Trattamento farmacologico della trazione vitreo-maculare

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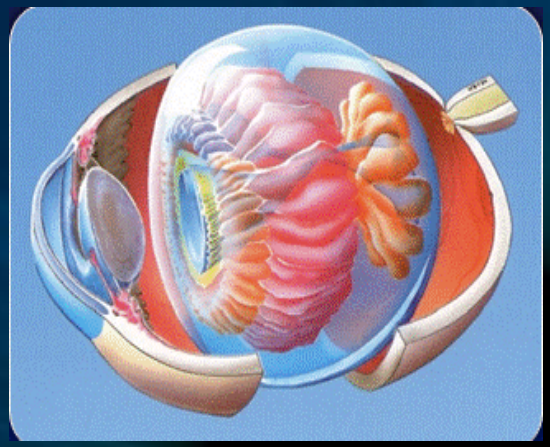
IL CORPO VITREALE[1]

- Composto per il 99% d'acqua
- 0,1 % macromolecole
  - glicoproteine
  - proteoglicani
  - collagene (tipo II,V, VI,IX e XI)
  - glicosamminoglicani
  - altre strutture proteiche (fibrillina)

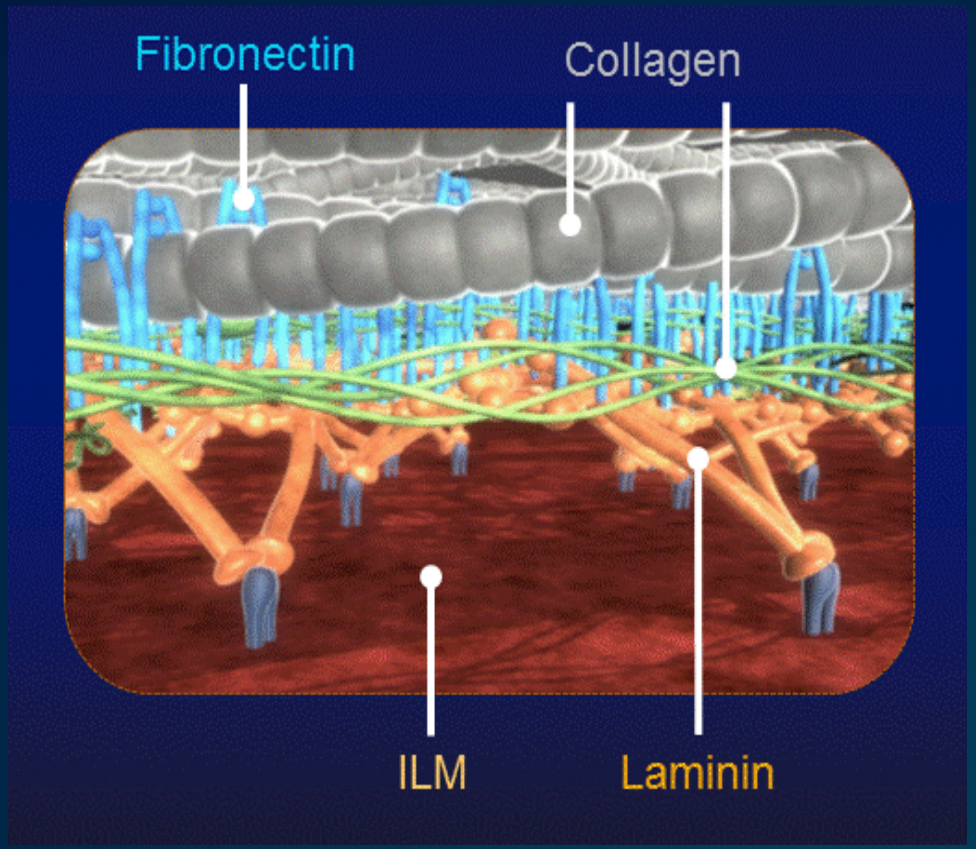


1. Ponsioen TL, et al Invest Ophthalmol Vis Sci. 2008, 49 (9): 4089-4095
Courtesy of Peter K Kaiser , MD

INTERFACCIA VITREORETINICA[1]

La corteccia vitreale è aderente alla ILM grazie alla presenza di macromolecole:

- Fibronectina
- Laminina
- Condroitin solfato
- Proteoglicani
- Collagene



Maggiore aderenza:

- Base del vitreo
- Equatore
- Al di sopra dei vasi retinici
- Disco ottico e macula

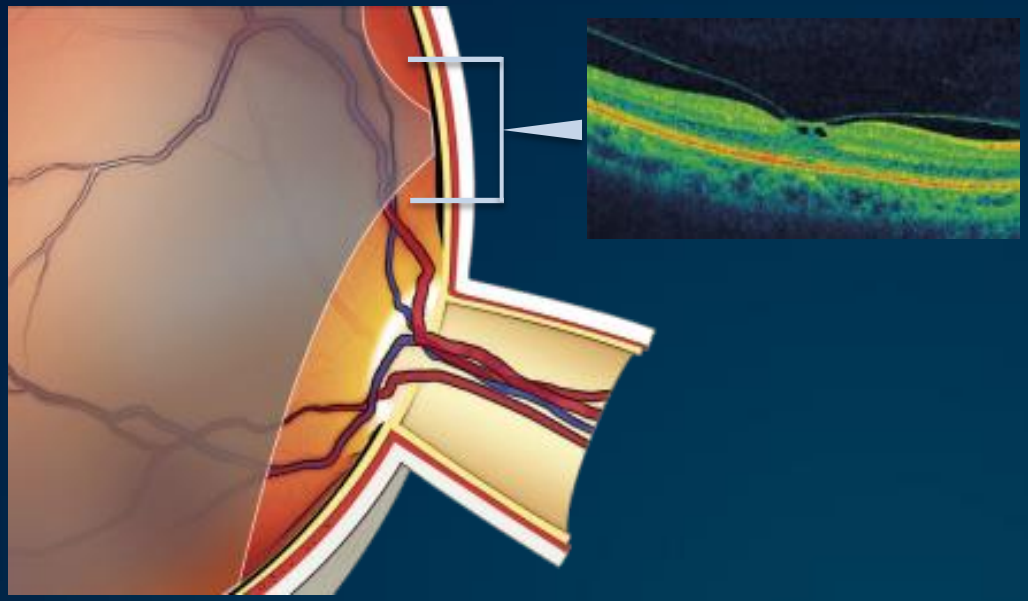
1. Ponsioen TL, et al Prog Retinal Eye Res 2010,29 580-595. Courtesy of Peter K Kaiser , MD

TRAZIONE VITREOMACULARE (VMT)

VMA: adesione del vitreo in macula senza alterazioni morfologiche

La presenza di forze tangenziali e antero-posteriori può determinare uno streching in macula

VMT



VMA in macula può indurre una VMT

1. Johnson MW. *Am J Ophthalmol* 2010;149:371

DISTACCO POSTERIORE DEL VITREO

DPV anomalo: progressione patologica

Distacco parziale del vitreo con adesioni persistenti nella regione maculare

- Forze di adesione anomale a una o più strutture del polo posteriore
- Deformazione trattiva del tessuto retinico

Anomala liquefazione o contrazione del vitreo con aumento del distacco della corteccia vitreale

Adesione anomala della corteccia vitreale alla membrana limitante interna (MLI)

oppure

Combinazione di entrambe

PVD Anomalo

Duker JS *et al. Ophthalmology* 2013;doi:10.1016/j.ophtha.2013.07.042

VMI Diseases

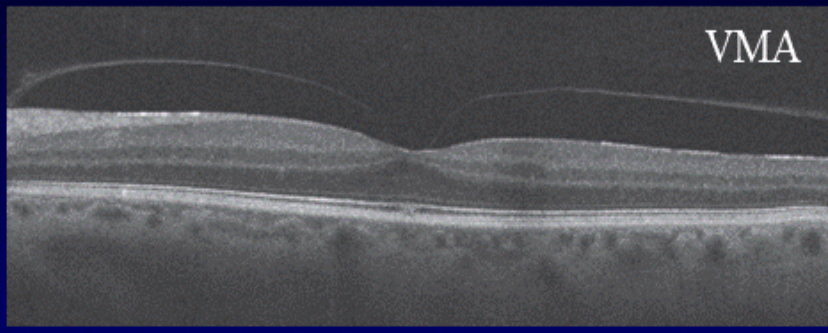
International Classification of Diseases of the Vitreomacular Interface (VMI)

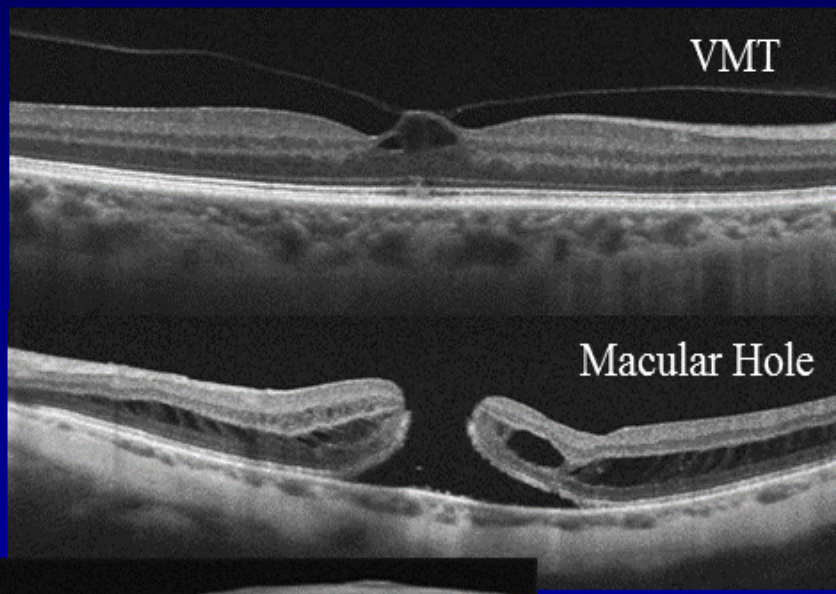
- International panel convened in 2012 to devise a new classification system for VMI disease
- Strictly Anatomic – OCT based
  - Objective
  - Not based on clinical findings
  - Not based on symptoms
- Simple, easy to use, predictive of surgical and pharmacological outcomes

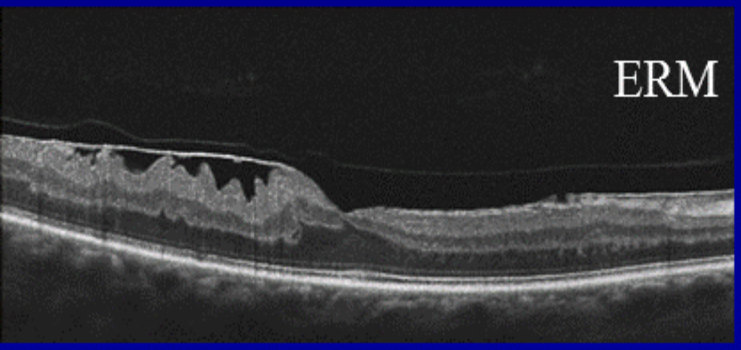
Courtesy of Jay S. Duker, M.D.

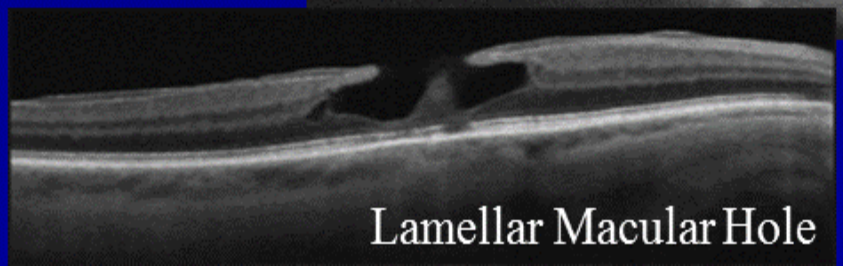
VMI Classification System: One Finding. Five Diseases.

- "Finding":
  - Vitreomacular Adhesion (VMA)
- Diseases:
  - Vitreomacular Traction (VMT)
  - Full-Thickness Macular Hole (FTMH)
  - Lamellar Macular Hole (LMH)
  - Epiretinal Membrane (ERM)



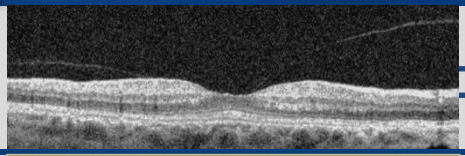
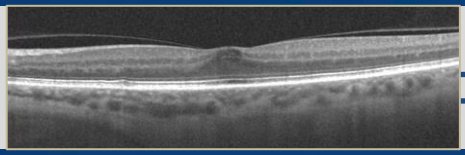
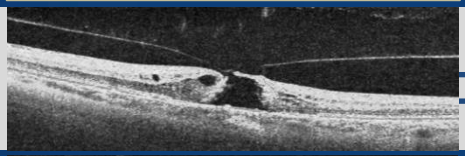
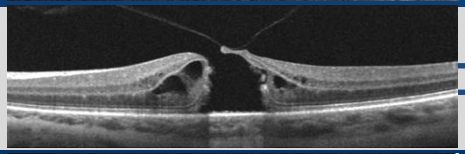
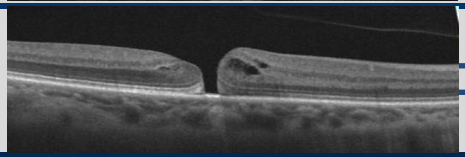






Courtesy of Jay S. Duker, M.D.

