clear corneal incision, change in endothelial cell density, corneal edema, and corneal incision edema.

Our study provides evidence supporting the application and popularization of the 3D surgical system in anterior segment surgery.

INTRODUCTION

Among the rapid advances in ocular surgery techniques over the past decade, three-dimensional (3D) visualization surgical systems represent a significant technological innovation in surgical practice. The NGENUITY® 3D visualization system was the first commercially available surgical system in ophthalmology; it was developed specifically for posterior segment surgeries in 2010 and first introduced by Eckardt and Paulo in 2016 to perform vitreous surgeries [1, 2]. Most previous studies that have described 3D surgical systems have focused on retinal procedures, although some articles have reported the role of this state-of-the-art device for

operations on the anterior segment, such as for cataract, strabismus, glaucoma, and corneal surgeries [3–6].

The 3D surgical system comprises a wide-screen 4K high-definition display with full resolution of 3840 × 2160 pixels, an Image Capture Module camera with two high-resolution sensors, an embedded processing unit (EPU) which can process over 3 GB of data per second, and polarized 3D glasses. The 3D system technically offers a high-resolution view even under high magnification and enables better depth perception due to improved light sensitivity and decreased aperture of the Image Capture Module camera [7, 8]. Under COVID-19 protocols, the 3D system shows unique superiority over binocular microscopes (BM) because it helps to maintain adequate social distance [9]. The live surgical image is processed by EPU using a specialized algorithm that optimizes image quality at a lower endoillumination level than the human eye. Previous studies have shown that the 3D system provides higher contrast and color balance than BM and reduced illumination for cataract surgery, which protects against retinal phototoxicity [10–12]. Moreover, the 3D system offers additional advantages including ergonomic comfort for surgeons and better coordination among the surgical team. This modality also serves as an educational tool for beginners in this surgical field [13–15].

Clear corneal incision (CCI) is the most popular and most commonly used incision in modern phacoemulsification. When constructed properly, it has the ability to self-seal without a suture. The integrity of CCI architecture is critical to obtaining optimal outcomes after cataract surgery. To our knowledge, no randomized controlled trial has evaluated the 3D surgical system from the perspective of the CCI architecture.

In this comparative study, we investigated the efficiency of the NGENUITY® 3D visualization system and compared its safety profile with that of a BM with regard to CCI architecture, corneal endothelial cell density (ECD), and postoperative central corneal thickness (CCT).

METHODS

Patients

This prospective, single-center randomized controlled trial included 60 consecutive patients with age-related cataract who were recruited from a day surgery center between January 5, 2021, and May 9, 2021. Based on a randomization sequence generator, patients were assigned to two groups: the 3D group (30 patients, 30 eyes) included those who underwent procedures using the NGENUITY 3D visualization system (Alcon Laboratories, Inc., Fort Worth, TX, USA), and the BM group (30 patients, 30 eyes) included those who underwent procedures using a conventional surgical microscope (Carl Zeiss Surgical GmbH, Oberkochen, Germany).

All participants provided written informed consent before study participation. The study was registered with ClinicalTrials.gov, NCT04839250. The study was approved by the Institutional Review Board of Wenzhou Medical University (2021-039-K-32). All procedures complied with the tenets of the Declaration of Helsinki.

Inclusion and Exclusion Criteria

The inclusion criterion for this study was diagnosis of age-related cataract that affected vision and activities of daily living, which necessitated phacoemulsification and intraocular lens (IOL) implantation surgery. Exclusion criteria were as follows: a history of Fuchs' endothelial dystrophy, corneal edema, or other corneal disease, a history of glaucoma, fundus diseases such as epiretinal membrane, or diabetic retinopathy that necessitated additional surgical procedures, a history of surgery of the eye being investigated in the current study, difficulty with cooperation for repeated measurements such as severe dry eye or small palpebral fissure, or poor image quality of any measurement.

