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Research Article

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Real-World Outcomes of the Ranibizumab Port Delivery System in Neovascular Age-Related Macular Degeneration and Diabetic Macular Edema: The SANTEE Study

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Key messages

What is known

• The ranibizumab port delivery system maintains vision with 24-week refill-exchange in randomized trials but peer-reviewed real-world data remains limited.

What is new

• In 81 consecutive eyes implanted by a single surgeon, no endophthalmitis, conjunctival erosion, implant dislocation, or explantation occurred over 92.5 implant-years.

• Most eyes were already managed with faricimab; the cohort's mean preimplant interval was 7.2 weeks. After implantation they were managed at a median refill-exchange interval of 25 weeks, addressing whether continuous delivery adds durability in eyes previously treated with a newer agent intended to extend treatment intervals.

Abstract

Purpose. To report real-world safety and treatment-procedure frequency with the ranibizumab port delivery system (PDS) in eyes with neovascular age-related macular degeneration (nAMD) or diabetic macular edema (DME), most of which managed with faricimab.

Methods. Retrospective, consecutive, single-center case series of 81 eyes (64 patients) implanted October 2024 to March 2026, followed to 28 September 2026. All eyes contributed to safety (92.5 implant-years); the 79 eyes followed ≥ 3 months contributed to effectiveness, assessed principally through the second refill-exchange.

Results. Of 79 effectiveness eyes, 61 had nAMD and 18 DME; 74 (93.7%) were on faricimab before implantation; the mean preimplant interval was 7.2 weeks. Over 92.5 implant-years there was no endophthalmitis, conjunctival erosion, implant dislocation, or explantation (upper 95% confidence limit 3.99 per 100 implant-years). Vitreous hemorrhage occurred in 4 eyes (3 with DME), 2 requiring vitrectomy. Four supplemental injections were given in 3 nAMD eyes. Median refill interval was 25 weeks; treatment procedures fell from 5.98 to 2.06 per nAMD eye and 5.72 to 2.00 per DME eye. Acuity was unchanged through the second refill-exchange and anatomic control was maintained. In an exploratory third-refill analysis of 22 nAMD eyes, acuity was 0.088 logMAR worse, substantially influenced by one eye.

Conclusion. In a cohort predominantly managed with faricimab before implantation, PDS was associated with a 25-week median refill interval and an approximately two-thirds reduction in anti-VEGF treatment procedures, with acuity maintained through the second refill-exchange and no endophthalmitis over 92.5 implant-years.

Introduction

Intravitreal anti-vascular endothelial growth factor (anti-VEGF) therapy for the treatment of neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME) is well established, but treatment burden limits effectiveness in practice [1]. Repeated treatments impose logistical demands on patients and caregivers, and nonadherence to treatment and follow-up is associated with poorer visual outcomes [1,2]. More durable agents and switching strategies can extend treatment intervals, although some eyes still require frequent injections [3-6]. In heavily pretreated eyes switched to faricimab, mean intervals extended from 5.8 to 8.2 weeks at one year, but only 15% reached ≥12 weeks and one-third remained on 4- to 6-week intervals [5]. Across pivotal durability trials, 17-23% of eyes still required intervals of 8 weeks or shorter; and up to 45% in TREND [7-10]. Further, greater fluid fluctuation during maintenance therapy has been linked to worse two-year acuity [11]. These limitations motivate the investigation of continuous drug delivery as an alternative to repeated bolus injections.

The port delivery system with ranibizumab (PDS; Susvimo, Genentech, South San Francisco, CA) is a surgically implanted, refillable reservoir that provides continuous intravitreal ranibizumab. It is approved in the United States for nAMD, DME, and diabetic retinopathy [12] and, since September 2026, in the European Union for nAMD, where the delivery platform is known as Contivue [13]. In ARCHWAY, PDS refilled every 24 weeks was noninferior and equivalent to monthly intravitreal ranibizumab in nAMD, with 98.4% requiring no supplemental treatment before the first refill [14-16]. PAGODA similarly demonstrated noninferiority in DME, with 95.9% requiring no supplemental treatment before the first refill [17]. Extension studies have further characterized long-term safety [18].

