VABYSMO DIABĒTA IZRAISĪTU TĪKLENES PATOLOĢIJU GADĪJUMOS

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Lekciju atbalsta Roche Latvija SIA

DIABĒTISKA MAKULOPĀTIJA – RETINOPĀTIJA, KAS SKAR MAKULAS RAJONU

Diabētiska makulas tūska – *šķidruma uzkrāšanās makulas rajonā dēļ pārmērīgi caurlaidīgiem asinsvadiem;*

Klīniski nozīmīga makulas tūska:

ETDRS klasifikācija

- Tīklenes sabiezināšanās makulas rajonā vai 500 µm rādiusā no tā; *vai*	- Cietie eksudāti makulas rajonā vai 500 µm rādiusā no tā ar apkārtējās tīklenes sabiezināšanos; *vai*	- Tīklenes sabiezināšanās zona ≥ 1 diska laukuma diametrā, no kuras kāda daļa ir 1 diska diametra zonā no makulas centra.

DIABĒTISKA MAKULOPĀTIJA

Fokāla tūska

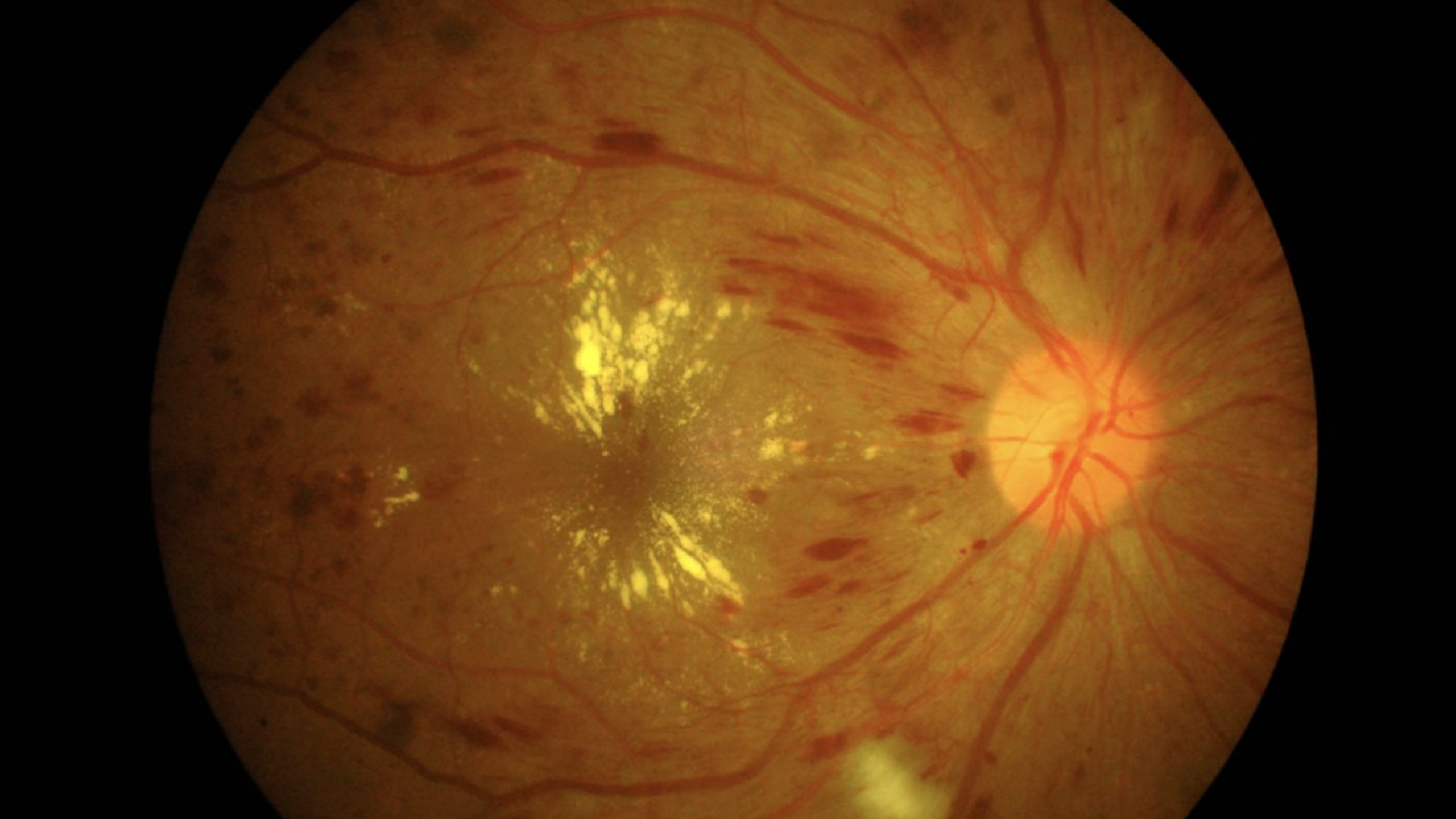
Difūza tūska

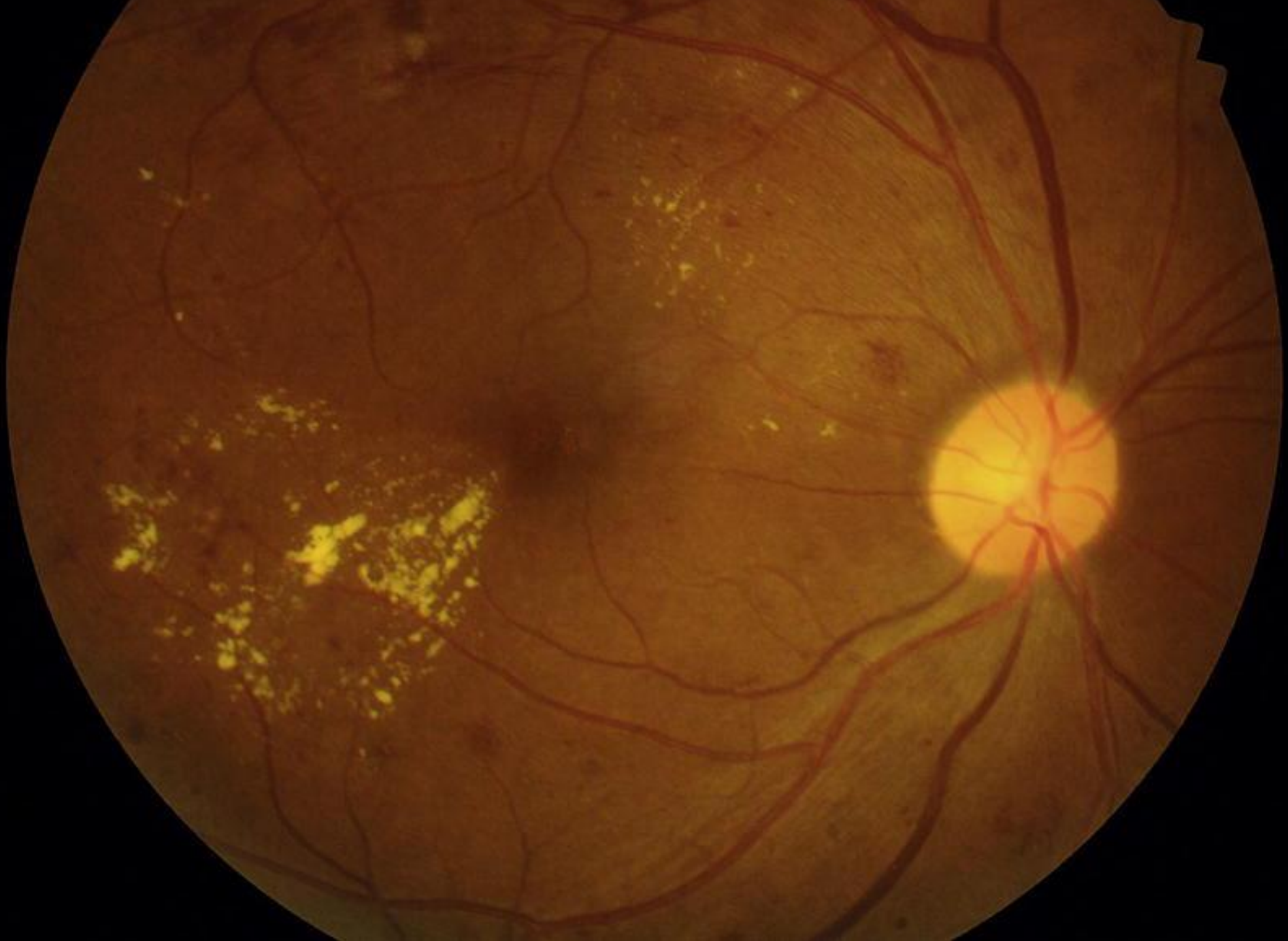
Išēmiska tūska

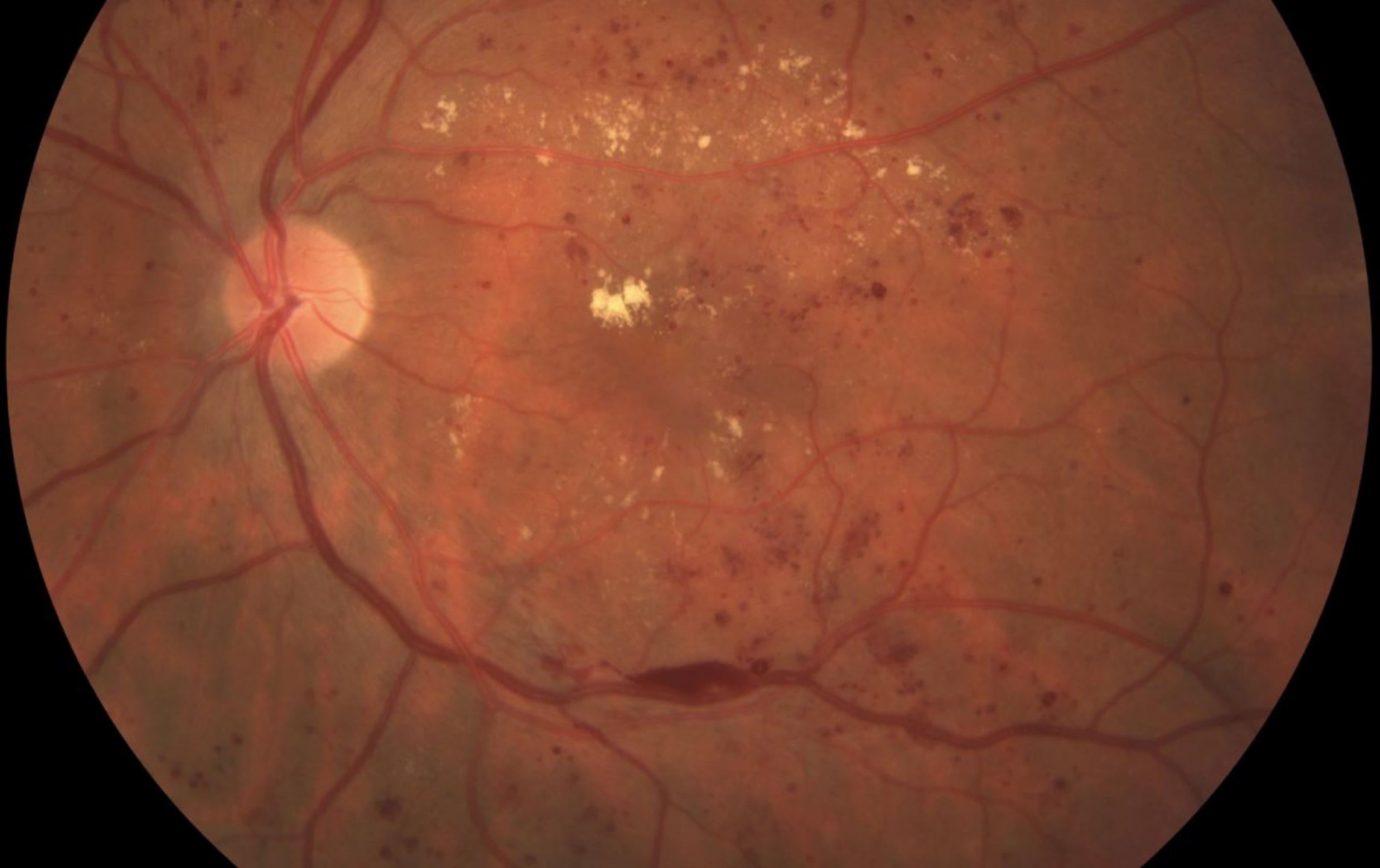
Jaukta tipa tūska

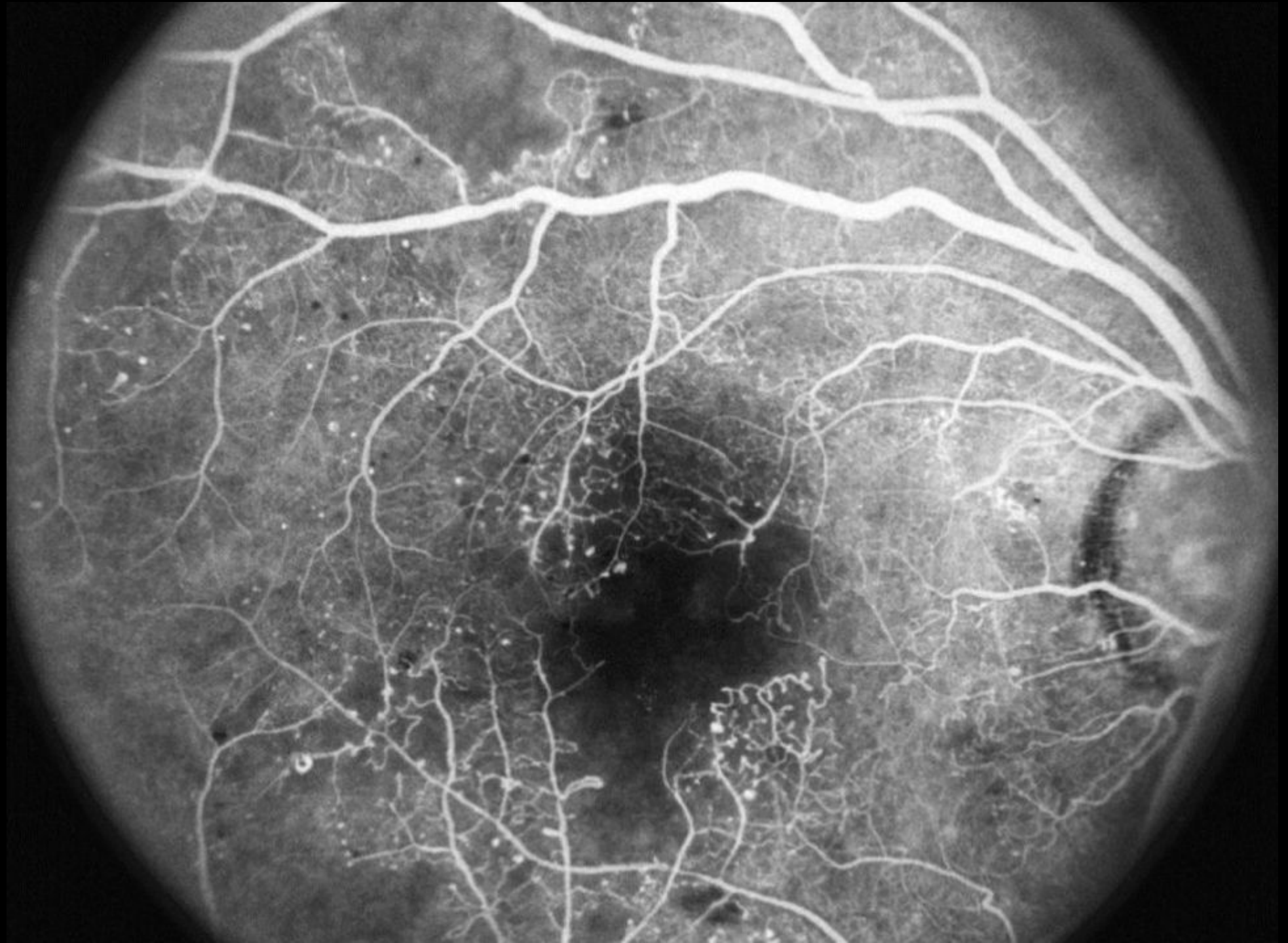
Trakcijas tipa diabētiska makulopātija (vitreoretināla patoloģija);

Ne-trakcijas tipa makulopātija (intraretināla)





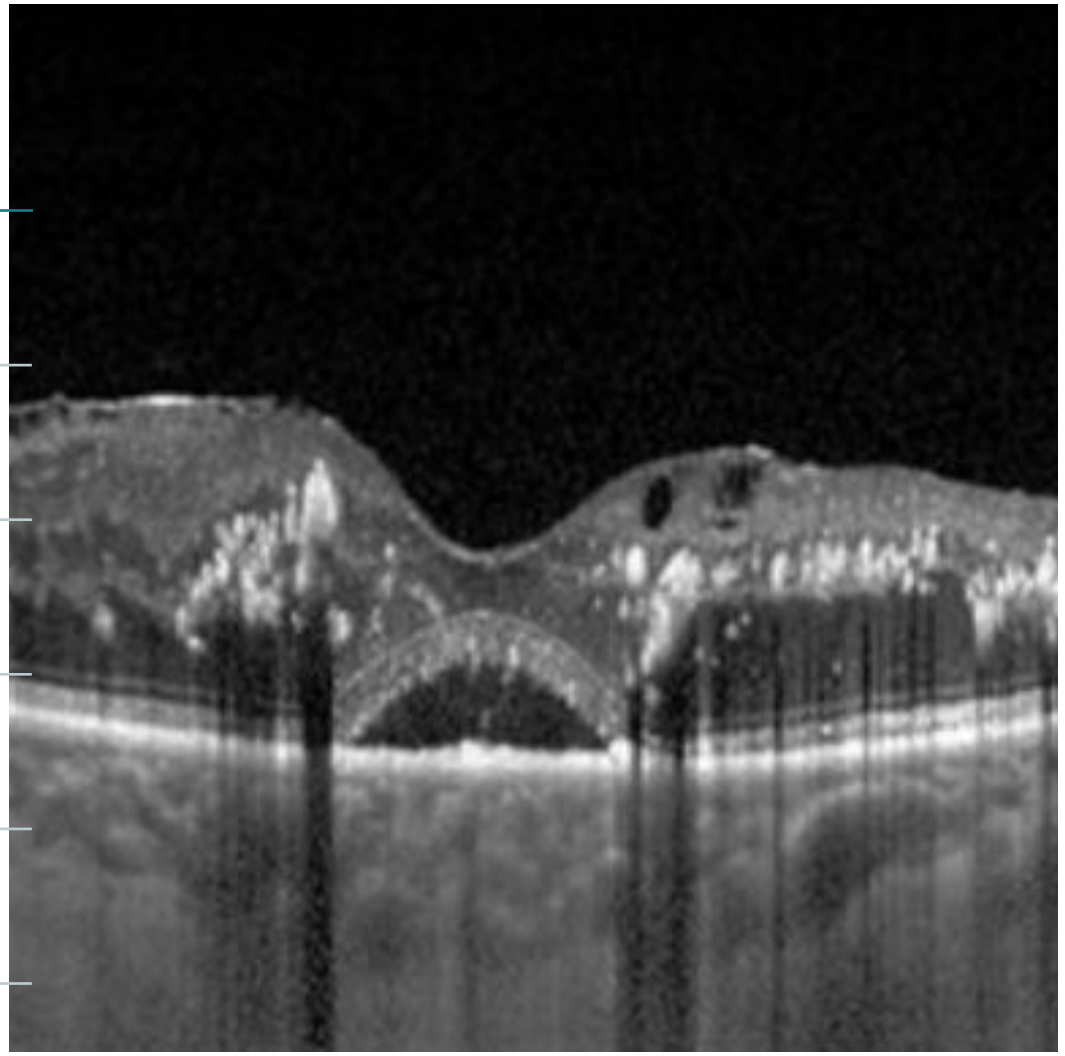




DIABĒTISKA MAKULAS TŪSKA OCT

Raksturojas ar:

- Elipsoīdās zonas un ārējās robežmembrānas izmaiņām;
- Intraretinālu hiperreflektīvu perēkļu esamība (cietie eksudāti);
- Vitreoretinālās savstarpējās saistības izmaiņas;
- Subfoveolāra šķidruma esamība;
- Intraretinālas cistas;
- Iekšējo tīklenes slāņu disorganizācija.



Diabētiska makulopātija - terapija

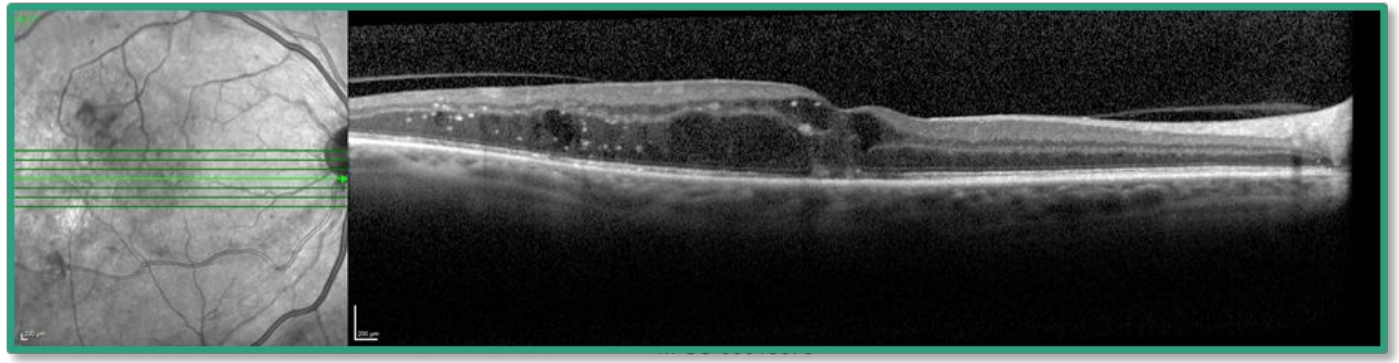
