

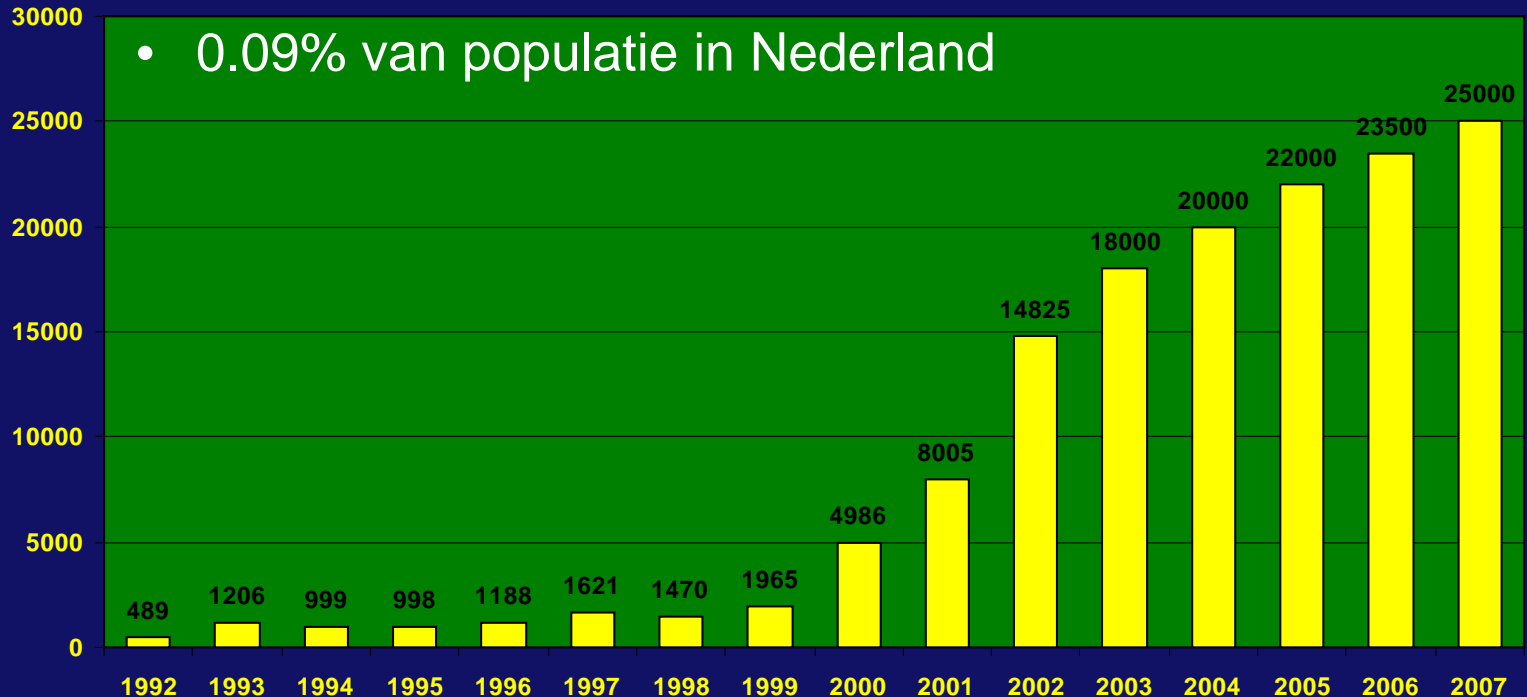
Hoe veilig is refractiechirurgie op de langere termijn?

Prof.dr. G.P.M.Luyten

Afdeling oogheelkunde
LUMC

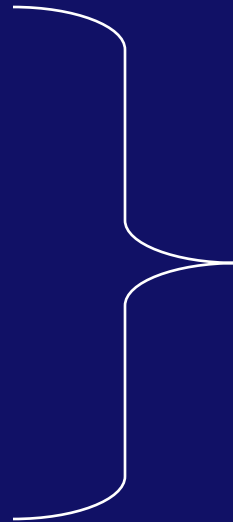


Refractiechirurgie in Nederland



- In EU in totaal ruim 600.000 procedures in 2005 (0.11% tot 0.46% van populatie).
- Ongeveer 93% van de procedures in EU bestaat uit het ooglaseren.

- Veiligheid
- Effectiviteit
- Voorspelbaarheid
- Stabiliteit
- Herbehandelingen
- Complicaties



Uniforme rapportage

- Nederlands Gezelschap voor refractiechirurgie
 - www.ooglaseradvies.org
 - Consensus refractiechirurgie
 - Registratie refractiechirurgen
 - Visitatie klinieken en refractiechirurgen

Dupps WJ, Kohnen Th, RosenES, Koch DD, Obstbaum SA,
Waring GO, Reinstein GO, Doyle Stulting R

JCRS, JRS and Cornea Januari 2011

UDVA	uncorrected distance visual acuity
UIVA	uncorrected intermediate visual acuity
UNVA	uncorrected near visual acuity
CDVA	corrected distance visual acuity
CIVA	corrected intermediate visual acuity
DCIVA	distance-corrected intermediate visual acuity
CNVA	corrected near visual acuity
DCNVA	distance-corrected near visual acuity

Dus!!!

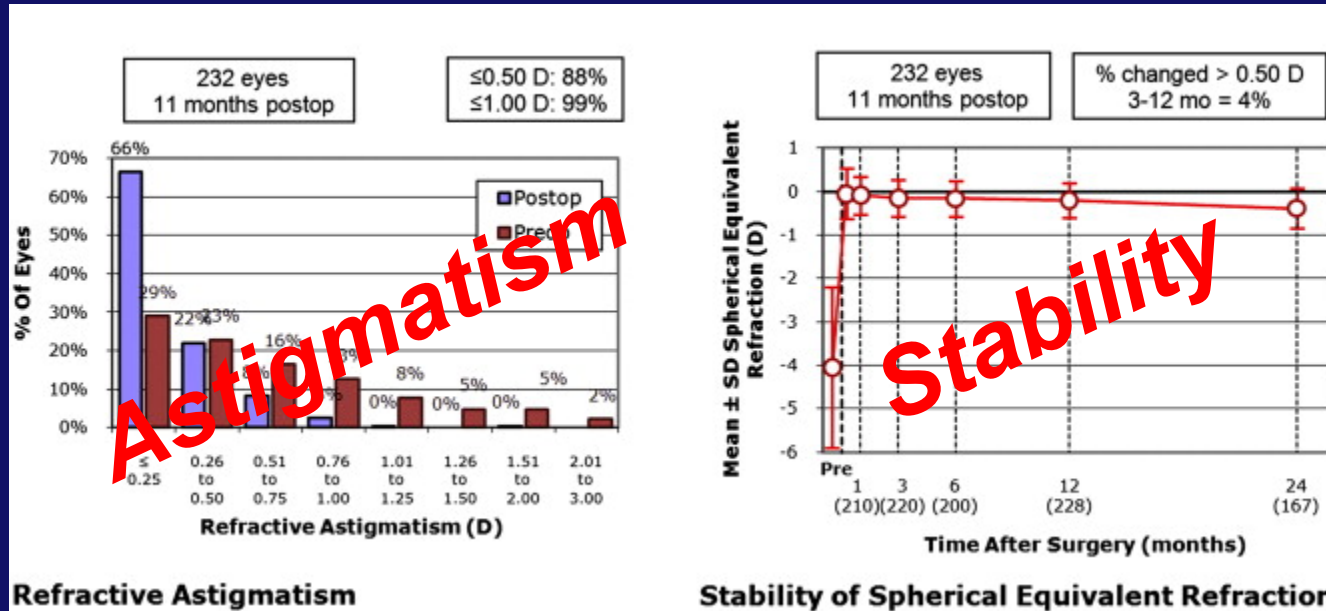
Geen “B” (Best)

Geen “S” (Spectacle)

- Visus data moeten worden geconverteerd naar LogMAR
- Visus 0,1 (logMAR) = ????

- Visus data moeten worden geconverteerd naar LogMAR
- Visus 0,1 (logMAR) = 0,8 (Snellen visus)
- **Magnification Requirement** = $1 / V$
- Dus Log MAR = $\log 1 / V$
= $\log 1 / 0,8 = 0,0969$
- Online converter: <http://www.myvisiontest.com/logmar.php>

Standardised graphs and terms for refractive surgery results



<http://www.londonvisionclinic.com/refractiveurgeryoutcomes>.