Adoption has nonetheless been tempered by safety concerns. The prescribing information carries a boxed warning for endophthalmitis [12], and conjunctival erosion, vitreous hemorrhage, and implant dislocation have also been described [19]. Most endophthalmitis cases reported across the PDS clinical studies were associated with conjunctival retraction or erosion [20], prompting refinements in conjunctival and Tenon's capsule handling [21]. Because PDS matches rather than exceeds the visual outcomes of monthly injection, procedure-related safety is central to adoption and is the primary focus of this series.

Published PDS evidence derives almost entirely from clinical trials and extension studies; to our knowledge no peer-reviewed routine-practice cohort reporting both safety and effectiveness after implantation has been published [22].

A further gap concerns faricimab-pretreated eyes. ARCHWAY, PAGODA, and PORTAL preceded routine faricimab use, leaving uncertain whether continuous delivery adds durability in eyes still requiring frequent treatment despite a second-generation agent.

For patients already treated with a newer agent intended to extend treatment intervals who still require frequent injections, the relevant question is whether the procedure-related risks of continuous delivery are acceptable given the reduction in treatment burden it offers. We therefore evaluated device- and procedure-related safety, refill durability, anti-VEGF treatment-procedure frequency, and indication-specific visual and anatomic outcomes following consecutive PDS implantation in a community vitreoretinal practice, where most eyes were receiving faricimab immediately beforehand.

Methods

Study design and patients

The SANTEE Study is a retrospective, consecutive case series conducted at Jervey Eye Group, Greenville, South Carolina. The University of South Carolina Institutional Review Board (IRB) determined that IRB review was not required; the study adhered to the Declaration of Helsinki.

Eighty-one consecutive eyes underwent PDS implantation from October 2024 through March 2026; follow-up ended September 28, 2026. Enrollment through March 2026 ensured that each eye had the opportunity to reach a minimum 24-week first refill-exchange. Visual and anatomic outcomes through the second refill-exchange constituted the principal nAMD effectiveness analysis; DME effectiveness outcomes and all observations at the third refill-exchange were exploratory. Baseline was the visit immediately before implantation. Scheduled postoperative assessments occurred at day 1, months 1 and 3, and the first, second, and third refill-exchanges, with additional visits for suspected increased disease activity. Visual acuity was analyzed at each scheduled visit after day 1, and central subfield thickness at each except month 1, when it was not routinely documented.

Effectiveness and treatment-procedure follow-up ended at each eye's last documented contact on or before the third refill-exchange, defined as the latest scheduled assessment, refill-exchange, or supplemental injection; exposure was calculated from implantation to that endpoint. Because refill timing was clinical rather than calendar-based, observation time varied, and annualized rates describe this variable follow-up period. Treatment-procedure frequency was analyzed only in eyes that reached at least one refill-exchange. Safety follow-up extended from implantation to study end or earlier withdrawal, death, or last contact.

Seventy-nine eyes with at least 3 months of documented postoperative follow-up formed the effectiveness cohort. Two eyes of one patient were lost to follow-up after month 1 and contributed to safety only. One eye implanted in late March 2026 had its first refill-exchange scheduled after the study end and was excluded from the treatment-procedure analysis. Eyes were implanted for nAMD or DME after demonstrating a response to intravitreal anti-VEGF therapy. Safety follow-up ended before the study end

date in 5 eyes: the 2 eyes lost to follow-up, 2 eyes of one patient who entered hospice subsequently withdrawing care, and 1 eye of a patient who died of causes unrelated to the device. Procedure-analysis follow-up ranged between 6.0 and 18.2 months (median, 12.0 months).

Surgical technique

All implantations were performed by a single surgeon using a consistent technique. A 27-gauge trocar was placed for infusion, and conjunctival peritomy with subsequent scleral diathermy was followed by a 3.4–3.5 mm scleral cut-down. Pars plana laser was applied before a 3.2-mm pars plana incision in every case [19]. Prolapsed vitreous was removed with the vitrector and the wound assessed for leakage before closure. Conjunctiva and Tenon's capsule were widely mobilized and reapproximated in a single tension-free layer [21]. Eighty of 81 implants were placed superotemporally; one was placed superonasally to preserve superotemporal tissue for possible future glaucoma surgery.