Procedures

All surgeries were performed by an experienced ophthalmic surgeon using the CENTURION[®] Vision System and Balanced Tip (Alcon Laboratories, Inc., Fort Worth, TX, USA) devices, and a foldable hydrophilic acrylic IOL was inserted into the capsular bag under topical anesthesia. Initially, a 2.2 mm single-plane CCI and a 1.0 mm side-port incision were created using a diamond keratome. The entire procedure was performed in the same manner in both groups. Our surgeon had performed over 50 cataract surgery procedures using the 3D surgical system prior to the present study.

Surgical parameters displayed on the phacoemulsification machine screen, including the total case time, the cumulative dissipated energy (CDE), total ultrasonography time, and irrigation fluid used, were recorded by the circuit nurse and documented by a research assistant immediately postoperatively. Using a Canon TX-20P non-contact tonometer (Canon Inc., Tokyo, Japan), intraocular pressure (IOP) was measured 2 h postoperatively.

After surgery, all patients were given topical steroidal eye drops (tobramycin and dexamethasone; Alcon Laboratories, Inc., Fort Worth, TX) four times a day and then tapered for 1 month, and antibiotic eye drops (levofloxacin; Santen, Inc., Suzhou, China) for 2 weeks.

Outcome Measures

The primary outcome was change in ECD and CCI architecture. The secondary outcomes were other clinical parameters including thickness of the CCI, corneal edema, and corrected distance visual acuity (CDVA). Postoperative follow-up visits were scheduled 1 day, 1 week (between 6 and 8 days), and 1 month (between 28 and 33 days) after surgery.

ECD was measured preoperatively and 1 month postoperatively with a non-contact specular microscope (EM-3000, Tomey, Nagoya, Japan). The rate of ECD loss was calculated as $ECD = (\text{preoperative ECD} - \text{postoperative ECD}) / \text{preoperative ECD}$. Anterior-segment

optical coherence tomography (AS-OCT) scan (CASIA SS-1000, Tomey, Japan) was performed by experienced technicians preoperatively and every follow-up visit postoperatively. In the current study, local detachment of Descemet's membrane, wound gaping at the endothelial aspect, gaping at the epithelial aspect, and misalignment of the incision were defined as complications of CCIs based on Calladine and Packard's report [16] (Fig. 1). CCI thickness and CCT were also recorded 1 day, 1 week, and 1 month postoperatively. Corneal edema was evaluated using the following formula: postoperative CCT (at 1 day or 1 week or 1 month) – preoperative CCT. The manifest refraction and CDVA were evaluated by a professional optometrist preoperatively and at the 1-month follow-up visit.

Statistical Analysis

The sample size was calculated using PASS [Power Analysis and Sample Size] software (version 2020, NCSS, LLC, Kaysville, UT, USA). This study was designed as a non-inferiority study. To verify that postoperative ECD in the 3D group was non-inferior to that in the BM group, we set the margin of non-inferiority at 300 based on published data [17]. A group sample size of 56 (28 per group) achieved 81% power to detect non-inferiority at a significance level of 0.025 (one-sided). We also calculated the sample size based on the rate of local detachment of Descemet's membrane, which was the most common corneal incision abnormality after cataract surgery. The frequency of

