European Contact Lens Society of Ophthalmologists ECLSO





Course de Base en Contactologie I – IV Basiskurs in Kontaktologie I - IV

Dr. med. Albert Franceschetti, Genève Michael Bärtschi, M.Sc.Optom. et M.Med.Educ., Bern

Optics and Contact Lenses

What should I know about optics and physiological optics when I fit contact lenses?

Visual acuity = 1.0

• US notation 20/20 (20 feet)

• Metric notation 6/6 (6 meters)

Decimal 10/10 (Monoyer)

Logarythmic

Distance spectacles-eye

- The position of the contact lens is different in relation to the eye. This is obviously the first criterion to take into consideration.
- According to the power of the spectacles, the difference Δ between the power of spectacle lenses and the contact lenses will be more or less important.

Formula

- D_L power of the glasses (supposed perfect correction)
- D_{CL} power of the contact lens (lens + tear meniscus)
- d distance between the lens and the contact lens
- Δ difference between the power D_{CL} and D_L

Δ

- $\Delta = D_{CL} D_{L}$ is always positive
- $\Delta = D_{CL} D_{L}$ increases if the distance eye-glasses increases
- The value d can be superior to 12mm if one uses trial lenses or refractor.

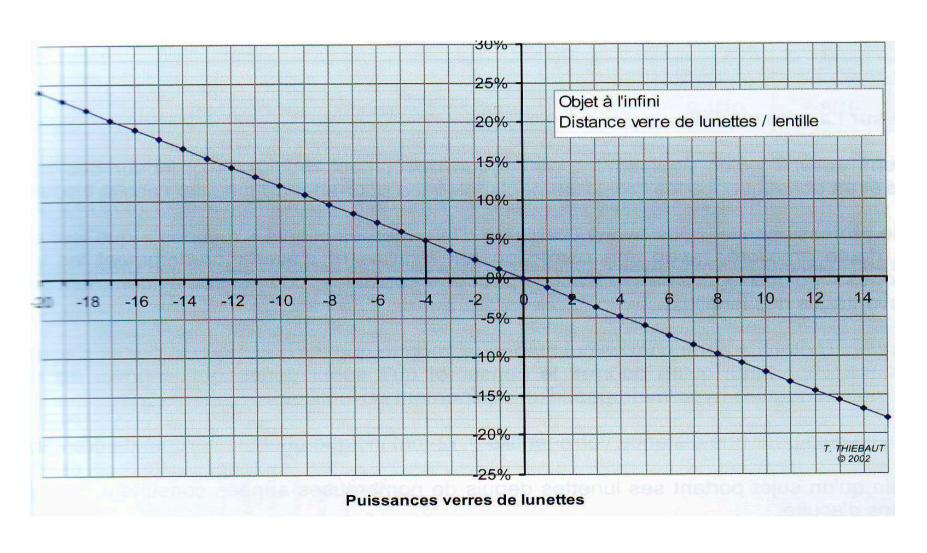
Variation of powers between the two systems (contact lenses and spectacle)

Distance eye- glasses	D_L	-20	-15	-10	-8	-5	+4	+10
	D _{CL}	-16.13	-12.71	-8.93	-7.30	-4.72	+4.20	+11.36
d=12m m	Δ	3.87	2.29	1.07	0.70	0.28	0.20	1.36
	D _{CL}	-15.38	-12.24	-8.70	-7.14	-4.65	+4.26	+11.76
D=15 mm	Δ	4.62	2.76	1.30	0.86	0.35	0.26	1.76

Magnification

- The distance eye-spectacles versus eye contact lens being different, the magnification of the retinal image will be different.
- This in turn will induce changes in the visual acuity.
- The relationship is linear.

Variation in % of the retinal image size as a function of the power of the glasses



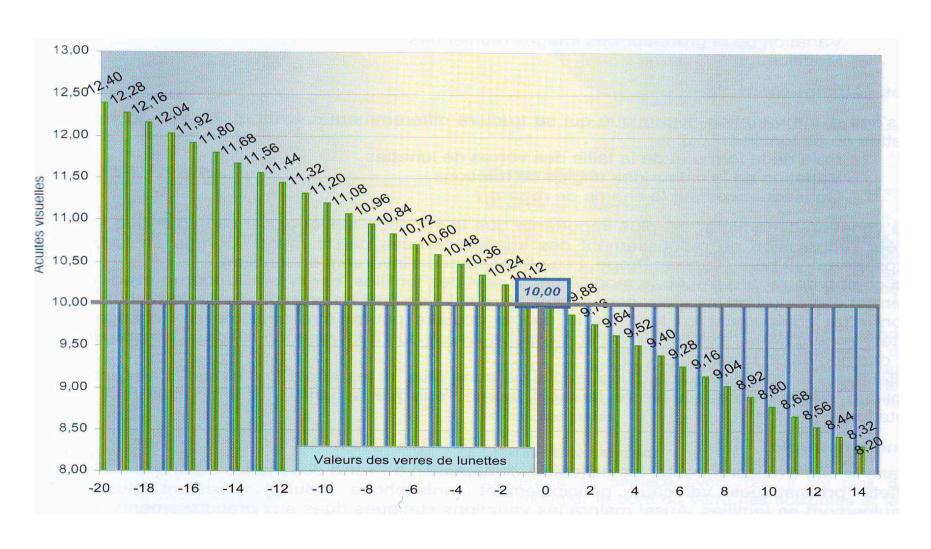
Visual acuity

 The myop will have a higher visual acuity with contact lenses, while the hyperop will have to accept a moderate loss in visual acuity.

Visual acuity

Spectacle power	-20	-15	-10	-5	+5	+10	+15
Retinal image ratio	1.24	1.18	1.12	1.06	0.94	0.88	0.82
VA Glasses	10/10	10/10	10/10	10/10	10/10	10/10	10/10
VA Contact lens	12.4/10	11.8/10	11.2/10	10.6/10	9.4/10	8.8/10	8.2/10

Comparison of the visual acuity with lenses with the 10/10 of glasses



Visual field

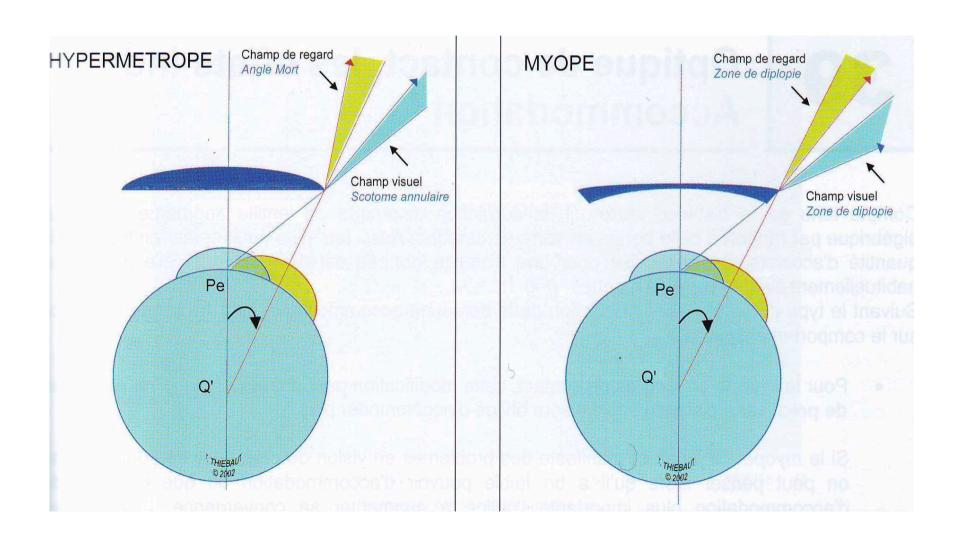
With spectacles :

the hyperop has a zone where he does not see (annular scotoma)

the myop has a zone of double vision in his field of vision

With contacts : none of the above occurs.

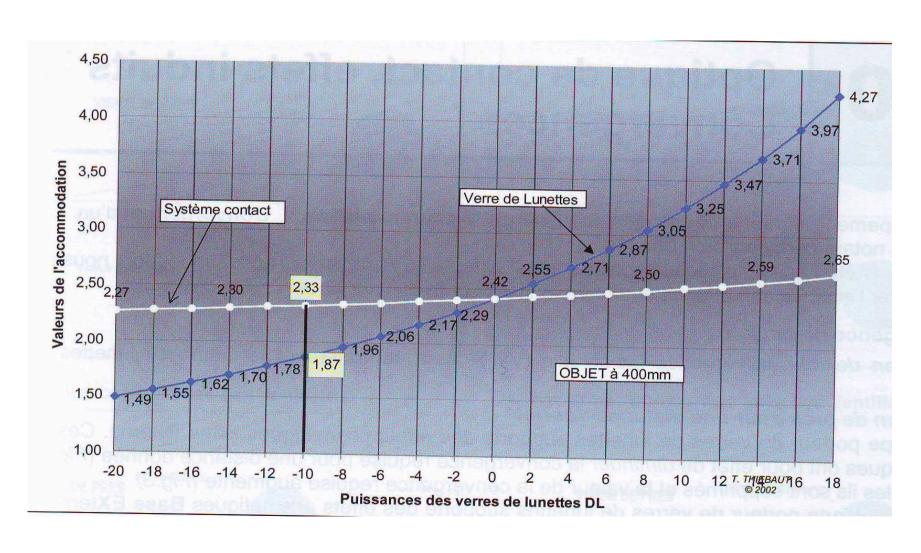
Visual field with spectacles



Accommodation and Contact Lens

- Because of the distance eye-lens, the accommodative requirement changes between contact lenses and glasses.
- A myop may have difficulty for near as the accommodative requirement will be more with contact lenses. This may give a problem in patients in their forties. They will require near vision correction much earlier with contacts than with glasses.
- For hyperops, there will be a reduced accommodative requirement. This may be come interesting in patients in their forties as it may allow to read better and prolong the time without near vision glasses.

Glasses/contact lenses: value of accommodation for an object at 400 m.

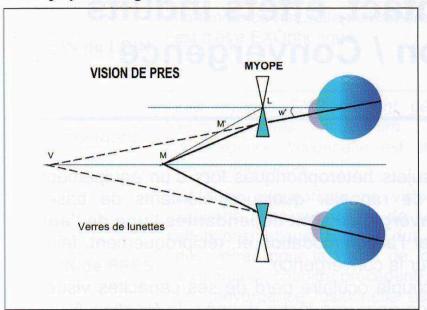


Convergence

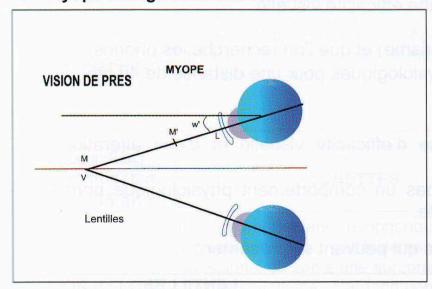
- For distance, the fusional vergence will be about the same with spectacles or contacts.
- For near, the myop has a base-in effect of the spectacles while the hyperop has a base-out effect of his spectacles.
- This is not the case with contacts