Data collection and definitions

Data were abstracted at the eye level: age at implantation, sex, laterality, indication, prior pars plana vitrectomy, pre-implant anti-VEGF agent and injection interval, best-corrected visual acuity (BCVA), central subfield thickness (CST) on spectral-domain optical coherence tomography, refill-exchange timing, supplemental injections, and device- and procedure-related adverse events. Device-related, intraocular, and conjunctival complications were assessed at each documented visit.

Best-corrected distance visual acuity was measured clinically on a Snellen chart and converted to logMAR, which was the scale for all inferential comparisons. Approximate ETDRS letter equivalents were calculated for descriptive presentation as $85 - 50 \times \text{logMAR}$, floored at zero; because of that floor, mean letter change need not equal $-50 \times$ mean logMAR change. Counting fingers and hand motions were assigned logMAR 2.0 and 3.0.

Pre-implant injection counts and treatment intervals were taken from each eye's injection record. Device eligibility requires response to at least 2 prior anti-VEGF injections, thus some eyes had a shorter treatment history and a correspondingly low count in that fixed window; pre-implant treatment interval was recorded separately to reflect treatment cadence at the decision to implant. Post-implant frequency was the number of refill-exchange procedures plus supplemental anti-VEGF injections divided by that eye's exposure time in years. The implantation and initial fill procedure is a one-time surgical event and thus was counted neither as a pre-implant injection nor as a post-implant treatment procedure; each eye was implanted at least 4 weeks after its last intravitreal injection. Complement-inhibitor injections were excluded from the supplemental injection count. The proportion of eyes free of supplemental injection

within each refill interval is reported separately, since inter-refill durability and overall procedure frequency answer different questions.

Statistical analysis

Because 16 patients contributed both eyes, and fellow eyes share systemic risk and access to care, confidence intervals for means and mean changes used patient-level resampling. Confidence intervals for mean changes were normal-based intervals using bootstrap standard errors from 5,000 patient-level resamples of paired eye-level changes, with P values from the corresponding z tests. Adverse events are reported as rates per 100 implant-years and as proportions of eyes, each with exact confidence intervals, which treat eyes as independent. nAMD and DME were analyzed separately and not compared, and baseline characteristics are described rather than formally tested. A post hoc sensitivity analysis of nAMD acuity excluded one eye with pre-existing subretinal fibrosis and an atypically favorable baseline reading. P values were not adjusted for multiple comparisons. Analyses were performed in Stata BE 19.5 (StataCorp LLC, College Station, TX).

Results

Cohort

The effectiveness cohort comprised 79 of 81 implanted eyes, from 63 patients of whom 16 (25.4%) underwent bilateral implantation. Mean age at implantation was 75.9 ± 7.5 years (range 56-93) and 38 of 63 patients (60.3%) were female. Sixty-one eyes (77.2%) were implanted for nAMD and 18 (22.8%) for DME. Three eyes (3.8%) had undergone prior pars plana vitrectomy. Seventy-four eyes (93.7%) had received faricimab as the immediate pre-implant agent, after a median of 7 prior faricimab injections (IQR 4-11); 78 of 79 eyes had received faricimab at some point. The mean pre-implant injection interval across the effectiveness cohort was 7.2 ± 2.4 weeks, with a median of 9 cumulative anti-VEGF injections before implantation (range 2-39). Fifty eyes completed the second-refill visit and 24 the third. Treatment procedures were analyzed in the 78 eyes that had reached at least one refill-exchange, over 76.9 implant-years (61.9 in nAMD and 15.0 in DME eyes). The safety cohort comprised all 81 implanted eyes of 64 patients (61 nAMD, 20 DME), with 92.5 implant-years of follow-up (median 14.7 months; range 1.0-23.0). Baseline characteristics of the effectiveness cohort are shown in Table 1.

Table 1. Baseline characteristics of the effectiveness cohort.

