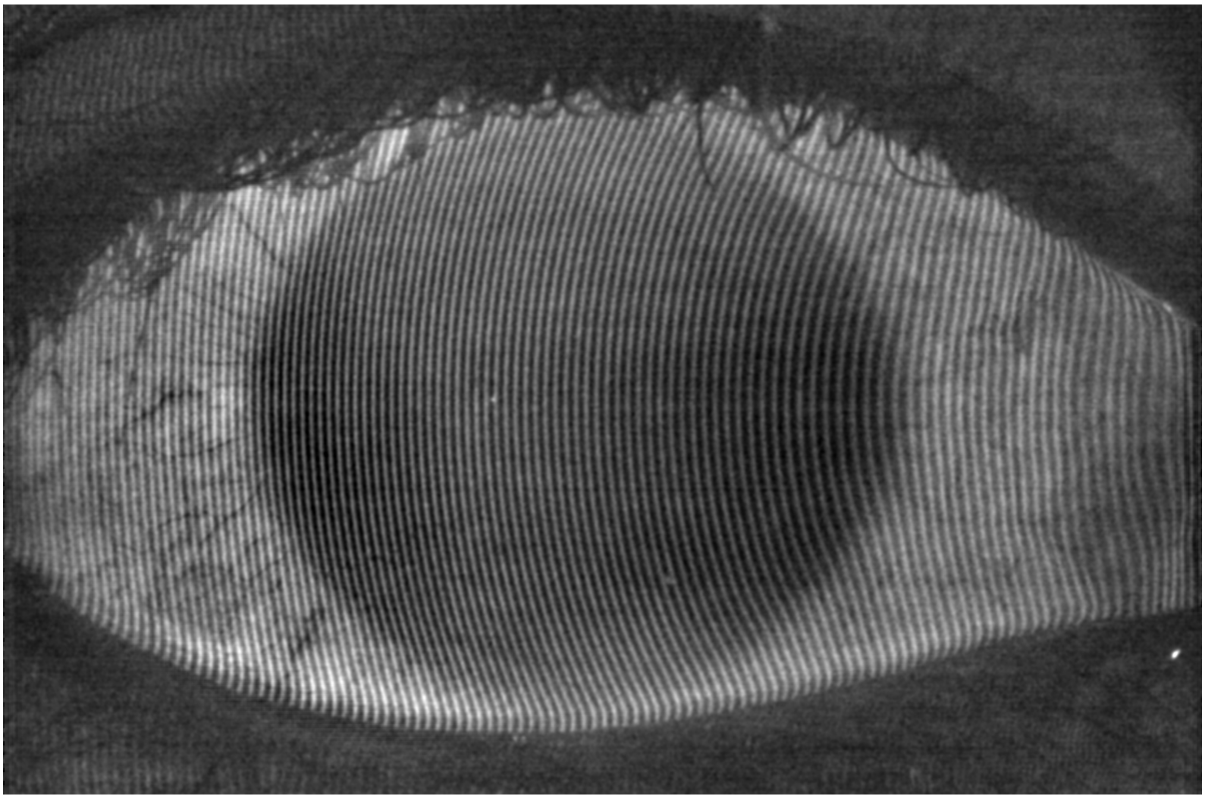
# Complications of
# Refractive Laser Surgery



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## Summary

The aim of this report is to give the reader an update on the latest results achieved with a technology that will improve refractive laser surgery outcomes considerably.

The report consists of two main chapters. In the introduction you will learn about the company BioShape. The current situation of refractive laser surgery and its perspectives are discussed. In the second part different findings of our clinical trials and their implications on the surgery's future are presented. The focus of this part is on the influence of the microkeratome cut and the peripheral ablation profile on the final outcome of the surgery. Both aspects might explain the relatively high incidence of night vision problems after surgery today.

In conclusion we have shown that today there are more risks associated with LASIK than with surface treatments like PRK or LASEK. We also have demonstrated the importance of an individual transition zone. Most of the surgeons and laser companies probably know about these risks but cannot eliminate them.

BioShape will continue its research and is now looking for a partner who likes to use the technology to learn more about today's hidden failures and who likes to find new ways to enhance his performance. The next step would be clinical trials on PRK and LASEK procedures as well as looking more deeply into microkeratome induced effects.


## Contact

Please contact us for more details on our technology and results. We at BioShape will be glad to answer any upcoming questions.

Please


- email to daniel@kluting.com or
- fax to +49 231 934 9004 (Europe).