CORRELAZIONE CLASSIFICAZIONI FM

Gass[1]		NEW (IVTS)[2]
Stage 0 macular hole		VMA in contralateral eye
Stage 1 macular hole		Symptomatic VMA (or VMT)
Stage 2 macular hole		FTMH – small (≤250 µm) or medium (>250 but ≤400 µm)
Stage 3 macular hole		FTMH – medium or large (>400 µm)
Stage 4 macular hole		FTMH – No VMA can be small, medium, large

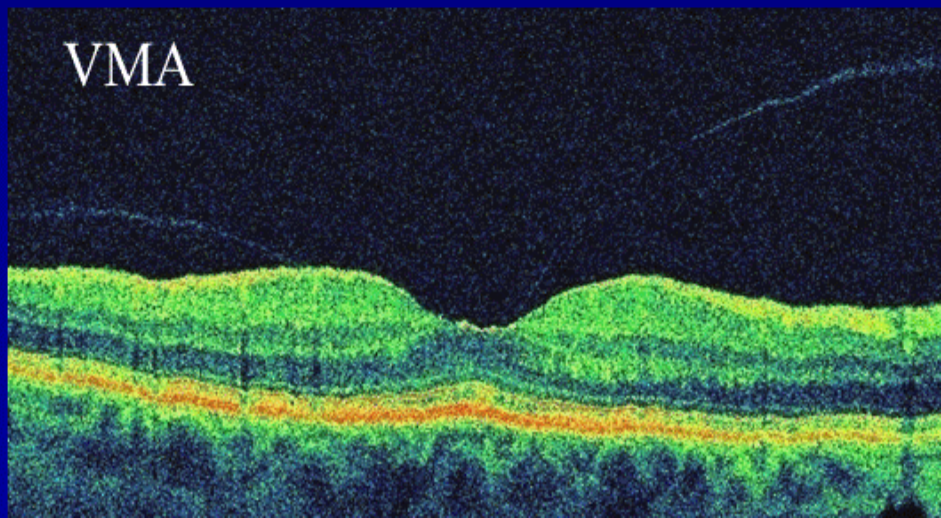
FTMH, full-thickness macular hole; VMA, vitreomacular adhesion; VMT, vitreomacular traction; IVTS, international vitreomacular traction study group

1. Wender J, Jumper JM. *Rev Ophthalmol*. February 15, 2007.
2. Duker JS, et al. *Ophthalmology*. 2013:120(12):2611-2619.

VMI Diseases

International Classification = No Stages
Stage 0 Now = VMA

- VMA in contralateral eye of a patient with FTMH – that eye has a 42 % risk of going to FTMH within 2 years
- If no VMA = 3%

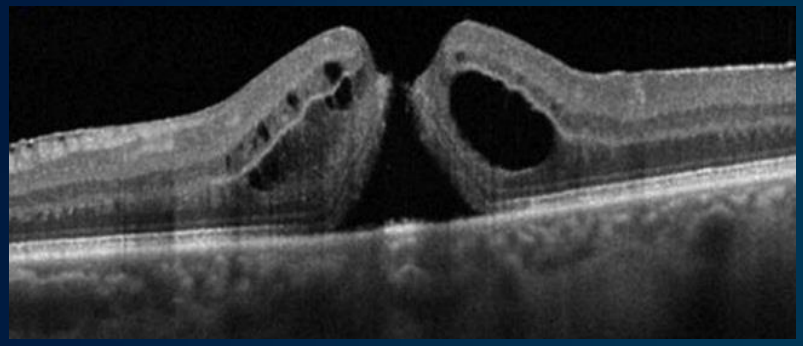


Courtesy of Jay S. Duker, M.D.

TRAZIONE VITREOMACULARE (VMT)

- VMT è implicata nella formazione di CME, ERM, e MH [1]
  - VMT focale (< 1500 µm) di solito porta alla formazione di MH , CME trazionale, e distacco di retina in fovea[2]
  - VMT ampia (> 1500 µm) è generalmente associata ad ERM, diffuso ispessimento della retina ,minor possibilità di recupero della depressione foveale[2]

Foro maculare a tutto spessore



CME, cystoid edema maculare ; ERM, epiretinal membrane; MH, macular hole; VMT, vitreomacular traction

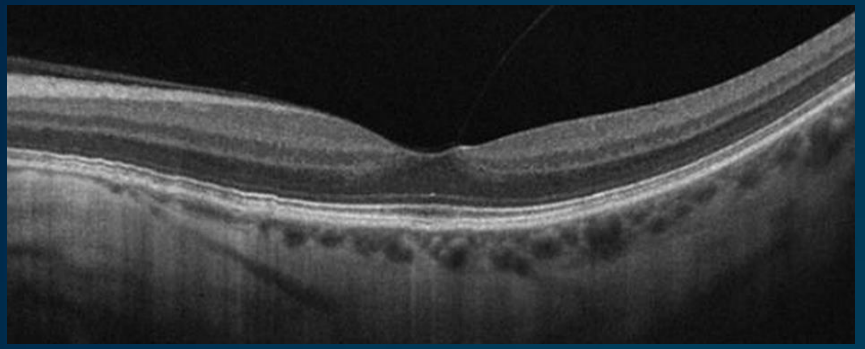
1. Shechtman DL, Dunbar MT. *Optometry* 2009;80:681
2. Bottós J *et al*. *J Ophthalmic Vis Res* 2012;7:148

SINTOMI E DIAGNOSI DI TRAZIONE VITREOMACULARE

- I sintomi variano da lieve visione offuscata con metamorfopsie a grave diminuzione della acuità visiva con fotopsie

- Il calo del visus può essere progressivo e svilupparsi lentamente per l'azione costante delle forze trazionali[1]

- La diagnosi di VMT è possibile grazie all'OCT[2,3] la cui alta risoluzione consente di verificare la presenza di VMA prima che i sintomi siano rilevabili



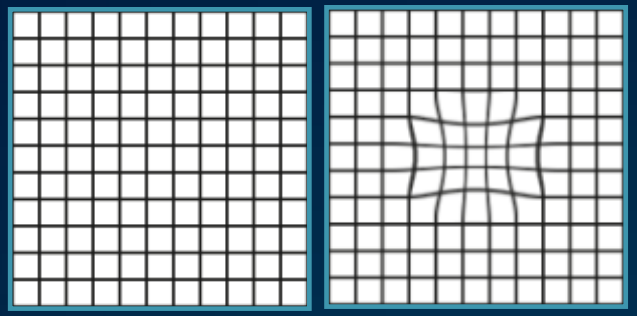
1. Bottós J *et al*. *J Ophthalmic Vis Res* 2012; 2. Stalmans P. *Retinal Physician.* 2011. 3. Carpineto P *et al*. *Eur Ophthalmic Rev* 2011;

DISTURBI VISIVI ASSOCIATI A TRAZIONE VITREOMACULARE

- Progressivo calo del visus,[1,2]

  può associarsi a :

  – Metamorfopsia (visione distorta)[1,2]
  – Fotopsia (presenza di lampi di luce)[2]
  – Micropsia (gli oggetti appaioni più piccoli della dimensione reale)[2]
  – Difetti del campo visivo centrale [1]



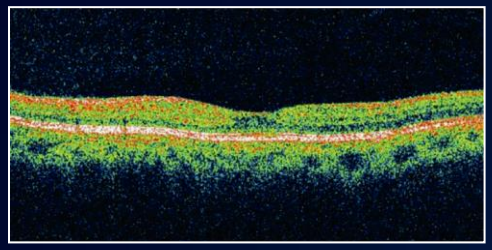
Metamorfopsia

Riduzione del visus

1. Dugel P. *Retina Today* April 2012;50
2. Hikichi T *et al. Am J Ophthalmol* 1995;119:55

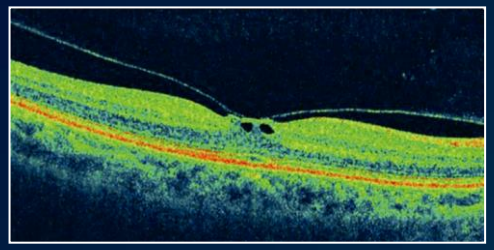
PROGRESSIONE DELLA TRAZIONE VITREOMACULARE A FORO MACULARE

OCT NORMALE



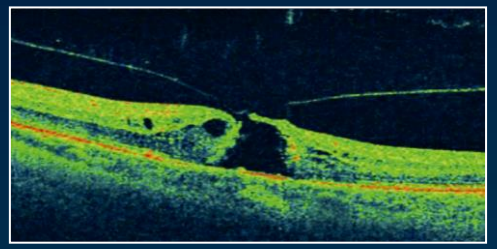
Normale visione

VMA ⇨ VMT



Metamorfopsia

VMT ⇨ foro maculare

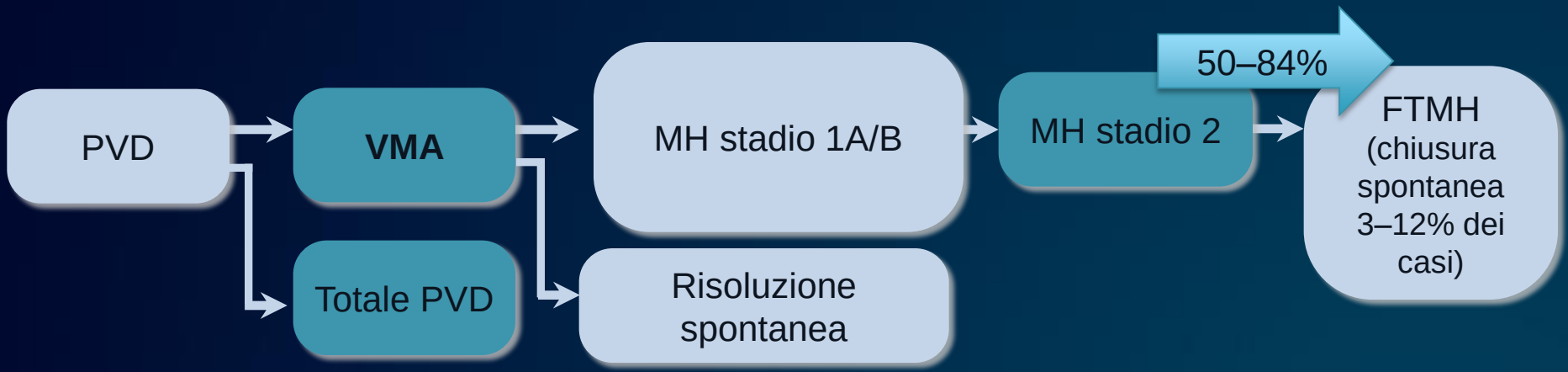


Scotoma centrale

OCT, optical coherence tomography; VMA, vitreomacular adhesion; VMT, vitreomacular traction

Epidemiologia di Adesione Vitreomaculare, Trazione Vitreomaculare e Foro maculare

- Dati epidemiologici sulla VMA, MH, e FTMH sono limitati
- L'introduzione dell' OCT ha facilitato la diagnosi di VMA incompleta e delle sue complicanze correlate[1]
- 50-84% dello stadio 2 MH passa allo stadio 3 o 4[2–5]
- La chiusura spontanea di un FTMH si verifica solo nel 3-12% dei casi [6]



1. Carpineto P *et al*. *Eur Ophthalmic Rev* 2011;5:69; 2. Guyer DR *et al. Arch Ophthalmol* 1992;110:1264; 3. Hikichi T *et al. Br J Ophthalmol* 1995;79:517; 4. Kim JW *et al. Ophthalmology* 1995;102:1818; 5. Kim JW *et al. Am J Ophthalmol* 1996;121:605; 6. American Academy of Ophthalmology Retina Panel. Preferred Practice Pattern®. Idiopathic Macular Hole, 2008. http://www.aao.org/ppp (accessed November 2012)

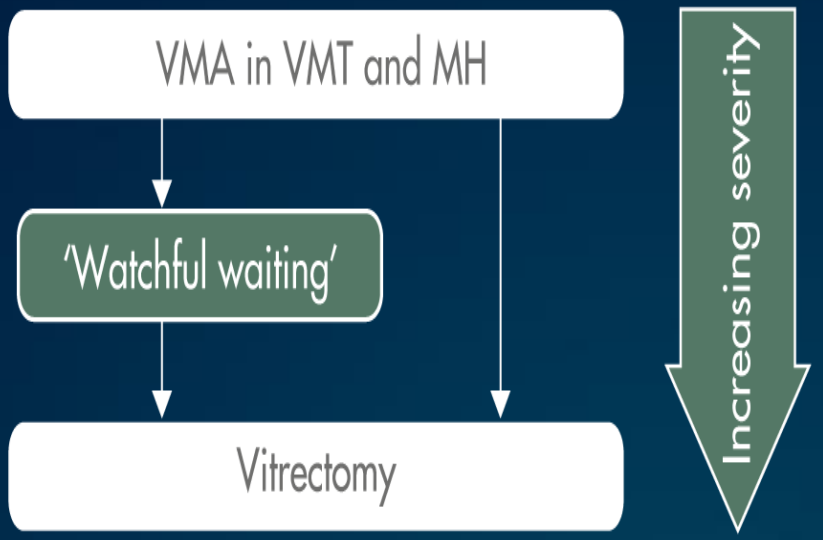
Attuali approcci terapeutici per il trattamento delle Adesioni vitreomaculari, Trazioni vitreomaculari e foro maculare

- ***"Watchful waiting"***

  Il peggioramento dei sintomi può giustificare l'intervento [1],

  ad esempio quando il paziente ha un grave rischio di perdita di visione centrale o severi disturbi visivi

- ***La chirurgia vitreoretinica è utilizzata per rimuovere l'adesione e le conseguenti forze trazionali***[2]



1. Girach A, Pakola S. *Expert Rev Ophthalmol* 2012;7:311;
2. Carpineto P *et al*. *Eur Ophthalmic Rev* 2011;5:69

I trattamenti farmacologici rappresentano una strategia alterntiva “ Watchful Waiting ”

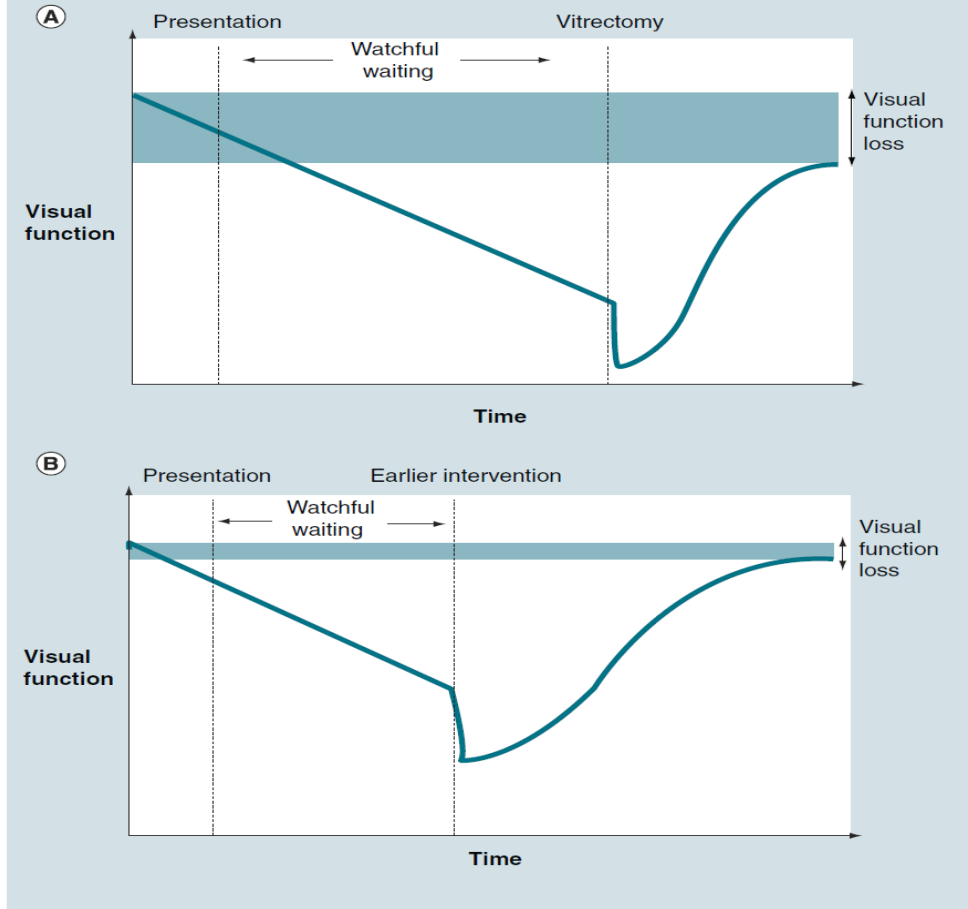


Figure 1. Progression of symptomatic vitreomacular adhesion until (A) symptoms are severe enough to warrant standard vitrectomy and (B) upon earlier intervention.