	Overall	nAMD	DME
Eyes, n	79	61	18
Patients, n	63	50	13
Patients with bilateral implantation, n	16	11	5
Age at implantation, y, mean ± SD*	75.9 ± 7.5	78.0 ± 6.2	67.9 ± 6.9
Age, range, y	56-93	65-93	56-77
Female patients, n (%)*	38 (60.3)	31 (62.0)	7 (53.8)
Right eye, n (%)	41 (51.9)	32 (52.5)	9 (50.0)
Prior pars plana vitrectomy, n (%)	3 (3.8)	2 (3.3)	1 (5.6)
Baseline BCVA, logMAR, mean ± SD	0.53 ± 0.59	0.55 ± 0.56	0.46 ± 0.67
Snellen equivalent of mean logMAR	20/68	20/72	20/58
Median logMAR (Snellen equivalent)	0.30 (20/40)	0.40 (20/50)	0.30 (20/40)
Approximate ETDRS letters, mean ± SD	60.3 ± 23.5	58.8 ± 24.5	65.6 ± 19.5
Baseline CST, µm, mean ± SD	293 ± 70	286 ± 55	317 ± 106
Pre-implant agent faricimab, n (%)	74 (93.7)	59 (96.7)	15 (83.3)
Any prior faricimab, n (%)	78 (98.7)	61 (100.0)	17 (94.4)
Prior faricimab injections, median (IQR)	7 (4-11)	8 (5-12)	7 (3-8)
Injections in 12 months before implantation, mean ± SD†	5.9 ± 2.1	6.0 ± 2.1	5.7 ± 2.3
Cumulative pre-implant anti-VEGF injections, n, mean ± SD	11.5 ± 8.4	12.1 ± 8.8	9.4 ± 6.8
Median (range)	9 (2-39)	11 (2-39)	7 (2-29)
Pre-implant injection interval, wk, mean ± SD	7.2 ± 2.4	7.3 ± 2.5	6.6 ± 1.7

Median, wk	8	8	7
Eyes reaching a second / third refill-exchange, n	50 / 24	40 / 22	10 / 2
Median follow-up to study end or last contact, mo	14.7	16.5	12.9
Procedure-analysis exposure, implant-years†	76.9	61.9	15.0

**Patient-level values. †Eyes that had reached at least one refill-exchange (78 eyes).*

Safety

Among all 81 implanted eyes there were no cases of endophthalmitis, conjunctival erosion, conjunctival retraction, implant dislocation, explantation, septum dislodgement, or retinal detachment over 92.5 implant-years. For each of these outcomes the upper limit of the two-sided 95% confidence interval was 3.99 events per 100 implant-years, or 4.45% of eyes. Vitreous hemorrhage occurred in 4 eyes (4.9%; 95% CI 1.36-12.16%; 4.33 per 100 implant-years, 95% CI 1.18-11.07), two of which required pars plana vitrectomy, at 5 and 12 weeks. Safety outcomes by event type are presented in Table 2. Three of the 4 hemorrhages occurred in DME eyes (3 of 20, compared with 1 of 61 nAMD eyes), and 2 of the 3 eyes with prior pars plana vitrectomy developed hemorrhage, compared with 2 of 78 eyes without (2.6%; Supplementary Table S1). With only four events, these proportions are considered descriptive. A further eye underwent vitrectomy at 4 weeks for a vitreous hemorrhage present before implantation; because the hemorrhage antedated surgery it was not counted as a device- or procedure-related event.

Table 2. Ocular adverse events and postoperative reoperations in all 81 implanted eyes.

Event	Eyes, n (%)	95% CI, % (exact binomial)	Rate /100 implant-yr	95% CI (exact Poisson)	nAMD, n	DME, n
Endophthalmitis	0 (0.0)	0.00-4.45	0.00	0.00-3.99	0	0
Conjunctival erosion	0 (0.0)	0.00-4.45	0.00	0.00-3.99	0	0
Implant dislocation	0 (0.0)	0.00-4.45	0.00	0.00-3.99	0	0
Implant removal / explantation	0 (0.0)	0.00-4.45	0.00	0.00-3.99	0	0
Conjunctival retraction	0 (0.0)	0.00-4.45	0.00	0.00-3.99	0	0
Septum dislodgement	0 (0.0)	0.00-4.45	0.00	0.00-3.99	0	0
Retinal detachment	0 (0.0)	0.00-4.45	0.00	0.00-3.99	0	0

Event	Eyes, n (%)	95% CI, % (exact binomial)	Rate /100 implant-yr	95% CI (exact Poisson)	nAMD, n	DME, n
Vitreous hemorrhage	4 (4.9)	1.36-12.16	4.33	1.18-11.07	1	3
Vitreous hemorrhage requiring PPV	2 (2.5)	0.30-8.64	2.16	0.26-7.81	0	2
Exposure, implant-years	—	—	—	—	74.6	17.9

