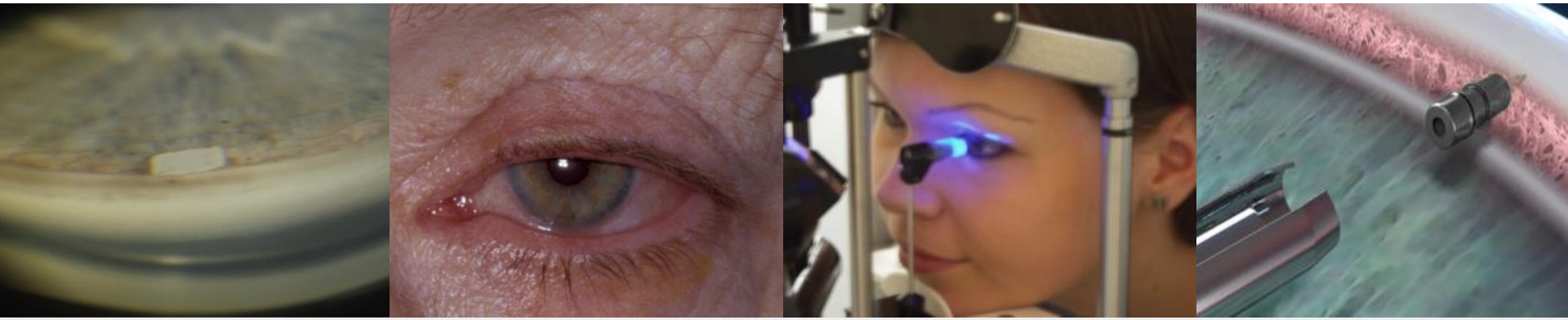
Medikamentöse Glaukomtherapie –

was gibt es, was kommt in naher Zukunft?

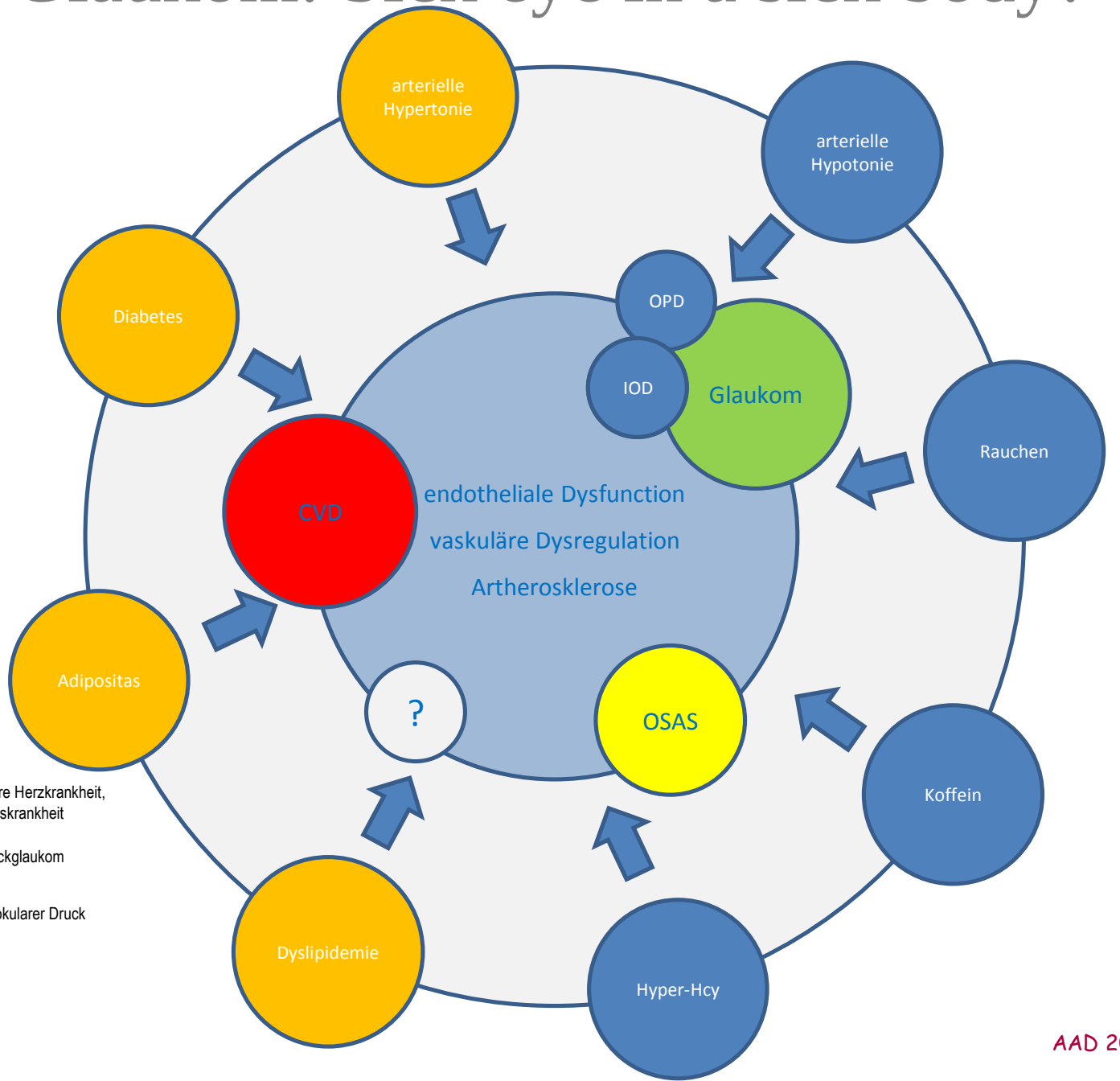


A. Jünemann

Dep. of General Ophthalmology
Medical University of Lublin
Poland

Universitätsmedizin
Rostock

Glaukom: Sick eye in a sick body?

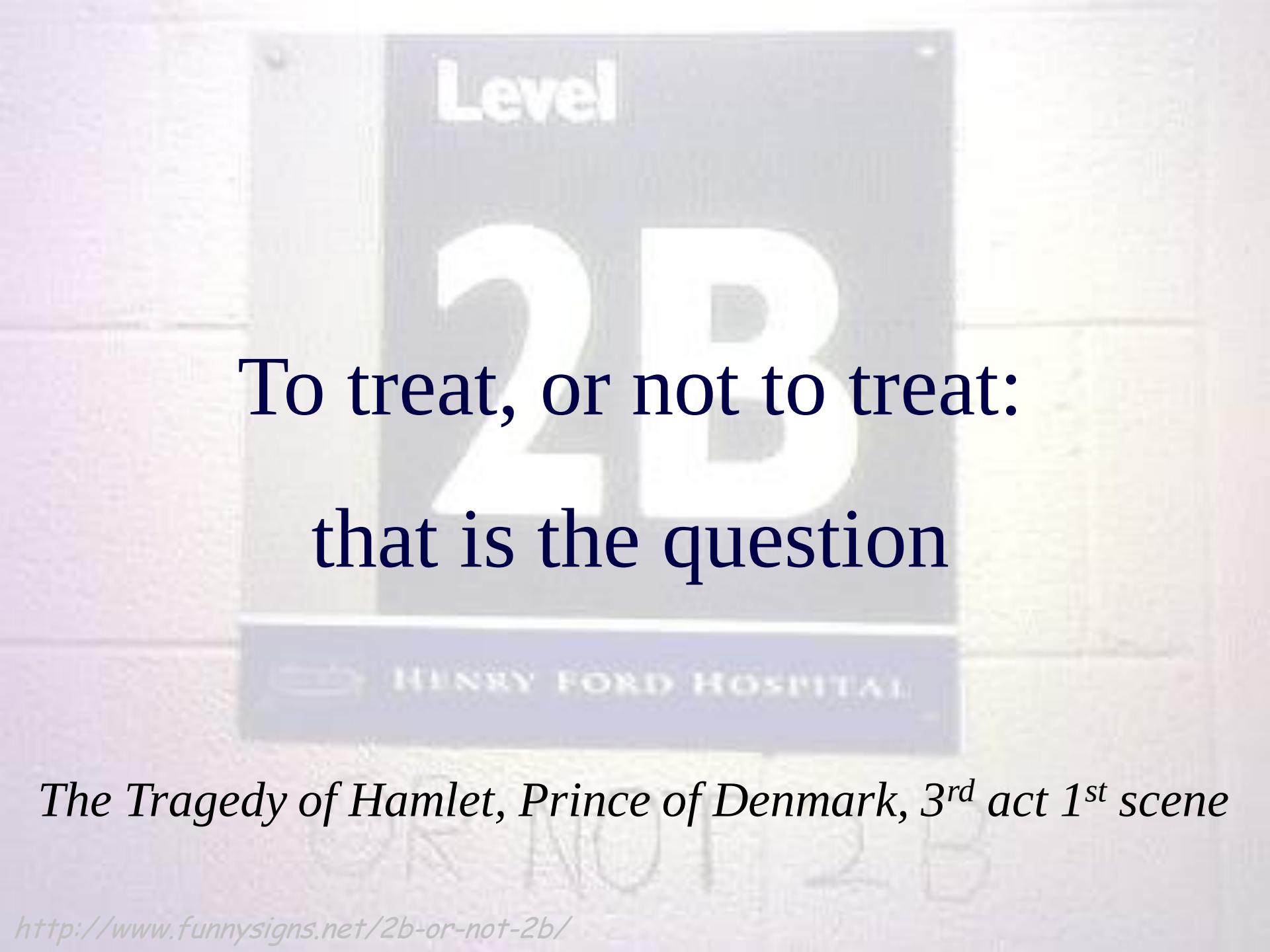


- metabolisches Syndrom
- CVD: kardiovaskuläre Erkrankung: koronare Herzkrankheit, Schlaganfall, periphere arterielle Verschlusskrankheit
- Glaukom: Offenwinkelglaukom, Normaldruckglaukom
- OPD: okulärer Perfusionsdruck, IOD: intraokularer Druck
- genetische Disposition
- OSAS: obstruktives Schlafapnoe-Syndrom
- Risikofaktor

Glaukomtherapie

„…derzeit ist der IOD der einzige

modifizierbare Risikofaktor…“



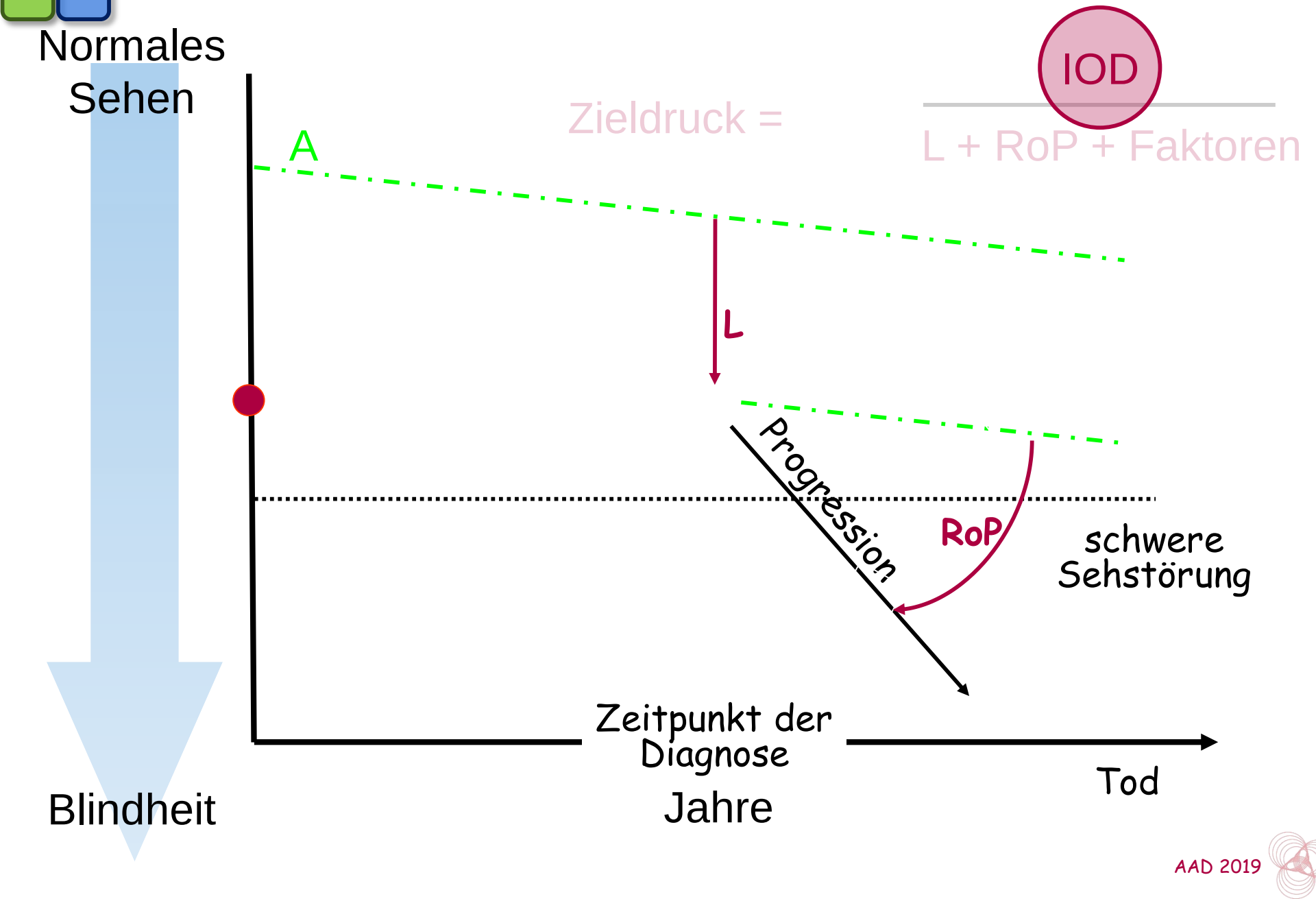
To treat, or not to treat:

that is the question

The Tragedy of Hamlet, Prince of Denmark, 3rd act 1st scene

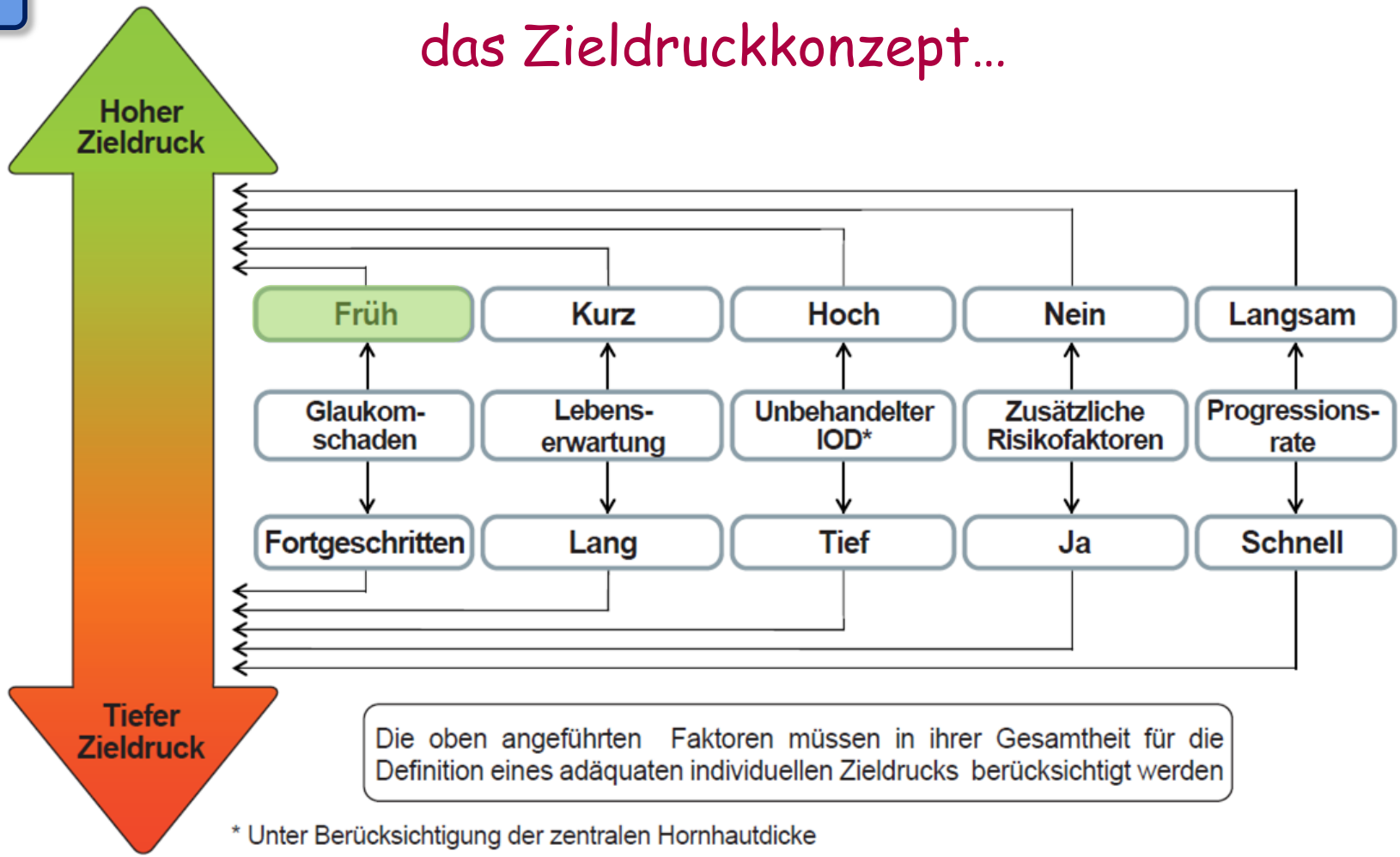
http://www.funnysigns.net/2b-or-not-2b/

Das therapeutische Konzept: Zieldruck



Das Dilemma

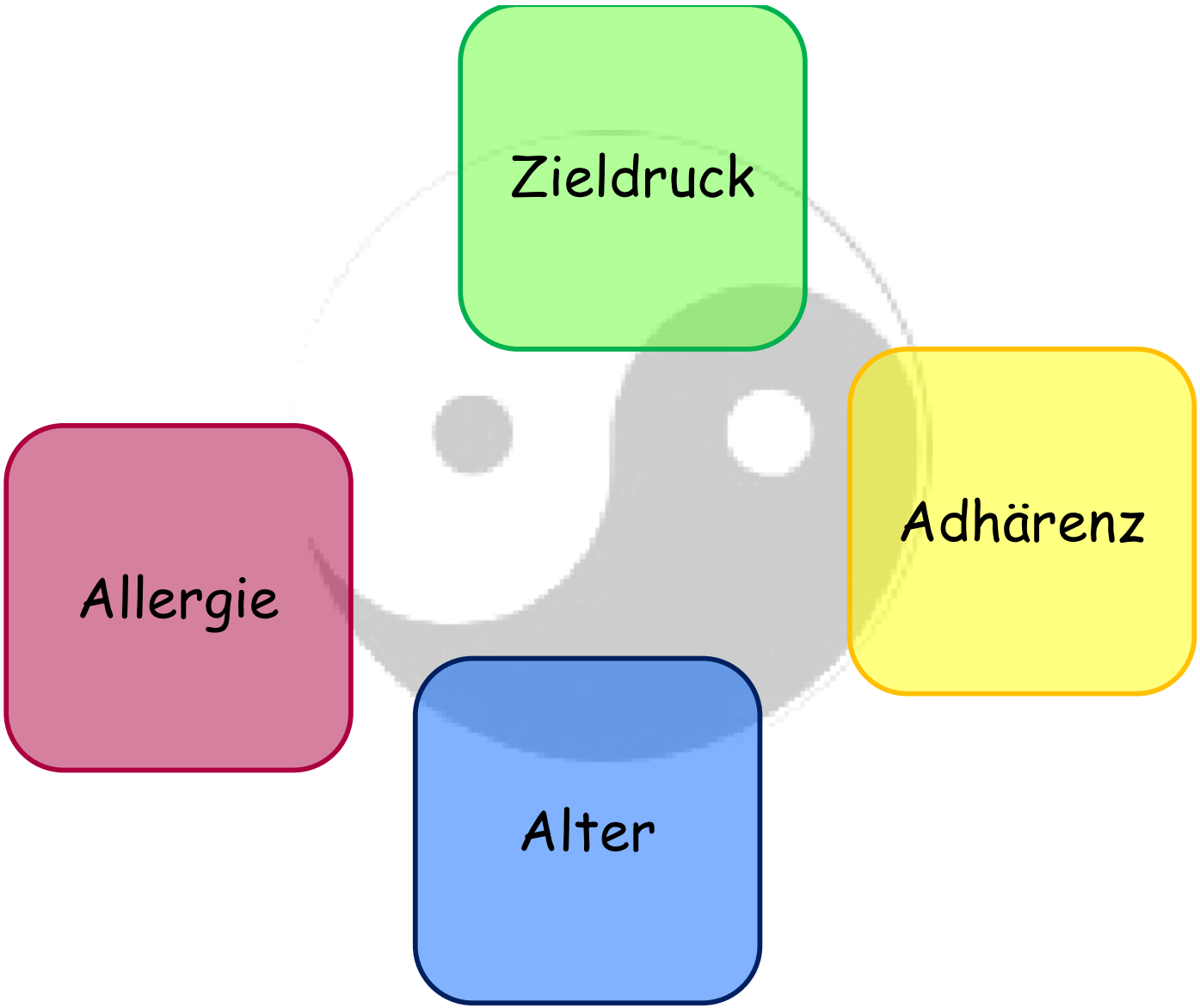
das Zieldruckkonzept…



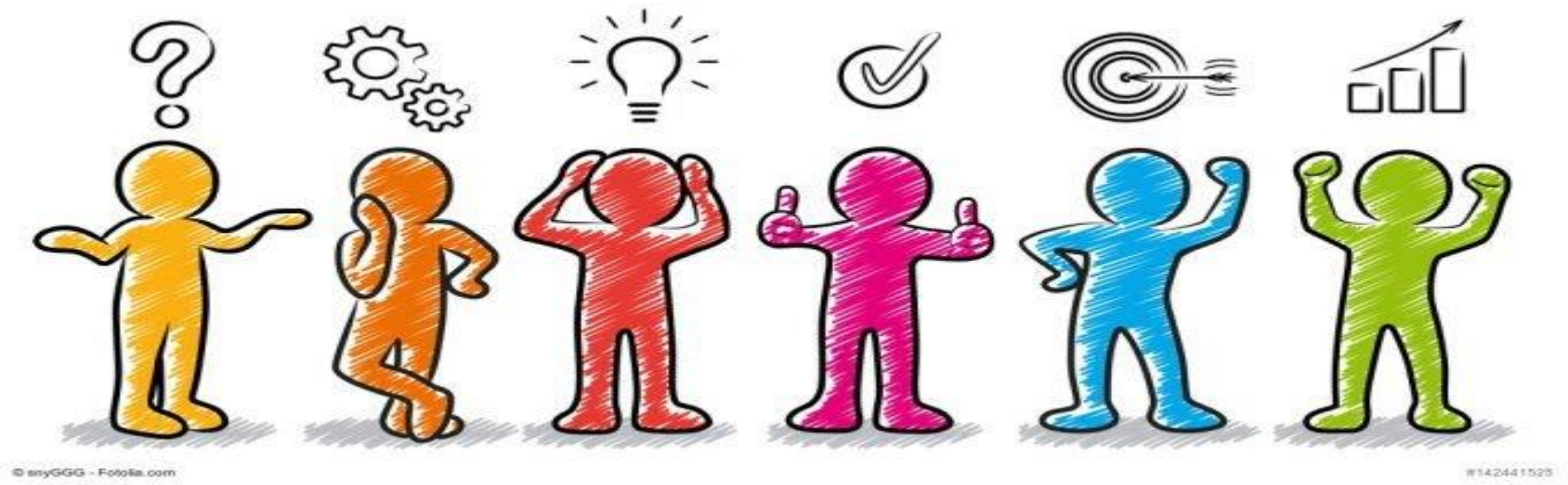
ist im Prinzip ein Mangelkonzept

Glaukomtherapie

Indikationen



Medikamentöse Glaukomtherapie



Medikamentöse Glaukomtherapie

Was gibt es?