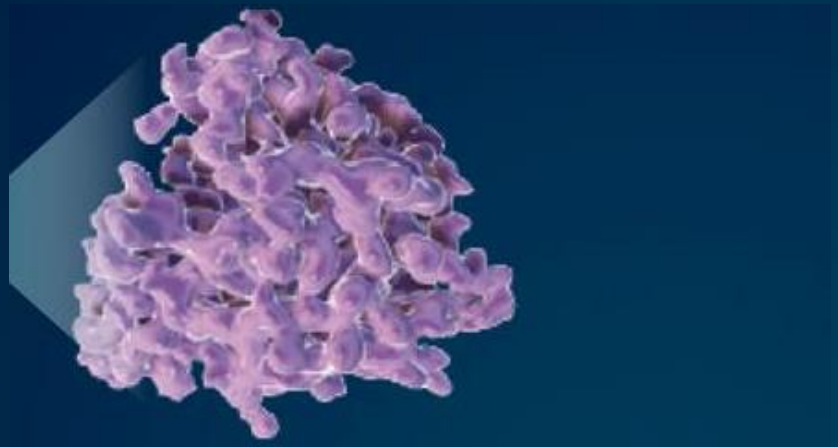
Girach A. Pakola S. Expert Rev. Ophthalmol. 7(4), 311-323 (2012)

OCRIPLASMINA

- L'Ocriplasmina (Microplasmina) è una forma tronca della plasmina umana prodotta con tecnica di DNA ricombinante , con proprietà catalitiche [1,2]

- Il bersaglio della sua attività proteolitica è rappresentato dalle componenti dell'interfaccia vitreoretinica
  - ✧ Laminina, fibronectina, collagene

Plasmin (88 kDa)



Ocriplasmin (27.2 kDa)

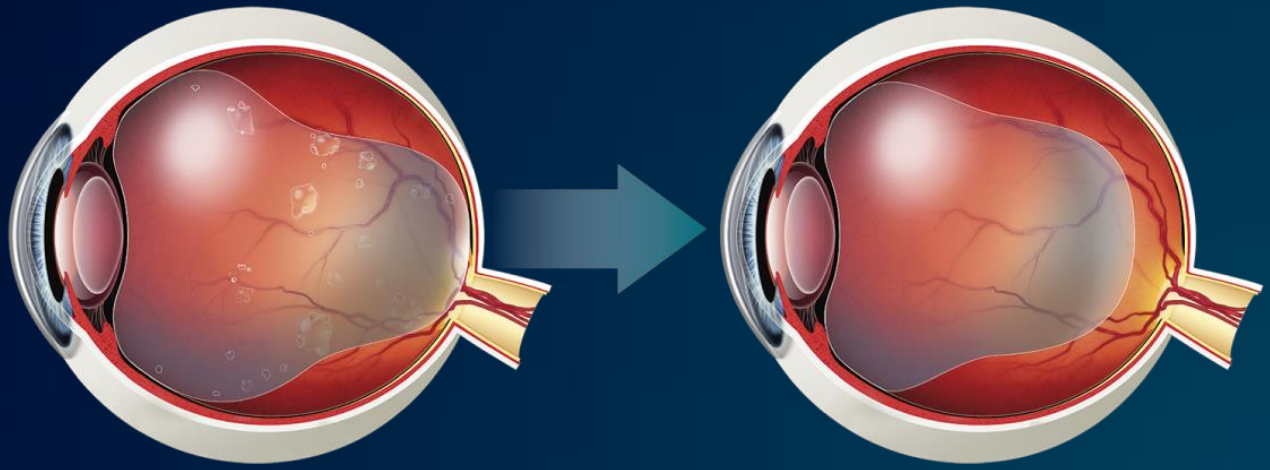
1. Nagai N *et al. J Thromb Haemost* 2003;1:307
2. de Smet M *et al. Invest Ophthalmol Vis Sci* 2009;50:814
3. Li X *et al. Graefes Arch Clin Exp Ophthalmol* 2002;240:56
4. Liotta LA *et al. Cancer Res* 1981;41:4629
5. Uemura A *et al. Arch Ophthalmol* 2005;123:209

Attività proteolitica dell' Ocriplasmina

- L' Ocriplasmina detiene l'attività enzimatica della plasmina e determina un duplice effetto :

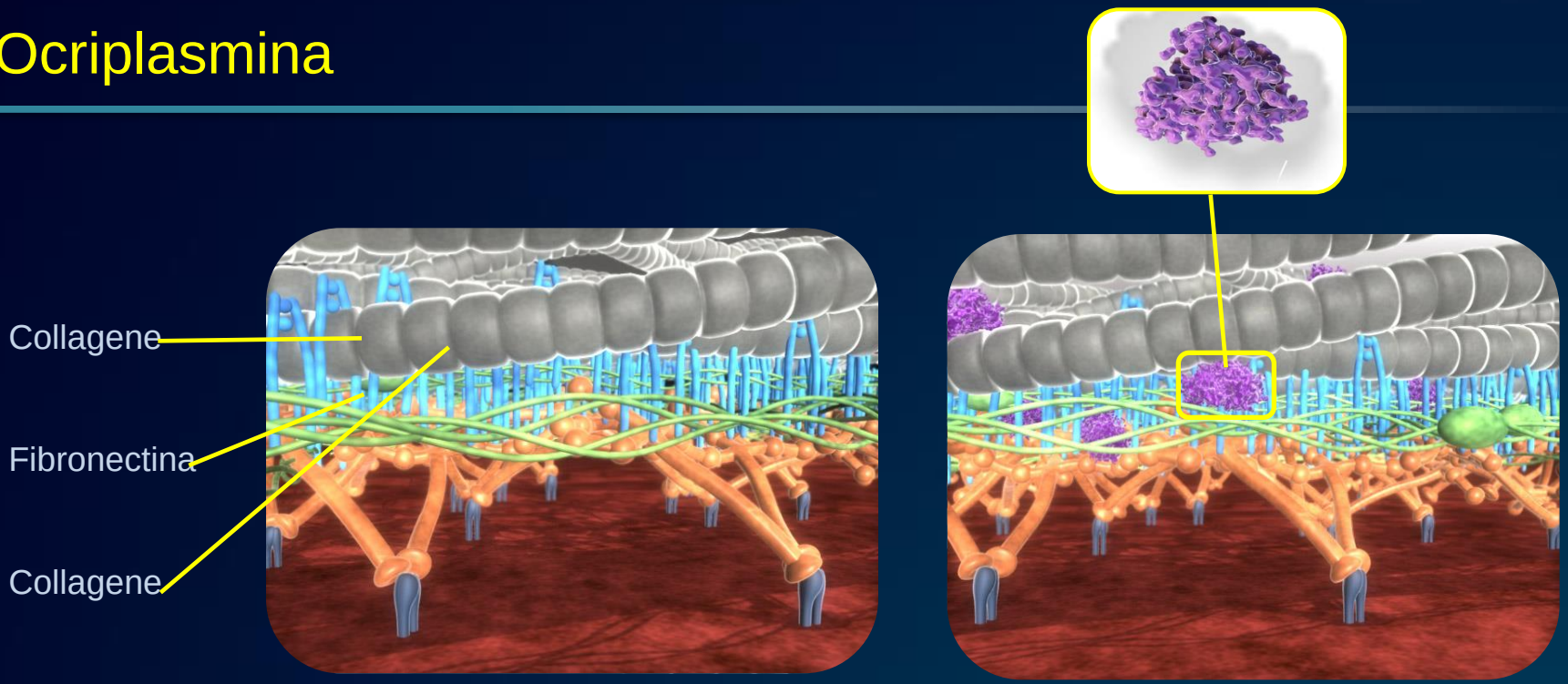
liquefazione vitreale

separazione vitreoretinica



1. Gandorfer A *et al. Invest Ophthalmol Vis Sci* 2004;45:641
2. Sebag J. *Retina Today* April 2012:55
3. de Smet MD *et al. Invest Ophthalmol Vis Sci* 2009;50:814
4. de Smet MD *et al. Ophthalmology* 2009;116:1349

Ocriplasmina

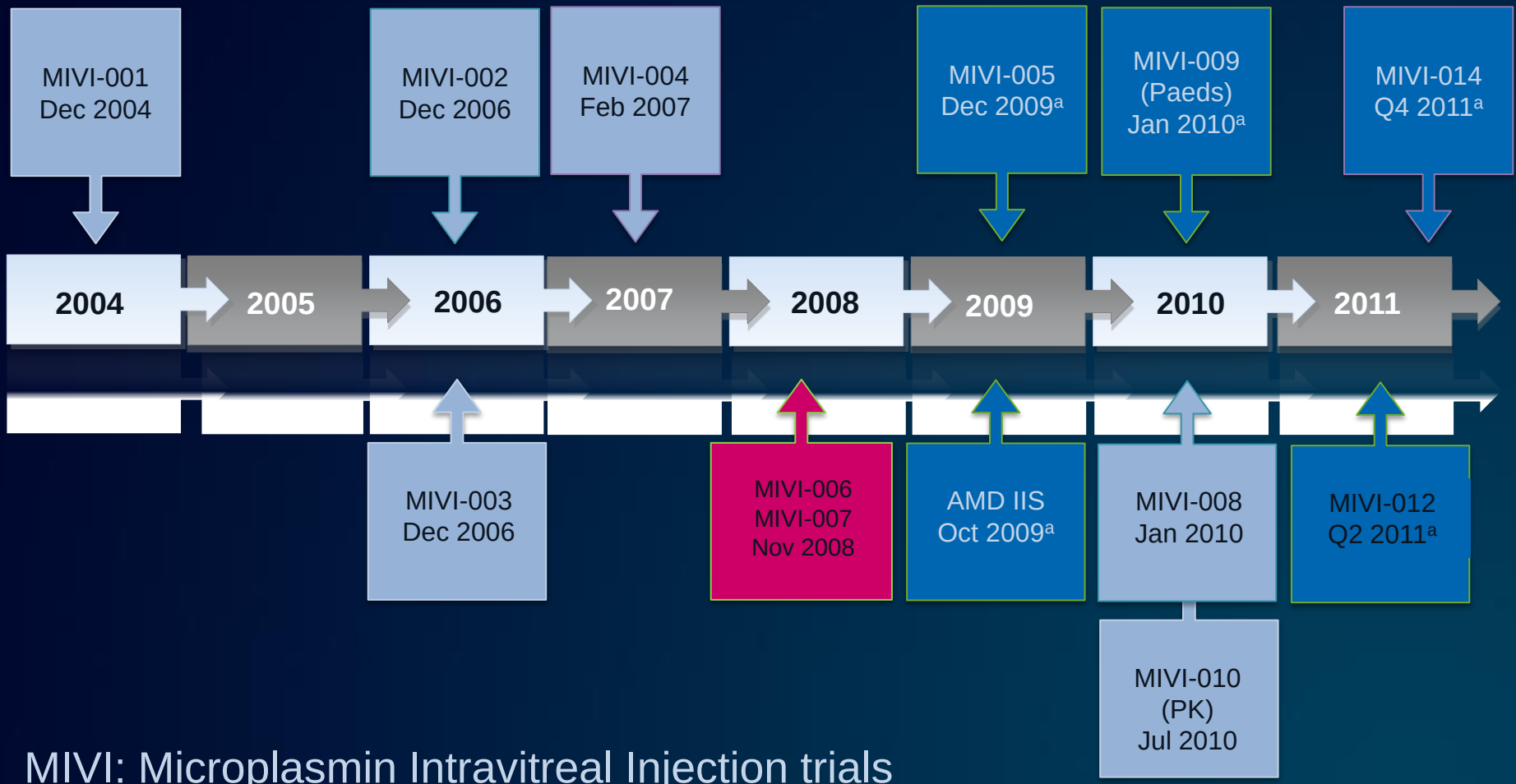


- Dati pre-clinici[1,2]
  - Targets: fibronectina, laminina e collagene
  - Induce liquefazione del vitreo e separazione del vitreo stesso dall'interfaccia vitreoretinica
  - Separa il vitreo dalla ILM (lasciando la ILM intatta a differenza della vitrectomia)

ILM: inner limiting membrane.