Visual acuity

Mean baseline BCVA was 0.55 ± 0.56 logMAR in nAMD eyes (Snellen equivalent of the mean, 20/72) and 0.46 ± 0.67 logMAR in DME eyes (20/58). A transient worsening at 1 month (+0.122 logMAR in nAMD eyes, +0.333 in DME eyes) had returned toward baseline by 3 months. At the second refill-exchange the change from baseline was +0.009 logMAR in nAMD eyes (95% CI -0.038 to +0.057) and +0.008 in DME eyes (95% CI -0.045 to +0.061). In the exploratory third-refill analysis, nAMD acuity was +0.088 logMAR from baseline (95% CI +0.013 to +0.164; 22 eyes). This change was substantially influenced by one eye with pre-existing subretinal fibrosis whose baseline reading was atypically favorable (see Discussion); excluding it, the change was +0.039 (95% CI -0.034 to +0.112). Values at each timepoint are given in Table 3 and Figure 1. One eye underwent its only refill-exchange at 50 weeks and was reassessed one month later to confirm resolution of subretinal fluid; because no second refill-exchange occurred, that eye contributes no acuity or CST value to the second-refill row. No values were imputed or carried forward.

Table 3. Best-corrected visual acuity by indication.

Timepoint	Eyes, n	logMAR, mean ± SD	Aprox. ETDRS letters	Baseline logMAR in paired analysis	Δ logMAR (95% CI)†	P†
nAMD						
Baseline (pre-implant)	61	0.55 ± 0.56	58.8 ± 24.5	—	—	—
1 month	61	0.68 ± 0.57	52.9 ± 24.4	0.55	+0.122 (+0.054 to +0.190)	<0.001
3 months	60	0.56 ± 0.59	58.9 ± 25.4	0.56	-0.005 (-0.046 to +0.035)	0.797
First-refill visit	60	0.56 ± 0.59	58.5 ± 25.7	0.56	+0.001 (-0.064 to +0.065)	0.984
Second-refill visit	40	0.53 ± 0.60	59.8 ± 26.1	0.53	+0.009 (-0.038 to +0.057)	0.694
Third-refill visit	22	0.62 ± 0.62	56.0 ± 26.3	0.53	+0.088 (+0.013 to +0.164)	0.022
DME						
Baseline (pre-implant)	18	0.46 ± 0.67	65.6 ± 19.5	—	—	—
1 month	18	0.79 ± 1.03	56.2 ± 27.5	0.46	+0.333 (-0.039 to +0.706)	0.079
3 months	18	0.30 ± 0.20	70.0 ± 10.2	0.46	-0.160 (-0.448 to +0.128)	0.276
First-refill visit	18	0.29 ± 0.15	70.6 ± 7.4	0.46	-0.172 (-0.481 to +0.137)	0.274
Second-refill visit	10	0.22 ± 0.15	73.9 ± 7.6	0.21	+0.008 (-0.045 to +0.061)	0.769
Third-refill visit	2	0.00 ± 0.00	85.0 ± 0.0	0.14	—‡	—

Baseline in paired analysis: mean pre-implant value of the eyes contributing at that visit. †Negative Δ logMAR indicates improvement. ‡Only 2 eyes, both of one patient, reached this visit. Because resampling is by patient, every resample contains the same two eyes, so no confidence interval or P value can be estimated; the observed changes were -0.18 and -0.10 logMAR.