Medikamentöse Glaukomtherapie

Pilocarpin

Epinephrin

Timolol

Pilocarpin+Timolol

Dorzolamid

Latanoprost

Brimonidin

Dorzolamid+Timolol

Brinzolamid

Travoprost

Bimatoprost

Latanoprost+Timolol

Bimatoprost+Timolol

Travoprost+Timolol

Brinzolamid+Timolol

Tafluprost

Brimonidin+Brinzolamid

Tafluprost+Timolol

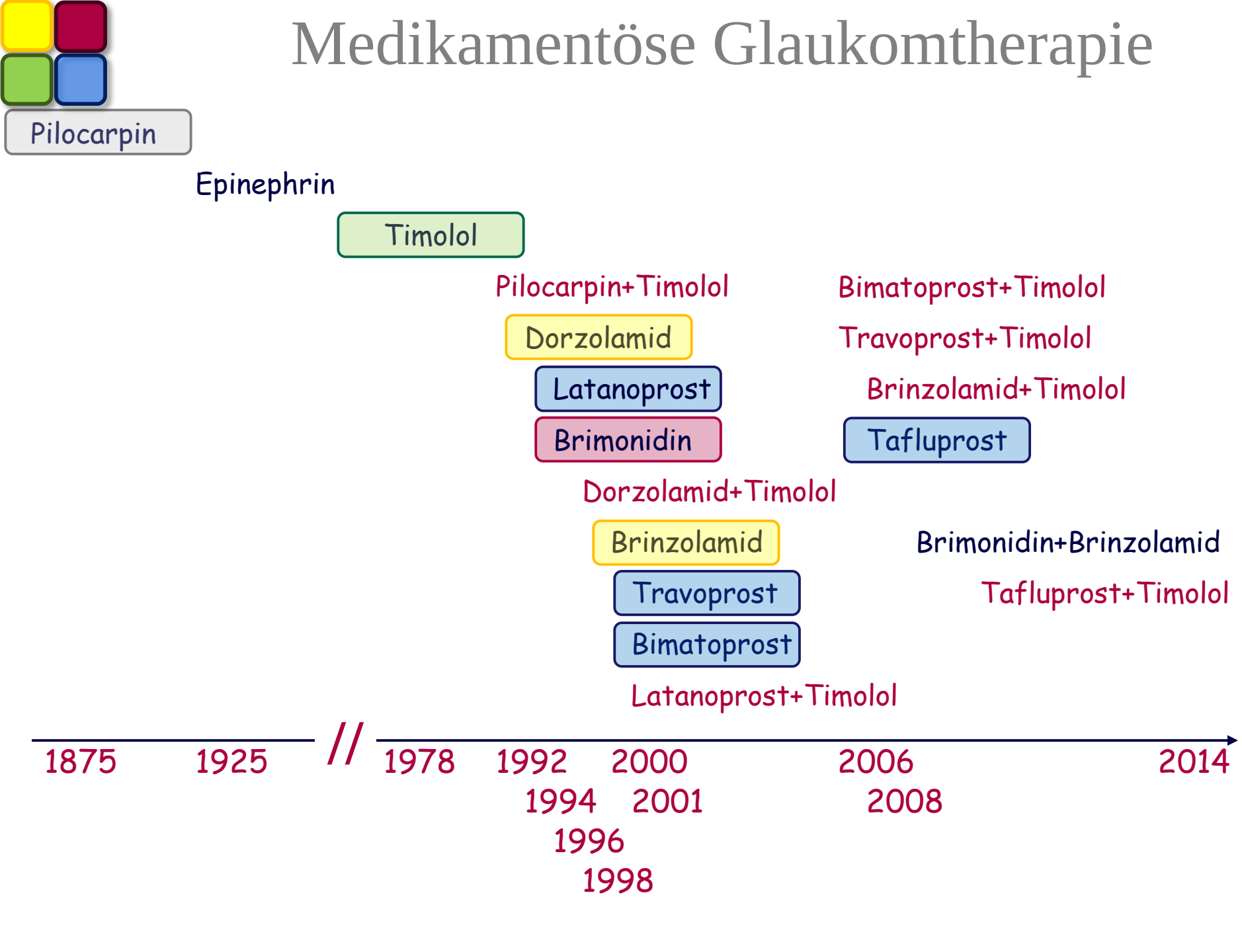
1875 1925 // 1978 1992 2000 2006 2014

1994 2001 2008

1996

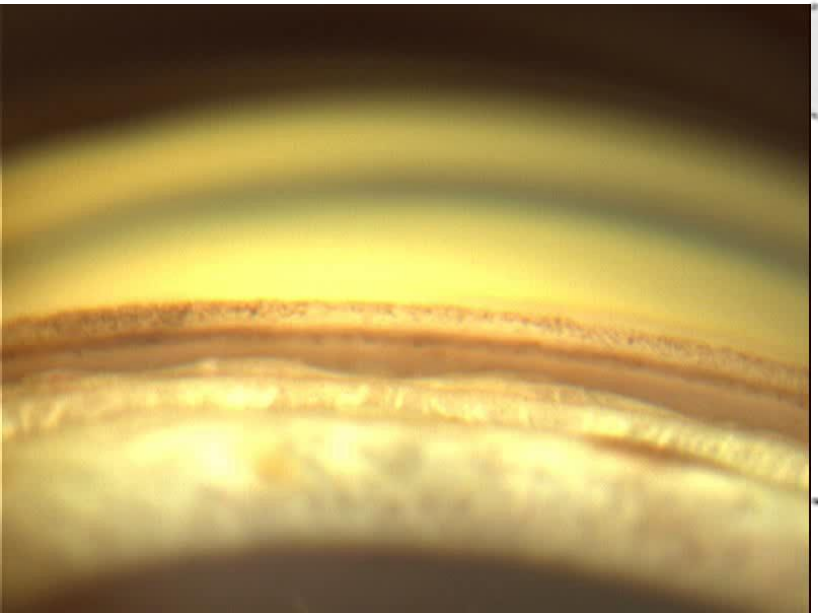
1998

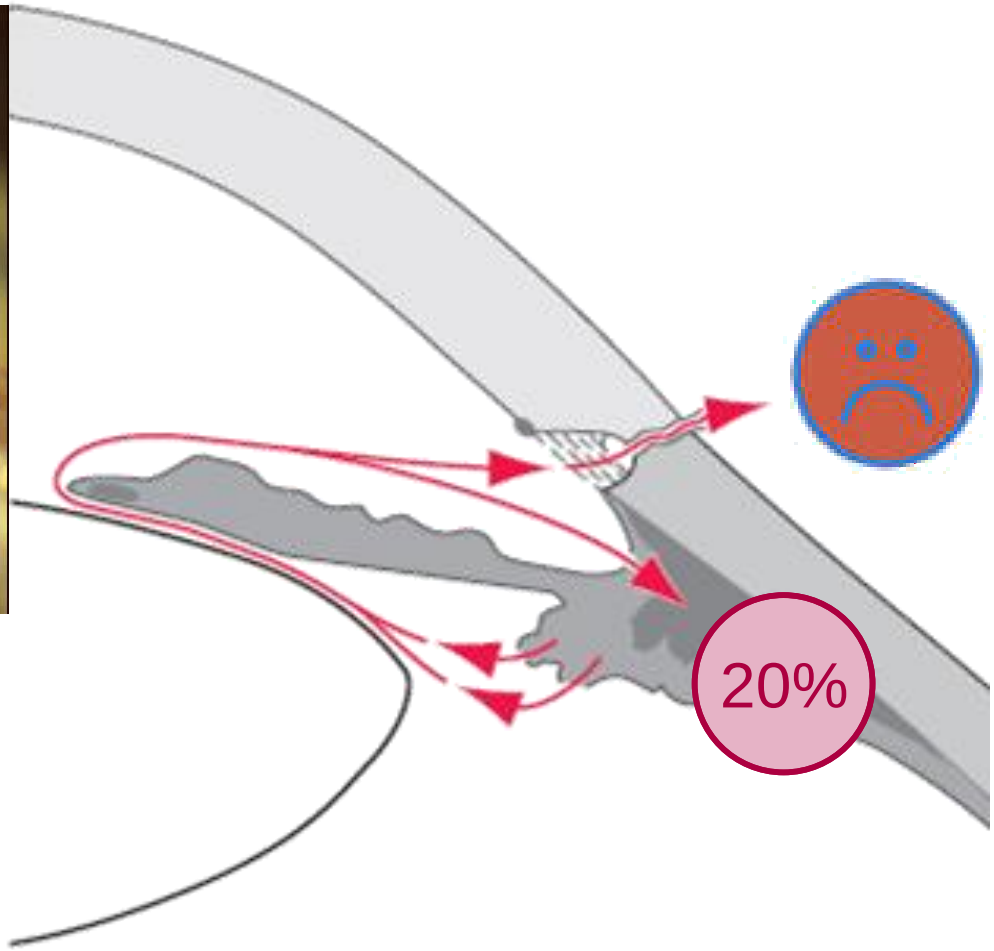
Medikamentöse Glaukomtherapie



Medikamentöse Glaukomtherapie

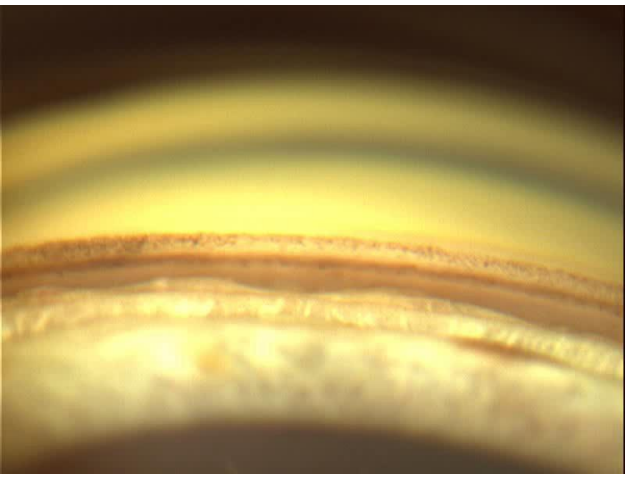
Was gibt es?

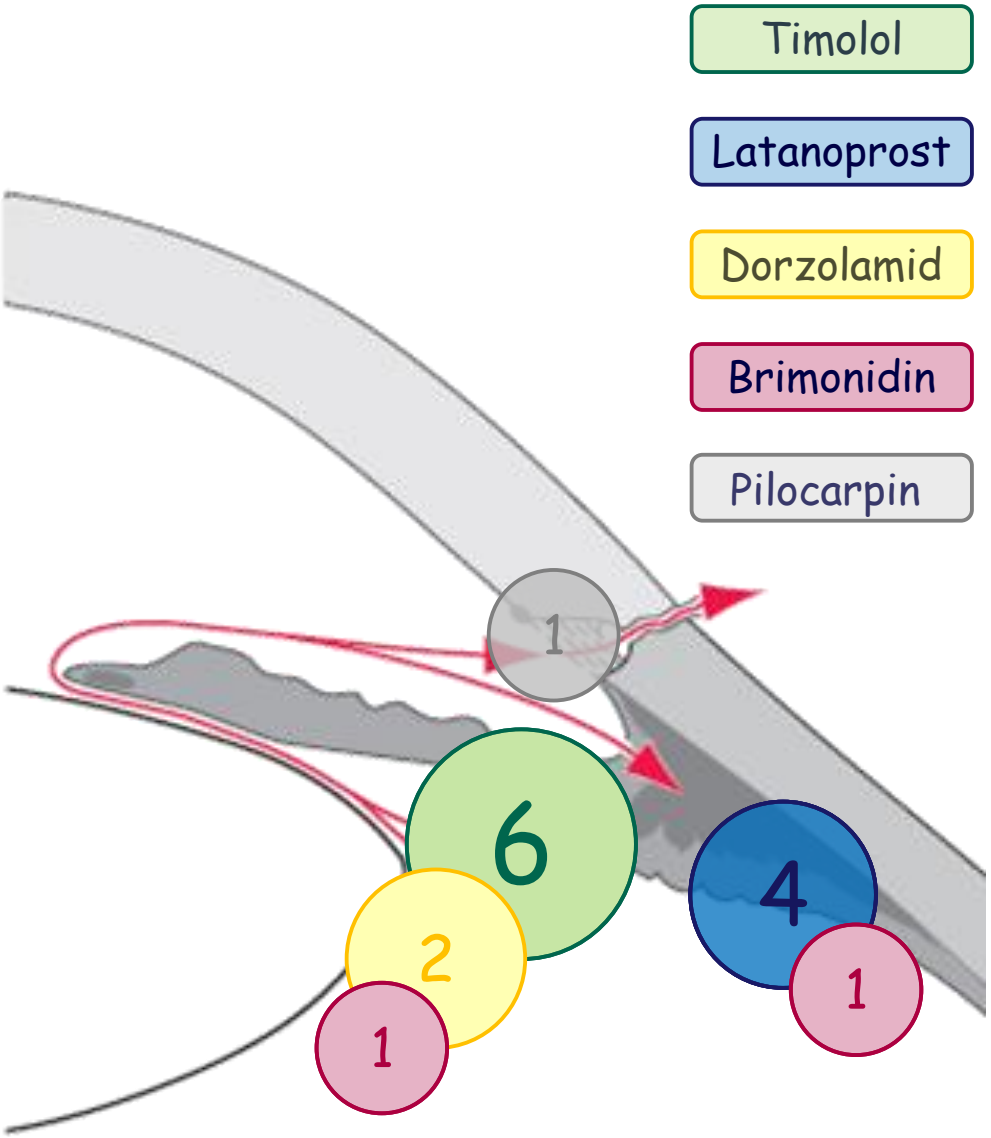




Medikamentöse Glaukomtherapie

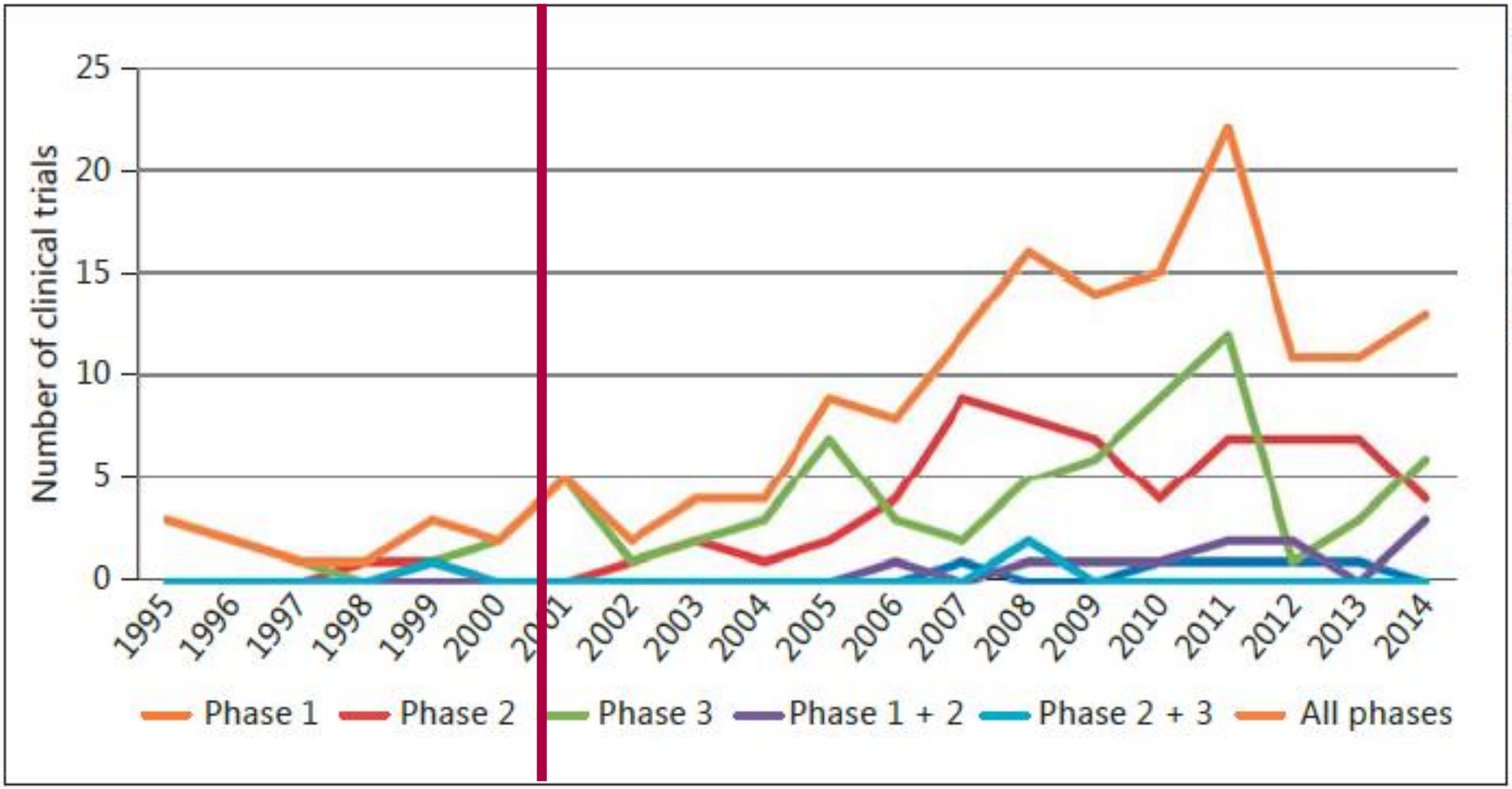
Was gibt es?





Medikamentenentwicklung Pipeline

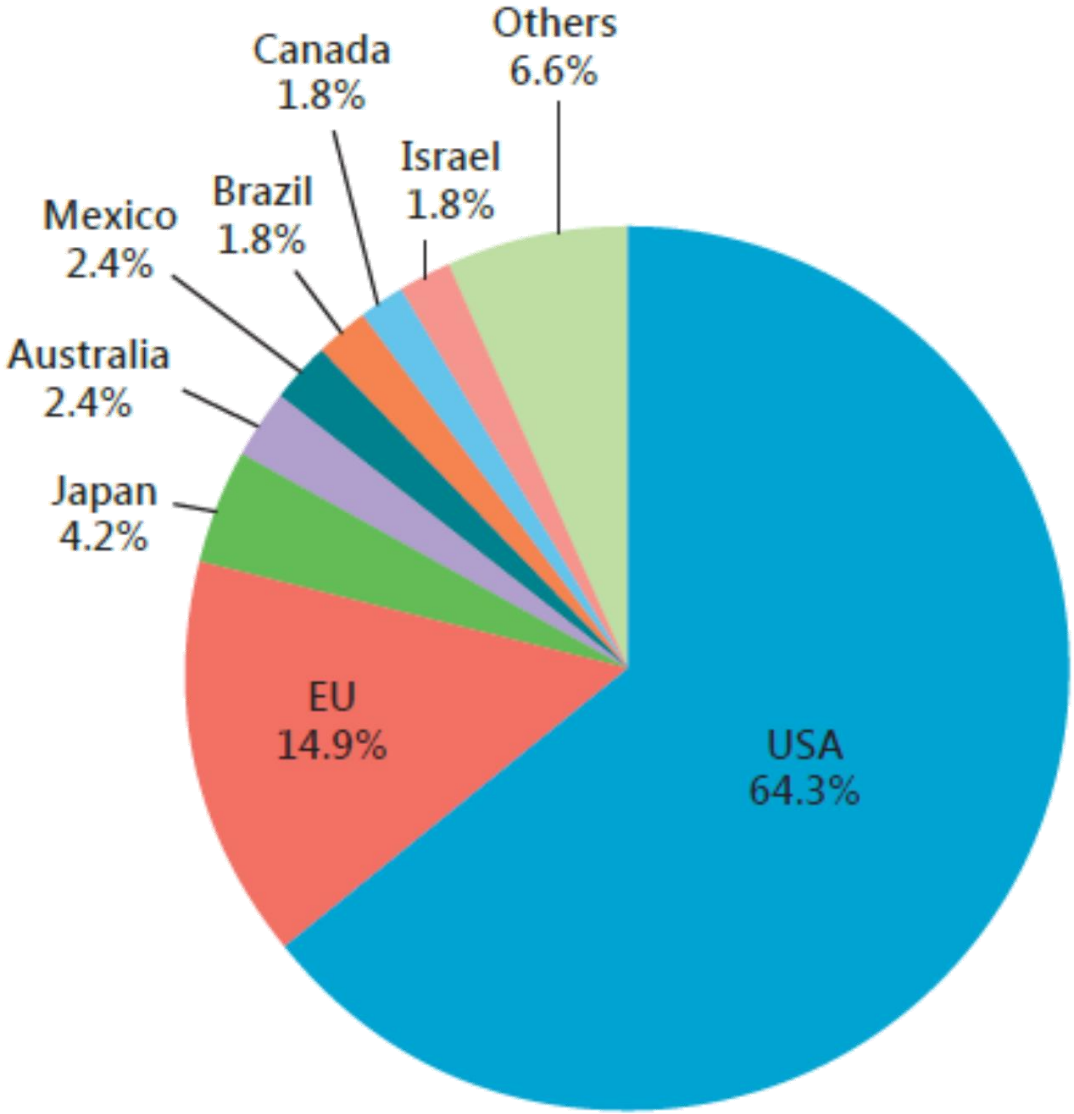
Medikamenten-bezogene Studien beim OWG



Vicente et al Ophthalmic Res 2017; 57: 201-207

Neue Ansätze

Verteilung klinischer Studien weltweit



Vicente et al Ophthalmic Res 2017; 57: 201-207

Drug development pipeline

Mechanism of action and different classes of drugs

	Phase 1	Phase 2	Phase 3	Phases 1 + 2	Phases 2 + 3	Total
IOP modulation						
Prostaglandin analogues	4	34	57	4	0	99 (62.7%)
Carbonic anhydrase inhibitors	0	3	10	0	1	14 (8.9%)
β-Blockers	0	4	2	1	0	7 (4.4%)
Angiostatic steroids	0	4	0	0	2	6 (3.8%)
α_2-Adrenergic agonist	0	2	1	1	0	4 (2.5%)
5-HT_{2A} receptor agonists	0	4	0	0	0	4 (2.5%)
Cyclin-dependent kinase inhibitors	0	1	0	0	0	1 (0.6%)
LIM-domain kinase 2 inhibitor	0	0	0	1	0	1 (0.6%)
A1 adenosine receptor agonists	0	1	0	0	0	1 (0.6%)
Macrolide	1	0	0	0	0	1 (0.6%)
Subtotal	5	53	70	7	3	138 (87.2%)
Neuroprotection						
NMDA receptor antagonists	0	0	2	0	0	2 (1.3%)
Catechin	0	0	0	1	0	1 (0.6%)
Subtotal	0	0	2	1	0	3 (1.9)
IOP modulation + neuroprotection						
Rho-kinase inhibitors	0	11	2	2	0	15 (9.5%)
Saffron	0	1	0	0	0	1 (0.6%)
Subtotal	0	12	2	2	0	16 (10.1%)
Seawater	0	0	0	1	0	1 (0.6%)
Total	5 (3.2%)	65 (41.1%)	75 (47.5%)	11 (7.0%)	3 (1.9%)	158 (100%)