TABLE 5 INITIAL MANAGEMENT RECOMMENDATIONS FOR PATIENTS WITH DIABETES

Severity of Retinopathy	Presence of Macular Edema	Follow-up (Months)	Panretinal Photocoagulation (Scatter) Laser	Focal and/or Grid Laser*	Intravitreal Anti-VEGF Therapy
Normal or minimal NPDR	No	12	No	No	No
Mild NPDR	No	12	No	No	No
	NCI-DME	3–6	No	Sometimes	No
	CI-DME†	1*	No	Rarely	Usually
Moderate NPDR	No	6-12‡	No	No	No
	NCI-DME	3–6	No	Sometimes	Rarely
	CI-DME†	1*	No	Rarely	Usually
Severe NPDR	No	3-4	Sometimes	No	Sometimes
	NCI-DME	2–4	Sometimes	Sometimes	Sometimes
	CI-DME†	1*	Sometimes	Rarely	Usually
Non-high-risk PDR	No	3-4	Sometimes	No	Sometimes
	NCI-DME	2-4	Sometimes	Sometimes	Sometimes
	CI-DME†	1*	Sometimes	Sometimes	Usually
High-risk PDR	No	2-4	Recommended	No	Sometimes[95,188]
	NCI-DME	2-4	Recommended	Sometimes	Sometimes
	CI-DME†	1*	Recommended	Sometimes	Usually

Anti-VEGF = anti-vascular endothelial growth factor; CI-DME = center-involved diabetic macular edema; NCI-DME = noncenter-involved diabetic macular edema; NPDR = nonproliferative diabetic retinopathy; PDR = proliferative diabetic retinopathy

Diabētiskas makulas tūskas ārstēšanas iespējas

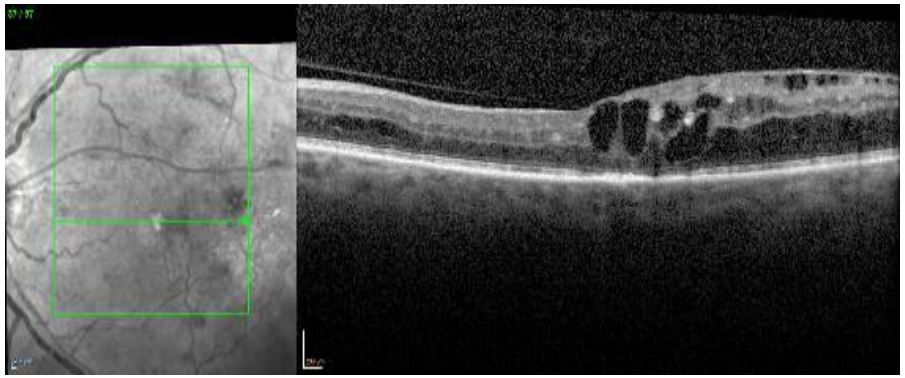
- Intravitreāla anti-VEGF/Ang-2 blokāde
- Intravitreāla anti-VEGF blokāde
- Intravitreāli kortikosteroīdi
- Fokāla makulāra lāzer-fotokoagulācija



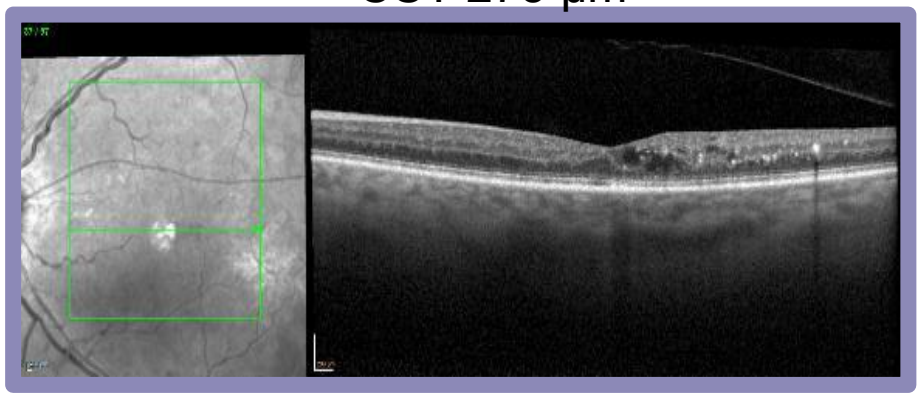
Intravitreāla anti-VEGF/Ang-2 terapija - pirmās izvēles terapija pie CI-DME