1. Gandorfer et al. Invest Ophthalmol Vis Sci. 2004;45:641–647. 2. In vitro experiments. ThromboGenics, Data on File.

Cronologia degli sviluppi clinici dell' Ocriplasmina



MIVI: Microplasmin Intravitreal Injection trials

Total number of patients treated to date: >800

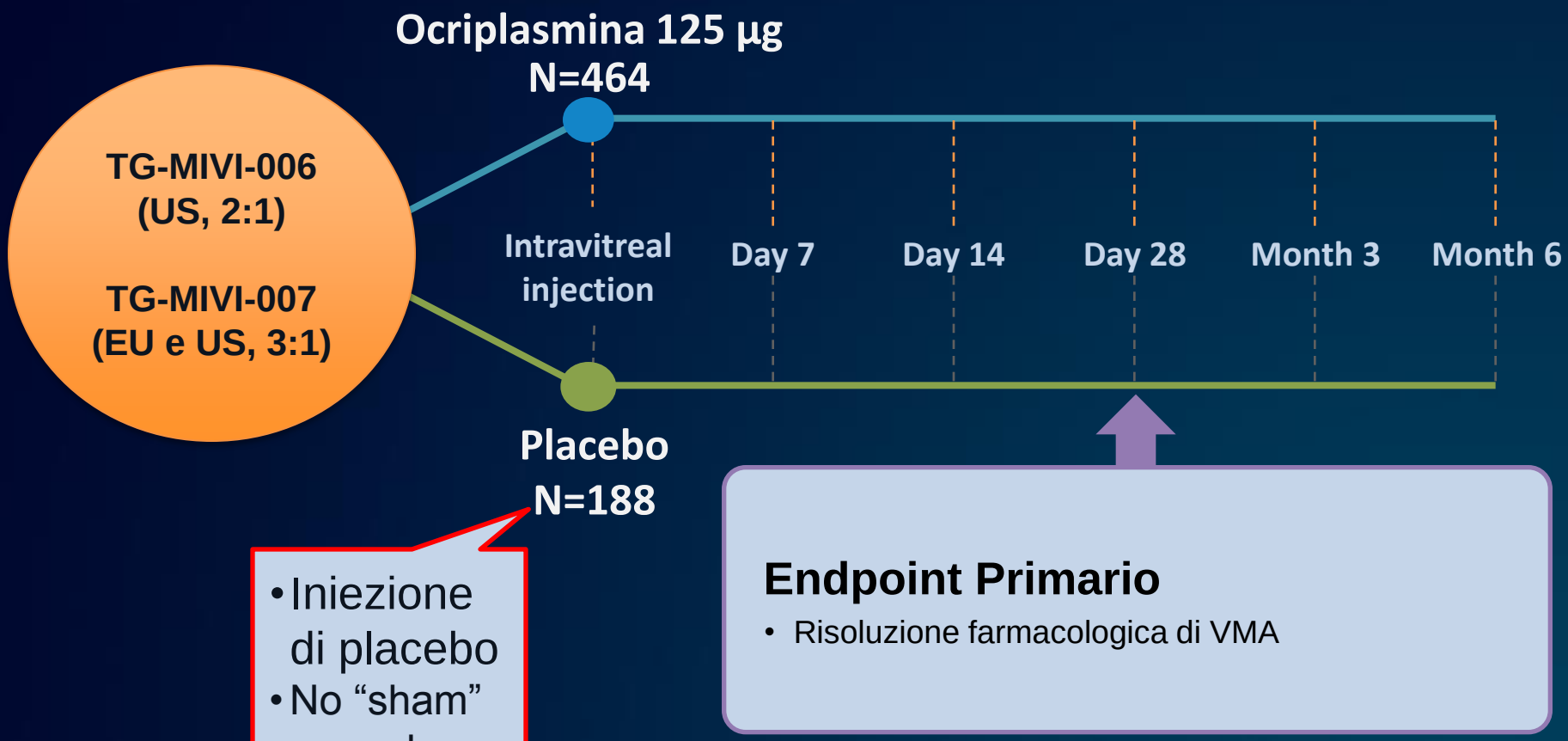
MIVI-006 e 007

MIVI-006 e MIVI-007: trial randomizzato, placebo-controllo, in doppio cieco, multicentrico per la valutazione dell' iniezione intravitreale di Ocriplasmina per il trattamento non chirurgico della VMA sintomatica

- Due studi in fase III
- Endpoint primario d'efficacia: risoluzione della VMA al 28mo giorno
- 6 mesi di follow-up
- in totale 652 occhi trattati

VMA, vitreous macular adhesion

Study Design



PVD, posterior vitreous detachment; VMA, vitreomacular adhesion

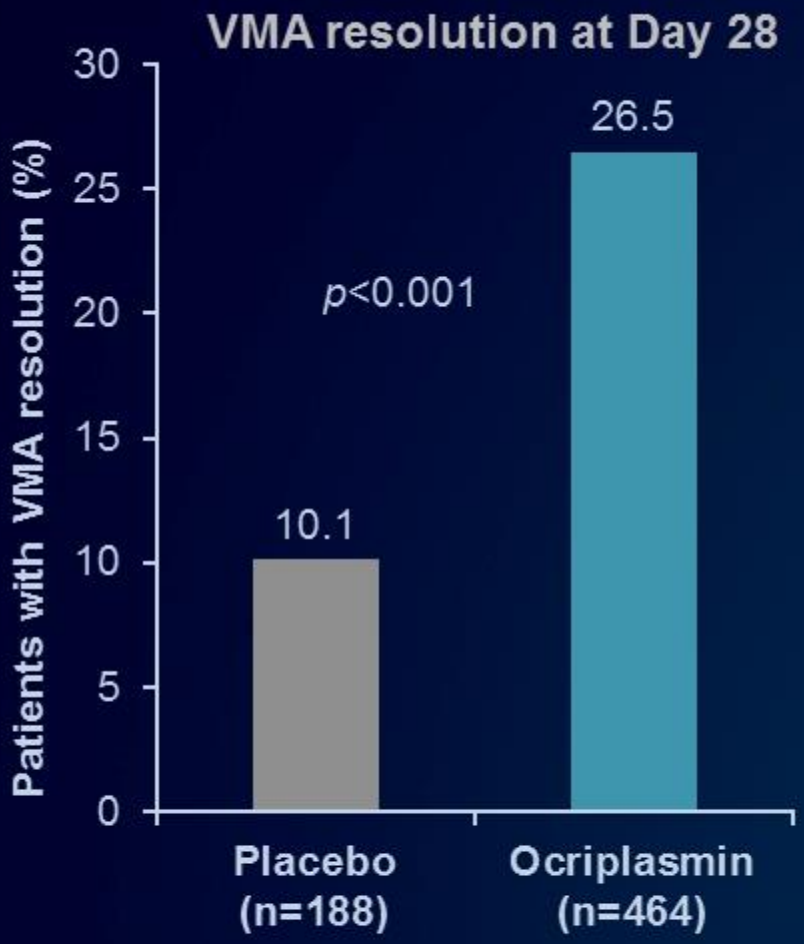
Dati demografici dei pazienti e caratteristiche della malattia al baseline

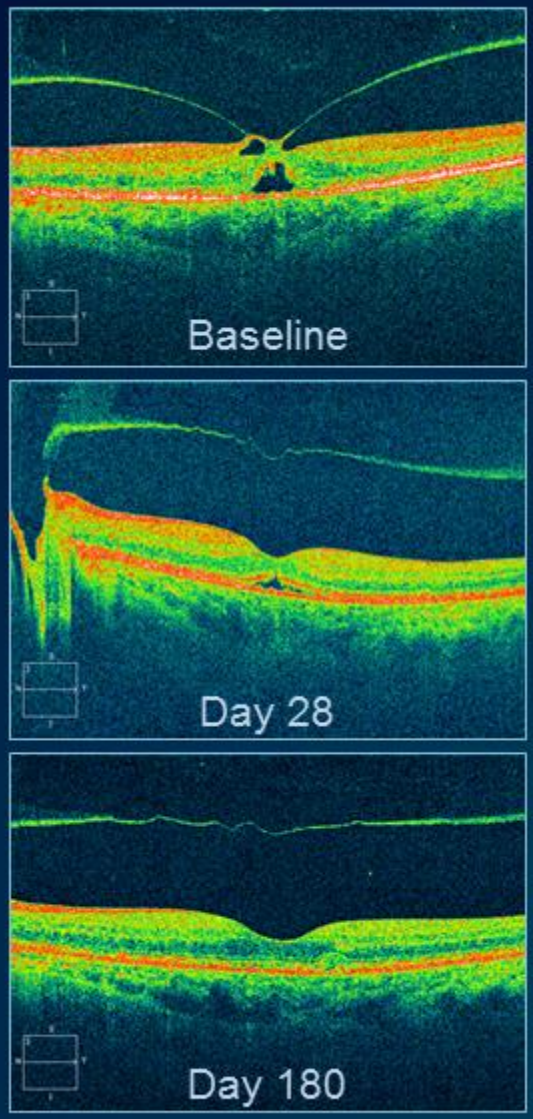
Caratteristiche	Placebo (n=188)	Ocriplasmina (n=464)
Età media , anni (range)	70.7 (24–97)	72.1 (18–93)
Femmine, n (%)	115 (61.2)	314 (67.7)
Bianchi, n (%)	174 (92.6)	428 (92.2)
Pseudofachici, n (%)	53 (28.2)	**172 (37.1)**
AV media al baseline BCVA, ETDRS (Snellen)	65.1 (4/10)	63.9 (4/10)
Caratteristiche della patologia , n %		
VMT	126 (67.0)	328 (70.7)
MH	47 (25.0)	106 (22.8)
ERM	68 (36.2)	**184 (39.7)**

I gruppi di studio avevano caratteristiche demografiche e della malattia di base simili, con due eccezioni: pseudofachia era più comune nel gruppo ocriplasmina rispetto al gruppo placebo (37,1% vs 28,2%, rispettivamente, p <0.05), e c'erano più donne nel ocriplasmin gruppo rispetto al gruppo placebo (67,7% vs 61,2%, rispettivamente, p <0.05)

Stalmans P *et al*. *N Engl J Med* 2012;367:606 (supplementary material)

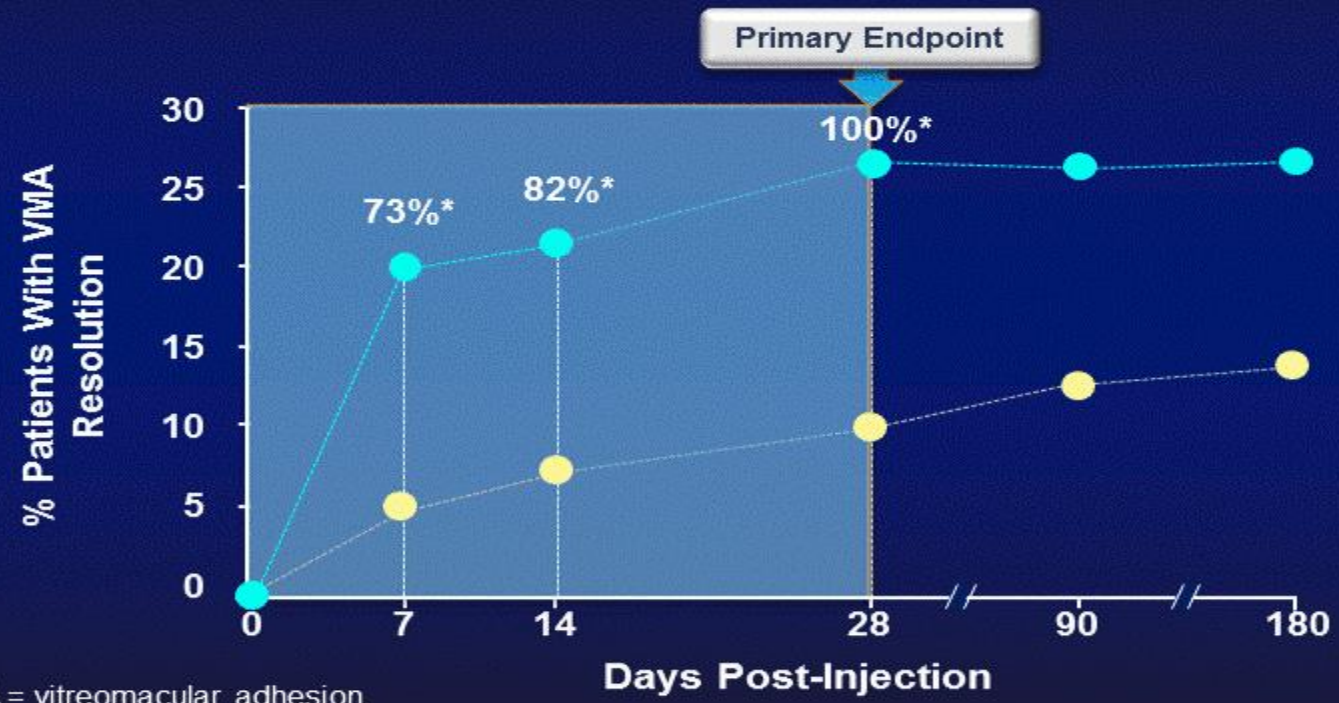
Percentuale di risoluzione di VMA al 28 mo giorno dopo una singola iniezione intravitreale di Ocriplasmina





Stalmans P, Benz MS, Gandorfer A *et al. N Engl J Med* 2012;367:606

Tempo di risposta in pazienti con risoluzione farmacologica di VMA



VMA = vitreomacular adhesion.
*Proportion of patients with VMA resolution relative to Day 28.
1.Stalmans P, et al. *New Engl J Med*. 2012;367:606-615.
2.Jetrea (ocriplasmin) [package insert]. Iselin, NJ: ThromboGenics, Inc.; 2012.

Courtesy of Peter K. Kaiser, M.D.