Difference between glasses and contacts for a myop

1. Myope corrigé avec des verres de lunettes

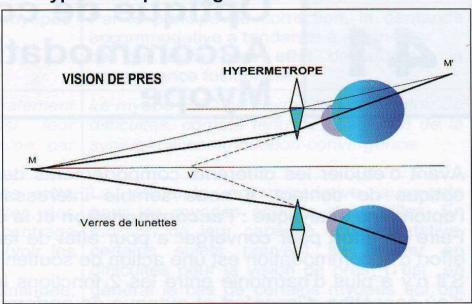


3. Myope corrigé avec des lentilles

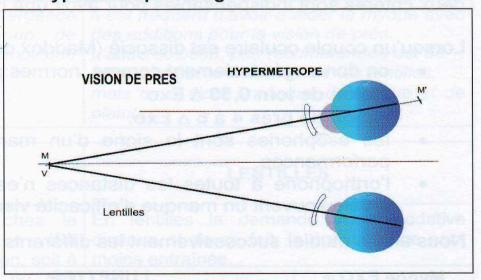


Difference between glasses and contacts for a hyperop

2. Hypermétrope corrigé avec des lunettes

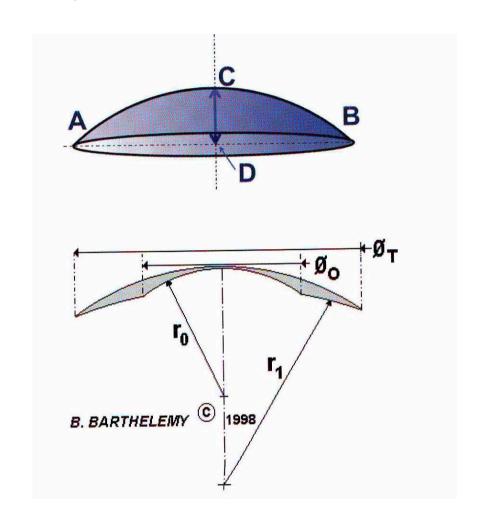


4. Hypermétrope corrigé avec des lentilles

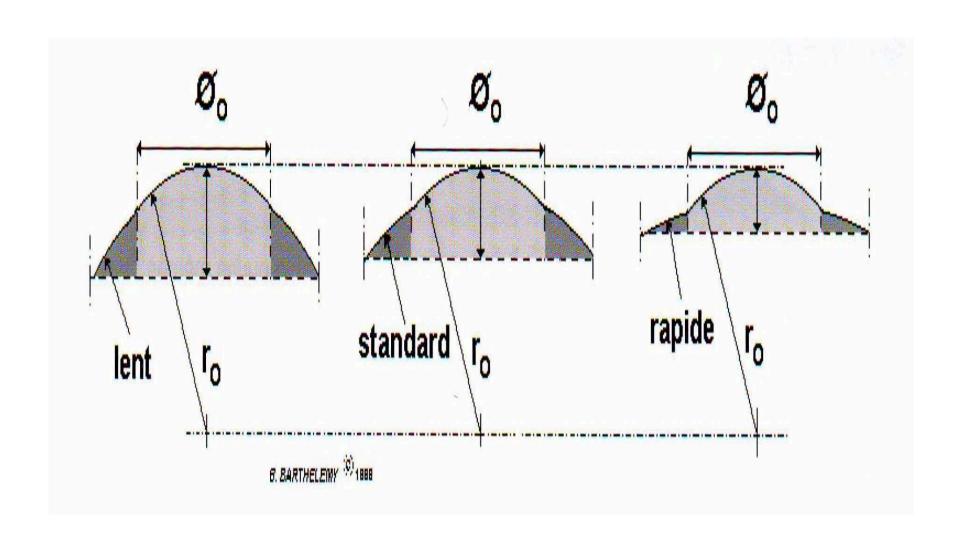


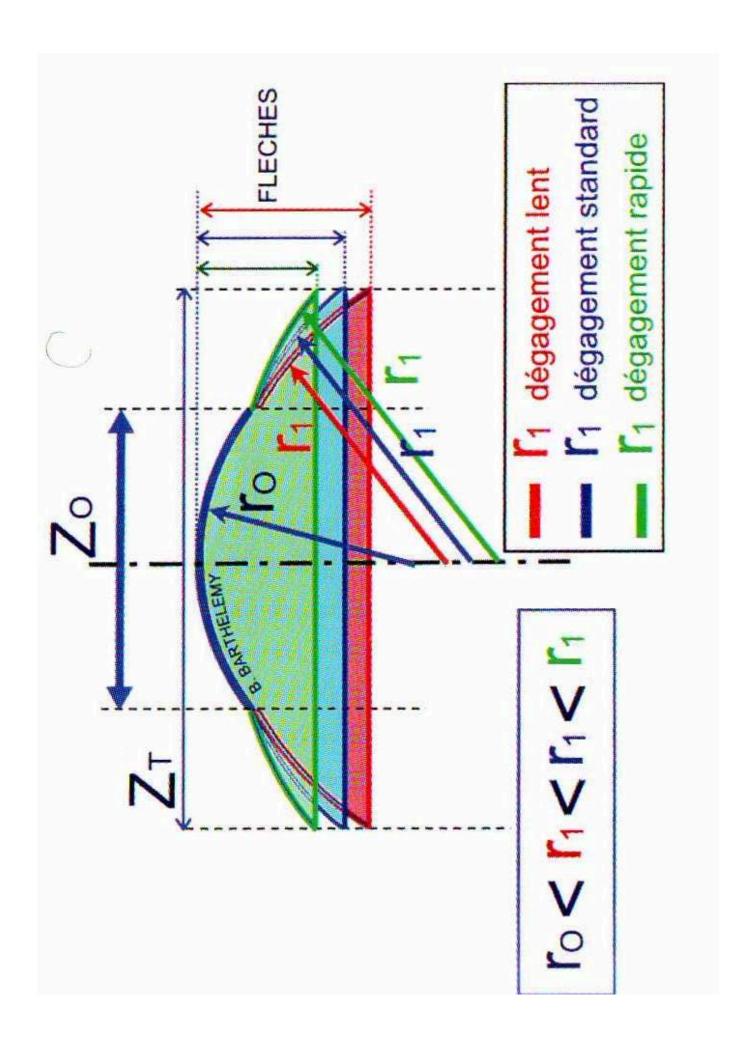
Rigid lens, now rigid gas-permeable lens (RGP)

- CD elevation
- R₀ radius
- \mathcal{O}_T total diameter
- Ø₀ optical zone



Bevel

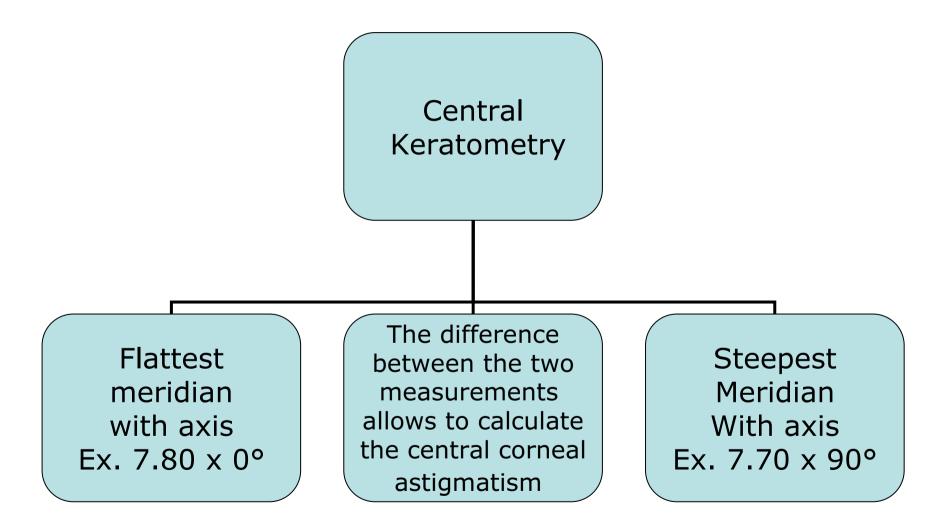




Keratometry

- Central: 2 measures: flattest with the axis steepest with the axis
- Peripheral (25°): 4 measures: flattest superior with axis flattest inferior with axis steepest superior with axis steepest inferior with axis

Central Keratometry



4 measures of the peripheral keratometry

Peripheral Keratometry at 25°

Superior radius of the flattest meridian with axis Ex.: 7.96 x 90° Inferior radius of the flattest meridian with axis Ex.: 7.94 x 270° Superior radius of the steepest meridian with axis Ex.: 7.70 x 90°

the steepest meridian with axis

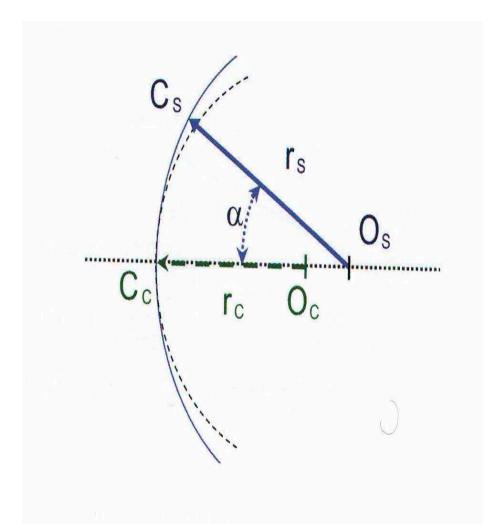
Inferior radius of

Ex.: 7.70 x 270°

Excentricity (e)

- It is the most common used index for asphericity of a surface.
- It expresses the peripheral flattening of the cornea (difference between the peripheral radius and the one measured with keratometry in the center)
- If e = 0 it is a circle
- If e = 1 it is a parabole
- If 0 ← e ← 1 it is an ellipse
- Negative e is used when periphery has a lower radius than center (ex. after laser surgery)

Eccentricity



Les mesures :

r_c: rayon apical (central)

r_s: rayon périphérique

 α : angle de la mesure périphérique

$$e = \sqrt{\frac{\left| r_s^2 - r_c^2 \right|}{r_s^2 \times \sin^2 \alpha}}$$

Mean eccentricity (as in automatic refractometer)

Example R.E.

```
Central keratometry: 7.90 at 0° and 7.70 at 90°. Average = 7.80
```

Peripheral at 25°:

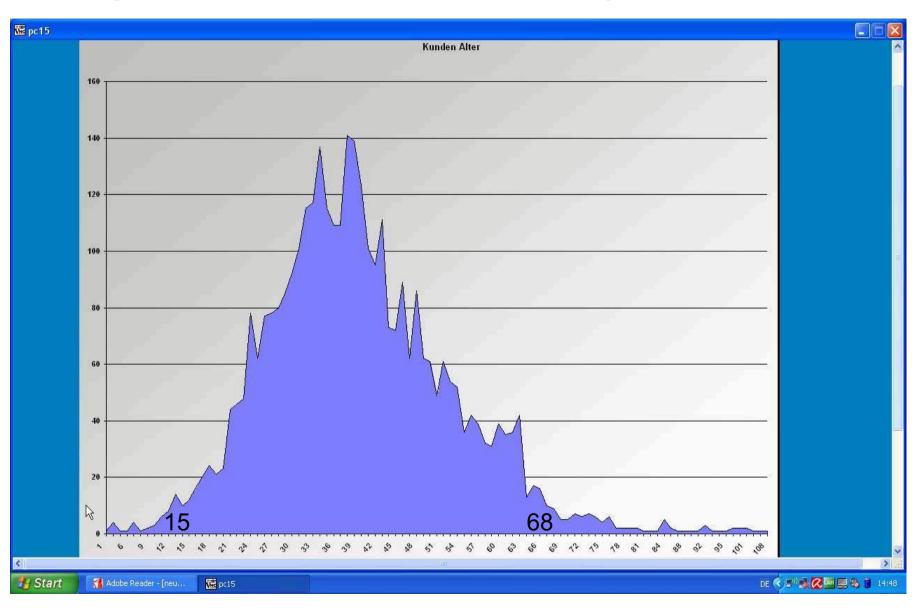
Horizontal meridian: nasal 8.05 at 0°, temporal 8.01 at 180°

Vertical meridian: superior 7.96 at 90°, inferior 7.94 at 270°.

Mean eccentricity : =
$$(8.05+8.01+7.96+7.94)/4 \approx 8$$

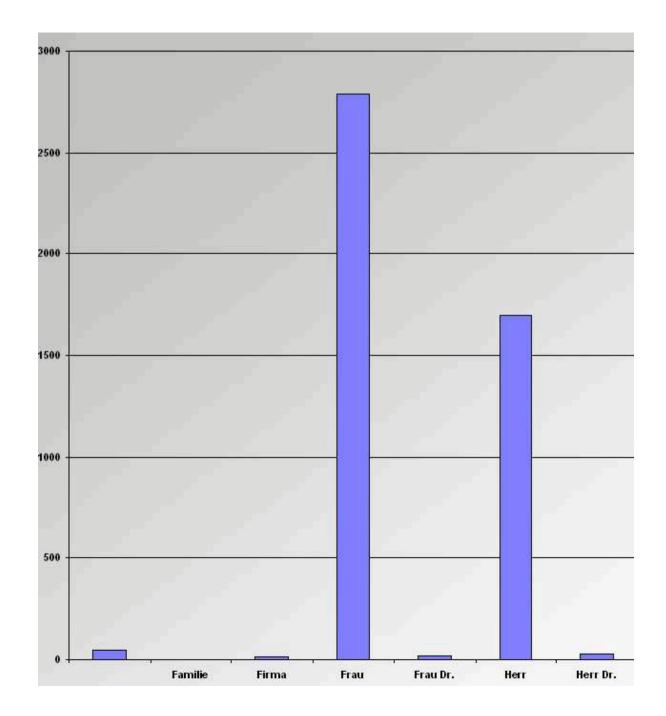
8.00 - 7.80 = flattening 0.20 e = 0.53

Typical CL wearers (25 to 60 yo)



Typical CL wearers

60% female vs. 40 male



Overview:

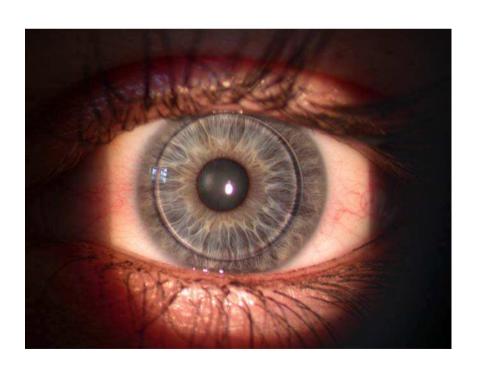
Hard = PMMA

Flexible = CAB, Si-Fl-MMA

Soft = Hydrogel, Si-Hydrogel

Hard = PMMA
Poly-Methylen-Methacrylat since 1930's - 1970
Extreme hard, stable, resistent, no oxygen

transmissibility (!)



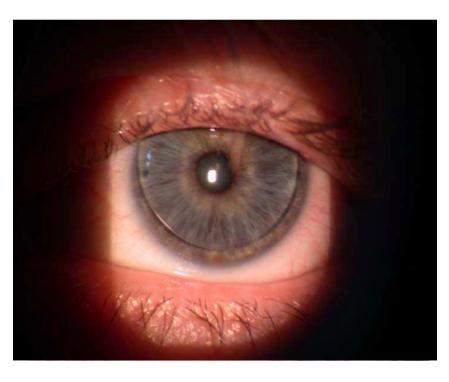
- Mostly small over all diameters of 8.5 to 9.3 mm.
- Single or bi-curve design.
- Daily wear (DW) 8-12 hours/day.
- Exchange every 10-25 years.
- Easy to clean.

Flexible = CAB Cellulose-Acetat-Butyrat since 1960's Dk 8



- Mostly small over all diameters of 8.8 to 9.9 mm.
- All powers.
- Bi- or multi-curve design.
- Daily wear (DW) 8-14 hours/day.
- Exchange every 3 5 years.
- Easy to clean, Protein deposits.

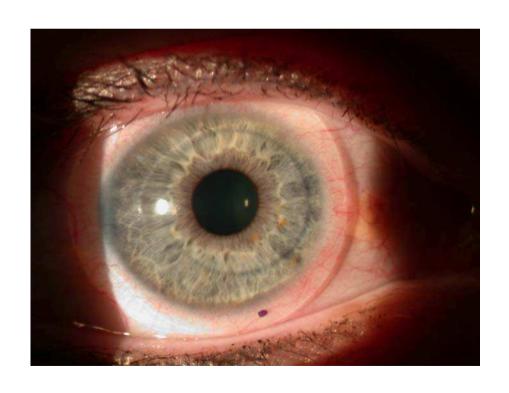
Flexible = Si-Fl-MMA
Silikon-Fluor-Methylen-Methacrylat since 1970's Dk
12 - 175



- All diameters between 8.8 to 11.5 mm.
- All powers.
- Multi- or aspheric curve design.
- Daily and extended wear (DW / EW) 12 - 24 hours/day.
- Exchange every 2 3 years.
- More difficult to clean, protein and lipid deposits.