# Introduction

## BioShape's background

The company BioShape was founded in 1999 by Stephan Schründer and Daniel Kluting in Berlin, Germany. BioShape has developed and patented a new technology to measure the eye's topography. This method has many advantages over existing systems in terms of accuracy and applicability. An outstanding feature is its usefulness for assessing the eye's shape even during refractive laser treatments.

BioShape's initial priority was to improve refractive laser surgery outcomes by assessing the eye's shape changes during the ongoing surgery. The 3d shape information would be used to fine tune the ablation profile resulting in an enhanced rate of successful refractive surgery outcomes. In other words: We have a controller which will insure that the laser procedure is performed correctly!

In the mean time we have widened the spectrum of applications towards general diagnostics connected with the eye's topology. A most recent example is the registration of single measurements with the eye looking at different directions to cover a field of more than 20mm diameter. This information is used to fit individual scleral lenses e.g. for keratoconus patients.

## Current situation of refractive laser surgery

About 8 Million patients worldwide have received corneal laser treatments to correct their vision. The predictability of the result has much improved over recent years. But still up to 20% of the patients require a retreatment. An even higher percentage complains of vision problems in low light conditions. These findings have a higher incidence for corrections above 5 diopters.

Unfortunately laser treatments of the cornea are known to still carry the risk of an uncertain outcome. And this fact was only slightly improved with the advent of refined diagnostics by wavefront aberrometers. Those machines can obviously only capture a fraction of the information which is necessary to plan the final outcome. Too many other factors influence the result. Refractive Surgery is still using the old technology, that the computer in the refractive laser is programmed and there is nothing that verifies that the laser works correctly. To adjust the laser to the individual cornea, that eye surgeons are using nomograms. Nomograms is another expression for the surgeon using guesswork and previous experience. With our technology we eliminate the guesswork, and confirm that the laser is actually performing the prescribed ablation.

In our clinical trials we are looking for answers to the following questions:

- What are the reasons of variable outcomes?
- What needs to be done to reduce the percentage of complications reliably and consistently?
- How can the worldwide acceptance of the method be increased?

Every treatment aims at individually optimizing the cornea's outer surface shape by remodeling it with high precision. A laser ablation profile is calculated based on sophisticated diagnosis. This profile is supposed to transform the cornea's shape. Until BioShape came up with their technology in 1999 there was no instrument on the market which measures the whole cornea's shape sufficiently accurate and well enough in the periphery. This new technology allows comparing the postoperative with the initial shape and it reveals the treatment effects altogether. Flap induced and other biomechanical effects as well as healing effects become visible.

We can get a much better understanding of all processes contributing to the final result. This will allow us to optimize future treatments and to reduce the incidence of unhappy patients. In addition it will enable to diagnose previously treated patients with unfavorable outcomes and to offer them an individual solution for their vision problem based on a refined diagnosis.

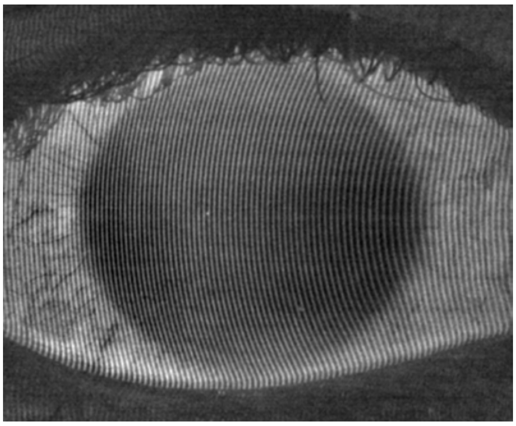
## Preliminary observations from clinical studies

In the course of clinical trials a variety of yet unknown effects were observed and quantified. Some of them are probably responsible for the relatively high incidence of night vision problems as they persist even until long after the surgery. Especially biomechanical reactions on the microkeratome cut and on the ablation profiles were in the focus of the investigations. Several assumptions were proven for the first time with real data. While the technology had previously discovered the effects it might in the future help to prevent them by adapting the procedure accordingly.

The clinical trials were initially performed to evaluate the potential capability of the technology to predict the outcome of LASIK treatments. Unfortunately the surface measurements were obscured by those biomechanical effects. So we could not demonstrate the predictive value of the technology for LASIK during these first trials. On the other hand we learned from a few PRK patients that our technology is well capable of an online control as originally intended. Right now we would like to share what we have learned about the side effects of LASIK.