- Pierādīta efektivitāte:
  - **Faricimabs (anti-VEGF, Ang-2);**
  - Aflibercepts;
  - Ranibizumabs;
  - Brolucizumabs;
  - Bevacizumabs.
- Efektīvāka terapija par lāzeru, glikokortikoīdiem;
- Laba okulārā un sistēmiskā drošība

0. ned. BCVA 56 burti
CST 425 µm



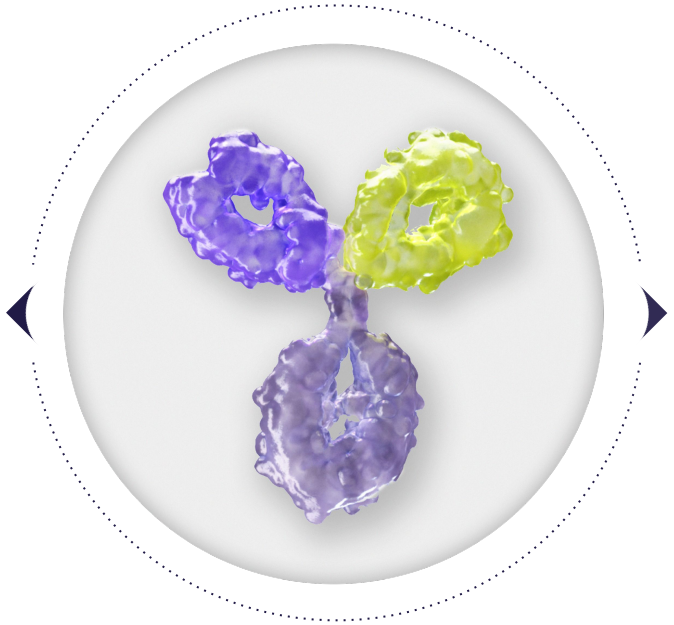
56. ned. BCVA 73 burti
CST 275 µm



VABYSMO - pirmā bispecifiskā antiviela, kas inhibē VEGF-A un Ang-2, mērķējot uz 2 slimības signālceļiem un nodrošinot ilgstošu aktivitāti un asinsvadu stabilitāti

Anti-VEGF-A Fab

Samazina asinsvadu caurlaidību
Inhibē neovaskularizāciju



Modificēts Fc

Samazina sistēmisko iedarbību
Samazina iekaisuma potenciālu

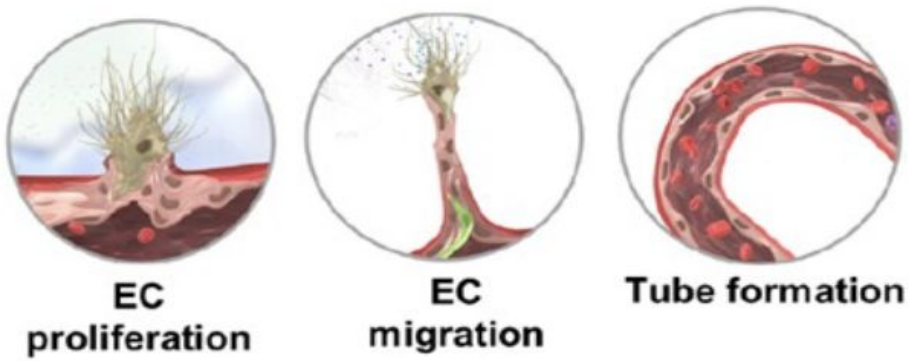
Anti-Ang-2 Fab

Stabilizē asinsvadus
Samazina asinsvadu caurlaidību
Samazina iekaisumu

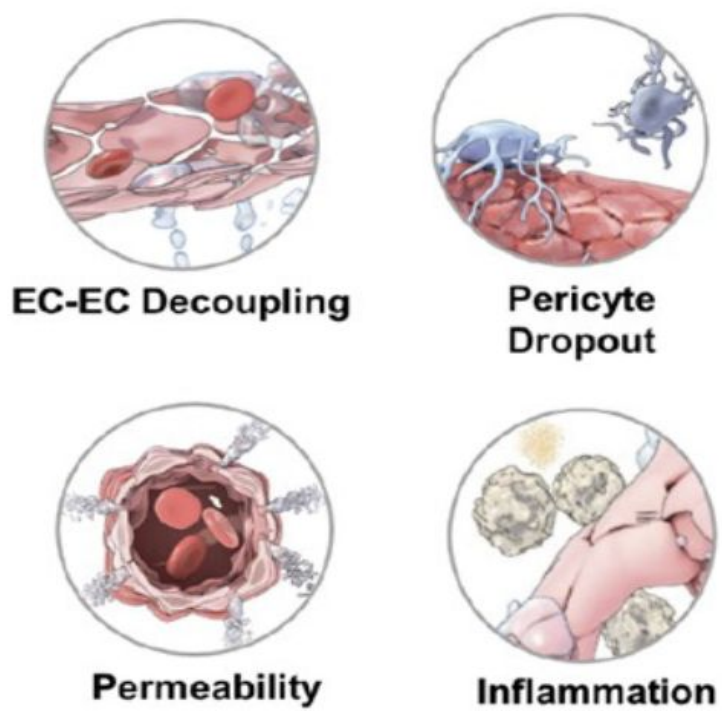
Regula JT, et al. *EMBO Mol Med*. 2016;8:1265–88, with correction in Regula JT, et al. *EMBO Mol Med*. 2019;11:e10666; Wykoff CC, et al. *Lancet*. 2022;399:741–55.

VEGF-A and Ang-2 Have Synergistic Functions in Neovascularization

⬆ VEGF-A
Neovascularization / Permeability



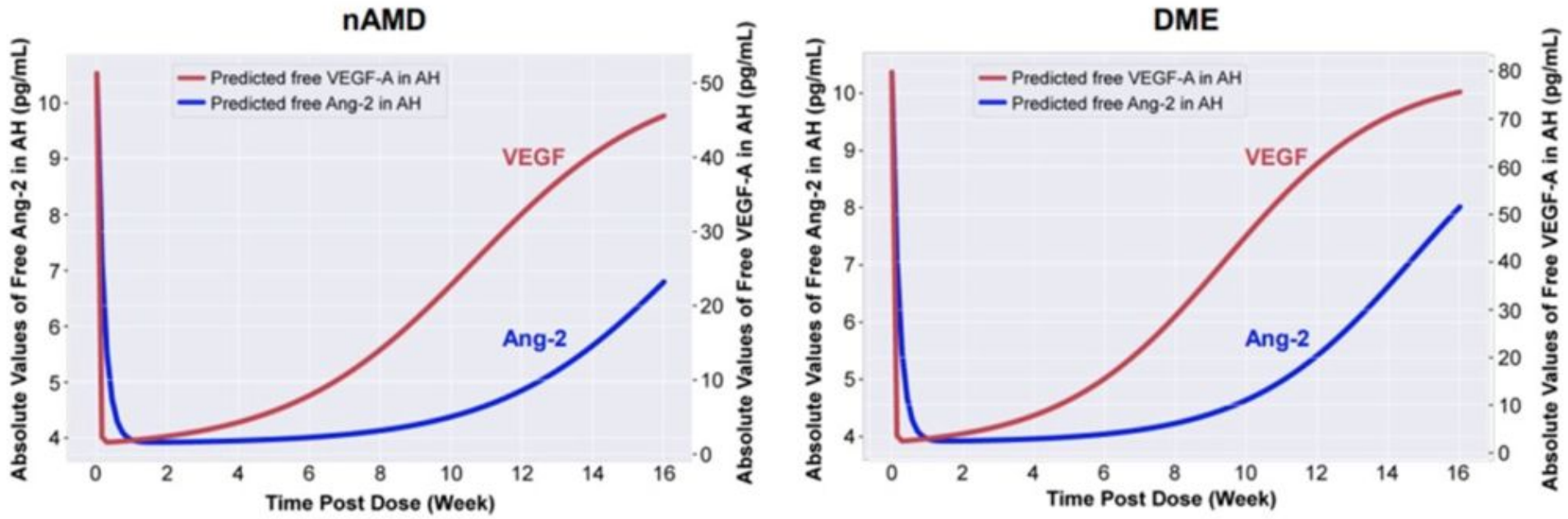
⬆ Ang-2
Vascular Instability



Ang-2, angiopoietin-2; EC, endothelial cell; VEGF, vascular endothelial growth factor

The Angiogenesis Foundation. www.scienceofang2.org/white-paper. Accessed 2/21/23.

Faricimab nodrošina ātru un noturīgu VEGF-A un Ang-2 intraokulārās līmeņa samazināšanos



AH, aqueous humor

Avery RL et al. Presented at: The American Academy of Ophthalmology Annual Meeting; Chicago, IL; 10/3/22.

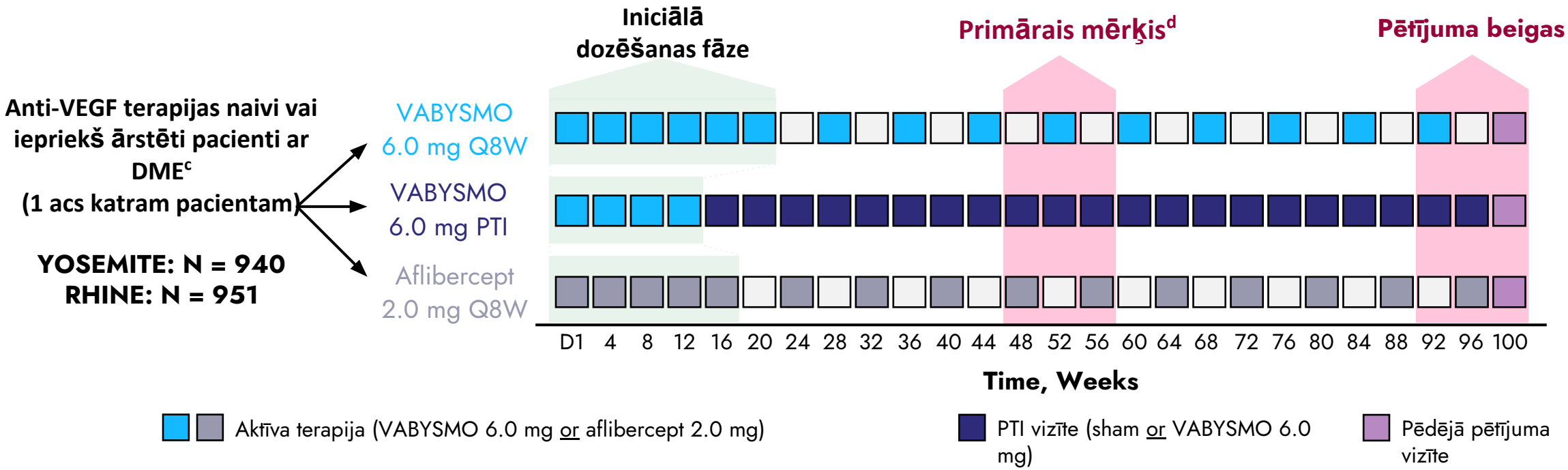
YOSEMITE un RHINE pētīja VABYSMO, lietojot Q8W vai izmantojot personalizēto dozēšanas intervālu līdz Q16W

YOSEMITE un RHINE

- 3. fāzes globāli, randomizēti, dubultmaskēts pētījums
- Pacienti ar centrālas izcelsmes DME (**CST ≥ 325 µm**)[a]
- **BCVA 25–73 ETDRS burti** (Snellen BCVA ~20/320–20/40)[b]

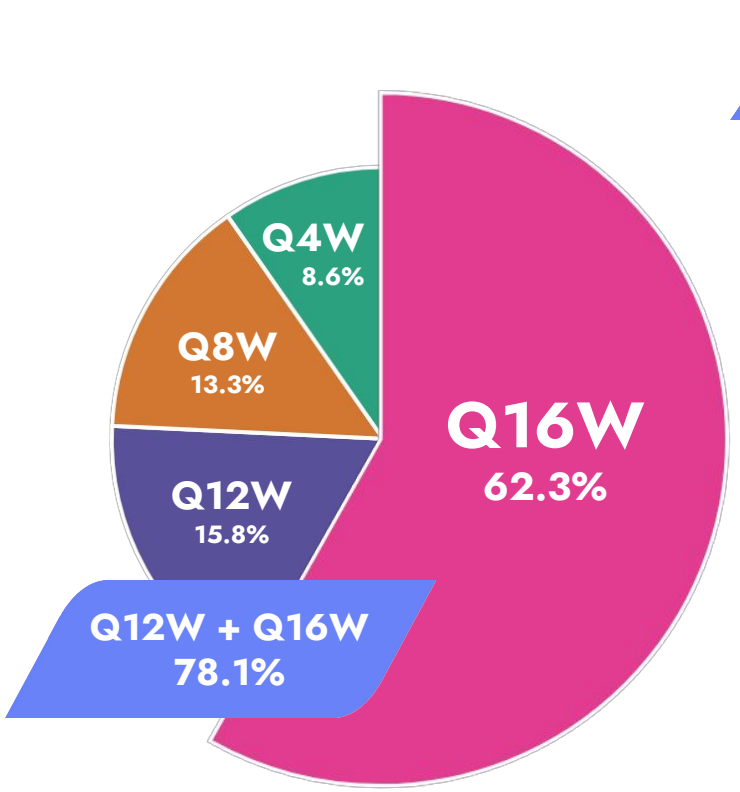
PTI ievades režīms

- Ārstēt un pagarināt dozēšanas režīms
- Intervāli piemērojami (**no Q4W līdz Q16W**) pamatojoties uz CST un BCVA izmaiņām aktīvo devu vizītēs



- [a] CST was measured as the distance from the internal limiting membrane to Bruch's membrane. [b] BCVA was measured using the ETDRS visual acuity chart at a starting distance of 4 m. [c] Previously anti-VEGF-treated eyes (treated ≥ 3 months before day 1) were limited to 25% of the total enrolment. [d] Primary efficacy endpoint: Adjusted mean BCVA change from baseline at 1 year, averaged over Weeks 48, 52, and 56.
BCVA, best-corrected visual acuity; CST, central subfield thickness; D, day; DME, diabetic macular edema; ETDRS, Early Treatment Diabetic Retinopathy Study; PTI, personalised treatment interval; Q4W, every 4 weeks; Q8W, every 8 weeks; Q16W, every 16 weeks; VEGF, vascular endothelial growth factor.
- Wykoff CC, et al. *Lancet*. 2022;399:741–55 (including Supplementary appendix).