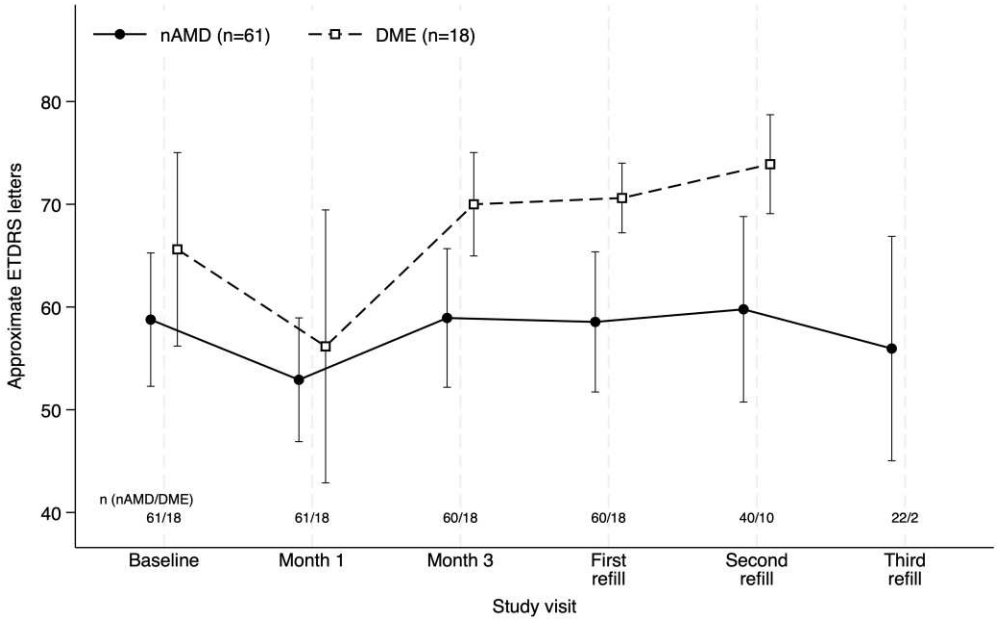


Figure 1. Mean best-corrected visual acuity by study visit, stratified by indication, expressed as approximate ETDRS letter equivalents converted from logMAR. Visits are ordered by protocol position rather than elapsed time; refill-exchange visits occurred at medians of approximately 25, 50, and 74 weeks after implantation. DME is not plotted at the third refill-exchange, which only 2 DME eyes, from the same patient, reached. Points are offset horizontally to avoid overlap. Numbers along the bottom of the plot indicate eyes contributing at each visit (nAMD/DME).

Anatomic outcomes

Pre-implant central subfield thickness averaged 286 ± 55 µm across all nAMD eyes and 317 ± 106 µm across all DME eyes. At the second refill-exchange the change from baseline was -10 µm in nAMD eyes (95% CI -17 to -2) and -18 µm in DME eyes (95% CI -52 to +15), and at the third refill-exchange -13 µm in nAMD eyes (95% CI -25 to -1). The nAMD reduction was small but consistent; the DME estimate is imprecise. Values at each timepoint are given in Table 4 and Supplementary Figure S1.

Table 4. Central subfield thickness by indication.

Timepoint	**Eyes, n**	**Mean CST (µm) ± SD**	**Baseline CST (µm) in paired analysis**	**Δ µm (95% CI)†**	**P†**
nAMD					
Baseline (pre-implant)	61	286 ± 55	—	—	—
3 months	60	280 ± 50	285	-6 (-16 to +5)	0.309
First-refill visit	60	277 ± 54	286	-9 (-21 to +3)	0.130
Second-refill visit	40	267 ± 39	277	-10 (-17 to -2)	0.010

Timepoint	Eyes, n	Mean CST (μm) ± SD	Baseline CST (μm) in paired analysis	Δ μm (95% CI)†	P†
Third-refill visit	22	269 ± 48	282	-13 (-25 to -1)	0.034
DME					
Baseline (pre-implant)	18	317 ± 106	—	—	—
3 months	18	282 ± 41	317	-35 (-80 to +9)	0.119
First-refill visit	18	283 ± 44	317	-35 (-85 to +15)	0.174
Second-refill visit	10	276 ± 33	295	-18 (-52 to +15)	0.282
Third-refill visit	2	270 ± 21	294	—‡	—

Baseline in paired analysis: mean pre-implant value of the eyes contributing at that visit. †Negative Δ indicates thinning. ‡Only 2 eyes, both of one patient, reached this visit. Because resampling is by patient, every resample contains the same two eyes, so no confidence interval or P value can be estimated; the observed changes were -34 and -13 μm.

Anti-VEGF treatment procedures

Across 76.9 implant-years in 78 eyes, there were 152 refill-exchange procedures and 4 supplemental anti-VEGF injections in 3 eyes. In nAMD eyes the number of observed treatments in the one year prior to implantation was 5.98 ± 2.09 before implantation and 2.06 ± 0.38 afterward (65.6% reduction; mean change -3.93, 95% CI -4.50 to -3.35); in DME eyes 5.72 ± 2.30 and 2.00 ± 0.05 (65.0% reduction; mean change -3.72, 95% CI -4.91 to -2.53) (Table 5). All 4 supplemental injections were given in nAMD eyes; none in DME eyes. Among nAMD eyes, 57 of 60 (95.0%) required no supplemental injection before the first refill-exchange, rising to 58 (96.7%) when the bridging injection is removed; individual injection timings are given in Supplementary Table S2. Median intervals were 25 weeks to the first refill-exchange, 25 weeks from first to second, and 24 weeks from second to third, with distributions by indication in Supplementary Table S3.