Soft = Hydrogel

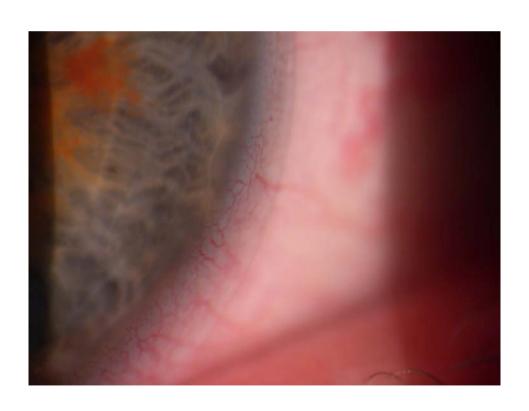
Poly-Hydroxy-Ethylen-Methacrylat (+) since 1963 (water content 38% -86%, Dk 8 - 45)



- All diameters between 12.0 to 18.0 mm.
- All powers.
- Single, multi- or aspheric curve designs.
- Daily (DW) 6 12 hours/day.
- Exchange daily to 2 years.
- disposable and conventional
- more protein deposits
- limbal redness

Soft = Hydrogel

Poly-Hydroxy-Ethylen-Methacrylat (+) seit 1963 (water content 38% -86%, Dk 8 - 45)

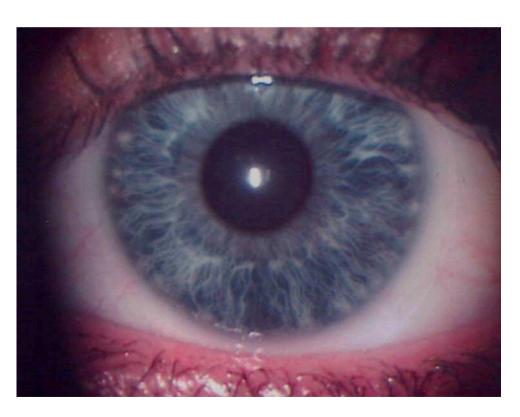


- All diameters between 12.0 to 18.0 mm.
- All powers.
- Single, multi- or aspheric curve designs.
- Daily (DW) 6 12 hours/day.
- Exchange daily to 2 years.
- disposable and conventional
- more protein deposits
- limbal redness

Materials

Soft = Silicone-Hydrogel

Silikon-Poly-Hydroxy-Ethylen-Methacrylat seit 1999 (water content 24% - 50%, Dk 55 - 175)



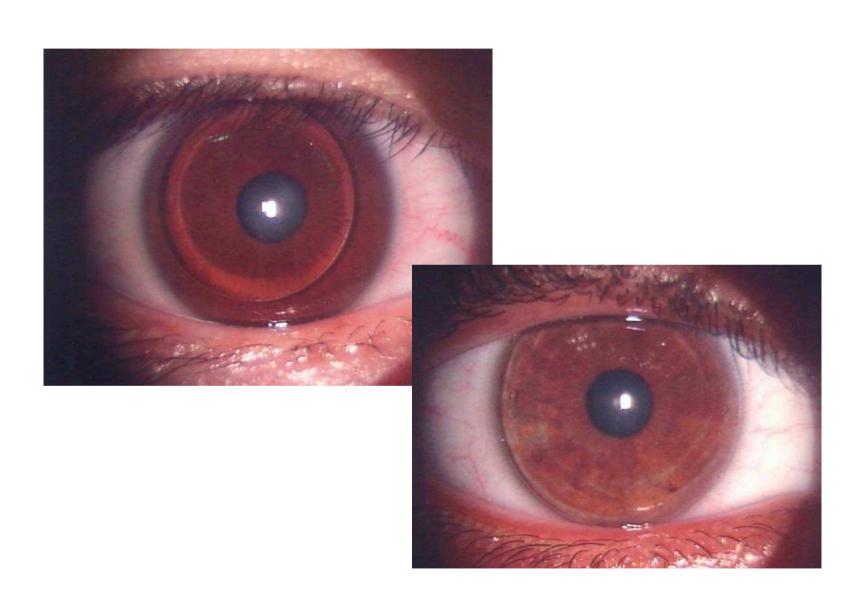
- All diameters between 12.0 to 18.0 mm
- All powers.
- Single, multi- or aspheric curve designs.
- Daily and extended wear (DW/EW) 12 -24 hours/day.
- Exchange weekly to 2 years.
- disposable and conventional
- more lipid deposits
- excellent therapeutic use
- "white eyes"

Pearls: Materials

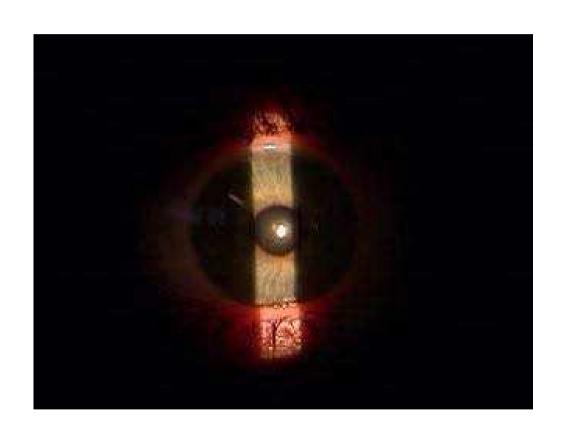
Hard and flexible materials:

- \emptyset 8,5 11,5 mm no water up-take
- + low to very high oxygen transmissibility
- + good tear exchange
- + long life
- + less deposits, less lens care
- + very good optical properties even for difficult or complex powers
- + Daily wear to extended wear
- + Therapeutic use possible
- longer adaptation time
- Higher risk of lost lenses
- Problems with dust and pollen

Hard and flexible lenses

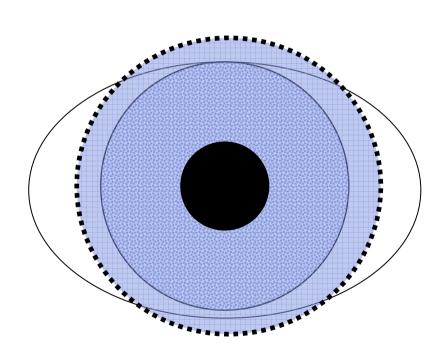


Hard and flexible lenses



Pearls: Materials

Soft and Silicone-hydrogel lenses:



- Low to very high oxygen transmissibility
- Less tear exchange
- Short life
- More deposits, more lens care
- Higher costs
- + short adaptation time
- + low risk of lost lenses
- + very little dust and pollen problems
- + occasional wear to extended wear
- + most powers possible
- + therapeutic use

Soft and Silicone-Hydrogel lenses





Anpasstabelle Kinder

Alter	KL Radien	n.E.
1. Monat	6.80 - 7.00 mm	0.0 - 0.3
6. Monat	7.00 - 7.20 mm	0.0 - 0.3
1 Jahr	7.20 - 7.40 mm	0.3 - 0.4
2 Jahre	7.40 - 7.60 mm	0.3 - 0.4
3 Jahre	7.60 - 7.80 mm	0.3 - 0.4
5 Jahre	7.60 - 8.00 mm	0.4 - 0.5
8 Jahre	7.60 - 8.00 mm	0.4 - 0.6





Anpasstabelle (Aphakie)

Alter	Refrawerte	KL Radien	Add.Nähe
1. Monat	+ 35 dpt	6.80 - 7.00 mm	+ 6.00 dpt
6. Monat	+ 30 dpt	7.00 - 7.20 mm	+ 5.00 dpt
1 Jahr	+ 25 dpt	7.20 - 7.40 mm	+ 4.00 dpt
2 Jahre	+ 23 dpt	7.40 - 7.60 mm	+ 3.75 dpt
3 Jahre	+ 21 dpt	7.60 - 7.80 mm	+ 3.50 dpt
5 Jahre	+ 20 dpt	7.60 - 8.00 mm	+ 3.25 dpt
8 Jahre	+ 18.5 dpt	7.60 - 8.00 mm	+ 3.00 dpt Text

Tabelle ungültig bei Mikrophthalmus oder Megalokornea!



Disposable system:

One-Day

1 - 4 weeks

Conventional system:
Several months to several years

Daily wear

VS.

extended wear

VS.

constant wear?

Daily wear:

From a few hours per month up to 12 hours per day

- One-Day lenses (soft CL)
- low Dk 8 45 (hard/flexible and soft CL)

Extended wear:

From 12 hours up to 16 hours per day

Middle - high Dk 50 - 86

(hard/flexible and Si-Hydrogel CL)

Constant wear:

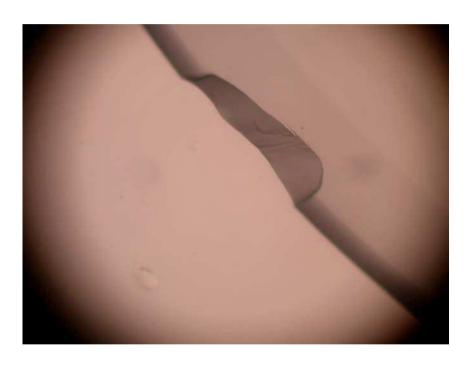
From 18 hours per day up to 24 hours per day

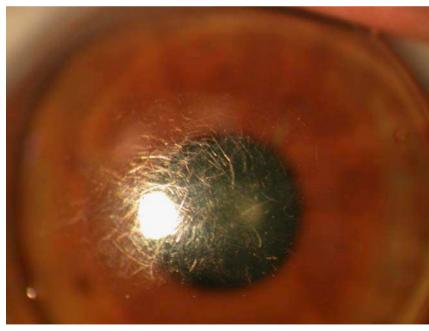
Extreme high Dk 87 – 175 (hard/flexible and Si-Hydrogel CL)

Pearls: Wearing Modality

- Multiple forms of wearing modality exist.
- Every modality has his materials and fitting technique.
- Wearing modality varies over time.
- Patients do not always follow the instructions.
- Read articles about risks VERY carefully !

Hygiene and lens care

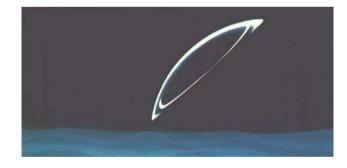




CARACTERISTICS

ABSOLUTELY NECESSARY:

- PRESERVE THE OCULAR PHYSIOLOGY
- RESPECT THE LENSES



Why do we have to use products to take care of our lenses?

- Biocompatibility, cleanliness, wettability and transparency are necessary for a good tolerance of the contact lenses.
- The lacrimal fluids in which lenses are soaked produce deposits and manipulations are causes of contamination.
- Smears and germs interact favoring each other:
 - Deposits are an ideal nutritional substrate for germs
 - Germs secret a biofilm which is adherent to the lens surface.

Three options are available for the contact lens specialist

- Daily disposable
- Multiple use with a lens care system chosen in agreement with the renewal rate and type of the lens. The choice must be understood by the patient, as its observance will determine the safety of wear.
- Permanent wear

Purpose of the lens care

- Prevent or eliminate the deposits by a cleaning
- Eliminate the germs by decontamination

Common properties of the care solutions which have to enter in contact with the eye surface

- Non toxic : a toxic care solution must be neutralized
- Sterile: after opening of the container, the prevention of contamination is obtained either by adding a conservative agent or using a unidose system (rinsing solutions) or an aerosol (rinsing solutions)
- Isotonic
- Buffered at a neutral pH

Etiology and consequences of the deposits on the contact lens

- The deposits come mainly from the ocular media
 - mostly from the tears
- The environment
 - Pollution
 - Cosmetics
 - Eye drops …..

The rate of formation of deposits varies greatly from one patient to the other

- Quality of tears, ocular dryness...
- Lenses: age, type of material soft or rigid -, ionic or non-ionic, hydrophility ...
- Environment : air condition, pollution, usage of cosmetics

One has to take these factors into consideration when choosing the lens care system and the frequency of renewal of the lens

Contamination of the lenses

- The infections can be of following origin :
 - Bacterial
 - Fungal
 - Viral
 - Amoeba
 - Non conventional transmissible agents (NCTA)

Bacterial contamination (1)

- Studies show that there an inversion of bacterial flora in the majority of contact lens wearers. The flora consists of a majority of gram negative -73% versus 35%
- External sources are more frequently responsible for the contamination - manipulation, case, etc – than the lacrimal film
- The lacrimal film is an excellent media for the growth of germs because of its neutral and stable pH, its temperature and the proteins it contains

Bacterial contamination (2)

- The deposits on the lens diminish the repulsion forces of the material – electric charge – allowing the bacteria to adhere
- The microorganisms dig themselves. They are able to adhere to the lenses because they produce polysaccharides, which in turn protect them from ocular defenses
- Gram negative bacteria are more often the cause of corneal ulcers in contact lens wearers
- The size of the bacteria is too large to penetrate in the material of the soft lenses

Fungal contamination

- Fungi can adhere to the surface of a relatively clean contact lens and penetrate into the matrix of the soft lens. They are not normally present in the lacrimal flora
- The fungi are Aspergillus, Fusarium and Candida. Sources of contamination are external (cosmetics, plants).
- Corneal lesions are a favoring factor

Viral contamination

- Viruses are the most feared infectious agents in a practice (Keratoconjunctivitis epidemica, herpes..)
- Viral hepatitis B ADN can be recovered from the tears of 40% of the affected patients
- Viral hepatitis C ADN can be found in 100% of the infected patient with the virus
- The possibility to acquire hepatitis C through the conjunctival mucosa is confirmed
- The Human Immunodeficiency Virus (HIV) has been isolated from tears of sero-positive contact lens wearers after 14-16 hours of wear but a transmission is highly improbable because of the very low concentration of the infected material

Amoebaean contamination

- Amoebas are unicellular organisms living in water –rivers, lakes, swimming-pools, tapwater...
- Their size 15 to 45 m
 μ for the trophozyte et 16x7 m
 μ for the cyst makes it impossible to enter the matrix of soft contact
- The spoilage of a contact lens with contaminated water may induce a contaminations of the
- The most frequent observed amoeba is Acanthamoeba

Prion

- At least 3 cases of transmission of Creuzfeldt-Jacob by corneal graft are on record
- The risk of transmission of the disease by a contact lens is unknown but can not be excluded. The trial lenses which may be used for several patients come under the European regulation 138 from March 2001
- A questionnaire is mandatory to precise the risk in each patient

INDICATION ==> CLASSIFICATION

CLEANING • CLEANING PRODUCT

DECONTAMINATION • DECONTAMINANT

CONSERVATION • CONSERVATION PRODUCT

RINCING • RINSING PRODUCT

INSERTION

DEPROTÉINISATION • DEPROTEINISATION PROD.