## Measuring principle and results

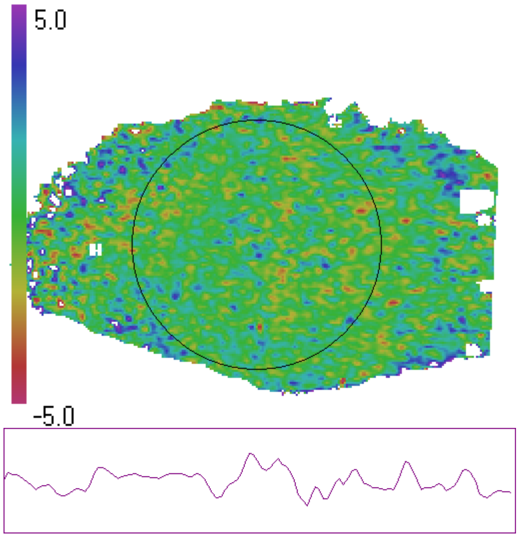
A UV pattern of parallel lines is projected onto the eye's surface. The pattern excites both cornea and sclera to emit fluorescence light which is detected by a camera. No liquid or tear film is needed. The lines appear bent due to a triangulation angle between projection and detection. The surface height information is calculated from the bent lines to an accuracy of a few microns.



Fluorescence pattern

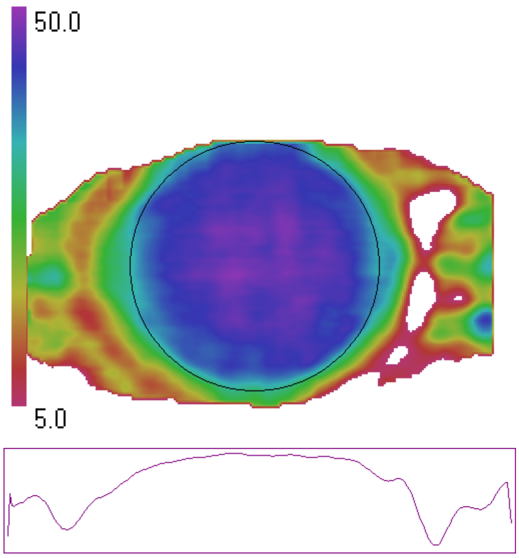
Well established algorithms are used for the registration of surfaces in 3d space. The surface data of the sclera allows doing this when the center is altered e.g. by a laser or a microkeratome.

The picture shows the difference of two separate measurements of the same eye (circle = 10mm diameter). The measurement and registration accuracy together are in the order of a few microns. A cross section along the line is given below the difference map.




Difference map and cross section

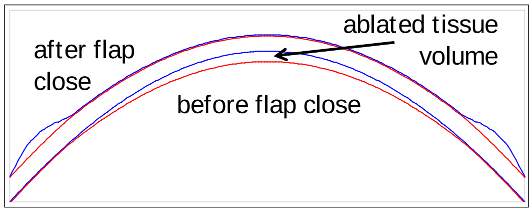
More informative maps can easily be derived from 3d height data. Especially curvature maps become independent of an axis which is a common source of misinterpretation today. Placido ring based topographers cannot measure height maps directly. Here is an example of a mean curvature map of an eye's surface (cornea with limbus and sclera, scale in diopters, circle 10mm). No other technology currently available can measure such a large area with such high precision. Normal topographies are restricted to the central 6-8mm diameter with decreasing accuracy towards the periphery.




Curvature map and cross section

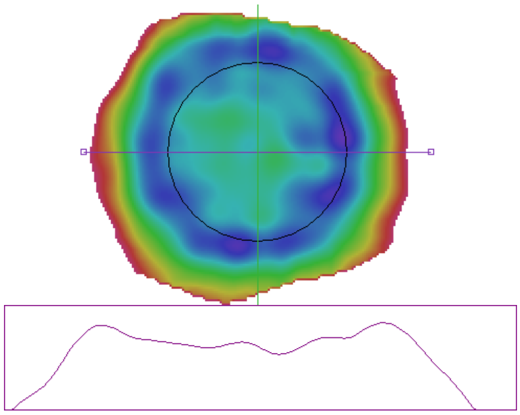
## Microkeratome associated effects

Microkeratomes are used to prepare a corneal flap under which the laser treatment is performed. While the laser pulses ablate stromal tissue the flap is folded away along the hinge. After finishing the treatment the surgeon repositions the flap in the bed. This is when two problems occur.