- Is refractiechirurgie veilig op langer termijn?
- Follow-up:
 - 90% moet worden vervolgd
 - 85% bij elk controle bezoek

- Aspect refractive surgery
- "Corneal Surgery, Laser"[Mesh] OR "Lasik"[All Fields] OR "PRK"[All Fields] OR "Phakic iol"[all Fields] OR "Laser Corneal Surgery"[All fields] OR "Photokeratectomy"[All fields] OR "Keratomileusis"[All fields] OR "Keratotomy, Radial"[Mesh] OR "radial keratotomy"[All Fields] OR "Lens Implantation, Intraocular"[Mesh] OR "intraocular lens implantation"[All Fields] OR "intraocular lens implantations"[All Fields]
- 14347 op 1/2/2011
- Aspect lange termijn efficacy and safety
- "Treatment Outcome"[Mesh] OR "treatment outcome"[All Fields] OR "efficacy"[All Fields] OR "effectiveness"[All Fields] OR "Safety"[Mesh] OR "safety"[All Fields] OR "adverse effects"[All Fields] OR "side effects"[All Fields] OR "Complications"[All Fields] OR "adverse effect"[All Fields] OR "side effect"[All Fields] OR "Complication"[All Fields]
- ruim 3 miljoen op 1/2/2011
- Combineren Aspect refractive surgery en lange termijn effect
- ("Corneal Surgery, Laser"[Mesh] OR "Lasik"[All Fields] OR "PRK"[All Fields] OR "Phakic iol"[all Fields] OR "Laser Corneal Surgery"[All fields] OR "Photokeratectomy"[All fields] OR "Keratomileusis"[All fields] OR "Keratotomy, Radial"[Mesh] OR "radial keratotomy"[All Fields] OR "Lens Implantation, Intraocular"[Mesh] OR "intraocular lens implantation"[All Fields] OR "intraocular lens implantations"[All Fields]) AND ("Corneal Surgery, Laser"[Mesh] OR "Lasik"[All Fields] OR "PRK"[All Fields] OR "Phakic iol"[all Fields] OR "Laser Corneal Surgery"[All fields] OR "Photokeratectomy"[All fields] OR "Keratomileusis"[All fields] OR "Keratotomy, Radial"[Mesh] OR "radial keratotomy"[All Fields] OR "Lens Implantation, Intraocular"[Mesh] OR "intraocular lens implantation"[All Fields] OR "intraocular lens implantations"[All Fields])
- 14347 op 2/2/2011

Pubmed search

- Aspect lange termijn
- "Time"[Mesh:NoExp] OR "long term"[All Fields] OR "Long-term"[All fields] OR "longterm"[All fields] OR "Time Factors"[Mesh]
- Combineren:
- ("Corneal Surgery, Laser"[Mesh] OR "Lasik"[All Fields] OR "PRK"[All Fields] OR "Phakic iol"[all Fields] OR "Laser Corneal Surgery"[All fields] OR "Photokeratectomy"[All fields] OR "Keratomileusis"[All fields] OR "Keratotomy, Radial"[Mesh] OR "radial keratotomy"[All Fields] OR "Lens Implantation, Intraocular"[Mesh] OR "intraocular lens implantation"[All Fields] OR "intraocular lens implantations"[All Fields]) AND ("Corneal Surgery, Laser"[Mesh] OR "Lasik"[All Fields] OR "PRK"[All Fields] OR "Phakic iol"[all Fields] OR "Laser Corneal Surgery"[All fields] OR "Photokeratectomy"[All fields] OR "Keratomileusis"[All fields] OR "Keratotomy, Radial"[Mesh] OR "radial keratotomy"[All Fields] OR "Lens Implantation, Intraocular"[Mesh] OR "intraocular lens implantation"[All Fields] OR "intraocular lens implantations"[All Fields]) AND ("Time"[Mesh:NoExp] OR "long term"[All Fields] OR "Long-term"[All fields] OR "longterm"[All fields] OR "Time Factors"[Mesh])
- 2 Cochrane reviews (niet in de set)
- Totaal 1448 artikelen

Selectie outcome PRK

- Uitsluiten
 - Hyperopie
 - Phakic IOL
 - Alleen engelstalig
 - Ouder dan 2004

- Shojaei etal., Cornea 2009;28:304-310
- Liu etal., Ophthalmologica 2008;222:386-390
- Alio etal., Am J Ophthalmol 2008;145:29-36
- Alio etal., Am J Ophthalmol 2008;145:37-45
- O'Connor etal., J Refract Surg 2006;22:871-7
- Pietila etal., J Rferact Surg 2004;20:110-5
- Honda etal., J Refract Surg 2004;20:116-20

LASEK/PRK outcome

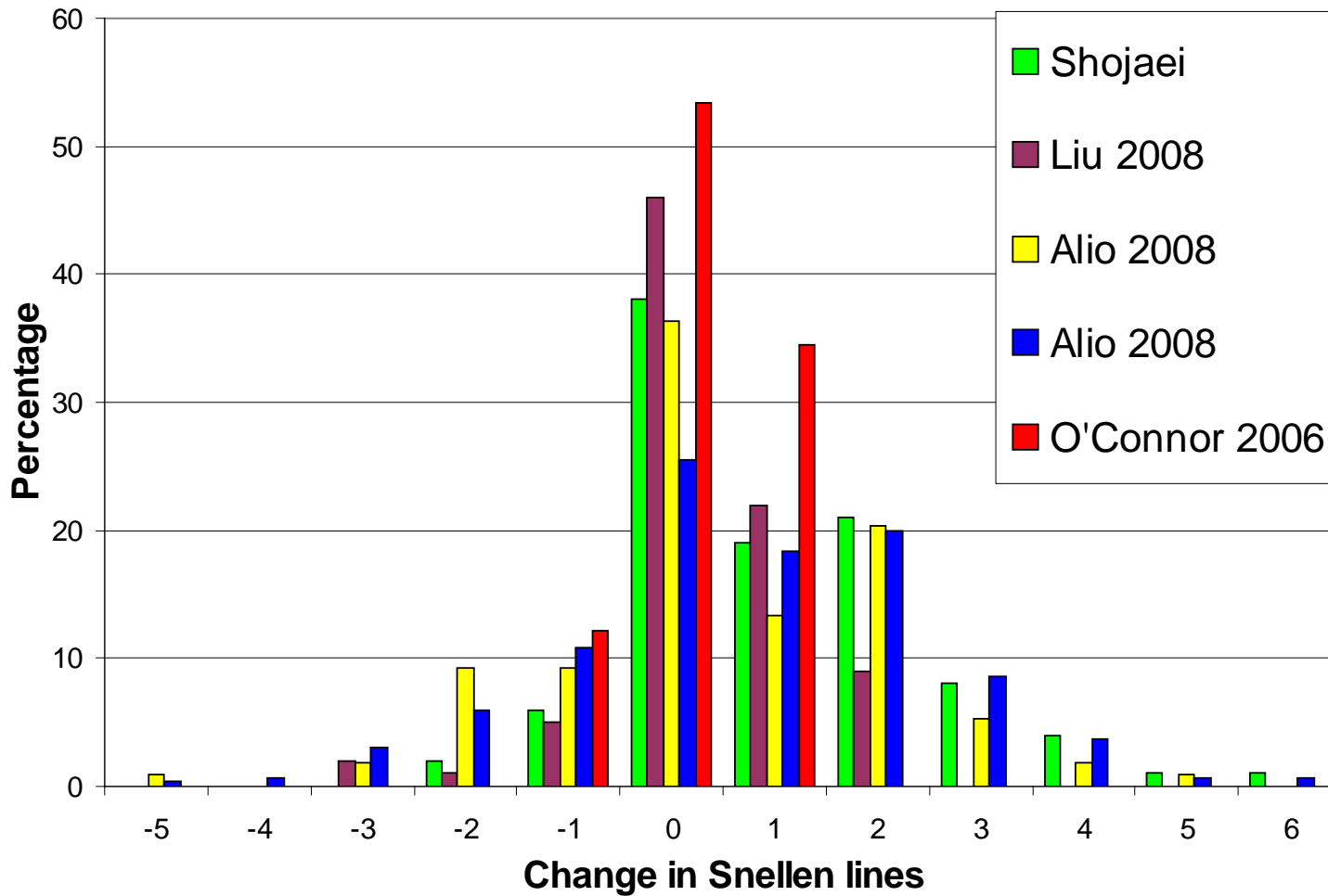
	Shojaei 2009		Liu 2008	Alio 2008	Alio 2008	O'Connor 2006	Pietila 2004	Honda 2004
	1997/1998		1994/95	1992/95	1992-95	1992-93	1991-93	1993-96
Eyes	184		177	225	267	133	92	165
Patients	107		92	138	191	80	55	
Gender (M/F)	69/38		24/26	72/66	89/102	18/21	30/39	
Age (yr)	33.4 ± 8.1		26.7	30.1 ± 9.8	32.1 ± 9.8	32.4 ± 8.45	31.8 ± 8.7	29.5 ± 7.1
SE (D)	-4.00 ± 1.84	-6.80 ± 1.74	-4.51 ± 0.76	-3.81 ± 1.29	-8.87 ± 2.25	-4.4. ± 1.58	-5.28 ± 2.55	-6.38 ± 1.75
Retreatment	4.31%			42%	46.4%	5,26%		
Follow-up yrs	8.4 ± 0.62	8.4 ± 0.62	11	10	10	12	8	5
Follow-up %	52.7%	52.7%	50%	38.65%	53.65%	48,75%	59.8%	10%

1. Safety (CDVA)

Verlies van ≥ 2 Snellen lijnen (CDVA)

- FDA <4 %
- NICE
 - PRK 0.5 % (0,0 – 20,5%)
 - LASEK 0.0 % (0,0 – 8,2%)
 - LASIK 0.6 % (0,0 – 3,0%)

