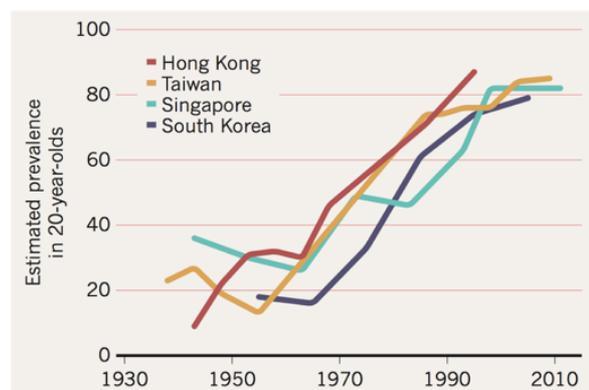


# Empfehlungen Minderung Myopieprogression ophthalmologischer Sicht Auswirkungen hoher Myopie

Wolf A. Lagrèze



2015 Nature



## THE MYOPIA BOOM

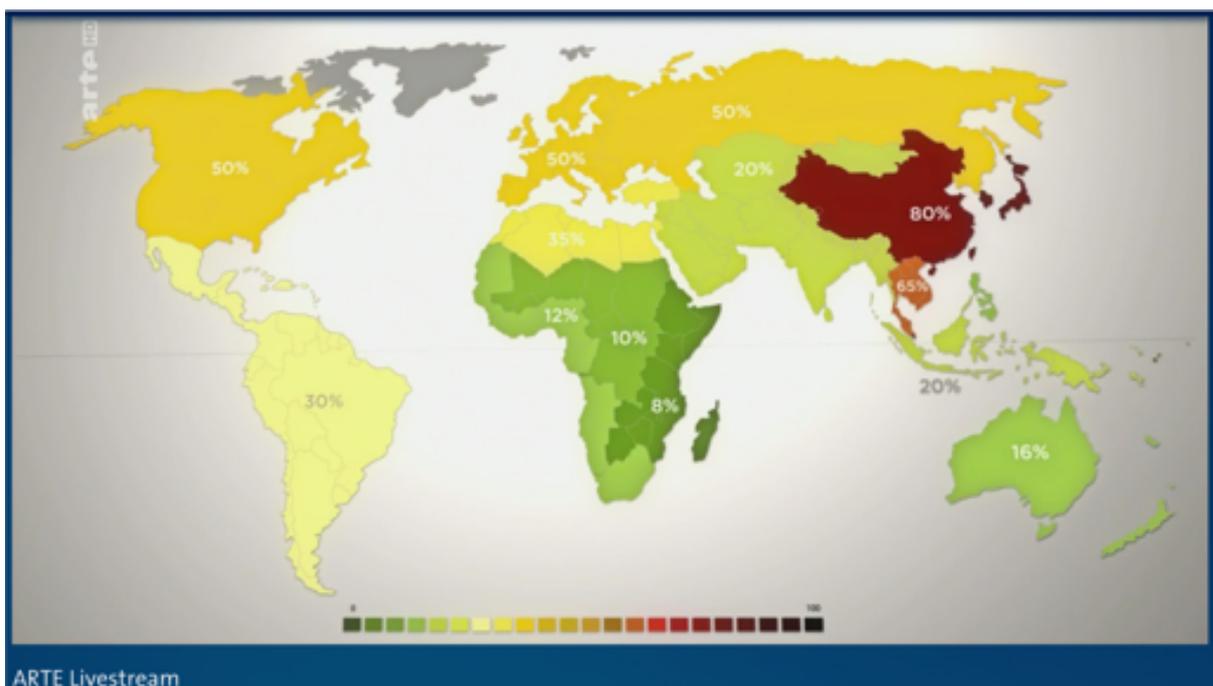
LÄSTIGE SEHSCHWÄCHE

## Wie Tageslicht vor Kurzsichtigkeit schützt

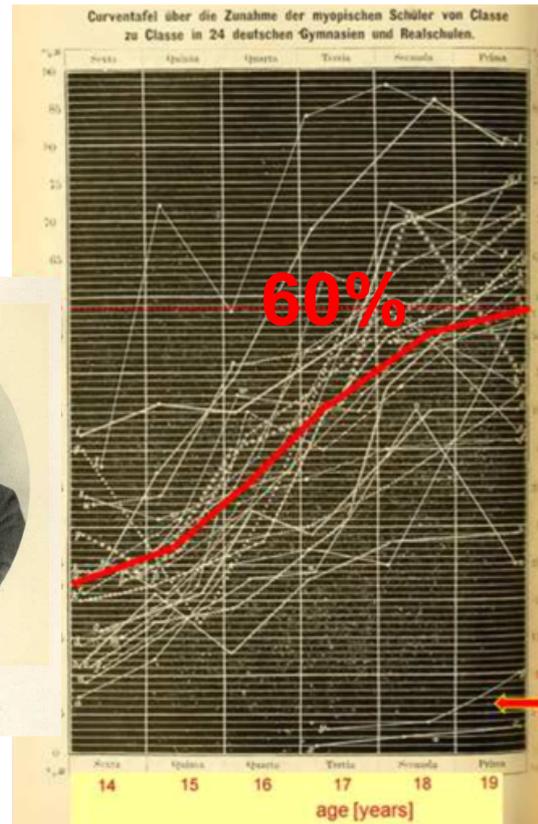
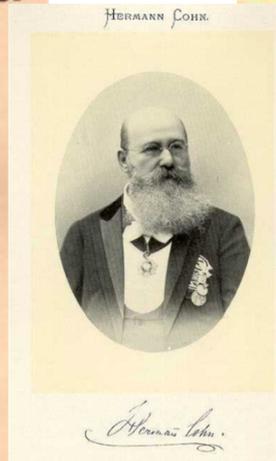
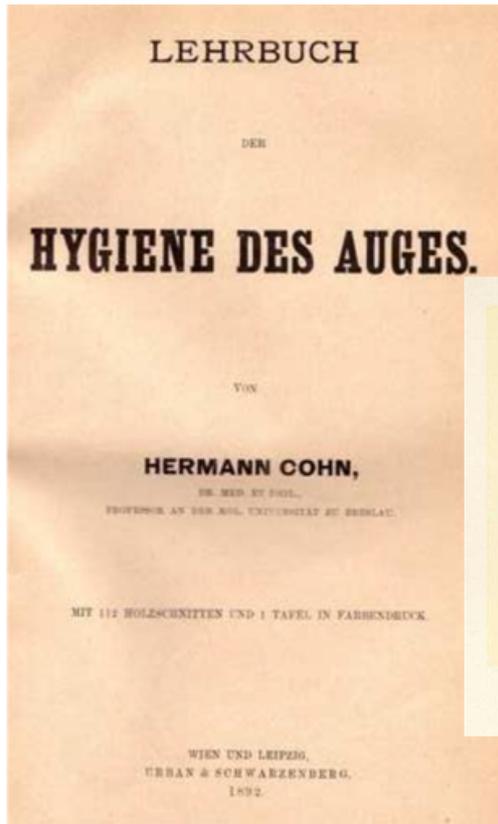
VON FELICITAS WITTE - AKTUALISIERT AM 23.05.2018 - 17:07



Kurzsichtigkeit ist eine Epidemie, Ärzte sorgen sich vor allem um Folgekrankheiten. Und Studien zeigen: Eltern haben recht, wenn sie ihre Kinder davor warnen, im Dunkeln zu lesen.