INSERTION PRODUCT

MULTIFONCTION PRODUCT

DECONTAMINANTS

OBJECTIVE : **FREE** THE LENSES

FROM MICRO-ORGANISMES *

BACTERICIDE, VIRUCIDE, ANTIFUNGAL ACTION ANTI-ACANTHAMOEBA ACTION

* <u>DECONTAMINATION</u> = CHEMICAL OR PHYSICAL ACTION IN ORDER TO ELIMINATE OR REDUCE THE NUMBER OF VIABLEMICRO_ORGANISMS (Living or inert media)

RANGE OF ACTION

GRAM + BACTERIAS STAPHYLOCOCCUS AUREUS

STREPTOCOCCUS

S.EPIDERMIDIS *

GRAM – BACTERIA <u>SERRATIA MARCESCENS</u>*

PSEUDOMONAS AERUGINOSA *

E.COLI

FUNGI FUSARIUM SOLANI

CANDIDA ALBICANS *

ASPERGILLUS NIGER

A.FUMIGATUS *

ISOCD 14729 –1992 * FDA 1994

Polymeric decontaminants (1)

- Large size molecules which do not penetrate in the matrix of the soft lenses, avoiding in such manner, the consecutive rejection
- They are less toxic than the conventional chemical products. They have a selective action by binding to the germ's membrane, inducing their rupture
- They are used in the multifunction solutions for the soft lenses and hard lenses

Polymeric decontaminants (2)

- Biguanides derivates: polyamino-propylbiguanide (PAPB), polyhexamethylene biguanide (PHMB), polyhexadine. They bind selectively to the phospholipides negatively charged of the membrane and provoke their rupture
- Quaternary Amonium: polyquad has a tensioactive capability and absorbs itself on the surface of the bacteria, isolating it from the nutrient substrate, preventing thus its proliferation. They interfere with bacteria metabolism and provoke a loss of cellular material towards the exterior

PHMB ACTIV AT LOW A CONCENTRATION

LENTILLES	SOUPLES	RIGIDES	
CONCENTRATION 0.00005%	0.0001%	0.0002%	0.0005%
CONCERTO SOUPLES	COMPLETE	CONCERTO RIGIDES	BOSTON SIMPLICITY
	SOLO care PLUS 10 mn	SOLO care HARD	BOSTON ADVANCE
	RENU MULTIPLUS		MENICARE PLUS

Oxidative decontaminants (1)

- They are extremely active if the time of contact is sufficient
- They are very toxic and require a full neutralization before replacing the lens on the eye
- The most widely used is the Hydrogen peroxide (H₂O₂). The neutralization requires the presence of a catalyzer:
 - Platinum disk
 - Catalase either a tablet added to the oxidative solution or diluted in a 2nd solution called neutralizing solution

Oxydative decontaminants (2)

- It can be presented without conservation agent
- After neutralization, it is transformed into water
- Sodium-hypochlorite is used for rigid lenses. It is very active against prions and plays an active role against protein deposits

Conventional chemical derivates

- Thiomersal (Mercury derivate)
- Chlorhexidine
- Benzalkonium chloride

 They are less used as they do penetrate into the soft lenses, provoking toxic or allergic reactions

Other chemical agents playing a role as decontaminant

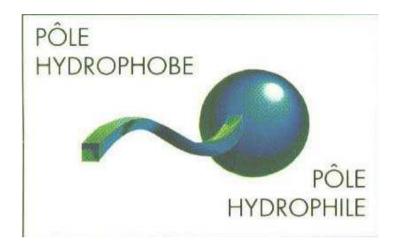
- Alcohol: Polyvinylic alcohol. It has a good decontaminant effect. It is used in the cleaning solutions.
- Chelators: The sodium-edetate (EDTA)
 binds to the calcium of the bacterial
 membrane, rendering it fragile and
 increasing thus the action of certain
 decontaminants. Their bactericide action
 allows to use them as conservative agent

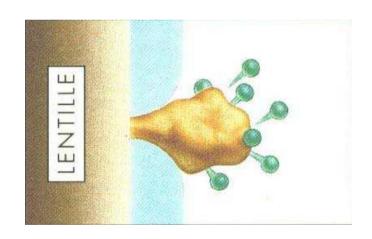
Temperature

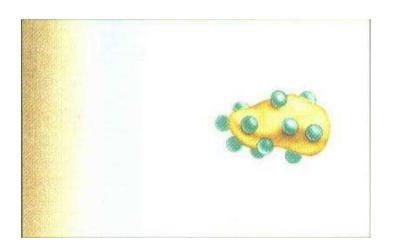
 Very effective, but modern soft lenses do not tolerate heat

Cleaning Agents

- Tensioactives or surfactants: they emulsify the debris and bring into solution the lipids by lowering the interfacial tension between the aqueous phase of the solution and the debris adherent to the surface. They « coat » the debris forming micelles - the hydrophilic pole toward the aqueous phase and the hydrophobic pole attached to the lipids. These micelles repulse each other creating a stable emulsion
 - Poloxamine, poloxamer
 - Amphoteric derivates, imidazoline







ANTILIPIDES ET ANTIMUCINES

DIFFERENT TYPES OF TENSIO-ACTIVES

Anionic	Cationic	Amphoteric	Non ionic
Sodium- Laurylsulfate LIQUINET Alkyl-ether- sulfate BOSTON ADVANCE TOTALCARE	Quaternary ammonium salts	Opterium- laurotesilate	Polysorbate 80 POLYCLEAN O-CLAIR Poloxamere SOLO-CARE+ CONCERTO HYDRON MULTIPLUS COMPLETE MENICARE+ Poloxamine RENU MULTIPLUS OPTIFREE EXPRESS

Conservative agents

- They have a bacteriostatic action
- They inhibit the proliferation of germs after opening the bottle
- The most widely used are:
 - Citric acid
 - EDTA
 - Polymeric decontaminants
 - Conventional decontaminants

Deproteination (1)

- They prevent or eliminate protein deposits strongly attached to the soft and/or hard lenses
- Their action can be active or passive
- While it is not necessary to deprotenise frequent replacement soft lenses, it is strongly recommended to do so for conventional soft lenses or for rigid gas permeable

Deproteination (2)

- The enzymes (active deproteination):
 - Papain comes from plants (tablets)
 - Pancreatin is of animal origin and is active against proteins, lipids, polysaccharides, glycoproteins and mucus (tablets or solution)
 - Subtilisin A & B : bacterial origin active against proteins (tablets to dissolve)

ENZYMATIC DEPROTEINISATION

TABLETS OR SOLUTIONS

WEEKLY

- ALCON	POLYZYM	PANCREATIN	Soft / Rigid lenses
- AMO	COMPLETE CP	SUBTILISIN A	Soft lenses
	ULTRAZYME	SUBTILISIN A	Soft lenses
- B&L	EFFICLEAN	SUBTILISIN A	Soft / Rigid lenses
- CIBA Visio	n UNIZYME	SUBTILISIN A	Soft / Rigid lenses
- HYDRON	TRIPLE ACTION	PANCREATIN 8	« EDTA
			Soft / Rigid lenses

DAILY

- ALCON SUPRACLENS PANCREATIN Soft / Rigid lenses

Monthly

- Menicon SP Intensive Cleaner HYPERCHLORID Rigid lenses

Deproteination (3)

- Passive deproteination : by chelating calcium ions:
 - Hydranate
 - Ionic shifting : citrate
 - Creating a film : HMPC
- Oxidants : certain oxidants do have deproteination action :
 - Mechanical action of the oxygen bubbles during neutralization
 - Efficacy of the sodium-hyper chlorite or the sodiumhypobromite (PROGENT)

Chelators

 They bind the calcium of the bacterial membrane, prevent calcium deposits and increase the action of certain decontaminants. Their bactericidal effect can be useful as conservative agent. The most widely used is EDTA.

Tonicity agents

- A solution must be isotonic to the tears (0.94-0.97) in order to achieve a good ocular tolerance
- An acceptable tonicity is from 0.6 à 1.5, ideal from 0.9 to 1.1%

Viscosity agents

- They «thicken» a solution, increasing their contact time with the lens. They can be found in comfort drops for contact lens wearers, solution for rigid gas permeable lenses (increase the insertion comfort) and in certain cleaning solutions (subjective role)
- The most frequently used are:
 - Polyvinylic alcohol
 - Polyethyleneglycol
 - Polypropyleneglycol
 - Hyaluronic acid

Comfort products

For SL / RL

- AQUIFY 5 ml CIBAVISION Sodium Hyaluronate
- CLENS 100 10 ml ALCON Polyquad, PEG,Tetronic 1304...

For SL

- ReNu Drops Confort B&L 5 x 0.60 ml Polyvidone 2%
 30 x 0.60 ml
- COMPLETE Blink 20 x 0.35 ml AMO Hyaluronate de sodium

Buffers

 They maintain the pH of the solution between 6.6 and 7.8 (zone of ocular comfort). A more alcaline pH may help to eliminate proteins, while an acid pH may be better for cleaning but in both cases, one will have to neutralize

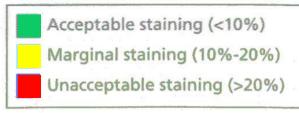
Multifunction solutions

- Surfactant or citrate
- Decontaminant : usually polymeric
- EDTA (prevents the deposition of calcium and increases the action of the decontaminant)
- Osmolarity agent
- Buffer

PRODUIT / FABRICANT	COMPOSITION
COMPLETE	PHMB 1 PPM
AMO	POLOXAMER 0.05%
	HPMC 0.15%
	EDTA 0.02%
	PHOSPHATES NACL KCL
CONCERTO SOUPLES	PHMB + HEXETIDINE
OCULAR SCIENCES	POLOXAMER
	MACROGOL
	EDTA
	PHOSPHATE
SOLO CARE SOFT Plus	PHMB 1 PPM
CIBA VISION	POLOXAMER 0.1%
	EDTA 0.025%/ AQUALUB
	PHOSPHATE
OPTI-FREE EXPRESS	POLYQUAD+ MAPD (ALDOX)
ALCON	EDTA 0.05%
	CITRATE
RENU MULTIPLUS	PHMB 1 PPM
B & L	POLOXAMINE 1%
	EDTA 0.1%
	HYDRANATE
	BORATE

Compatibility of silicone hydrogel with Multipurpose Solution

	Unisol ¹ 4 Saline	Clear Care ⁴	Opti-free Express ¹	Opti-free Replenish ¹	Renu Moistureloc ³	Renu Multiplus ³	Walmart MPS (Renu MP)	Target MPS (Renu MP)	Complete Moisture Plus ²	Aquify ⁴
Acuvue ⁵ 2	1%	1%	2%	5%	25%	1%	1%	1%	2%	1%
Proclear ⁶	1%	Testing Ongoing	1%	2%	No Further Testing	57%	Testing Ongoing	Testing Ongoing	16%	Testing Ongoing
Acuvue Advance ⁵	1%	1%	1%	1%	No Further Testing	13%	16%	13%	20%	2%
Acuvue Oasys ⁵	2%	1%	3%	5%	10%	9%	12%	8%	5%	3%
Purevision ³	2%	1%	4%	7%	6%	73%	71%	76%	48%	21%
O2 Optix ⁴	2%	1%	2%	5%	7%	24%	41%	28%	18%	3%
Focus Night & Day ⁴	2%	1%	2%	3%	No Further Testing	24%	36%	24%	16%	3%
Biofinity ⁶	Testing Ongoing	Testing Ongoing	Testing Ongoing	Testing Ongoing	No Further Testing	Testing Ongoing	Testing Ongoing	Testing Ongoing	Testing Ongoing	Testing Ongoing
Update February 2		H ₂ O ₂	POL	YQUAD	Biguanides					



GJ Andrasko, KA Ryen, RJ Garofalo, JM Lemp www.staininggrid.com Febr 2007

Oxydative system

- A solution $H_20_23\%$
- 1 step: neutralization by a disc of platinum or a tablet of catalase. Advantage: simplicity
 - Inconvenience: the concentration drops immediately, long procedure
- 2 steps : neutralization by a liquid catalase
 Advantage : speed

For permanent wear

- No up-keep necessary
- However, the patient must have a case and a product at hand if for any reason he has to take the lens out
- One has to prescribe him lubricating drops

Instruments

Auto-Refractometer
Subjective Refraction
Cornea-Topographer
Slitlamp
Sodium-Fluorescein
Wratten-Filter

Instruments

Auto-Refractometer subjective Refraction Cornea-Topographer

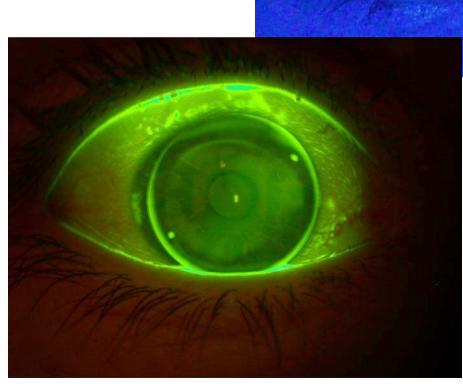




Instruments

Slitlamp Sodium-Fluorescein Wratten-Filter





Pearls: Instruments

It needs about the same instruments and technical professional skills for a contact lens specialist to fit CL's as for a traditional ophthalmology practices needs for the anterior segment.

- -Topography and subjective refraction for the technical parameters.
- Digital slit lamp and fluorescein for biology and physiology.

- Analyze refractive power and topography for CL suitability.
 - Assess the *patient* for CL suitability.
- Choose CL *type* and *material* according to the wearing modality.
- Define wearing modality according to planned wearing time.

Case 1:

26 yo women, office job

-3.0 dpt / -2.50 -0.5 cyl 180°

CL for sport and holidays, probably later for every day use

Type: ??

Soft lenses, 1-Day (single-use) lenses

Case 2:

31 yo men, truck driver

-3.00 - 2.75 18° / -2.50 -1.75 165°

CL for working hours

Type: ??

Hard/Flexible, Soft or Si-Hydrogel toric lenses

Case 3:

76 yo women, EBM dystrophy

-1.00 - 0.75 95° / -0.50 -1.00 105°

CL for therapeutic use

Type: ??

Si-Hydrogel lenses (spheric or toric)

Fitting procedure

- *CL material* according to the wearing modality.
- Base curve and over all diameter according to the corneal radii and size.
- -Power according to subjective refraction reduced to corneal level (delta 0 mm).
- Wearing modality according to planned wearing time.