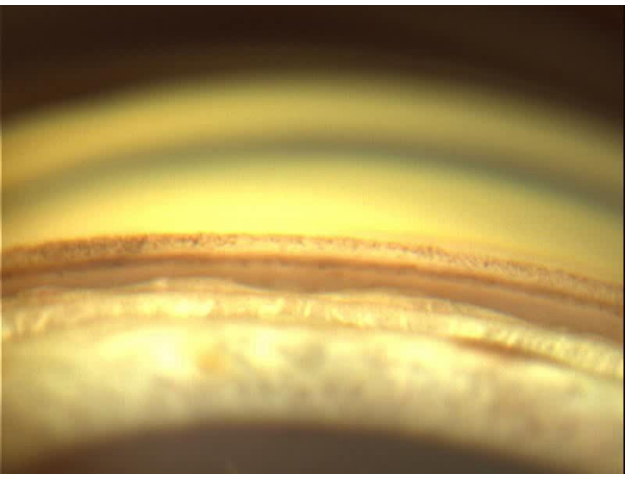
Vicente et al Ophthalmic Res 2017; 57: 201-207

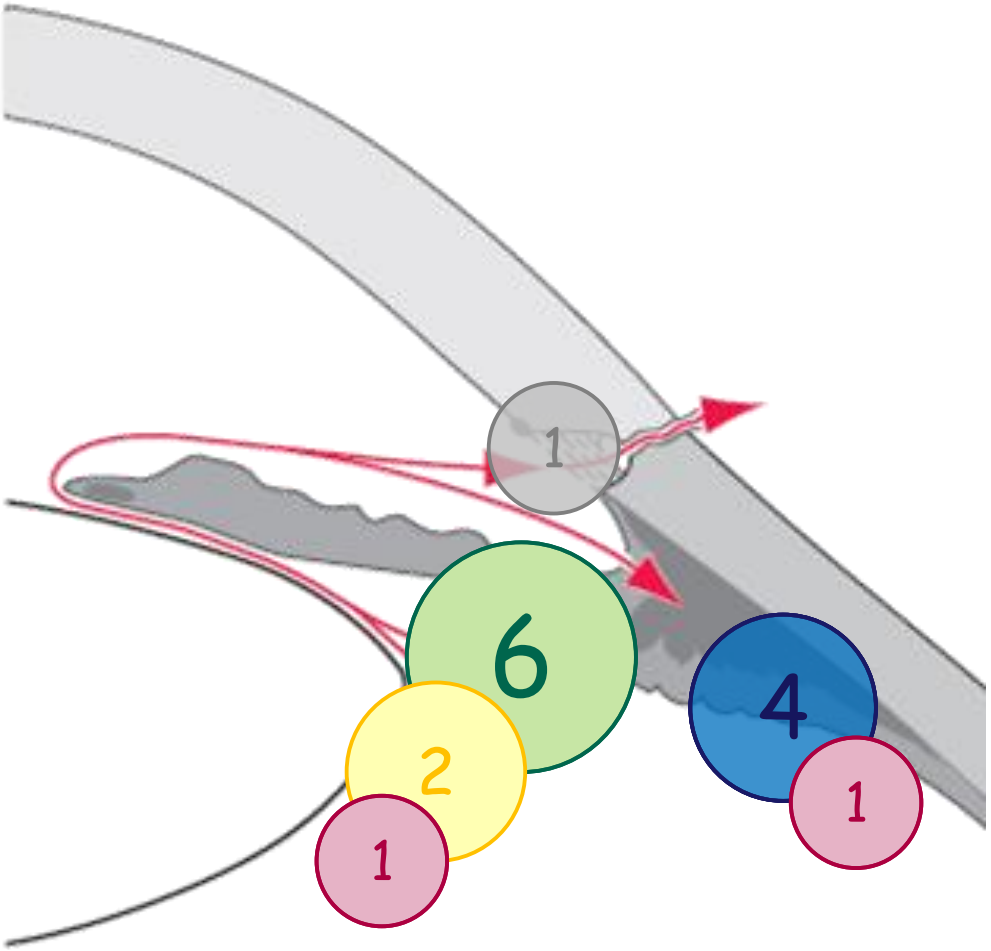
Medikamentöse Glaukomtherapie

Was kommt in naher Zukunft?

Medikamentöse Glaukomtherapie

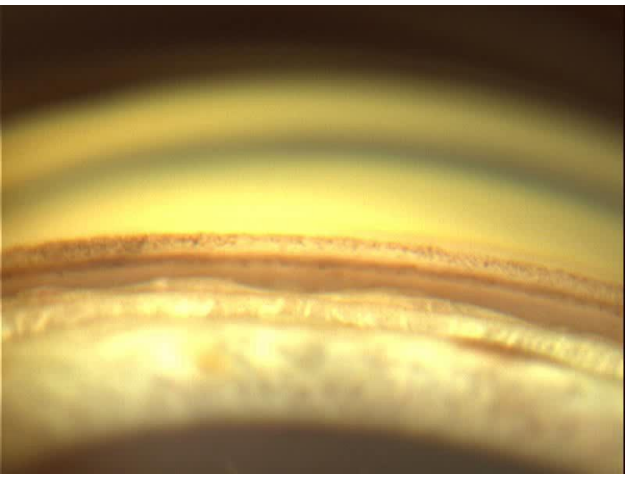
Was kommt in naher Zukunft?

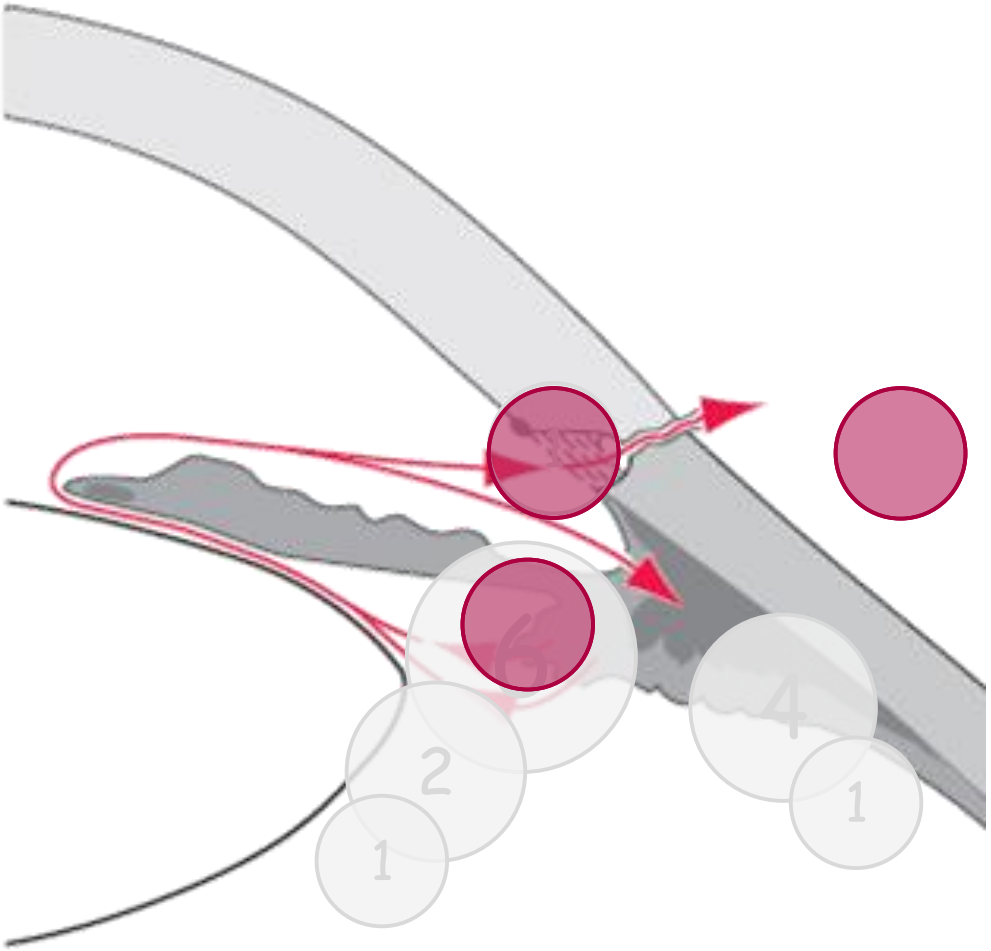




Medikamentöse Glaukomtherapie

Rho-Kinase Inhibitor





Rho-Kinase Inhibitor

Netarsudil (Rhopressa®)

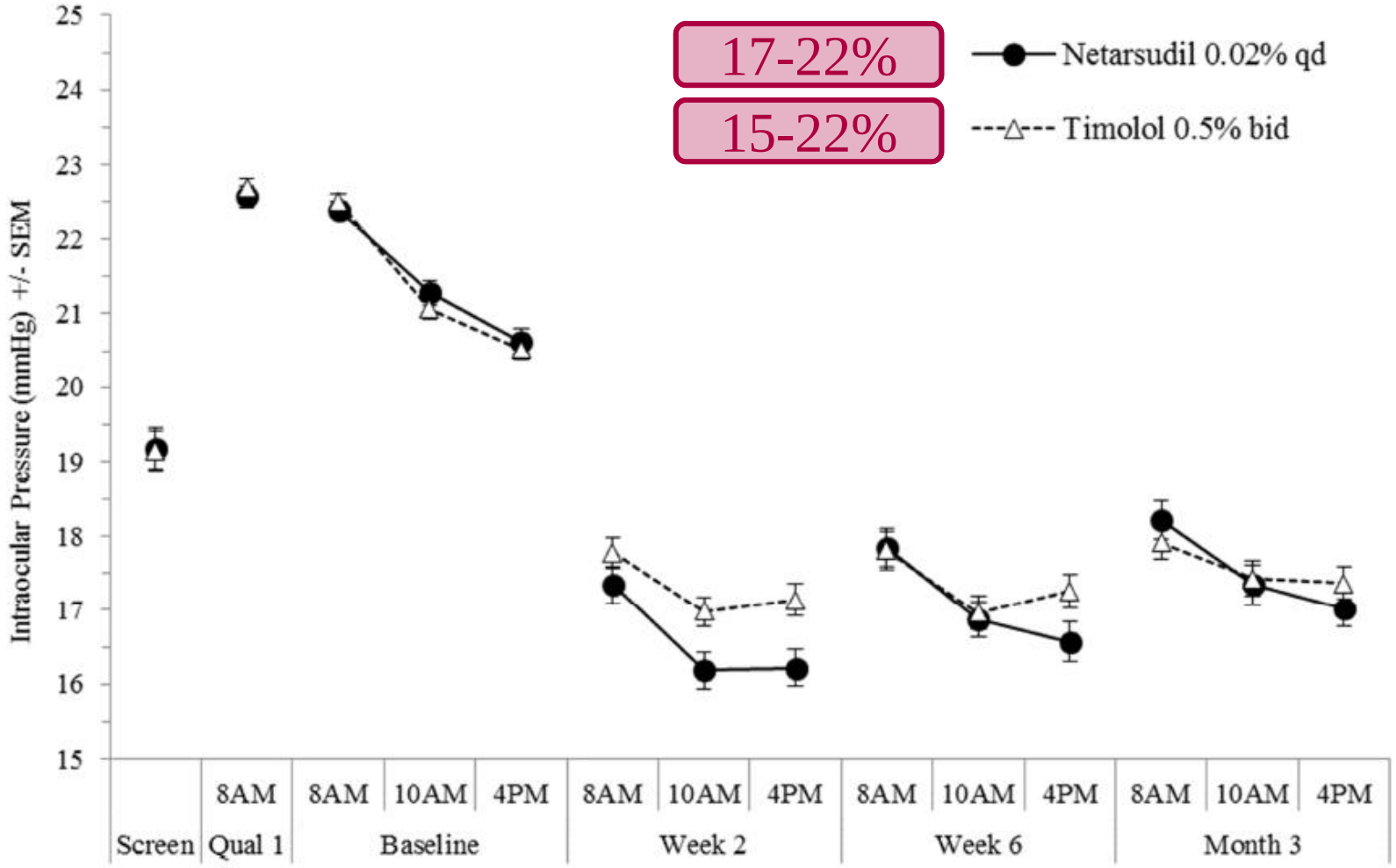
- steigert den trabekulären Abfluss
  - Rho-Kinase Inhibitor
- reduziert die Kammerwasserproduktion
  - Norepimephrin-Transporter Inhibitor
- senkt den episkleralen Venendruck

3-facher Wirkmechanismus der IOD-Reduktion

Wang et al J Glaucoma 2015; 24: 51-54

Netarsudil (Rhopressa®)

ROCKET I und II (Phase 3-Studien), FDA-Approval 2017

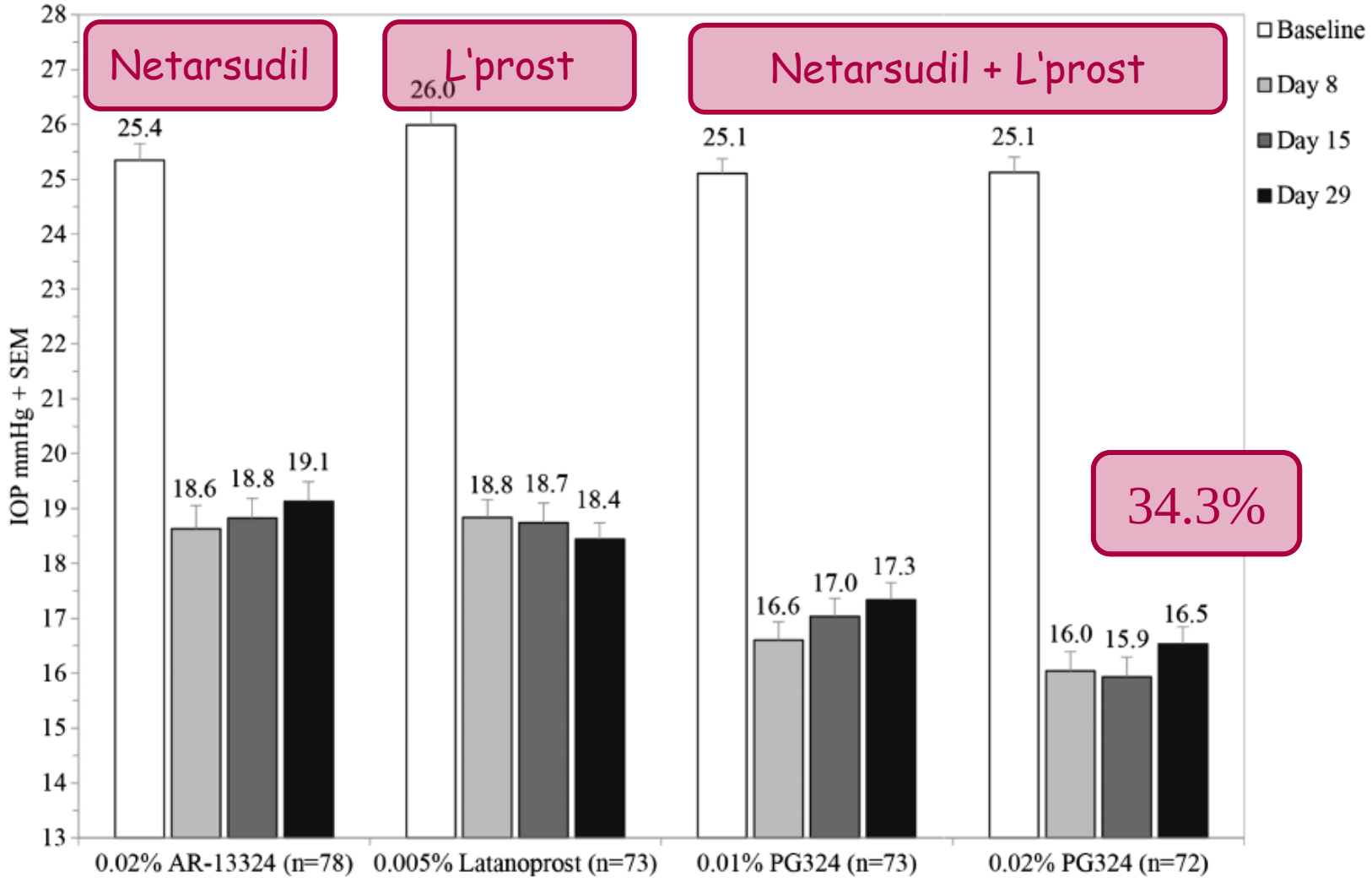


Serle et al Am J Ophthalmology 2018; 123: 302-307

AAD 2019

Netarsudil + Latanoprost (Rocklatan®)

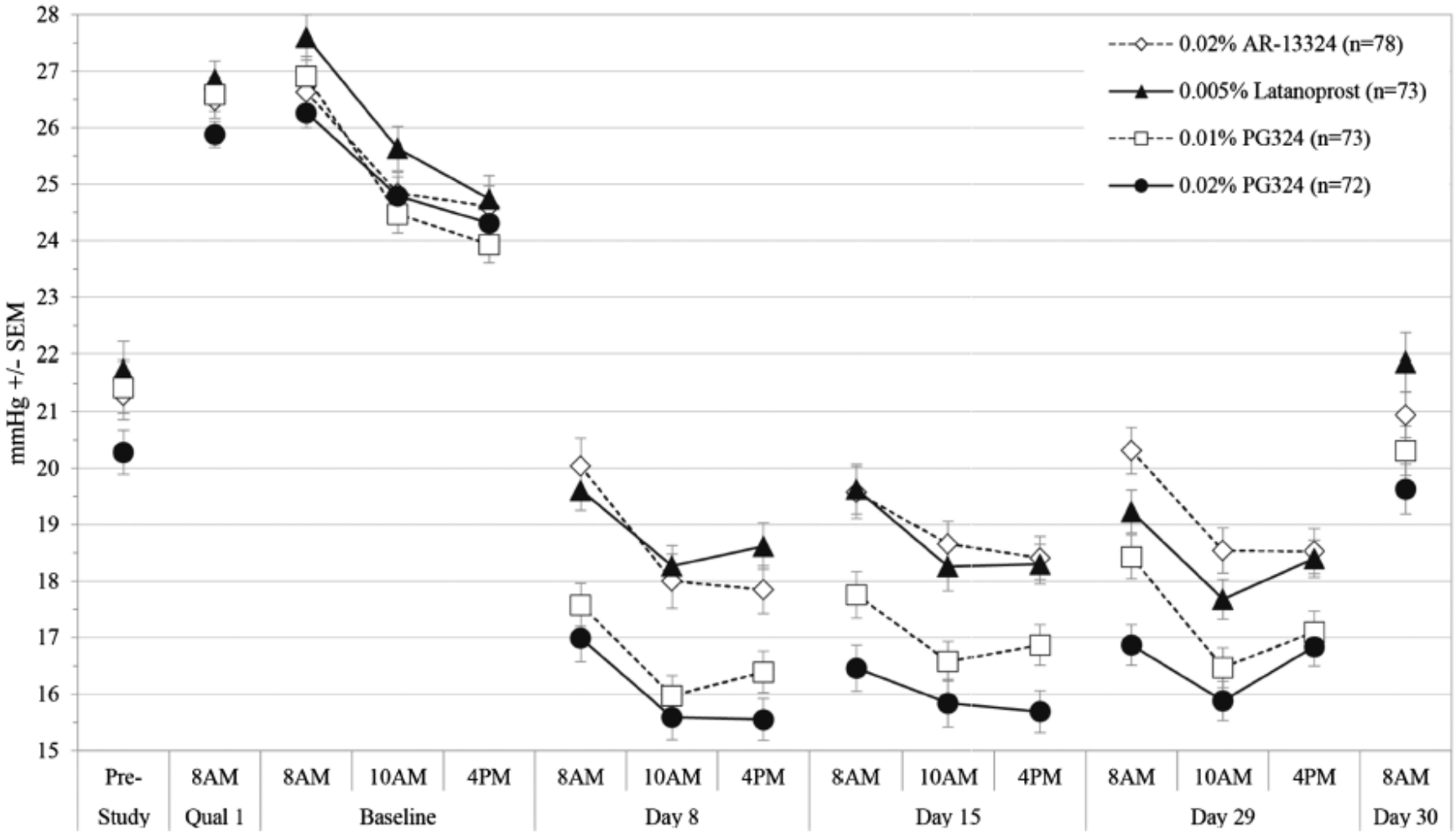
4-facher Wirkmechanismus: Netarsudil + 1



Lewis et al Br J Ophthalmol 2016; 100: 339-344

Netarsudil + Latanoprost (Rocklatan®)

4-facher Wirkmechanismus: Netarsudil + 1



mild asymptomatic conjunctival hyerpemia (~ 40%)

Lewis et al Br J Ophthalmol 2016; 100: 339-344

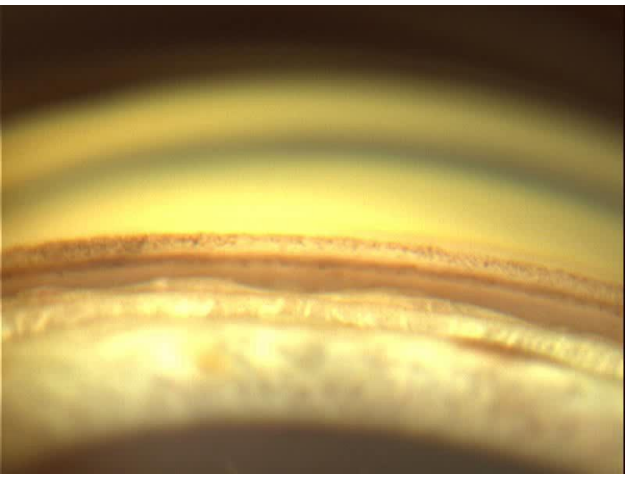
Netarsudil (Rhopressa®)

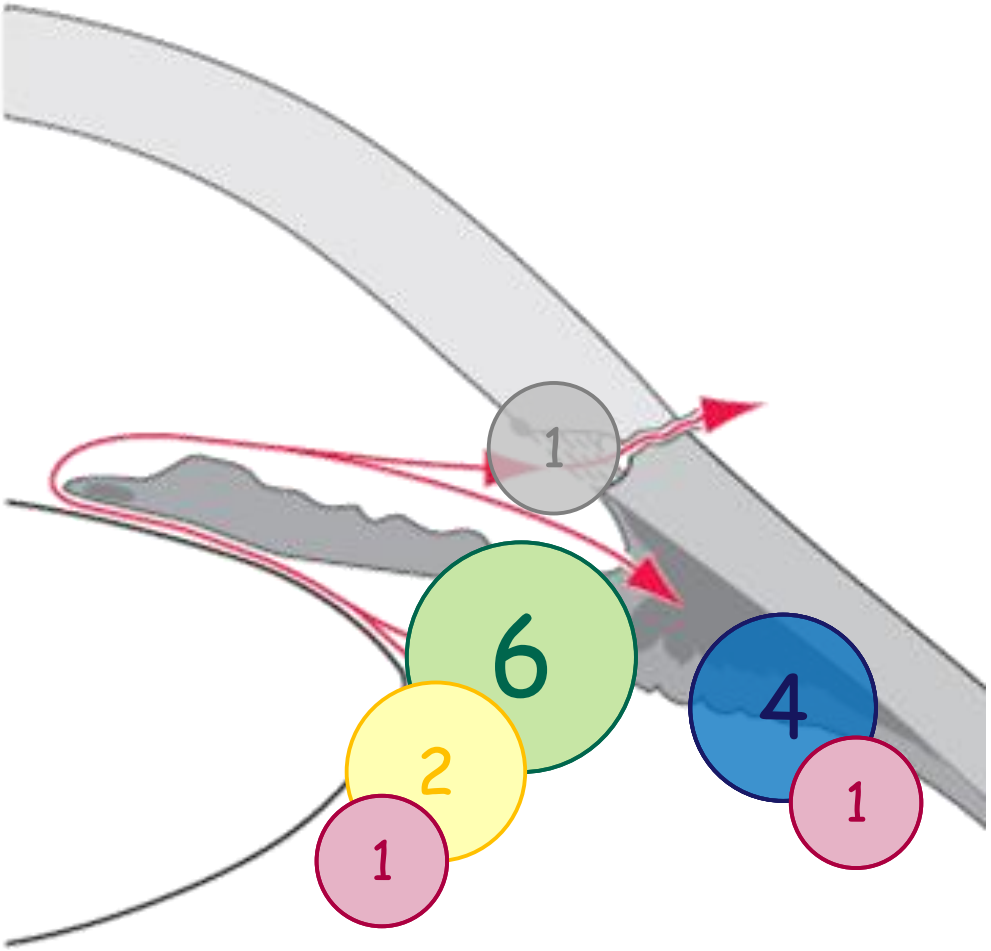
Zusammenfassung

- Rho-Kinase Inhibitor
  - Effektive Drucksenkung wie Timolol
  - Effektivität über 12 Monate
- 3-facher Wirkmechanismus
  - Steigerung des trabekulären Abflusses
  - Senkung der Kammerwasserproduktion
  - Senkung des episkleralen Venendrucks
- 1x täglich
- US FDA approval 2017

Medikamentöse Glaukomtherapie

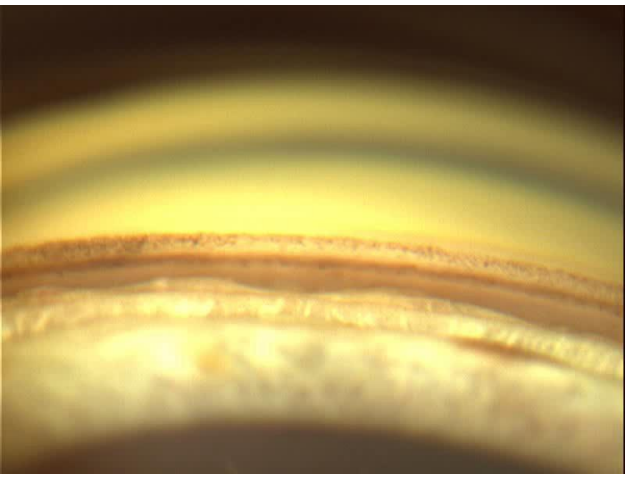
Was kommt in naher Zukunft?