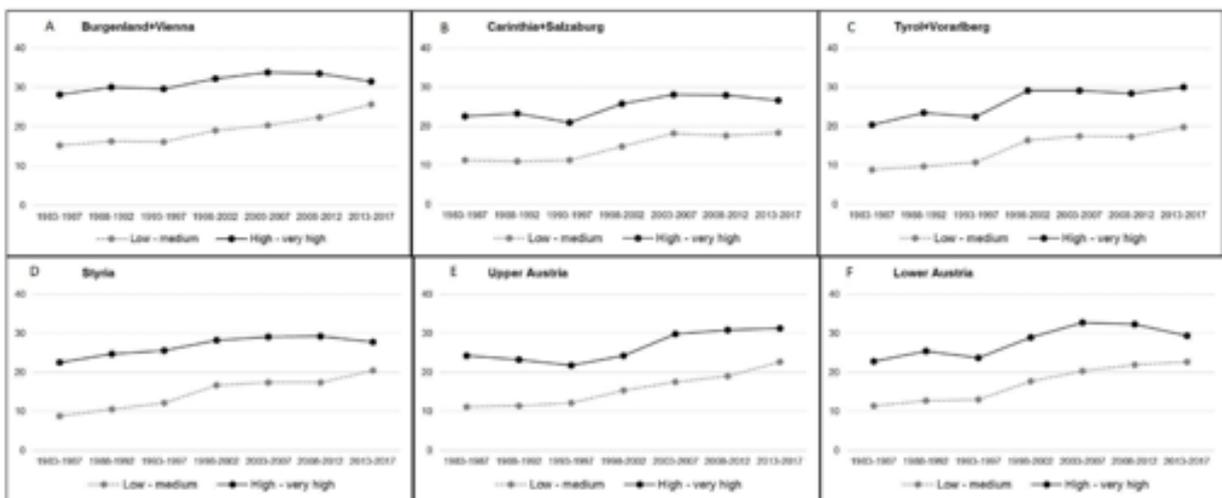


# Im Jahr 1892 ....



# Wird Myopie häufiger?

## Österreich, Rekruten



n = 1.507.063 über 35 Jahre: 14% -> 24%

Lower education 11% -> 22%

Higher education 25% -> 30%

# KIGGS 2003 – 2006 *versus* 2014 – 2017

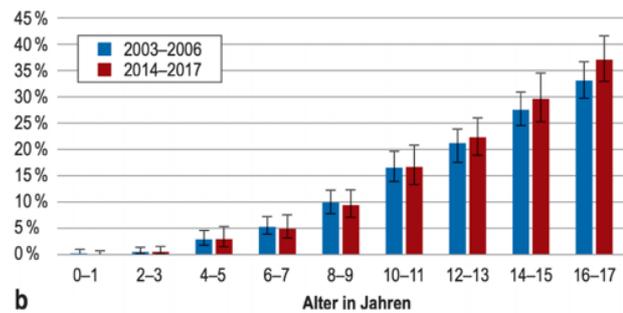
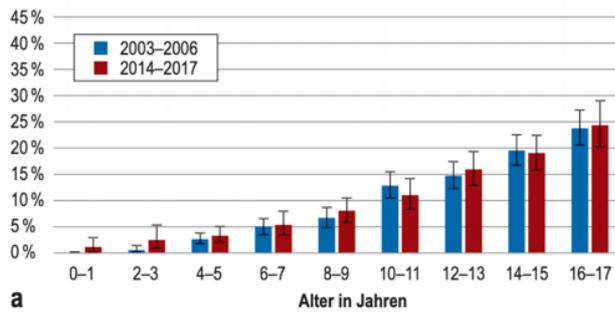
Deutschland, Kinder, n = 17.640



25%

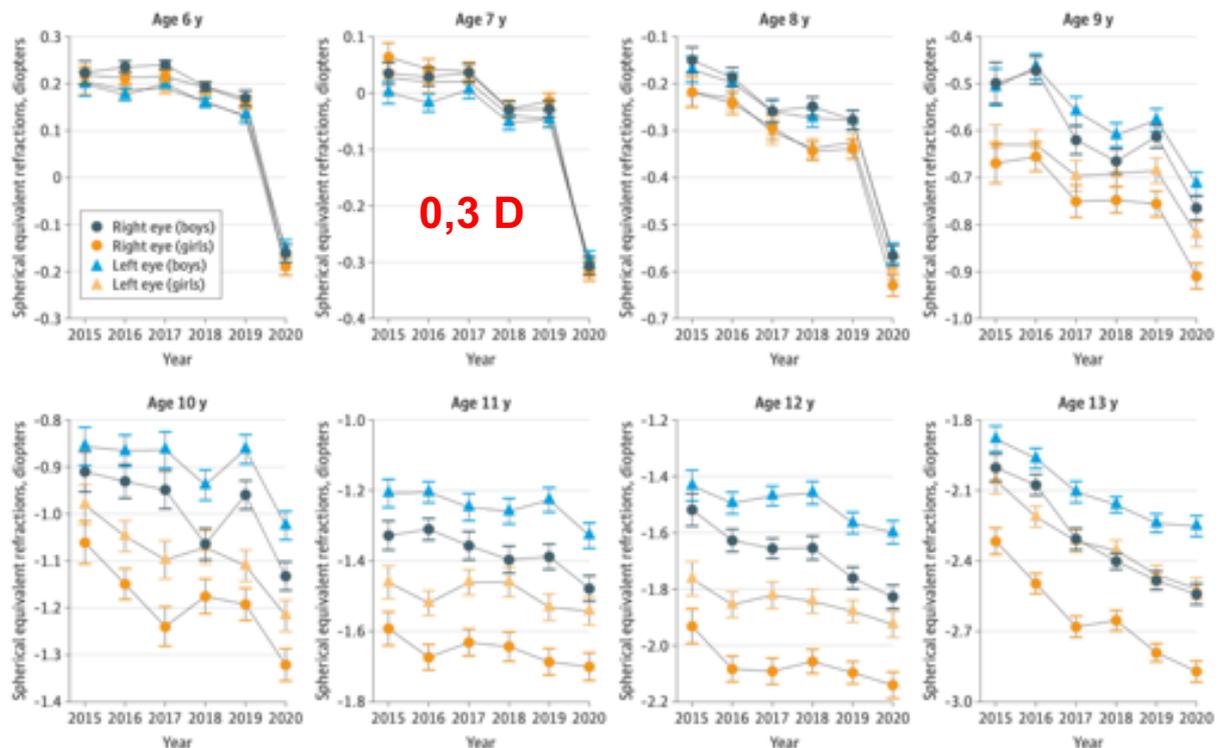


35%



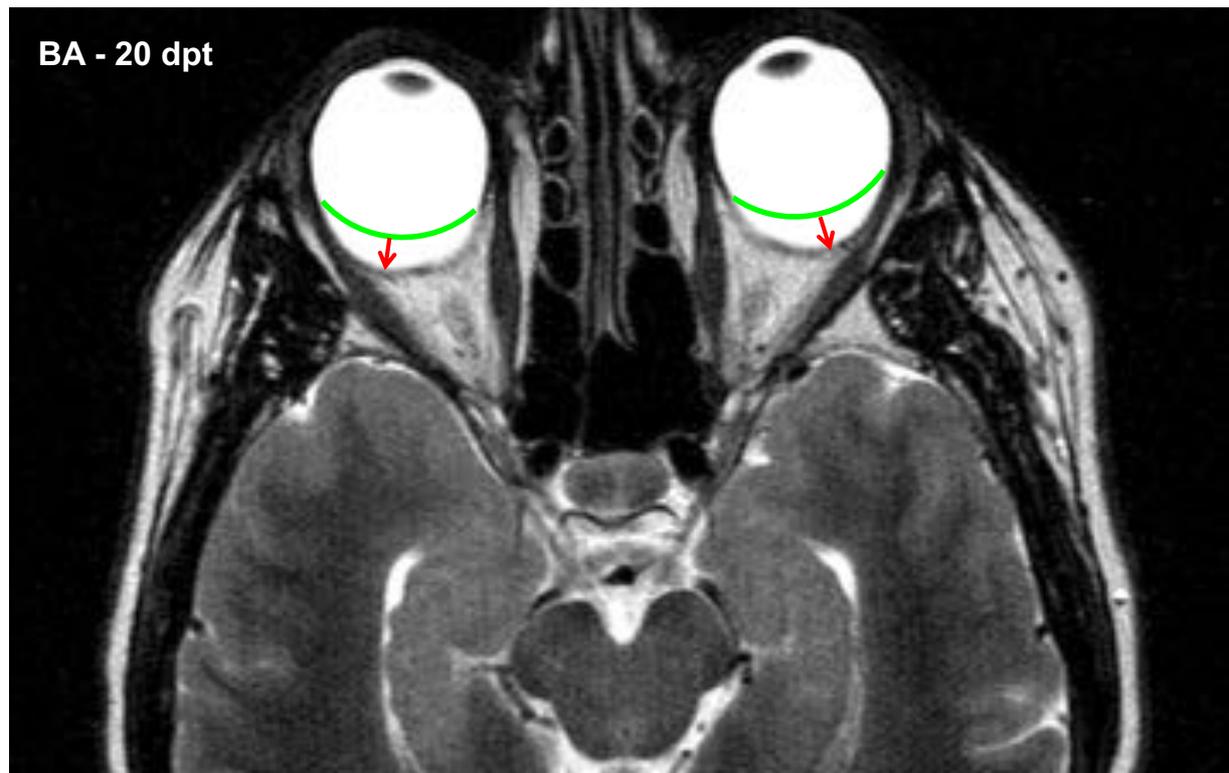
Schuster A et al. Dtsch Arztebl Int 2020