1. Safety (CDVA)

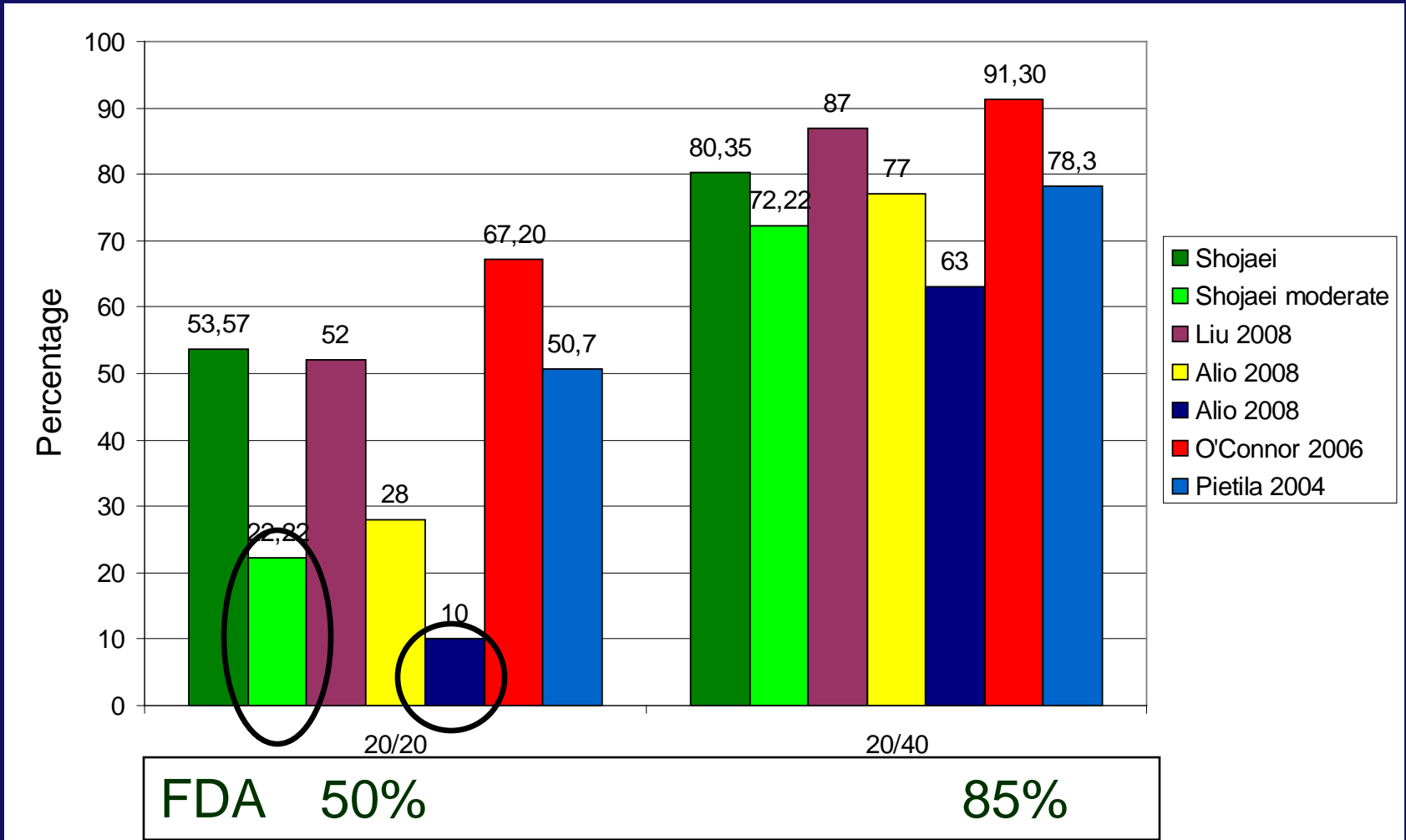


Lange termijn resultaten (8 tot 12 jaar)

1. Safety (Complications)

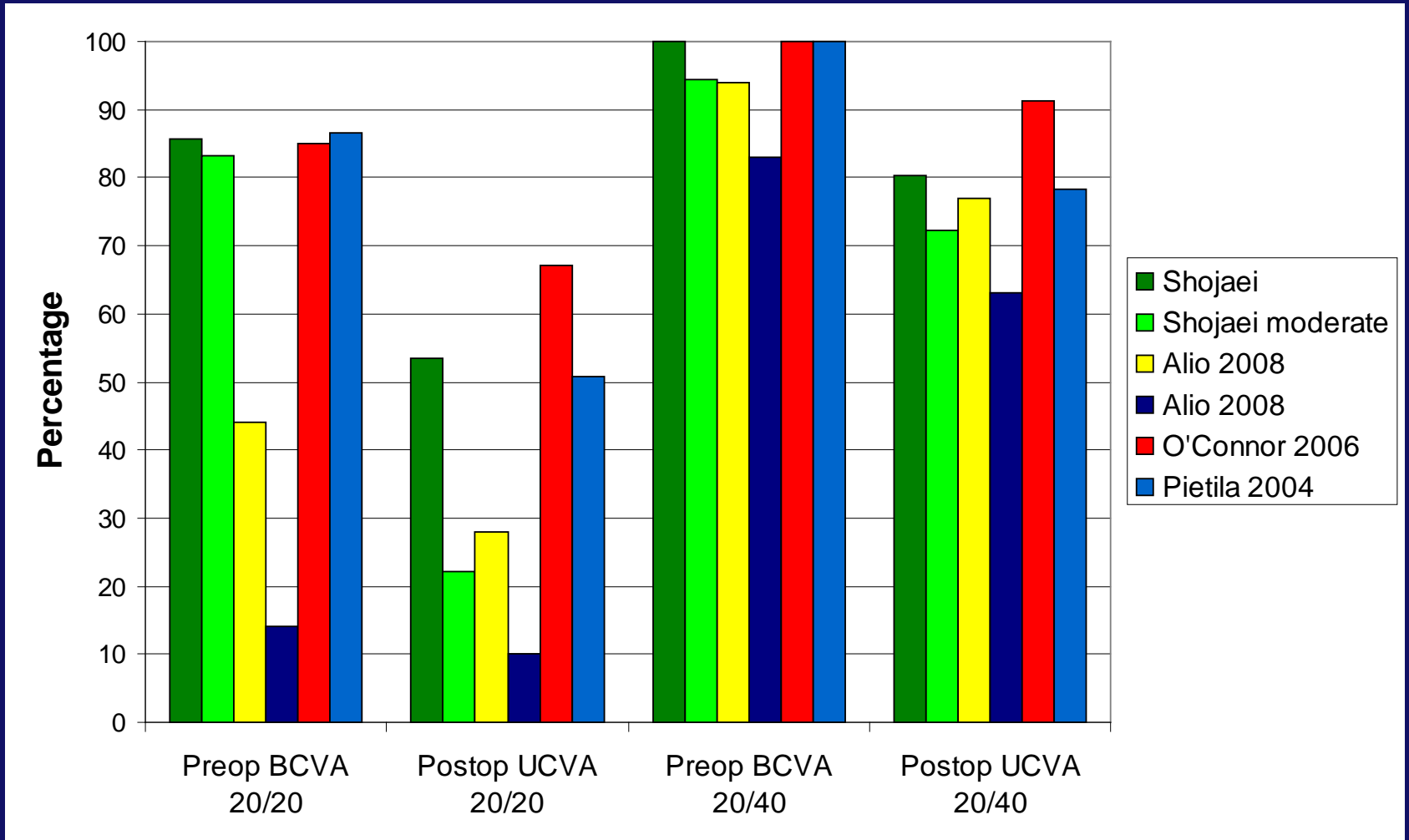
- Alio et al 2008 ≤ 6 D myopia
 - Cataract 3 eyes (3 lines)
 - Diabetic retinopathy 2 eyes (5 lines)
 - Retinal detachment 1 eye (10 lines)
 - Corneal scar (herpes) 1 eye (3 lines)
- Alio et al., 2008 ≥ 6 D myopia
 - Cataract 6 eyes (>2 lines)
 - Retinal detachment: 1 eye (8 lines)
 - Choroidal neovascularisation: 3 eyes (4- 6 lines)
 - Macular hole: 1 eye (5 lines)
 - Corneal scar (NVII paralysis): 1 eye (4 lines)
 - Haze: 2 eyes (3 lines)