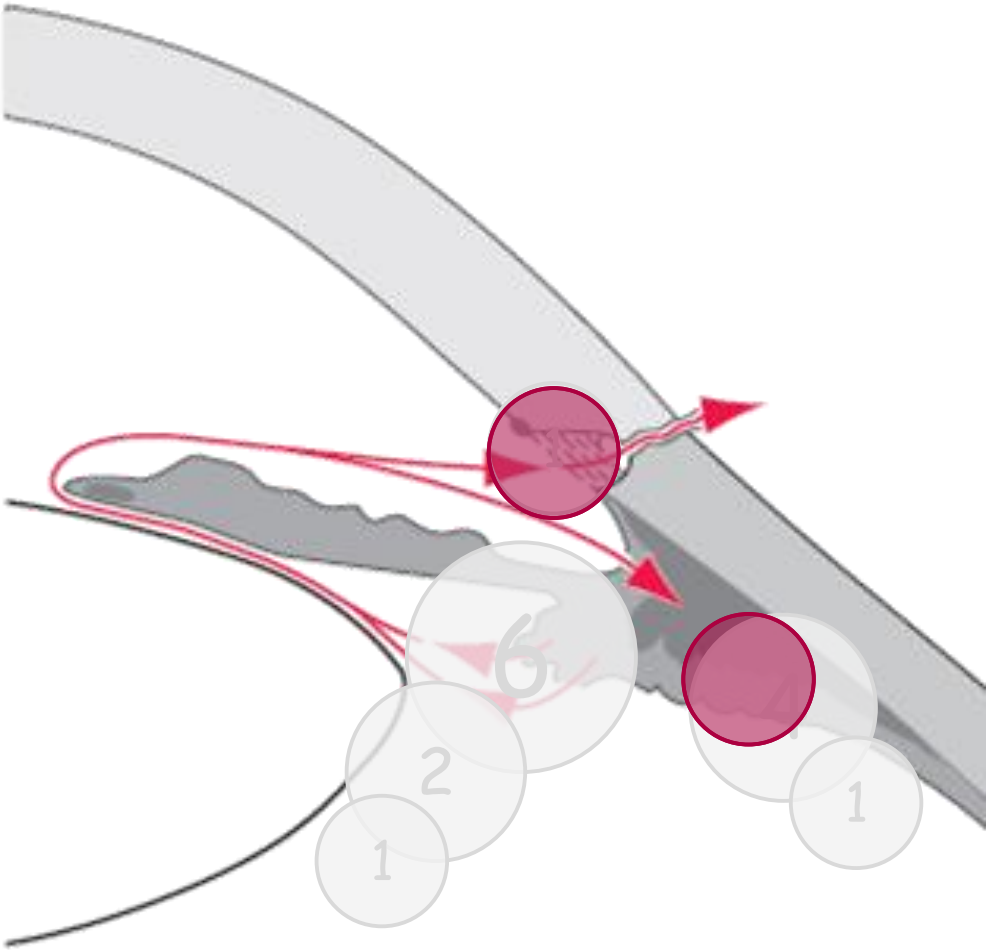




Medikamentöse Glaukomtherapie

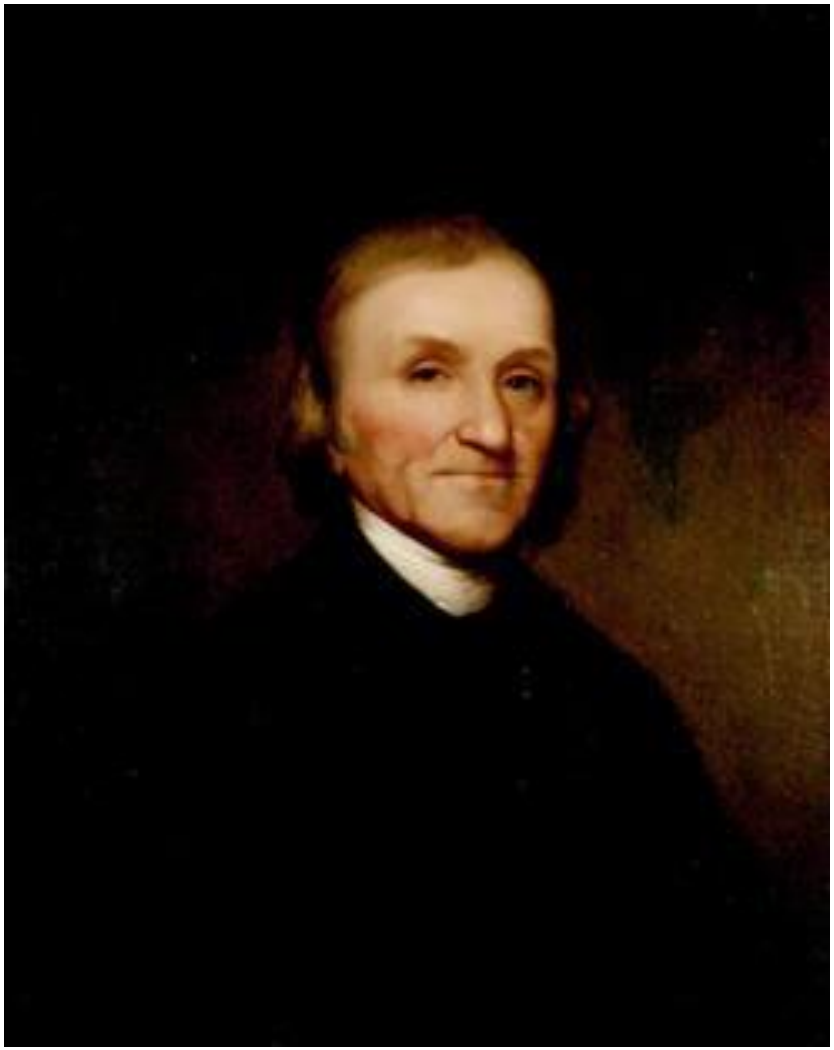
Stickstoffmonoxid (NO)-Donatoren





Stickstoffmonoxid (NO)

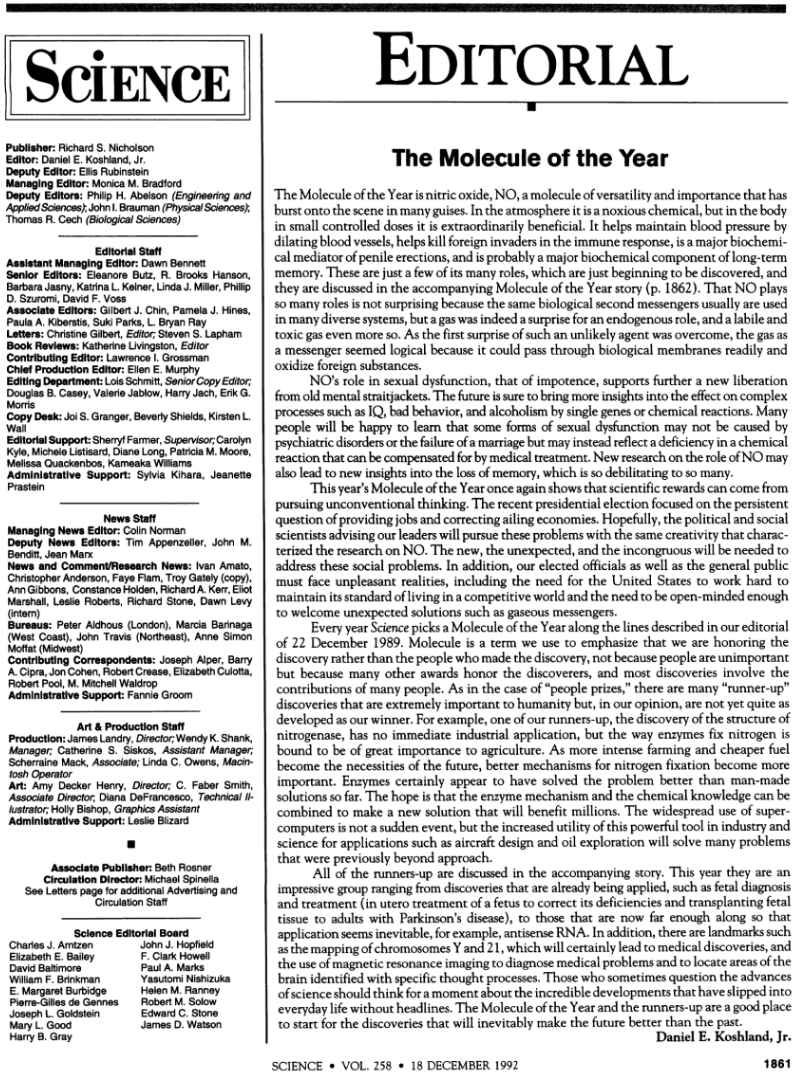
entdeckt ~1770 von Joseph Priestley



1733 – 1804
English chemist and theologian

Stickstoffmonoxid (NO)

„Molecule of the year" 1992



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EDITORIAL

The Molecule of the Year

The Molecule of the Year is nitric oxide, NO, a molecule of versatility and importance that has burst onto the scene in many guises. In the atmosphere it is a noxious chemical, but in the body in small controlled doses it is extraordinarily beneficial. It helps maintain blood pressure by dilating blood vessels, helps kill foreign invaders in the immune response, is a major biochemical mediator of penile erections, and is probably a major biochemical component of long-term memory. These are just a few of its many roles, which are just beginning to be discovered, and they are discussed in the accompanying Molecule of the Year story (p. 1862). That NO plays so many roles is not surprising because the same biological second messengers usually are used in many diverse systems, but a gas was indeed a surprise for an endogenous role, and a labile and toxic gas even more so. As the first surprise of such an unlikely agent was overcome, the gas as a messenger seemed logical because it could pass through biological membranes readily and oxidize foreign substances.

NO's role in sexual dysfunction, that of impotence, supports further a new liberation from old mental straitjackets. The future is sure to bring more insights into the effect on complex processes such as IQ, bad behavior, and alcoholism by single genes or chemical reactions. Many people will be happy to learn that some forms of sexual dysfunction may not be caused by psychiatric disorders or the failure of a marriage but may instead reflect a deficiency in a chemical reaction that can be compensated for by medical treatment. New research on the role of NO may also lead to new insights into the loss of memory, which is so debilitating to so many.

This year's Molecule of the Year once again shows that scientific rewards can come from pursuing unconventional thinking. The recent presidential election focused on the persistent question of providing jobs and correcting ailing economies. Hopefully, the political and social scientists advising our leaders will pursue these problems with the same creativity that characterized the research on NO. The new, the unexpected, and the incongruous will be needed to address these social problems. In addition, our elected officials as well as the general public must face unpleasant realities, including the need for the United States to work hard to maintain its standard of living in a competitive world and the need to be open-minded enough to welcome unexpected solutions such as gaseous messengers.

Every year *Science* picks a Molecule of the Year along the lines described in our editorial of 22 December 1989. Molecule is a term we use to emphasize that we are honoring the discovery rather than the people who made the discovery, not because people are unimportant but because many other awards honor the discoverers, and most discoveries involve the contributions of many people. As in the case of "people prizes," there are many "runner-up" discoveries that are extremely important to humanity but, in our opinion, are not yet quite as developed as our winner. For example, one of our runners-up, the discovery of the structure of nitrogenase, has no immediate industrial application, but the way enzymes fix nitrogen is bound to be of great importance to agriculture. As more intense farming and cheaper fuel become the necessities of the future, better mechanisms for nitrogen fixation become more important. Enzymes certainly appear to have solved the problem better than man-made solutions so far. The hope is that the enzyme mechanism and the chemical knowledge can be combined to make a new solution that will benefit millions. The widespread use of supercomputers is not a sudden event, but the increased utility of this powerful tool in industry and science for applications such as aircraft design and oil exploration will solve many problems that were previously beyond approach.

All of the runners-up are discussed in the accompanying story. This year they are an impressive group ranging from discoveries that are already being applied, such as fetal diagnosis and treatment (in utero treatment of a fetus to correct its deficiencies and transplanting fetal tissue to adults with Parkinson's disease), to those that are now far enough along so that application seems inevitable, for example, antisense RNA. In addition, there are landmarks such as the mapping of chromosomes Y and 21, which will certainly lead to medical discoveries, and the use of magnetic resonance imaging to diagnose medical problems and to locate areas of the brain identified with specific thought processes. Those who sometimes question the advances of science should think for a moment about the incredible developments that have slipped into everyday life without headlines. The Molecule of the Year and the runners-up are a good place to start for the discoveries that will inevitably make the future better than the past.

Daniel E. Koshland, Jr.

Koshland E Jr. The molecule of the year. Science 1992; 258: 1861

Stickstoffmonoxid (NO)

Nobel-Preis in Physiologie/Medizin 1998

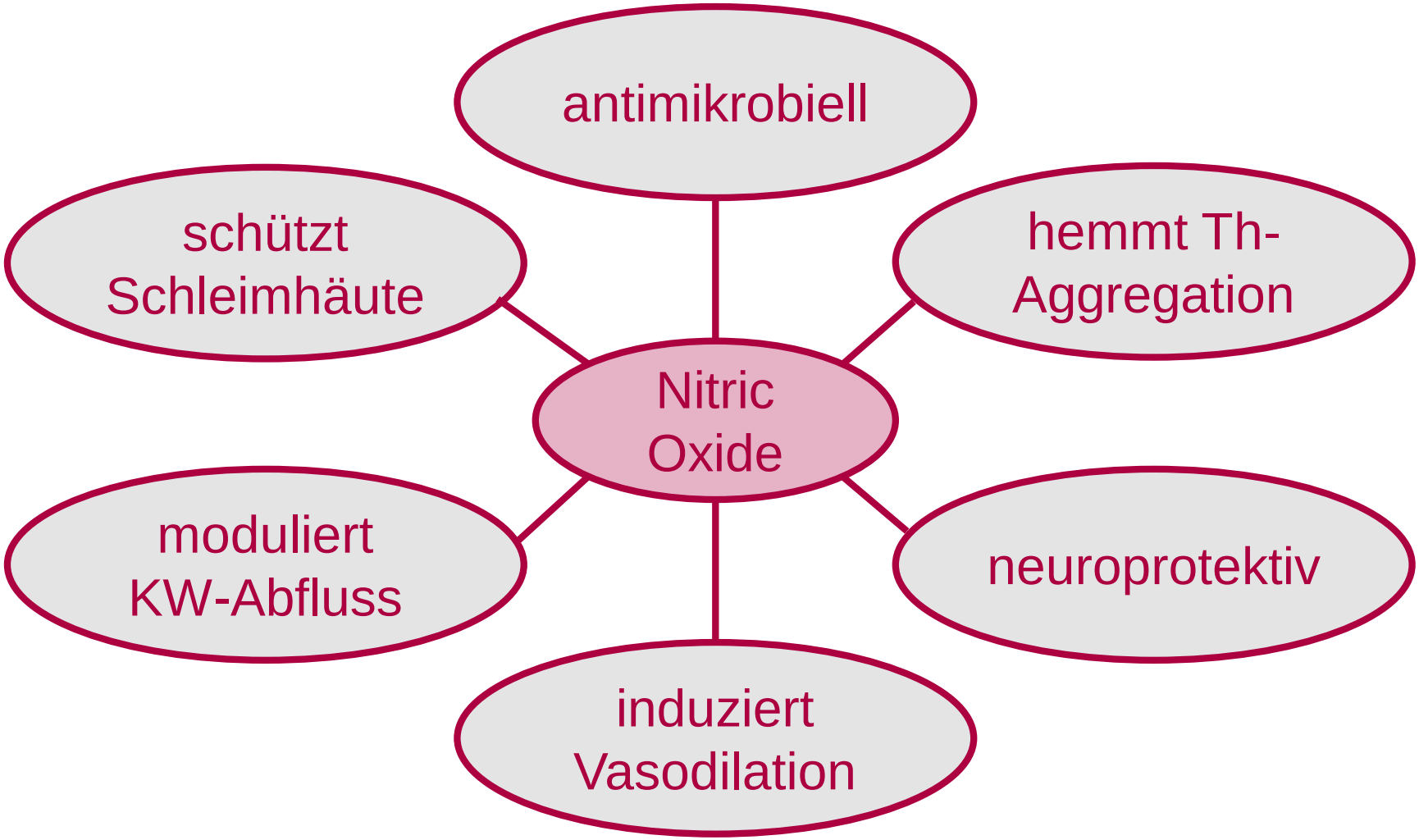
Furchgott, Ignarro and Murad

„concerning NO as a signaling molecule in the cardiovascular system“

Koshland E Jr. The molecule of the year. Science 1992; 258: 1861

Stickstoff (NO)

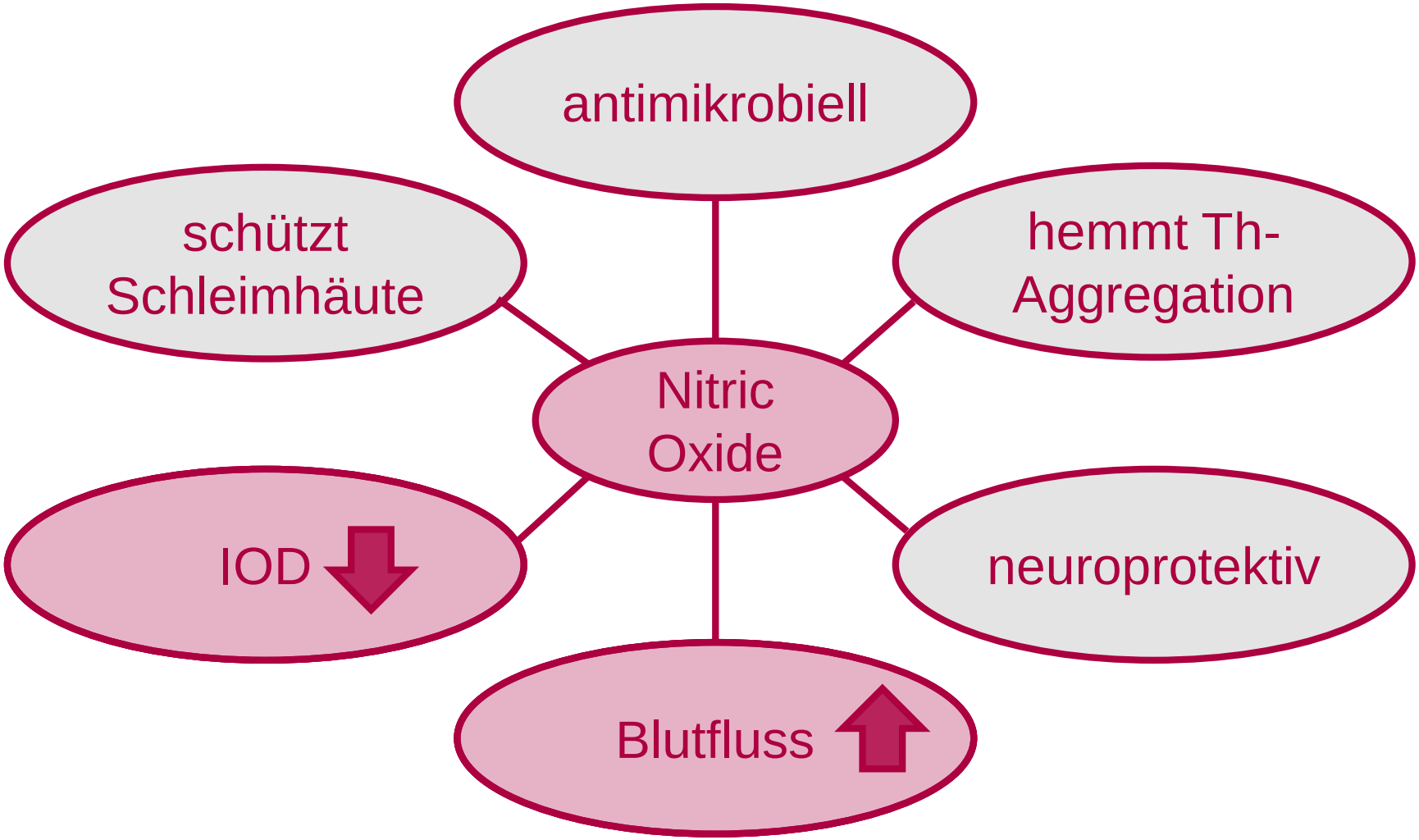
Rolle von NO in den biologischen Systemen



Kumar et al Biomed Pharmacother 2017; 85: 182-201

Stickstoff (NO)

