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Clinical Performance and Outcomes of a 20 000 Cuts-per-Minute, 25-Gauge, Beveled-Tip Vitrectomy Probe

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Abstract

Purpose: To report the clinical outcomes and instrument performance of a 25-gauge, 20 000 cuts-per-minute (cpm), beveled-tip vitrectomy probe system. **Methods:** This prospective consecutive case series comprised eyes having primary pars plana vitrectomy (PPV) using a 20 000 cpm vitrectomy probe system (20 000 cpm group). The main outcome measures were the rate of success, operative times, number of steps, 3-month distance-corrected visual acuity (DCVA), ancillary instruments use, and adverse events (AEs). A comparative analysis with the results of a previously published series of eyes that had PPV with a 10 000 cpm, beveled-tip vitrectomy system (10 000 cpm group) was performed. **Results:** The study included 55 eyes. The surgical objectives were attained in all eyes. The mean logMAR DCVA improved from 0.96 preoperatively to 0.35 postoperatively (at 3 months) ($P < .0001$). The mean ($\pm$SD) total operative time, core vitrectomy time, shave vitrectomy time, and total vitrectomy time was 1964.27 $\pm$ 846.92 seconds, 174.87 $\pm$ 116.23 seconds, 478.41 $\pm$ 387.30 seconds, and 655.60 $\pm$ 397.53 seconds, respectively. The mean number of surgical steps was 4.05 $\pm$ 1.06 and of ancillary instrument exchanges, 3.23 $\pm$ 1.89. The mean postoperative day 1 pain score was 0.16 $\pm$ 0.46. Two eyes had elevated intraocular pressure postoperatively and 1 eye had hypotony. There were fewer ancillary instrument exchanges ($P < .001$) and fewer AEs ($P = .044$) in the 20 000 cpm group than in the 10 000 cpm group. **Conclusions:** Both the 20 000 and 10 000 systems are effective and safe for the treatment of various vitreoretinal indications. The potential advantages of the 20 000 system include reduced use of ancillary instrumentation and lower AE rates.

Keywords

20 000 cuts-per-minute vitrectomy, pars plana vitrectomy, vitreoretinal surgery, minimally invasive vitrectomy system, surgical efficiency, Hypervit

Introduction

The surgical efficiency and safety of pars plana vitrectomy (PPV) systems have steadily improved since the first closed-system PPV was performed by Robert Machemer in the 1970s. The first was a single-port, 17-gauge system with a maximum cut rate of 400 cuts per minute (cpm).[1] The introduction of microincision vitrectomy systems has further facilitated surgical access to the posterior segment of the eye while reducing ocular trauma, operative times, and complications.[2,3]

Beveled-tip cutter probes, a more recent innovation, have been shown to achieve higher aspiration rates and greater reflux flow velocities.[4] We previously found several clinical advantages of 10 000 cpm, beveled-tip probes (Ultravit, Alcon Surgical), such as decreased operative times and multifunctionality.[5] A recently introduced 20 000 cpm, beveled-tip, dual-blade vitrectomy probe system (Hypervit, Alcon Surgical) has significantly faster cutting speeds, enhanced vitreous flow dynamics, reduced vitreous turbulence, and better intraoperative tissue stability (Figure 1).[6] These advantages may translate to shorter vitrectomy times while decreasing retinal traction and preventing iatrogenic damage to delicate ocular tissues. We performed this study to examine the clinical outcomes, surgical efficiency, instrument performance, and safety of the new 20 000 cpm vitrectomy system.

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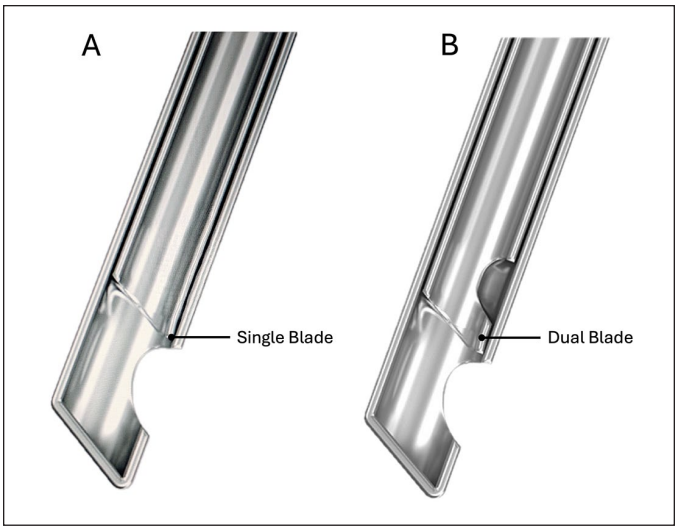

Figure 1. Schematic of (A) a conventional single-blade, 10 000 cpm probe and (B) a dual-blade, 20 000 cpm probe.
Abbreviation: cpm, cuts per minute.

Methods

A single-center prospective study enrolled a consecutive series of eyes having primary PPV at the Peregrine Eye and Laser Institute (PELI) from April 1, 2021, to January 24, 2022. The study was performed in compliance with Good Clinical Practice guidelines and the tenets of the Declaration of Helsinki. The study protocol was approved by the PELI Institutional Review Board and is registered at clinicaltrials.gov (ID# NCT04404296).