2. Efficacy (UDVA of 20/20 and 20/40)



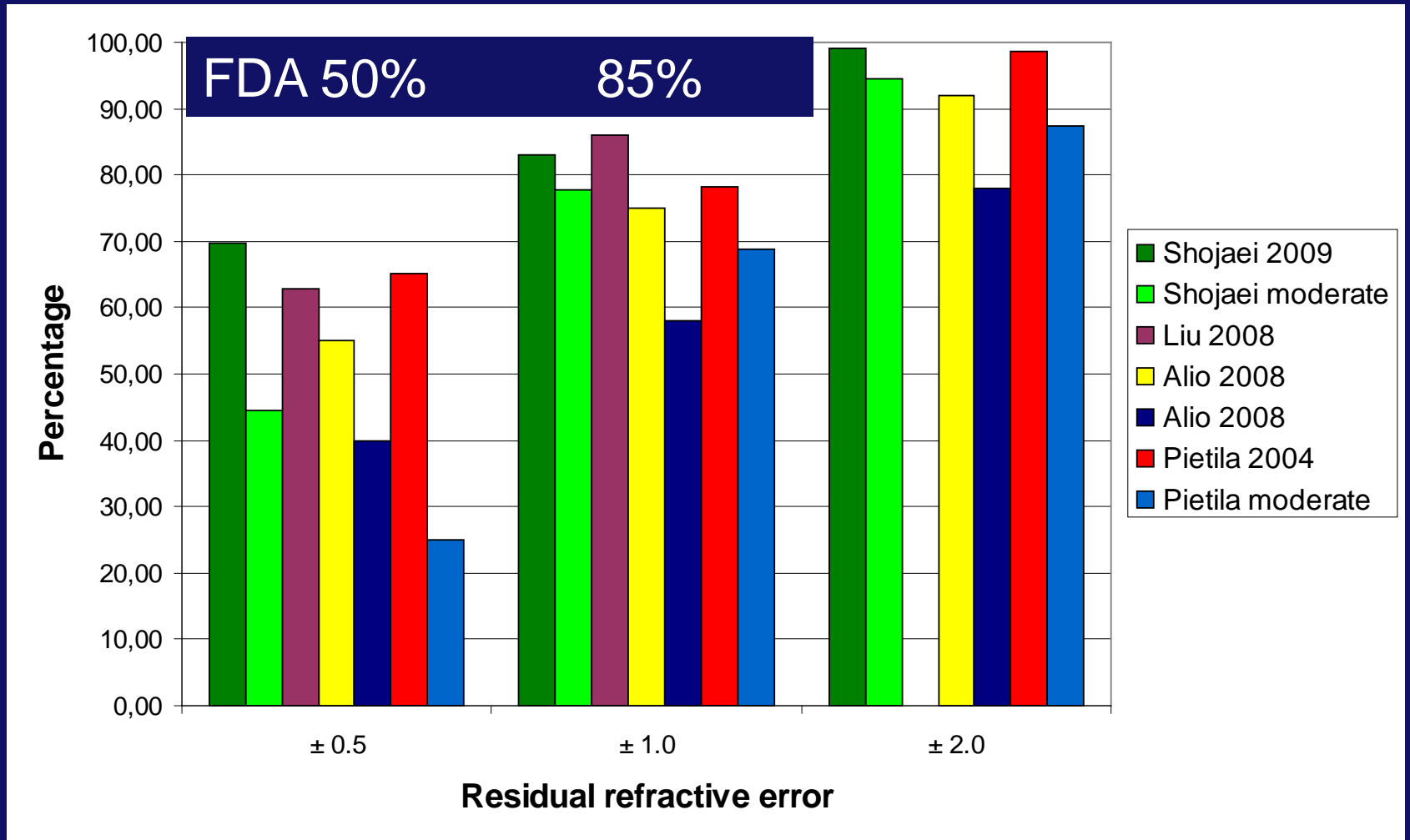
Lange termijn resultaten (8 tot 12 jaar)

2. Efficacy (UDVA of 20/20 and 20/40)



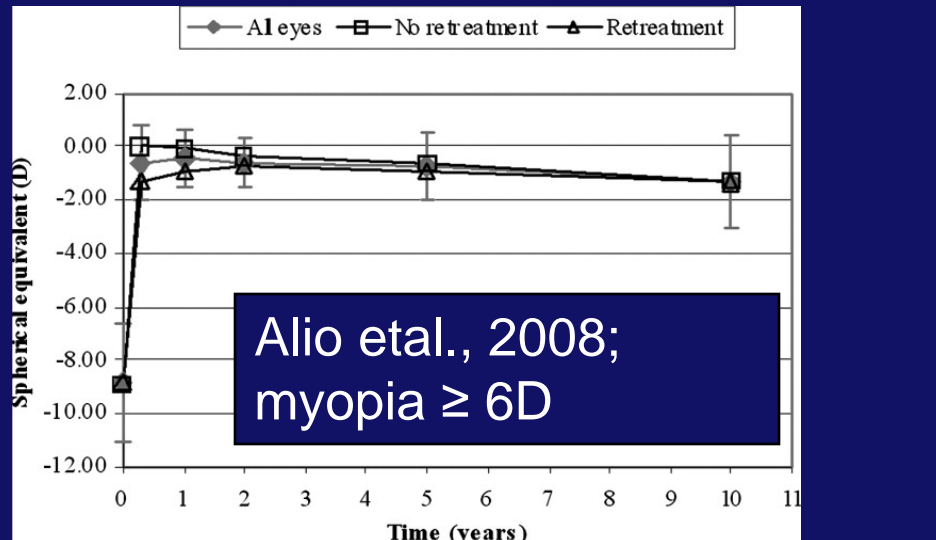
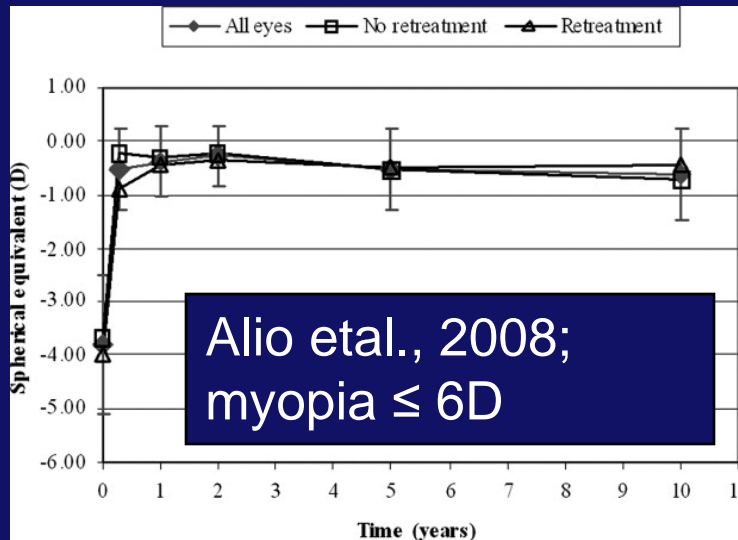
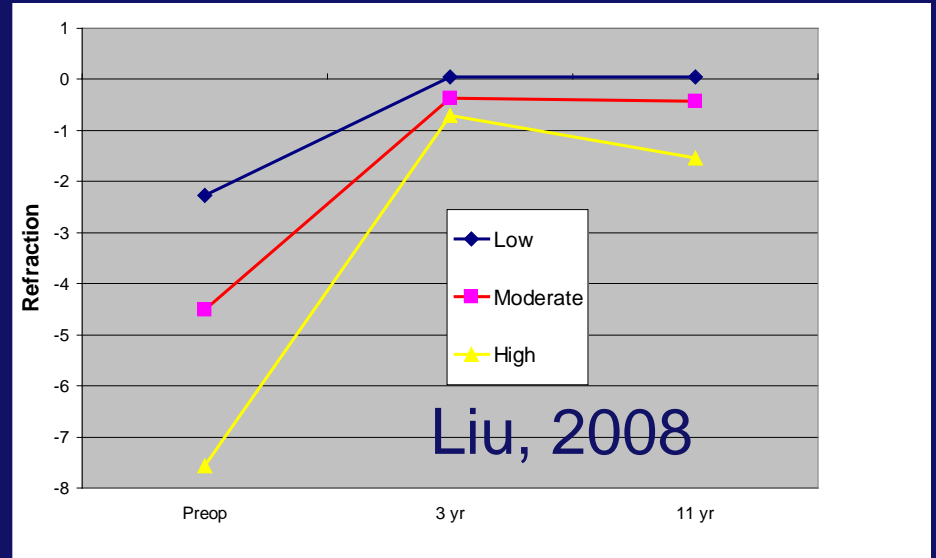
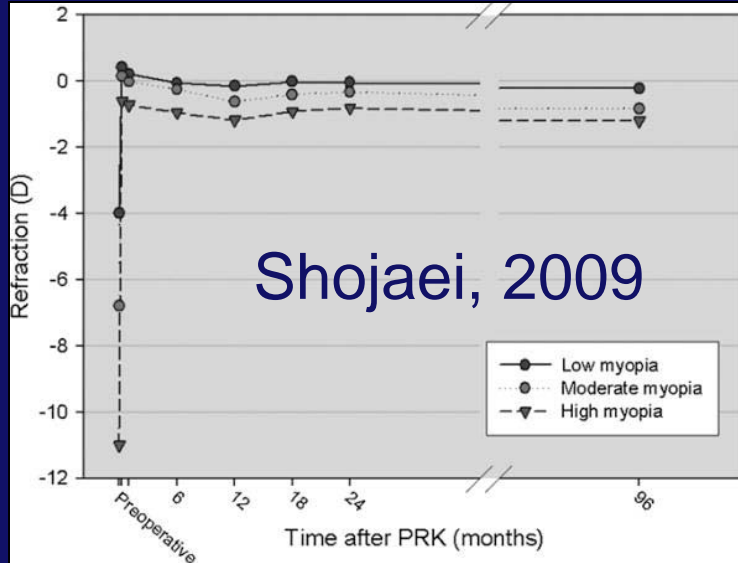
Lange termijn resultaten (8 tot 12 jaar)

3. Residual refractive error



Lange termijn resultaten (8 tot 12 jaar)

4. Stability



4. Stability

Refractieve stability (ANSI Z80.11 2007)

Standard for laser systems for corneal reshaping

1. Twee postoperatieve controles ten minste 3 maanden uit elkaar
2. 95% van de ogen < 1 D tussen twee refracties
3. Gemiddelde verandering van $< 0,5$ D per jaar (0,04 D / maand) (gepaarde analyse)