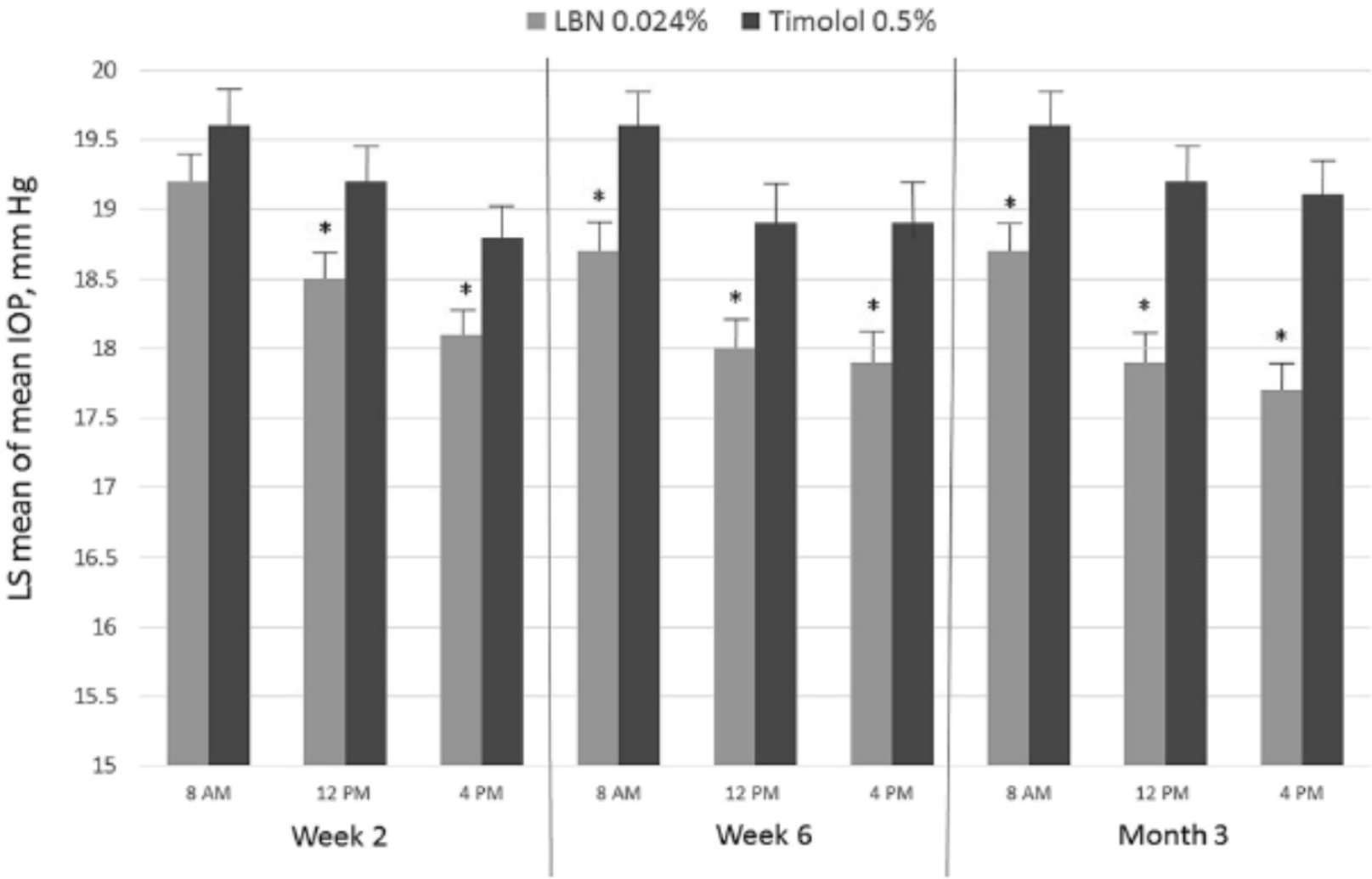
Rolle von NO in den biologischen Systemen



Kumar et al Biomed Pharmacother 2017; 85: 182-201

Latanoprostene bunod 0.024% (Vyzulta®)

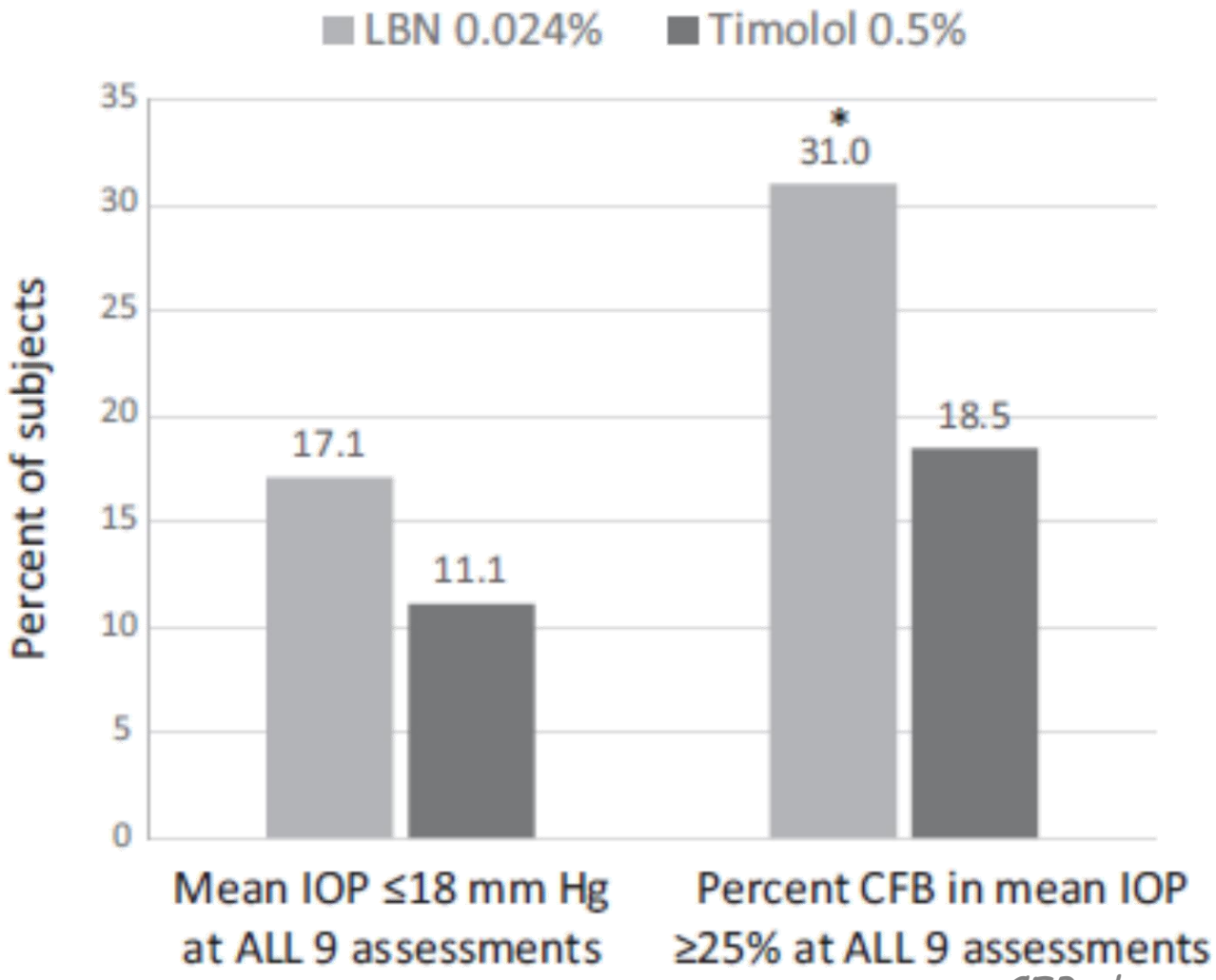
LUNAR (Phase III)



Medeiros et al Am J Ophthalmol 2016; 168: 250-259

Latanoprostene bunod 0.024% (Vyzulta®)

LUNAR (Phase III)

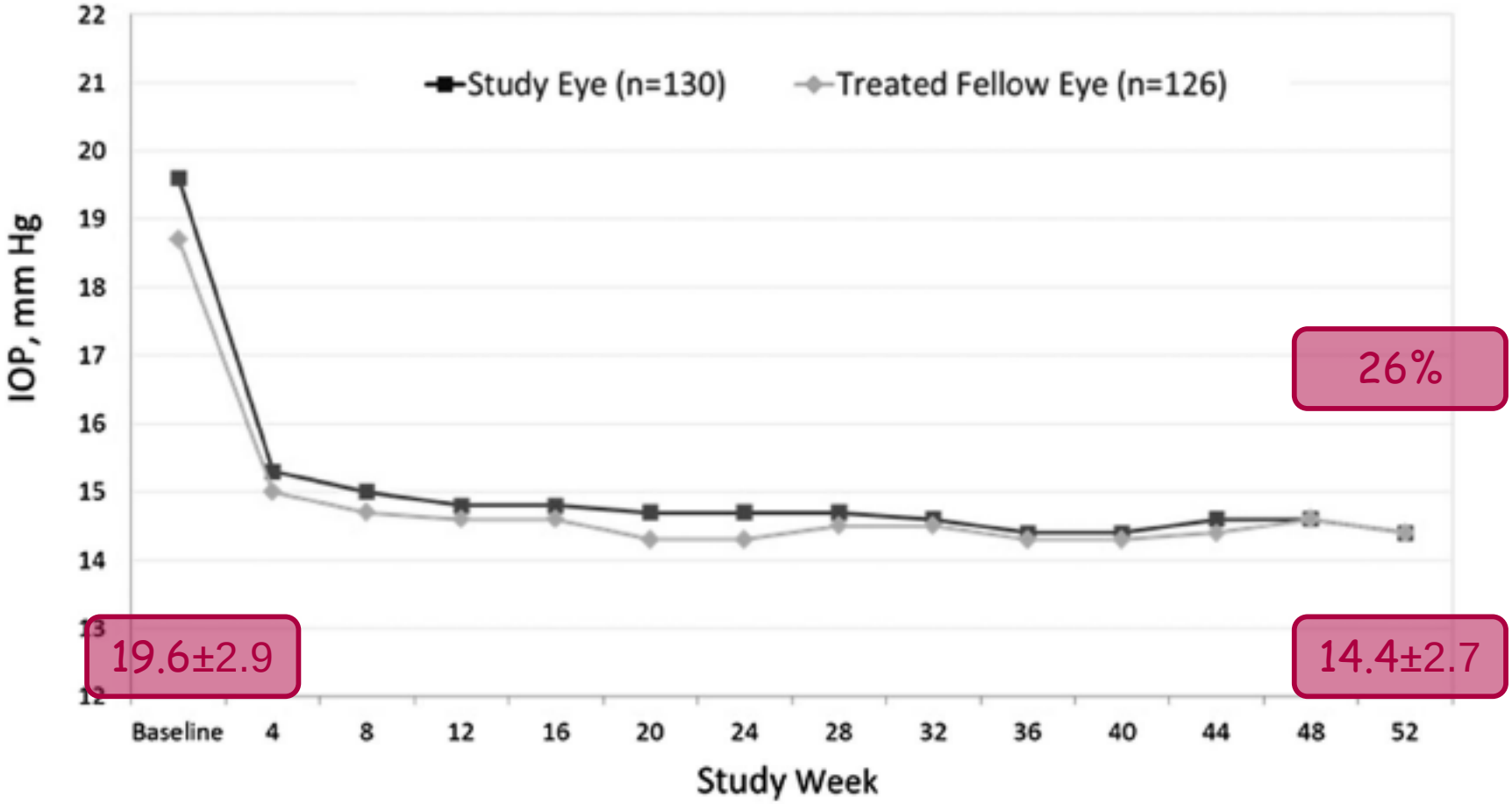


CFB change from baseline

Medeiros et al Am J Ophthalmol 2016; 168: 250-259

Latanoprostene bunod 0.024% (Vyzulta®)

JUPITER (phase III)



Kawase et al Adv Ther 2016; 33: 1612-1627

Latanoprostene bunod 0.024% (Vyzulta®)

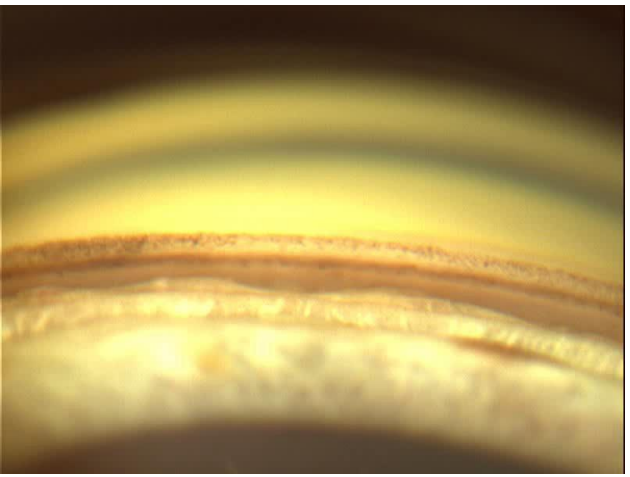
Zusammenfassung

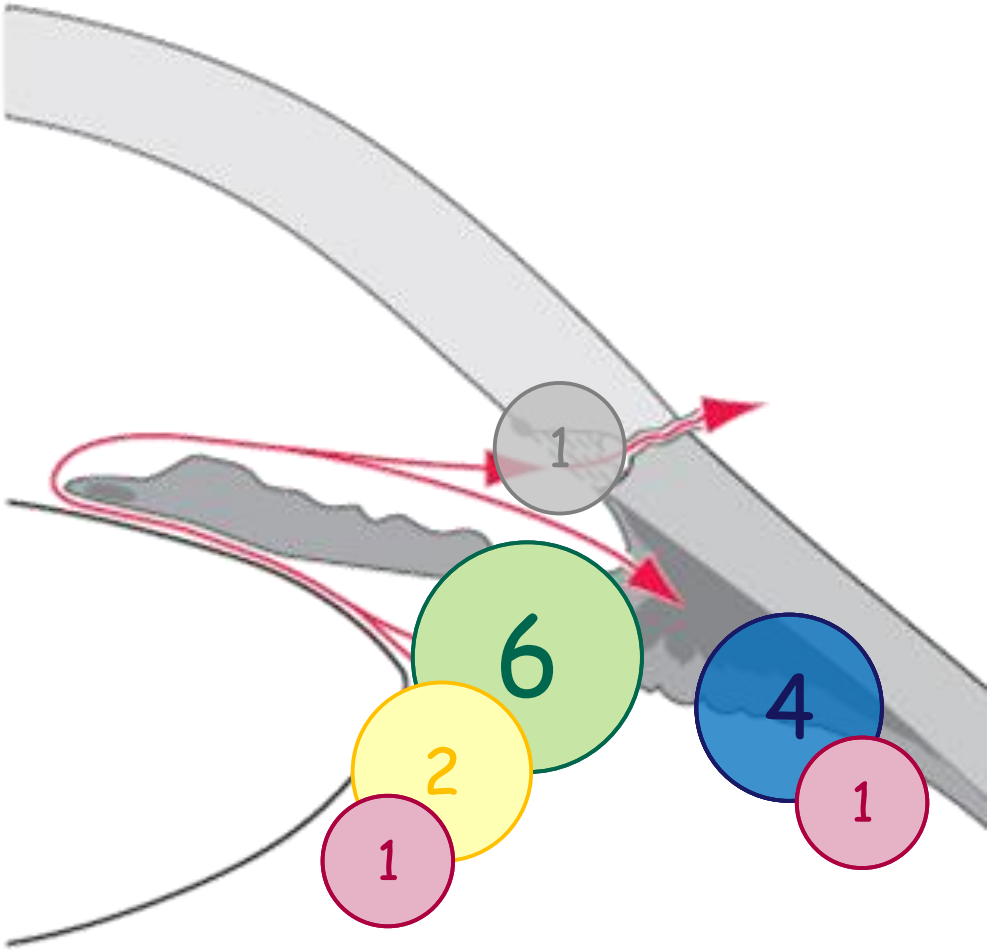
- NO-freisetzendes Prostglandin $F_{2\alpha}$-Analogon
  - effektiver als Timolol oder Prostaglandin-Analogon
  - Effektivität über 12 Monate
- 2-facher Wirkmechanismus
  - Steigerung des uveoskleralen Ablusses (Prostaglandin)
  - Steigerung des trabekulären Abflusses (NO-Freisetzung)
- 1x täglich
- US FDA approval 2017

Kaufman Exp Opinion Pharmacother 2017; 18: 433-444

Medikamentöse Glaukomtherapie

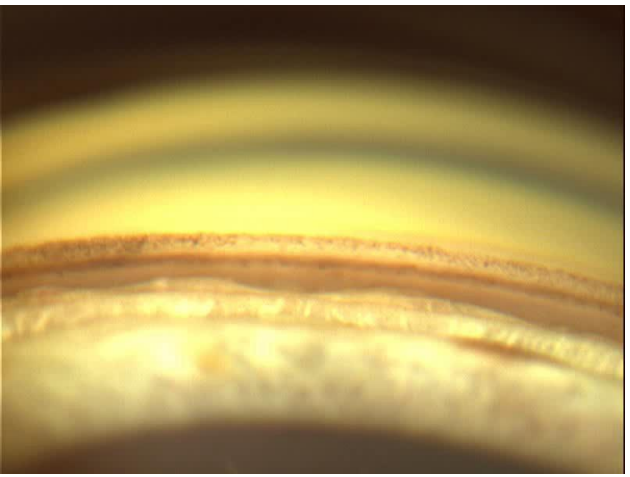
Was kommt in naher Zukunft?

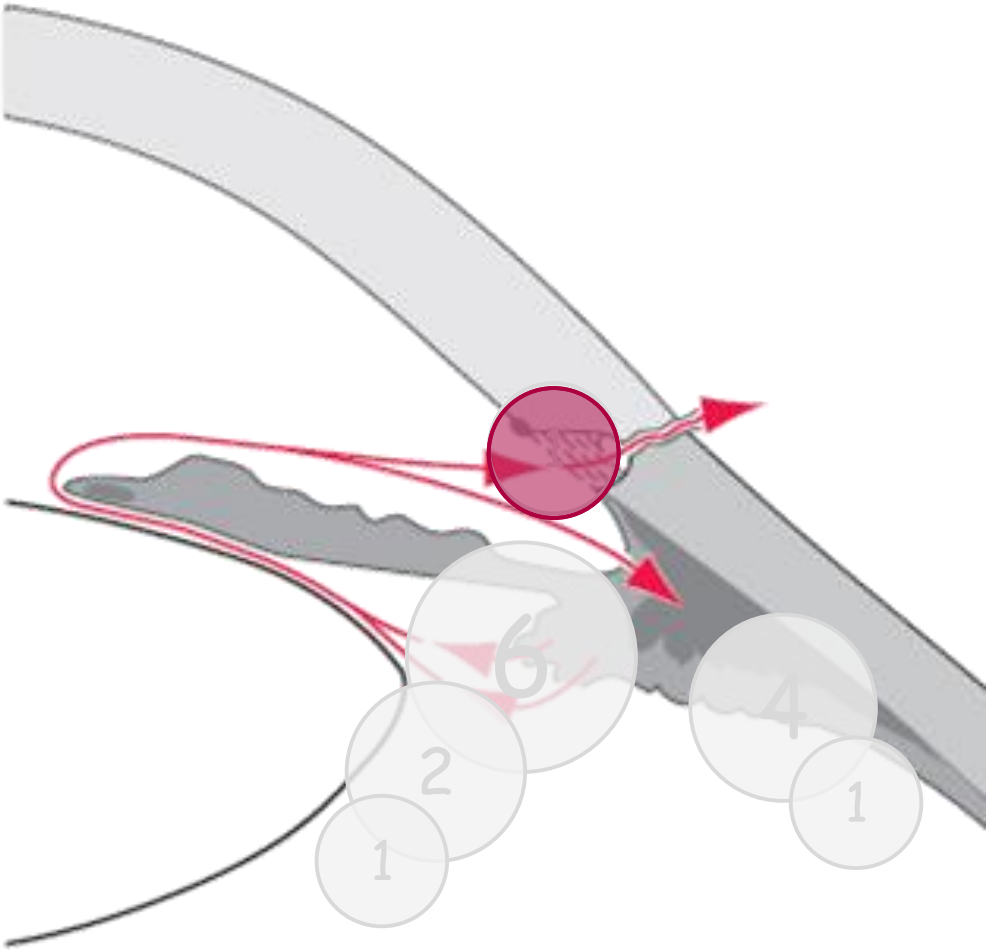




Medikamentöse Glaukomtherapie

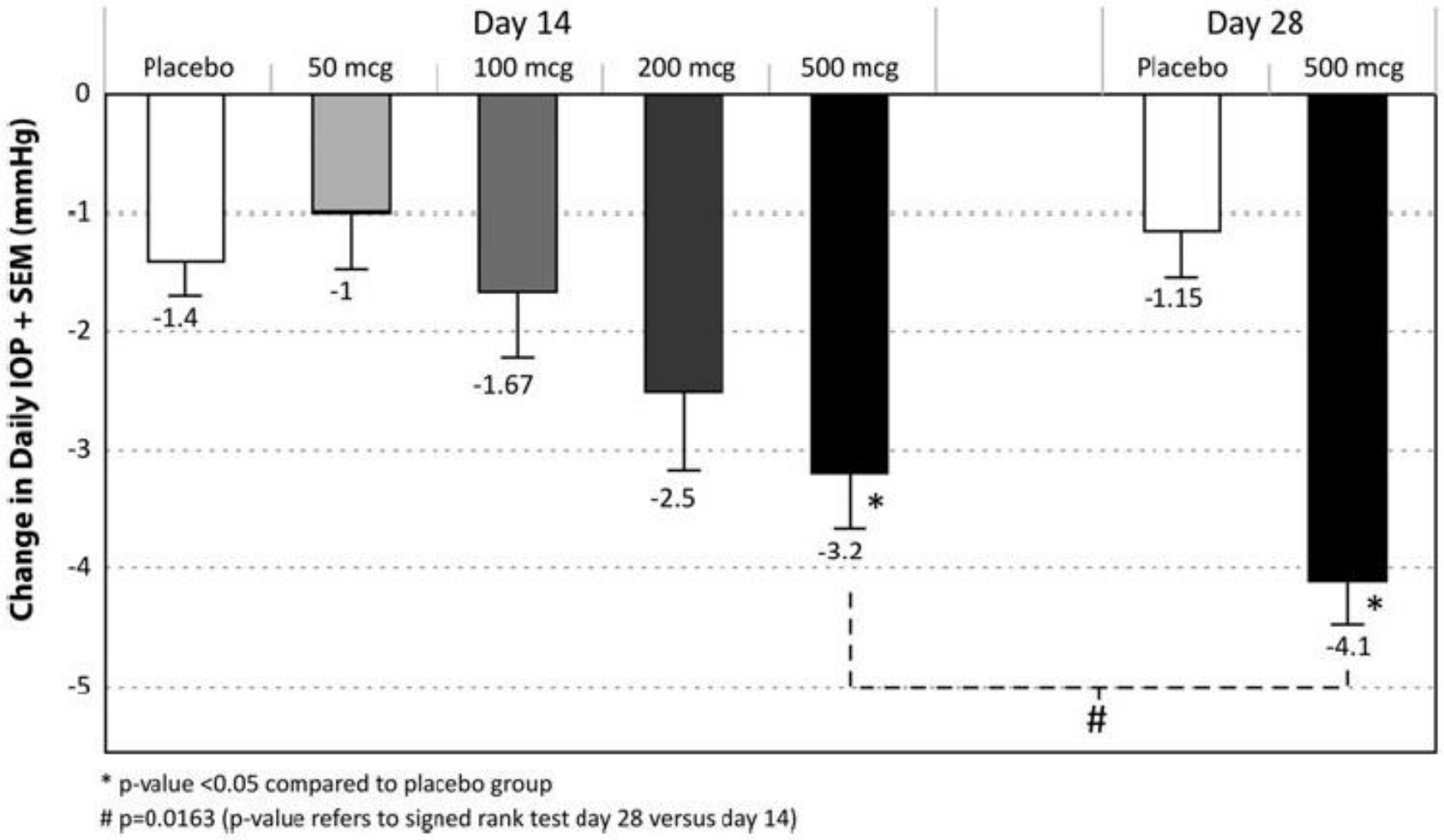
Adenosin-Rezeptor Agonisten





Trabodenoson

selektiver Adenosin-A1-Rezeptor Agonist



* p-value <0.05 compared to placebo group

p=0.0163 (p-value refers to signed rank test day 28 versus day 14)

Myers et al J Ocular Pharm Ther 2016; 32: 555-562

AdenosinRezeptor Agonist

Trabodenoson (selective A1 Rezeptor agonist)

https://eyewire.news/articles/inotek-announces-top-line-results-for-matrx-1-first-phase-3-trial-of-trabodenoson-for-glaucoma/

Medical Affairs - Aerie Pharma... | nobelpreis für physiologie ode... | Inotek Fails Phase 3 Trial of ...