96. nedēļā > 60% ar VABYSMO - ārstēti pacienti sasniedza ievadi Q16W un ~80% sasniedza ievadi ≥ Q12W



Vidējais injekciju skaits 2. gadā (60.–96. nedēļa)[b]

VABYSMO PTI: 3 injekcijas

VABYSMO Q8W: 5 injekcijas

Aflibercept Q8W: 5 injekcijas

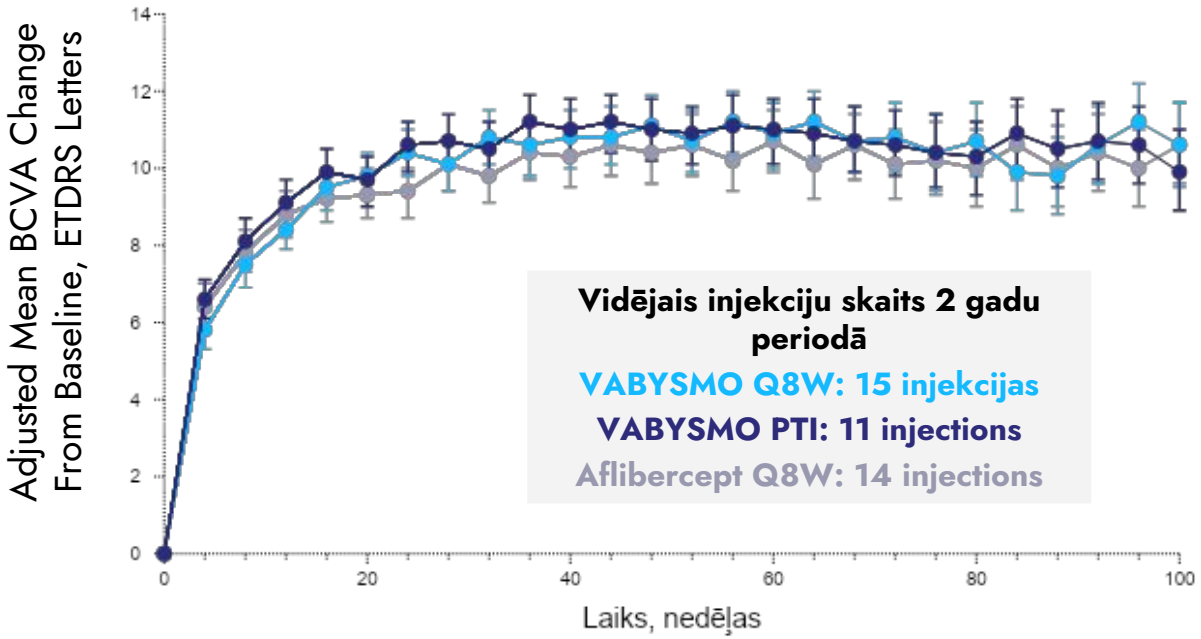
[a] Proportion of patients in the pooled faricimab PTI arms on Q4W, Q8W, Q12W, or Q16W dosing at Week 96, among those who had not discontinued the study at the Week 96 visit. [b] Results are presented for the pooled YOSEMITE/RHINE safety evaluable population (faricimab Q8W, n = 630; faricimab PTI, n = 632; aflibercept Q8W, n = 625).

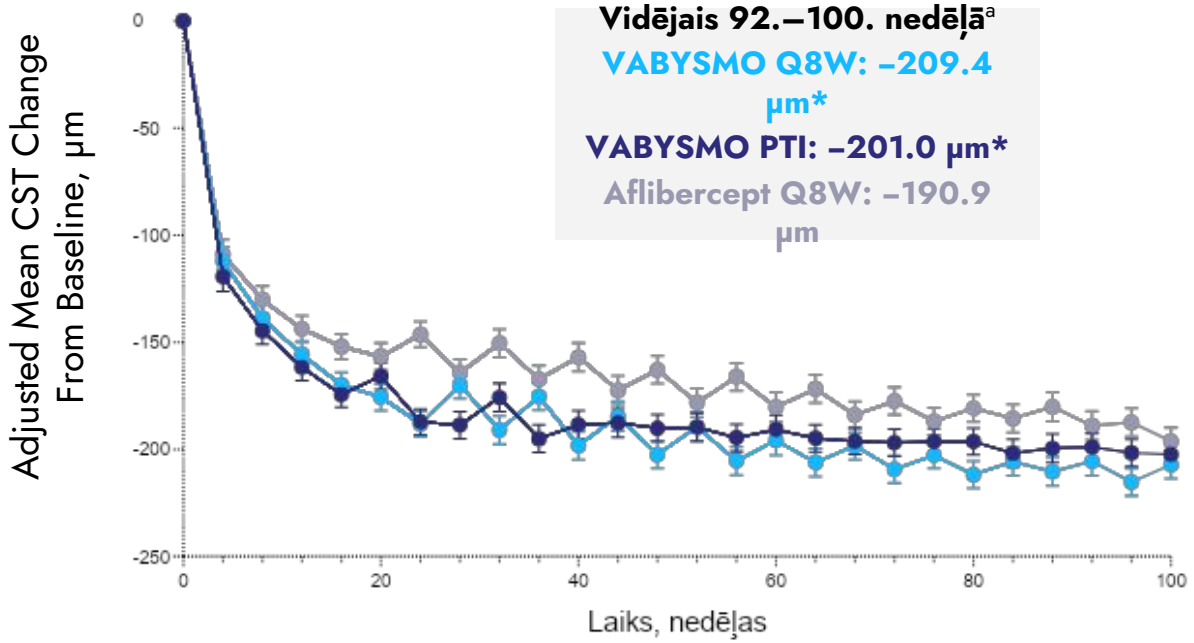
PTI, personalised treatment interval; Q4W, every 4 weeks; Q8W, every 8 weeks; Q12W, every 12 weeks; Q16W, every 16 weeks.

Baumal CR, et al. AAO, Chicago, IL. 30 September–3 October 2022.

Redzes uzlabošanās un izteiktāka CST samazināšanās ar VABYSMO saglabājās 2 gadu garumā vs aflibercept

YOSEMITE/RHINE Pooled





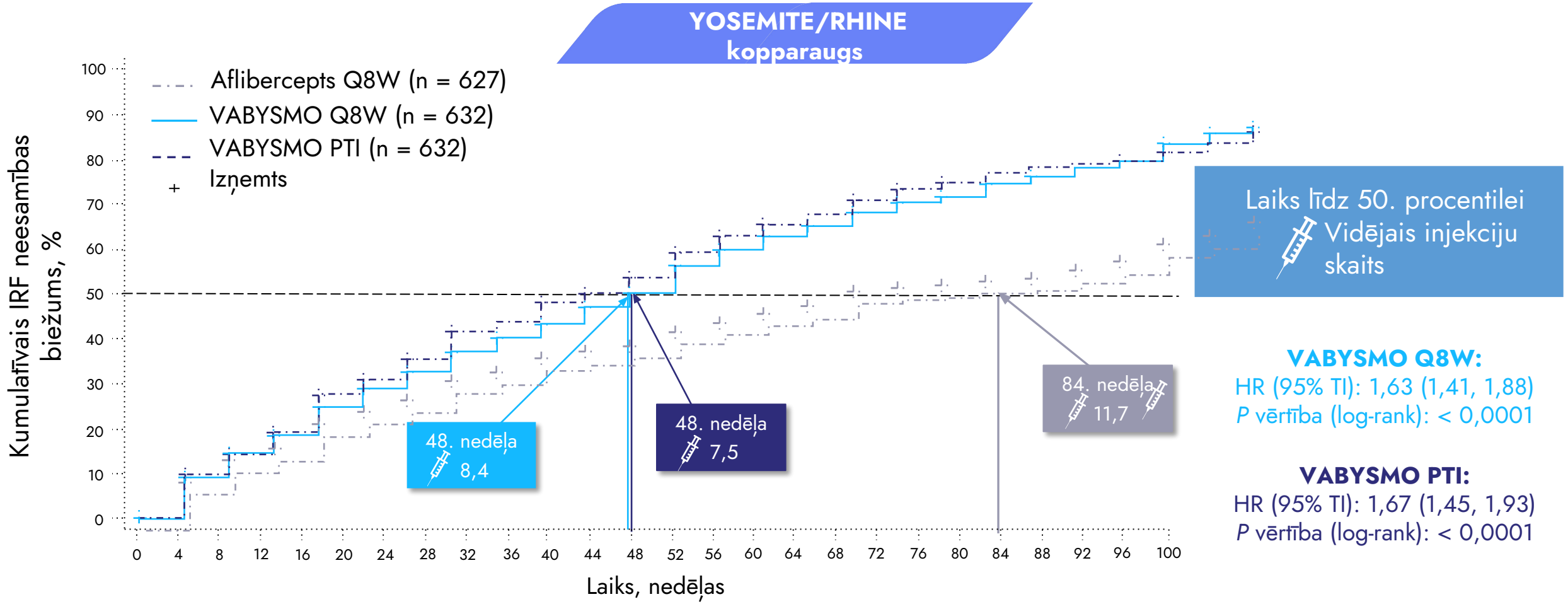
Aflibercept Q8W (n = 627) VABYSMO Q8W (n = 632) VABYSMO PTI (n = 632)

•Test for superiority: * Nominal *P* < 0.05 versus aflibercept Q8W. *P* values are nominal and not adjusted for multiplicity; no formal statistical conclusion should be made based on the *P* values. Clinical significance has not been established and conclusions regarding treatment effect cannot be drawn. [a] Adjusted mean change from baseline at 2 years, averaged over Weeks 92, 96, and 100. Results are based on a mixed model for repeated measures analysis, adjusted for treatment group, visit, visit-by-treatment group interaction, baseline BCVA or CST (continuous) as applicable, baseline BCVA (< 64 vs ≥ 64 ETDRS letters), prior intravitreal anti-VEGF therapy (yes vs no), region (United States and Canada, Asia and rest of the world), and study (YOSEMITE vs. RHINE). 95% CI error bars are shown.

•BCVA, best-corrected visual acuity; CST, central subfield thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; PTI, personalised treatment interval; Q8W, every 8 weeks; VEGF, vascular endothelial growth factor.

•Khurana RN, et al. The Retinal Society Annual Scientific Meeting, Pasadena, CA. 2–5 November 2022.

Lielākam skaitam ar VABYSMO Q8W līdz Q16W ārstēto pacientu IRF neesamība tika sasniegta ātrāk un ar mazāku injekciju skaitu nekā ar aflibercepta (*post hoc*)



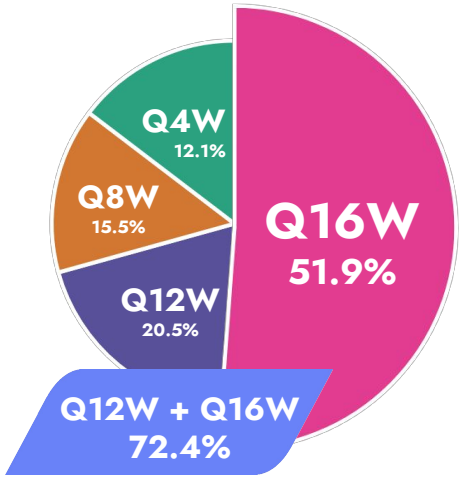
Kopsavilkumi par laiku līdz pirmajai intraretinālā šķidruma neesamībai ir Kaplan-Meier aplēses.
IRF — intraretinālais šķidrums; PTI — personalizēts terapijas intervāls; Q8W — ik pēc 8 nedēļām; Q16W — ik pēc 16 nedēļām.
Khurana RN, et al. The Retinal Society Annual Scientific Meeting, Pasadena, CA. 2–5 November 2022.