Myopie < 6 D: -0.10 ± 1.08 tot -0.58 ± 0.72

Myopie 6 tot 10D: -0.72 ± 2.11 tot -0.84 ± 0.48

(follow-up 8 en 12 jaar)

5. Complicaties

LASIK

- Button hole flap 0.48%
- Incomplete flap 0.48%
- Epitheel ingroei 0.48%
- Ectasie 0.2% (0% tot 0.87%)
- Visusverlies > 2 regels 0.6%
- Microbiele keratitis 0.16%
- DLK 1.4%
- Vitroeretinale complicaties 0.29%

LASEK/PRK

- Haze graad 2 1/45
- Ectasie na lasek/prk 0%
- Visusverlies > 2 regels 0% tot 8.2%
- Microbiele keratitis lasek 0% tot 3.4%

- Grade Description

0 Normal clarity

+0.5 Barely perceptible haze

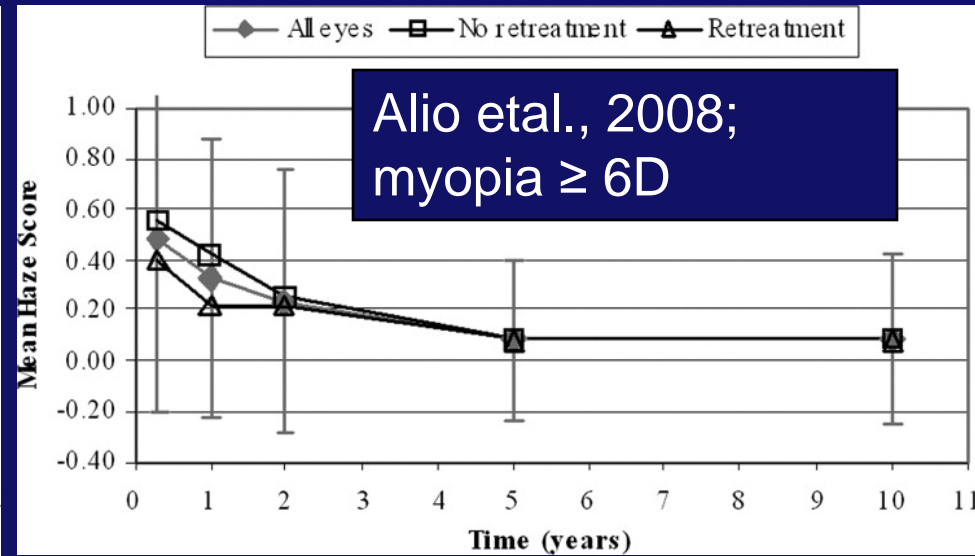
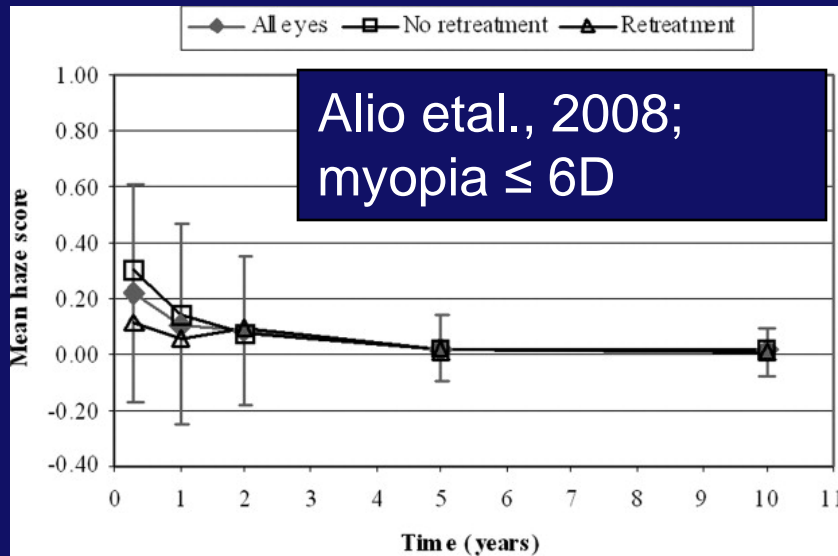
+1 (trace) Faint haze easily seen by broad oblique illumination that can be diffuse or evenly spread throughout the treatment zone or that can have a lacy or reticular appearance

+2 (mild) Discrete haze visible with difficulty by direct focal slit-lamp examination, with a more granular confluent pattern than trace haze

+3 (moderate) Moderately dense corneal opacity that partially obscures iris detail in direct illumination but does not interfere with refraction

+4 (marked) Severely dense opacity that completely obscures iris details and interferes with retinoscopy

Corneal Haze Severity	No. Eyes			Sum (% of All Eyes With Haze)
	Low Myopia (≤ -6.00 D)	Moderate Myopia (-6.10 to -10.00 D)	High Myopia (> -10.00 D)	
0.5	2	2	6	10 (45.45)
1	—	3	4	7 (31.81)
2	—	—	3	3 (4.54)
3	—	2	—	2 (9.09)
4	—	—	—	0
Sum (% of group)	2 (1.78)	7 (19.44)	13 (28.26)	22 (100.0)



6. Conclusie LASEK / PRK

- Stabiele visus ongecorrigeerd en gecorrigeerd
- Stabiele refractie
- Verminderde visus is meestal niet gerelateerd aan Excimer laser behandeling
- Regressie is gerelateerd aan hoogte van de correctie.
- Refractiechirurgie is veilig en betrouwbaar mits uitgevoerd volgens de daarvoor geldende richtlijnen en door ervaren, gekwalificeerde oogartsen.



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Laser in situ keratomileusis versus long-term contact lens wear: Decision analysis

Hall T McGee, William D. Mathers

J. Cataract Refract Surg 2009;35:1860-67

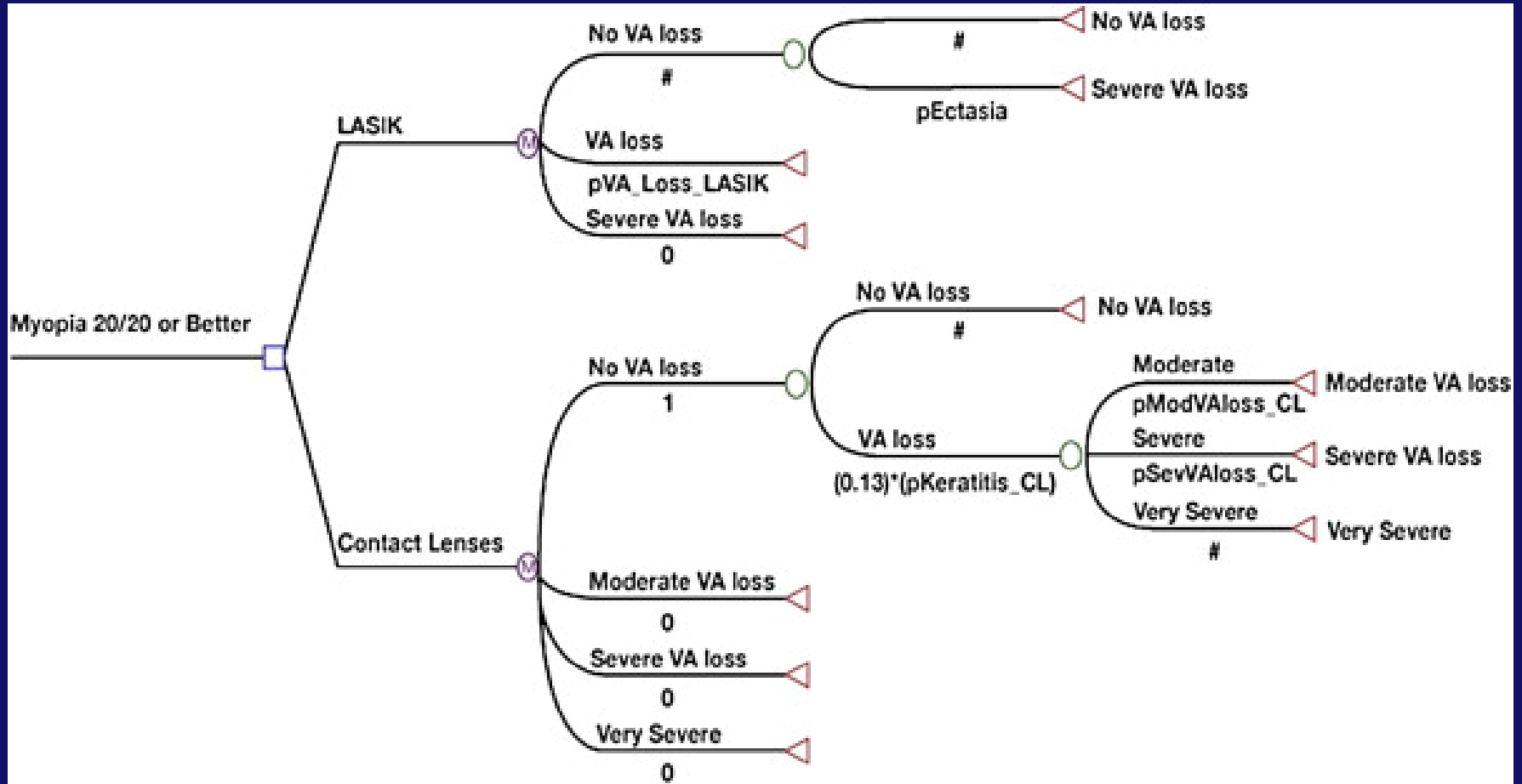


- USA in 2005
 - 8 miljoen LASIK
 - 36 miljoen contactlens dragers
- Europa: 600.000 ingrepen (0,11 – 046% van de populatie)
- Nederland: 25.000 ingrepen (0,09%)

