• Clinical Research •

Comparison of three-dimensional surgical system versus binocular microscope for implantable Collamer lens implantation: a randomized clinical trial

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Abstract

● **AIM:** To compare the efficacy, safety, visual outcomes, satisfaction, and comfort of three-dimensional (3D) heads-up visualization system-assisted and conventional microscopic implantable Collamer lens (ICL) surgery.

● **METHODS:** Patients undergoing ICL or Toric ICL (TICL) implantation were enrolled and randomized into two groups: TM group (under a conventional microscope) and 3DM group (under NGENUITY 3D visualization system). Ocular parameters were assessed preoperatively and at 1wk, 1, 3, and 6mo postoperatively. The duration of key surgical steps and the incidence of complications were recorded. Patient-reported outcomes (dry eye, visual quality, comfort) and surgeon satisfaction were assessed using standardized questionnaires.

● **RESULTS:** The study included 98 eyes of 98 refractive error patients (17 males), 50 eyes in TM group (age 27.74±5.65y), and 48 eyes in 3DM group (age 29.20±4.89y). Efficacy, safety, quality of vision (QoV), dry eye symptoms, and patients' satisfaction at 6mo were not significant across the time points of 1wk, 1, 3 and 6mo. No complication was observed in either group. The 3DM group was associated with a longer main step operation time (P=0.037) but better patient visual comfort (P<0.001). The difference in surgical fluency was not statistically significant (P=0.067). Notably, surgeons reported no delays or discomfort and rated the 3DM system significantly higher in image resolution, range of view, depth perception, color contrast, and postural comfort (all P<0.001).

● **CONCLUSION:** For ICL surgery, the use of the NGENUITY 3D visualization system achieves comparable surgical efficacy, safety, and patient satisfaction to procedures performed under a traditional microscope, while delivering superior intraoperative visual performance and postural comfort for the surgeon. These ergonomic and visual advantages make it a promising tool for enhancing clinical practice and surgical training.

● **KEYWORDS:** three-dimensional surgical visualization system; implantable Collamer lens V4c; myopia; visual outcome

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INTRODUCTION

Since its introduction in 2011, the implantable Collamer lens (ICL) featuring a central port (ICL V4c) has become a well-established, safe, and effective option for correcting myopia, particularly in patients with high myopia or those who are not candidates for corneal refractive surgery[1-2]. In parallel, three-dimensional (3D) heads-up visualization systems have been increasingly adopted in ophthalmic surgery since their introduction in 2009[3]. By shifting the surgeon's view from the microscope eyepieces to a high-resolution stereoscopic display, these systems offer improved ergonomics, reduced neck and back strain, and potentially enhanced surgical precision by allowing multiple team members to share the same, magnified operative view[4]. Consequently, 3D systems have been predominantly studied and validated in surgical domains such as cataract[5-7], vitreoretinal surgery[8-10], and laser-assisted *in situ* keratomileusis (LASIK) surgery[11], where their benefits

in depth perception and reduced intraocular illumination are particularly advantageous.

ICL implantation is a high-precision anterior segment procedure. Accurate centration and alignment of the lens are paramount for achieving optimal visual and refractive outcomes, especially when correcting astigmatism with Toric ICL (TICL)[12-13]. Patients are frequently young, high myopes who are sensitive to intraoperative light, which can cause discomfort, photophobia, and difficulty in maintaining fixation. These factors may compromise patient cooperation, a critical element for the safe unfolding and positioning of the ICL within the confined space of the posterior chamber. Therefore, a surgical platform that combines superior, adjustable visualization for the surgeon with a potentially less stimulating and more comfortable experience for the patient represents a compelling theoretical advancement for ICL surgery.

However, despite this strong theoretical synergy between 3D visualization technology and the specific requirements of ICL surgery, a significant gap exists in the literature. Current evidence for 3D systems remains largely confined to other ophthalmic subspecialties[3], and robust, prospective comparative clinical data evaluating their application specifically in ICL implantation is notably lacking. This study was designed to directly address this evidence gap. We conducted a prospective comparative evaluation of ICL implantation performed using the NGENUITY® 3D visualization system versus the conventional microscope. Our primary objectives were to assess and compare the two platforms in terms of procedural efficacy, safety, visual and refractive outcomes, and perioperative experiences from both the surgeon's and the patient's perspectives.