Occorre ricordare che la risoluzione della VMA può avvenire anche al 3° mese. Innesco meccanisco

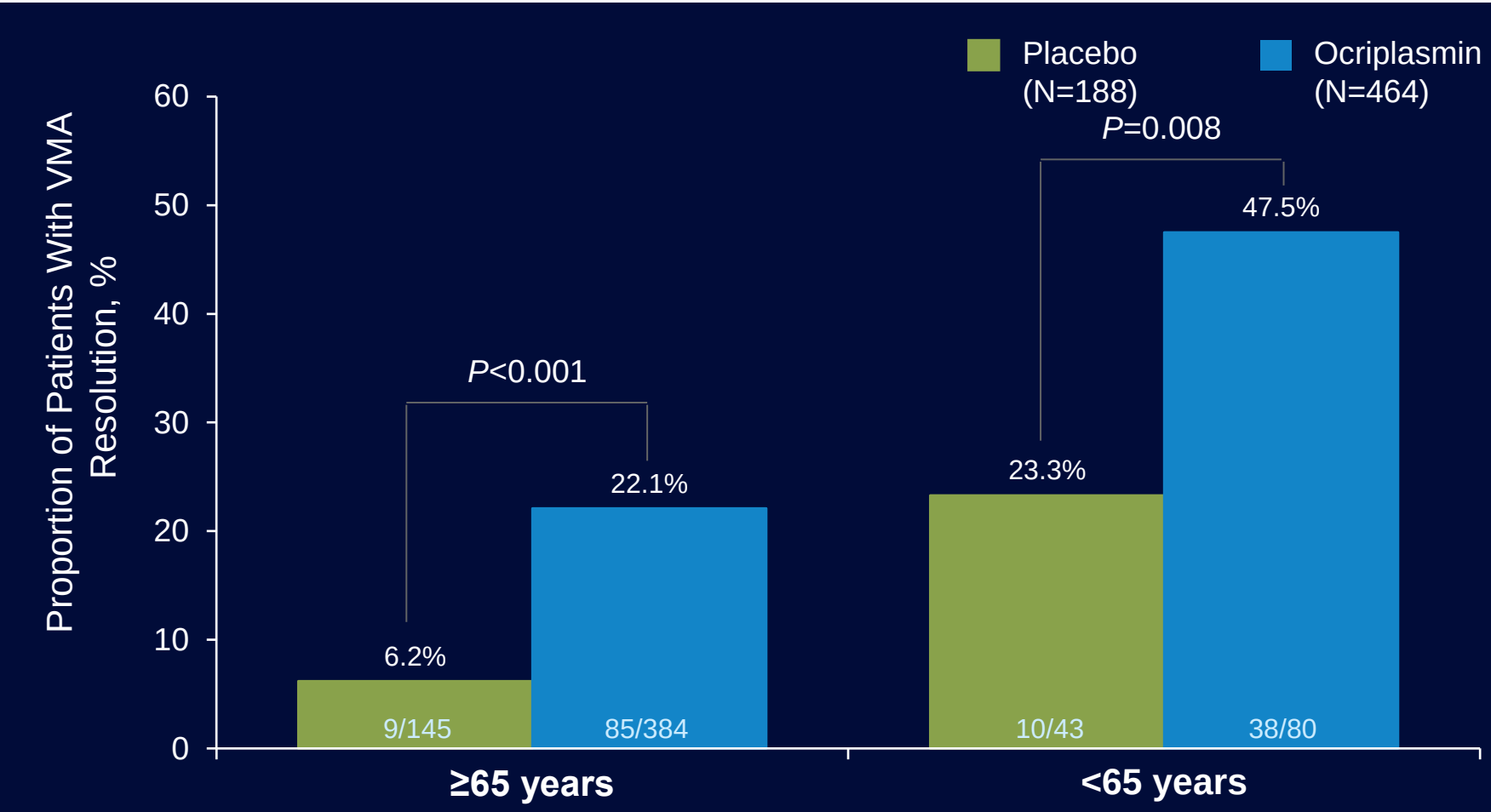
Independent Baseline Features Predictive of Pharmacologic VMA Resolution

Baseline Characteristics	Placebo (N=188)	Ocriplasmin (N=464)
Age <65 years, n (%)	43 (22.9)	80 (17.2)
FTMH present, n (%)	47 (25.0)	106 (22.8)
VMA diameter ≤1500 µm, n (%)*	123 (69.9)	314 (71.4)
ERM absent, n (%)	119 (63.3)	270 (58.2)
Phakic, n (%)	135 (71.8)	292 (62.9)

* **VMA diameter** percentages based on total patients in Modified Full Analysis Set

Data on file. ThromboGenics, Inc. 2012
ERM, epiretinal membrane; FTMH, full-thickness macular hole; VMA, vitreomacular adhesion

Age and VMA Resolution at Day 28 By Treatment Group



Data on file. ThromboGenics, Inc. 2012.
Chang LK et al. Am J Ophthalmol 2008; 146(1): 121-127
VMA, vitreomacular adhesion

Independent Baseline Features Predictive of Pharmacologic VMA Resolution

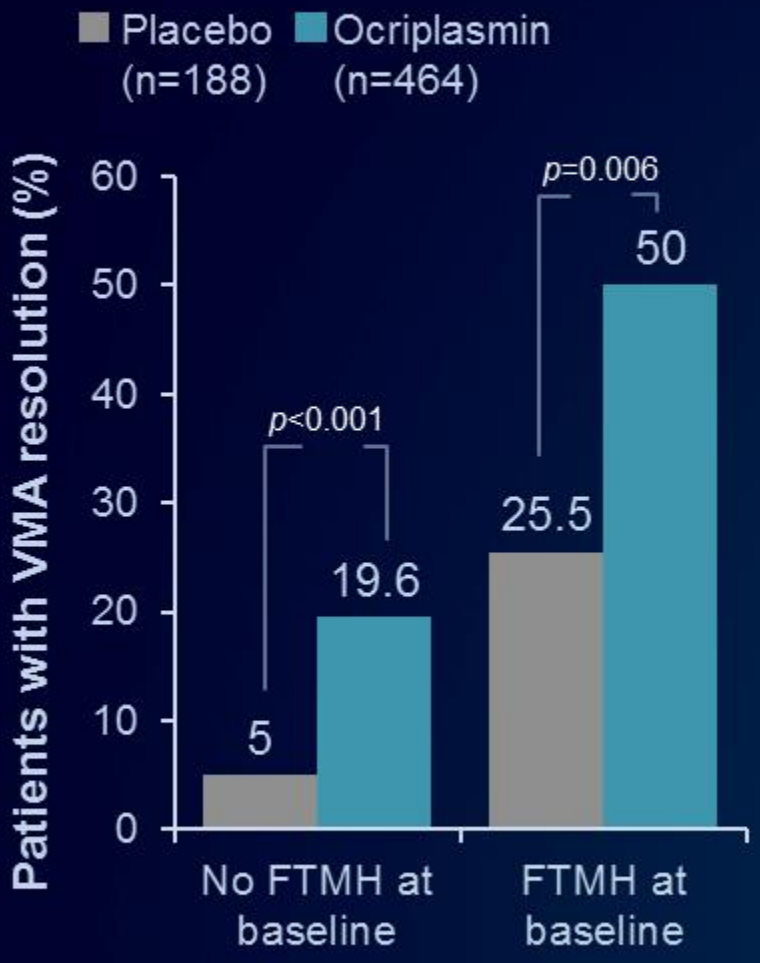
Baseline Characteristics	Placebo (N=188)	Ocriplasmin (N=464)
Age <65 years, n (%)	43 (22.9)	80 (17.2)
FTMH present, n (%)	47 (25.0)	106 (22.8)
VMA diameter ≤1500 µm, n (%)*	123 (69.9)	314 (71.4)
ERM absent, n (%)	119 (63.3)	270 (58.2)
Phakic, n (%)	135 (71.8)	292 (62.9)

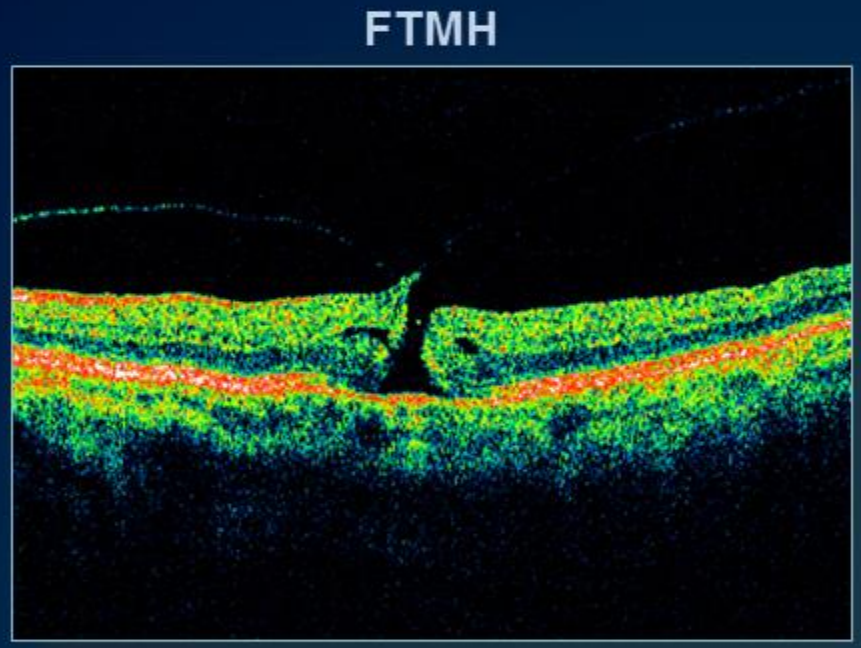
* **VMA diameter** percentages based on total patients in Modified Full Analysis Set

Data on file. ThromboGenics, Inc. 2012

ERM, epiretinal membrane; FTMH, full-thickness macular hole; VMA, vitreomacular adhesion

Presence of FTMH Identified as Predictive Baseline Characteristic for VMA Resolution at Day 28





ThromboGenics. Data on file. 2013

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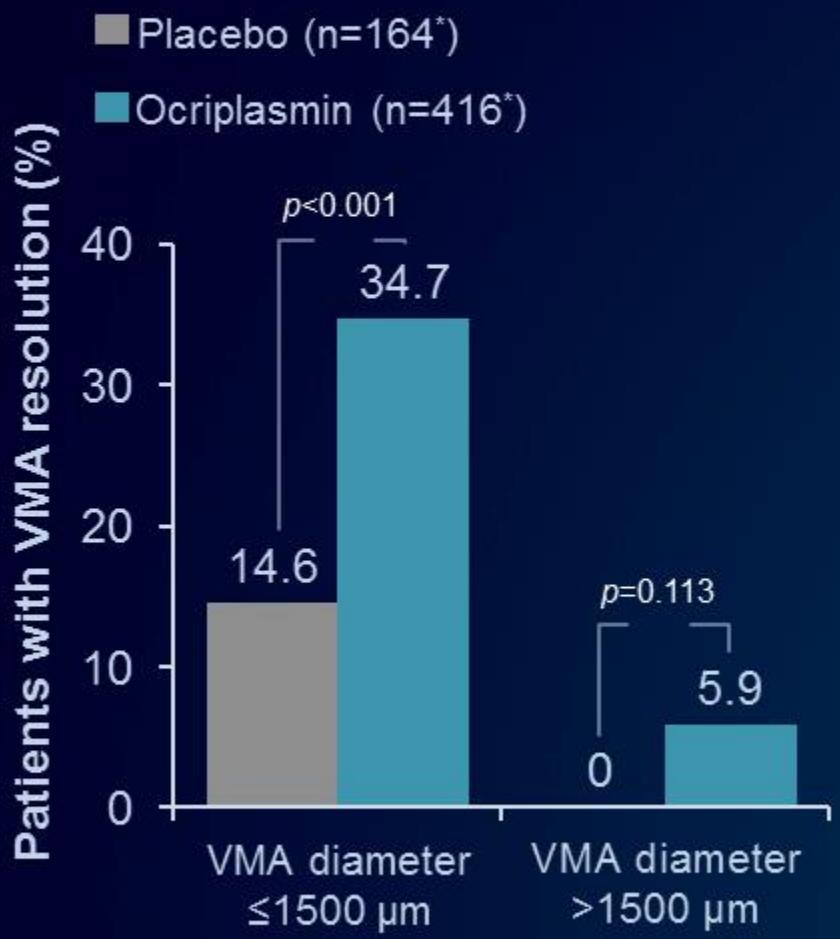
* **VMA diameter** percentages based on total patients in Modified Full Analysis Set

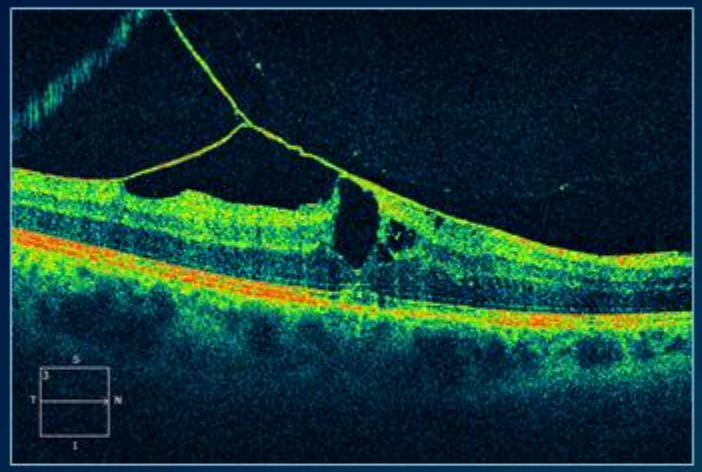
Data on file. ThromboGenics, Inc. 2012

ERM, epiretinal membrane; FTMH, full-thickness macular hole; VMA, vitreomacular adhesion

VMA Diameter ≤1500 µm Is a Baseline Predictor for VMA Resolution at Day 28



Broad VMA diameter



*24 patients in the placebo arm and 48 in the ocriplasmin arm did not have a baseline measurement of VMA diameter; VMA diameter percentages based on total patients in Modified Full Analysis Set