Eyes with the following surgical indications were included: nonresolving vitreous hemorrhage (VH), noninfectious vitritis, epiretinal membranes (ERMS), lamellar and full-thickness macular holes (MHs), vitreomacular traction (VMT), rhegmatogenous retinal detachment (RRD), tractional RD (TRD), retained lens fragments, and a dislocated intraocular lens (IOL). Excluded were eyes with a history of glaucoma, previous glaucoma surgery, scleral thinning, any ocular infection within 3 months, significant corneal opacification obscuring surgical visualization, clinically significant cataract without simultaneous lens removal, poorly dilating pupils (< 5.0 mm maximum dilation), concomitant scleral buckling, and choroidal detachment.

At all visits, patients had a comprehensive eye evaluation, including distance-corrected visual acuity (DCVA) and intraocular pressure (IOP) measurements, a slit lamp examination, and a dilated retinal examination. IOP measurements were performed using Goldmann applanation tonometry. Elevated IOP was defined as greater than 22 mm Hg, while hypotony was defined as less than 5 mm Hg.

A trained retina surgeon (H.S.U., P.S.C., or J.T.F.) performed PPV using the 25-gauge, 20 000 cpm vitrectomy system (20 000 cpm group). A wide-angle viewing system (Resight 700, Zeiss Medical Technology) and a high-magnification contact lens (HR Direct High Mag Surgical Lens, Volk Optical, Inc) were used for surgical visualization. Trocars were uniformly inserted 3.5 mm from the limbus. Core vitrectomy was performed using the following continuously open-port settings: IOP, 25 mm Hg; maximum vacuum, 650 mm Hg; cut rate, 20000 cpm. Shave vitrectomy was performed using the following settings: IOP, 25 mm Hg; maximum vacuum, 200 mm Hg; cut rate, 20 000 cpm. Visualization for membrane peeling was enhanced using brilliant blue G or trypan blue refluxed into the retinal surface. Initial internal limiting membrane (ILM) or ERM flap edges were created using an ILM forceps or nitinol loops. Membrane removal was performed using a retinal forceps, the 20 000 cpm vitrectomy system, or both.

For RRD, the 20 000 cpm tip was used to perform fluid–air exchange and aspirate subretinal fluid through preexisting breaks or drainage retinotomies outside the macular area. A soft-tip, backflush handpiece (25-gauge Grieshaber Advanced Backflush DSP, Alcon Surgical) was used to complete aspiration of residual fluid. Endophotocoagulation was performed around retinal breaks or along the equatorial region, followed by application of tamponade agents.

Postoperative follow-up was performed at 1 day, 1 week, 1 month, and 3 months. The main outcome measures included the rate of surgical success, total operative time (measured from first trocar insertion to last trocar removal), core vitrectomy time, shave vitrectomy time, and total vitrectomy time (measured as core vitrectomy time + shave vitrectomy time). These times were recorded by the circulating nurse using a stopwatch. Other main outcome measures were the perioperative IOP, number of surgical steps, number of times ancillary instruments were used, DCVA, and adverse events (AEs). Surgical success was defined as achievement of the surgical objective for the given indication (eg, reattachment of the retina for RRD). The number of surgical steps, a surrogate measure of surgical complexity, was determined by counting the number of the following procedures that was performed per case: PPV, ERM or ILM peeling, fluid–air exchange, endolaser treatment, tamponade introduction (silicone or gas), amniotic membrane application, lens material or IOL removal, and secondary implantation.

Pain was reported on postoperative day (POD) 1 using the following ordinal scale: 0 = no pain; 1 = mild pain not requiring medication; 2 = moderate pain requiring medication, persisting for less than half of the day the patient was awake; 3 = moderate pain requiring medication, persisting for more than half of the day the patient was awake; 4 = pain requiring medication and that interrupts sleep.

These current study outcomes were compared with previously published results from a cohort that had PPV using the 10 000 cpm vitrectomy system (10 000 cpm group).[5] In this previous study, PPV was performed by the same group of 3 surgeons using the same equipment for the same surgical indications.

Stata software (version 17, StataCorp LLC) was used for statistical analysis. Descriptive analyses included mean summaries for continuous data and frequencies and percentages for categorical data. The comparison of continuous patient characteristics and surgical outcomes between the 2 vitrectomy systems was performed using a 2-sample *t* test or Wilcoxon rank sum (Mann-Whitney) test. The latter was used when the assumptions of

normality (using the Shapiro-Wilk test) or homogeneity (using the Levene test) were not met. Categorical variables were compared using the Pearson χ^2 test. The Wilcoxon signed rank test was used to compare the preoperative and 3-month postoperative DCVA between the 2 vitrectomy systems. All tests were 2-sided. Statistical significance was set at $P < .05$. All mean values are ± SD.