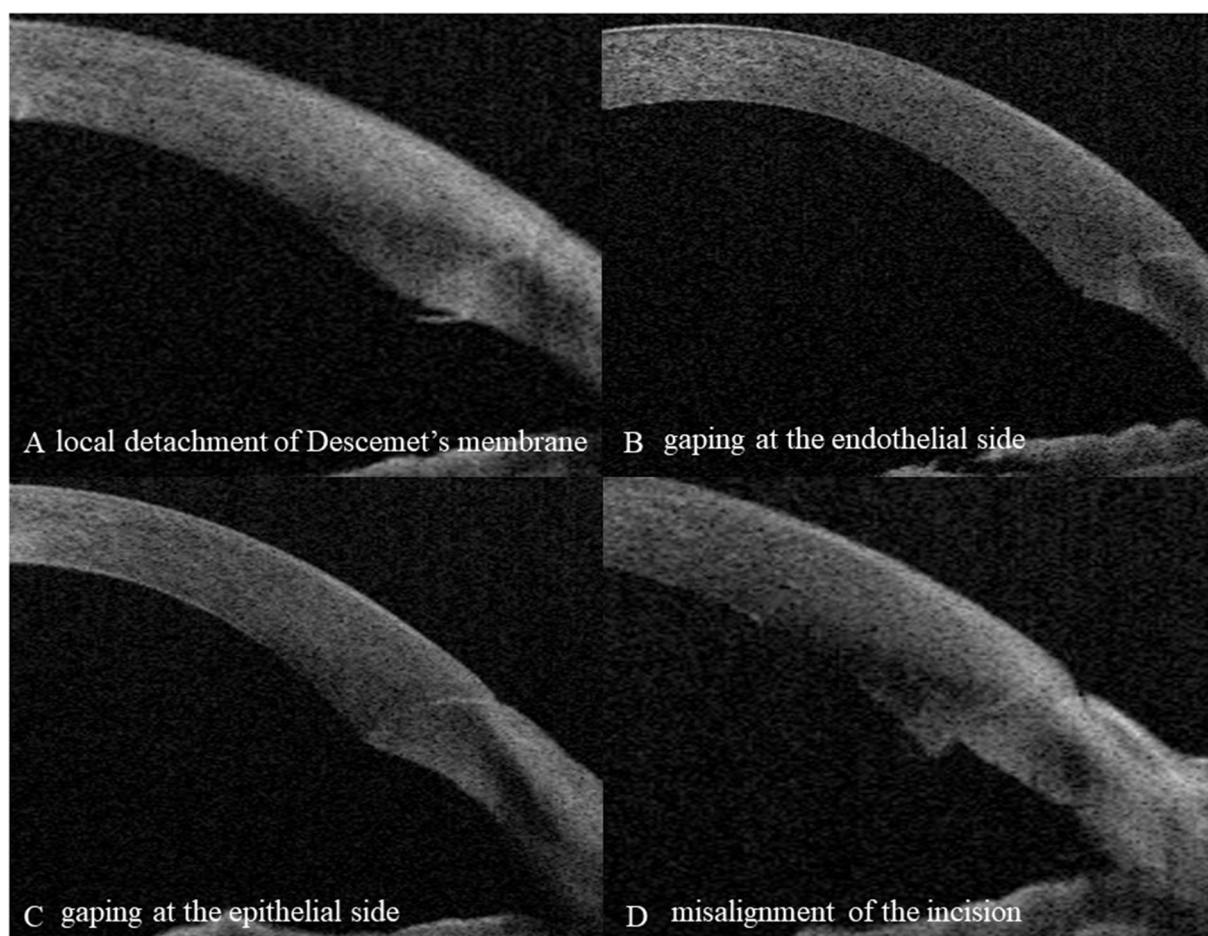


Fig. 1 Images of clear corneal incision obtained by anterior segment optical coherence tomography. **a** Local detachment of Descemet's membrane. **b** Gaping at the endothelial side. **c** Gaping at the epithelial side. **d** Misalignment of the incision

local detachment of Descemet’s membrane was 30–63% based on published data and expert opinion [16, 18–20]. This sample size was calculated with a two-tailed test for type I error of 5%, type II error of 20%, and an estimated loss rate of 10%. The result suggested 27 participants in each group or a total of 54. Statistical analysis was performed using SPSS Statistics version 26 software (IBM Corporation, Armonk, NY, USA), and data are expressed as mean ± standard deviation and/or percentages. The Kolmogorov–Smirnov test was used to evaluate data distribution normality. The independent-samples *t* test was used for continuous data that

conformed to a normal distribution, and the Mann–Whitney *U* test was used otherwise. We calculated the percentage of the specific architectural features of each incision at each follow-up time point and used Fischer’s exact test or Pearson χ^2 analysis for intergroup comparison. All tests were two-sided, and a *p* value of < 0.05 was considered statistically significant.