Vraagstelling:

*Is lifetime risico op visus verlies bij
contact lens dragers hoger dan bij
refractie chirurgie?*

Markov model



1. Myopie: ≤ 6 D
2. Lasik vs contact lens
3. LASIK
 1. Geen visus verlies
 2. Vroeg postop visus verlies
 3. Laat postop visus verlies (ectasie)
4. Contact lenses
 1. Geen visus verlies
 2. Matig visus verlies
 3. Ernstig visus verlies
 4. Zeer ernstig visus verlies

Alle patienten



Tijd (risico op infectieuze keratitis / jaar)

- LASIK patienten (risico op visus daling)
 - Veel kleine studies
 - Basis grootste follow-up studie
 - Hammond et al., Refractive surgery in the United states Army, 2003-2004; Ophthalmology 2005;112:184-190
- Contact lens patienten
 - Cheng et al., Incidence of contactlens associated microbial keratitis and its morbidity. Lancet 1999;354:181-185

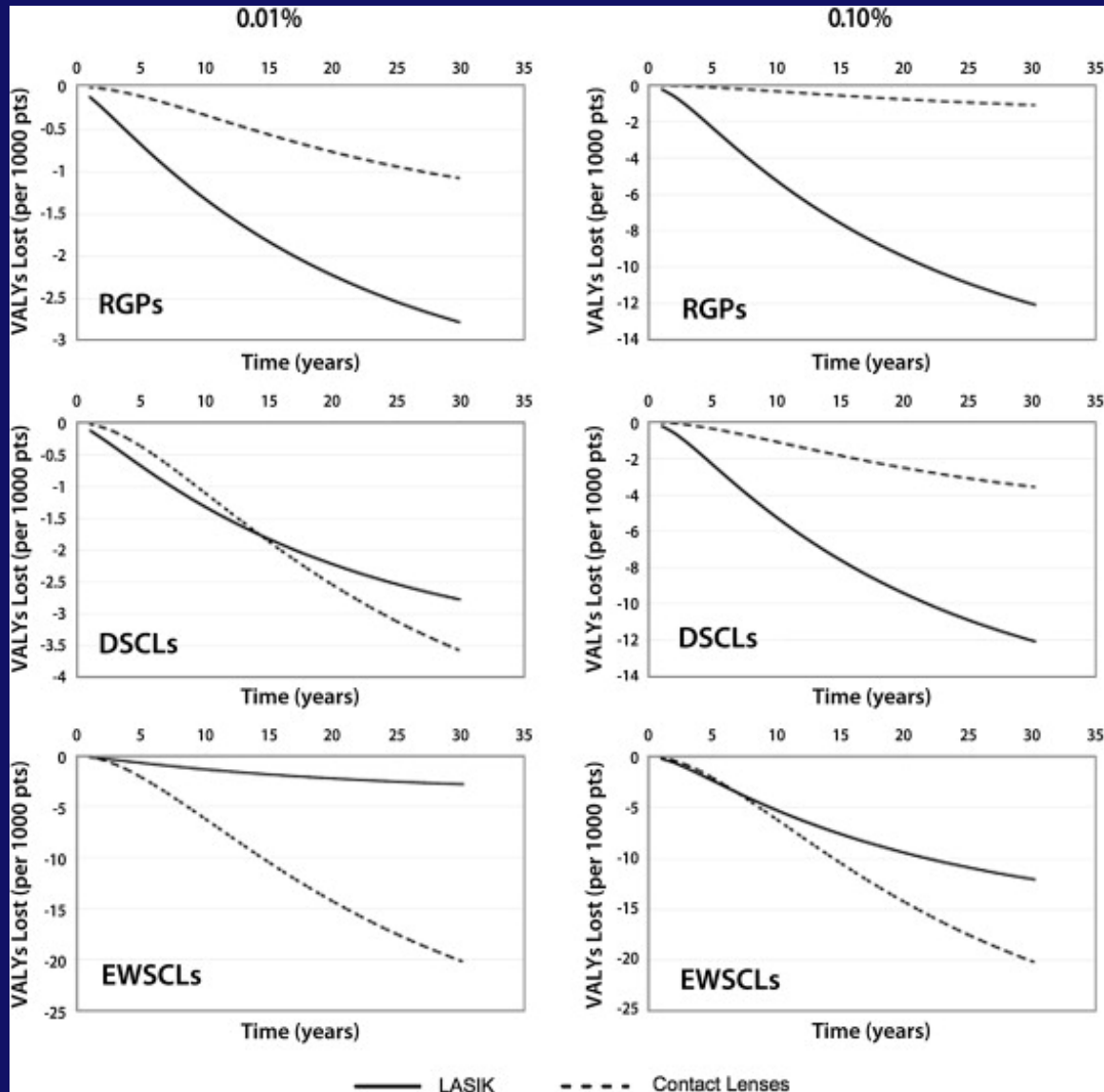
Visual State	Published Definition	Definition in Present Study (Snellen VA)	LogMAR Equivalent VA*
Contact lenses			
Moderate VA loss	20/30–20/60	20/30	0.18
Severe VA loss	20/70 or worse	20/70	0.54
Very severe VA loss	Light perception	20/800	1.60
LASIK			
Vision loss	More than 1 line of VA lost (no patient worse than 20/40)		20/30 0.18
Ectasia	Pre-management 20/108 Post-management 20/37		20/70 0.54

Probability of vision loss

Variable Description	Value (%)	Range* (%)		
		Low	High	
Early VA loss from LASIK	0.06	0.0	1	
Ectasia from LASIK	0.02	0.0	0.2	
Contact lens–related keratitis(/yr)	0.035	0.01	0.2	Type contact lens
Any VA loss from keratitis	13	NA	NA	
Moderate VA Loss	58.3	20.8	91.7	
Severe VA Loss	33.3	0.0	70.8	
Very severe VA Loss	8.3	0.0	16.7	
Discount rate	5	0.0	7	

30 cycles (jaren)

Visual acuity-adjusted life years



LASIK vs contact lenses?

- Populations
 - Refractive surgery in United states army; 2000-2003
 - Incidence contactlens-associated microbial keratitis (1999)

- Conclusions:
 - Harde gas-permeabele lenzen veiliger dan LASIK
 - LASIK is veiliger dan zachte lenzen bij laag risico op ectasie
 - LASIK is veiliger dan extended wear contactlenzen.

LASIK vs contact lenses?

- Populations
 - Refractive surgery in United states army; 2000-2003
 - Incidence contactlens-associated microbial keratitis (1999)

- Conclusions:
 - Harde gas-permeabele lenzen veiliger dan LASIK
 - LASIK is veiliger dan zachte lenzen en extended wear contactlenzen.

1. Onder de huidige geldende richtlijnen is refractiechirurgie veilig en geeft stabiele resultaten
2. Harde contact lenzen meest veilig
3. Nieuwe studies blijven noodzakelijk om de nieuwste technologie te evalueren.



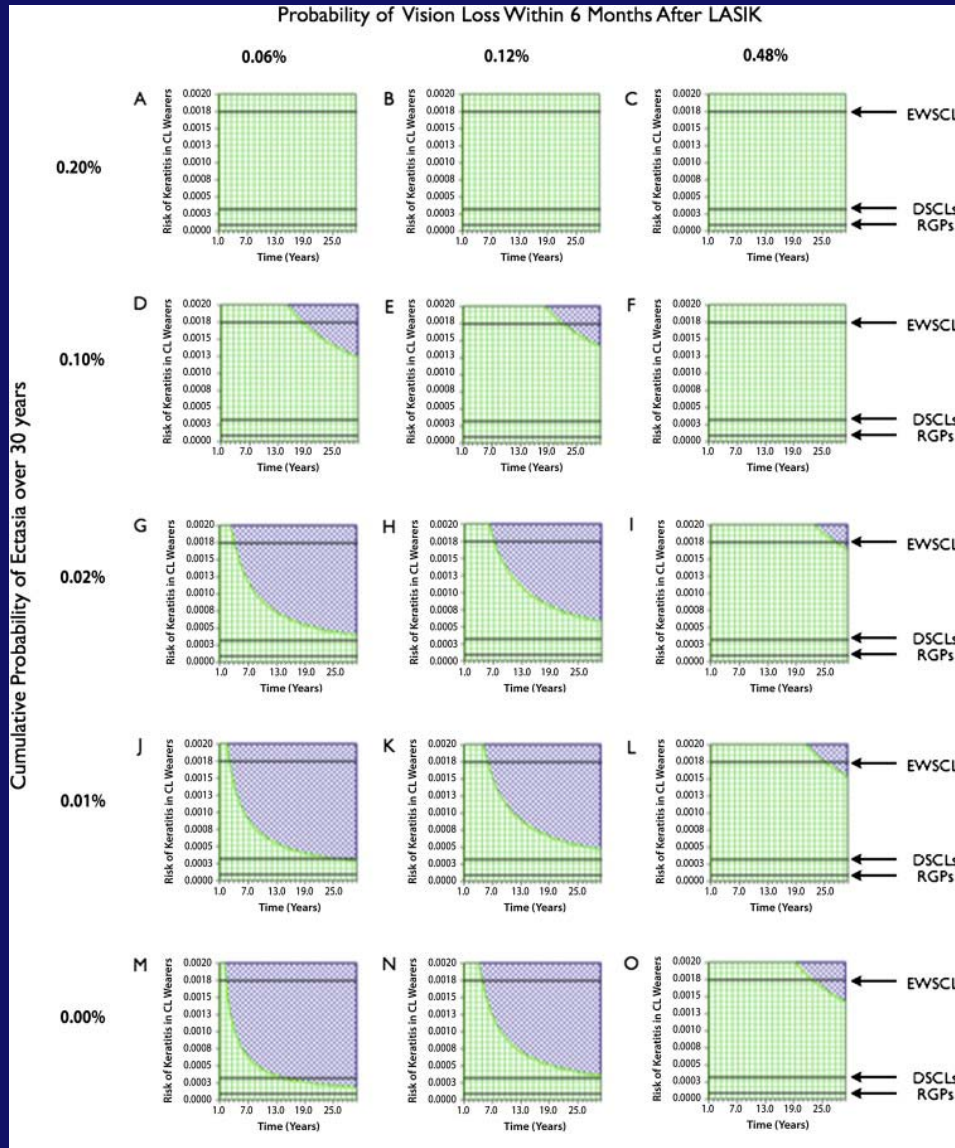
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Dank voor uw aandacht