PARTICIPANTS AND METHODS

Ethical Approval The study project was approved by the Ethics Committee of Tianjin Medical University Eye Hospital (Approval No.2025KY-31). The study was conducted in accordance with the Declaration of Helsinki and informed consent was obtained from all participants. The study was registered under the clinical trial number ChiCTR2500106934.

Study Design and Setting Totally 98 patients (98 eyes) who underwent ICL or TICL surgery between July 2023 and December 2023 in Tianjin Medical University Eye Hospital were randomly allocated to the TM group (traditional microscope group, n=50) and the 3DM group (NGENUITY 3D visualization group, n=48). All patients underwent bilateral surgeries. To ensure statistical independence and avoid bias in subjective questionnaire outcomes, only the first-operated eye of each patient was included in the final analysis.

Patients were randomly assigned to the TM group or the 3DM group using a random number table. Randomization was performed at the patient level. Allocation concealment was implemented using sequentially numbered, opaque, sealed envelopes, which were opened immediately before the procedure.

Inclusion and Exclusion Criteria All participants met the general indications for ICL surgery: 1) age≥18y; 2) patients with a stable refractive error, defined as a change of ≤0.50 diopter (D) per year, maintained for at least 2y; 3) patients who refrained from contact lens use for 2wk prior to enrollment; 4) patients with an anterior chamber depth (ACD) of 2.8 mm or greater, measured from the endothelium; 5) patients with an endothelial cell density (ECD) of 2000 cells/mm^2 or more. Additional inclusion criteria for this study were: 1) patients referred for their first ICL surgery (either eye); 2) patients possessing a preoperative best-corrected visual acuity (BCVA) of ≥0.8. Patients were excluded if they had additional ocular diseases, a history of ocular surgery or trauma, systemic ailments impacting the eyes, or psychiatric issues.

Outcome Measures Demographic and clinical data were obtained from the electronic medical record (EMR) system, including age, gender, operative eye details, ocular diseases, and surgical history, choice of ICL or TICL, uncorrected distance visual acuity (UDVA), BCVA, intraocular pressure (IOP), manifest refraction, and slit-lamp bio-microscopy findings. BCVA was assessed using an international standard visual acuity chart and converted to the logarithm of the minimum angle of resolution (logMAR).

The primary outcome was surgical efficacy index (postoperative UDVA/preoperative BCVA) and safety index (postoperative BCVA/preoperative BCVA). Changes in BCVA were categorized as "improved", "stable", or "worsened" based on the comparison between preoperative and postoperative measurements.

Surgical Outcomes and Assessment All procedures were conducted by an experienced ICL surgeon (Zhao SZ). The decision to implant a TICL was based on the manufacturer's recommendations and standard clinical practice, primarily for eyes with significant astigmatism. For lower degrees of astigmatism, spherical ICLs were implanted following a standard refractive assessment. The power and size of the ICL were determined using the manufacturer's online calculation software (STAAR Surgical). Input parameters included the white-to-white measurement (Lenstar LS 900, HAAG-STREIT AG, Switzerland), the sulcus-to-sulcus (MD300-L, Tianjin MEDA, China), the corneal diameter and ACD (Pentacam HR, OCULUS, Germany). Before surgery, the surgeon delineated the zero-horizontal axis on a slit light while the patient was positioned upright, in order to account for any potential cyclotorsion that might occur when the patient is lying supine.

Surgeries in the TM group were conducted using the OPMI Lumera T surgical microscope (Carl Zeiss, Germany). In the 3DM group, the NGENUITY® 3D Visualization

System (Alcon, USA) was employed. When using the 3D system, the surgeon viewed the procedure through polarized glasses on a display screen positioned 1.5 m away (Figure 1). The magnification settings were kept consistent between both groups to ensure comparability. Additionally, for the microscopic surgery, the illumination settings were adjusted to 3.5 for the purpose of ICL surgery.

Intraoperative quantitative measures included the duration of the main surgical steps, which was defined as the time from the start of surgical incision to the completion of ICL implantation, recorded using a timer. Intraoperative and postoperative complications such as shallow anterior chamber or no anterior chamber, corneal edema, hemorrhage, and ocular hypertension (IOP≥21 mm Hg), were documented. Patient were observed in the hospital for two hours after surgery for IOP monitoring.