RESULTS

A total of 60 eyes were included in the present study and randomly assigned to the 3D group or

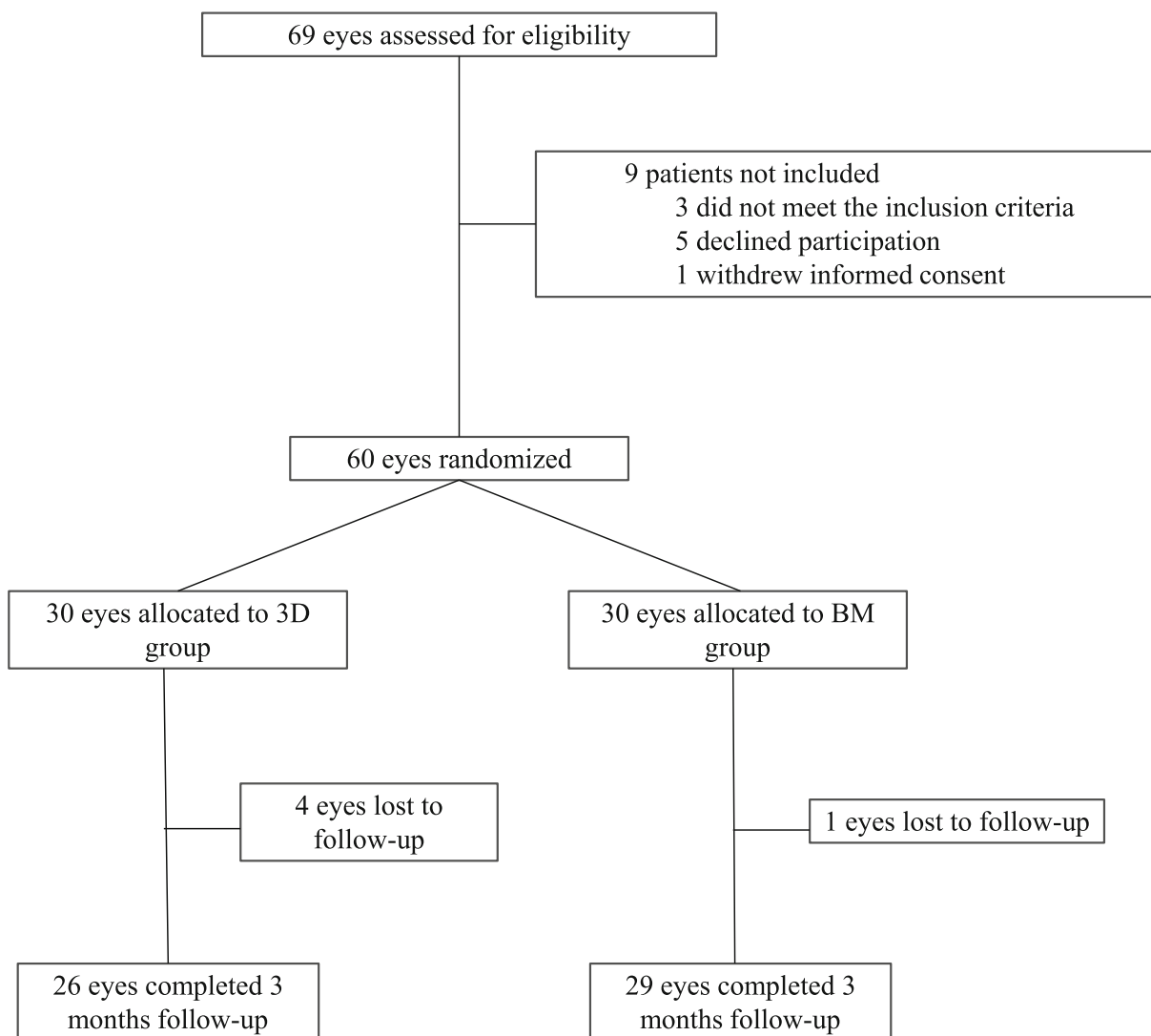


Fig. 2 Study design flow diagram. *3D* three-dimensional visualization system, *BM* binocular microscope