# Corona Effekt in China, n = 123.535



Wang J et al. JAMA Ophthalmol 2021

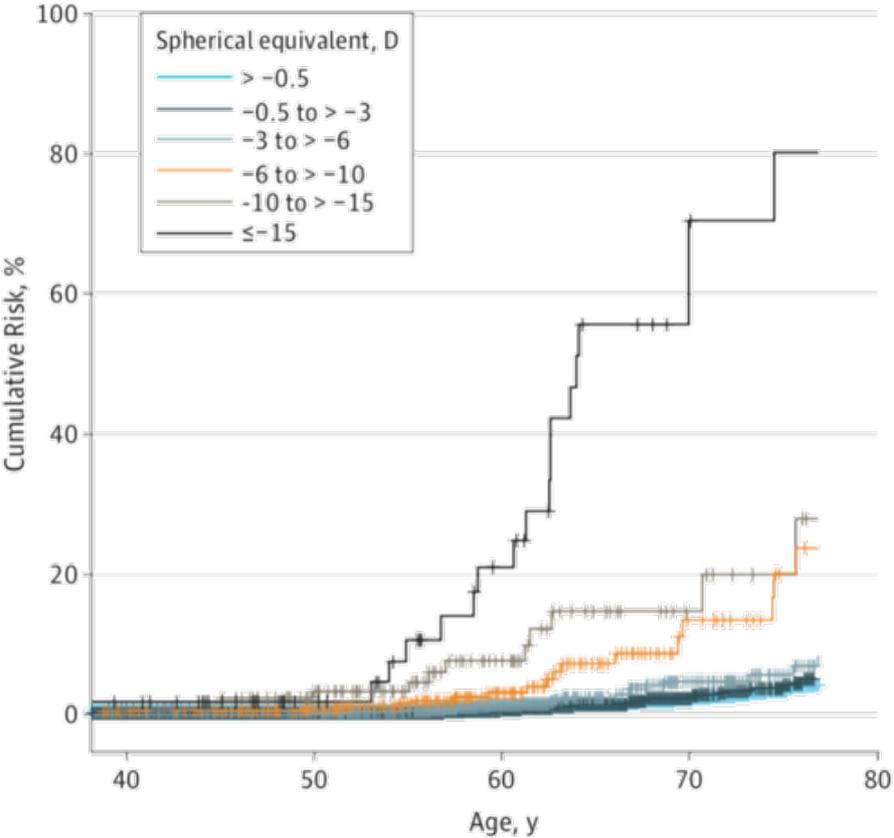
## Hohe Myopie > 26 mm, < - 6 D



## Pathologische Myopie

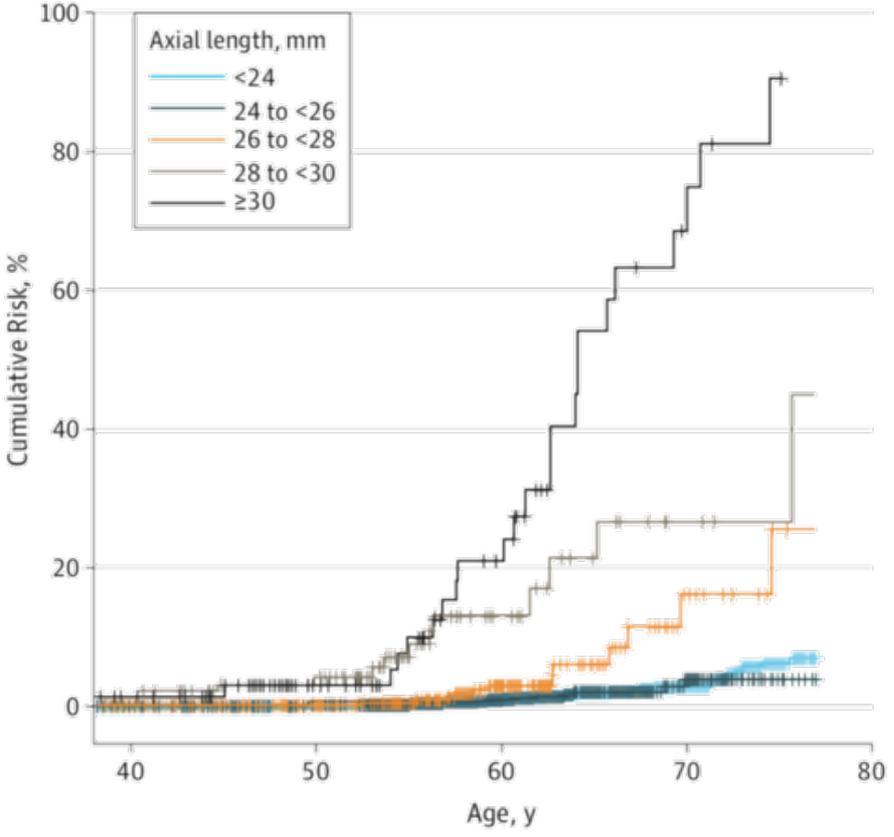


# Risiko Visus < 0,3 nach Alter und Refraktion



Tideman J et al.  
JAMA Ophthalmol 2016

# Risiko Visus < 0,3 nach Alter und Achslänge



Tideman J et al.  
JAMA Ophthalmol 2016

Natürlicher Verlauf pathologische Myopie mit Fokus mCNV

Einschluss 2014 – 2016, 30 deutsche Prüfzentren

261 screened, 150 eingeschlossen

AL = 30,2 mm SE = - 14,2 D (-9,4 D)

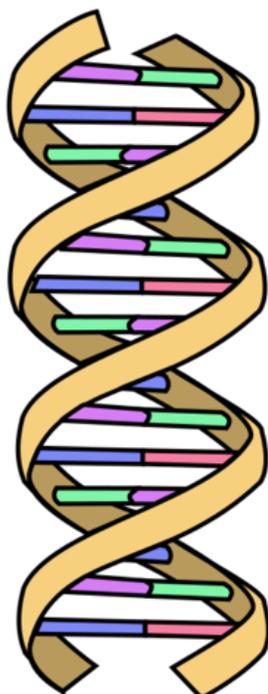
Beobachtung 1x jährlich über 3 Jahre

**Table 1.** Five predefined morphological disease risk criteria and number of study eyes/patients matching this group

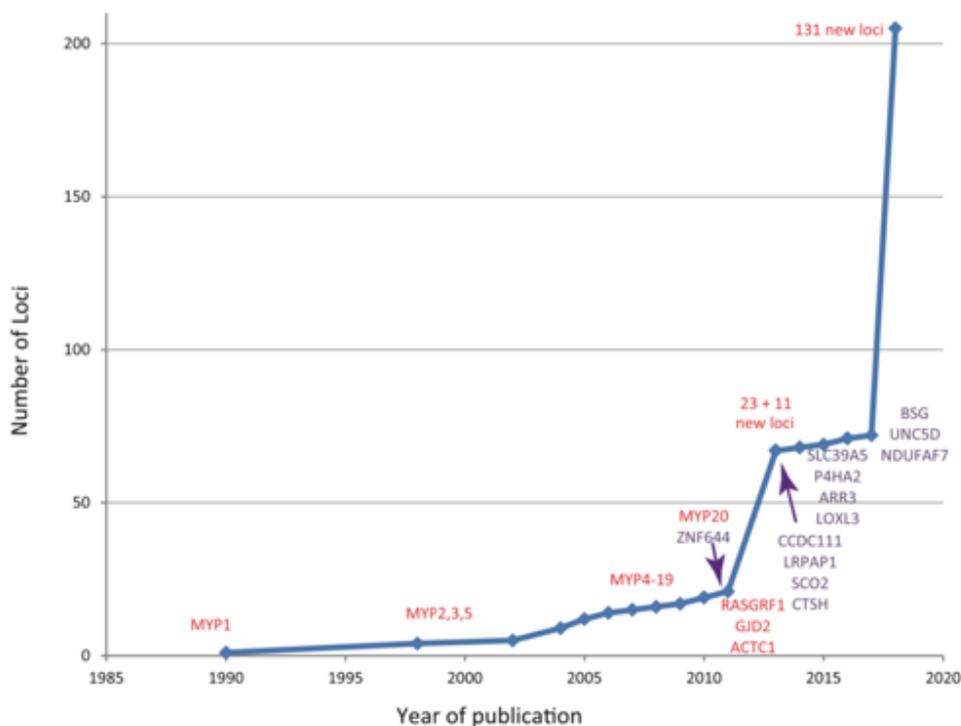
Diagnosis	n
1 Subfoveal choroidal thinning <sup>a</sup>	50
2 Enhanced choroidal curvature length <sup>b</sup>	7
3 Lacquer cracks	49
4 Patchy atrophy (minimal total atrophic lesion size >5 mm <sup>2</sup> )	22
5 Preexisting mCNV in fellow eye	22