ThromboGenics. Data on file. 2013

Independent Baseline Features Predictive of Pharmacologic VMA Resolution

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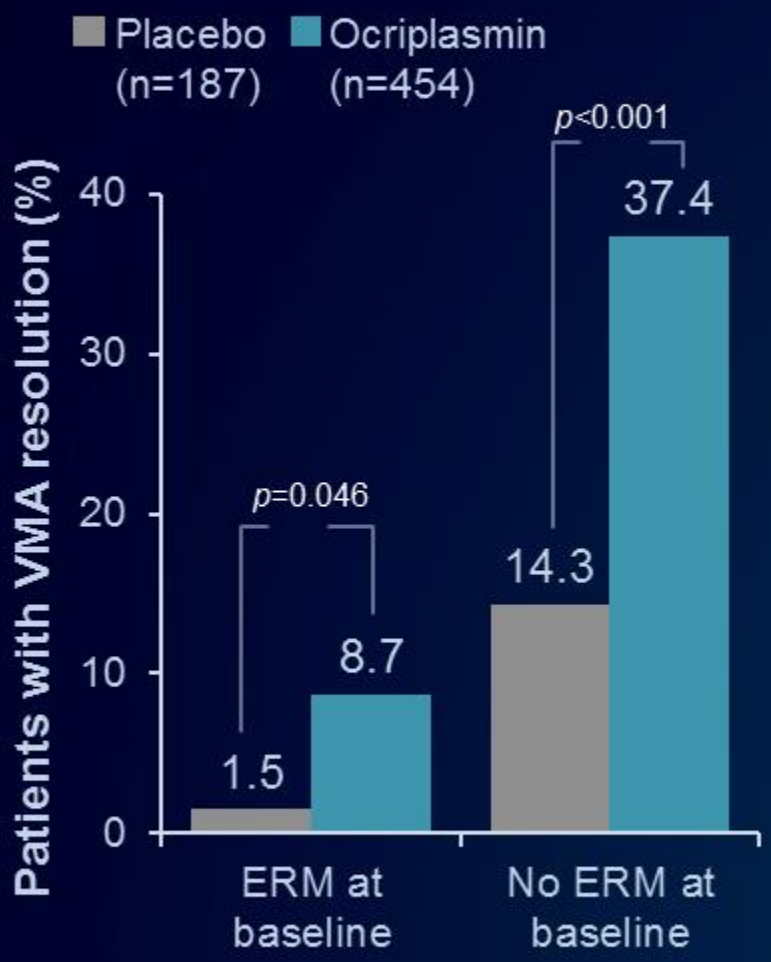
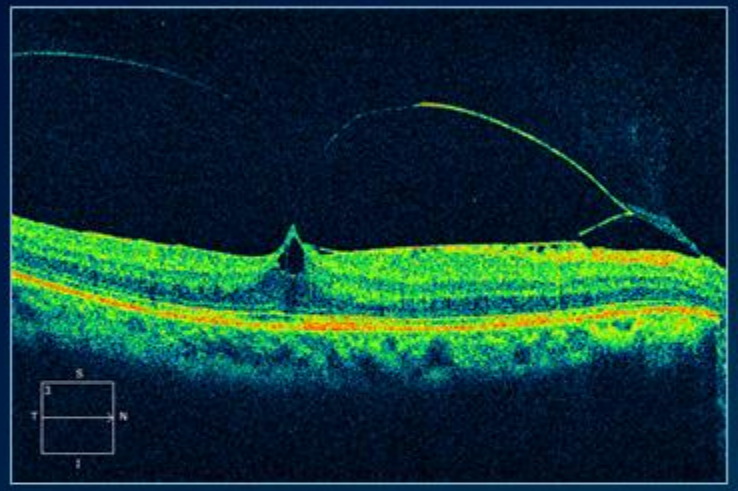
Data on file. ThromboGenics, Inc. 2012

ERM, epiretinal membrane; FTMH, full-thickness macular hole; VMA, vitreomacular adhesion

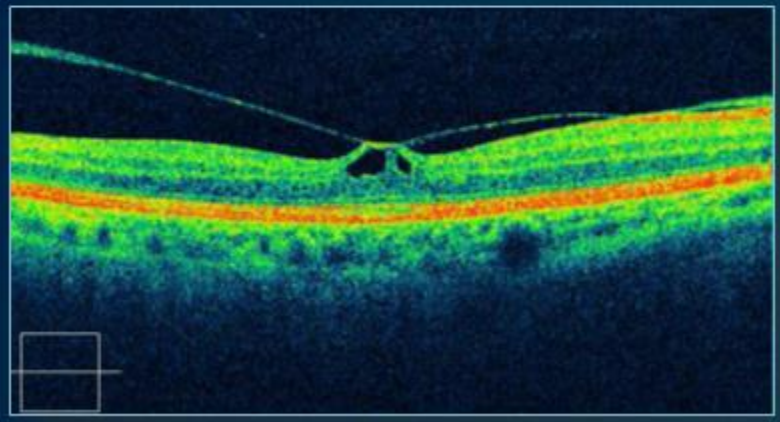
Absence of ERM Is a Predictive Baseline Characteristic for VMA Resolution at Day 28



VMT with ERM



VMT with no ERM



*One patient in the placebo arm and 10 in the ocriplasmin arm had no recorded information regarding baseline ERM status

ThromboGenics. Data on file. 2013

Independent Baseline Features Predictive of Pharmacologic VMA Resolution

Baseline Characteristics	Placebo (N=188)	Ocriplasmin (N=464)
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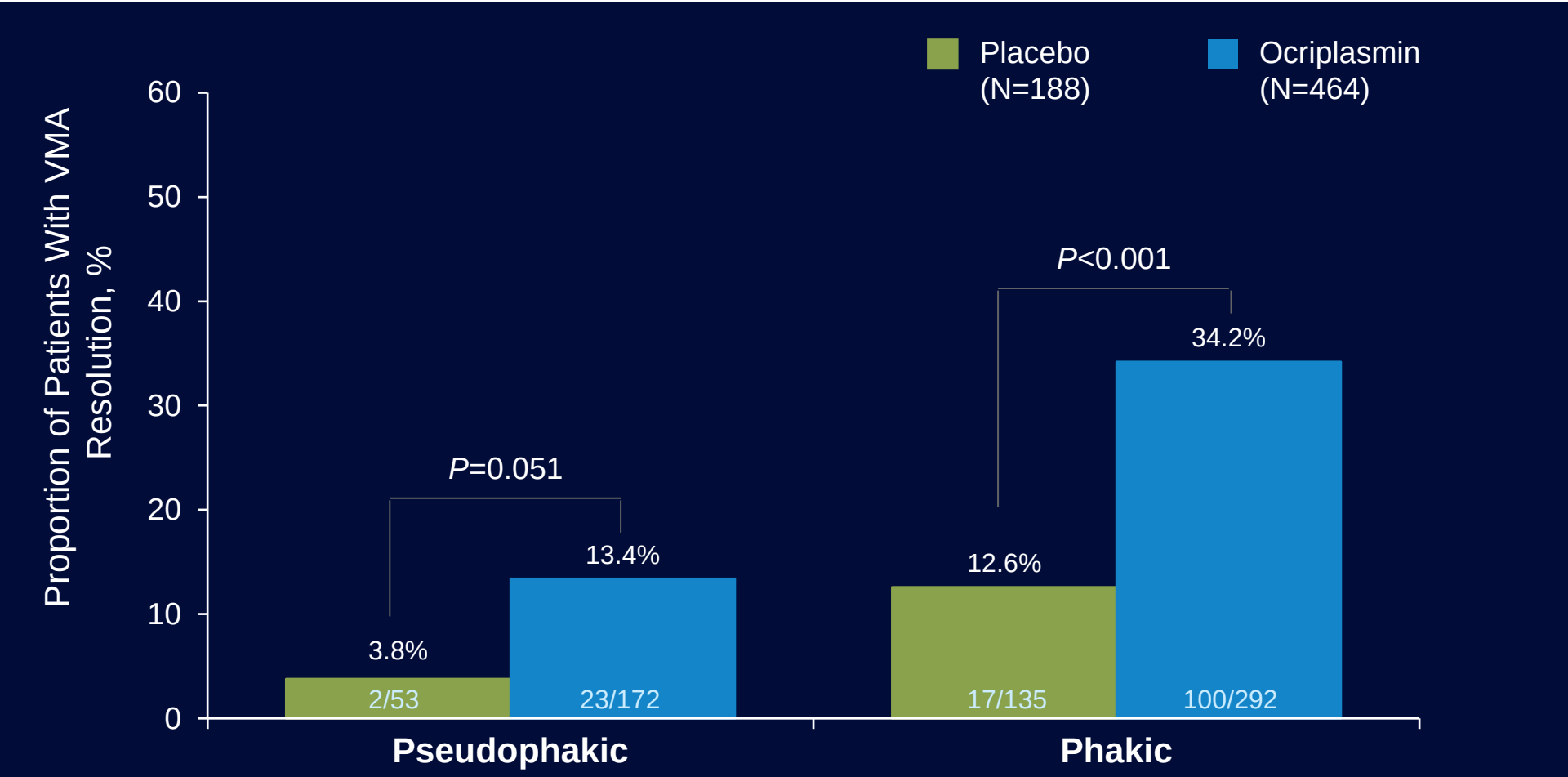
Data on file. ThromboGenics, Inc. 2012
ERM, epiretinal membrane; FTMH, full-thickness macular hole; VMA, vitreomacular adhesion

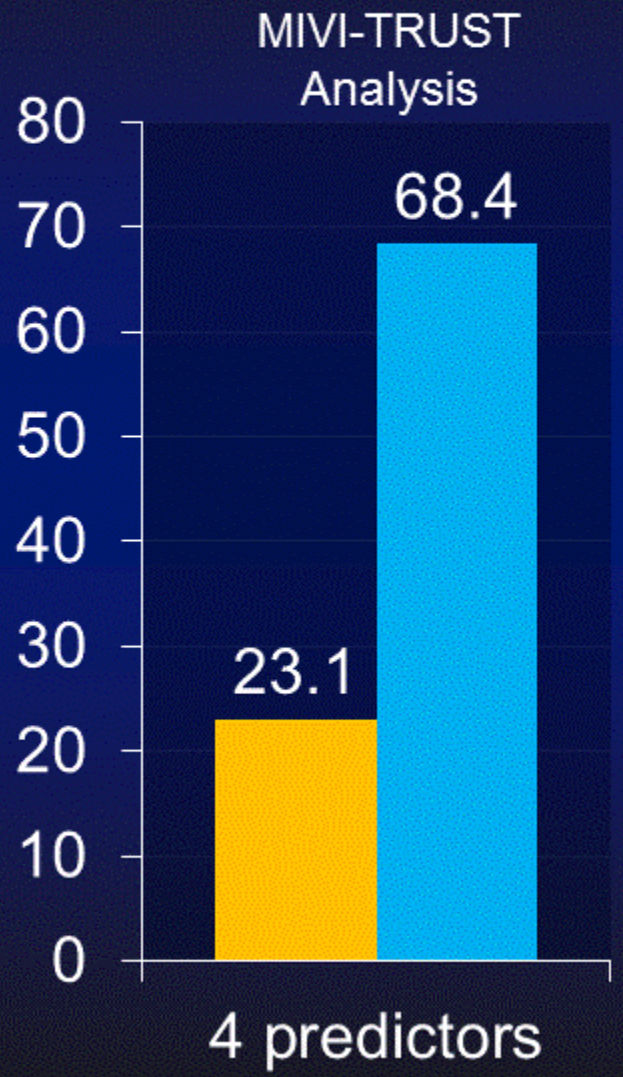
Baseline Lens Status and VMA Resolution at Day 28 By Treatment Group



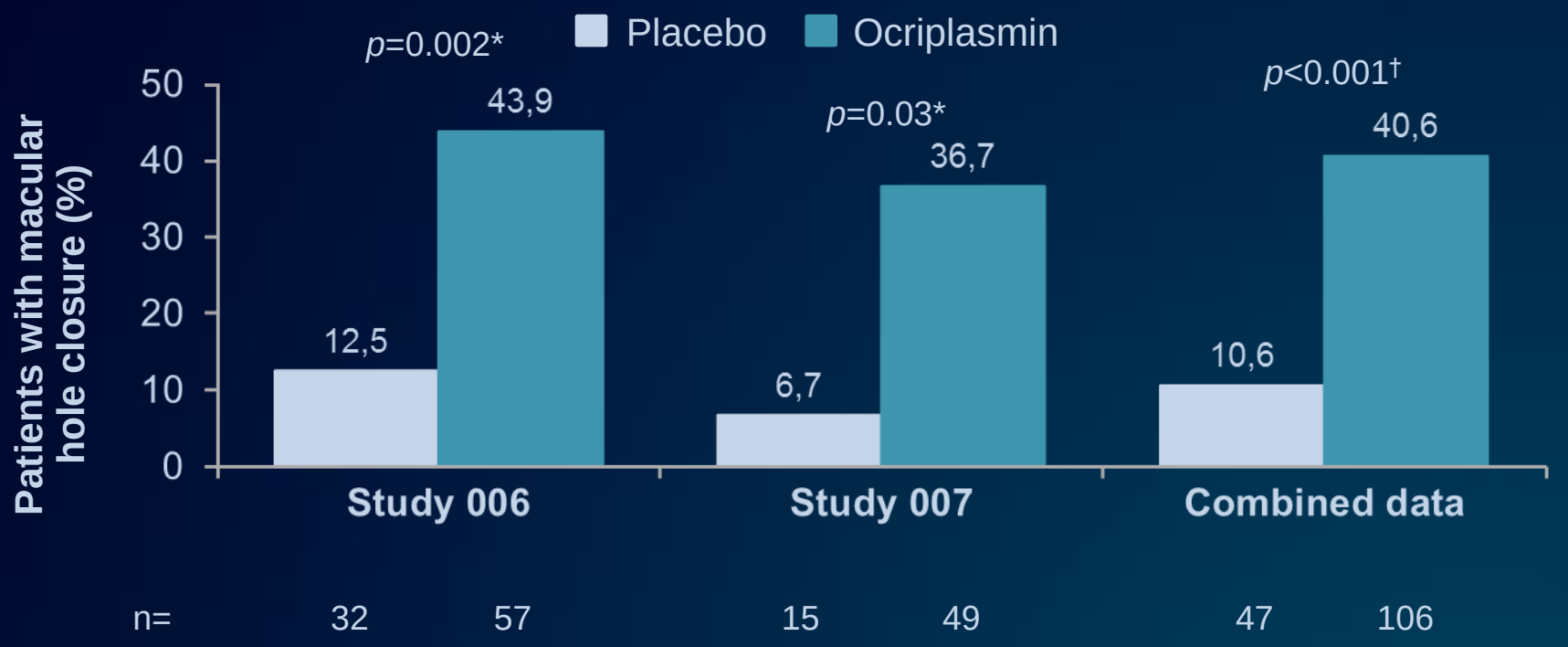
Data on file. ThromboGenics, Inc. 2012
VMA, vitreomacular adhesion

“Very Good” Candidates for Ocriplasmin

“Very Good” Candidates
VMA <1500
No ERM
Phakic
< 65 years



Chiusura di foro maculare al 28 mo giorno



La percentuale è rimasta superiore nel gruppo trattato con Ocriplasmina vs placebo fino alla fine dello studio