96. nedēļā > 60% ar VABYSMO-ārstēti pacienti sasniedza ievadi Q16W un ~80% sasniedza ievadi ≥ Q12W

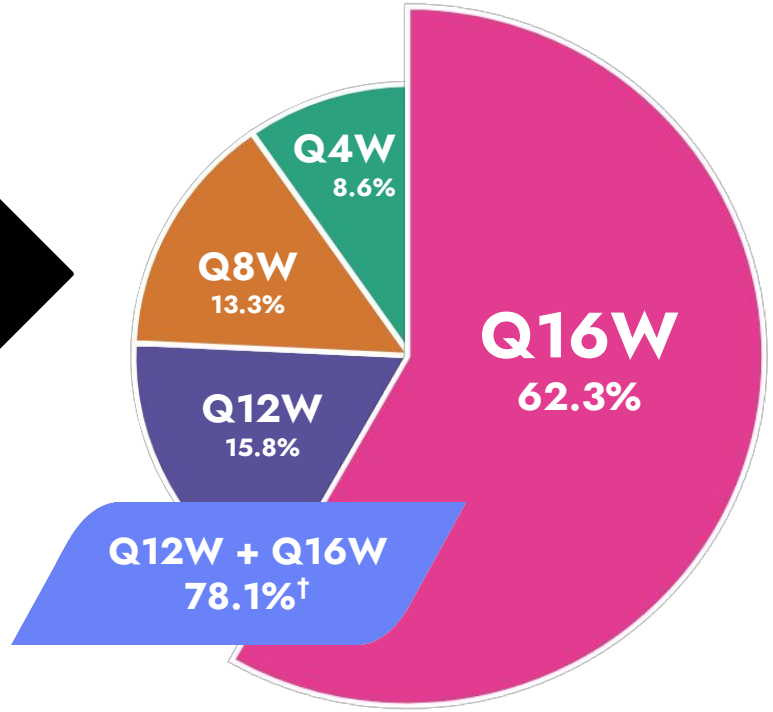
YOSEMITE/RHINE Pooled (N = 632)

VABYSMO grupas terapijas intervāli:

52. nedēļa*



96. nedēļa



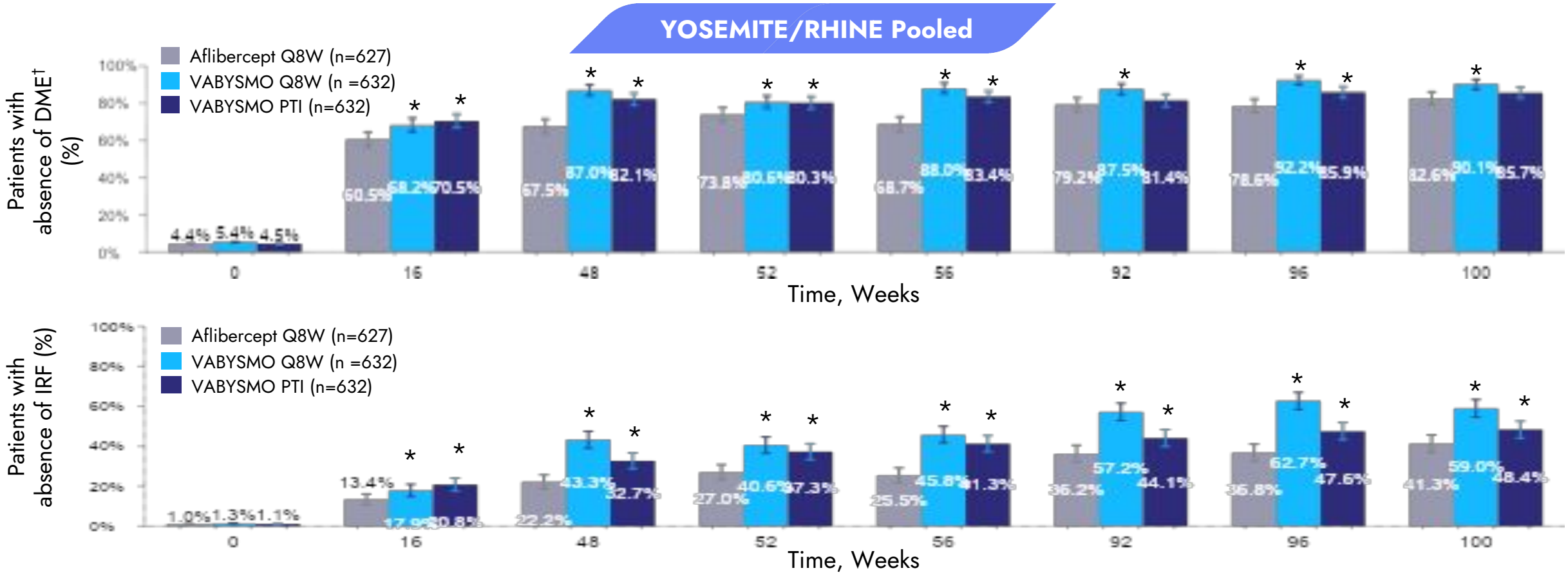
- **Vidējais injekciju skaits 2.gadā**
- **VABYSMO Q8W: 5 injekcijas**
- **VABYSMO PTI: 3 injections**
- **Aflibercept Q8W: 5 injections**

•Percentages are based on number of patients randomised to the VABYSMO arm who had not discontinued the study at the Week 52 and Week 96 visit. Treatment interval was defined as the treatment interval decision made at that visit; *based on the primary analysis; †sum of Q12W and Q16W percentages shown; calculated proportion of patients who achieved Q12W or Q16W dosing at Week 96 is 78.049%.

•PTI, personalised treatment interval; QxW, every x weeks.

•Wong TY, et al. EURETINA, Hamburg, Germany. 1–4 September 2022.

Vairāk pacientu sasniedza DME (CST <325 µm)† izzušanu un IRF izzušanu ar VABYSMO Q8W un PTI līdz Q16W vs aflibercept Q8W 2 gadu laika periodā‡



•CMH test for superiority: * Nominal p<0.05 versus aflibercept Q8W; nominal p>0.05 where no asterisk is shown; p values are nominal and not adjusted for multiplicity; no formal statistical conclusion should be made based on the p values. Clinical significance has not been established, and conclusions regarding treatment effect cannot be drawn; † Absence of DME was defined as CST <325 µm, measured as the distance from the internal limiting membrane to Bruch's membrane. Weighted proportions were estimated using the CMH method, stratified by baseline BCVA (<64 vs ≥64 ETDRS letters), prior intravitreal anti-VEGF therapy (yes vs no), region (United States and Canada vs rest of the world), and study (YOSEMITE vs RHINE). Baseline values are not weighted; 0% of patients had absence of DME at screening, which was up to 28 days ahead of baseline. Weighted proportions for the aflibercept Q8W arm presented for the VABYSMO Q8W versus aflibercept Q8W comparison; ‡ In general, a numerically greater proportion of patients receiving VABYSMO achieved an absence of DME and IRF over time compared with aflibercept. 95% CI error bars are shown. BCVA, best-corrected visual acuity; CMH, Cochran-Mantel-Haenszel; CST, central subfield thickness;
DME, diabetic macular edema; ETDRS, Early Treatment Diabetic Retinopathy Study; IRF, intraretinal fluid; PTI, personalised treatment interval; QxW, every x weeks; VEGF, vascular endothelial growth factor.

•Wong TY, et al. EURETINA, Hamburg, Germany. 1–4 September 2022.

YOSEMITE un RHINE pierādīja noturīgu efektivitāti kontrolētā slimības periodā, lietojot faricimab režīmā līdz 1 x 16 nedēļās

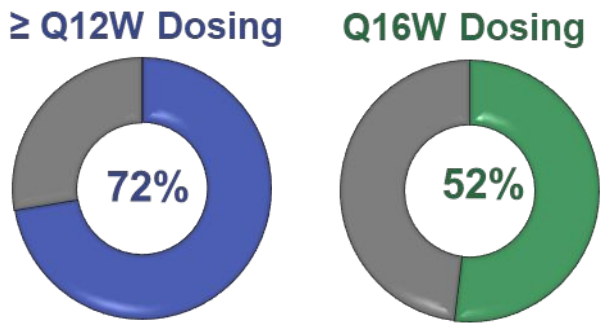
Faricimab

Faricimab darbojas uz **vairākiem signālceļiem,** veicinot **asinsvadu stabilitāti,** kā rezultātā tiek panākts ilgstošāks terapijas efekts, vienlaikus **saglabājot redzes uzlabošanos ilgterminā**

Redzes uzlabošanās ilgterminā

BCVA uzlabošnās, salīdzinot ar sākotnējiem datiem sasniedza **> 50% pacientu no faricimab PTI grupas ievades režīmā Q16W** 52. terapijas nedēļā

Ilgstošs efekts līdz ievadei 1 x 16 ned. Faricimab PTI grupā



DME slimības kontrole

Agrīni un uzlaboti anatomiskie rādītāji faricimab grupā, salīdzinot ar aflibercept:

- **Izmaiņas CST rādītājos** izteiktākas faricimab
- Vairāk pacienti sasniedza **DME izzušanu**[a]
- Vairāk pacienti sasniedza **IRF izzušanu**

Drošuma rādītāji

Faricimab bija labi panesams. **Nav ziņoti vaskulīta vai okluzīva retinīta gadījumi**

Ilgtermiņa rezultāti

YOSEMITE un RHINE 2-gadu pētījumi. The RHONE-X ilgtermiņa pagarinājuma pētījums, kurš sniegs datus par 4 gadu terapiju

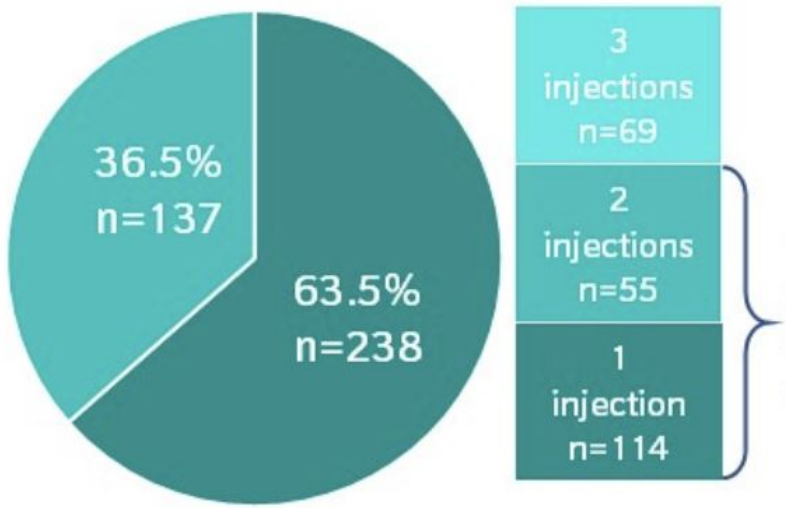
[a] Absence of DME was defined as CST < 325 µm, measured as the distance from the internal limiting membrane to Bruch's membrane.
BCVA, best-corrected visual acuity; CST, central subfield thickness; DME, diabetic macular edema; IRF, intraretinal fluid; PTI, personalized treatment interval; Q12W, every 12 weeks; Q16W, every 16 weeks.