Melzer C et al.  
Ophthalmologica 2018

## Risikofaktoren: Genetik versus Verhalten



# Myopie assoziierte SNP

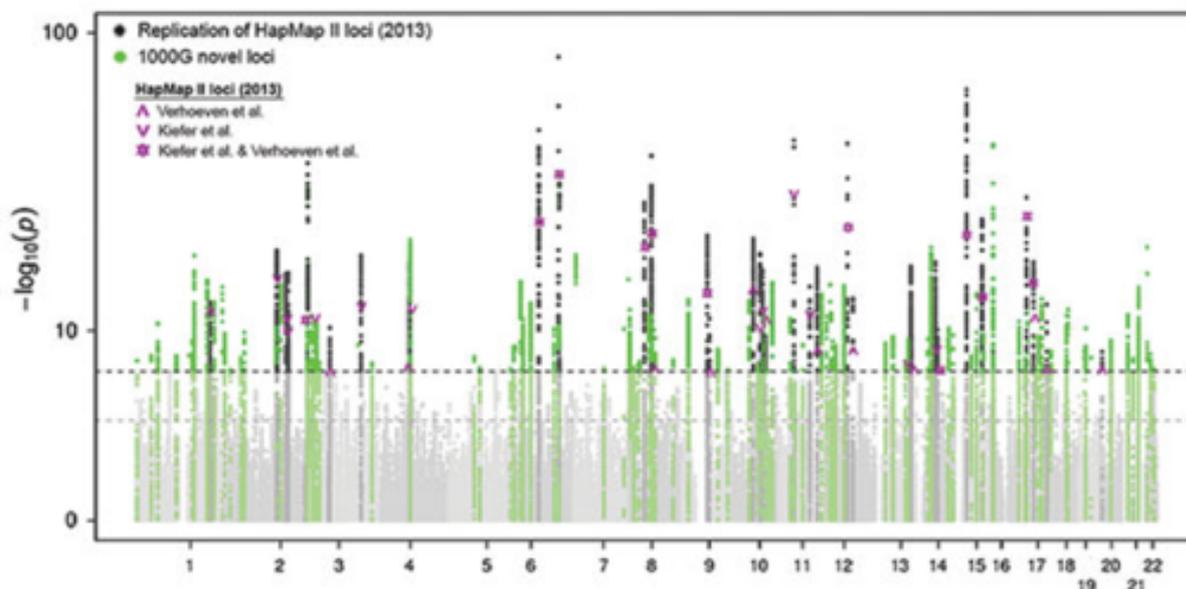


Tedja M et al. Invest Ophthalmol Vis Sci 2019

# GWAS Studien

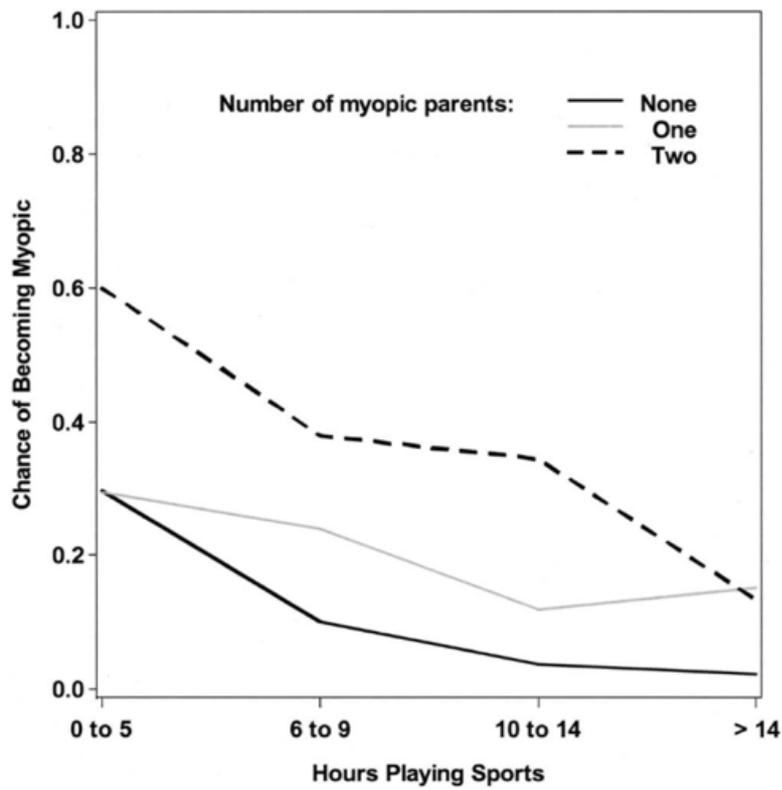
n = 160.420    161 Gene

Genetische Varianz → 8% Variation im Phänotyp



Tedja M et al. Nature Genetics 2018

# Refraktion Eltern versus Verhalten

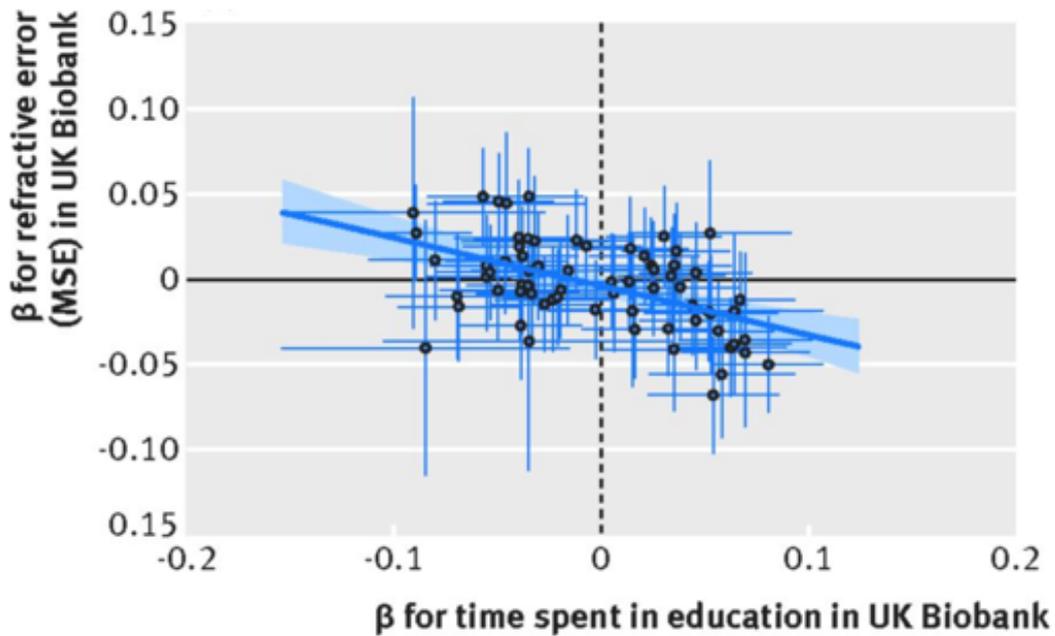


Jones L et al.  