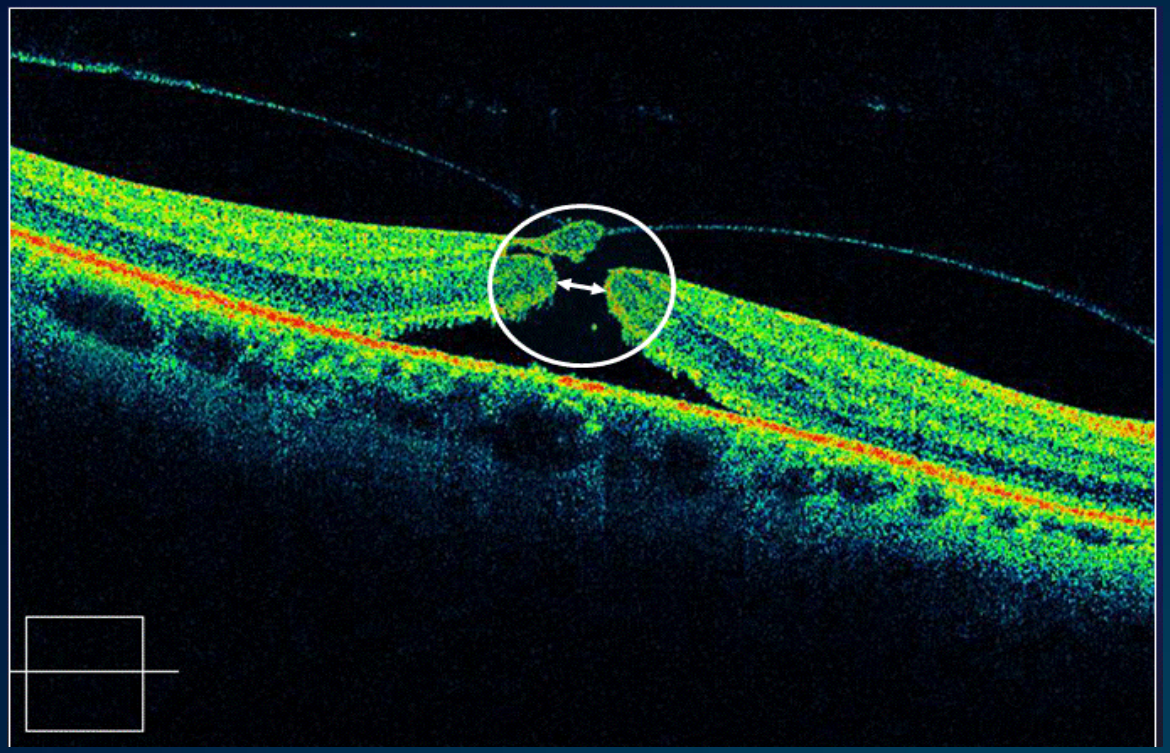
*Fisher's exact test; †Cochran–Mantel–Haenszel test, stratified by study

p-values were not adjusted for multiplicity

Stalmans P *et al. N Engl J Med* 2012;367:606

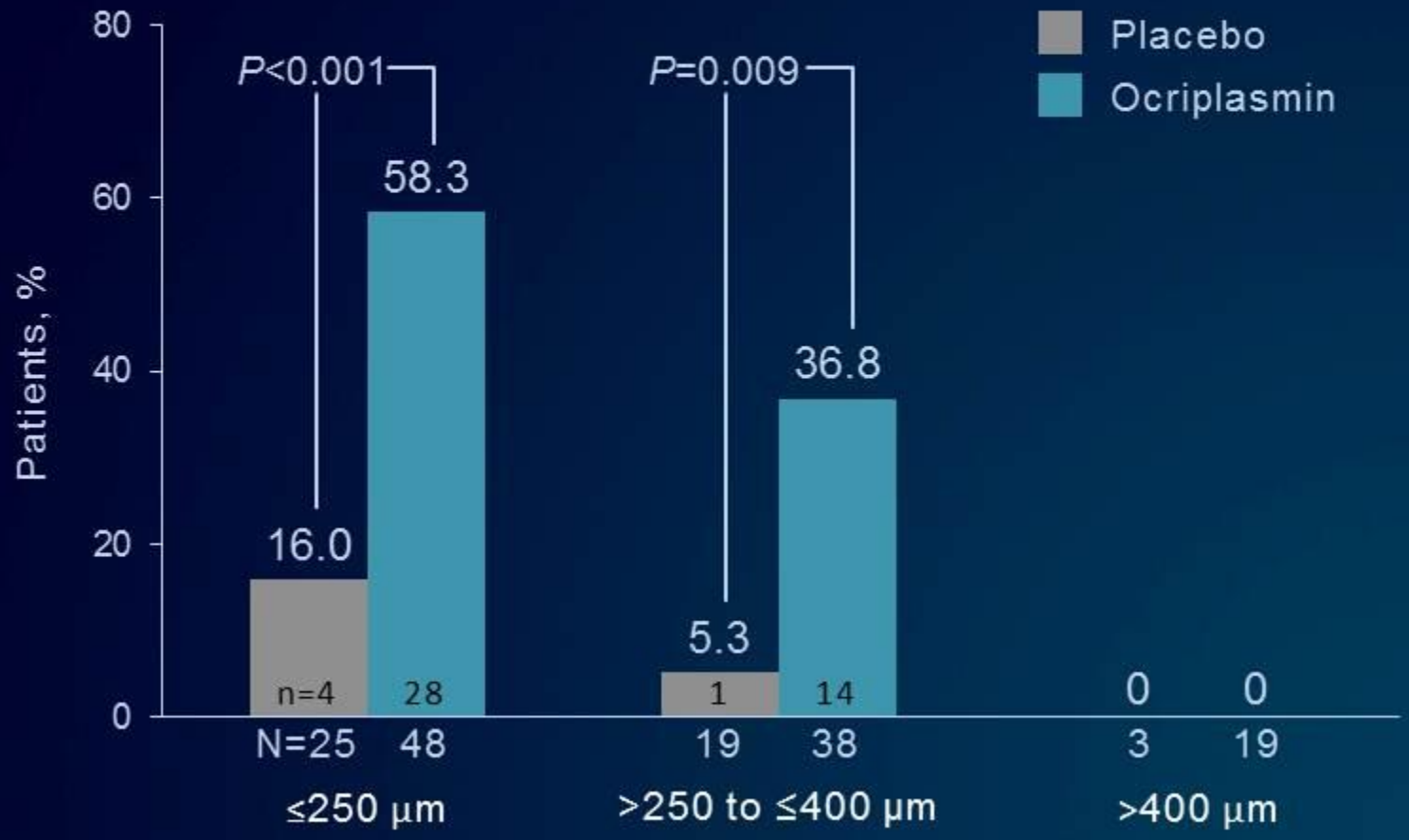
DIMENSIONI DEL FORO MACULARE A TUTTO SPESSORE FTMH

piccolo ≤ 250 µm
medio > 250 ≤400 µm
grande > 400 µm



Courtesy of Peter k. Kaiser, MD

Patients with FTMH ≤250 µm More Likely to Achieve Hole Closure at Day 28



Kaiser, P. Macular Society 2013; Oral

Two Patient Types to Consider Treating With JETREA®

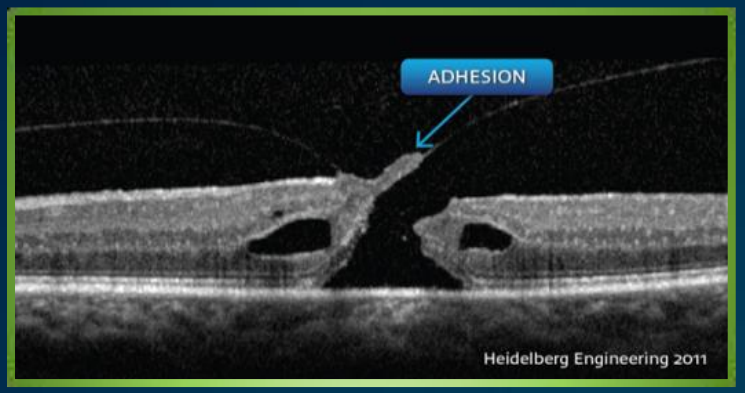
Vitreomacular Traction (VMT)

- Without ERM
- Adhesion size ≤ 1500 µm

JETREA® provides a method to treat patients early and may improve their symptoms.

Vitreomacular Traction (VMT) with Macular Hole

- Macular hole diameter ≤400 µm
- Without ERM
- Adhesion size ≤ 1500 µm



JETREA® can be used as a first line, less invasive option before PPV.

REALE ESPERIENZA CLINICA NEL MONDO

Post approvazione Ocriplasmina

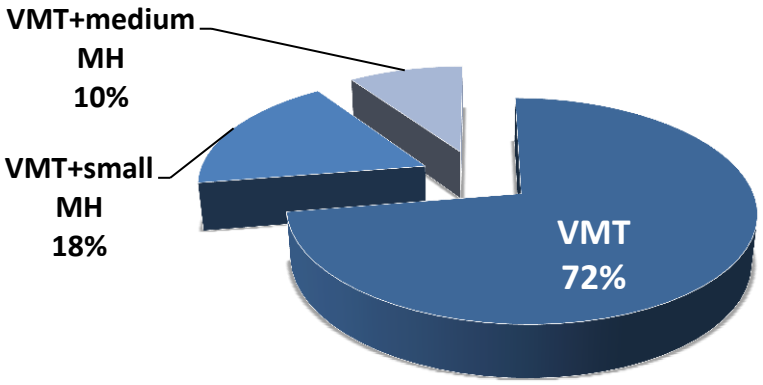
	% di risoluzione VMT				
	Totale	Diametro VMA 1500 µm	NO ERM	FTMH presenti	% di totale chiusura dei MH
Phase 3 trials	26,5	34,7	37,4	50	40,6
Bascom Palmer	42,1	50	54,5	66,7	50
Cole Eye	47,1	61,5	50	NR	80
California Retina	56	n/a	56,5	72,7	36,4
NJ Retina	35	38	41,5	73,3	32

Italy treatment outcomes

Esperienza fornita da Alcon

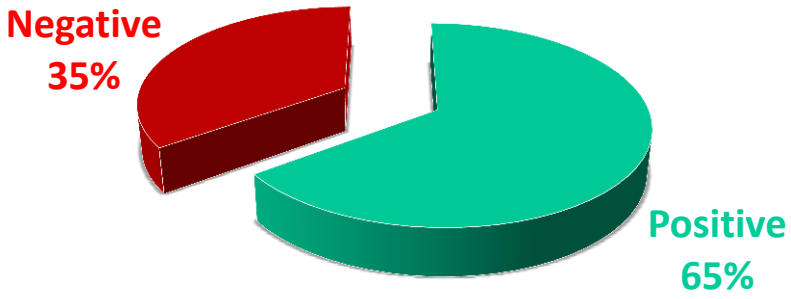
Real life
Fascia CNN

Patient Profiles

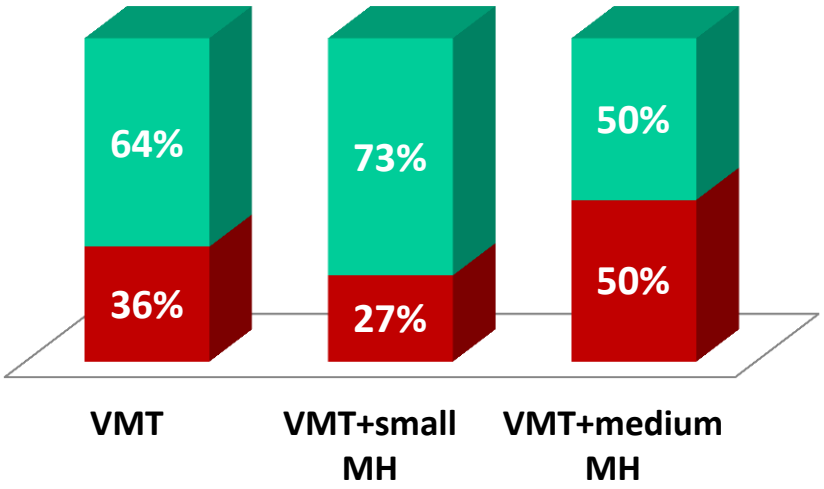


- 167 patients injected
- Treated mostly VMT patients
- Higher overall success rate compare to MIVI 6 and 7 studies due to rigorous patients selection
- Higher success rate in small MH closure although in a small patient population