Wagenknecht gibt Lin... | Vorgeschlagene Sites

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01.03.17

Inotek Fails Phase 3 Trial of Trabodenoson for Glaucoma

Source: Inotek

Clinical Trials | Inotek Pharmaceuticals

VISABILITY MICRO-INSERT SYSTEM

Inotek Pharmaceuticals announced topline results of MATrX-1, the first pivotal phase 3 trial of trabodenoson for the treatment of primary open-angle glaucoma or ocular hypertension. The trial

125% DE 18:28 11.03.2019

https://eyewire.news/articles/inotek-announces-top-line-results-for-matrx-1-first-phase-3-trial-of-trabodenoson-for-glaucoma/

AdenosinRezeptor Agonist

Trabodenoson (selective A1 Rezeptor agonist)

Physiology and Pharmacology

Trabodenoson, an Adenosine Mimetic With A_1 Receptor Selectivity Lowers Intraocular Pressure by Increasing Conventional Outflow Facility in Mice

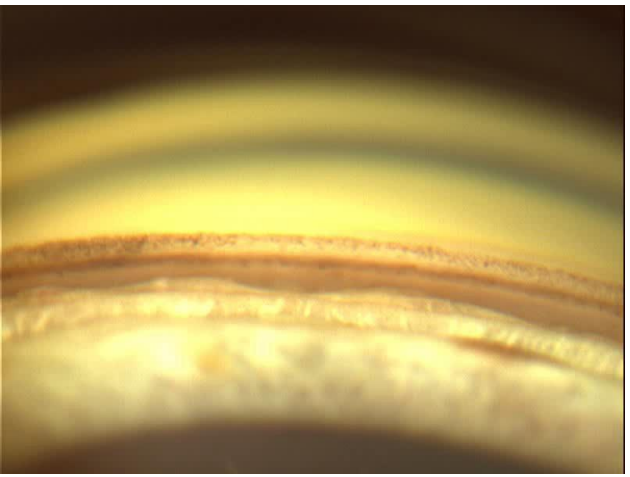
Guorong Li,[1] Karen Y. Torrejon,[2] Andrea M. Unser,[2] Feryan Ahmed,[2] Iris D. Navarro,[1] Rudolf A. Baumgartner,[3] David S. Albers,[3] and W. Daniel Stamer[1]

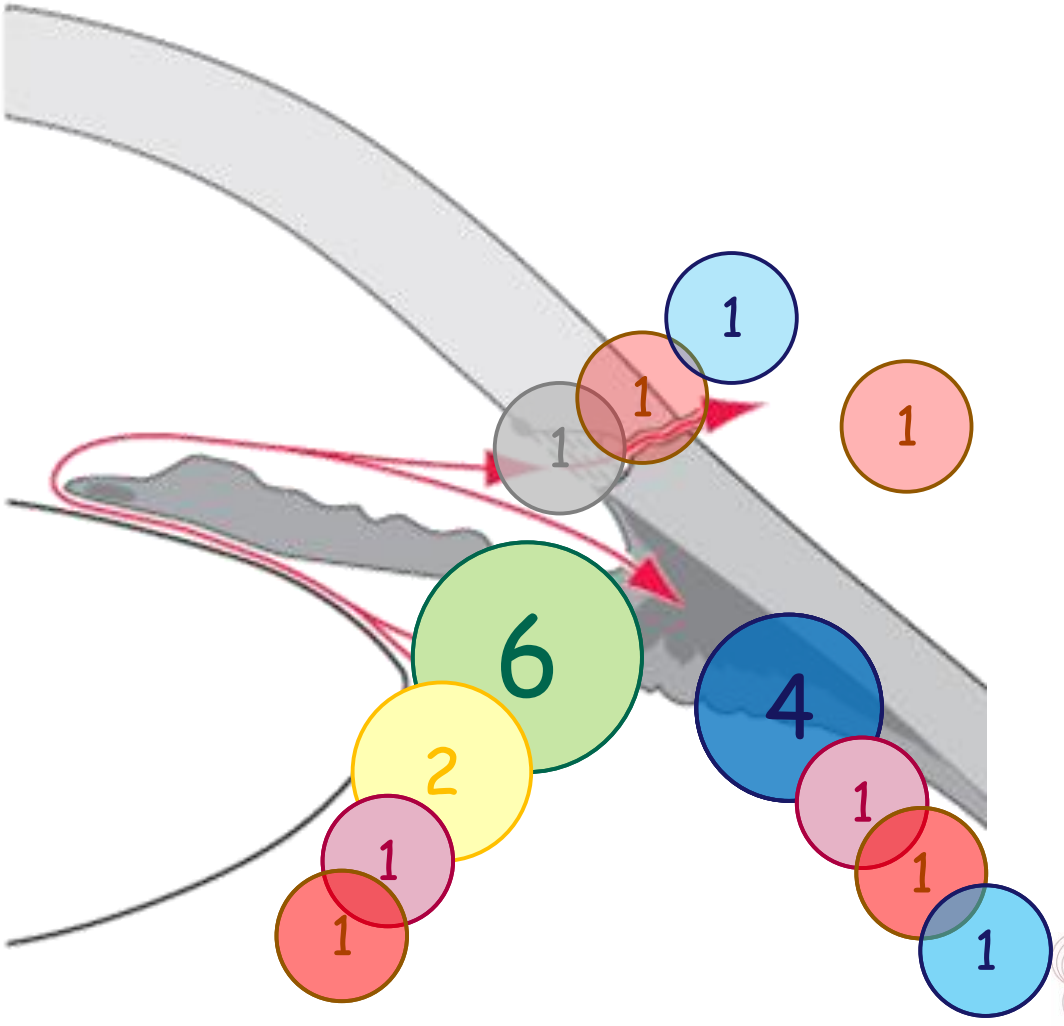
[1]Department of Ophthalmology, Duke University, Durham, North Carolina, United States
[2]Glauconix Biosciences, Inc., Albany, New York, United States
[3]Inotek Pharmaceuticals Corporation, Lexington, Massachusetts, United States

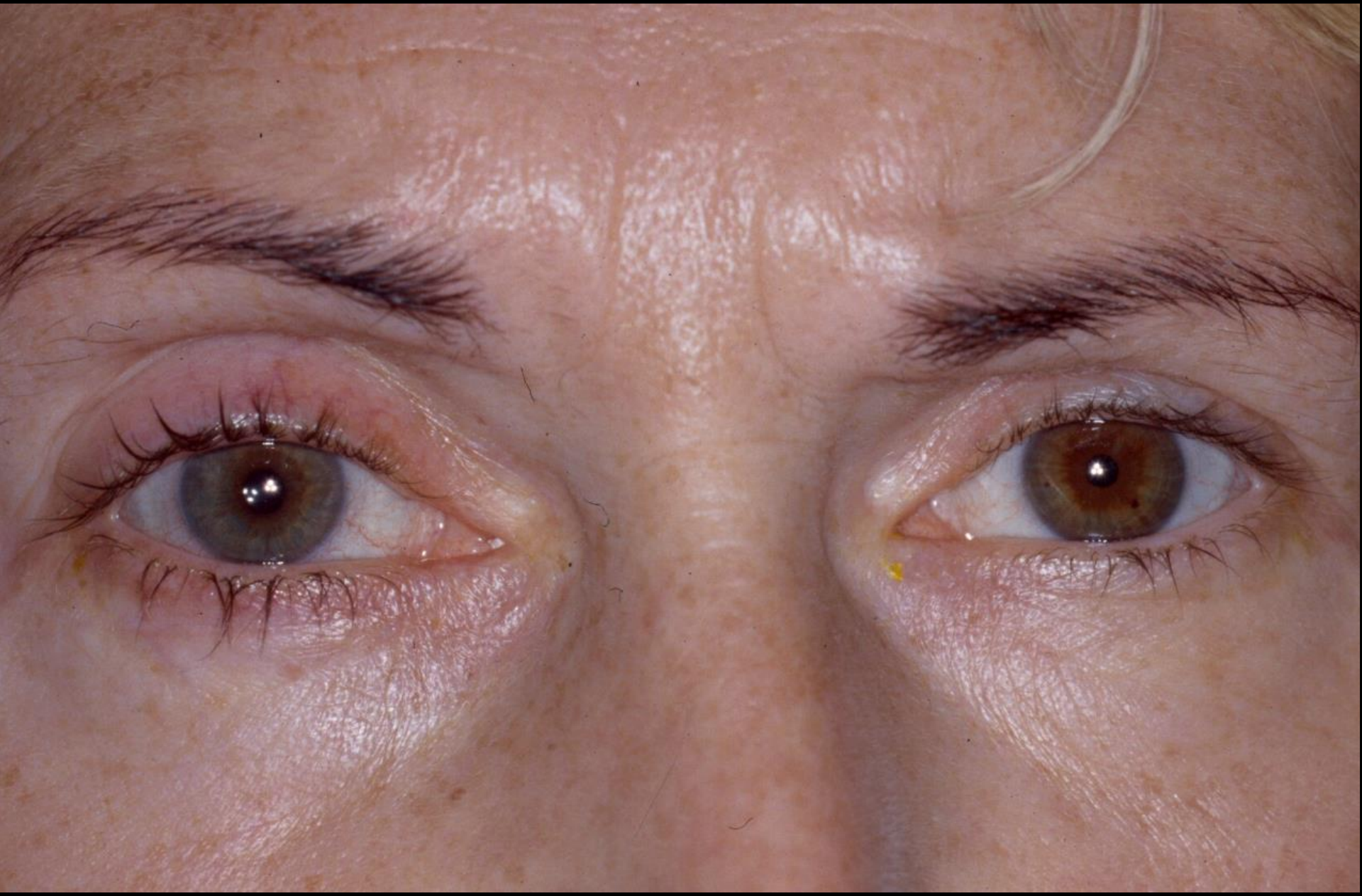
Li et al IOVS 2018; 59: 383-392

Medikamentöse Glaukomtherapie

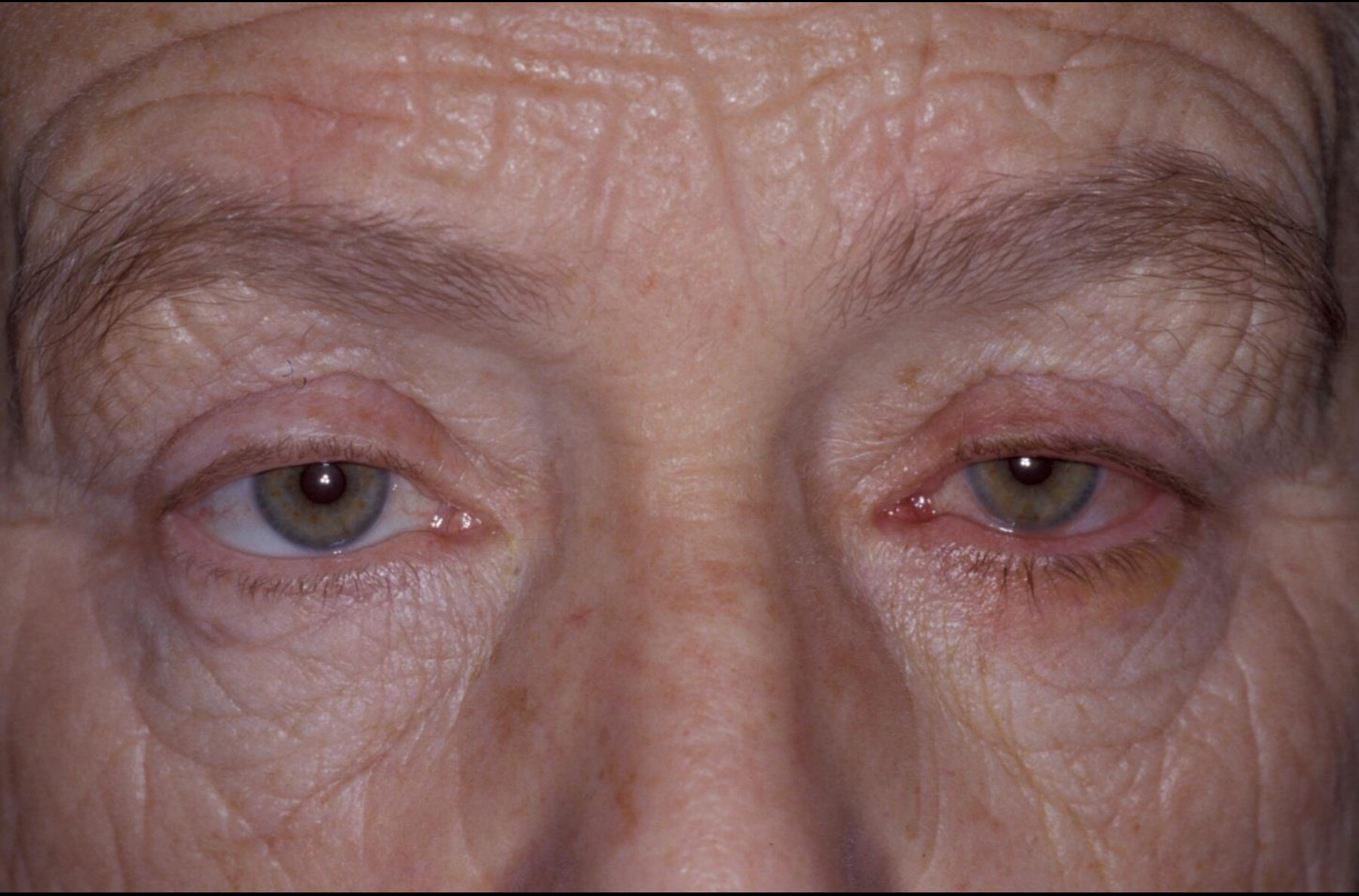
Was kommt in naher Zukunft?





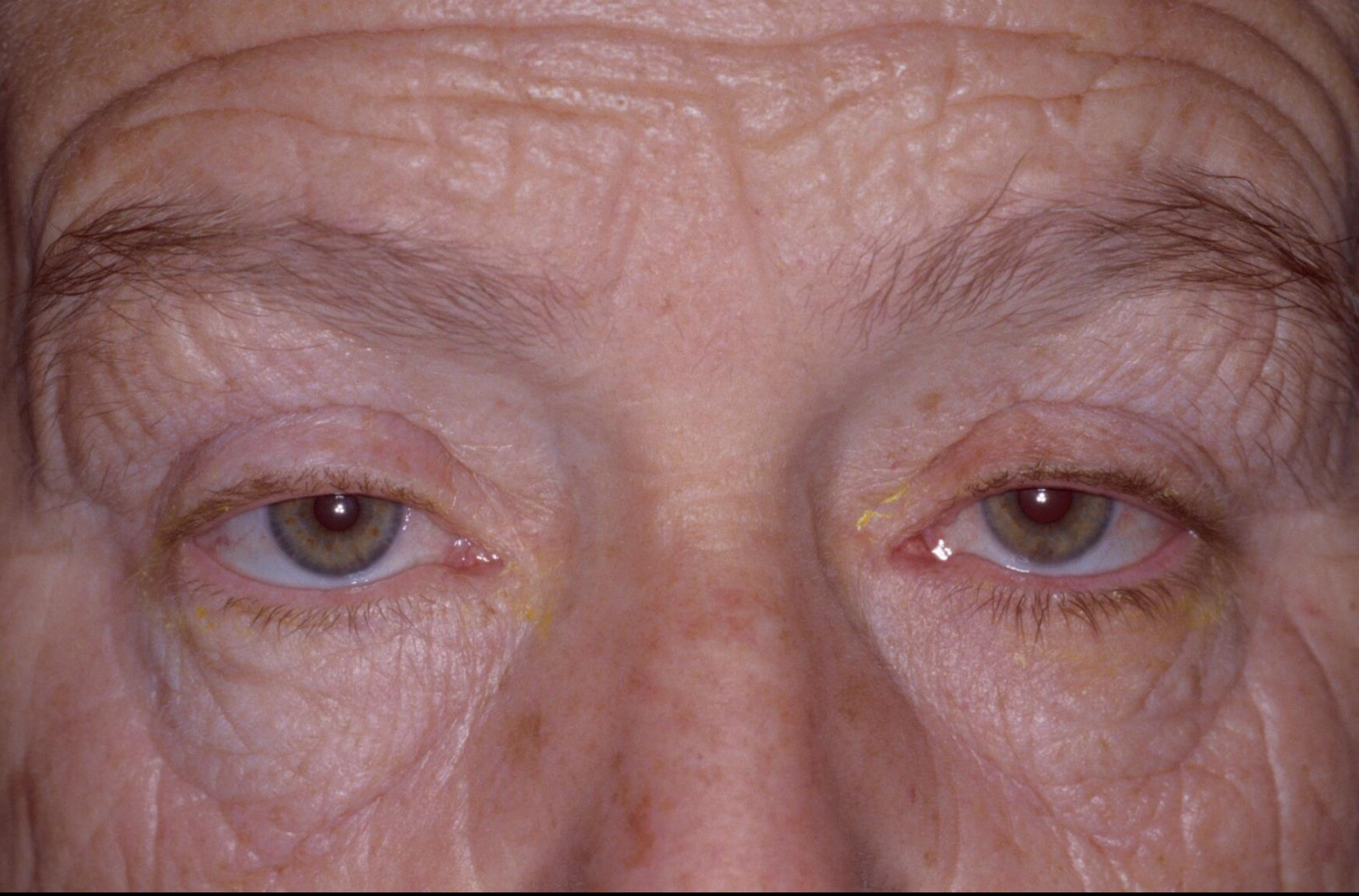


Monotherapie rechtes Auge



2fach Therapie linkes Auge

AAD 2019



nach Absetzen der Augentropfen

AAD 2019

Medikamentöse Glaukomtherapie

Was kommt noch?

Medikamente

https://www2.stadtbibliothek-reutlingen.de/-1/veranstaltungsauswahl/newletterbilder/sprach-tandem/view


Adhärenz
Medikamente

Medikamentöse Glaukomtherapie

Adhärenz und Persistenz

Drugs don't work in patients

who don't take them

Everett Koop

U.S. Surgeon General

Medikamentöse Glaukomtherapie

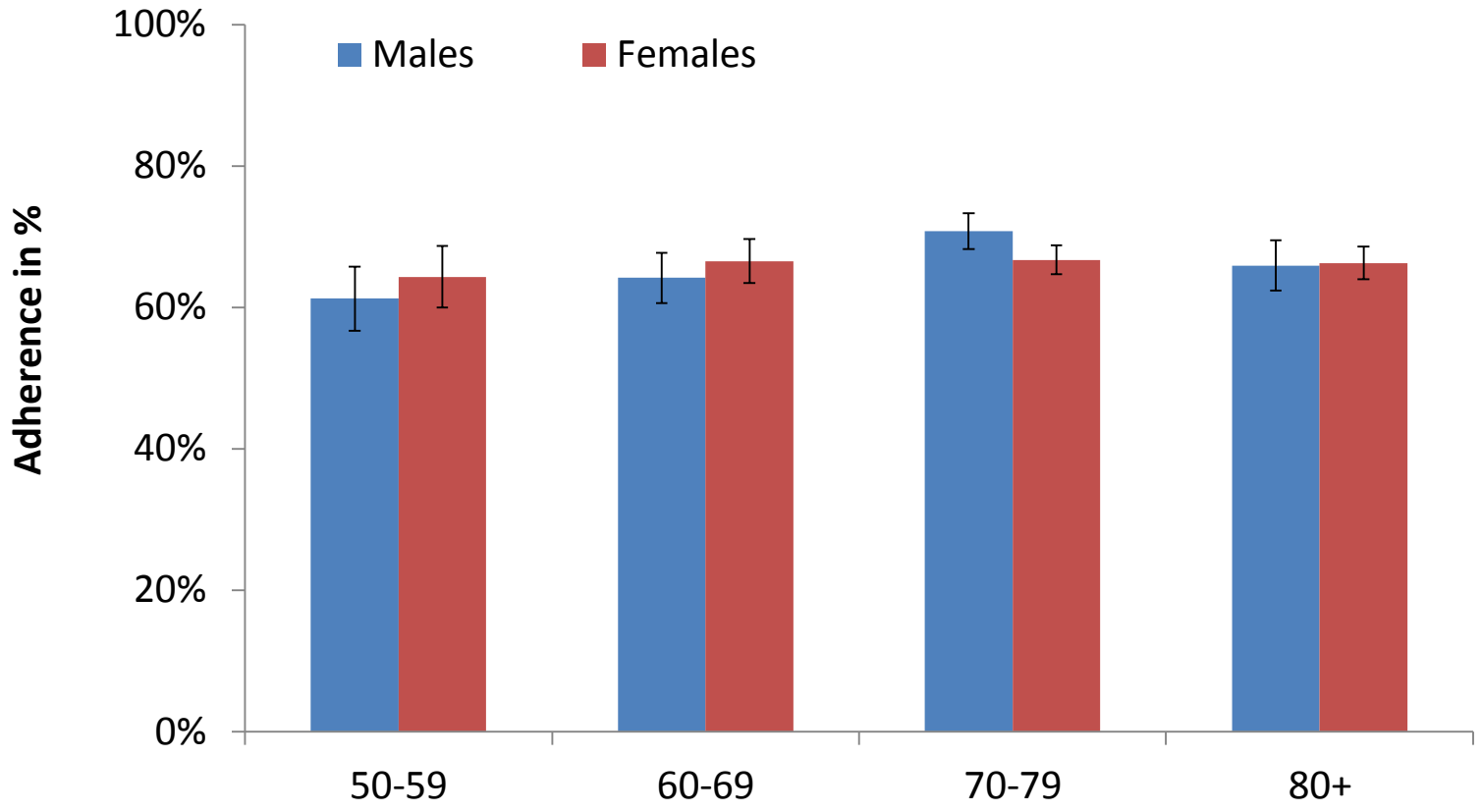
Faktoren für Non-Compliance

- habe mittags keine Möglichkeit zu tropfen
- habe vergessen zu tropfen
- Tropfschema ist zu kompliziert
- ohne Tropfen brennen die Augen nicht
- nehme keinen Therapieeffekt wahr
- kann die Tropfen nicht applizieren

Adams et al Pharm Res 2019; 36: 25

Adhärenz 2010 in MV

Einlösen von Rezepten



im Mittel lösen 33.5% ihr Rezept nicht ein

Frech et al (RESPONSE): AOK (WIdO) in Zusammenarbeit mit Prof. Doblhammer (Rostocker Zentrum zur Erforschung des demographischen Wandels)

Medikamentöse Glaukomtherapie

Wie kann ich Sie motivieren?