Invest Ophthalmol Vis Sci  
2007

# Verhalten im Nahbereich



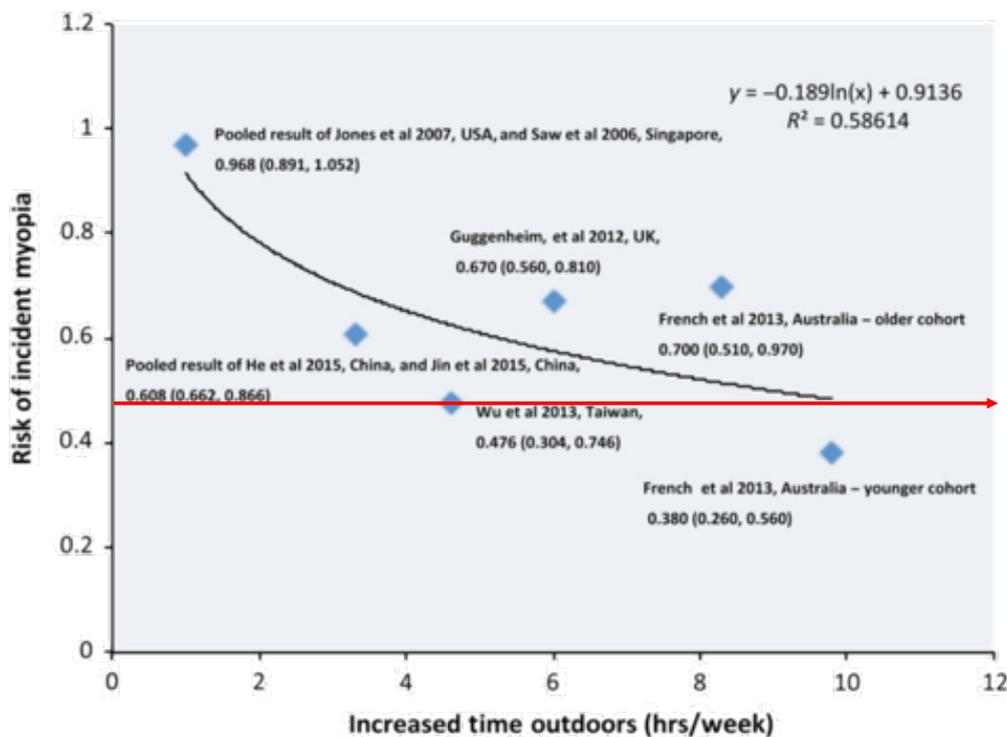
# Umweltfaktoren: Einfluss Nahsicht



Mendelian Randomisation Study, UK: 0,3 D / Jahr Ausbildung

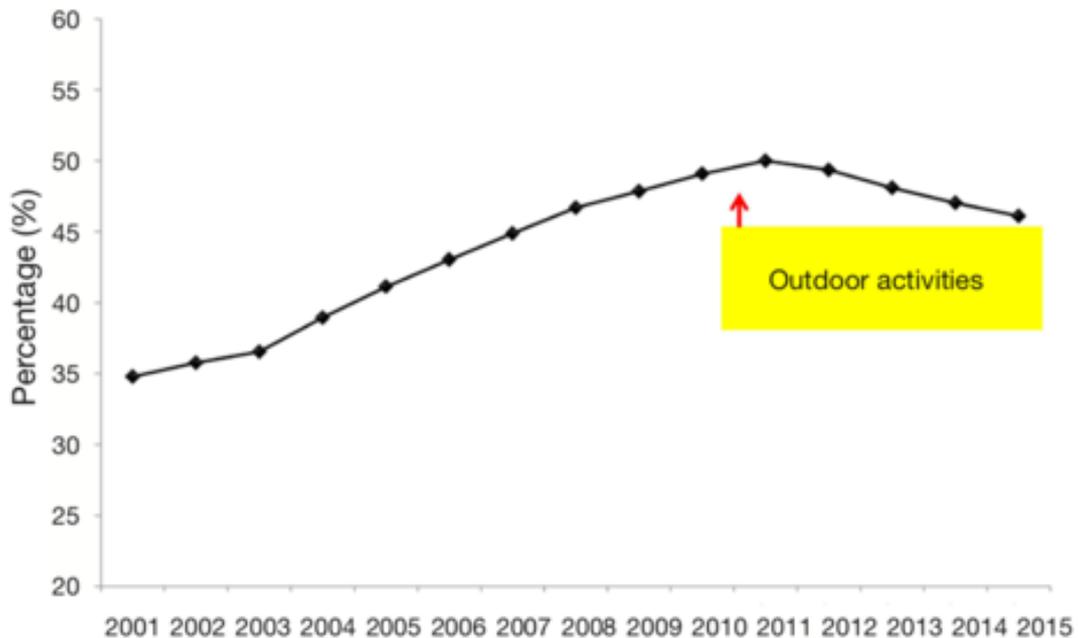
Mountjoy E et al. BMC 2018

# Umweltfaktoren: Tageslicht



2 h / Tag =  
halbes Risiko

Xiong S et al. Acta Ophthalmol 2017



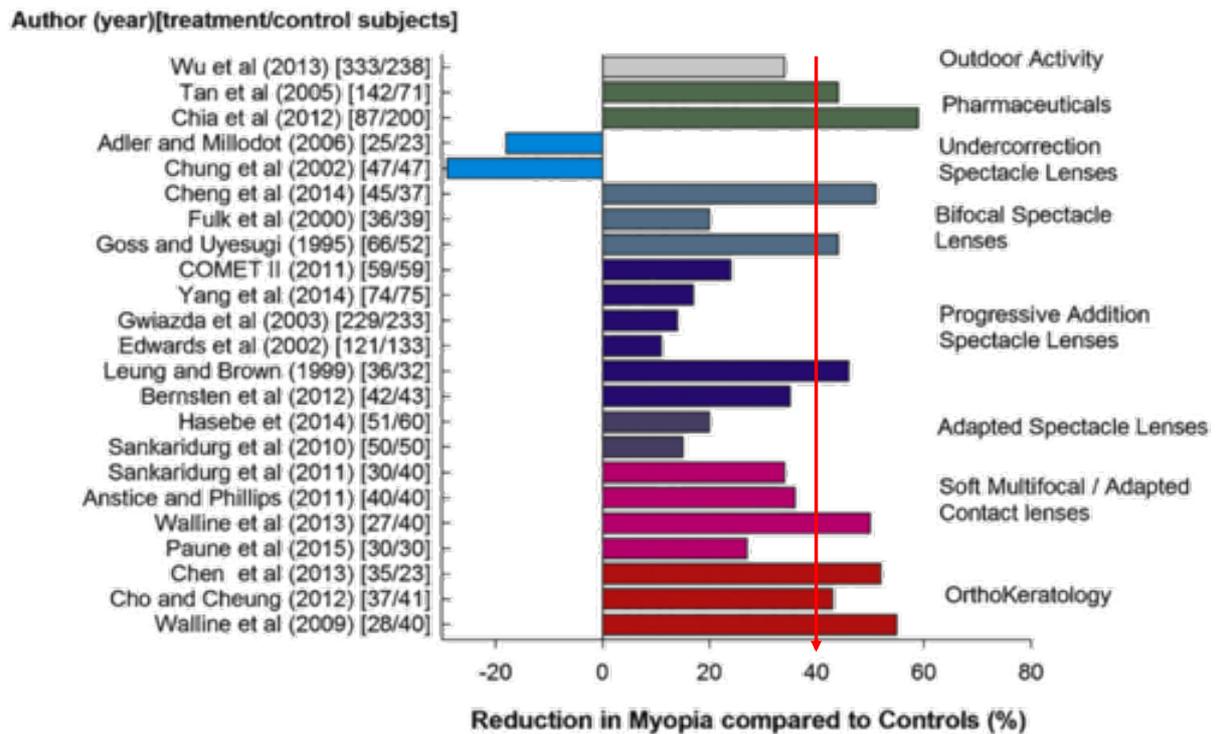
Taiwan Student Vision Care Program  
Wu P et al. Ann Eye Sci 2018

