Keratoconus Treatment with the Keraflex Procedure – 18 Months Follow-up

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Commercial Interest: NONE

Keraflex – non-invasive refractive correction procedure developed by AVEDRO

Procedure consists of two steps:

- Keraflex application by means of AVEDRO's VEDERA system
- Accelerated CXL Riboflavin 0,1 %; 30 mW / 3 minutes
- flattening of the cone / regularize the cornea / corrects refractive error
- possibility to improve patients uncorrected visual acuity
- increase the tolerance to wear contact lenses & glasses

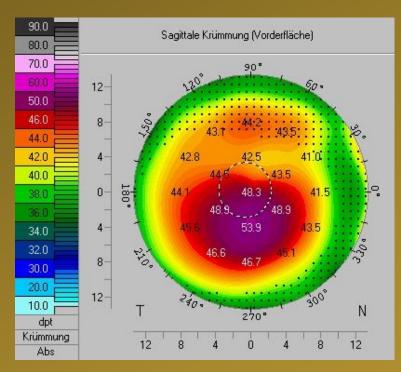
The VEDERA KXS system delivers a single low energy microwave pulse lasting approximately 50 milliseconds. This single pulse raises the temperature of the selected region of corneal stroma to approximately 65 degrees centigrade.

It shrinks the collagen and forms a ring-shaped lesion in the anterior 150 microns of the stroma. Simultaneously the neighboring tissue and especially Bowman's membrane are protected by an automated cooling process.

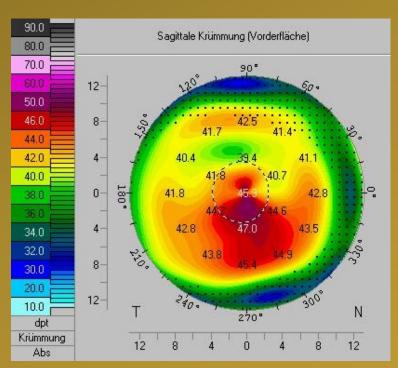
The shrinking process results in flattening the cone and helps to regularize the cornea. At the same time it corrects the refractive error that was produced by the steepening in part or completely.

We try to achieve an over-correction. Since collagen shrinking is only a temporary effect we stabilize the new shape of the cornea by applying the second step of the procedure: corneal collagen crosslinking.

Topography Pre/After Keraflex



Keratoconus Pre-Keraflex (KXL)



Keratoconus
One Week PostKeraflex (KXL)

Vedera system with accessoires





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Procedure Animation



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Post-Keraflex (12 months)

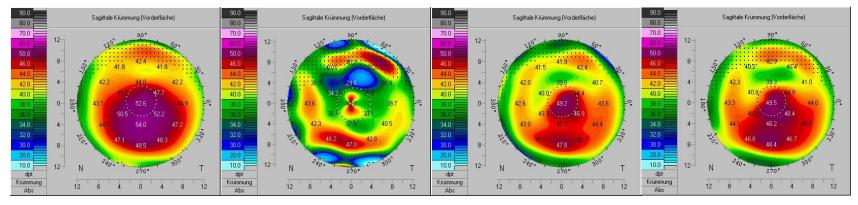
Post-Keraflex (1 minute)



We started performing the Keraflex treatment in October of 2010. Our number of patients is not yet sufficient to offer a general opinion on the procedure.

I will therefore present two cases which are typical for our early results. We test the visual acuity with and without pinhole, because the ring shaped lesion is disappearing overtime.

| PATIENT 1 | objective refraction | UCVA | UCVA pinhole | K1 | K2 | K1/K2 diff |
|------------------------|-------------------------|------|-----------------|------|------|------------|
| Pre-OP | -5,5 -0,5 / 108° | 0,12 | | 49,9 | 50,9 | |
| 6 months Post-KXL/CXL | +0,25 -1,0 / 156° | 0,4 | 1,0p | 44,6 | 45,2 | 5,3 / 5,7 |
| 12 months Post-KXL/CXL | -0,75 +0,75 / 137° | 0,6 | 1,0p | 44,7 | 44,9 | 5,2 / 6,3 |
| 18 months Post-KXL/CXL | -0,5 -1,0 / 129° | 0,4 | 0,6 | 45,3 | 46,6 | 4,6 / 4,3 |