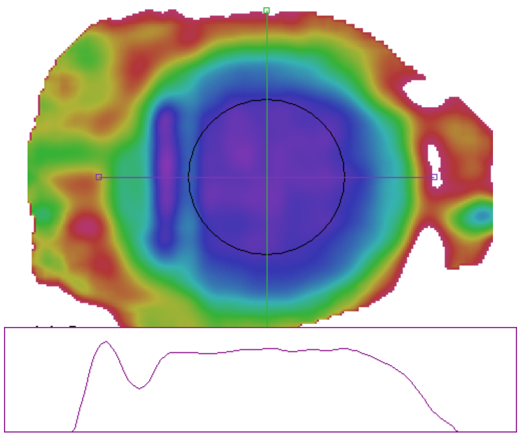

Flap (blue) and bed (red)

**A.** The flap (blue line) does not fit in the bed (red line) any more after the treatment as the myopic ablation decreases the size of its underlying surface. So the flap will pile up peripherally at the barrier of the bed’s edge (upper curve). On the right is an example of the bulging. The peripheral curvature is up to 7 diopters larger than the central curvature (black circle = 6mm).



Curvature after flap close
with peripheral bulging

**B.** A fold remains in the flap at the hinge position. This results in a curvature gradient. Here is a picture of an eye after completed wound healing. Note the blue vertical area which separates the violet sea. There the curvature drops by about 7 diopters. The effect starts at less than 3mm from the center (black circle = 6mm). In other examples the effect was up to 12 diopters. This might depend on the flap thickness.

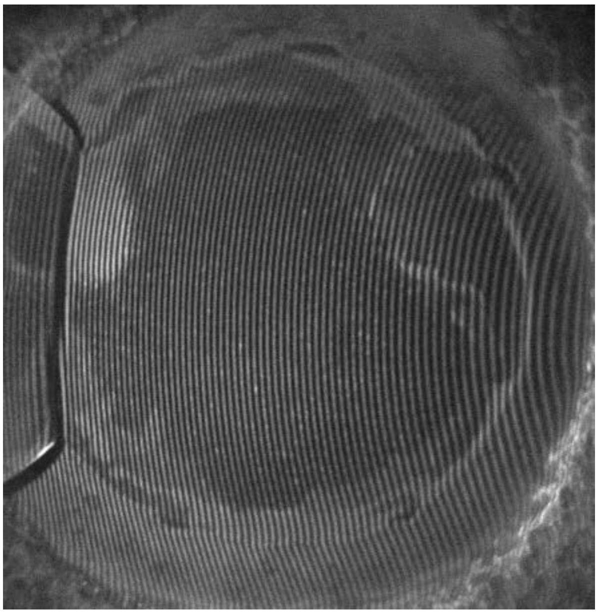


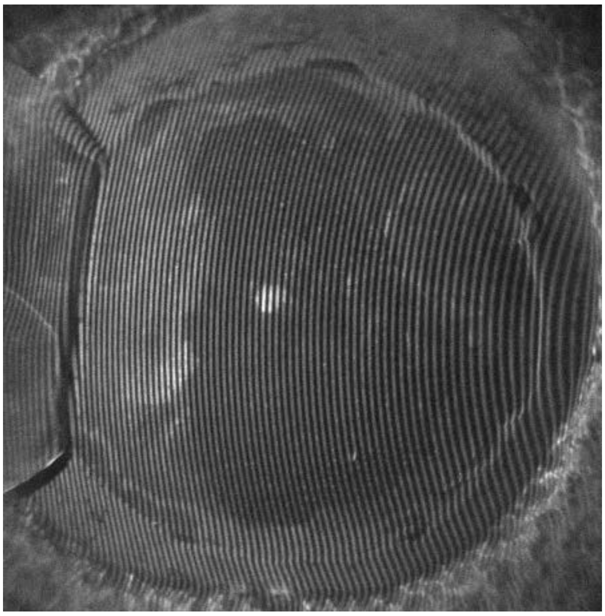
Curvature after flap close
with hinge fold

Both effects were observed even many weeks after surgery in corneal regions that other instruments cannot measure. The induced changes often reach well into the optical zone. This probably influences the cornea’s night vision performance. The effects have not yet been described in the literature. Obviously they do not occur with PRK which seems to be much safer in this context.