Table 1 Baseline characteristic of the patients

	3D group, <i>n</i> = 26	BM group, <i>n</i> = 29	<i>p</i> value
Female subjects	14 (52%)	18 (62%)	0.440 [†]
Mean age at surgery, years	70.2 ± 10.6	72.1 ± 11.3	0.509 [‡]
Preoperative CDVA, logMAR	0.79 ± 0.57	0.89 ± 0.50	0.479 [‡]
Mean preoperative endothelial cell count	2549 ± 194	2506 ± 189	0.403 [‡]
Mean preoperative CCT, μm	545 ± 33	539 ± 25	0.447 [‡]
Mean anterior chamber depth, mm	3.19 ± 0.38	3.23 ± 0.47	0.164 [*]
LOCS III-C, median (range)	2 (1–4)	2 (1–4)	0.313 [‡]
LOCS III-N, median (range)	2 (0–3)	2 (0–4)	0.905 [‡]
LOCS III-P, median (range)	2 (1–5)	2 (0–5)	0.922 [‡]

Data are number of patients (%), mean (SD), median (range)

3D three-dimensional visualization system, BM binocular microscope, LogMAR logarithm of the minimum angle of resolution, CDVA corrected distance visual acuity, CCT central corneal thickness, LOCS III Lens Opacities Classification System III, N nuclei, C cortex, P posterior subcapsular

*Independent-samples *t* test

[†] χ^2 test

[‡]Mann–Whitney *U* test

BM group (Fig. 2). Baseline characteristics including sex distribution, age, CDVA, ECD, CCT, anterior chamber depth, and the Lens Opacities Classification System III mean values were similar between the 3D and BM groups (Table 1). Five eyes (four from the 3D and one from the BM group) were lost to follow-up at 1 week or 1 month and were therefore excluded from the study. No intra- or postoperative complications occurred over the 1-month follow-up in either group.

ECD was significantly reduced from 2549 ± 194 to 2372 ± 349 cells/mm², with a loss rate of 8.1%, in the 3D group ($p = 0.026$) and from 2506 ± 189 to 2223 ± 429 cells/mm² ($p = 0.002$) with a loss rate of 12.3% in the BM group; however, no intergroup difference was observed in loss rates (Table 2). Figure 3 shows an intergroup comparison of the percentage of CCIs associated with each architectural feature. Local detachment of Descemet's membrane was observed in 50% and 51.7% of patients 1 day postoperatively and in 23.1% and 37.9% of patients 1 week postoperatively in the 3D and BM groups, respectively, and was not detected

1 month postoperatively in either group. The incidence of gaping at the endothelial aspect was 15.4% and 10.3% in the 3D and BM groups, respectively, 1 day postoperatively and decreased to 7.7% and 10.3%, respectively, at the 1-week follow-up visit. Finally, only one patient showed this abnormal architectural feature in each group. Gaping at the epithelial aspect was less common; this complication occurred in only 11.5% of patients in the 3D group and 6.9% patients in the BM group at the 1-day follow-up visit and in only one patient in the BM group at the 1-week follow-up visit. Differences in CCI architecture were statistically nonsignificant in both groups across all time points.

CDVA at the 1-month follow-up was significantly improved in both groups (Table 2). In the 3D group, CCI thickness was 860.6 ± 49.5 , 837.7 ± 52.1 , and 744.5 ± 51.8 μm at 1 day, 1 week, and 1 month after surgery, respectively. In the BM group, CCI thickness was 876.7 ± 47.0 , 830.1 ± 62.3 , and 775.1 ± 68.9 μm at 1 day, 1 week, and 1 month after surgery, respectively. No statistically

Table 2 Postoperative outcomes between groups

	3D group, <i>n</i> = 26	BM group, <i>n</i> = 29	<i>p</i> value
Postoperative CDVA, logMAR	0.13 ± 0.18	0.12 ± 0.13	0.671*
Postoperative endothelial cell count	2372 ± 349	2223 ± 429	0.159*
Thickness of corneal incision D1	860.6 ± 49.5	876.7 ± 47.0	0.150 [†]
Thickness of corneal incision W1	837.7 ± 52.1	830.1 ± 62.3	0.769*
Thickness of corneal incision M1	744.5 ± 51.8	775.1 ± 68.9	0.056 [†]
Postoperative corneal edema D1	49.02 ± 17.56	46.66 ± 27.95	0.62 [†]
Postoperative corneal edema W1	21.19 ± 20.62	21.31 ± 18.89	0.97 [†]
Postoperative corneal edema M1	11.9 ± 16.15	15.24 ± 10.61	0.84 [†]