	Minus			KL			Plus	0.30
TATE OF	1	Abstand Hor	nhautsche	itel – inner	er Brilleng	asscheitel		
14mm	12mm	10mm	8mm	0mm	8mm	10 mm	12mm	14mm
3.13	3.11	3.09	3.07	3.00	2.93	2.91	2.90	2.88
3.40	3.38	3.36	3.34	3.25	3.17	3.15	3.13	3.11
3.68	3.65	3.63	3.60	3.50	3.40	3.38	3.36	3.34
3.96	3.93	3.90	3.87	3.75	3.64	3,61	3.59	3.56
4,24	4.20	4.17	4.13	4.00	3.88	3.85	3.82	3.79
4.52	4.48	4.44	4.40	4.25	4.11	4.08	4.04	4.01
4.80	4.76	4.71	4.67	4.50	4.34	4.31	4.27	4.23
5.09	5.04	4.99	4.94	4.75	4.58	4.54	4.49	4.45
5.38	5.32	5.26	5.21	5.00	4.81	4.76	4.72	4.67
5.67	5.60	5.54	5.48	5.25	5.04	4.99	4.94	4.89
5.96	5.89	5.82	5.75	5.50	5.27	5.21	5.16	5.11
6.25	6.18	6.10	6.03	5.75	5.50	5.44	5.38	5.32
6.55	6.46	6.38	6.30	6.00	5.73	5.66	5.60	5.54
6.85	6.76	6.67	6.58	6.25	5.95	5.88	5.81	5.75
7.15	7.05	6.95	6.85	6.50	6.18	6.10	6.03	5.96
7.45	7.34	7.24	7.13	6.75	6.40	6.32	6.24	6.17
7.76	7.64	7.52	7.41	7.00	6.63	6.54	6.46	6.38
8.07	7.94	7.82	7.70	7.25	6.85	6.76	6.67	6.58
8.38	8.24	8.11	7.98	7.50	7.08	6.98	6.88	6.79
8.70	8.55	8.40	8.26	7.75	7.30	7.19	7.09	6.99
9.01	8.85	8.70	8.55	8.00	7.52	7.41	7.30	7.19
9.33	9.16	8.99	8.83	8.25	7.74	7.62	7.51	7.40
9.65	9.46	9.29	9.12	8.50	7.96	7.83	7.71	7.60
9.97	9.78	9.59	9.41	8.75	8.18	8,05	7.92	7.79
10.30	10.09	9.89	9.70	9.00	8.40	8.26	8.12	7.99
10.63	10.41	10.19	9.99	9,25	8.61	8.47	8.33	8.19
10.96	10.72	10.49	10.28	9.50	8.83	8.68	8.53	8.39
11.29	11.04	10.80	10.60	9.75	9.04	8.88	8.73	8.58
11.63	11.36	11.11	10.87	10.00	9.26	9.09	8.93	8.77

Lens-eye distance (delta)

	Minus			KL Plus					
3.5	Abstand Hornhautscheitel – innerer Brillenglasscheitel								
14mm	12mm	10mm	8mm	0mm	8mm	10mm	12mm	14mm	
3.13	3.11	3.09	3.07	3.00	2.93	2.91	2.90	2.88	
3.40	3.38	3.36	3.34	3.25	3.17	3.15	3.13	3.11	
3.68	3.65	3.63	3,60	3.50	3.40	3.38	3.36	3.34	
3.96	3.93	3.90	3.87	3.75	3.64	3.61	3.59	3.56	
4.24	4.20	4.17	4.13	4.00	3.88	3.85	3.82	3.79	
4.52	4.48	4.44	4.40	4.25	4.11	4.08	4.04	4.01	
4.80	4.76	4.71	4.67	4.50	4.34	4.31	4.27	4.23	
5.09	5.04	4.99	4.94	4.75	4.58	4.54	4.49	4.45	
5.38	5.32	5.26	5.21	5.00	4.81	4.76	4.72	4.67	
5.67	5.60	5.54	5.48	5.25	5.04	4.99	4.94	4.89	
5.96	5.89	5.82	5.75	5.50	5.27	5.21	5.16	5.11	
6.25	6.18	6.10	6.03	5.75	5.50	5.44	5.38	5.32	
6.55	6.46	6.38	6.30	6.00	5.73	5.66	5.60	5.54	
6.85	6.76	6.67	6.58	6.25	5.95	5.88	5.81	5.75	
7.15	7.05	6.95	6.85	6.50	6.18	6.10	6.03	5.96	
7.45	7.34	7.24	7.13	6.75	6.40	6.32	6.24	6.17	
7.76	7.64	7.52	7.41	7.00	6.63	6.54	6.46	6.38	
8.07	7.94	7.82	7.70	7.25	6.85	6.76	6.67	6.58	
8.38	8.24	8.11	7.98	7.50	7.08	6.98	6.88	6.79	
8.70	8.55	8.40	8.26	7.75	7.30	7.19	7.09	6.99	
9.01	8.85	8.70	8.55	8.00	7.52	7.41	7.30	7.19	
9.33	9.16	8.99	8.83	8.25	7.74	7.62	7.51	7.40	
9.65	9.46	9.29	9.12	8.50	7.96	7.83	7.71	7.60	
9.97	9.78	9.59	9.41	8.75	8.18	8.05	7.92	7.79	
10.30	10.09	9.89	9.70	9.00	8.40	8.26	8.12	7.99	
10.63	10.41	10.19	9.99	9.25	8.61	8.47	8.33	8.19	
10.96	10.72	10.49	10.28	9.50	8.83	8.68	8.53	8.39	
11.29	11.04	10.80	10.60	9.75	9.04	8.88	8.73	8.58	
11.63	11.36	11.11	10.87	10.00	9.26	9.09	8.93	8.77	

Fitting procedure

Hard/Flexible contact lens:

- BC according the real cornea radii.
- Smaller over all diameter for faster tear exchange or larger for quicker adaptation and less dust problems.
- 3. Power according calculation formula.
- 4. Slit lamp check after insertion for centration and movement.
- 5. Fluorescein check for adequate design (BC and asphericity).
- 6. Introduction about lens care system and wearing modality during adaptation phase.
- 7. Schedule for next visit in 1 week, 1 month, 3-6 months.

Fitting procedure

- Soft and Silicone-Hydrogel contact lens:
- BC according the real cornea radii PLUS 0,4 to 1,2 mm depending the chosen material.
- 2. Diameter app. 2 mm larger than the visible corneal diameter.
- 3. Power according calculation formula.
- 4. Slit lamp check after insertion for centration and movement.
- 5. Introduction about lens care system and wearing modality during adaptation phase.
- 6. Schedule for next visit in 1 week, 1 month, 3 6 months.

Contact lens description

Minimal parameters for orders / description:

Company CL Type / Material / Geometry / BC / Power / Diameter / Reference

Galifa / Balance 59% / B / 8.30 mm / -7.75 dpt / 14.0mm / Mueller

Falco AS / Boston XO blue / nE 0.4 / 7.85 mm / +4.25 dpt / 10.2 mm / Bart

Lens care system:

e.g. AO-Sept, Optifree Express, Complete, Boston Advance, Menicon SP

Wearing modality: DW, EW, CW

Next visit, points of special interest

Complications



Fussarium keratitis CH March 2006

Risk ratio according to wearing modality



Risk for microbial or fungal keratitis?

Daily wear (1 - 4 / 10'000)

VS.

extended wear (2.5 - 8 / 10'000)

VS.

constant wear ? $(2 - 22 / 10^{\circ}000)$

In our practice **1 case** of MK in 26 years (DW & peripheral!).

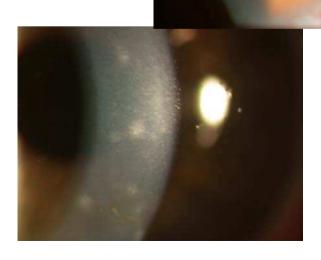
AIK, SIK or CLPU? up to 6 % (temporarily)

Papillary conjunctivitis in EW?
Up to 6 % (seasonal?)

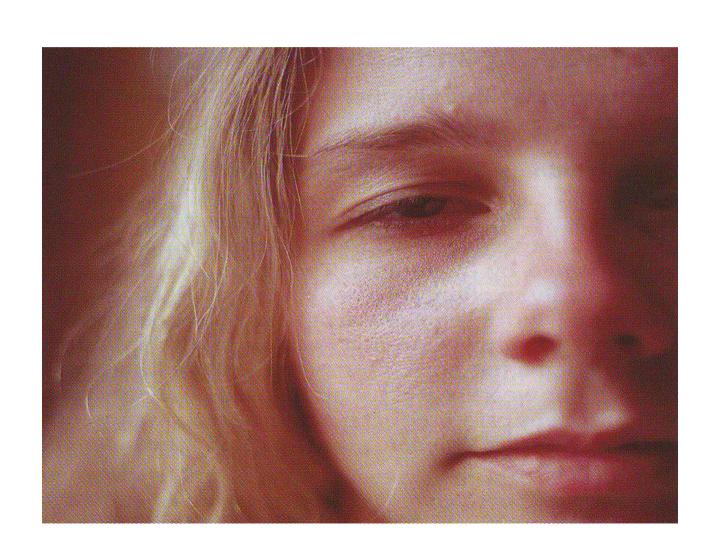
MK vs. CLPU vs. IK/AIK

- microbial keratitis MK (bacterial or fungal, single infiltrate, scar, irreversible, vision loss)
- contact lens related peripher ulcer CLPU (bacterial toxins, single infiltrate, scar, reversible over time, no vision loss)
- (asymptomatic) infiltrative keratitis SIK/AIK (viral or unspecific, no scar, reversible in months, no vision loss)



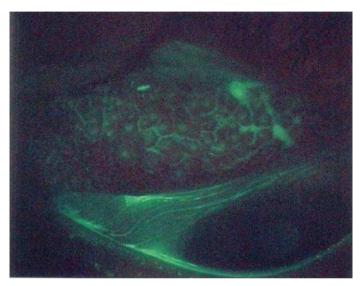


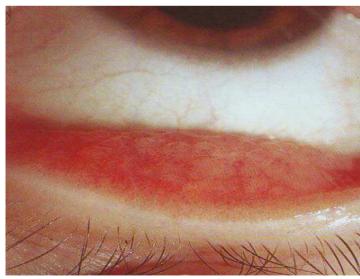
Pseudo-ptosis with moderately tolerated hard lenses