Results

Fifty-five eyes were enrolled and completed the 3-month follow-up visit schedule (Table 1). The mean patient age was 56.76 ± 13.26 years (range, 28-82); 28 patients (51%) were men (Table 2). The mean baseline logMAR DCVA was 0.96 ± 0.80 (range, 0.0-2.0) (Table 3). The mean preoperative IOP was 16.04 ± 5.55 mm Hg (range, 8-37). The indications for PPV were vitreous hemorrhage (31%), RD (rhegmatogenous, tractional, or exudative) (31%), ERM (9%), vitritis (5%), intolerable floaters (2%), dropped IOL (2%), and dropped lens material (2%). Seven eyes (13%) had multiple surgical indications; 2 eyes presented with a TRD with VH (4%), while 1 eye each presented with MH with ERM, MH with VMT, RRD with vitritis, ERM with TRD, and ERM with VH (2% each) (Table 1).

Surgical Objectives

The surgical objectives were achieved in all eyes. The mean logMAR DCVA improved from 0.95 to 0.35 by the 3-month postoperative visit ($P < .0001$) (Figure 2). Table 2 shows the mean total operative time, mean core vitrectomy time, mean shave vitrectomy time, and the mean total vitrectomy time. The ranges were 420 to 3600 seconds, 45 to 540 seconds, 46 to 2220 seconds, and 151 to 2340 seconds, respectively. The mean number of times ancillary instruments were used or exchanged was 3.23 ± 1.89 (range, 1-12) (Table 4).

Safety

With regard to safety, the mean IOP was 11.60 ± 5.63 mm Hg (range, 2-30) on POD 1 day. Perioperative AEs included hypotony in 1 eye (2%) on POD 1 day and elevated IOP in 2 eyes (4%) at the end of the surgery (Table 1). No eye required sclerotomy suturing for a wound leak. These AEs were deemed to be not clinically significant or sight-threatening. PPV with the 20 000 cpm vitrectomy system was well tolerated, with a mean POD 1 pain score of 0.16 ± 0.46 (range, 0-2) (Table 4).

20 000 cpm System vs 10 000 cpm System

The patient demographics and level of surgical complexity were similar between the 20 000 cpm group and 10 000 cpm group (Table 2). The surgical objectives were achieved for all patients in both groups. The 3-month postoperative DCVA was significantly better in the 20 000 cpm group ($P < .0001$), although there were no significant differences in VA outcomes between the 2 groups ($P = .6698$) (Figure 2). The number of ancillary instruments used and the incidence of intraoperative AE were significantly lower in the 20 000 cpm group than in the 10 000 cpm group ($P = .0002$ and $P = .044$, respectively). The POD 1 IOP and POD 1 pain score were similar between the groups ($P = .8670$ and $P = .4907$, respectively) (Table 4)

The mean shave vitrectomy time and total vitrectomy time were significantly longer in the 20 000 cpm group ($P = .0054$ and $P = .0288$, respectively). There were no statistically significant differences in the core vitrectomy time or total vitrectomy time between the groups ($P = .1114$ and $P = .6055$, respectively) (Table 2).

Conclusions

Vitrectomy instrumentation development is continuously evolving, with a trend toward smaller gauges, faster cut rates, a shorter tip-to-tissue distance, and multifunctionality. Our study found that the new 20 000 cpm vitrectomy system can be used by different surgeons to achieve surgical success safely and efficiently for various vitreoretinal conditions. We also explored how metrics, such as the surgery duration, use of ancillary instruments, and surgical outcomes, can be influenced by cutter probe design.

Surgical success was achieved in all eyes in this series. The 25-gauge 20 000 cpm vitrectomy system combines an increased cutting velocity and a beveled tip that facilitates access to surgical tissue planes. Compared with single-blade probes, dual-blade probes have an additional port in the inner tube, allowing for doubling of cut rates and a 100% increase in the duty cycle (Figure 1).[7] The advantages of a beveled tip over a conventional flat tip include higher aspiration rates and greater reflux flow velocity.[6] In the 20 000 cpm group, the core vitrectomy tended to be faster and more efficient than in the 10 000 cpm group although the difference did not reach statistical significance.

In theory, the faster cutting speeds using the dual-blade system and the beveled tip fluidics can contribute to an increased vitreous flow rate and better surgical efficiency, although a larger sample may be needed to confirm this effect.[4,6,8] The reduced peak traction and pulsatile flow translated into consistent globe IOP, stable tissues during shave vitrectomy, precise dissection, and a lower rate of intraoperative AEs. Unlike in the 10 000 cpm series, there were no cases of iatrogenic retinal breaks or retinal and vitreous bleeding using the 20 000 cpm cutter iteration.

Two studies previously compared the performance of single-blade and dual-blade probes ex situ using both 25-gauge and 27-gauge diameter lumens on balanced salt solution and diluted swine vitreous.[6,9] Steel et al[9] reported faster aspiration rates, reduced nearfield effects, and peak traction forces using dual-blade, flat-tip probes than using single-blade, beveled-tip probes.[9] Inoue et al[4,6] compared single-blade and dual-blade beveled tip probes and reported increased efficiency using the dual-blade tip, which achieved faster aspiration rates. In a recent study, Doi et al[10] compared these 2 systems in a small retrospective series of eyes having PPV for idiopathic ERM using 27-gauge instrumentation. They reported shorter operative times in the 20 000 cpm group than in the 10 000 cpm group.[6,10]

Table 1. Data From the Current Study.