YOSEMITE RHINE

FARETINA-DME (IRIS® Registry Data)

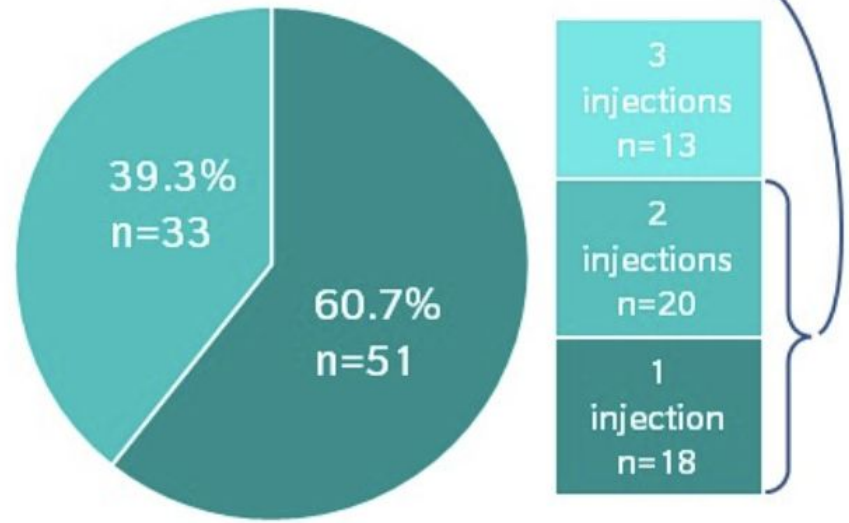
- Most eyes previously treated with anti-VEGF, 20/40 or better vision
- Most eyes extended dosing interval >6 wk after 2 injections
- VA stable over 4 injections

Previously treated eyes with ≥4 injections (n=375)



- 1-3 initial injections at >6 wk intervals
- 4 initial injections at 2-6 wk intervals

Treatment-naïve eyes with ≥4 injections (n=84)



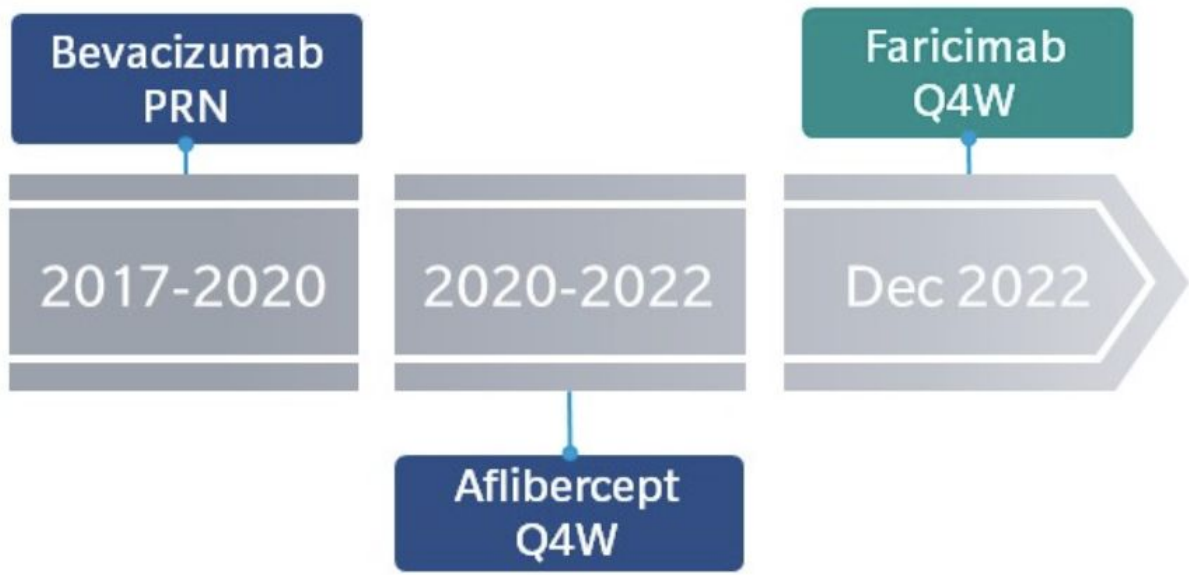
- 1-3 initial injections at >6 wk intervals
- 4 initial injections at 2-6 wk intervals

VA, visual acuity

Ali F et al. Presented at: Hawaiian Eye and Retina; Kauai, HI; 1/17/23.

65-Y-Old Woman With DME OU

- **DME OU diagnosed 2017**
- **Baseline BCVA**: 20/60
- **Ocular history**: Vision stable (20/50-20/60) past year
- **Patient background**: Presented in 2022, after moving from Houston, TX
  - Has received injections Q4W >1 y before moving

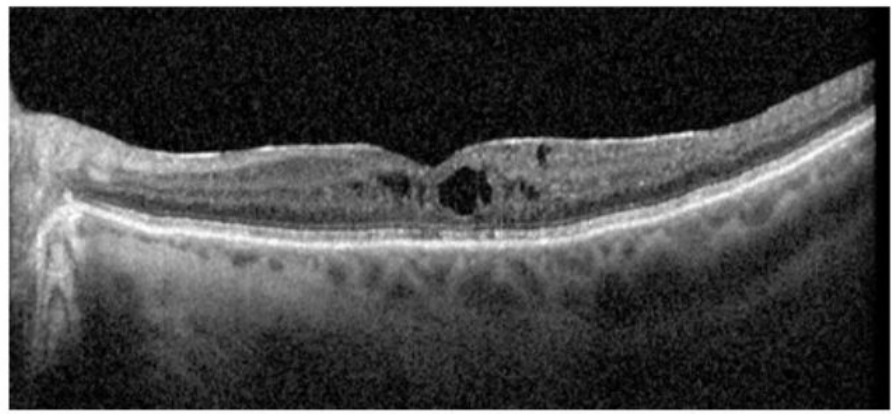


OU, both eyes; PRN, pro re nata

Case study courtesy of Arshad M. Khanani, MD, MA

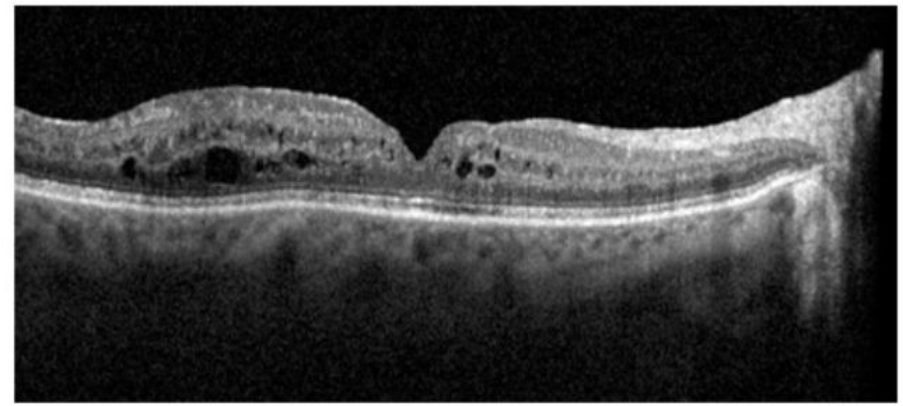
Baseline, 4 Wk After Last Aflibercept Injection

OS



March 4, 2022
BCVA 20/60;
CST 317 µm
Baseline, 4 wk after last aflibercept injection

OD

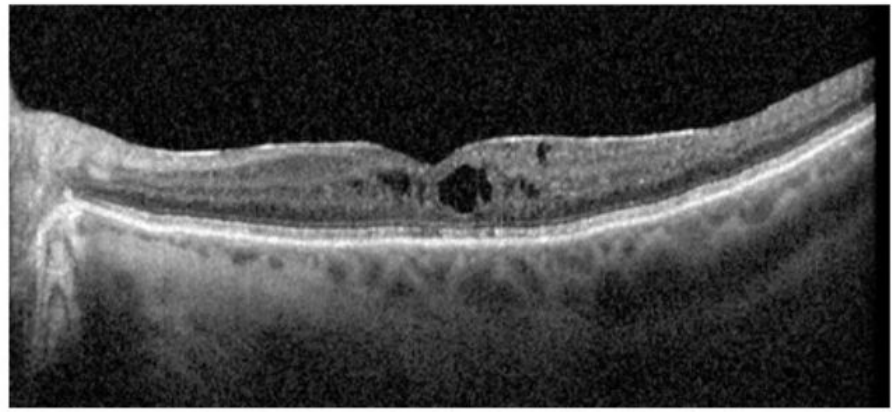


March 4, 2022
BCVA 20/50;
CST 330 µm
Baseline, 4 wk after last aflibercept injection

Case study courtesy of Arshad M. Khanani, MD, MA

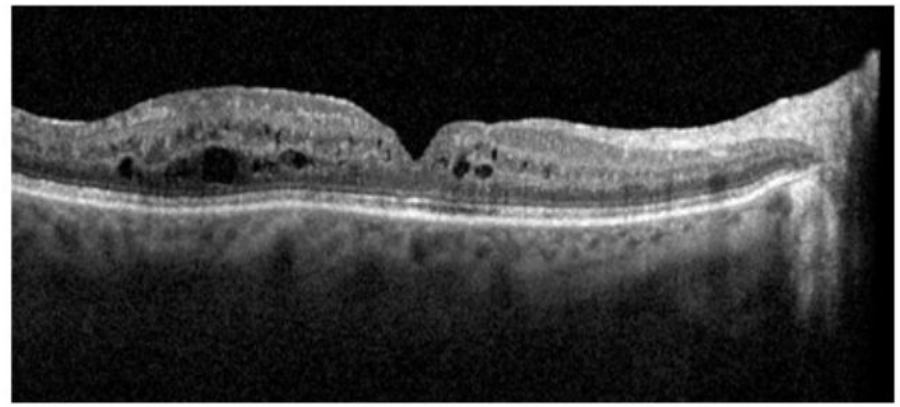
OS Treated With Faricimab Q4W

Baseline



March 4, 2022
BCVA 20/60;
CST 317 µm
Faricimab #1 given

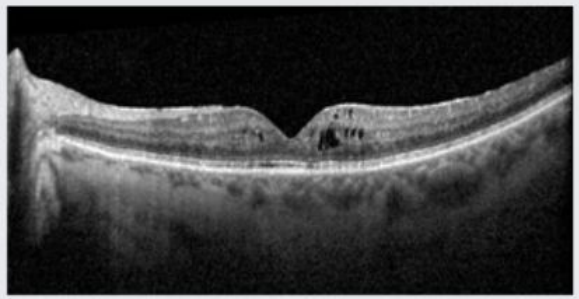
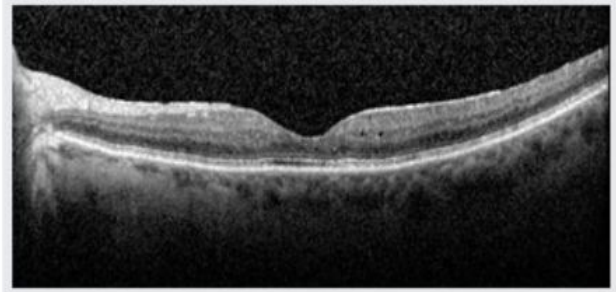
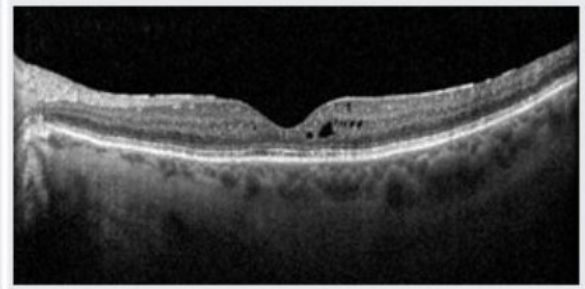
4 Wk After Faricimab #1



Apr 1, 2022
BCVA 20/60;
CST: 275 µm
Faricimab #2 given

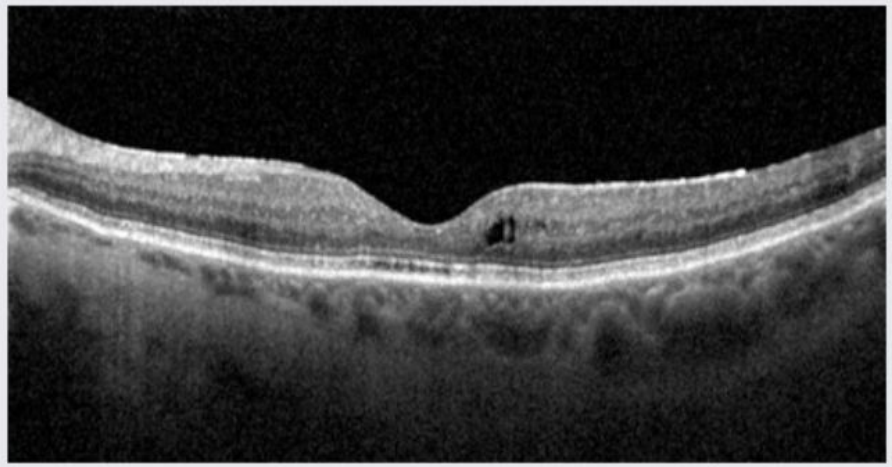
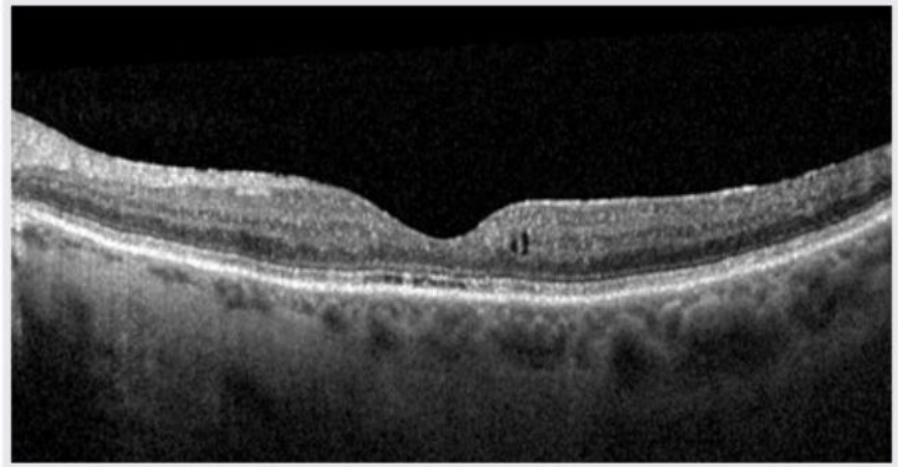
Case study courtesy of Arshad M. Khanani, MD, MA

OS Treated With Faricimab Q4W

May 10, 2022 5 Wk After Faricimab #2		June 7, 2022 4 Wk After Faricimab #3		July 8, 2022 4 Wk After Faricimab #4	
BCVA: 20/40	**CST:** 275 µm	**BCVA:** 20/40	**CST:** 217 µm	**BCVA:** 20/30	**CST:** 234 µm
					