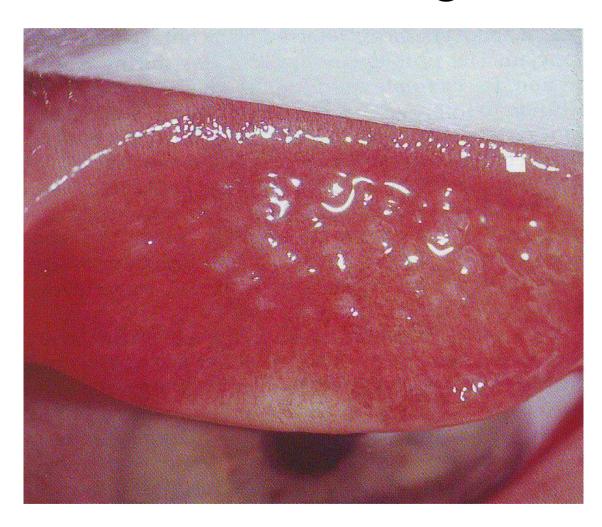
Gigant Papillary Conjunctivitis GPC



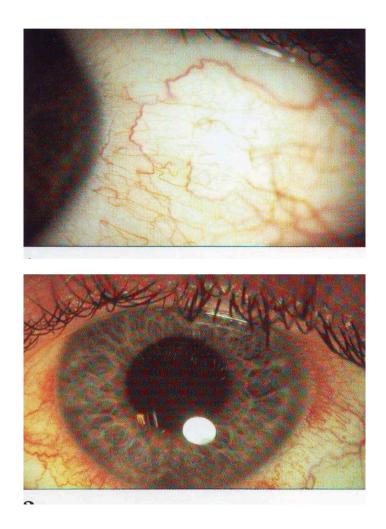


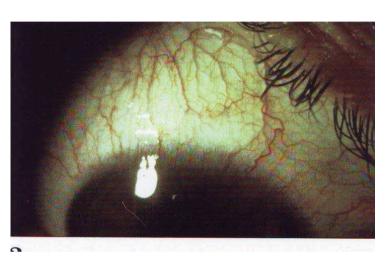


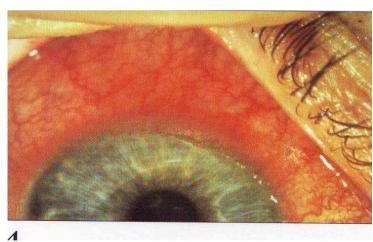
GPC-scaring



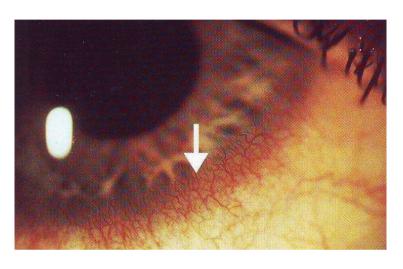
Conjunctival hyperemia

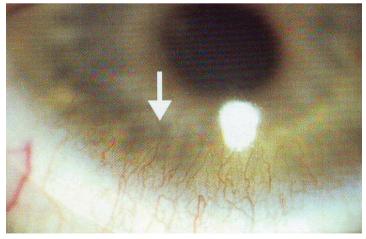


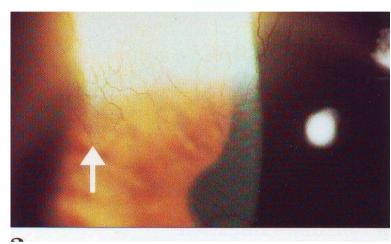


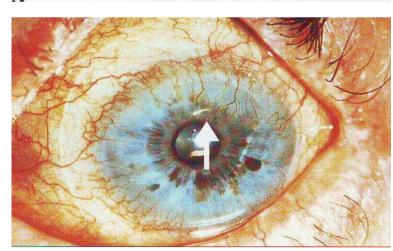


Neovascularisation

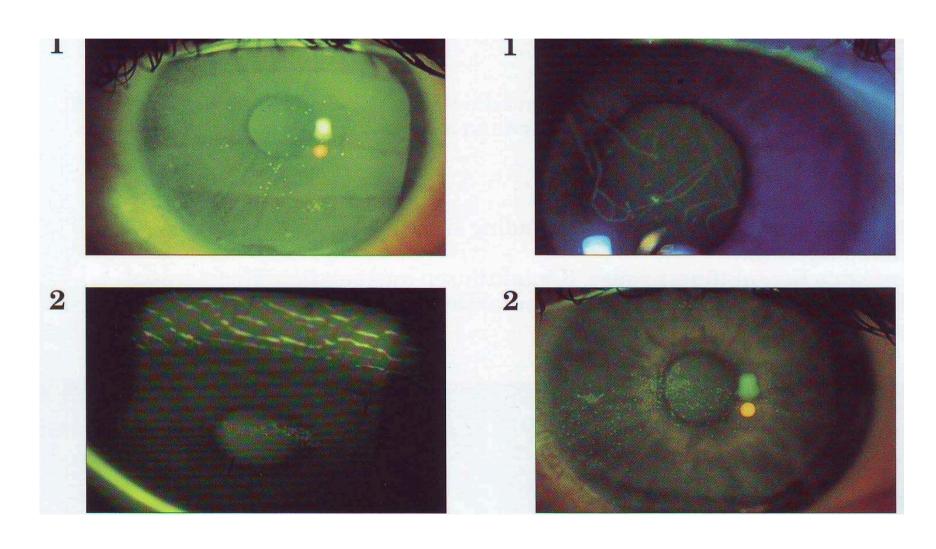




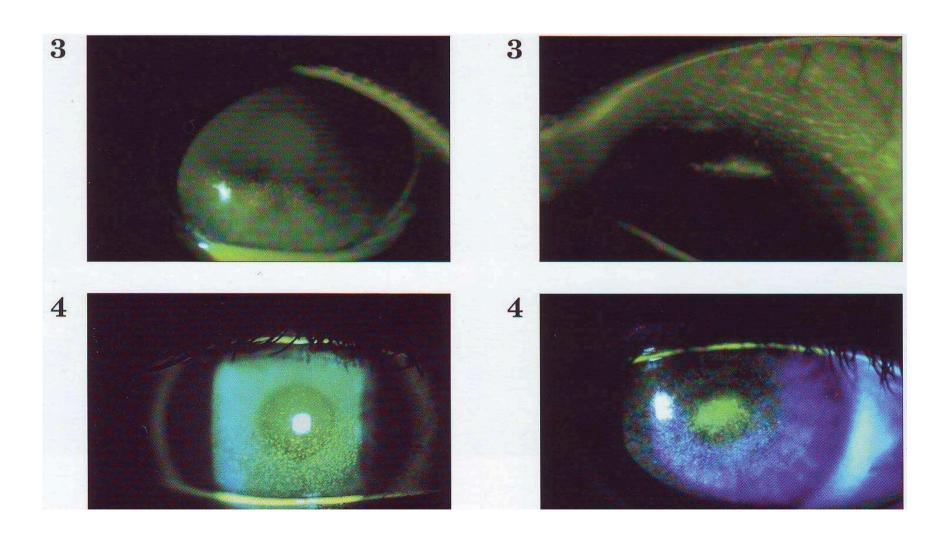




Corneal erosions (1)

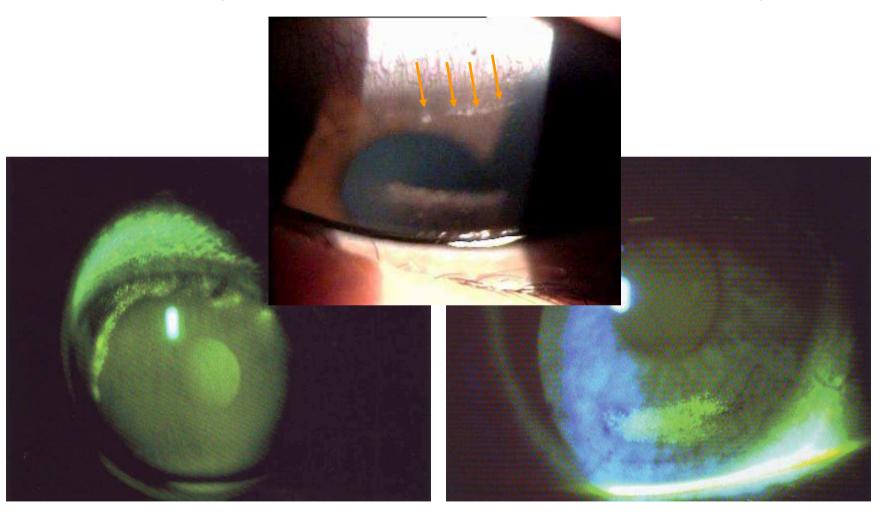


Corneal erosions (2)



Upper and inferior arcuate staining

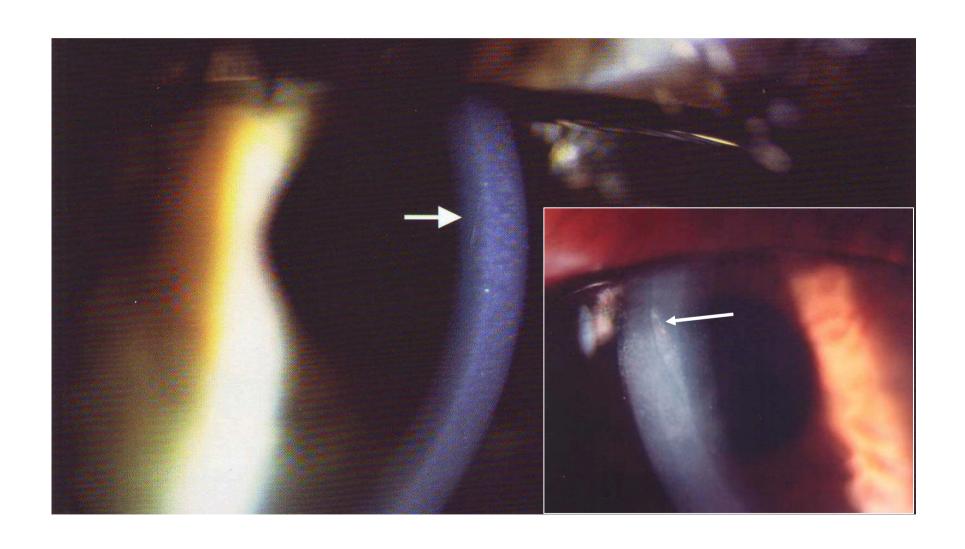
SEAL (Superior Epithelial Arcuate stain)



3-9 o'clock staining



Striae

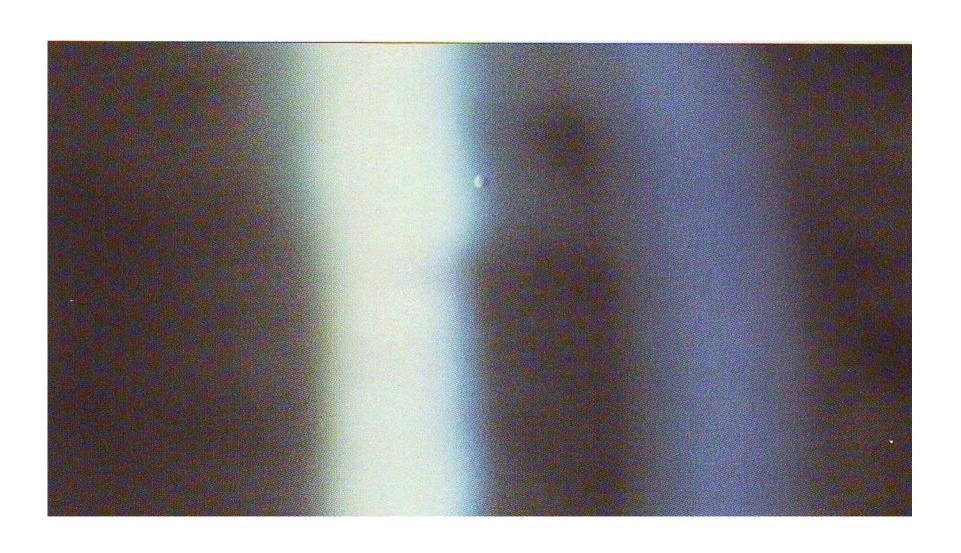


Microcysts



Mikrozysten

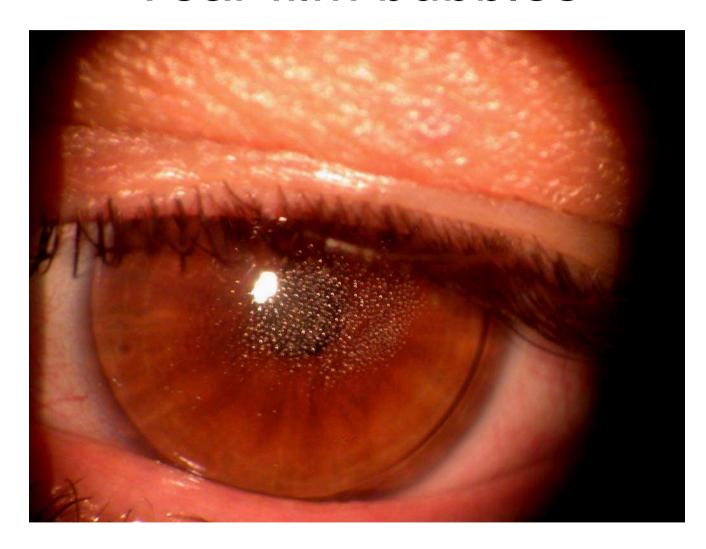
Vacuoles



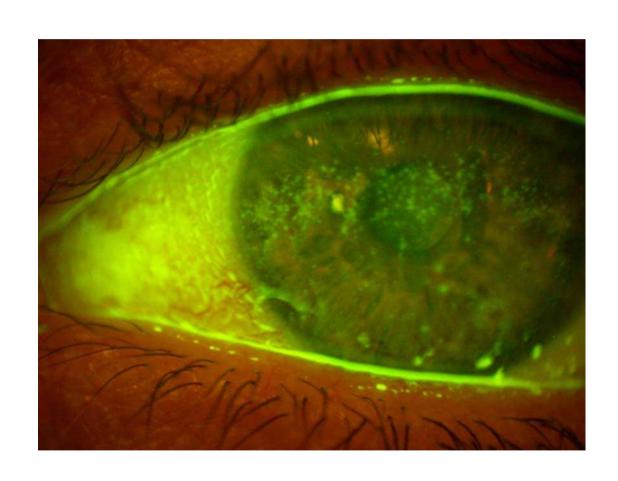
Mucin Balls



Tear film bubbles



Therapeutic CL



Therapeutic Contact Lenses

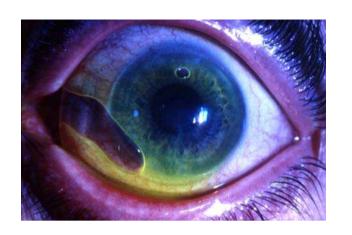
We have been using therapeutic contact lenses since 1970s

- Protect the cornea
- Improve visual acuity
- Promote corneal healing
- Provide patient comfort

Rigid Gas-Permeable Scleral Contact Lenses

Can be used on extended-wear basis

- Persistent epithelial defects
- Ocular surface disorders
 (Cicatricial pemphigoid, exposure keratitis, superior limbal keratoconjunctivitis, Stevens-Johnson sydrome, and dry eye of various etiologies)
- Following chemical burns in order to prevent symblepharon formation
- Not recommended to be the first choice in cases where therapeutic soft contact lenses could be applied
- Should be cleaned at least once or twice daily on waking hours



Therapeutic Soft Contact Lenses

Conventional Soft Contact Lenses (Hydrogels)

Low-water content (<50%), thin lenses

High-water content (>50%), thick lenses

Disposable Contact Lenses

Frequent Replacement Contact Lenses

Silicone Hydrogel Contact Lenses

Silicone Hydrogel Materials

	NIGHT&DAY	PureVision	Acuvue Advance	Air Optix	Acuvue Oasys
Material	Lotrafilcon A Fluoroether- based	Balafilcon Co-polymer of TRIS vinyl carbamate derivative	Galyfilcon	Lotrafilcon B	Senofilcon A
Water Content	24 % Non-ionic	35 % Ionic	47 % Non-ionic	33 % Non-ionic	38 % Non-ionic
Dk/t	175	110	85	138	147
Surface Treatment	25nm plasma coating- continuous hydrophilic surface	Plasma oxidation glassy silicate "islands"	No surface coating hydroclear	25nm plasma coating-continuous hydrophilic surface	No surface coating hydroclear
Base Curve	8.4 / 8.6	8.6	8.3 / 8.7	8.6	8.4
Diameter	13.8	14.0	14.0	14.2	14.0
Power	-10 to + 6	-12 to +6	-12 to + 8	-10 to + 6	-12 to +8
Center thickness (- 3.00D)	0.08	0.09	0.07	0.08	0.07
Other		Visibility tint	UV blocking visibility tint	Visibility tint	UV blocking visibility tint

Overnight Corneal Edema

The eye with no CL 4 % (Physiological overnight edema)

Conventional Soft CL 10 - 12 %

RGP 6 - 12 %

Silicone Hydrogels 3.6 - 3.8 % (No additional overnight corneal swelling) *Fonn,* 1997

Purpose of Fitting Therapeutic Contact Lenses

Pain relief

Bullous keratopathy, epithelial erosions, abrasions, filamentary keratitis, and following keratoplasty and laser refractive surgery

Enhancement of corneal healing

Persistent epithelial defects, neurotrophic keratitis, neuroparalytic keratitis, chemical burns, toxic epitheliopathy and post surgical epithelial defects

Corneal protection

Recurrent corneal erosion, lid and lash problems and scars, after ptosis surgery

Improvement of vision

Corneal irregularities, dry eye, bullous keratopathy

Corneal hydration

Eyelid defects, lagophtalmos, neuroparalytic keratitis

Corneal sealing / splinting

Corneal lacerations, perforations

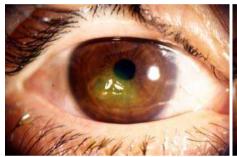
Therapeutic Contact Lenses

Adjunctive Therapy

Traditional treatment of the underlying disease process can be continued while the contact lens is in position.