- das Wissen über die Glaukomerkrankung steigern
- therapeutisches Konzept passt zum Lebenstil
- max. 2 Fläschchen, max. 2x täglich tropfen
- das Tropfen beibringen
- Erinnerungshilfen planen (Rituale)
- Familie mit einbinden
- Bei jeder Kontrolle nach Nebenwirkungen fragen

Drug delivery Systems

Drug Delivery Systems

Die ideale Charakteristik

- Effektivität ≥ 6 Monate
  - Vergleichbar (non-inferior) zu PG-Analoga (ø ß-Blocker)
- okuläres AE-Profil ≥ besser/gleich topisches PG
- Bio-degradierbar, kein invasives Entfernen
- Implantation/Injektion als „in-office“ - Prozedur
- Konstante IOD-Senkung
  - Circadiane Rhythmik, AH-Dynamik

Adams et al Pharm Res 2019; 36: 25

Drug Delivery Systems

Technologien

- extraokuläre Systeme
  - periokuläre Ringe
  - punktum plugs
  - intrakanalikuläre Implantate
- intraokulare Systeme
  - subkonjunktival
  - intrakameral (injizierbare Depots, Implantate)

Drug Delivery Systems

Extraokulare Systeme

- weniger invasiv
- simple „in-office“ - Prozedur
- „selfi“ - Prozedur
- keine Endophthalmitis
- Problem: stabile Lokalisation

Adams et al Pharm Res 2019; 36: 25

Drug Delivery Systems

Extraokulare Systeme

Table I Clinically Evaluated Extraocular Sustained Release Systems

System/Device	Drug	Sponsor	Duration endpoint	Clinical Phase
Periocular ring	bimatoprost	Allergan / ForSight Vision5	6 months	Ph 2
Punctal plug	latanoprost	Eximore Ltd	6 months	Ph 1/2
Punctal plug	latanoprost	Mati Therapeutics	3.5 months	Ph 2
Canalicular insert	travoprost	Ocular Therapeutix	3 months	Ph 3
Punctal plug	bimatoprost	Vistakon Pharmaceuticals	14 days	Ph 2

Adams et al Pharm Res 2019; 36: 25

Drug Delivery Systems

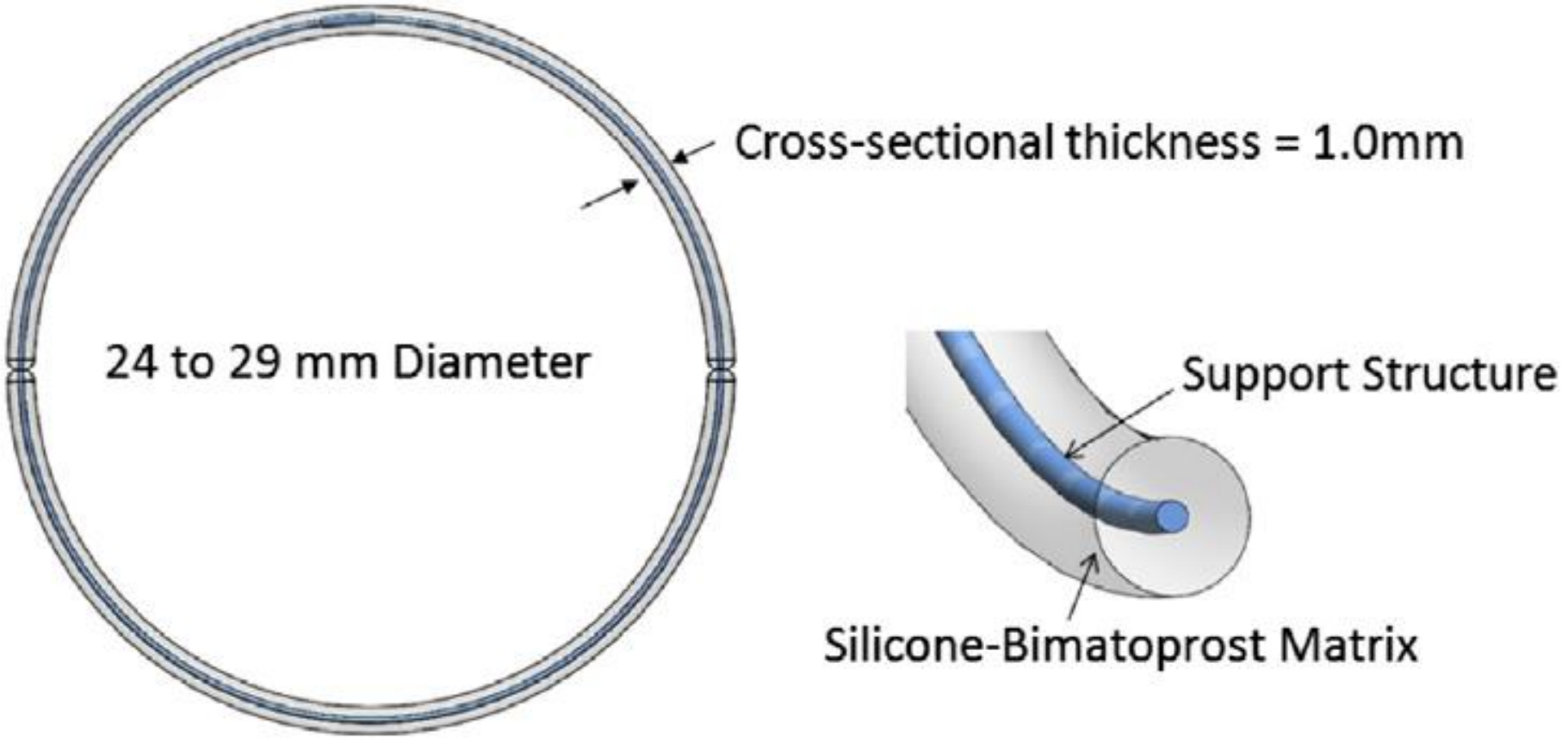
Bimatoprost ocular ring

- ForSight Vision5
- Polypropylen-Struktur, Silikon (24 – 29 mm)
- 35µg/d (Tag 0) - 6µg/d (Tag 180)
- Gesamtdosis
  - 2.5 mg Bimatoprost
  - 1.6 mg Bimatoprost 0.03% (9µg/d)
- Problem: stabile Lokalisation

Brandt et al Ophthalmology 2016; 123: 1685-1694

Drug Delivery Systems

Bimatoprost ocular ring



Brandt et al Ophthalmology 2016; 123: 1685-1694

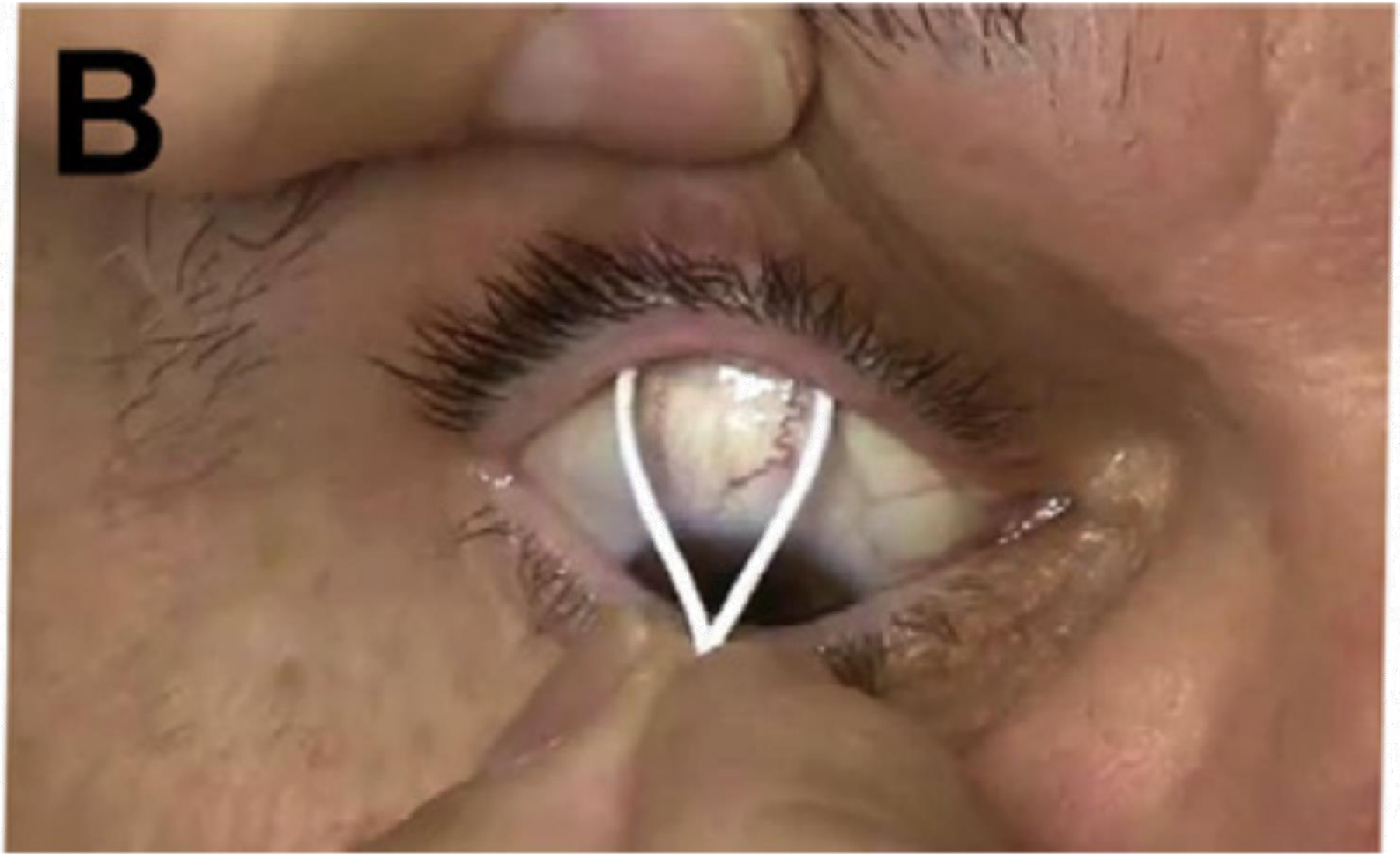
Drug Delivery Systems

Bimatoprost ocular ring

Brandt et al Ophthalmology 2016; 123: 1685-1694

Drug Delivery Systems

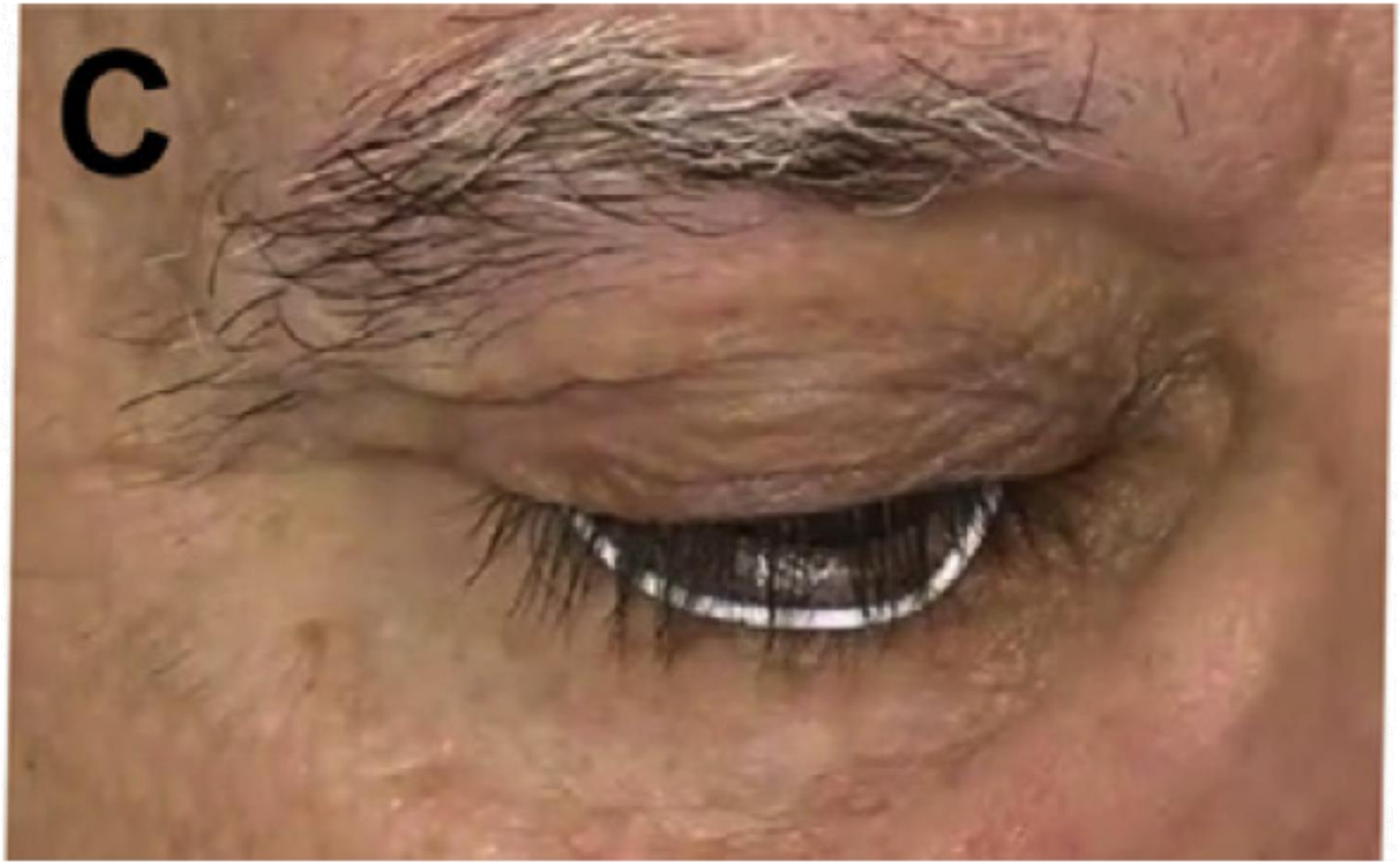
Bimatoprost ocular ring



Brandt et al Ophthalmology 2016; 123: 1685-1694

Drug Delivery Systems

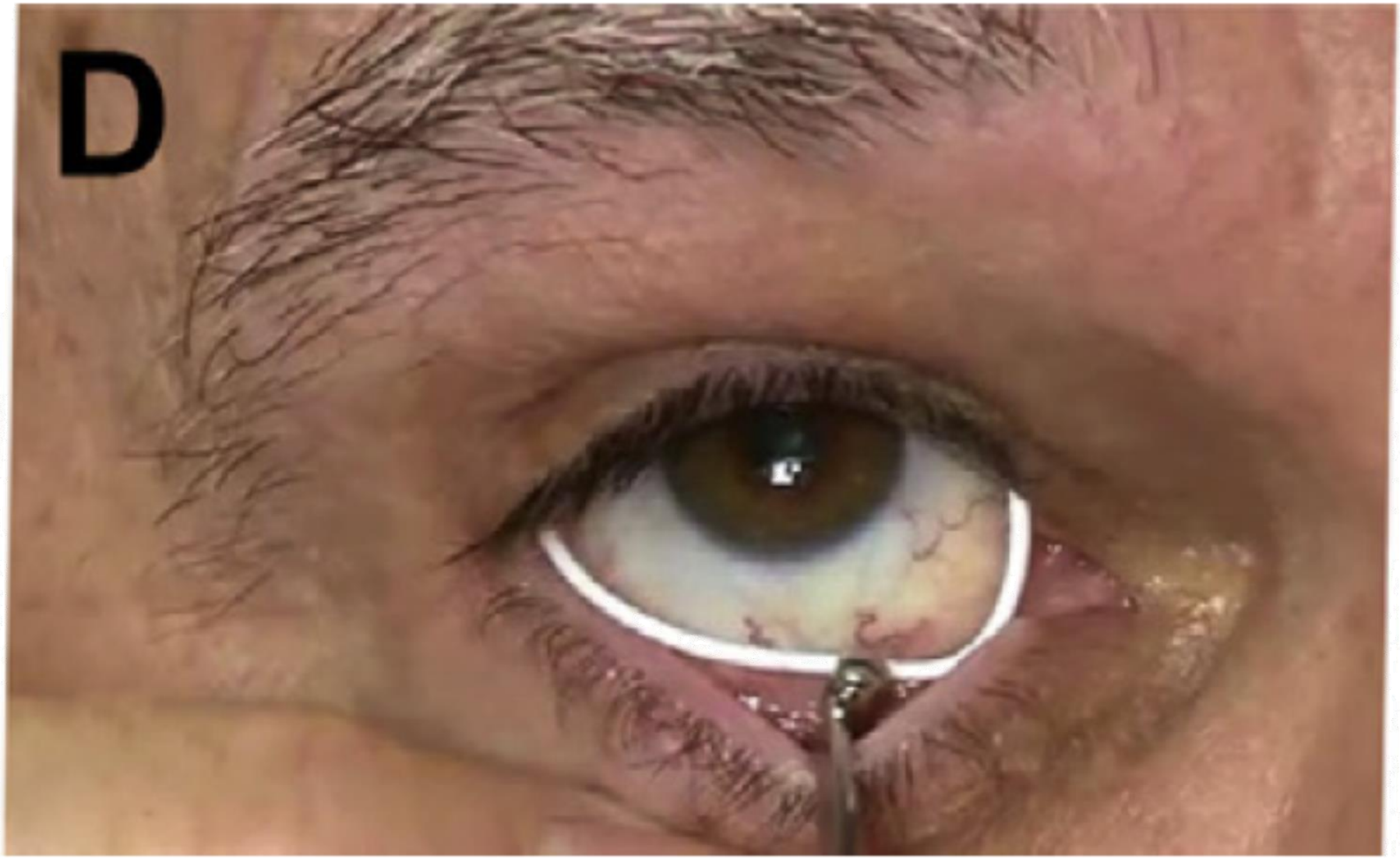
Bimatoprost ocular ring



Brandt et al Ophthalmology 2016; 123: 1685-1694

Drug Delivery Systems

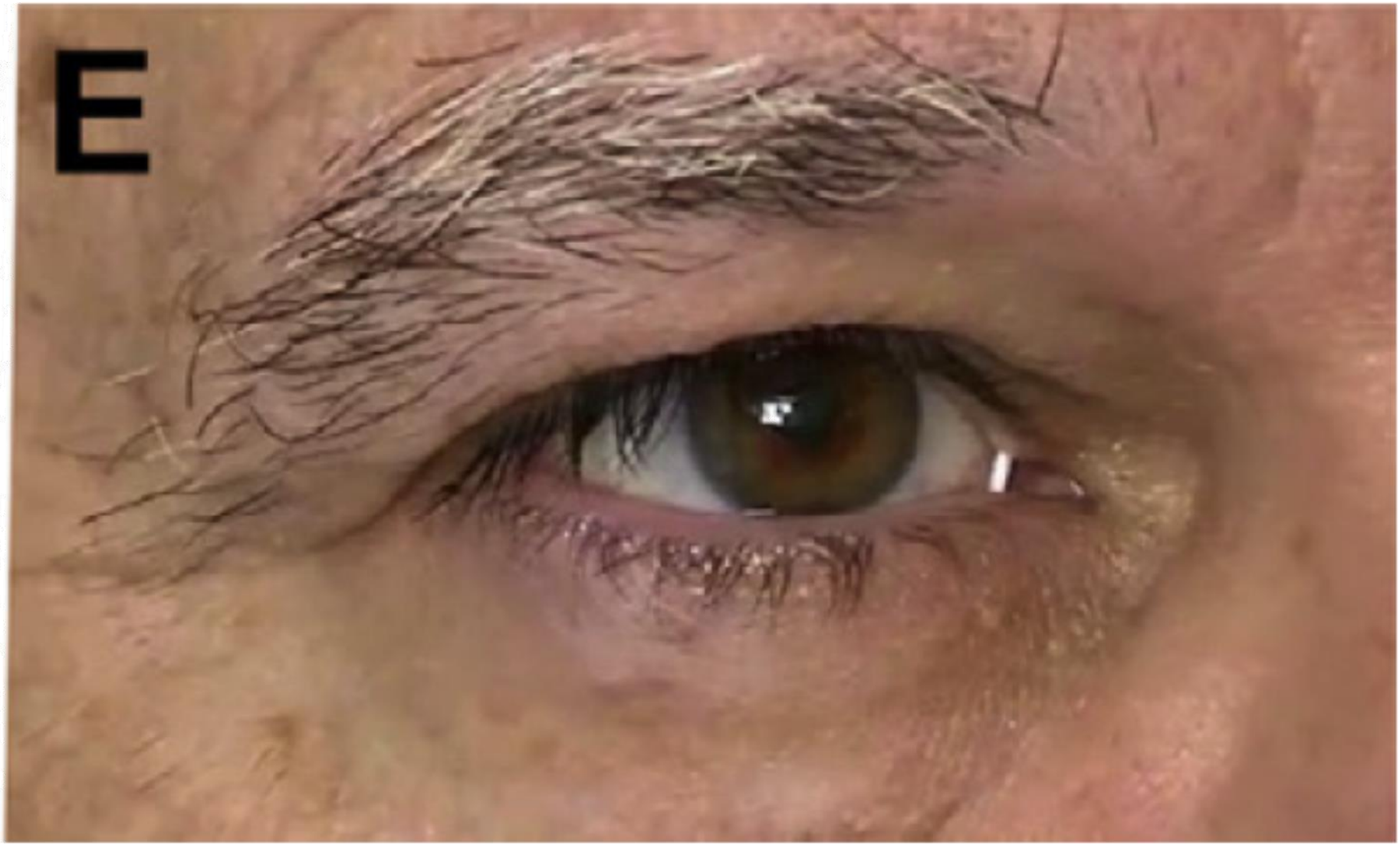
Bimatoprost ocular ring



Brandt et al Ophthalmology 2016; 123: 1685-1694

Drug Delivery Systems

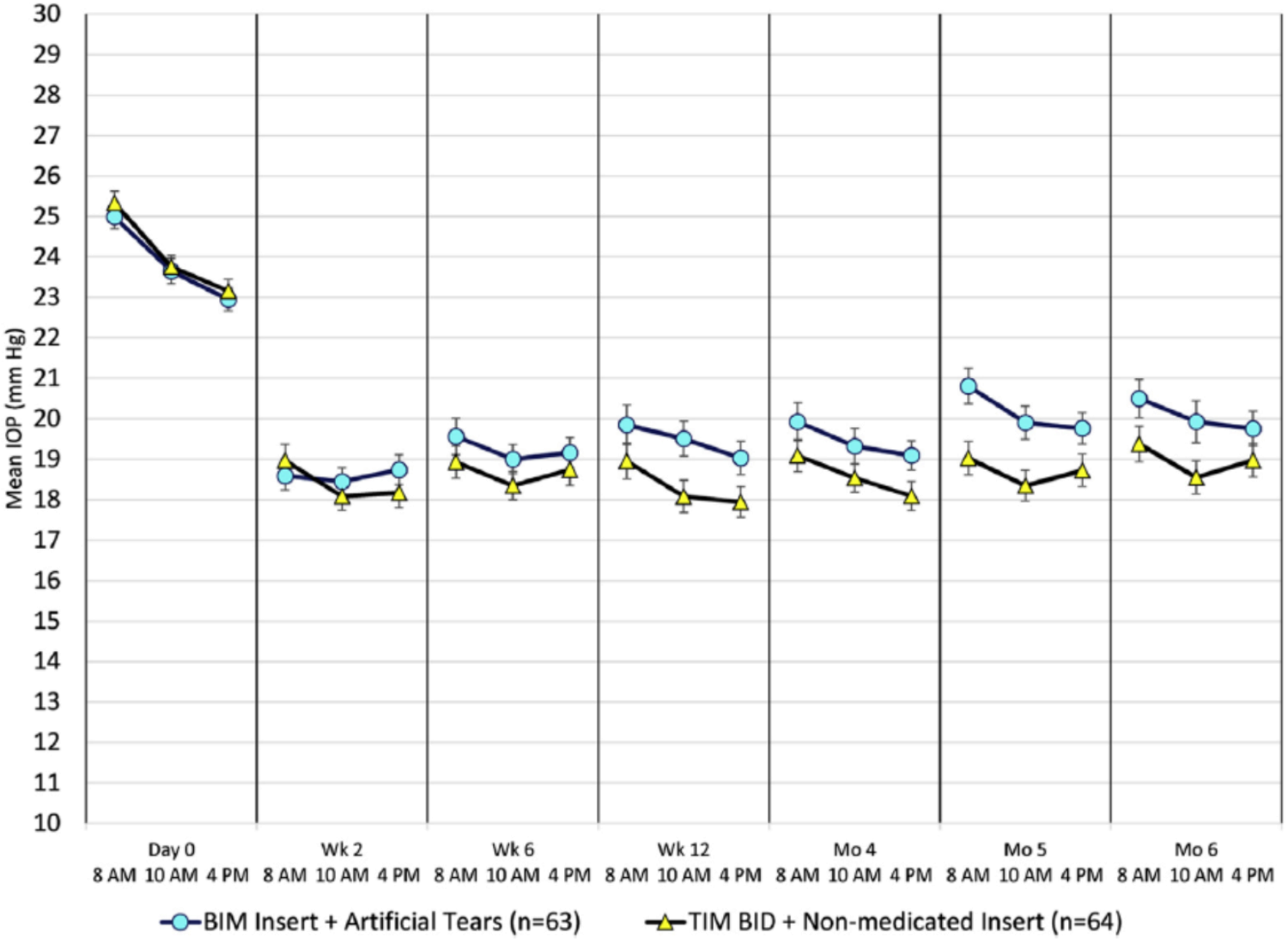
Bimatoprost ocular ring



Brandt et al Ophthalmology 2016; 123: 1685-1694

Drug Delivery Systems

Bimatoprost ocular ring



Brandt et al Ophthalmology 2016; 123: 1685-1694

Drug Delivery Systems

„Intraokulare" Systeme

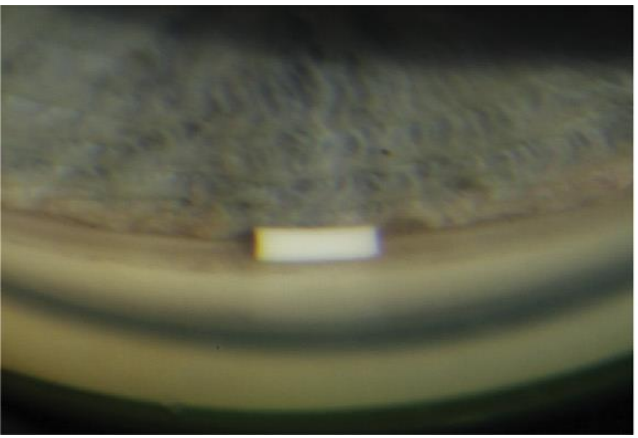
Table II Clinically Evaluated Intraocular Sustained Release Systems