## Was bringt Progressionsminderung?

Minderung Myopieprogression 33%

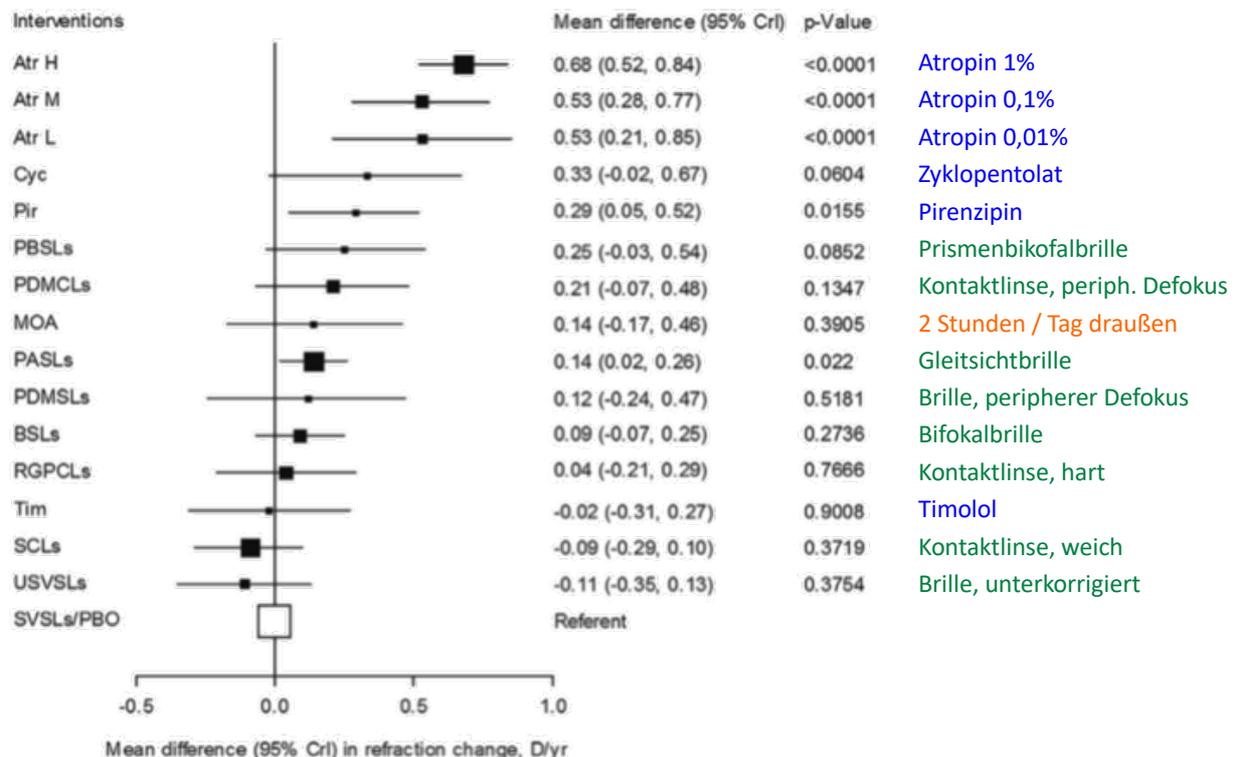
Minderung Rate hoher Myopie 73%

# Übersicht Interventionsmöglichkeiten

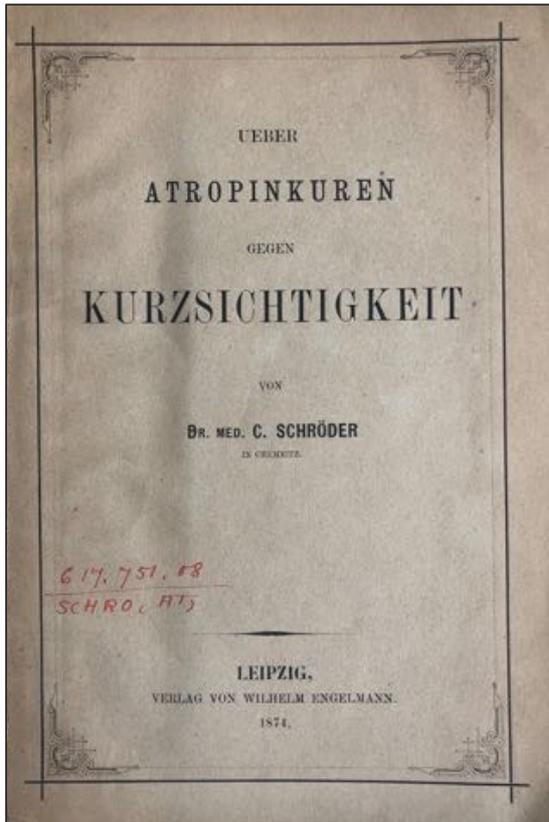


Wolffsohn J et al. Contact Lens and anterior eye 2016

# Metaanalyse



Huang J et al. Ophthalmology 2016



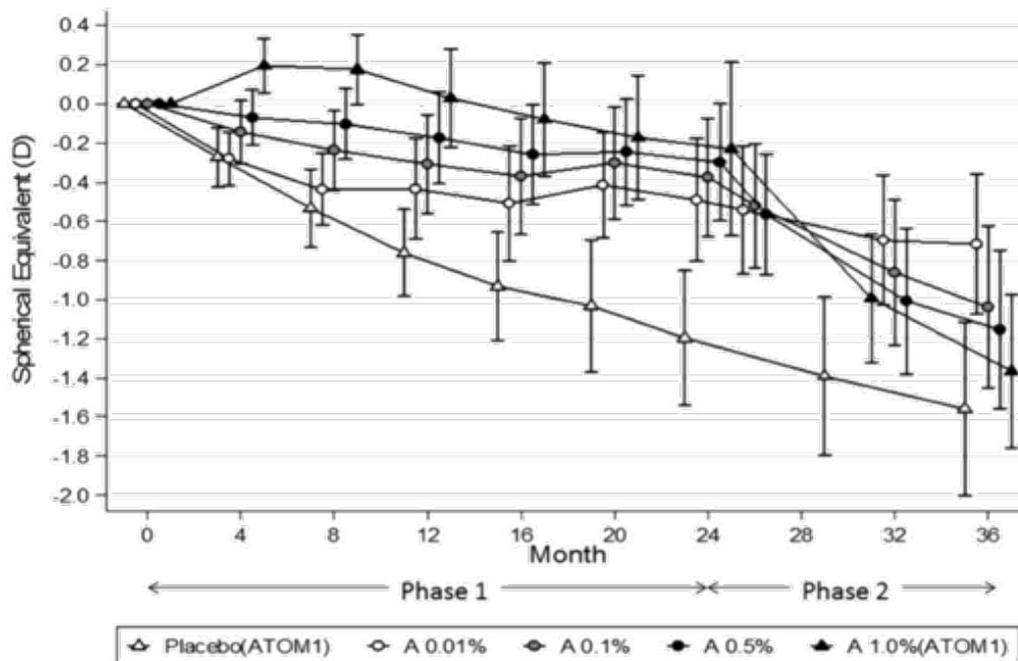
ON THE ATROPINE TREATMENT OF ACQUIRED AND PROGRESSIVE MYOPIA. With a Table of Cases. By HASKET DERBY, M.D.

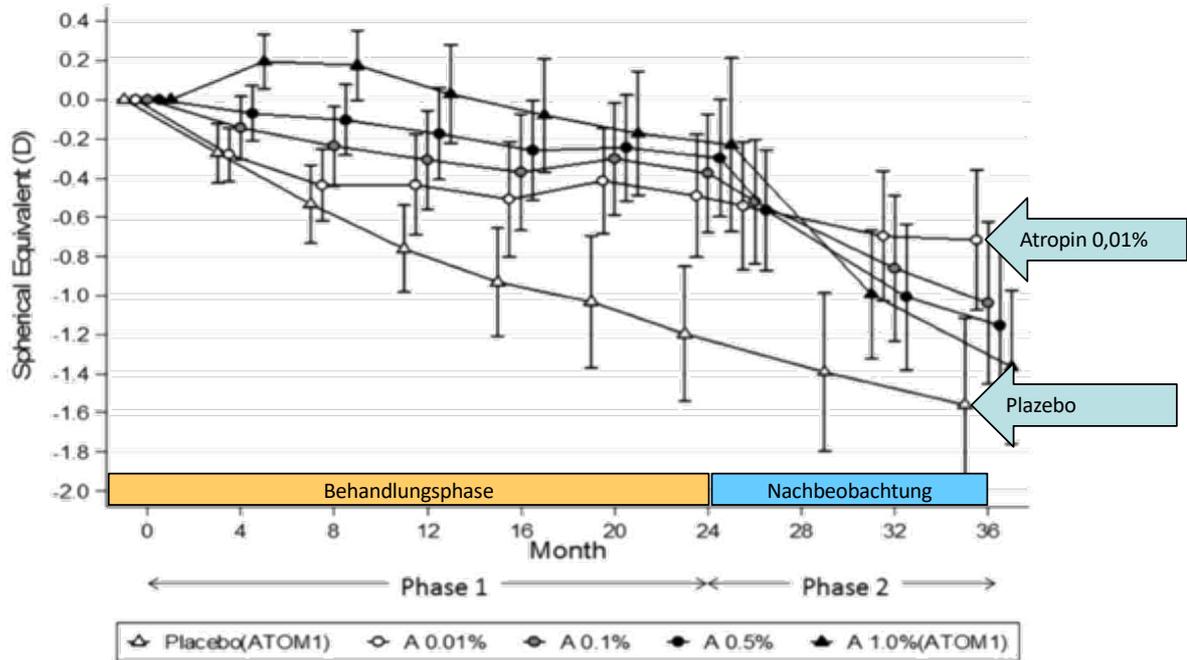
THE recent therapeutics of progressive and of acquired myopia have received but moderate attention from English writers on ophthalmology. Accepting apparently the dictum of Donders, that the cure of this error of refraction belongs to the class of things "devoutly to 'be wished for'" with unquestioning faith, they have contented themselves with discussing the division of the external recti, in cases where weakness of the interni is found, and in going into the general question of prophylactics. The investigations that have been going on, especially in St. Petersburg and Basle, within the past six years, have attracted very little attention elsewhere, judging at least from current ophthalmic literature. It is therefore with less diffidence that I present a few results of my own, and, having nothing original as regards method to bring before the Society, briefly direct its attention to some departures from the received doctrines on this subject which a few years have inaugurated. Though few in number, they are by no means unimportant.