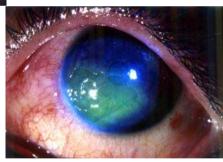
- Prophylactic topical antibiotics (2-3 times daily)
- Preservative-free artificial tears (in the morning and few times daily)
 - Dry eye more frequent use!
 - Keratoconjunctivitis sicca temporary or permanent punctal plugs
- According to the nature of the disease
 - Topical steroids
 - Anti-glaucomatous agent
 - Hypertonic solutions (bullous keratopathy)

Corneal abrasions

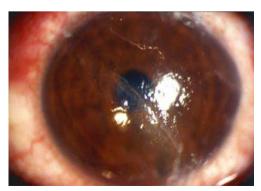


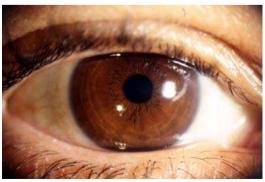


Reduces pain
Promotes epithelial healing







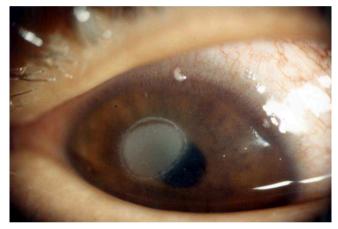


Topical antibiotics – more frequent use Preservative–free artificial tears

Persistent epithelial defects

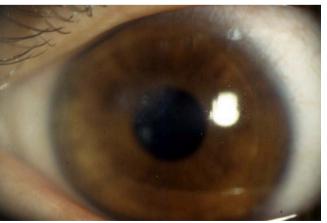
(neurotrophic, neuroparalytic, keratoconjunctivitis sicca, herpes simplex)





Promotes epithelial healing Improvement of vision





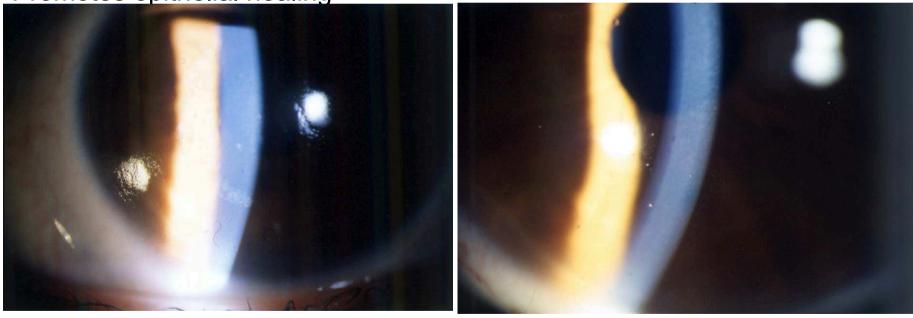
Topical antibiotics Preservative–free artificial tears

Vernal keratoconjunctivitis Shield ulcer

Recurrent corneal erosions due to epithelial basement membrane (traumatic, corneal dystrophies)

Pain relief

Promotes epithelial healing

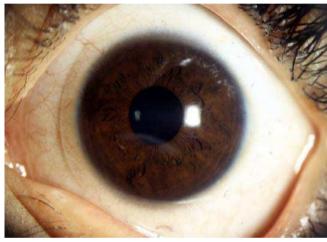


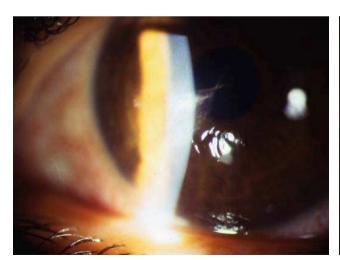
CL wear continued about 3 months after complete healing

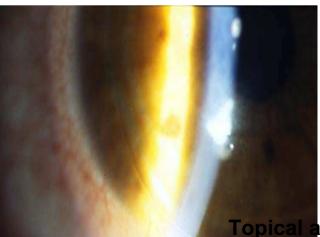
The action of the lids, particularly during eye opening in the morning, responsible for initiating a recurrent episode

Corneal lacerations











Topical antibiotics – more frequent use Preservative–free artificial tears

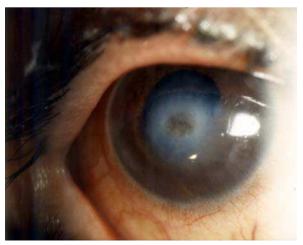
Corneal perforations (± cyanoacrylate tissue glue)





traumatic





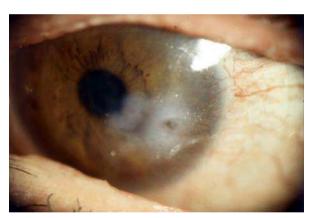
descematocoele

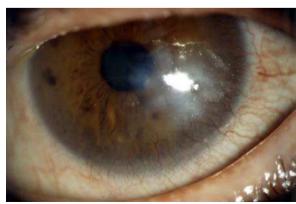
Corneal melting (rheumatoid arthritis, peripheral corneal disorders)

Traditional treatment of the underlying disease process should be continued while the contact lens is in position.









- Post-surgical wound leakage
 - filtering surgery
 - penetrating keratoplasty
 - cataract surgery
- Post-surgical leaks after trabeculectomy with or without Mitomycin-C
 - large diameter (15-20 mm) bandage contact lens

Dry eye - KCS

Reduces pain
Promotes epithelial healing
Improves vision

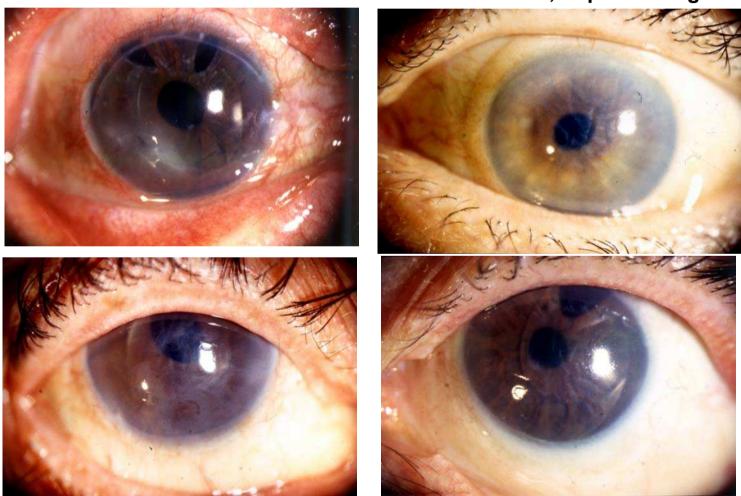




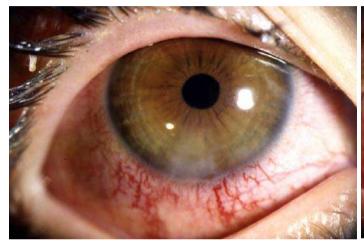
Prophylactic topical antibiotics
Preservative–free artificial tears; more frequent use
± punctal occlusion

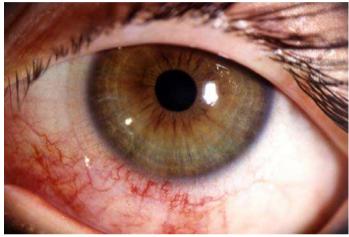
Bullous keratopathy

Pain relief, avoids photophobia, may improve vision until PKP Adjuctive therapy: Topical antibiotics, Hypertonic solutions, Preservative-free artificial tears, Topical anti-glaucoma agents



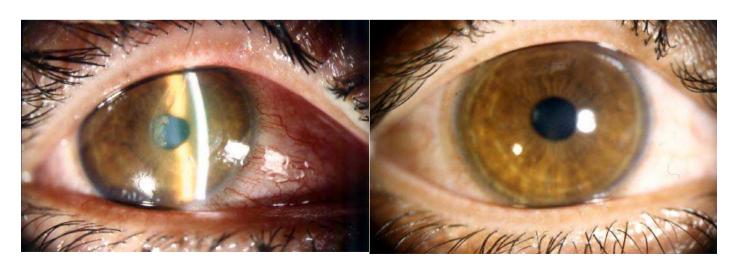
Thermal and chemical burns





acetone

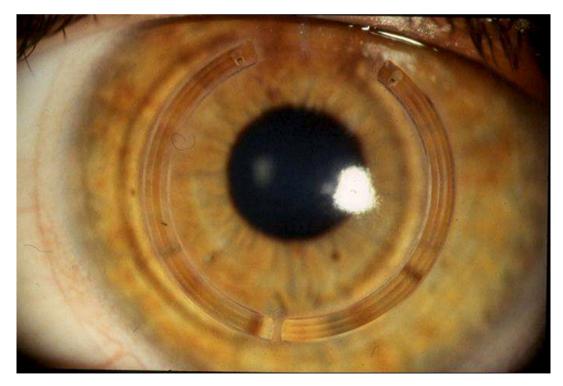
Topical antibiotics, soft steroids, Preservative–free artificial tears



acid

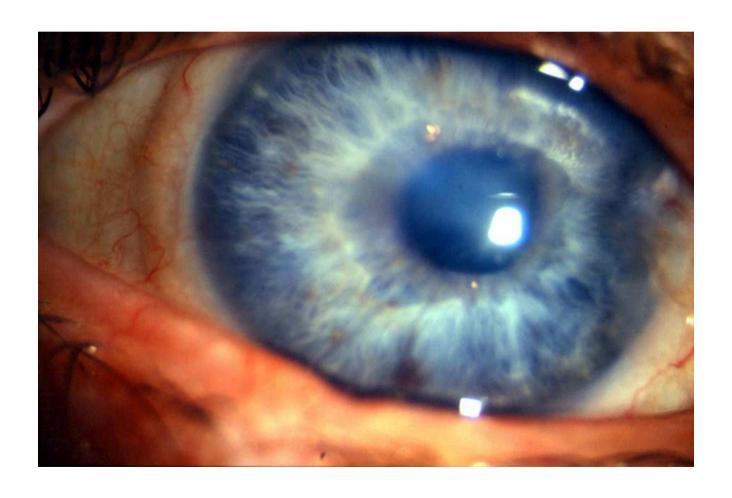
Following refractive surgery (PRK, LASIK, LASEK, epi-LASIK, INTACS)

Routinely used after PRK, LASEK, epi-LASIK; for pain relief and promotion of corneal healing



Epithelial erosion at 12 o'clock

Corneal protection (trichiasis, entropion, lagophthalmos, tarsal scarring)



Therapeutic Contact Lenses Indications

Masking Defects and Cosmesis

- Traumatic mydriasis
- Congenital or traumatic aniridia
- Albinism
 - Colored contact lenses
 - Clear pupillary aperture
- Total opaque corneas
 - Colored contact lenses
 - Black pupillary aperture





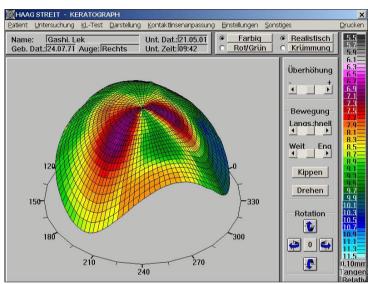


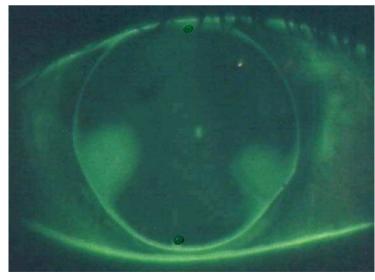




Diseases:

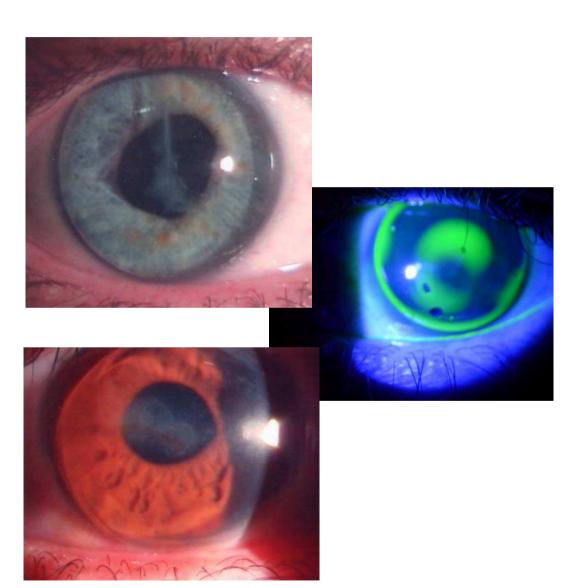
- Keratoconus
- Terrien disease
- Marginal degeneration
- Epithelial basement
 membrane dystrophy
- Fuchs Endothelial dystrophy



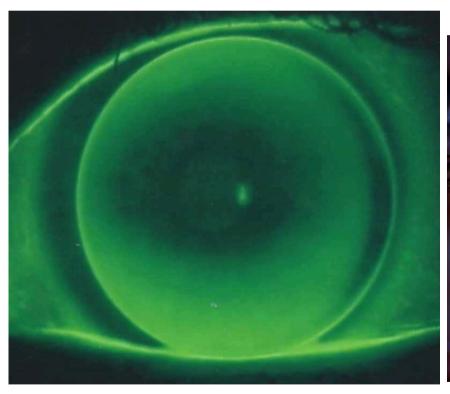


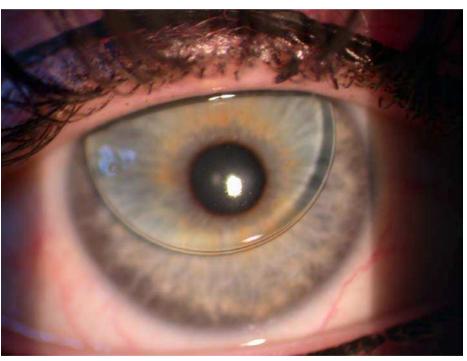
Traumata:

- Foreign bodies
 - post surgery
- post infections
 - post burns

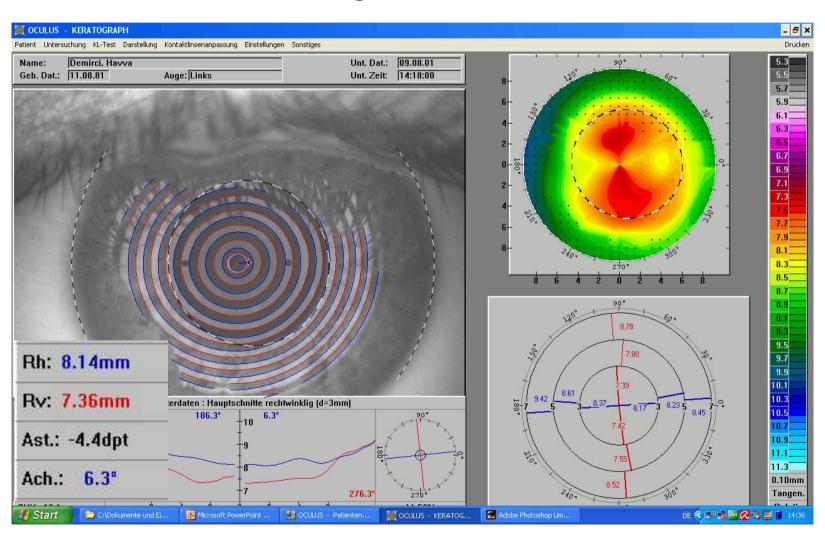


Astigmatism

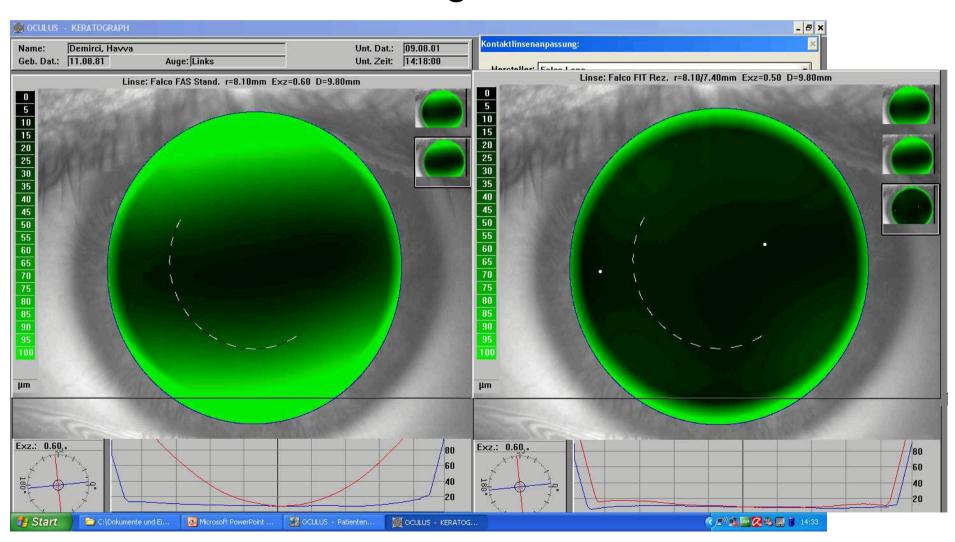


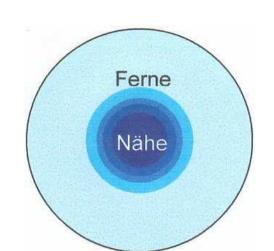


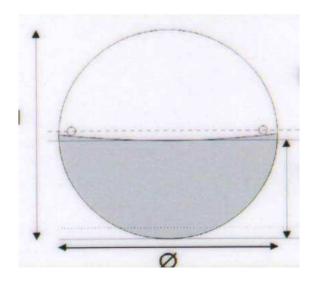
Astigmatism



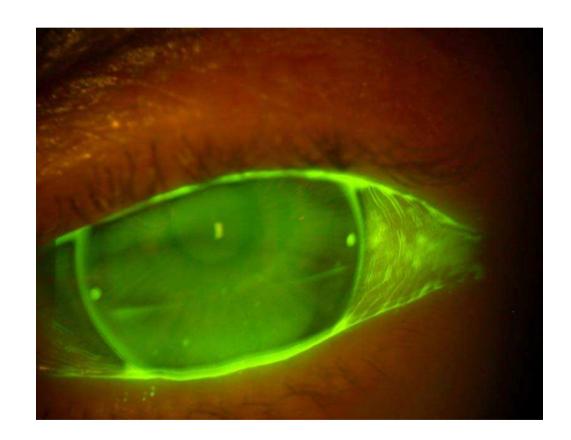
Complex contact lenses Astigmatism



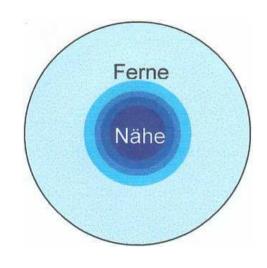


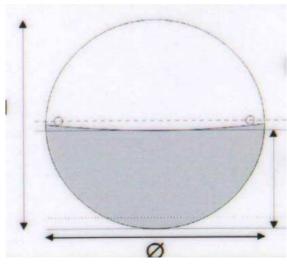


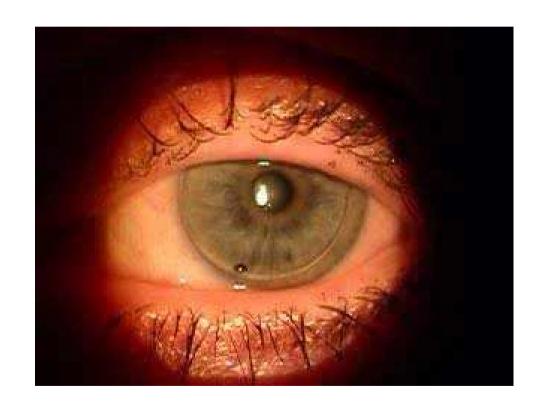
Presbyopia









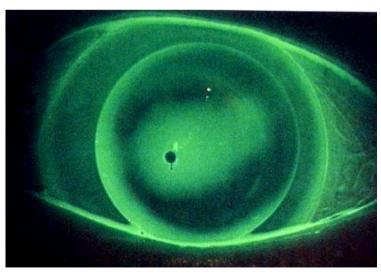


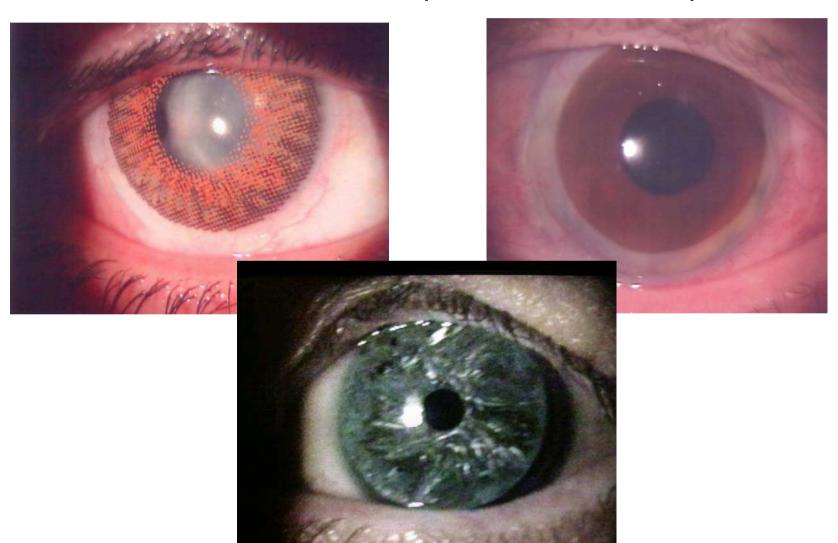
Protective or aesthetic reasons

- Entropium
- Recurrent corneal erosion
- artificial Irises or pupils
- Piggyback system

(flexible on top of soft lens)



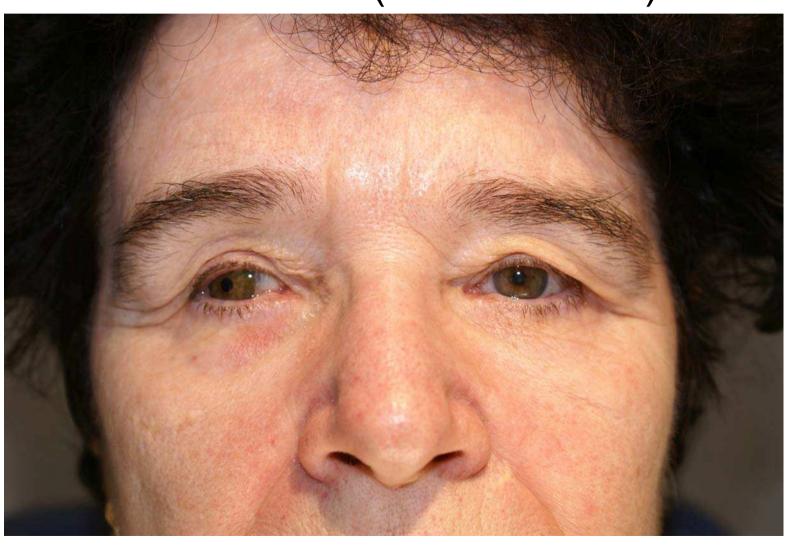




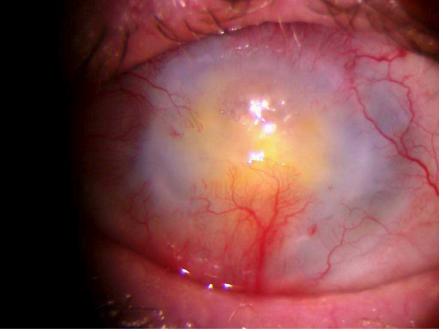


















After CL fit management

- -Regular Eye and CL checks (every 3, 6 or 12 months)
- -Check for subjective symptoms and wearing time
- -Check for Hygiene and lens care routine
- -Check for deposits, centration, movement and fit (fluorescein)
- -Check for physiological and physical integrity
- -Check for Vcc and refractive changes
- -Discuss the results and the prognosis
- -Make adjustments if necessary
- -Give final advices

Contact Lenses : Legislation Tarmed

Tarmed (1)

- In the Tarmed, you find positions for contact lens fitting, which is to be expected as Swiss Medicare does pay for contact lenses if certain conditions are fulfilled.
- There is a Contact lens committee of the Swiss Ophthalmological Society, who is responsible for this field.

Special categories where contact lenses will be paid by the basic insurance (1)

LiMA 25.02.01

CHF. 180.- per eye, once a year In case of :

- modifications of the refraction due to a disease à (i.e., cataract, diabetes, macular pathology, oculomotor muscle imbalances, amblyopia, following a medication)
 - following an operation

(i.e. cataract, glaucoma, retinal detachment)

Special categories where contact lenses will be paid by the basic insurance (2)

LiMA 25.02.02

CHF. 270.- per eye, once a year If:

- visual acuity is improved by 2/10 in comparison to a correction by glasses
 - myopia ≥ 8.00
 - hyperopia \geq + 6.00
 - anisometropia of at least 3 Diopters, in case of discomfort

Special categories where contact lenses will be paid by the basic insurance (3)

LiMA 25.02.03

CHF. 630.- per eye, without time limitations in case of :

- irregular astigmatism
- keratoconus
- pathology or lesion of the cornea
- a necessity after a corneal operation
- iris defect

Tarmed (2)

- 1st rule: the pre-fitting consultation. All the necessary investigations will be done as a normal ophthalmological examination.
- Then comes the fitting part. If it is done the same day, remember to register as a second session.

Tarmed (3)

• 2nd principle: frequent replacement lenses or dailies do not require a true adptation. That is why we recommend to use the following positions:

 00.0610 Instruction to patient by a specialist to teach him how to measure or treat, per period of 5 min.

PM 9,57 PT 9,34 5 min Total 18,91

Tarmed (4)

Simple Adaptation :

08.1510 PM 105.22 PT 142.31 Total 247.53 55 min (one eye) 08.1520 PM 143.49 PT 194.05 Total 337.52 75 min (both eyes)

Non-toric lenses

Validity two months

Materiel: Index 1.66

Tarmed (5)

Adaptation, difficult case :

08.1530 PM 143,49 PT 194,05 Total 237,52 75 min (one eye) 08.1540 PM 181,75.PT 245,80 Total 427,55 95 min (two eyes)

Aspheric, aphakic ou bifocal lenses

Validity two months

Materiel: Index 2.5

Tarmed (6)

Adaptation, very difficult case :

08.1550 PM 181.75 PT 245.80 Total 427.55 95 min (per eye)

Special or Keratoconus lens

Valable deux mois

Matériel : Indice 3.5

Tarmed (7)

Unilateral control of position after two months :

08.1560 PM 11.48 PT 15.52 Total 27.00 6 min (one eye) 08.1570 PM 19.13 PT 25.87 Total 45.00 10 min (two eyes)

Included change and possible cleaning by the specialist

Tarmed (8)

After two months :
 re use the same TARMED position if adpatation
 not yet completed

Tarmed (9)

For frequent replacement lenses or daily lenses:

Follow the instructions of the company. The prices should be those of the market.

European Health = an entity in construction

The 25 Mars 1957, the Treaty of Rome excluded from the European competence health problems

50 years later, one has to accept the weight of European authorities in the medical scene.

Responsibility of the manufacturer

R&D Introduction on the market

- Possibility to follow the track of the product
- indications for best use, requirement of explicit user's guide and complete information of the consumer
- declaration of any incident or accident to the responsible authority

Responsibility of the contact lens prescriber

- Clear and detailed prescription
- Complete information complete of the future contact lens wearer on the medical device
- Follow-up
- Information on the advised frequency of renewal
- Declaration in case of incident to the proper authority

Exemple of prescription for contact lenses

- Acuvue Advance
- OD 4.50
- OG 4.75
- R_o 8,3
- Daily wear (12 h. max.)
- Change every two weeks

- Care product : AOsept
- Change the case with every new bottle
- Validity of prescription6 months

Obligation of information

- On the hygiene
- On the lens care :
 - complete prescription of the products
 - their use
 - their validity
 - the change of cases....
- How to behave
 - when there would bea red eye, at the swimming pool...
 - driving
 - if there is prolonged wear...

MATERIOVIGILANCE

Health Ministry in each member state In Switzerland: Swissmedic

The Imputation

Every incident in connection with the medical device should be declared. The user has not to bring the proof of causality

The contradiction of the present situation

- Ambiguity of the European legislator placing the contact lenses and the products in class II, the same as the intraocular implants
- and the National authorities letting the supermarkets distribute lenses and products under the idea of free circulation of goods

Swiss situation with regards to afocal lenses

- European legislations are copied in Switzerland
- Swissmedic does not want to discuss afocal lenses before we have a series of disasters
- However the « Gebrauchsgegenstände, Kosmetika und Tabak » division has taken some measures to restrict the distribution of these lenses and inform the population

A few recommandations...

- Do not use, if possible soft trial lenses
- The rigid lenses that do not fit should be returned to the manufacturer Two possibilities:
 - a. there is no risk: the manufacturer may reuse them reutilize
 - b. there is a risk: indicate that the lens should be destroyed

Conclusions

- Have well established routines
- Remember to wash your hands before and after you have inserted a lens in the eye of a patient
- Be careful
- Avoid cases that look like making problems
- Ask for advice to the University Departments or the Commission of the Swiss Ophthalmological Society