System/Device	Drug	Sponsor	Duration endpoint	Clinical Phase
Intracameral rod: BimatoprostSR	bimatoprost	Allergan	4 months	Ph 3
Intracameral rod: ENV515	travoprost	Aerie (Envisia)	12 months	Ph 2
Intracameral rod: PA5108	latanoprost acid	PolyActiva	6 months	Ph 1
Sunbconjunctival liposomal depot: POLAT-001	latanoprost	Peregrine Ophthalmic	3 months	Ph 2
Sunbconjunctival insert: Eye-D/VS101	latanoprost	BioLight Life Sciences Ltd. / ViSci Ltd.	3 months	Ph 1/2
Sunbconjunctival implant/rod: Durasert™ platform	latanoprost	EyePoint Pharmaceuticals/ Pfizer	3–6 months	Ph 1
Sclera-anchored implant: iDose	travoprost	Glaukos Corporation	12 months	Ph 3

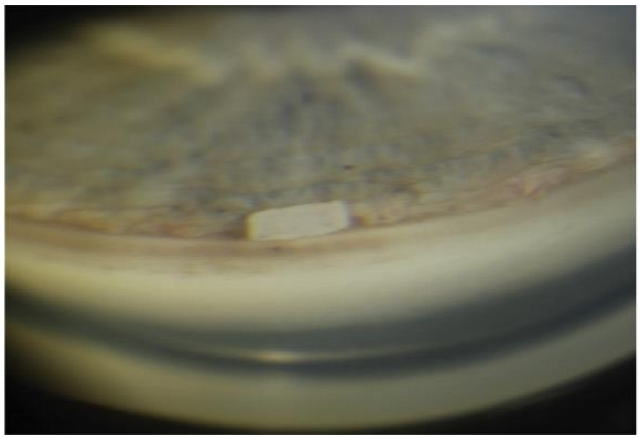
Adams et al Pharm Res 2019; 36: 25

Drug Delivery Systeme

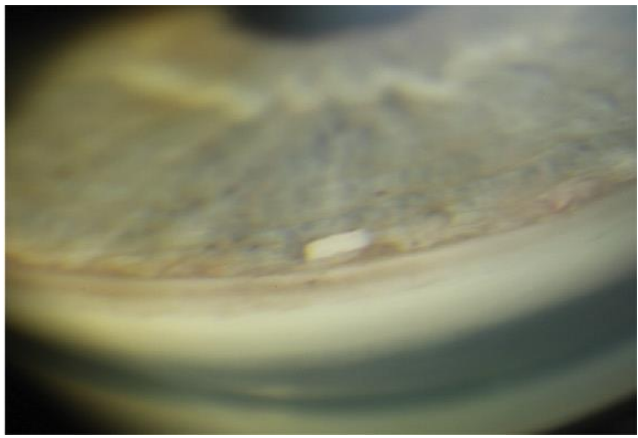
Bimatoprost-Implantat (Phase I/II)



2 Wochen



9 Monate

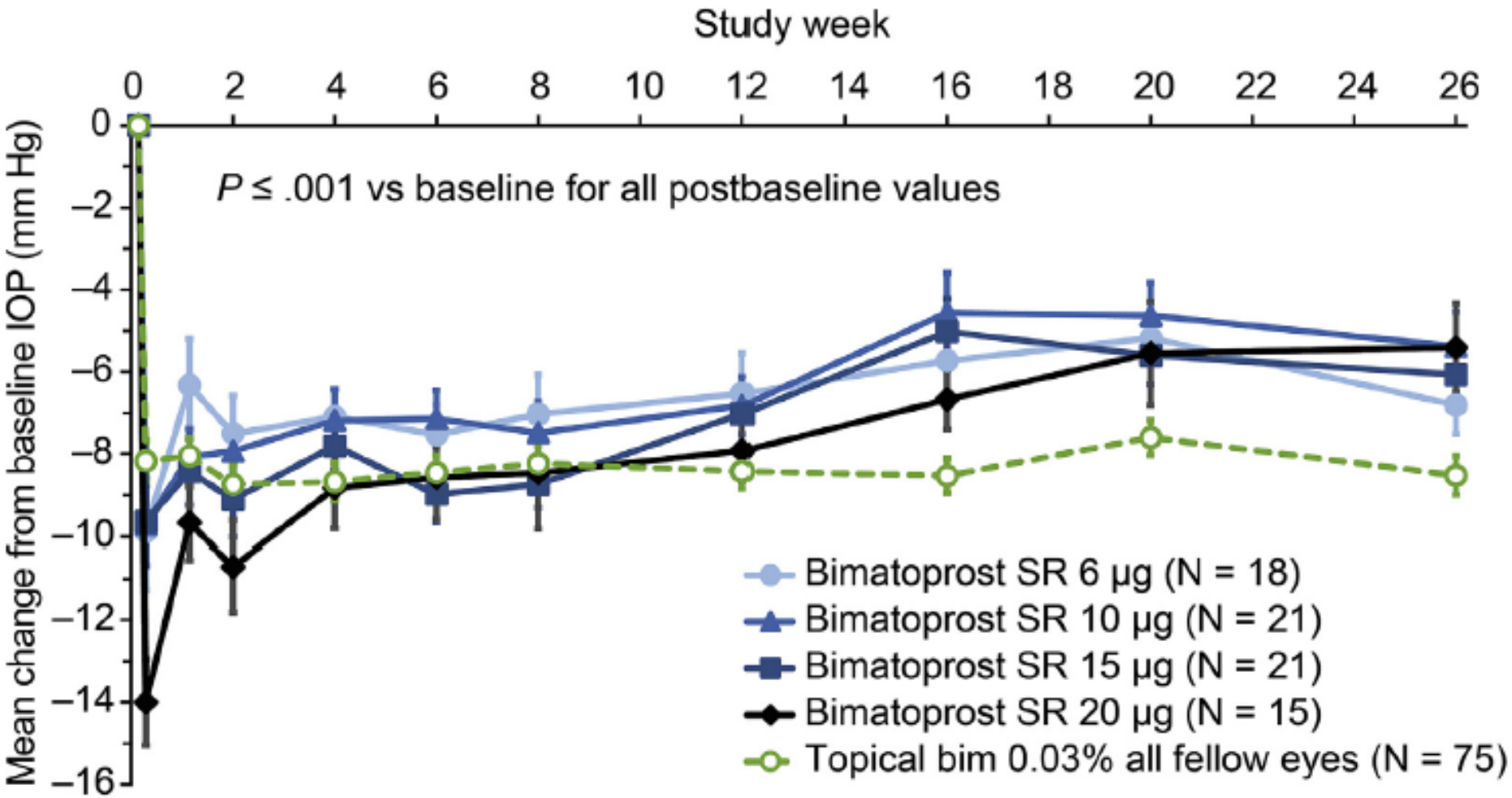


12 Monate

Lewis et al Am J Ophthalmol 2017;175:137–147

Drug Delivery Systeme

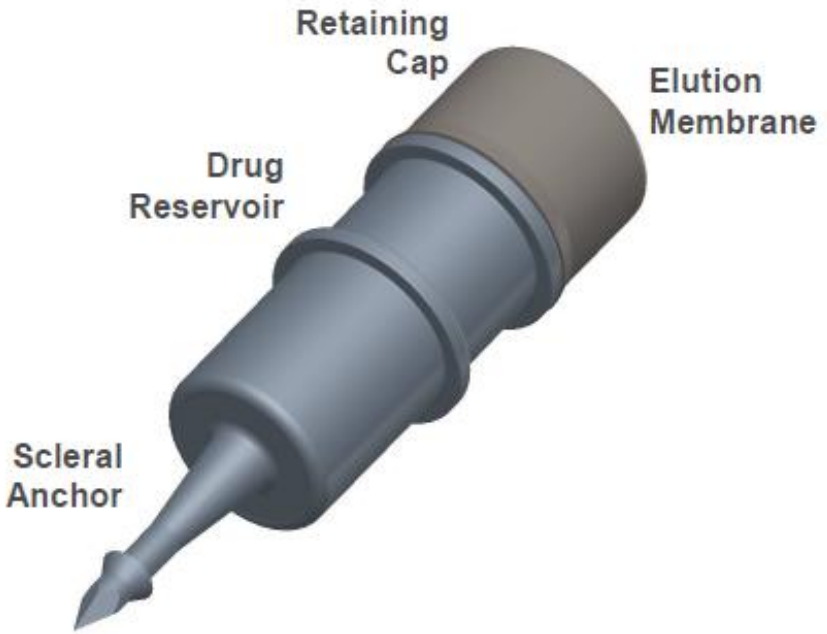
Bimatoprost-Implantat (Phase I/II)



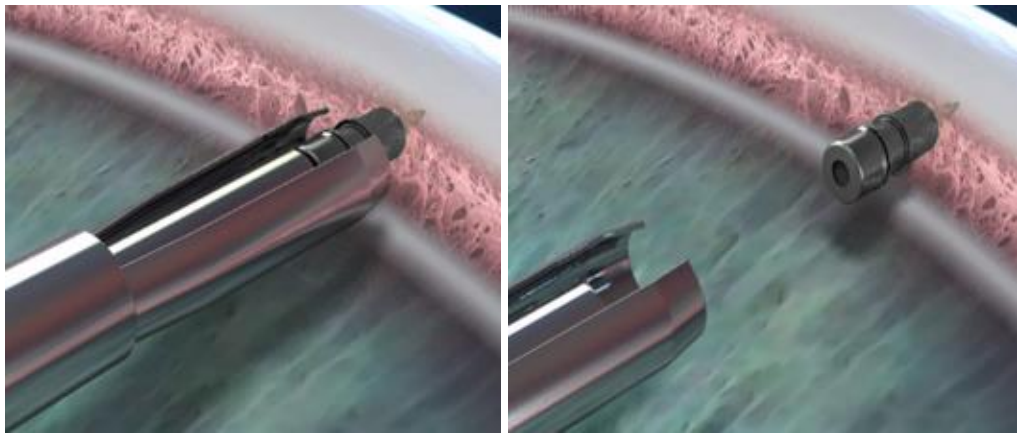
Lewis et al Am J Ophthalmol 2017;175:137–147

Drug-Delivery Systeme

iDose Travoprost

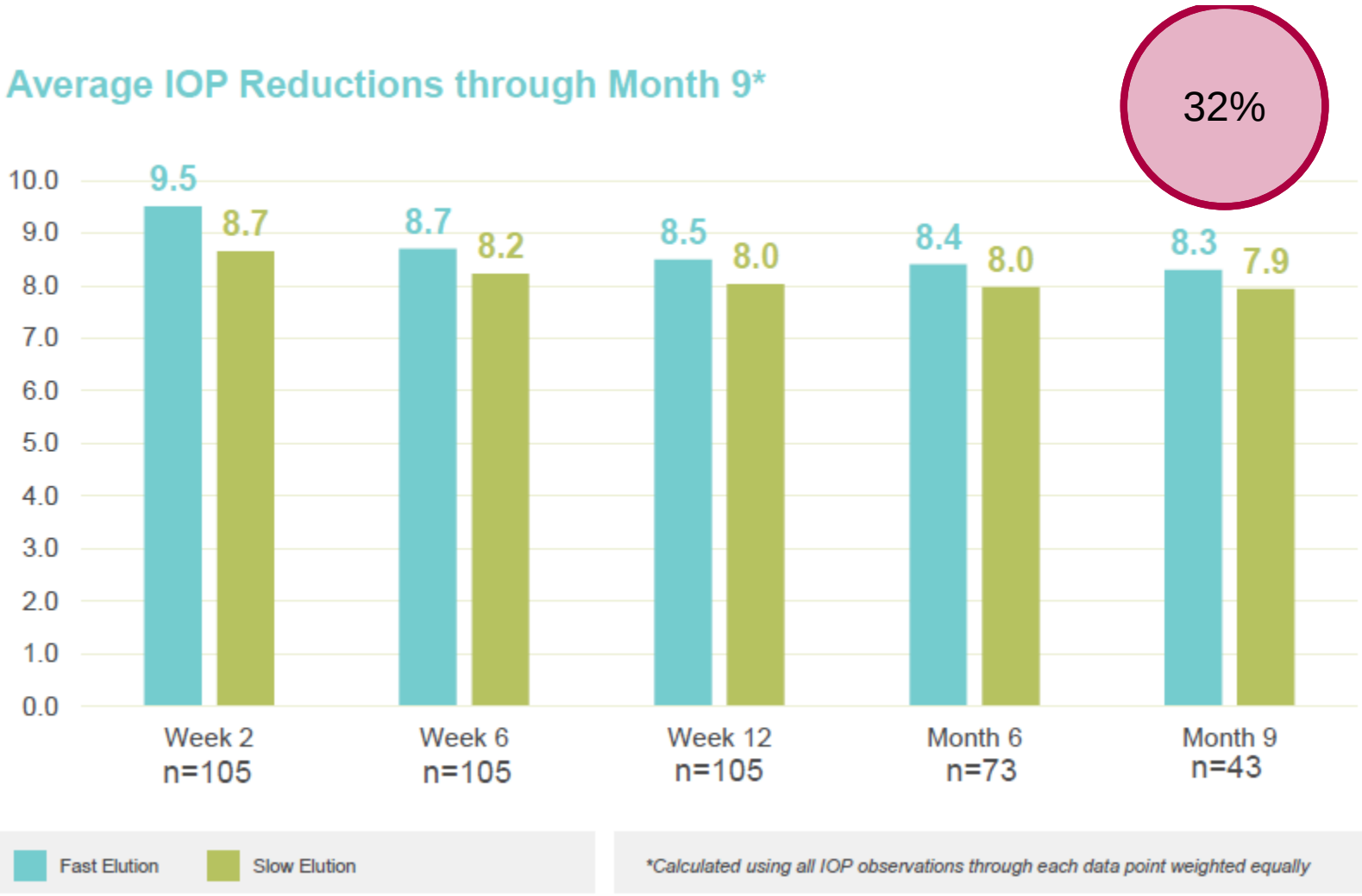


- Titan
- Größe: 1800 x 500µm
- Travoprost
- Membran-kontrollierte Elution



iDose Travoprost

US Phase II Studie

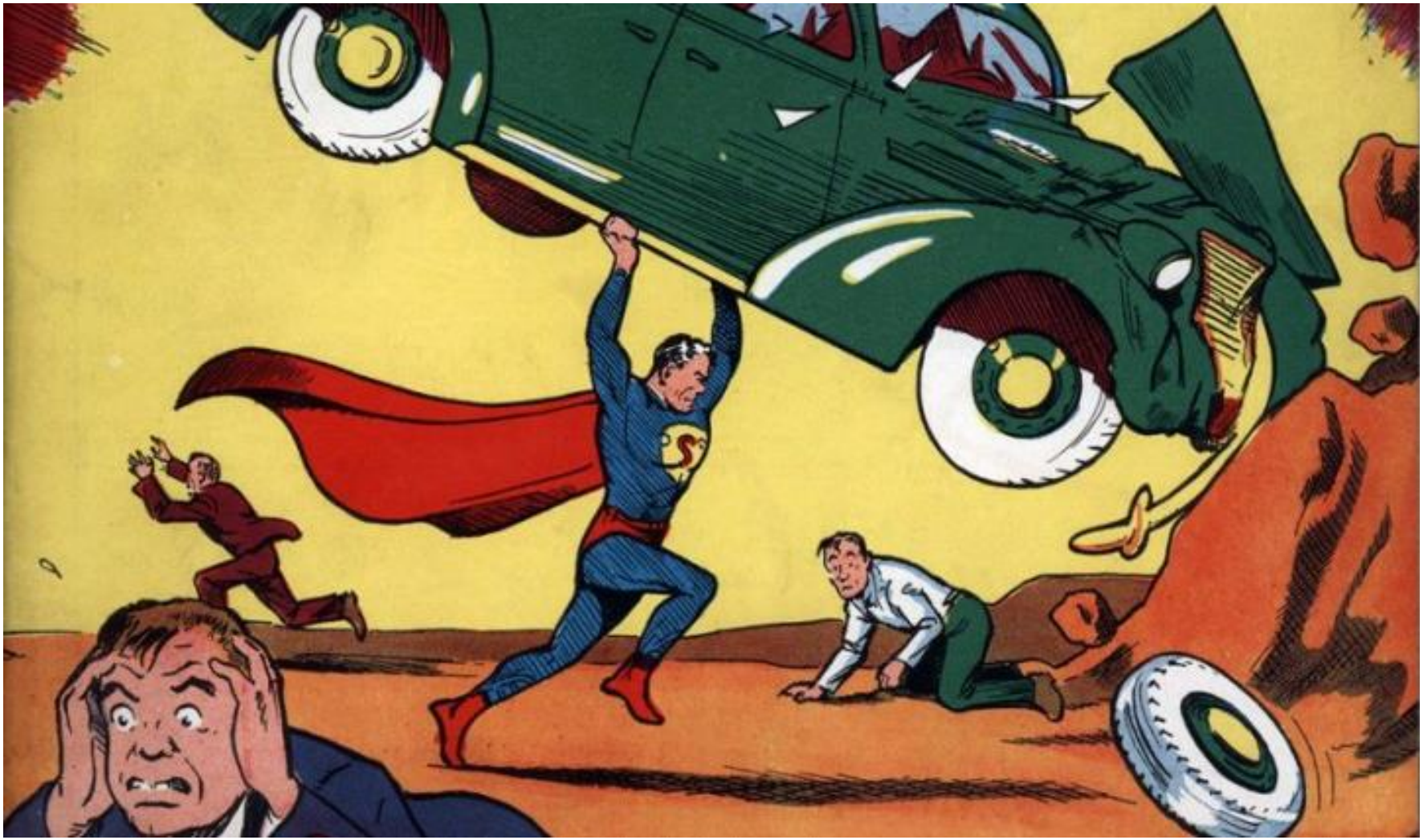


Innovative Therapien

Die Herausforderungen

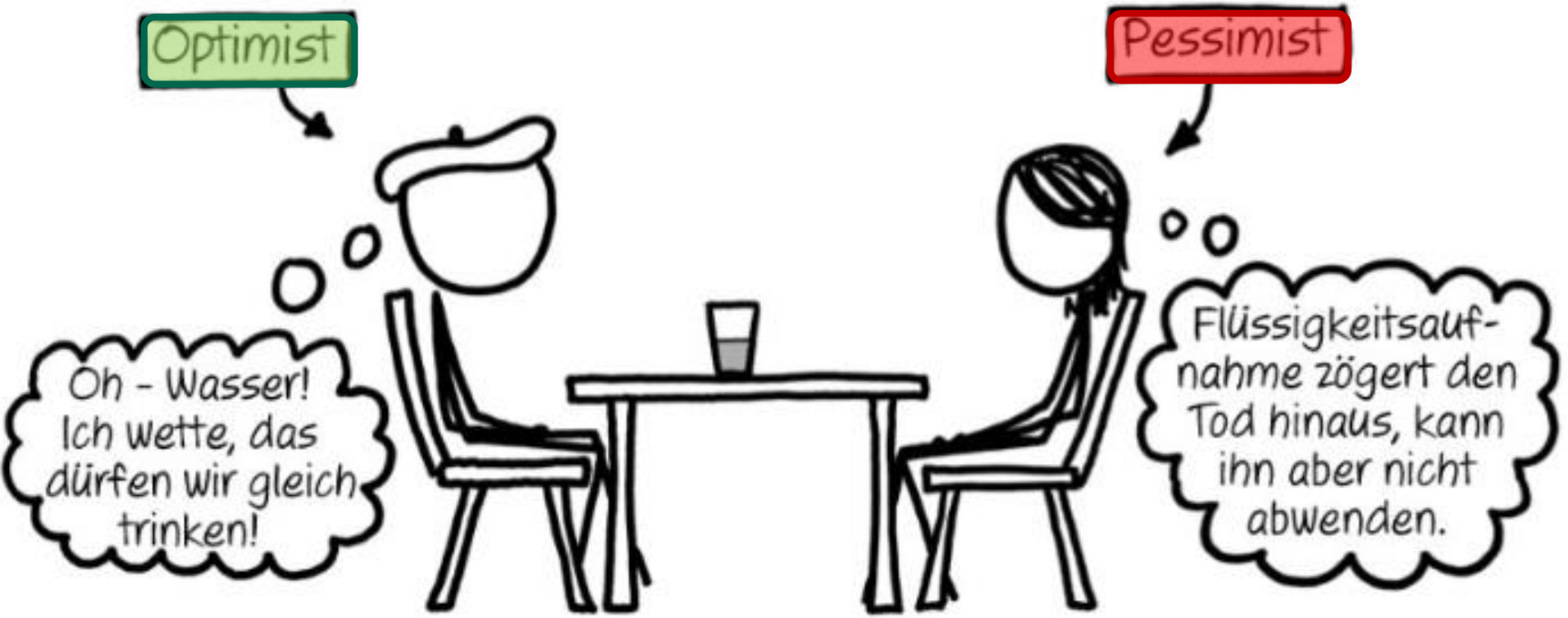
Innovative Therapien

Die Herausforderungen



Innovative Therapien

Die Herausforderungen



Medikamentöse Glaukomtherapie

Was gibt es, was kommt in naher Zukunft?

- 5 Wirkstoffklassen, BAC-freie und fixe Kombinationen
- Rho-Kinase Inhibitor (Rhopressa®)
- NO-Donator (Vyzulta®)
- Drug Delivery-Systeme

Mit dem Alter

siehst du immer mehr.