Pt	Age (y)	Sex	Diagnosis	Surgical Steps	Steps (n)	Core Time (s)	Shave Time (s)	PPV Time (s)	Total OR Time (s)	Day 1 IOP (mm Hg)	Times Ancillary Instruments Placed in Eye	Objectives Achieved?	Wound Leak?	Pain Score (0–4)	LogMAR Distance-Corrected Visual Acuity			AEs	Comment
															Preop	Month 3	Change		
1	71	F	MH	PPV, MD, LX, FAX, GT	5	150	107	257	3530	6	8	Yes	No	0	0.20	0.10	−0.10	No	—
2	32	M	RD	PPV, MD, LX FAX, GT	5	120	860	980	2160	7	3	Yes	No	0	0.00	0.00	0.00	No	—
3	57	F	MH + VMT	PPV, MD, LX, FAX, GT	5	460	276	736	2513	8	5	Yes	No	0	0.70	0.40	−0.30	No	—
4	64	F	VMT	PPV, MD, LX, FAX	4	305	377	682	2661	11	8	Yes	No	0	0.90	0.70	−0.20	No	—
5	55	F	ERM	PPV, MD, FAX, LX, GT	5	67	385	452	2710	26	5	Yes	No	1	1.30	0.80	−0.50	Yes	IOP elevation
6	64	M	VH	PPV, PE, PCIOL, FAX, LX	5	450	240	690	1800	22	2	Yes	No	0	1.30	0.20	−1.10	No	—
6	56	M	RLF	PPV, LX	3	149	234	383	1879	21	1	Yes	No	1	2.30	0.10	−2.20	No	—
8	71	M	VH	PPV, PE, PCIOL	3	70	81	151	1304	22	1	Yes	No	0	1.30	0.10	−1.20	No	—
9	63	F	ERM + VIT	PPV, MD, LX	3	222	210	432	1532	15	4	Yes	No	0	0.00	0.00	0.00	No	—
10	70	M	TRD	PPV, MD, FAX, LX	4	245	689	934	2540	10	5	Yes	No	0	2.00	1.00	−1.00	No	—
11	36	F	RRD	PPV, MD, LX FAX, GT	5	214	734	948	3090	12	4	Yes	No	0	0.00	0.00	0.00	No	—
12	73	F	ERM	PPV, ERM/D, ILM, LX, FAX	5	240	1000	1240	2160	2	4	Yes	No	0	0.30	0.30	0.00	Yes	Hypotony
13	71	M	ERM + MH	PPV, ERM/D, ILM, FAX GT LX	5	60	240	300	2400	5	5	Yes	No	0	0.20	0.10	−0.10	N	—
14	65	M	TRD + VH	PPV, FAX, LX	2	240	360	600	1080	8	4	Yes	No	0	0.20	0.00	−0.20	No	—
15	28	F	VIT	PPV, LX, FAX	3	160	600	760	1800	14	2	Yes	No	0	0.20	0.10	−0.10	No	—
16	53	F	TRD	PPV, ERM, FAX, LX	4	125	600	725	1320	14	3	Yes	No	0	1.30	1.00	−0.30	No	—
17	82	F	TRD	PPV, ERM, ILM, FAX, LX	5	100	700	800	1800	16	4	Yes	No	0	1.30	1.30	0.00	No	—
18	68	M	RRD	PPV, LX, FAX, GT	4	120	810	930	1800	16	2	Yes	No	0	0.70	0.60	−0.10	No	—
19	39	M	TRD + VH	PPV, ERM/D, ILM, FAX, LX, GT	6	240	660	900	3000	10	3	Yes	No	0	2.00	0.30	−1.70	No	—
20	44	M	RRD	PPV, LX FAX, GT	4	120	720	840	1440	12	2	Yes	No	0	0.00	0.00	0.00	No	—
21	68	M	MH	PPV, ERM, ILM, FAX, LX	6	60	600	660	3600	30	4	Yes	No	1	0.20	0.20	0.00	No	IOP elevation
22	57	M	RD	PPV, FAX, LX, GT	4	60	420	480	1560	6	3	Yes	No	0	2.00	0.30	−1.70	No	—
23	48	M	VH	PPV, LX	2	120	480	600	1080	13	2	Yes	No	0	2.00	0.10	−1.90	No	—
24	59	F	RD	PPV, FAX, LX, GT	4	240	540	780	2220	10	3	Yes	No	0	0.00	0.00	0.00	No	—
25	56	F	RD	PPV, FAX, LX, GT	4	60	660	720	2460	10	2	Yes	No	0	1.30	0.30	−1.00	No	—