CDVA corrected distance visual acuity, D1 first day after surgery, W1 1 week after surgery, M1 1 month after surgery, 3D three-dimensional visualization system, BM binocular microscope

*Mann–Whitney *U* test

[†]Independent-samples *t* test

significant difference was noted between the two groups ($p = 0.150$, 0.769 , and 0.056 , respectively). Postoperative corneal edema thickness, which was most remarkable at the 1-day visit, was $49.02 \pm 17.56 \mu\text{m}$ in the 3D and $46.66 \pm 27.95 \mu\text{m}$ in the BM group and gradually diminished over 1 week and 1 month (Fig. 4). No intergroup differences were observed in edema thickness across time points ($p = 0.62$, 0.97 , and 0.84 , respectively).

The mean surgical time was 11.3 ± 8.0 min in the 3D and 15.9 ± 9.8 min in the BM group; the difference was statistically nonsignificant ($p = 0.058$) (Table 3). Similarly, the difference in the mean ultrasonography time between the 3D and the BM groups was statistically nonsignificant ($p = 0.180$). We observed no intergroup difference in the mean CDE, irrigation fluid used, or IOP measured 2 h postoperatively ($p = 0.837$, 0.872 , and 0.772 , respectively).

DISCUSSION

Studies performed over the past decade have confirmed the reliability of the NGENUITY® 3D visualization system, and this relatively new digital equipment is being widely accepted by the ophthalmological community owing to

superior image quality, user-friendliness, and easy maneuverability. Evidence-based research has confirmed that the efficiency and safety of the 3D surgical system used in routine ophthalmological procedures are equal to the efficiency and safety of standard surgical devices [1, 3]. In this prospective, randomized controlled study, we investigated the efficacy and safety of the 3D surgical system, specifically with regard to ECD loss rate and CCI architecture.

Corneal transparency is important to maintain postoperative visual quality and patient satisfaction; patients expect good visual acuity immediately after surgery. Many factors, including ocular variables (nuclear hardness, patient age, and anterior chamber depth [ACD]) and surgical variables (prolonged phacoemulsification time, fluid turbulence, surgical instrument- or IOL-induced endothelial cell injury), may increase the risk of endothelial cell loss and associated changes in corneal thickness. We also controlled the baseline characteristics between the 3D and BM groups and used the CENTURION® Vision System and Balanced Tip to reduce the phacoemulsification energy transmitted to the cornea and the incision site and designed our study carefully to eliminate this bias (Table 1). In this study, we observed no

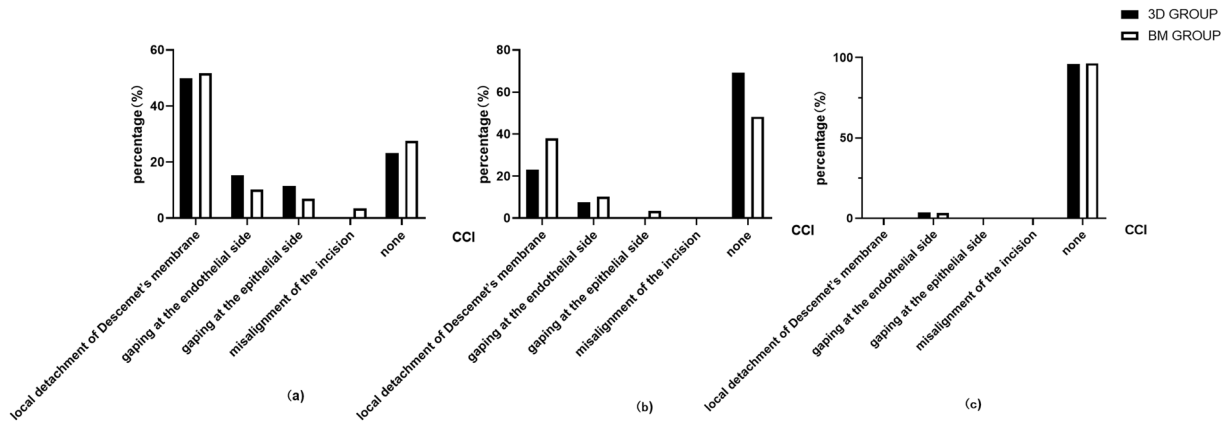


Fig. 3 Change in clear corneal incision in 3D group and BM group. **a** Observation at 1 day postoperatively. **b** Observation at 1 week postoperatively. **c** Observation at 1 month postoperatively. *3D* three-dimensional visualization system, *BM* binocular microscope