Table 5. Anti-VEGF treatment-procedure frequency, by indication.

Metric	nAMD (60)	DME (18)
Anti-VEGF injections in the 12 months before implantation†	5.98 ± 2.09	5.72 ± 2.30
Post-implant annualized treatment procedures (observed count ÷ exposure)	2.06 ± 0.38	2.00 ± 0.05
refill-exchange procedures	1.97 ± 0.14	2.00 ± 0.05
supplemental anti-VEGF injections	0.08 ± 0.39	0.00 ± 0.00
Change in annualized frequency	-3.93 ± 2.13	-3.72 ± 2.29
Relative reduction, %	65.6	65.0
95% CI for change	-3.93 (-4.50 to -3.35)	-3.72 (-4.91 to -2.53)

†Pre-implant frequency is the observed number of anti-VEGF injections documented during the 365 days before implantation; post-implant frequency is the observed number of refill-exchange procedures plus supplemental anti-VEGF injections divided by follow-up time in years. Implantation surgery, monitoring visits, and complement-inhibitor injections are excluded.

Discussion

In this consecutive series of 81 eyes implanted at a single community vitreoretinal practice, PDS treatment was associated with maintained visual acuity and anatomy through the second refill-exchange; with a decrease in annualized anti-VEGF treatment events from a mean of approximately 6 before implantation to 2 afterward. Over 92.5 implant-years there were no cases of endophthalmitis, conjunctival erosion, implant dislocation, or explantation. Most eyes had been managed with faricimab before implantation, a population not represented in the pivotal trials.

Seventy-four of 79 eyes (93.7%) were receiving faricimab immediately before implantation; the remaining 5 were on aflibercept 2 mg (2 eyes), aflibercept 8 mg, ranibizumab, or bevacizumab. In a single-center series of heavily pretreated eyes switched to faricimab, mean intervals extended from 5.8 to 8.2 weeks over one year [5]. Most of our eyes had already made that transition and were treated approximately every 7 weeks at implantation; afterward they were managed at a median refill-exchange interval of 25 weeks. The two intervals are defined differently, the pre-implant treatment interval determined by disease activity and the refill interval by a fixed schedule; therefore durability between refills is best reflected in the rarity of supplemental treatment events. Thus, these data address a question the trial literature does not: whether continuous delivery adds durability in eyes previously treated with a newer agent intended to extend treatment intervals [22].

A multicenter real-world series reported in abstract form found a mean time to first refill-exchange of 7.5 months in 53 nAMD eyes, with rescue injection required in 3 [23]. Our findings are consistent with that experience and extend it by quantifying exposure and reporting adverse event rates with exact confidence

intervals. First, among nAMD eyes, 57 of 60 (95.0%) required no supplemental injection before the first refill-exchange, rising to 58 (96.7%) when the bridging injection is removed; no DME patients required supplemental treatment. ARCHWAY and PAGODA also reported infrequent supplemental treatment, although differences in populations and observation windows preclude direct comparison [14, 15, 17]. Second, treatment-procedure frequency captures how often patients undergo an in-office anti-VEGF procedure. Counting only supplemental injections would omit refill-exchanges, which are scheduled procedures with their own risks, and would report a reduction approaching 99% rather than the roughly two-thirds reduction patients experience. That estimate covers anti-VEGF procedures only; implantation surgery, monitoring visits, and complement-inhibitor injections are excluded.

One supplemental injection illustrates a practical barrier to timely refill-exchange. That eye received a bridging injection from an injecting physician in another state who was not performing refill-exchanges and underwent refill-exchange at 50 weeks rather than at the scheduled interval. Access to clinicians trained in refill-exchange may affect continuity when care is shared across practices.