26	57	M	RD	PPV, FAX, LX, GT	4	120	2220	2340	2960	5	3	Yes	No	0	1.30	0.40	−0.90	No	—
27	33	M	RD	PPV, FAX, LX, GT	4	120	270	390	2220	8	2	Yes	No	0	0.00	0.00	0.00	No	—
28	45	M	RRD	PPV, LX, FAX, GT	4	110	874	984	2256	12	2	Yes	No	0	1.30	0.70	−0.60	No	—
29	70	F	ERM	PPV, MD, LX, FAX	4	180	180	360	1380	10	3	Yes	No	0	0.50	0.20	−0.30	No	—
30	52	M	RD	PPV, MD, FAX, AM, LX, ST	6	120	60	180	2580	6	4	Yes	No	0	2.30	1.30	−1.00	No	—
31	55	M	VH	PPV, MD, LX, FAX	4	60	180	240	1680	21	3	Yes	No	0	2.00	0.10	−1.90	No	—
32	55	M	DIS	PPV, RIOL, SIOL, LX	4	180	780	960	2400	5	2	Yes	No	1	0.30	0.00	−0.30	No	—
33	59	F	VH	PPV, ERM, ERM/D, FAX, GT	4	46	46	219	1200	8	3	Yes	No	0	2.00	1.00	−1.00	No	—
34	40	F	RRD	PPV, FAX, LX, ST	4	145	728	873	2160	14	3	Yes	No	0	1.30	2.00	0.70	No	—
35	70	F	ERM	PPV, ERM/D, ILM, FAX, LX	5	180	660	840	2640	8	4	Yes	No	0	0.30	0.20	−0.10	No	—
36	53	F	MH	PPV, ERM/D, ILM, FAX, LX, GT	6	180	720	900	3360	5	4	Yes	No	0	0.40	0.30	−0.10	No	—
37	34	M	VH	PPV, PE, FAX, LX	4	150	498	648	2040	12	2	Yes	No	0	2.00	0.00	−2.00	No	—
38	62	F	ERM	PPV, MD, LX, FAX	3	180	274	454	1620	12	3	Yes	No	2	0.40	0.10	−0.30	No	—
39	64	F	VIT	PPV, LX, FAX	3	120	360	480	540	13	2	Yes	No	0	0.40	0.20	−0.20	No	—
40	48	F	VH	PPV, MD, LX, FAX	4	360	300	660	1680	10	2	Yes	No	0	2.00	0.40	−1.60	No	—
41	57	F	VH	PPV, LX	2	120	300	420	660	12	2	Yes	No	0	0.10	0.00	−0.10	No	—
42	57	F	VH	PPV, LX, FAX	3	120	120	240	420	7	12	Yes	No	2	0.30	0.30	0.00	No	—
43	75	M	RRD + VIT	PPV, PE, LX, FAX, ST	5	540	660	1200	3420	19	5	Yes	No	0	2.00	0.80	−1.20	No	—
44	73	F	VH	PPV, PE, LX	5	240	420	660	1740	13	2	Yes	No	1	2.30	0.00	−2.30	No	—
45	64	M	VH	PPV, LX	2	60	360	420	660	14	2	Yes	No	0	2.00	1.30	−0.70	No	—
46	82	F	ERM	PPV, MD, LX, FAX	4	480	120	600	3600	12	3	YES	No	0	2.00	0.40	−1.60	No	—
47	48	F	VH	PPV, MD, LX, FAX	4	420	180	600	1440	10	2	Yes	No	0	2.00	0.30	−1.70	No	—
48	47	M	ERM + VH	PPV, PE, PCIOL, ERM/D, LX, FAX	6	120	150	270	1020	7	2	Yes	No	0	0.30	0.20	−0.10	No	—
49	56	M	ERM	PPV, ERM/D, FAX, LX	4	120	480	600	1680	8	1	Yes	No	0	0.70	0.40	−0.30	No	—
50	44	M	VH	PPV, ERM/D, FAX, LX	4	180	300	480	2040	18	5	Yes	No	0	1.30	0.80	−0.50	No	—
51	49	F	VIT	PPV, LX, FAX	3	180	150	330	720	12	2	Yes	No	0	0.00	0.00	0.00	No	—
52	35	M	RRD	PPV, FAX, LX, GT	4	180	1740	1920	3240	10	2	Yes	No	0	0.10	0.00	−0.10	No	—
53	82	M	VH	PPV, LX, FAX	3	45	120	165	660	10	2	Yes	No	0	0.30	0.00	−0.30	No	—
54	49	F	RRD	PPV, FAX, LX, GT	4	105	300	405	1920	5	3	Yes	No	0	0.00	0.00	0.00	No	—
55	57	M	VH	PPV, LX	2	60	180	240	660	6	2	Yes	No	0	1.00	0.10	−0.90	No	—