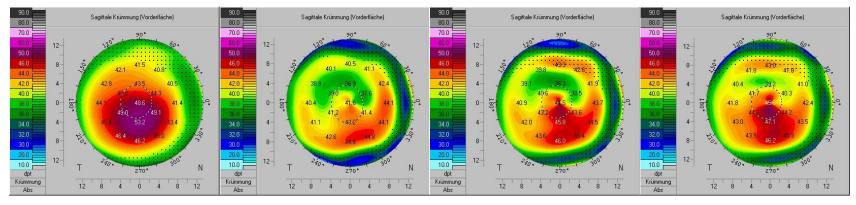
Pre-OP

Immediately Post-KXL/CXL

3 months Post-KXL/CXL

18 months Post-KXL/CXL

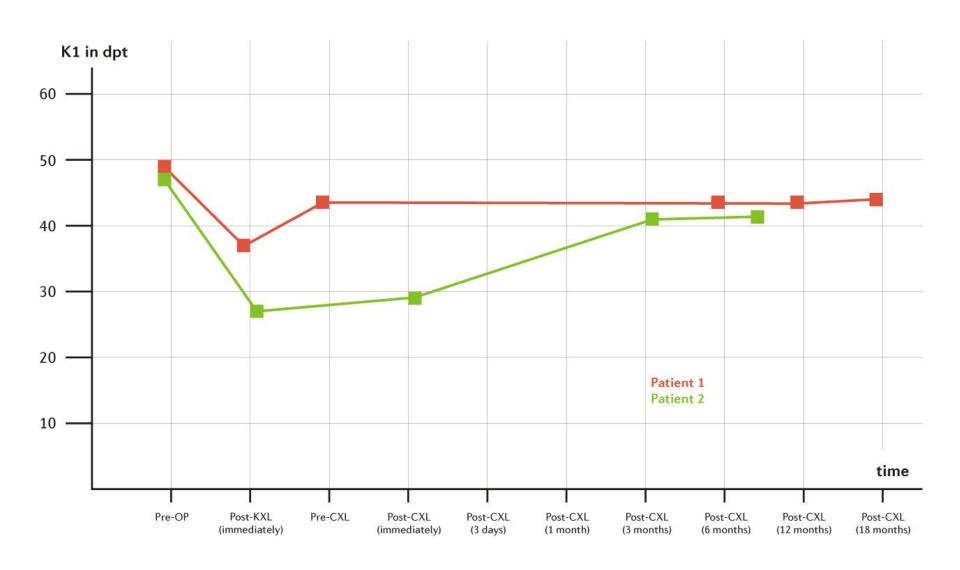
| PATIENT 2 | objective refraction | UCVA | UCVA pinhole | K1 | K2 | K1/K2 diff |
|-----------------------|-------------------------|------|-----------------|------|------|------------|
| Pre-OP | -1,25 -1,5 /77° | 0,5 | | 46,7 | 47,8 | |
| 3 months Post-KXL/CXL | 0,0 -0,25 / 99° | 0,5 | 0,8 | 41,0 | 43,8 | 6,7 / 4,0 |
| 7 months Post-KXL/CXL | +2,75 -1,0 /46° | 0,6 | 0,8 | 42,3 | 44,7 | 4,4 / 3,1 |



Pre-OP Immediately Post-KXL/CXL

1 month Post-KXL/CXL

7 months Post-KXL/CXL

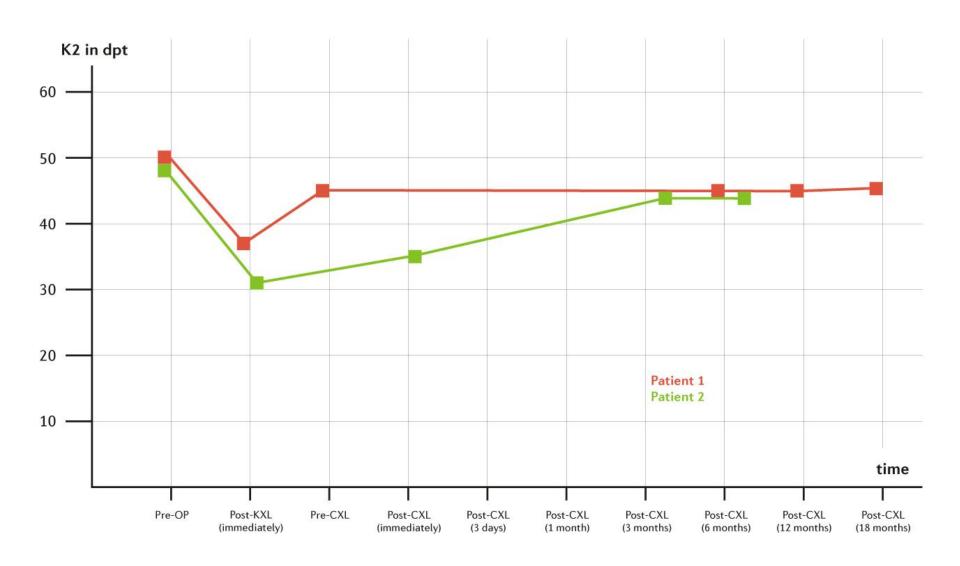


- typical initial reduction of up to 6 diopters in corneal curvature immediately
- also immediately regression → therefore crosslinking almost immediately after Keraflex

Further Research

short time high energy longer time low energy

crosslinking



Summary Keraflex

- brilliant method for flattening the cornea
- non-invasive & little time-consuming
- + improves uncorrected visual acuity
- + increases tolerance for wearing contact lenses & glasses
- not yet precise enough
- crosslinking not sufficient to prevent regression

Promising modality to correct keratoconus! Further research is necessary!

Thank You!

Paulig Augenklinik | Praxis

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