Speaking of the pain in and fatigue of the eyes experienced

Trans Am Ophthalmol Society 1874

## ATOM 1 & 2-Studien





Chia A et al. Am J Ophthalmol 2014; 157: 451

## LAMP-Studie: 0% 0,01% 0,025% 0,05%

438 Myope, 4 – 12 Jahre

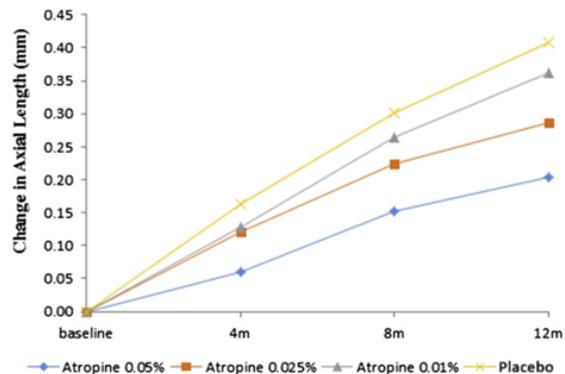
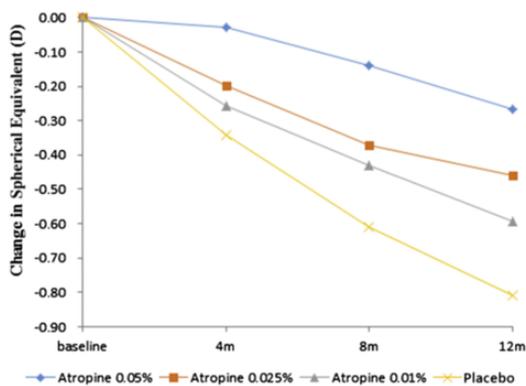
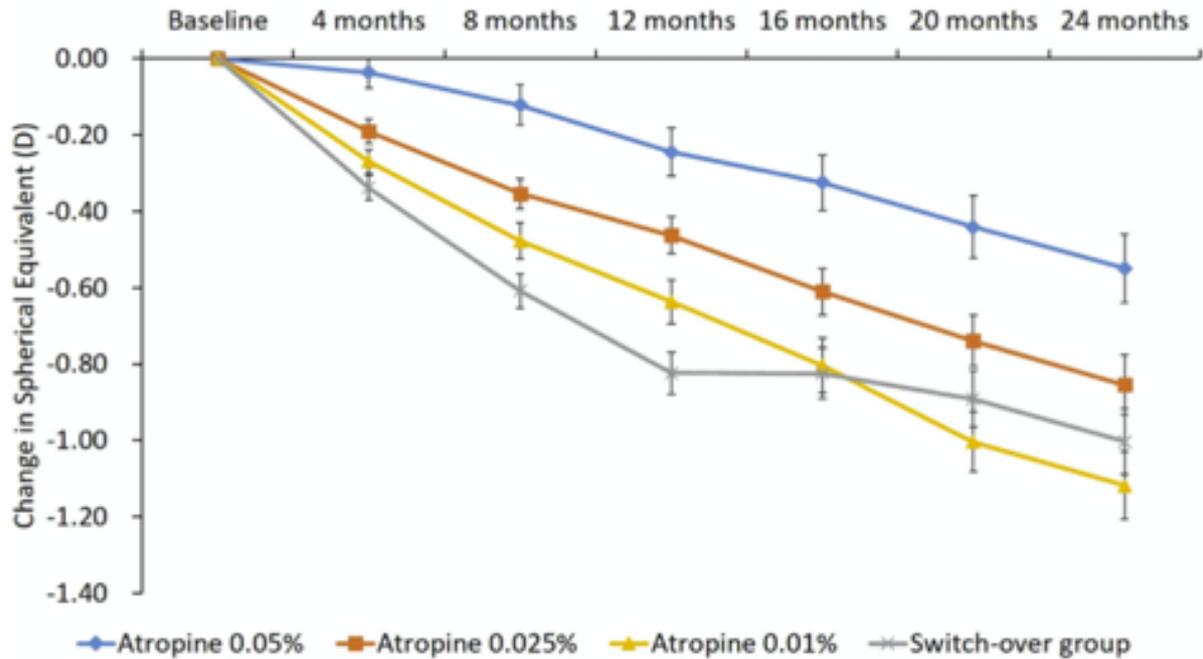


Table 3. Side Effects and Adverse Events

	0.05% (n=109)		0.025% (n=108)		0.01% (n=110)		Placebo (n=111)		P Value
	n	%	n	%	n	%	n	%	
Photochromatic glasses needed	33	30.3%	37	34.3%	33	30.0%	44	39.6%	0.39
Progressive glasses needed	1	0.9%	0	0.0%	2	1.8%	1	0.9%	0.86
Photophobia at 2 wks	34	31.2%	20	18.5%	6	5.5%	14	12.6%	<0.001 <sup>ns</sup>
Photophobia at 1 y <sup>1</sup>	8	7.8%	6	6.6%	2	2.1%	4	4.3%	0.27
Allergic conjunctivitis	3	2.8%	7	6.5%	7	6.4%	7	6.3%	0.57
Hospitalization	3	2.8%	5	4.6%	3	2.7%	2	1.8%	0.66

Yam J et al. Ophthalmology 2018

# LAMP-Studie: Phase 2 PLC → 0,05%



Yam J et al. Ophthalmology 2020

## Clinicaltrials.gov: myopia + atropine = 26



Design	Country	Acronym	n	Age min	Age max	Arms	Duration	F/U	Outcome #	Status	
0.01% vs PL	Ireland / UK	CHAMP-UK	289	6	12	2	3	1	SE	NCT03690089*	Recruiting
0.01% vs PL	Ireland	MOSAIC	250	6	12	2	2	1	SE	2018-004775-13*	Recruiting
0.01% vs PL	USA (PEDIG)	MTS1	186	5	13	2	2	0.5	SE	NCT03334253	Recruiting
0.01% vs ∅	Oman	AIMS	150	6	15	2	2	1	SE	NCT03508817	Recruiting
0.01% vs PL	Hong Kong		80	7	10	2	2	0.5	SE	NCT03374306	Active, not recruiting
0.01% vs PL	Hong Kong		80	7	10	2	1.5	0	SE, AL	NCT03374306	Active, not recruiting
0.01% vs PL	Germany	AIM	334	6	11	2	2	1	SE	NCT03865160	Not yet recruiting
0.01% vs 0.03% vs PL	USA / Intern.	STAAR	840	3	14	5	3	1	SE	NCT03918915**	Recruiting
0.01% vs 0.1% vs PL	USA		420	3	12	3	4	0	SE	NCT03942419***	Recruiting
0.01% vs 0.1% vs PL	Denmark	APP	150	6	12	3	2	1	SE, AL	NCT03911271	Recruiting
0.01% vs 0.005% vs NSAID	Taiwan		150	6	12	5	1	0	SE, AL	NCT03402100	Recruiting
0.01% vs 0.02% vs PL	USA / Intern.	CHAMP	483	3	17	3	3	1	SE	NCT03350620*	Recruiting
0.01% vs 0.01% + 1%	China		222	7	12	2	2	0.5	SE, AL	NCT03949101	Enrolling by invitation
0.01% + OK vs OK	Hong Kong	BAM	60	6	11	2	2	0	AL	NCT02955927	Active, not recruiting
0.01% vs 0.1% + bf CL	USA		49	7	10	2	3	0	SE	NCT03312257	Active, not recruiting
0.01% vs PL, Prophylaxis	Singapore	ATOM3	570	5	9	4	2	1	SE	NCT03140358	Recruiting

\* Nevakar, \*\* Sydnexis, \*\*\* Eyenovia

10 ausgeschlossen (Nebenwirkungen / Aderhauteffekte)

Suchdatum: 20. September 2019

# Deutsche Studie in Vorbereitung: AIM-Studie



Berlin  
Bonn  
Freiburg  
Göttingen  
Hamburg  
Hannover  
Köln  
Leipzig  
Magdeburg  
Mainz  
München  
Münster  
Heidelberg  
Regensburg  
Würzburg

Refraktion      Retinomax  
Achslänge      IOL Master  
  
Visus              ETDRS Tafeln  
Kontrast          MARS Tafeln  
Pupille            PlusoptiX  
Akkommod.      RAF-Rule

Speichelproben

9 Visiten über 3 Jahre

Rosenheim  
Ahaus

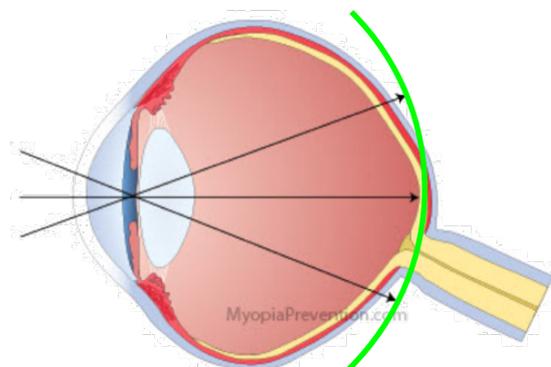
**0% – 0,01% – 0,02%**

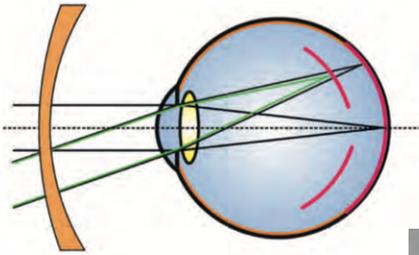


**DFG** Deutsche  
Forschungsgemeinschaft

[mail@lagreze.de](mailto:mail@lagreze.de)