Abbreviations: AE, adverse events; AM, amniotic membrane; DIS, dislocated Intraocular lens; ERM, epiretinal membrane/peel; ERM/D, epiretinal membrane/dissection; FAX, fluid–air exchange; GT, gas tamponade; ILM, internal limiting membrane/peel; IOP, intraocular pressure; LX, endolaser photocoagulation; MD, membrane dissection; MH, macular hole; OR, operative; PCIOL, posterior chamber intraocular lens; Pe, phacoemulsification; Pt, patient; PPV, pars plana vitrectomy; Rd, retinal detachment; RIOL, removal of dislocated intraocular lens; RLF, retained lens fragments; RRD, rhegmatogenous retinal detachment; SIOL, secondary intraocular lens implantation; ST, silicone oil tamponade; TRD, tractional retinal detachment; VH, vitreous hemorrhage; VIT, vitritis; VMT, vitreomacular traction.

Table 2. Comparison of Patients' Characteristics by Vitrectomy Group.

Characteristic	20 000 cpm (n = 55)	10 000 cpm (n = 50)[a]	*P* Value
Age	56.76 ± 13.26	57.16 ± 13.45	.8796[b]
Sex, n (%)			.751[c]
Female	27 (49)	23 (46)	
Male	28 (51)	27 (54)	
Mean surgical steps (n) ± SD	4.05 ± 1.06	4.28 ± 1.52	.5425[d]
Mean core vitrectomy time (s) ± SD	174.87 ± 116.23	203.7 ± 119.55	.1114[d]
Mean shave vitrectomy time (s) ± SD	478.41 ± 387.30	330.20 ± 319.82	.0054[d,e]
Mean total vitrectomy time (s) ± SD	655.60 ± 397.53	533.90 ± 389.29	.0288[d,e]
Mean total operative time (s) ± SD	1964.27 ± 846.92	1890.90 ± 890.36	.6055[d]

[a]Data from Uy et al 2022 study.[5]
[b]*t* test.
[c]Pearson χ^2 test.
[d]Wilcoxon rank sum (Mann-Whitney) test.
[e]Statistically significant.

Table 3. Comparison of Preoperative DCVA and 3-Month Postoperative DCVA.

	Mean ± SD		
DCVA	20 000 cpm (n = 55)	10 000 cpm[a] (n = 50)	*P* Value
Preop	0.96 ± 0.80	1.23 ± 0.88	.1026
3 months postop	0.35 ± 0.43	0.71 ± 0.65	<.0001[b,c]

Abbreviation: DCVA, distance-corrected visual acuity.
[a]Data from Uy et al 2022 study.[5]
[b]Wilcoxon signed rank test.
[c]Statistically significant.

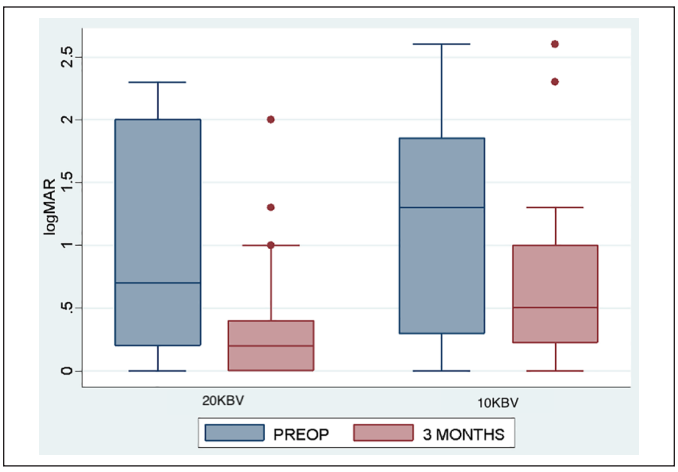

Figure 2. Comparison of distance-corrected visual acuity at the preoperative visit and 3-month postoperative visit.
Abbreviations: 10KBV, 10 000 cpm vitrectomy system; 20KBV, 20 000 cpm vitrectomy system.

Our study compared the use of the 20 000 cpm beveled-tip probe with the 10 000 cpm beveled-tip probe across different surgical indications and identified several advantages favoring the higher velocity system. The 20 000 cpm vitrectomy system allowed surgeons to decrease the number of instrument exchanges, which

Table 4. Comparison of Surgical Outcomes by Vitrectomy Group.

Outcome	20 000 cpm (n = 55)	10 000 cpm[a] (n = 50)	*P* Value
Mean IOP day 1 ± SD	11.60 ± 5.63	11.98 ± 8.27	.8670[b]
Mean ancillary instrument exchanges ± SD	3.23 ± 1.89	4.48 ± 1.91	.0002[b,d]
Surgical success, n (%)	55 (100.00)	50 (100.00)	—
No wound leak, n (%)	55 (100.00)	50 (100.00)	—
Mean pain score ± SD	0.16 ± 0.46	0.20 ± 0.45	.4907[b]
Mean logMAR DCVA ± SD			
Preop	0.95 ± 0.80	1.23 ± 0.88	.0612[b]
3 months postop	0.35 ± 0.43	0.71 ± 0.65	.0007[b,d]
Change	−0.60 ± 0.7	−0.52 ± 0.5	.6698
Adverse events, n (%)			.044[c,d]
None	52 (94.55)	41 (82.00)	
Yes	3 (5.45)	9 (18.00)	

Abbreviations: DCVA, distance-corrected visual acuity; IOP, intraocular pressure.
[a]Data from Uy et al 2022 study.[5]
[b]Wilcoxon rank sum (Mann-Whitney) test.
[c]Pearson χ^2 test.
[d]Statistically significant.

may decrease the risk for infection stemming from repeated entry and exit of instruments as well as enhance surgical efficiency. Although we previously reported on the versatility of the 10 000 cpm beveled tip in performing various surgical maneuvers,[5] we observed that the 20 000 cpm probe can perform these more efficiently. We believe that this enhanced efficiency is likely attributable to the increased aspiration rate and an influx angle that is more perpendicular to the probe, as reported by Inoue et al.[6]

Anecdotally, the surgeons in this study reported faster core vitrectomy vitreous aspiration and reduced vitreous turbulence. The former and latter are subjective parameters that are difficult to quantify. This study explored more quantitative measures, such as the number of AEs, the number of instrument exchanges, and time efficiency.