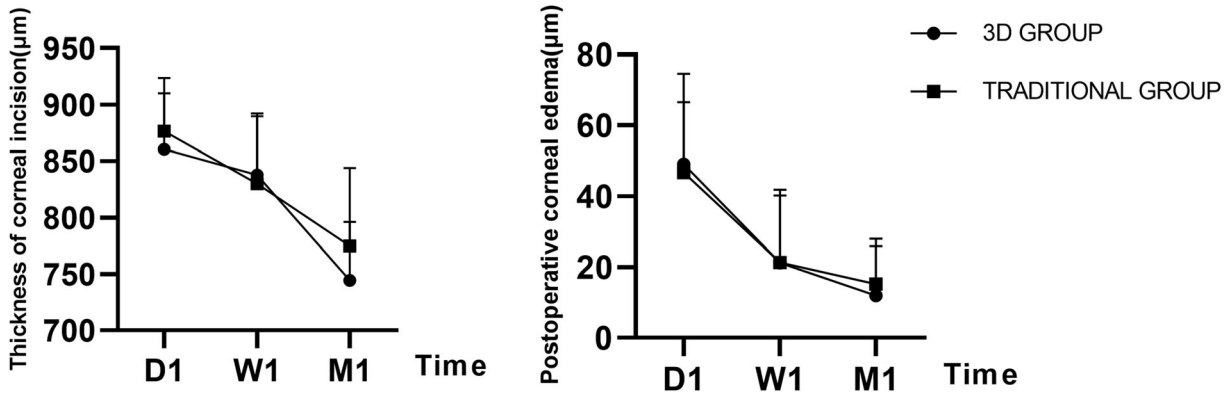


Fig. 4 Change in corneal incision thickness and postoperative corneal edema. Left: corneal incision thickness decreased over 1 month; no difference was found between the two groups. Right: postoperative corneal edema diminished over 1 month; no difference was found between the two groups. *3D* three-dimensional visualization system, *BM* binocular microscope

intergroup difference in endothelial cell loss; this finding coincides with that reported in another randomized clinical trial [17]. In terms of corneal edema, a recently published article noted that the 3D system could reduce corneal edema in eyes with narrow ACD (≤ 3 mm); however, no difference was found in eyes with deeper ACD (> 3 mm) [21]. The average ACD values in our study were 3.19 ± 0.38 mm (3D group) and 3.23 ± 0.47 mm (BM group), which might explain why we did not observe the difference in postoperative corneal edema.

A well-adapted CCI is important to reduce the risk of endophthalmitis and improve postoperative visual acuity. We used AS-OCT (a non-contact tool that provides high-resolution images for visualization of the anterior segment) to accurately observe changes in corneal incision architecture, CCI thickness, and CCT. To our knowledge, the present study is the first to compare the safety of the 3D surgical system with regard to CCI architecture, demonstrating that the 3D surgical system is comparable to the traditional microscope. Local detachment of Descemet’s membrane was the most common

Table 3 Comparison of surgical parameters between two groups

	3D group n = 26	BM group n = 29	p- value
Total case time, minutes	11.3 ± 8.0	15.9 ± 9.8	0.058*
CDE, seconds	5.87 ± 7.8	5.53 ± 4.2	0.837*
total ultrasound time, seconds	31.6 ± 12.0	37.6 ± 20.3	0.180*
Irrigation fluid used, ml	52.58 ± 12.3	53.41 ± 13.6	0.872 [†]
IOP 2 hours after surgery, mmHg	17.4 ± 5.3	17.0 ± 5.5	0.772 [†]