Within two hours postoperatively, patients completed a standardized interview comprising four specific queries, each rated on a numeric scale from 0 (not at all) to 10 (extremely). The operating surgeon’s subjective experience was assessed using a customized questionnaire evaluating visual comfort, surgical fluency, physical discomfort (headache or backache), procedural delays, and the quality of the visual system (image resolution, field of view, depth perception, color contrast, and postural comfort). The surgeon’s subjective experience and comfort level were assessed using a 5-point Likert scale, where 1 indicated “very poor” and 5 indicated “very good”. For analytical purposes, the scores were categorized into three ordinal levels: “Low” (scores 1–2), “Normal” (score 3), and “Excellent” (scores 4–5). This classification is based on the inherent structure of the scale, which distinguishes the neutral rating from distinctly positive and negative ratings.

Statistical Analysis All statistical analysis was conducted using SPSS 25.0 and GraphPad Prism 8.0. The mean±standard deviation (SD) or median was used to present continuous variables. Differences between the two groups were assessed using the Mann-Whitney *U* test or the *t*-test for continuous data, and the Chi-square test or Fisher’s exact test for categorical data. A two-sided *P* value of less than 0.05 was considered statistically significant.

RESULTS

Clinical Characteristics Figure 2 was the study flow chart. Finally, 98 patients were enrolled and randomly assigned. A total of 91 eyes of 91 patients were included in the final analysis. The mean age was 27.74±5.65y in the TM group and 29.20±4.89y in the 3DM group. Baseline demographic and clinical characteristics are summarized in Table 1. There were no significant differences between the two groups regarding these parameters.

Surgical Efficacy Postoperative efficacy was comparable between the two groups at all follow-up time points (Table 2).

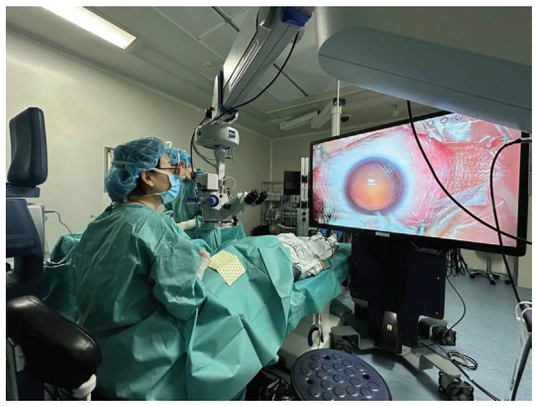

Figure 1 Utilization of a 3D surgical system in ICL surgery The image showcases the view seen by the surgeon through the 3D visualization system during the surgical procedure. 3D: Three-dimensional; ICL: Implantable Collamer lens.

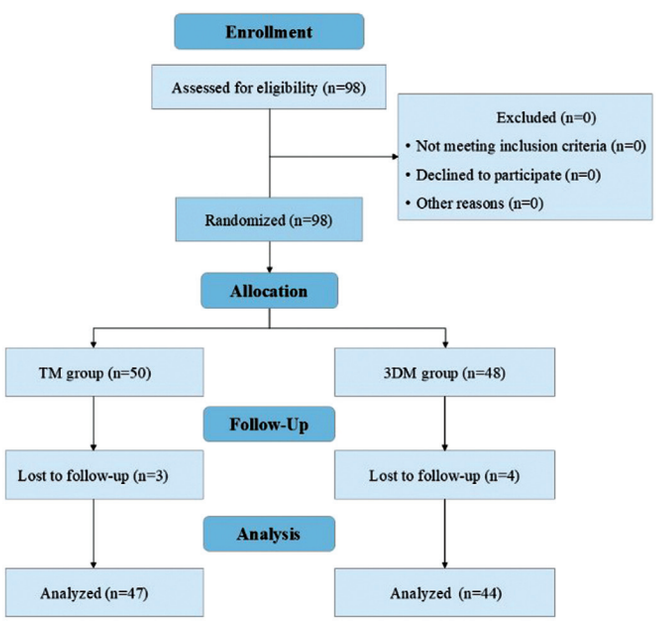

Figure 2 Study flow chart TM group: Traditional microscope group; 3DM group: NGENUITY 3D visualization group.

All eyes achieved a UDVA of at least 0.10 logMAR (Figure 3A). TM group (45/47) and 3DM group (41/44) had a UDVA equal to or better than the preoperative BCVA (Figure 3B).

Surgical Safety No complications were observed during or after the surgery, and all procedures were completed uneventfully throughout the six-month follow-up period. The safety index remained consistently high and comparable between the two groups at all time points (Table 2).