g.p.m.luyten@lumc.nl



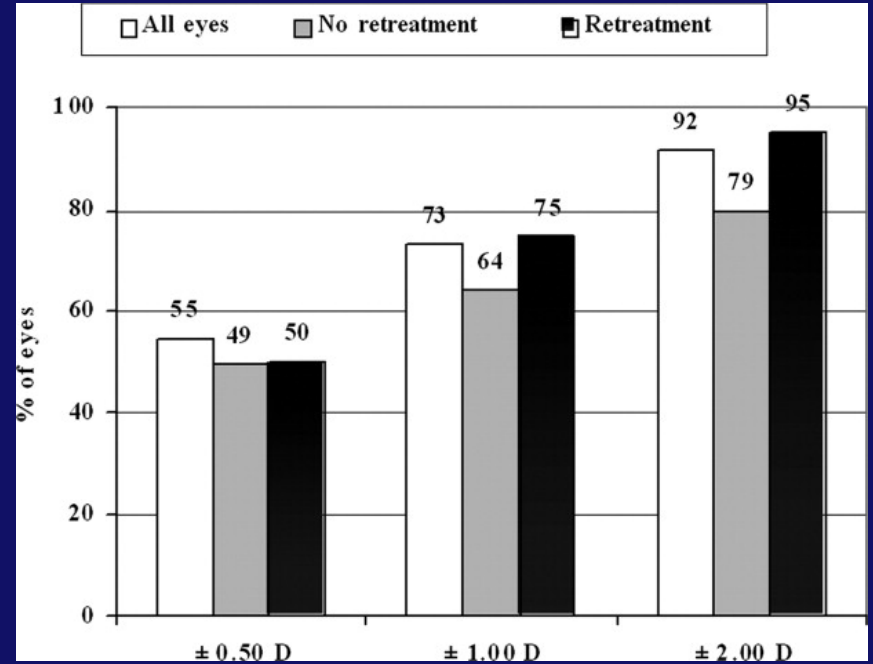
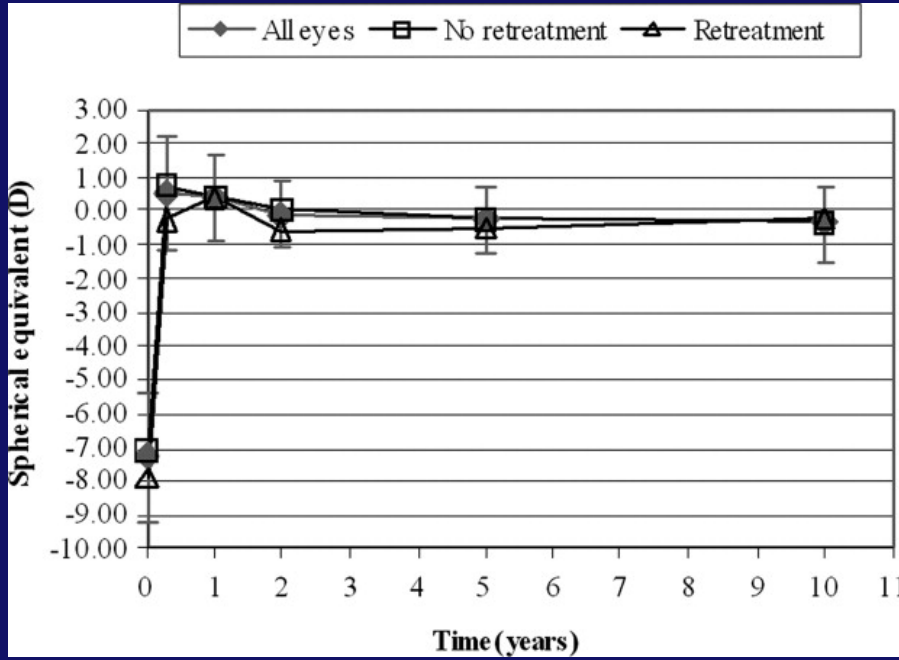
Sensitivity early VA loss after LASIK and late by ectasia



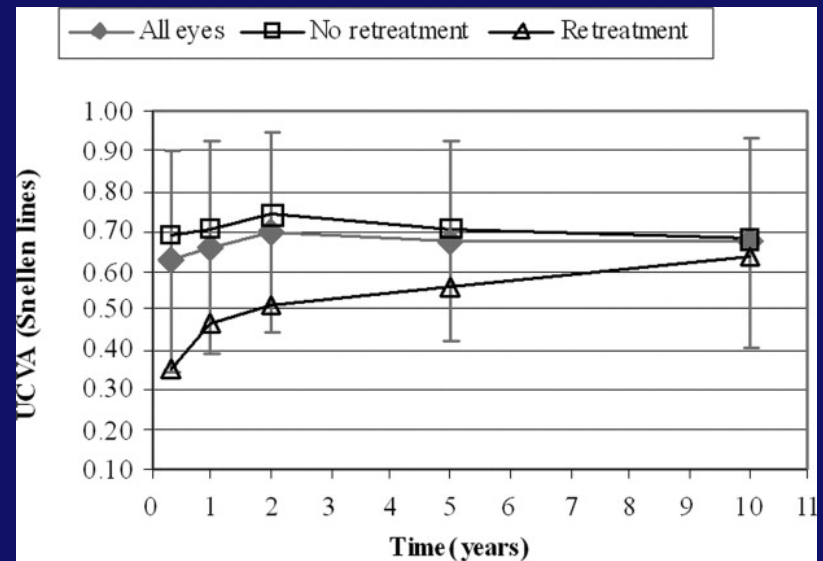
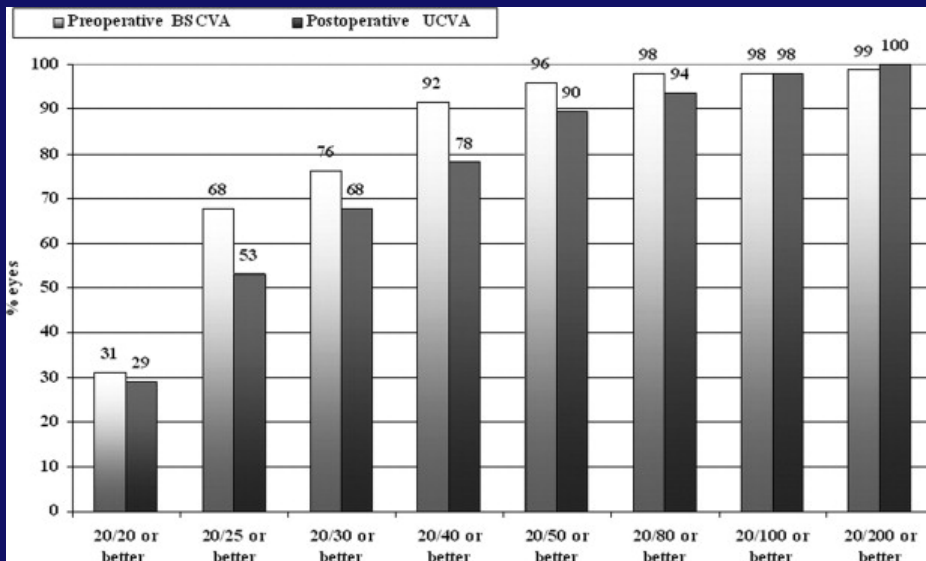
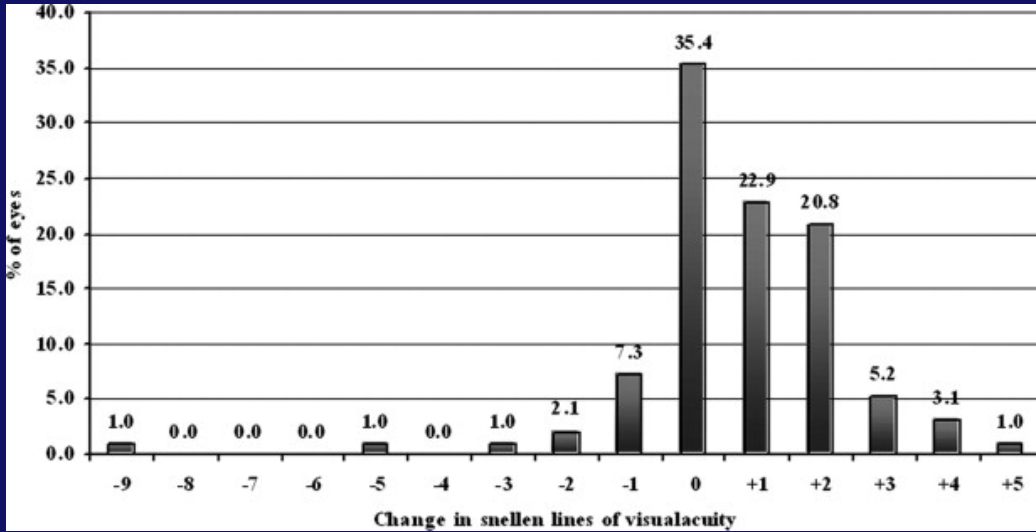
- **Ten-year follow-up of laser in situ keratomileusis for myopia of up to -10 diopters.**
- Alió JL, Muftuoglu O, Ortiz D, Pérez-Santonja JJ, Artola A, Ayala MJ, Garcia MJ, de Luna GC
- Am J Ophthalmol 2008;145:46-54