Overall Success Rate

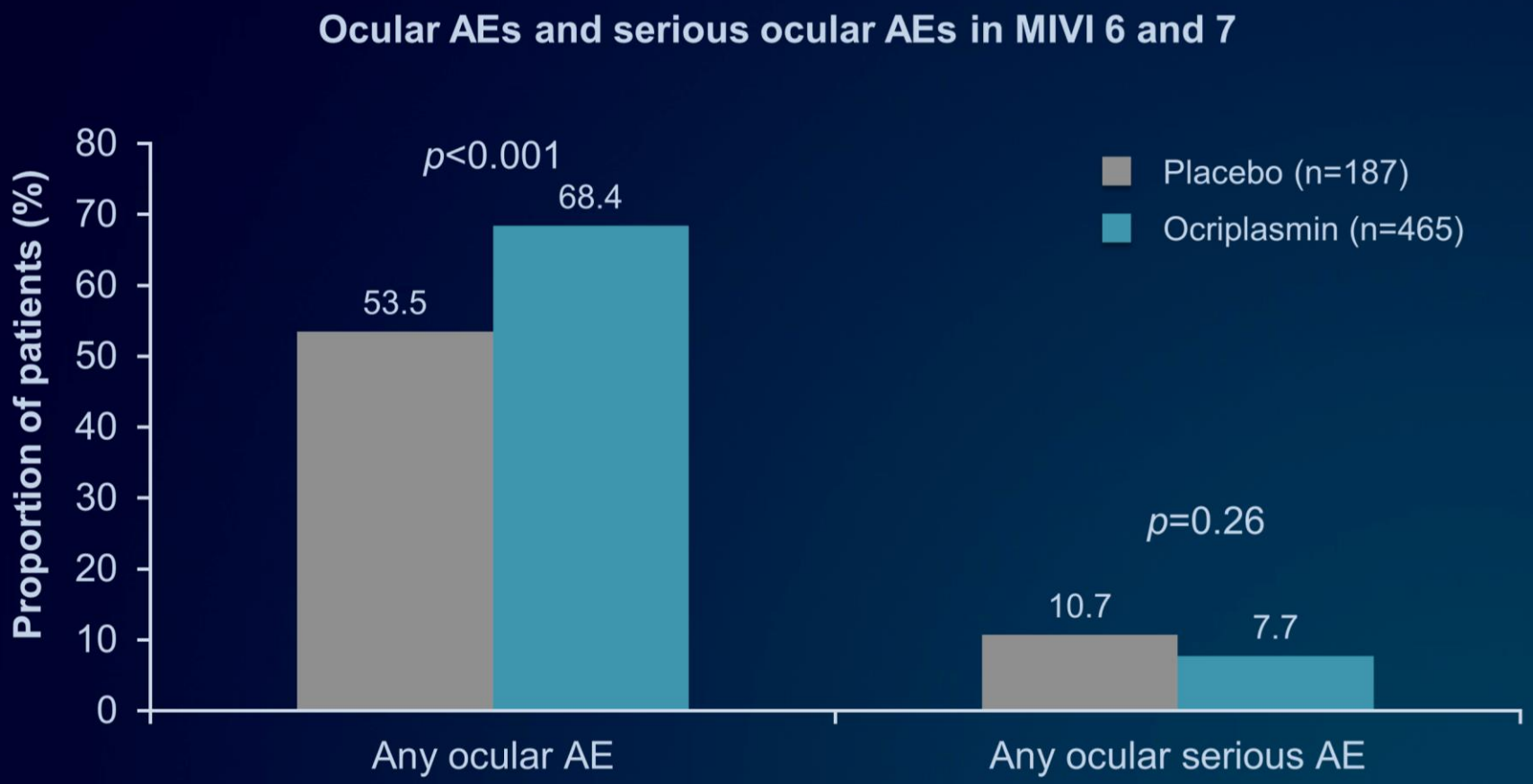


% VMT resolution & MH closure



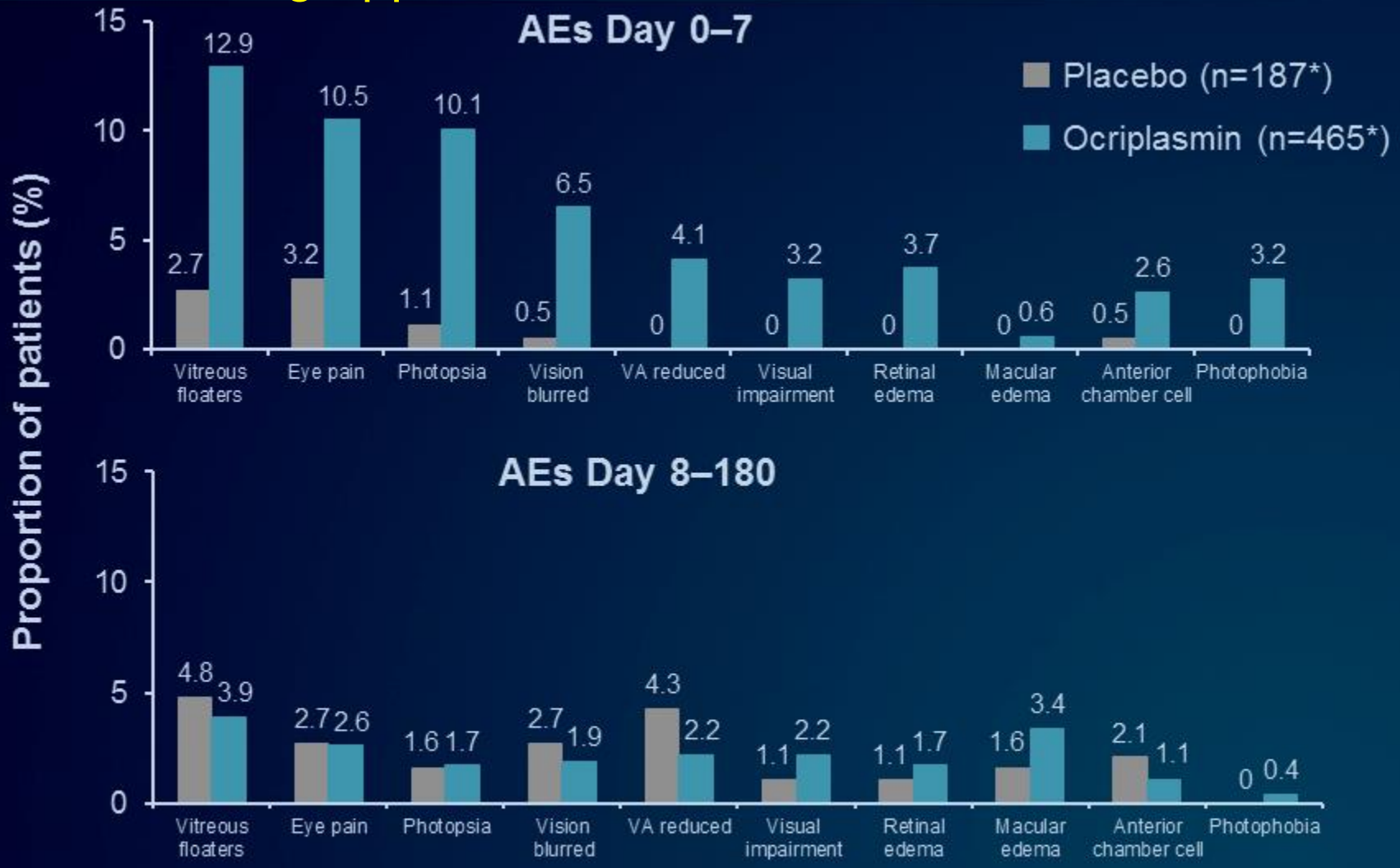
Profilo di sicurezza dell’Ocriplasmina MIVI 6/7

Eventi avversi oculari MIVI 6/7



Eventi avversi gravi legati al distacco di vitreo

Dopo il settimo giorno l'incidenza degli eventi avversi sono simili nei due gruppi



*One patient randomly assigned to placebo inadvertently received ocriplasmin and was included in the ocriplasmin group

Kaiser P. *Retina Society* 2012:oral

SEVERI EVENTI AVVERSI OCULARI

Event, n (%)	Placebo (n=187)	Ocriplasmin (n=465)	p-value*
Any serious AE	20 (10.7)	36 (7.7)	0.26
Macular hole	16 (8.6)	24 (5.2)	0.15
Retinal detachment	3 (1.6)	2 (0.4)	0.16
Reduced VA	1 (0.5)	3 (0.6)	0.94

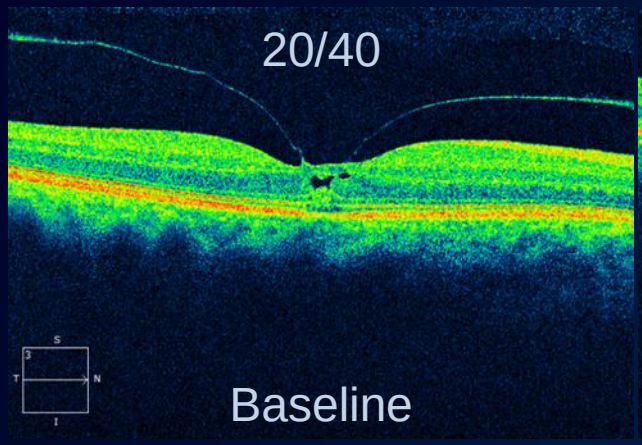
**p*-values were calculated with the use of the Cochran–Mantel–Haenszel test, stratified according to study

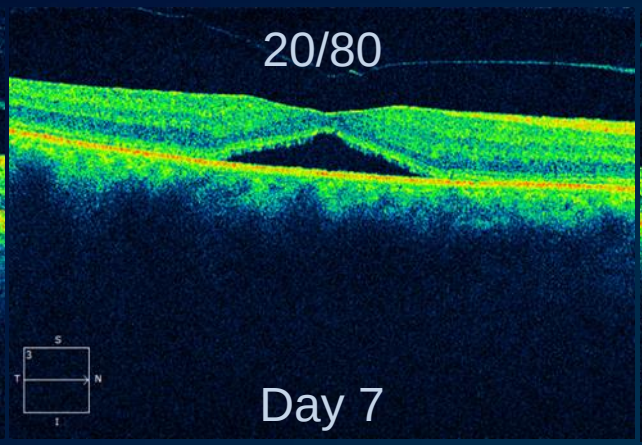
A serious ocular adverse event was identified as such by the investigator and was defined as an adverse event that met one of the following descriptions: an event resulting in persistent or clinically significant disability, incapacity, or both; an event requiring inpatient hospitalization or prolongation of an existing hospital stay; or an event that was considered to be medically important

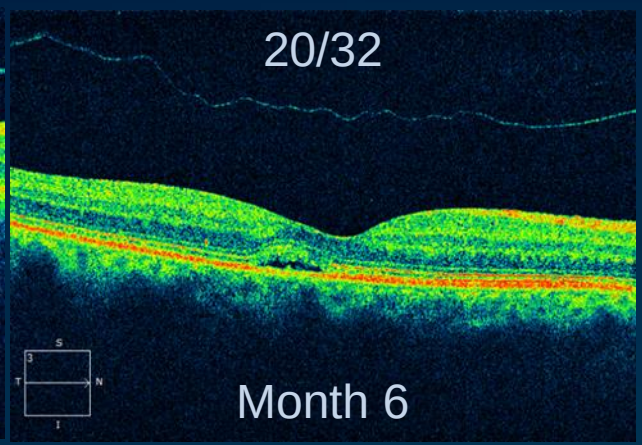
p-values were not adjusted for multiplicity

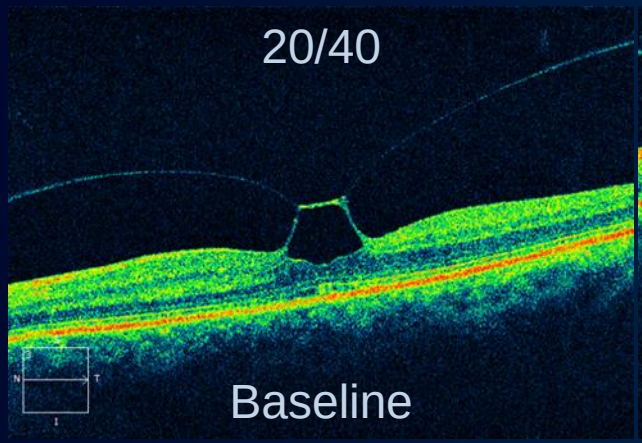
Stalmans P *et al*. *N Engl J Med* 2012;367:606

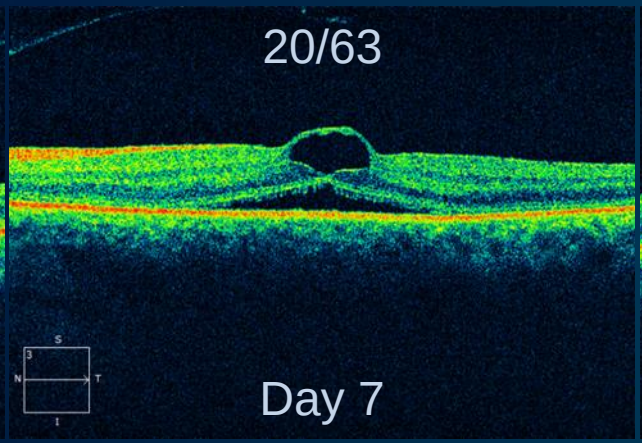
VMA Resolution in Patients with Acute Vision Decrease (MIVI 6/7)

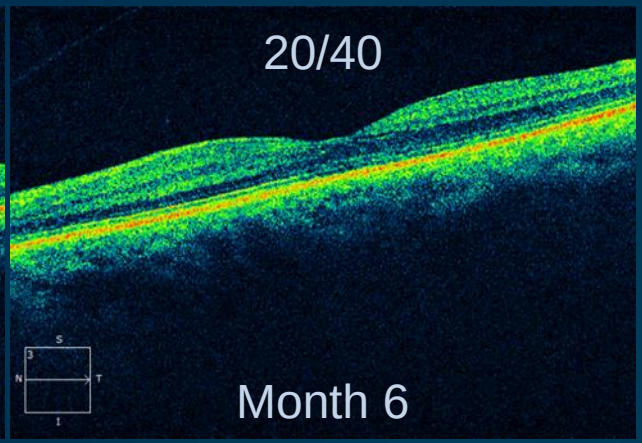












ThromboGenics. Data on file. 2013

Working in progress

Studies due to commence in 2014*

Single arm: ocriplasmin administered according to the label

- M-13-056[1]
  - Interventional phase IV study based in Europe and Canada[2]
  - Planned enrollment: N~400
  - Primary endpoint: VMA resolution at Day 28
  - Intended follow-up: 6 months
  - Estimated completion date: October 2015
- ORBIT (Ocriplasmin Research to Better Inform Treatment)[3]
  - Observational, prospective, phase IV study based in the US
  - Planned enrollment N~1500
  - Primary outcome measures (all within 12 months)
    - ✧ VMA resolution by SD-OCT
    - ✧ FTMH closure by SD-OCT
    - ✧ Change in VA from baseline
    - ✧ Occurrence and time to vitrectomy
  - Other outcome measures (all within 12 months)
    - ✧ Monitoring of ADRs
    - ✧ Change from baseline in ocular signs and symptoms over time
  - Estimated completion date: March 2016

Ongoing clinical trials

- OASIS[4]: Currently ongoing
  - Phase IIIb, randomized, sham-controlled, double-masked study based in the US
  - Patients with symptomatic VMA (N=220)
  - Ocriplasmin administered according to the label
  - Primary endpoint: VMA resolution at Day 28
  - Estimated completion date: April 2015

Registries

- INJECT[5]: Open for enrollment
  - Non-randomized worldwide study
  - Ocriplasmin administered according to the label; local standards of care will apply
  - Planned enrollment: N~1500
  - Efficacy evaluations will include: VMT resolution and MH closure, BCVA and NEI VFQ-25
  - Final visit recommended at ~Month 12

*Studies registered but not currently recruiting patients (as of March 12, 2014)

1. Clinicaltrials.gov. NCT02035748 (accessed March 2014); 2. Alcon Research Ltd. Data on file. 2014; 3. ClinicalTrials.gov. NCT02079883 (accessed March 2014); 4. Clinicaltrials.gov. NCT01429441 (accessed March 2014); 5. Alcon Research Ltd. Data on file. 2013

Conclusions

- Il *Watchful waiting nel caso di* trazione vitreomaculare (VMT) può portare a danni retinici irreversibili, cisti e formazione di fori.
- La risoluzione spontanea di VMT si verifica raramente.
- La chirurgia vitreoretinica resta indicata in caso di riduzione del visus o per la progressione della patologia, ma il trauma chirurgico è un'evenienza possibile così come le complicanze.
- Il trattamento farmacologico di distacco del vitreo può essere tempestivo e causando una minore manipolazione della retina e consente di migliorare la visione in un numero considerevole di pazienti.