Operation Time of Key Surgical Steps The duration of the key surgical steps differed significantly between two groups. The median operation time was 67s (interquartile range; IQR: 62, 80) in the TM group compared to 88s (IQR: 65, 92.75) in the 3DM group (*P*=0.037). The time of 3DM group was longer than TM group.

Patient-Reported Outcomes Patient-reported outcomes, assessed *via* validated questionnaires, are detailed in Table 3.

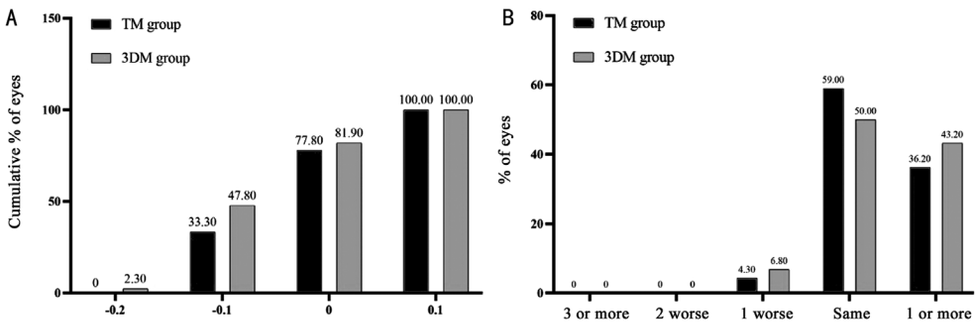

Figure 3 Refractive outcomes at 6mo after ICL of two groups A: Cumulative UDVA. All eyes achieved a UDVA of at least 0.10 logMAR. B: Changes in lines of BCVA. TM group and 3D group had a UDVA equal to or better than the preoperative BCVA. ICL: Implantable Collamer lens; UDVA: Uncorrected distance visual acuity; BCVA: Best-corrected visual acuity; logMAR: Logarithm of the minimum angle of resolution; TM group: Traditional microscope group; 3DM group: NGENUITY 3D visualization group.

Table 1 Clinical characteristics of the patients at baseline

Parameters	TM group (*n*=47)		3DM group (*n*=44)		*P*
	Mean±SD	Range	Mean±SD	Range	
Age (y)	27.74±5.65	21, 46	29.20±4.89	19, 40	0.192[a]
Gender (male/female)	8/39		9/35		0.676[b]
Study eye (right/left)	18/29		14/30		0.520[b]
Type of lens (ICL/TICL)	21/26		22/22		0.613[b]
IOP (mm Hg)	16.19±1.79	13.90, 19.00	16.55±1.82	13.90, 19.00	0.350[a]
Preoperative spherical error (D)	-8.20±2.10	-13.00, -4.25	-7.95±2.45	-13.20, -1.75	0.583[c]
Preoperative cylinder (D)	-1.43±1.28	-5.00, 0	-1.41±1.15	-3.75, 0	0.940[c]
Preoperative SE (D)	-8.91±2.14	-13.88, -5.00	-8.66±2.45	-14.00, -3.25	0.608[c]
Preoperative BCVA (logMAR)	0.004±0.02	0, 0.10	0.016±0.04	0, 0.22	0.097[c]
Myopia grade, *n* (%)					
Low	0		1 (2.3)		
Media	10 (21.3)		9 (20.5)		0.825[c]
High	37 (78.7)		34 (77.3)		
Astigmatism grade, *n* (%)					
Low	18 (38.3)		17 (38.6)		
Media	17 (36.2)		13 (29.5)		0.752[c]
High	12 (25.5)		14 (31.8)		

[a]Independent samples *t*-test; [b]Chi-squared test; [c]Mann-Whitney *U* test; ICL: Implantable Collamer lens; TICL: Toric implantable Collamer lens; IOP: Intraocular pressure; SE: Sphere equivalent; D: Diopter; BCVA: Best-corrected visual acuity; logMAR: Logarithm of the minimum angle of resolution; SD: Standard deviation; TM group: Traditional microscope group; 3DM group: NGENUITY 3D visualization group.

Table 2 Efficacy and safety indices of two groups

Clinical characteristics	Time point	TM group (*n*=47)	3DM group (*n*=44)	*P*[c]
Efficacy	1wk	1.18±0.18	1.11±0.18	0.110
	1mo	1.23±0.19	1.15±0.14	0.062
	3mo	1.19±0.16	1.13±0.13	0.112
	6mo	1.19±0.20	1.12±0.13	0.128
Safety	1wk	1.18±0.18	1.12±0.16	0.123
	1mo	1.22± 0.17	1.15±0.14	0.126
	3mo	1.19±0.16	1.13±0.13	0.112
	6mo	1.19±0.20	1.12±0.13	0.128

[c]Mann-Whitney *U* test. TM group: Traditional microscope group; 3DM group: NGENUITY 3D visualization group.