Faricimab #3 given		Faricimab #4 given		Faricimab #5 given	

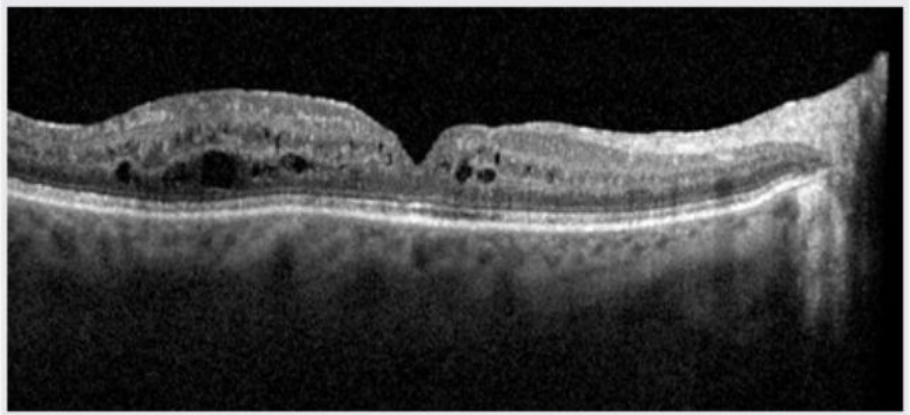
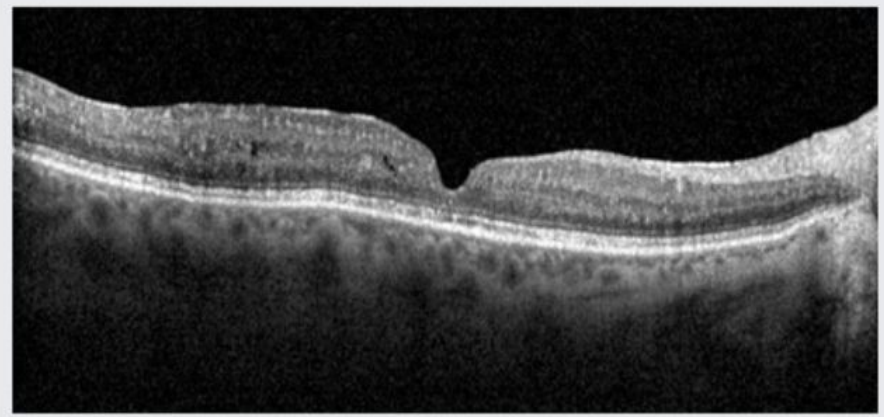
Case study courtesy of Arshad M. Khanani, MD, MA

OS Treatment Interval Extended to Q8W

Aug 5, 2022 4 Wk After Faricimab #5		Oct 7, 2022 8 Wk After Faricimab #6	
BCVA: 20/40	**CST:** 234 µm	**BCVA:** 20/30	**CST:** 219 µm
			
Faricimab #6 given		Faricimab #7 given	

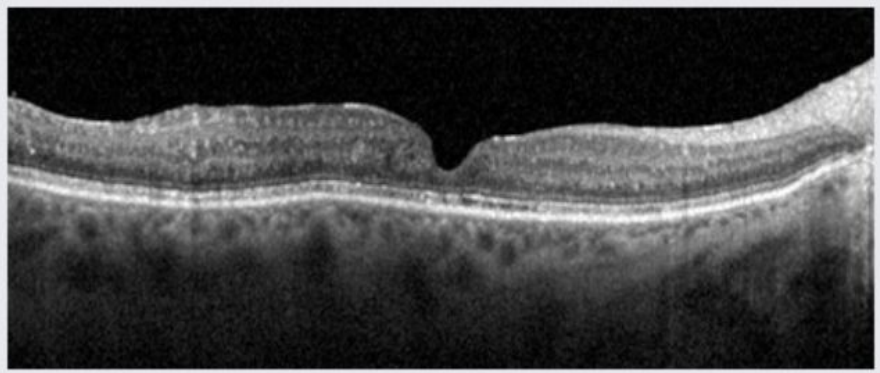
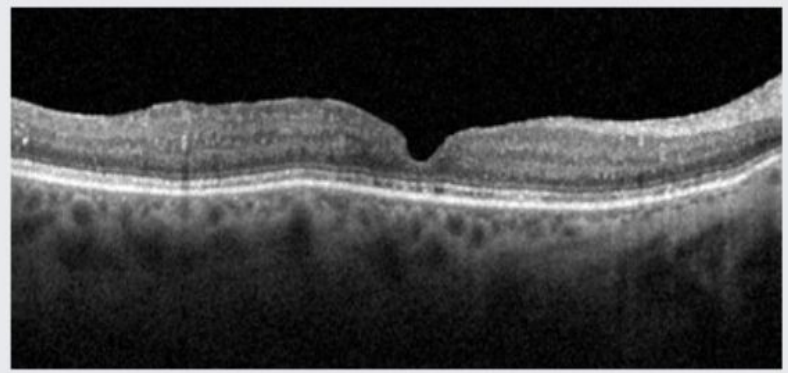
Case study courtesy of Arshad M. Khanani, MD, MA

OD Treated With Faricimab Q4W

Mar 4, 2022 4 Wk After Last Aflibercept		Apr 1, 2022 4 Wk After Faricimab #1	
BCVA: 20/50	**CST:** 330 µm	**BCVA:** 20/30	**CST:** 219 µm
			
Faricimab #1 given		Faricimab #2 given	

Case study courtesy of Arshad M. Khanani, MD, MA

OD Treatment Interval Extended to Q8W

Aug 5, 2022 4 Wk After Faricimab #5		Oct 7, 2022 8 Wk After Faricimab #6	
BCVA: 20/30	**CST:** 243 µm	**BCVA:** 20/40	**CST:** 231 µm
			
Faricimab #6 given		Faricimab #7 given	

Case study courtesy of Arshad M. Khanani, MD, MA

Summary: Patient With DME OU Switched to Faricimab Q4W, Extended to Q8W

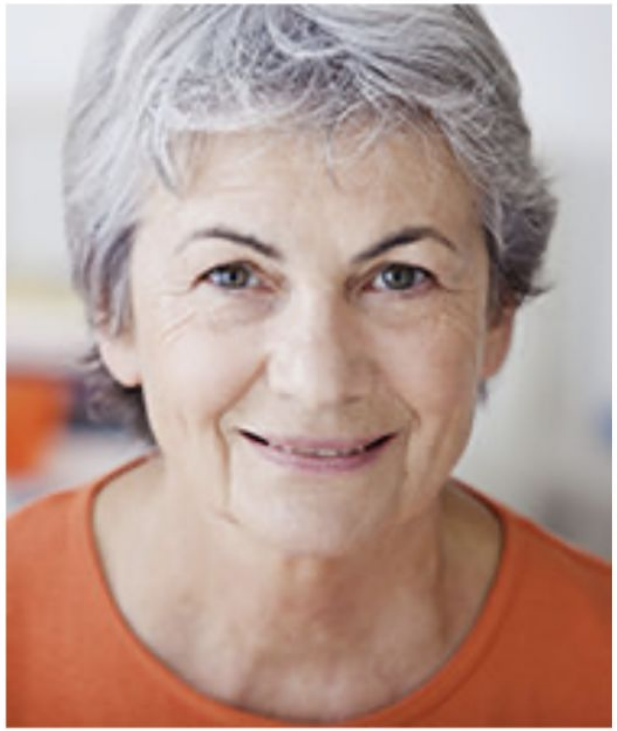
OS		OD	
4 wk after last aflibercept	Most recent visit	4 wk after last aflibercept	Most recent visit
BCVA: 20/60	BCVA: 20/30	BCVA: 20/50	BCVA: 20/40
CST: 317 µm	CST: 219 µm	CST: 330 µm	CST: 231 µm

- Patient with DME switched to faricimab Q4W, then extended to Q8W between March and October 2022
- Patient continuing Q8W treatment, plan to extend further
- No new safety signals observed

Case study courtesy of Arshad M. Khanani, MD, MA

Patient Presentation

71-Y-Old Woman With 39-Y History of T2D



Mar 2011

- Age 60 y
- HbA1c: 7.1%
- s/p extensive PRP OU >10 y ago
- VA 20/32 OU
- IOP 17 OU mm HG
- 1+ NSC OU

June 2015

- Develops DME OD
- Initiated on aflibercept Q4W, extended to Q12W

June 2022

- Has received 33 aflibercept injections to date
- Significant DME recurrence
- Worsening vision
- Patient reluctant to shorten dosing interval

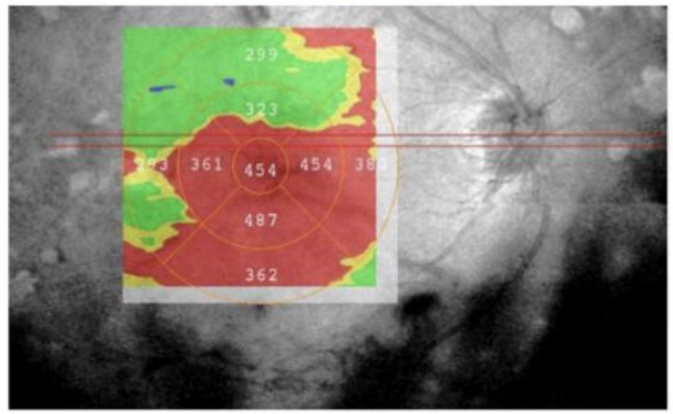
IOP, intraocular pressure; NSC, nuclear sclerotic cataract; OD, right eye; OU, both eyes; PRP, panretinal photocoagulation; Q4W, every 4 wk; Q12W, every 12 wk; s/p, status post; T2D, type 2 diabetes; VA, visual acuity

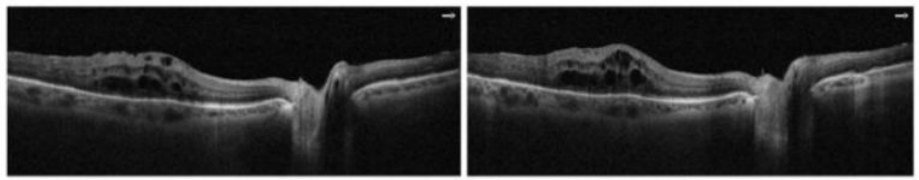
Case study courtesy of Nancy M. Holekamp, MD

Treatment Decision

Patient Is Switched to Faricimab

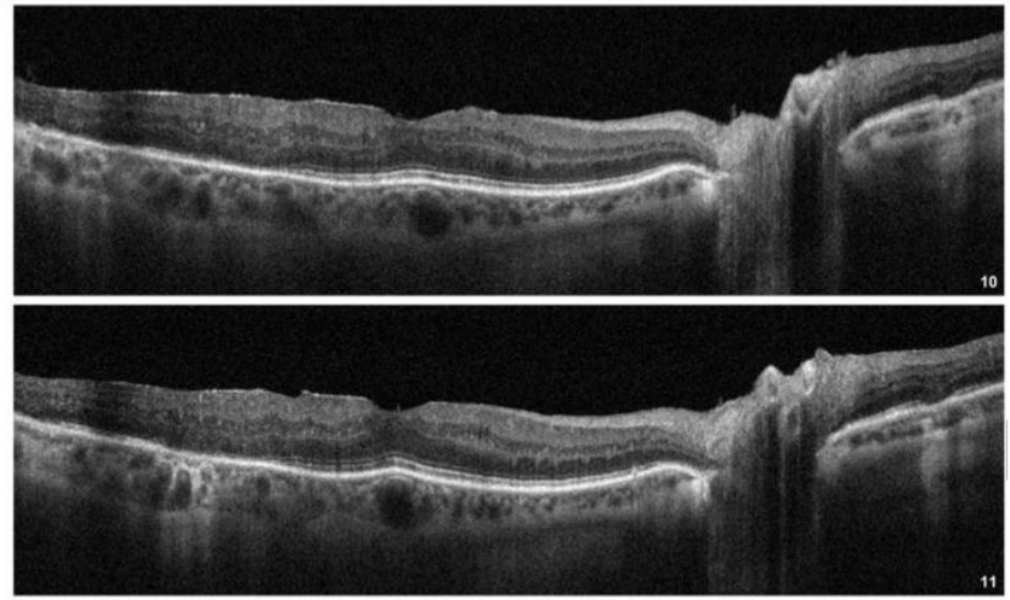
Day of Switch to Faricimab (May 5, 2022)





VA 20/63 OD

1 Mo After Faricimab (June 9, 2022)



VA 20/32^{+2} OD

Patient Presentation

74-Y-Old Woman With 8-Y History of DME OU

OS

DME diagnosis: Sept 9, 2014

Baseline BCVA: 20/40

Treated with

- 3 — Ranibizumab
- 96 — Aflibercept (Q4W, 8 y; Dec 2014–Jan 2022)
- 1 — Faricimab (Feb 28, 2022)