Our safety experience was favorable. Vitreous hemorrhage occurred in 4 eyes, 2 requiring vitrectomy at 5 and 12 weeks; this is within the range reported in pivotal trials [15] and can arise from intraoperative bleeding from the pars plana at the scleral incision site [19]. Three of our four hemorrhages occurred in eyes with DME, and two of the three previously vitrectomized eyes developed postoperative hemorrhage; these observations warrant study but do not establish either characteristic as a risk factor.

Visual acuity was unchanged through the second refill-exchange, which is the anticipated result. These eyes were stable on frequent anti-VEGF therapy before implantation, and the value of the device lies in maintaining that stability at a fraction of the treatment frequency rather than in producing further gains. The small decline in nAMD acuity at the third refill-exchange rests on 22 eyes and was substantially influenced by a single eye with pre-existing subretinal fibrosis. Its baseline reading of 20/150 was the best recorded prior to implantation; after implantation it ranged from 20/400 to counting fingers, with stable central subfield thickness. Longer follow-up in more eyes is needed to characterize outcomes beyond the second refill-exchange. The transient worsening at 1 month had returned toward baseline by 3 months and is a useful point in preoperative counseling.

Visual and anatomic outcomes in the DME cohort were broadly consistent with PAGODA, and no DME eye required supplemental treatment during analyzed follow-up despite substantial pre-implantation treatment burden [17].

Limitations

This study is retrospective, uncontrolled, single-center, and subject to the selection biases inherent in that design. Effectiveness is reported through the third refill-exchange, which 24 of 79 eyes reached; third-refill estimates rest on 22 nAMD and 2 DME eyes; later-visit availability primarily reflected staggered implantation, though death, hospice withdrawal, and loss to follow-up also contributed. Selection criteria evolved during the series: later eyes were implanted after shorter treatment histories, including eight with three or fewer prior injections, which would tend to reduce rather than inflate the measured reduction in treatment procedures. Geographic atrophy status and treatment was recorded but not analyzed in this report.

Pre-implant treatment frequency was based on documented injections during a fixed 365-day window, whereas post-implant frequency was annualized over variable follow-up anchored to refill sequence. In eyes with less than 12 months of prior treatment history, the pre-implant window included untreated time and may therefore underestimate treatment intensity at the time of implantation; these comparisons should be interpreted as descriptive measures of observed procedure burden. Because follow-up was defined by refill sequence, elapsed observation time varied among eyes, and outcomes at the second refill-exchange do not represent a uniform 12-month assessment. Effectiveness observations beyond the third refill-exchange were outside the scope of this analysis; safety events were captured through the study end date or the applicable earlier censoring date.

Two eyes of one patient were lost to follow-up after 1 month; they contributed to safety through their last contact but were excluded from effectiveness, and because loss to follow-up may be related to outcome, their subsequent course is unknown. Visual acuity was measured on a Snellen chart rather than by protocol ETDRS refraction, so letter scores are conversions.

Conclusions

In this single-center retrospective series of eyes predominantly treated with faricimab before implantation, PDS was associated with maintained visual acuity and anatomical control through the second refill-exchange, and an approximately two-thirds reduction in anti-VEGF treatment procedures. No endophthalmitis, conjunctival erosion, implant dislocation, or explantation occurred over 92.5 implant-years; vitreous hemorrhage occurred predominantly in eyes with DME or prior vitrectomy, two of such eyes required vitrectomy post-implantation to clear the vitreous hemorrhage. For patients who continue to require frequent injections despite a second-generation agent, these findings support continuous delivery as an option for substantially reducing anti-VEGF treatment procedures.

Author contributions A.E.P. Conceptualization, Methodology, Investigation, Resources, Data curation, Formal analysis, Visualization, Writing – original draft and Writing – review and editing manuscript, Supervision. J.M.-S. Data curation, Writing – original draft. All authors reviewed and approved the final version of the manuscript.

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Data availability The dataset supporting the findings of this study is not publicly available to protect patient privacy but may be available from the corresponding author upon reasonable request.

Declarations

Ethics approval The University of South Carolina Institutional Review Board determined that IRB review was not required. The study adhered to the Declaration of Helsinki.

Consent to participate Not applicable.

Competing interests A.E.P. consultant and speaker bureau Genentech/Roche. J.M.-S. has no relevant financial or non-financial interests to disclose. Roche/Genentech had no role in study design, data collection, analysis, interpretation, or manuscript preparation.

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