# Hyperopie in der Peripherie fördert Myopie

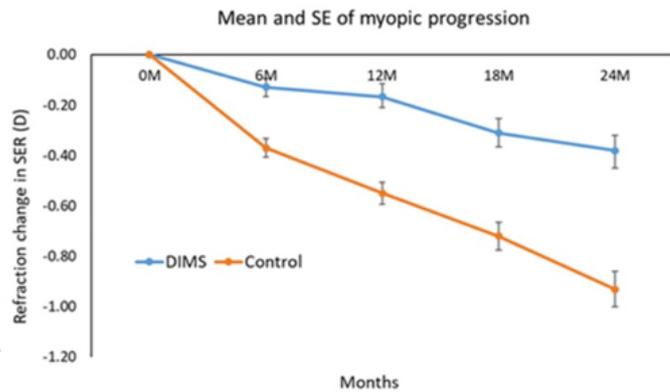
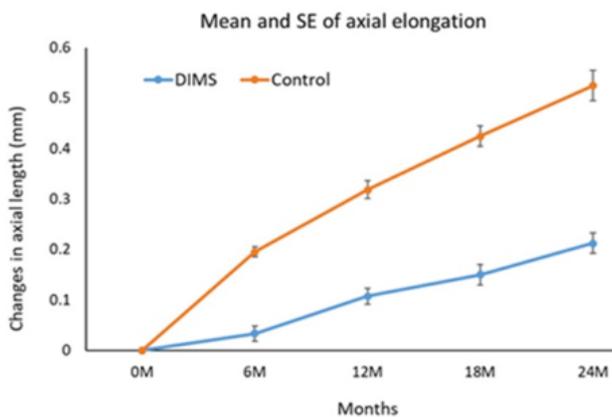
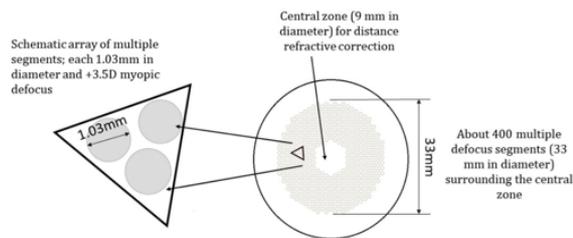




Wesemann W. DOZ 2019



## Defocus incorporated multiple segments (DIMS)



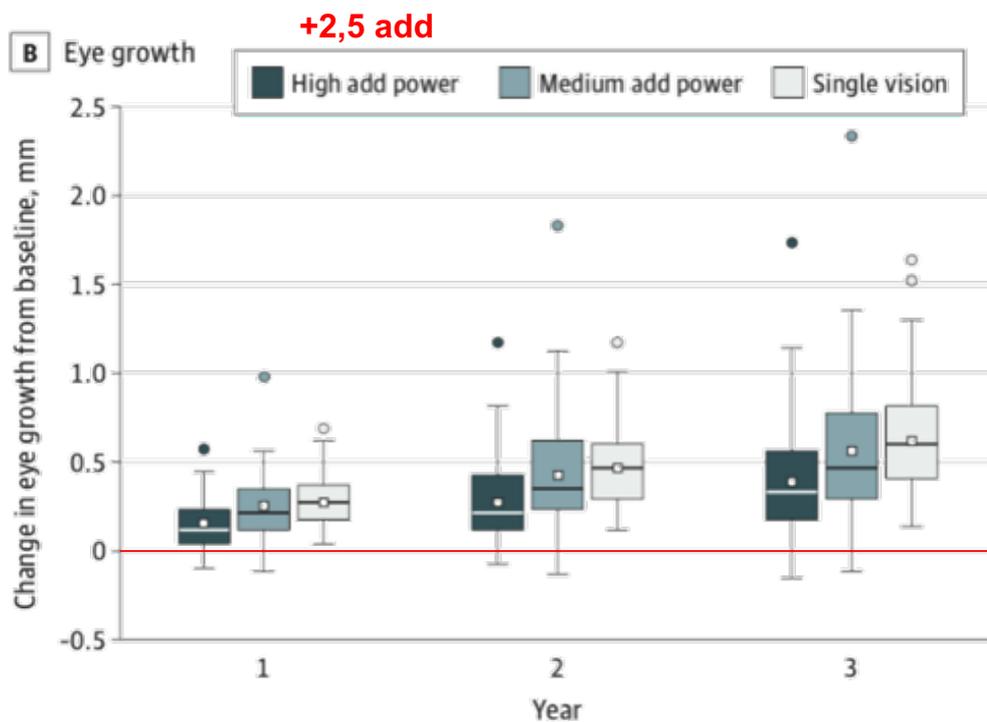


Charenton-le-Pont, 5 October 2020 - Essilor, the world's leading ophthalmic optics company, recently launched Stellest™ lens, a new generation of spectacle lens solutions in the fight against myopia. Interim findings of an ongoing clinical trial show more than 60% slowdown in myopia progression on average, when compared to children wearing single vision lenses.

**NEWS**  
2021.01.26  
A LOOK BACK AT

[www.essilor.com](http://www.essilor.com)

## Multifokale Kontaktlinsen (BLINK-trial)



Walline J et al. JAMA 2020

## Nevakar and Théa Enter into Licensing Agreement for the Commercialization of NVK-002 (Atropine for the Treatment of the Progression of Myopia in Children) in Europe



Nevakar, Inc.

January 28, 2021 · 3 min read



-- Potential to receive up to \$135 million upon the successful attainment of several key regulatory and sales milestones --

BRIDGEWATER, N.J. and CLERMONT-FERRAND, France, Jan. 28, 2021 (GLOBE NEWSWIRE) -- Nevakar Inc. ("Nevakar"), a biopharmaceutical company developing multiple assets in the ophthalmic and injectable areas, and Laboratoires Théa ("Théa") announced today that they recently entered into an exclusive licensing agreement for the commercialization of NVK-002 in Europe. NVK-002 is a proprietary, investigational, preservative-free eye drop administered nightly and intended for slowing the progression of myopia in children ages three to 17. It is currently under clinical evaluation in the CHAMP (Childhood Atropine for Myopia Progression) study, a Phase III clinical trial being carried out in the U.S. and Europe.

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Symbol	Last Price	Change	% Change
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[www.finance.yahoo.com](http://www.finance.yahoo.com)

## Fazit

Eltern, Tageslicht, Leseabstand relevante Faktoren

0.01% Atropin sicher und effektiv

Dosisoptimum noch unklar und ethnienpezifisch

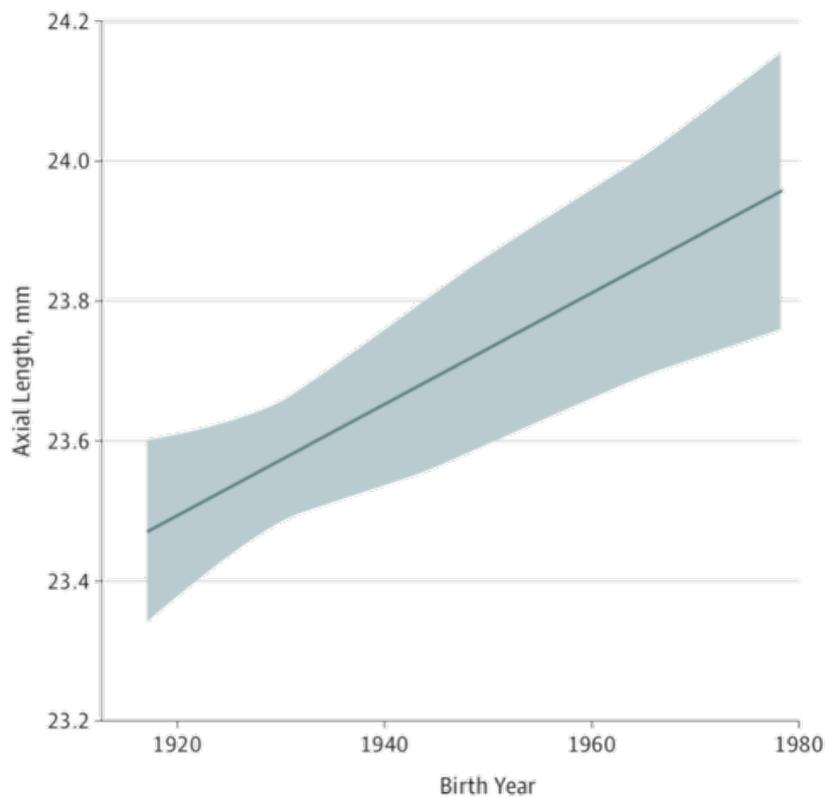
Zulassung bald

Spezialoptiken ähnlich effektiv (auch additiv)

Flut klinischer Studien

Progressionsminderung ausreichend möglich

# 60 Jahre erfolgreiche biologische Adaptation



Ca. 0,5 mm /  
halbes Jhrd.

Tideman J et al.  
JAMA Ophthalmol 2016

## ... an moderne Sehgewohnheiten



..., aber nicht auf Kosten der Makula