At the 1wk postoperative visit, the median quality of vision (QoV) questionnaire score was lower in the 3DM group than in the TM group (P=0.004). However, this intergroup difference in QoV scores was not sustained at subsequent follow-up time points. Furthermore, scores on the Ocular Surface Disease Index (OSDI), which assesses dry eye symptoms, showed no statistically significant differences between the two groups at any follow-up visit.

The data from the standardized questionnaire regarding patients' responses were showed in Table 4. Throughout the procedure, patients in both groups reported feeling no discernible dazzle from the light from the microscope. There were no significant differences between the groups in terms of subjective comfort rating and pain during surgery. Similarly,

Table 3 QoV and OSDI of two groups

Clinical characteristics	Time point	TM group (*n*=47)	3DM group (*n*=44)	*P*[c]
QoV	1wk	6.00 (4.00, 8.00)	4.00 (4.00, 5.00)	0.004[d]
	1mo	5.00 (4.00, 6.00)	6.00 (4.00, 8.00)	0.172
	3mo	4.00 (4.00, 5.00)	4.00 (3.00, 5.00)	0.336
	6mo	7.00 (6.00, 8.00)	8.00 (6.25, 8.75)	0.351
OSDI	1wk	10.42 (8.33, 14.58)	10.42 (8.85, 14.06)	0.899
	1mo	10.42 (8.33, 12.50)	10.42 (8.85, 14.06)	0.415
	3mo	10.42 (8.33, 12.50)	10.42 (8.33, 11.98)	0.284
	6mo	4.17 (2.08, 6.25)	6.25 (4.17, 6.25)	0.109

[c]Mann-Whitney *U* test. [d]*P*<0.01. QoV: Quality of vision; OSDI: Ocular Surface Disease Index; TM group: Traditional microscope group; 3DM group: NGENUITY 3D visualization group.

Table 4 Patients' subjective experience median, range

Questions	TM group	3DM group	*P*[c]
Q1. Did you experience glare from the microscope light during the surgical procedure	0.0 (0.0, 2.0)	0.0 (0.0, 1.0)	0.127
Q2. How comfortable were you with the light on during the procedure	7.0 (5.0, 9.0)	8.0 (6.0, 8.0)	0.843
Q3. Were you experiencing any discomfort or pain while the operation was being performed	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	0.894
Q4. Have you experienced any visual disturbances due to glare from the microscope light postoperatively	0.0 (0.0, 2.0)	0.0 (0.0, 2.0)	0.770

Patients answered all questions on a numerical scale of 0 (no, not at all) to 10 (yes, extremely). [c]Mann-Whitney *U* test. TM group: Traditional microscope group; 3DM group: NGENUITY 3D visualization group.

no significant changes were identified in the assessments of visual disturbances associated to glare following surgery. At 6mo after operation, the satisfaction scores of patients were 96.13±1.93 in the TM group and 96.23±2.12 in the 3DM group (*P*=0.815).

Surgeon's Subjective Experience and Comfort Comparison to the TM group, procedures performed using the 3D visualization system received significantly higher scores for visual and postural comfort (all *P*<0.001), with the better results obtained for image resolution, view filed, depth of field, and color contrast. No statistically significant difference was observed in the fluency of the surgical technique (*P*=0.067). Surgeon did not complain delay or physical discomfort (headache or backache) in either group. The above results were shown in the Table 5.

Table 5 Subjective experience and comfort of surgeon

Questions	TM group	3DM group	*P*[c]
Visual comfort, *n* (%)			<0.001
Low	1 (2.1)	0	
Normal	22 (46.8)	4 (9.1)	
Excellent	24 (51.1)	40 (90.9)	
Surgical fluency, *n* (%)			0.067
Low	0	0	
Normal	11 (23.4)	4 (9.1)	
Excellent	36 (76.6)	40 (90.9)	
Headache or backache, *n* (%)			/
Yes	0	0	
No	47 (100)	44 (100)	
Delay, *n* (%)			/
Yes	0	0	
No	47 (100)	44 (100)	
Image resolution (1–5)	2.94±0.34	3.54±0.35	<0.001
Field of view (1–5)	2.51±0.29	3.83±0.37	<0.001
Depth perception (1–5)	2.84±0.33	3.56±0.34	<0.001
Color contrast (1–5)	2.97±0.19	3.69±0.29	<0.001
Postural comfort (1–5)	2.93±0.21	3.68±0.34	<0.001

[c]Mann-Whitney *U* test. TM group: Traditional microscope group; 3DM group: NGENUITY 3D visualization group.