CDE cumulative dissipative energy, 3D three-dimension visualization system, BM binocular microscope, IOP intraocular pressure

*Mann–Whitney U test. [†]Independent sample t-test

complication in both groups in this study. We observed this effect in approximately 50% of CCIs 1 day postoperatively; however, spontaneous reattachment of Descemet's membrane was seen in all patients 1 month postoperatively. The same changes were observed with regard to other CCI architectural features. Previous studies have reported a high rate of local detachment of Descemet's membrane, which may be attributable to unintentional stripping during creation of the main incision, repeated manipulation of instruments through the incision, and the effects of ultrasound energy, especially in micro-incision surgery [16, 20, 22]. Hand–eye coordination and stereopsis are vital during the overall surgical process, especially during lens fragmentation and phacoemulsification, when surgeons try to avoid lens fragment collision with the cornea and to reduce the ultrasound energy delivered to the cornea. The 3D system maintains the depth of field even at high magnification, which provides better ACD perception, thereby increasing the intraocular surgical safety and decreasing the damage to the cornea. However, in a questionnaire-based study, the authors found less

visibility and field depth in 25% of 3D cataract surgery cases [1]. This discomfort experienced by cataract surgeons can be explained by their lack of familiarity with changing the focus as frequently as retina surgeons do. Periodic adjustments in the plane of focus are necessary to achieve the best visibility and perception of space. Frequent adjustments in focus are performed during cataract surgery, particularly during continuous circular capsulotomy, chopping, and polishing [9]. There is an appreciable lag of 50–70 ms with the NGENUITY system, which is significant in anterior segment surgeries and may relate to intra- or postoperative complications. However, the surgeon found no evidence of this in any of the cataract surgeries in the present study.

Three previously published articles have described no difference in the total surgical time between the 3D system and BM [3, 17, 23]. However, one study reported that the duration of cataract surgery was 5 min shorter with the use of the 3D surgical system [24]. We observed no reduction in total surgical time, ultrasonography time, total CDE, or irrigation fluid used in the 3D versus BM group; this result is consistent with the findings of previous research. Application of the 3D surgical system in cataract and macular surgery is associated with a shorter learning curve compared with traditional BM [9, 13]. Notably, the surgeon who participated in this study familiarized herself with the new method relatively rapidly without much effort. With 50 cases of practice, the surgeon achieved expert skill in manipulating this new machine.

The COVID-19 pandemic has significantly affected routine medical practice, with greater attention to personal protection among physicians as well as patients, even after the pandemic transition to normalcy. Personal protective equipment such as face shields and goggles for close work and maintenance of adequate social distance have become imperative. Compared with close-work microscopes, the 3D digital display can achieve the aforementioned objectives while ensuring social distancing. The 3D surgical system offers high-resolution images, which are clearly visible even at a distance; therefore, this modality is a

promising teaching aid for residents and fellows during and even after the pandemic recedes.

Despite the strengths of this research, we acknowledge the following limitations of our study: (1) The single-center design of this small-scale study performed by a single ophthalmic surgeon is a drawback. (2) Although many studies have reported a short learning curve, it is known that the 3D system is associated with a learning curve that should not be ignored. (3) A longer follow-up period is important to better understand long-term outcomes.

We limited the scope of the current research to uncomplicated cataract surgeries; further studies should be performed under less than optimal conditions such as in patients with small eyes, high myopia, and a shallow anterior chamber to validate the findings of this study. A multicenter randomized controlled trial with long-term follow-up is essential to compare the 3D system and BM.

CONCLUSION

In conclusion, our study highlights the effectiveness and safety of the 3D surgical system compared with conventional BM as a useful surgical approach to cataract surgery. This innovative technique may be useful for cataract surgeries.

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Disclosures. Zehui Zhu, Pingjun Chang, Feng Huang, Songqing Shen, Xiaomeng Zhao, Xinpei Ji and Yune Zhao declare that they have no competing interests.

Compliance with Ethics Guidelines. The study was approved by the Institutional Review Board of Wenzhou Medical University (2021-039-K-32). The study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. All patients were aware of the collection of their data for this study and signed a consent form at the time of enrollment.

Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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