The 20 000 cpm system resulted in fewer surgical AEs (eg, postoperative hypotony, IOP elevation at the end of surgery)

Table 5. Currently Available Vitrectomy Systems With Dual-Blade Probes.

Cutter Probe	Vitrectomy Machine	Manufacturer	Maximum Cut Fate (cpm)
Bi-Blade	Stellaris Elite	Bausch + Lomb	15 000
Continuous flow cutter	OS4	Oertli Instrumente AG	10 000
Hypervit	Constellation	Alcon Surgical	20 000
UNO Colorline MACH2	MegaTRON S4HSP	Geuder	12 000
Opti-Vit Twedge	Optikon 2000	Optikon	20 000
Two-dimensional cutter	EVA NEXUS	DORC	20 000

than the 10 000 cpm system. The reasons for the fewer AEs are unclear but likely include better fluid dynamics, which improved the efficiency of vitreous removal, resulting in reduced vitrectomy probe maneuvering and trauma to the sclerotomy wounds and better wound sealing. Because of the lower expectation for wound leaks, the surgeons also did not try to compensate for wound leakage by overpressurizing the eye with fluid, gas, or silicone oil (SO). We believe that reduced tractional forces and tissue mobility using the 20 000 cpm cutter were the main contributors to the reduced iatrogenic incidents in this series. Nevertheless, we recommend that surgeons who are starting out with this new cutter probe lower their initial vacuum settings as they familiarize themselves with the performance characteristics of new instrumentation and optimize their settings as they progress on the learning curve.

There were also no cases of iatrogenic retinal breaks, nicked retinal vessels, or retinal redetachment in the 20 000 cpm cohort compared with the 10 000 cpm cohort. Decreased pulsatile traction or deflection of adjacent vitreous using the 20 000 cpm probe resulted in better vitreous and retinal stability and less propensity for iatrogenic trauma.[9] Steel et al[9] also found reduced pulsatile traction using the 20 000 cpm system and that the probe tip configuration (ie, flat vs beveled) was unlikely to be clinically relevant. In addition, the region of high tissue velocity was smaller with the 20 000 cpm device in the study by Steel et al. This reduced area of instability and increased precision may also explain the decrease in inadvertent aspiration of retinal tissue noted in our study.

In a study by Doi et al[10] using similar instrumentation, both vitrectomy systems showed similar IOP stability and a similar rate of scleral wound closure. The better 3-month visual outcomes in the 20 000 cpm series may be a result of the decreased incidence of clinically significant AEs and/or differences in the disease stage of the patients at the time of treatment.

Our results showed unexpectedly longer mean shave vitrectomy and total vitrectomy times using the 20 000 cpm probe than the 10 000 probe. We attribute this to our decision to lower the shave vitrectomy maximum vacuum settings to 200 mm Hg from the 300 mm Hg setting used in our earlier 10 000 cpm study. This change was done with the assumption that the higher vitreous flow rates achievable with the 20 000 cpm probe would maintain or reduce the shave vitrectomy operative duration. We have now readjusted our shave vitrectomy maximum vacuum settings back to 300 mm Hg.

It is important to note that the total operative time and the total vitrectomy time were similar in the 2 groups, despite the longer shave vitrectomy times. The shorter mean core vitrectomy time and the reduced need for instrument exchanges likely compensated for the longer shave vitrectomy times. These findings highlight the need to adjust vitrectomy machine settings to optimize surgical time efficiency.

Doi et al[10] reported significantly shorter vitrectomy times using the 20 000 cpm system when using standardized vacuum settings (0-650 mm Hg) in both groups. The differences in operative durations across studies may be explained by the different set of surgical indications, case complexities, probe sizes, and surgeon preferences.[5] Doi et al used 27-gauge instruments rather than the 25-gauge probes used in both of our series. A recent meta-analysis by Ma et al[11] found varying performance of 27-gauge systems and 25-gauge systems depending on the surgical indication, with longer operative times in more complex cases. VA and surgical complications have also been shown to vary with probe size.[11]

A growing number of vitrectomy platforms are incorporating dual-blade probes that double cutting speeds to effect faster and smoother vitreous clearance as well as enhance tissue stability. This list will grow longer as the technology matures[12] (Table 5). These instrument platforms may perform differently under varying surgical situations. We recommend that physicians try out several systems to find out which one works best in their hands.