## Epithelial ingrowth

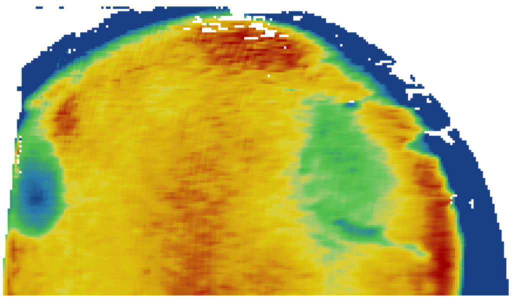
Epithelial cells migrating under the flap are a common problem. A solution is to lift the flap and mechanically scrape the cells away. Unfortunately sometimes the surgeon cannot see the cells well enough as they are transparent. A system which visualizes the piles of cell layers would help optimizing the procedure. Here is an example.

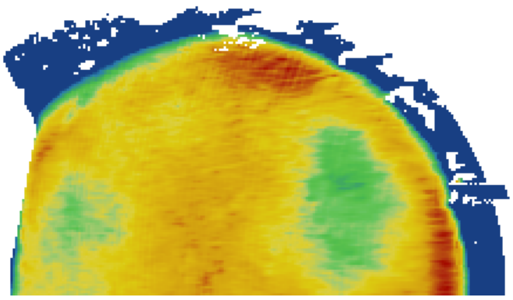




Before… … and after scraping

The white cells on the left are well visible under the laser's microscope. Those on the right are not. Hence the surgeon using visible light to see the cells can only remove those on the left. Here is the result.





Before… … and after scrape

The colors show height maps after subtracting a best fitting sphere from the bed. The height of the cell area on the left was much reduced while there is hardly any change on the right. So if the right cells were also responsible for the distorted vision they are still present. This example shows that the technology can help the surgeon to visualize irregularities which can compromise the patient's vision. It can thus support him to manually optimize the surface.

## Blend zone

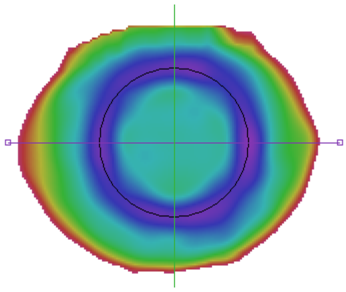
The blend zone connects the circular area of fully corrected treatment according to Munnerlyn with the non treated region. A smooth transition is required to prevent a sudden curvature change which might compromise the night vision quality for large pupils. The transition zone adds to the Munnerlyn profile resulting in a deeper over all ablation depth.

We applied a Munnerlyn treatment with -5 diopters at 6mm optical zone to experimental clinical data in a computer model. Linearly tapered transition zones with different height shifts (0, 20µm and 40µm) extending until 9mm were added. Finally an individual transition zone calculated from height data was compared.

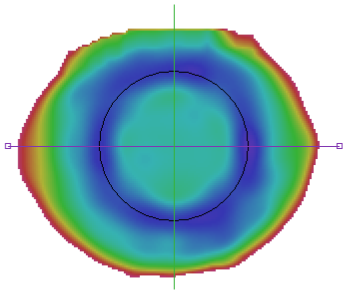
The cross sections show the differences of the resulting curvatures. All treatments show elevated curvatures in the periphery. Increasing the shift of the linear transition zones lowers this elevation. However the individual transition zone gives the best result considering height of the elevation and its distance from the optical center simultaneously. The gradient of these values might be important for good vision at low light levels.

This strongly supports the idea to generally optimize the transition zone based on high resolution 3d surface measurements.

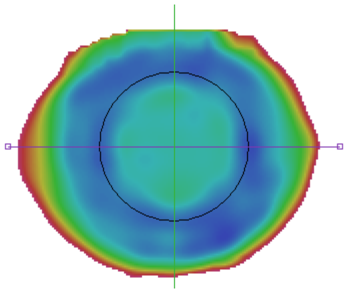
Curvature maps:



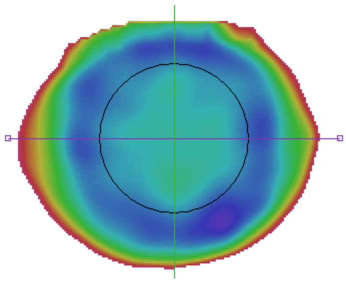
no transition zone



linear transition with 20µm shift



linear transition with 40µm shift



individual transition