Characteristics	Data
Mean age \pm SD (range), yrs	33.2 \pm 9.9 (17 to 57)
Gender	
Male	33
Female	36
Sphere \pm SD (range), D	-6.53 \pm 1.82 (-1.00 to -9.50)
Cylinder \pm SD (range), D	-1.44 \pm 1.07 (0 to -5.00)
SE \pm SD (range), D	-7.27 \pm 1.94 (-1.63 to -9.88)

Alio et al., 2008, LASIK



Alio et al., 2008, LASIK

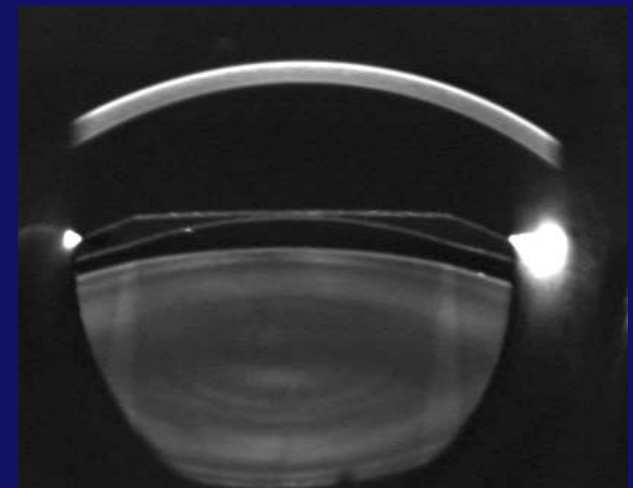


Complications	No. of Eyes (%)				
	3 mth	1 yr	2 yrs	5 yrs	10 yrs
Surgical complications					
Epithelial ingrowth	0 (0)	2 (2.1)	3 (3.1)	3 (3.1)	3 (3.1)
Peripheral melting	0 (0)	1 (1.0)	2 (2.1)	2 (2.1)	2 (2.1)
Punctate keratopathy	5 (5.2)	4 (4.1)	3 (3.1)	2 (1.3)	0 (0)
Flap stria	1 (1.0)	2 (2.1)	2 (2.1)	2 (2.6)	2 (2.1)
Corneal ulcer	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)
Complications related with myopia					
Cataract	0 (0)	1 (1.0)	4 (4.1)	5 (5.2)	
Myopic maculopathy	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	3 (3.1)
RD or RD surgery	0 (0)	0 (0)	1 (1.0)	1 (1.0)	
CNV	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.0)

- Photorefractive keratectomy (PRK) versus Laser-assisted in-situ keratomileusis (LASIK) for myopia
- Alex J, Shortt, Bruce DS Allan
- Conclusion: LASIK gives a faster visual recovery than PRK but the effectiveness of these two procedures is comparable. Further trials using contemporary techniques are required to determine whether LASIK and PRK are equally safe

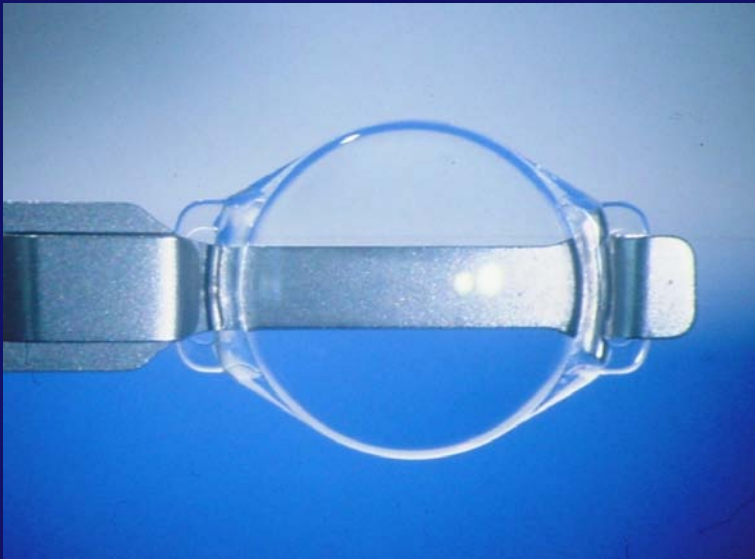
Kunstlens implantatie

- Iris gefixeerde lenzen
 - Artisan lens
 - Artiflex lens (foldabel)
- Achterste oogkamer lenzen
 - ICL
- Kamerhoekgesteunde lenzen
 - Nuvita

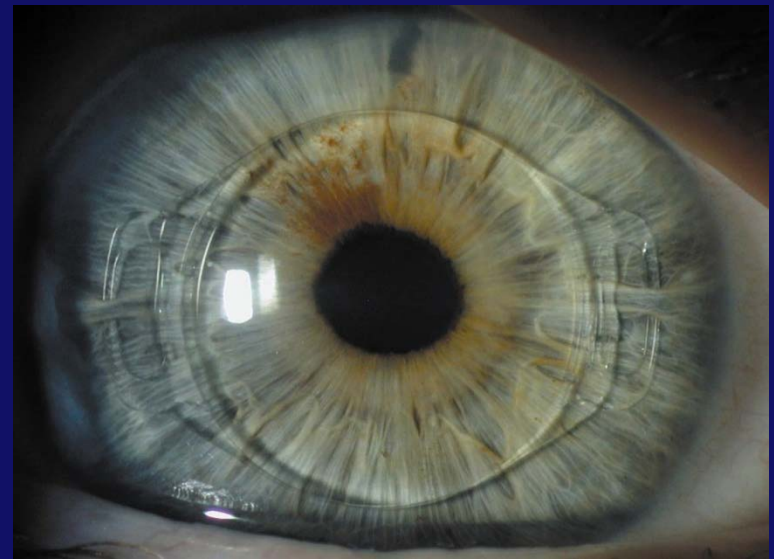


Verschillende modellen voorste en achterste oogkamer lenzen. Hier in Nederland wordt de voorkeur gegeven aan niet-kamerhoek gesteunde lenzen. Waarschijnlijk wordt er in de toekomst meer achterste oogkamerlenzen gebruikt.

Iris gefixeerde lenzen



Artiflex



Na implantatie

4. *Behandeling*

- **Kunstlensimplantatie**
- Poliklinisch, lokale verdoving
- Steriel afdekken, ooglidspreider
- Incisiegrootte afhankelijk van lenstype (3.2, 5 of 6 mm)
- Inbrengen van IOL in VOK en fixeren aan iris
- Hechten wond
- Oogverband

- **Lasik**

- Eerste paar uur branderig, tranend
- Visusherstel op behandeldag, minimaal 80%
- Geen significante napijn
- Visus stabiliseert na 6 tot 12 weken
- Eerste week antibiotica en steroid gtt, daarna alleen kunsttranen

- **Lasek**

- Eerste dag weinig last met goed zicht
- De 2 tot 4 dag kan pijnlijk zijn zolang het epitheel open is
- Visus daalt eerste dagen, herstelt en stabiliseert na 6 tot 12 weken
- Eerste week antibiotica en steroid gtt, NSAID, pijnstillers de eerste dagen, steroïden afbouwen in 2 maanden

- **Lensimplantaties**
- Meestal geen napijn
- Visusherstel afhankelijk van wondgrootte, 50 tot 80% eerste dag
- Visus stabiliseert na 6 tot 12 weken
- Postoperatief antibiotica, steroid en NSAID gtt 4 weken

5. Complicaties na laseren

- Lasik

- Blijvende droge ogen
- Glare en halo's
- Diffuse Lamellaire Keratitis (graad I t/m III)
- Striae
- Epitheelingroei
- Infectieuze keratitis
- Gedecentreerde behandeling
- Ectasie van de cornea

- Lasek / PRK

- Blijvende droge ogen
- Glare en halo's
- Keratitis
- Gedecentreerde behandeling
- Subeptheliale haze van mild tot ernstig
- Ectasie van de cornea