The beveled-tip design incorporates a 30-degree oblique angle on the cutter probe head in contrast to the 0-degree angle on a conventional flat-tip probe. Coupled with a shorter port-tip distance of 0.009 μm, this angled tip allows closer approximation of the cutter probe surface to the retinal surface and facilitates entry and more precise dissection of various tissues (eg, vitreous and preretinal membranes). The effect of this design on vitrectomy fluidics has been well described by Inoue et al[4] using a 10 000 cpm single-cutter iteration.

Briefly, 10 000 beveled-tip cutters exhibit faster aspiration of balanced saline solution and vitreous material than flat-tip probes as well as greater fluid reflux velocity. In general, the beveled tip design produces a relatively greater aspiration rate and flow from the proximal side (toward the cutter shaft) than flat-tip probes. These behaviors suggest that beveled-tip cutter probes may enhance efficient and safer removal of core, retrolental, and anterior cortical vitreous and more efficient flushing of preretinal hemorrhages and material using the 10 000 cpm beveled tip. The potential disadvantages include slower removal of vitreous and other materials distal to the cutter port, such as when dissecting vitreous on the retinal surface, as well as an enhanced potential

for unplanned aspiration of fluctuant, anteriorly detached retinal tissues. Slower distal aspiration may aid in the precision and safety when performing lift-and-shave or shovel-and-cut maneuvers where there are underlying retinal tissues.

These laboratory investigations also suggest that surgeons might consider using a 180-degree shaft rotation and a tilted, posterior-facing port opening to facilitate removal of posterior, preretinal materials; inducing posterior vitreous detachment; or taking advantage of these different spatial aspiration rates when performing a reverse Swiss-roll technique. The fluid dynamics of a dual-blade, beveled-tip cutter probe have yet to be fully elucidated and reported.

Our collective experiences with the 20 000 cpm vitrectomy system have been positive. We observed enhanced tissue stability and fewer AEs using this device. However, we advise caution when transitioning because surgeons may become overconfident with the system's enhanced tissue stability feature. Having gained familiarity with the instrument's performance, we have since adjusted our 20 000 cpm machine settings back to our original 10 000 cpm system vacuum and infusion pressure settings, after which the vitrectomy times have become shorter. In addition, the multifunctional beveled-tip feature consistently facilitates tissue dissection, removal of preretinal materials (eg, heme, triamcinolone particles, SO droplets, and fluid–air exchange.

Our practice maintains a stock of the following 3 probe sizes: flat-tip 23-gauge, beveled-tip 25-gauge, and beveled-tip 27-gauge. One weakness of the dual-blade platform is the lack of a 23-gauge probe, which can remove larger particles (eg, retained lens material, SO droplets, foreign objects) more quickly. When extensive dissection is expected (eg, in cases of diabetic retinopathy), the smaller 27-gauge tip enables entry into tighter tissue planes and can be used to manipulate thin membranes, such as ERMs or the ILM. The larger 25-gauge has an advantage when the situation mainly calls for removal of vitreous gel and fluid–air exchange (eg, in cases of vitreous hemorrhage, ERM, MH) because the larger caliber enables faster vitreous flow rates. Using different probe sizes requires maintaining a larger inventory of ancillary instruments and creates supply management issues.

Some limitations of our study include a relatively small sample, which prevented subanalysis of different surgeons and different surgical indications. Rare but serious AEs, such as endophthalmitis, could not be detected in this small series. Our comparison with our previous case series of the 10 000 cpm vitrectomy system is also limited by the lack of randomization into intervention and standardization of surgical indications at baseline. Larger randomized studies may allow for analyses of different surgical indications and complexities. We believe that a randomized, head-to-head comparison of 10 000 cpm cutter and 20 000 cpm cutter in a particular disease group (eg, MH or RD) would provide the most robust data regarding instrument performance. We are working on upcoming disease-specific study protocols.

A comparison of the 2 instrument models would be more valid if surgical data from both single-blade groups and dual-blade groups were obtained concurrently or within a short interval of 6 months or less. However, we believe that in general, the present paper's comparison of these 2 case series is valid because the data were generated by the same surgeons in the same operating room setup with the same support staff. Because the study data were obtained from the first 50 or so surgical cases performed by these surgeons using each cutter probe iteration, the study results would reflect similar learning curve effects.

In summary, we report the use of a new 20 000 cpm vitrectomy system and compared the current clinical results with our previous set of patients who had surgery using the 10 000 cpm system. Both systems were effective and safe when performing vitreoretinal surgery for various indications. The potential advantages of the 20 000 cpm system include reduced use of ancillary instrumentation and a better safety profile than the current systems that use a lower cut rate.

Authors' Note

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Ethical Approval

This study complied with Good Clinical Practice guidelines and was conducted in accordance with the tenets of the Declaration of Helsinki. The study protocol was approved by the PELI Institutional Review Board and is registered at clinicaltrials.gov (ID# NCT04404296).

Statement of Informed Consent

Written informed consent for pars plans vitrectomy and anesthesia were obtained after thorough discussion of the risks and benefits of the patient-specific procedures.

Declaration of Conflicting Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of the article.

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