DISCUSSION

This study demonstrates that ICL surgery performed using the NGENUITY 3D visualization system achieves comparable clinical outcomes to conventional microscopy, including visual acuity, refractive results, patient-reported satisfaction, and safety profile, with no complications observed in either group. This finding aligns with prior reports on vitreoretinal[9,14] and cataract surgeries[15-16], which have also documented equivalent anatomical success and complication rates.

Patient-reported outcomes, visual quality score and OSDI score and overall satisfaction, showed no significant differences between the two groups at the final follow-up. Although a transient discrepancy QoV score was noted at the one-week postoperative assessment, this finding was not sustained at subsequent visits and was not considered clinically significant. Moreover, satisfaction with the procedure was elevated in both groups, and no statistically significant difference was observed.

A notable operational finding was the longer main surgical time associated with the 3D system, a result consistent with the observations of Kelkar *et al*[17]. This may be attributed to the initial adaptation period or more meticulous surgical maneuvers facilitated by the enhanced visualization[11]. Crucially, this time difference did not translate into any compromise in clinical safety or efficacy.

Beyond equivalence in primary outcomes, our study highlights several distinct advantages of the 3D platform. First, regarding subjective visual and ergonomic experience, questionnaire results confirmed significantly superior ratings for the 3D system in image resolution, field of view, depth perception, color contrast, and postural comfort. The 3D system changed surgeons' habitual head-down operating posture via an upright viewing position, substantially reducing neck and shoulder strain and alleviating fatigue and discomfort during surgery. This ergonomic benefit is a consistent finding across studies on 3D surgical systems[18-20].

Second, an emerging benefit is the potential for reduced intraoperative light exposure[21]. While our study did not directly measure light intensity, prior research on cataract surgery indicates that 3D systems allow for significantly lower microscope illumination without compromising visualization, thereby potentially decreasing the risk of retinal phototoxicity and light-associated glare[22-24]. Similar advantages have been suggested in other ocular surgeries[24-27]. This represents a valuable area for future investigation specifically in ICL surgery.

A further benefit of the NGENUITY 3D technology is its superior utility in surgical education[28-29]. The 3D polarized glasses offer stereoscopic surgical images simultaneously and synchronously, helping participants and beginners better understand intraocular anatomy and surgical steps, thus improving teaching effectiveness. Chhaya *et al*'s[30] study further confirmed that 3D visualization technology can significantly enhance the learning efficiency of intraocular ophthalmic surgery. Building on this foundation, the glasses-free 3D system eliminates the need for polarized glasses, offering an unobstructed and more accessible viewing experience. This key ergonomic and logistical advantage is anticipated to further amplify its practical benefits in clinical training and educational settings[31].

A theoretical concern with 3D visualization system is image, which could be more perceptible during rapid anterior segment maneuvers. However, in our clinical experience and as reflected in surgeon feedback, this delay was minimal and did not impede surgical fluency or safety, corroborating findings from other studies[32].

The current study has several limitations. First, to ensure surgical homogeneity, only one experienced surgeon performed surgeries using both methods. Its single-surgeon, single-center design, while ensuring procedural consistency, may limit generalizability. In the future, larger-scale, multi-center randomized controlled trials involving multiple surgeons are necessary to validate our findings. Second, the preliminary assessment of perceptual differences *via* questionnaires necessitates more objective metrics in future work. Furthermore, the learning curve of surgeons associated with the 3D system requires further study. Despite these constraints, our study offers valuable insights that can inform the design of more extensive research endeavors.

In conclusion, the NGENUITY 3D heads-up visualization system is a safe and effective alternative to the traditional microscope for ICL implantation, delivering equivalent clinical outcomes while providing tangible benefits in surgeon ergonomics, visual clarity, and educational value. The 3D visualization augments depth perception, while the heads-up display promotes an ergonomic surgical posture and enriches the visual experience for the entire surgical team. It is anticipated to evolve into a novel modality of eye surgery in the future.

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