OD

DME diagnosis: Sept 9, 2014

Baseline BCVA: 20/40

Treated with

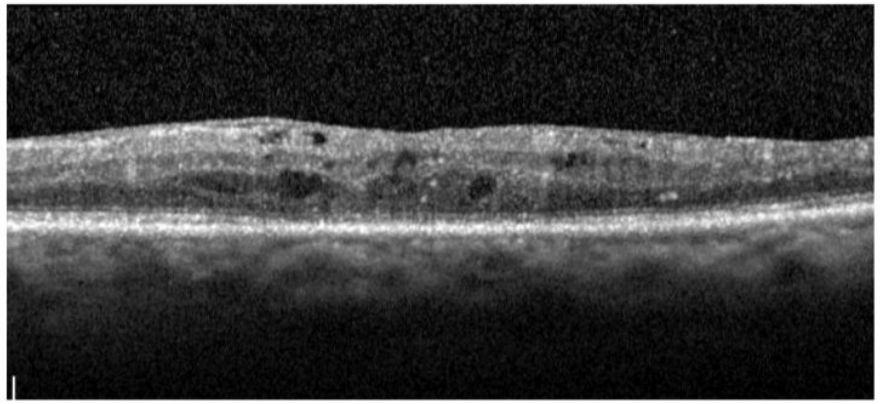
- 3 — Ranibizumab
- 96 — Aflibercept (Q4W, 8 y; Dec 2014–Jan 2022)
- 1 — Faricimab (Feb 28, 2022)

BCVA, best-corrected visual acuity; OD, right eye; OS, left eye; OU, both eyes; Q4W, every 4 wk

Case study courtesy of Nancy M. Holekamp, MD

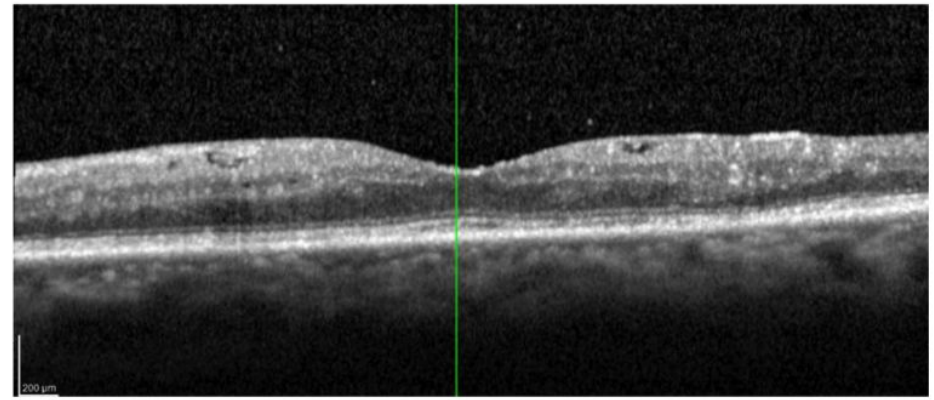
Follow Up

2-Wk Follow-up Visit (OS and OD)



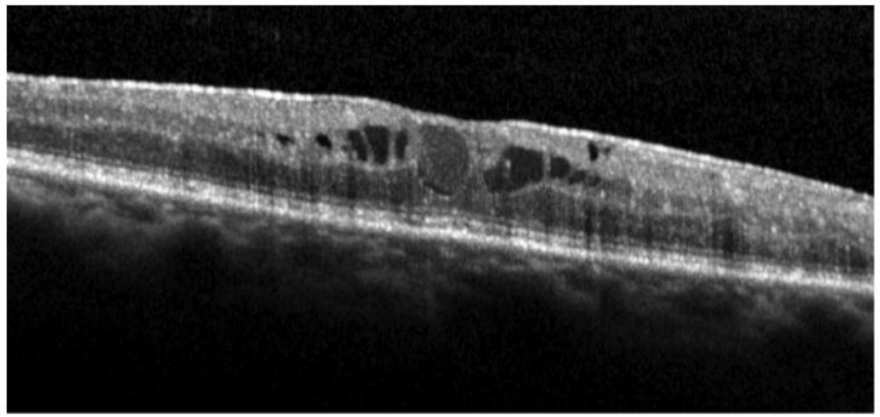
OS *Before* Faricimab

VA 20/32^{-2}
OCT: Feb 28, 2022



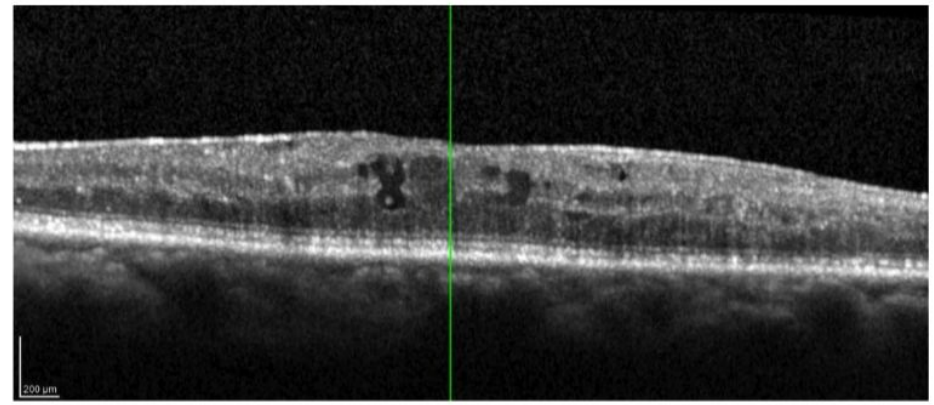
OS ≈2 Wk *After* Faricimab

VA 20/32^{-2}
OCT: Mar 16, 2022



OD *Before* Faricimab

VA 20/32^{-2}
OCT: Feb 28, 2022



OD ≈2 Wk *After* Faricimab

VA 20/32^{-2}
OCT: Mar 16, 2022

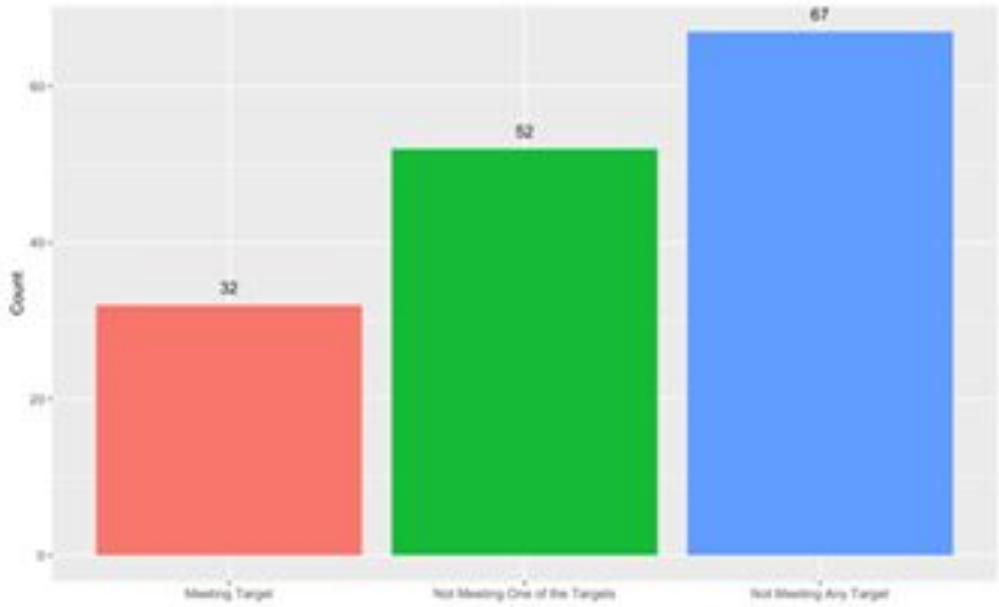
OCT, optical coherence tomography; VA, visual acuity Case study courtesy of Nancy M. Holekamp, MD

Iceland Liechtenstein Norway grants

PerDiRe

Target blood pressure

	Meeting Target (systolic & dyastolic) BP	Not Meeting One of the Targets (S or D) BP	Not Meeting Any Target	p-value
n (%)	32 (21.2)	52 (34.4)	67 (44.4)	0.0022



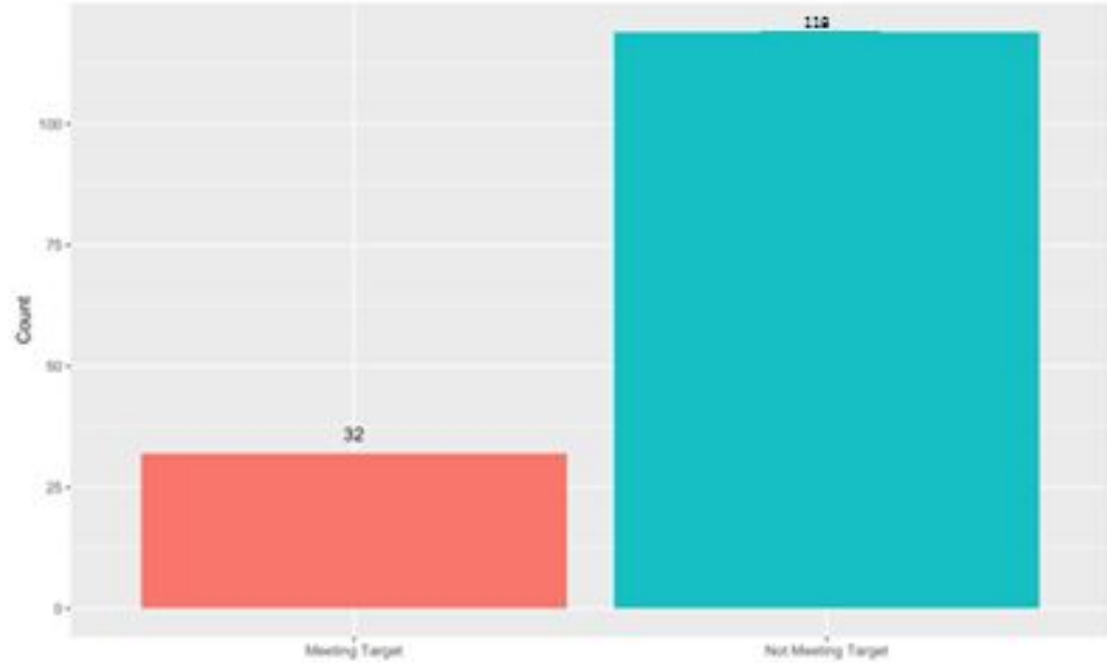
Target blood pressure

Patients that:

meet blood pressure target (<130/<80 mmHg) - 78.7%

don't meet BP target-21.3%

p<0.01




Report
Log out
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Birth Date / Sex
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Diabetes mellitus, typus I
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Retinal Camera Report
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Both Eyes
Comparison
Progression
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13:16:58 Color
36 %
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Comment
Comment

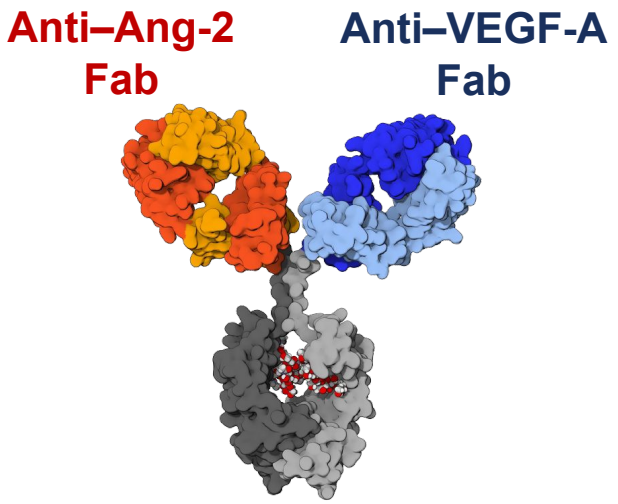
Diabētiskas makulopātijas terapija

- **Anti-VEGF/Ang-2 vai Anti-VEGF ir uzskatāmas par pirmās izvēles terapiju lielākajā daļā gadījumu ar centrālu diabētisku makulas tūsku un redzes zudumu;**

- Vispirms jāapsver novērošana acīs ar labu redzes asumu, neraugoties uz centrālu makulas tūsku ar anti-VEGF/Ang-2 vai Anti-VEGF pielietošanu gadījumā, ja redzes asums sāk samazināties;

- Jebkurā gadījumā diabētiskas makulas tūskas ārstēšanas pamatā ir laba sistēmiskās hiperglikēmijas, hiperlipidēmijas un hipertensijas kontrole

Faricimab: kopsvilkums



Jauna terapijas iespēja pacientiem ar DME, kuriem:

- Nav pietiekoša atbildes reakcija uz anti-VEGF terapiju (jauns darbības mehānisms)
- Pastāvīga slimības aktivitāte
- VA pasliktināšanās

Pēc 4 mēnešu piesātinošās devas, faricimab var ievadīt režīmā līdz reizei 16 nedēļās, atkarībā no atbildes reakcijas

DME klīniskajos pētījumos faricimab parādīja līdzvērtīgu efektivitāti Q16W ievades režīmā un slimības aktivitātes samazināšanos, salīdzinot ar aflibercept Q8W

PALDIES PAR UZMANĪBU!