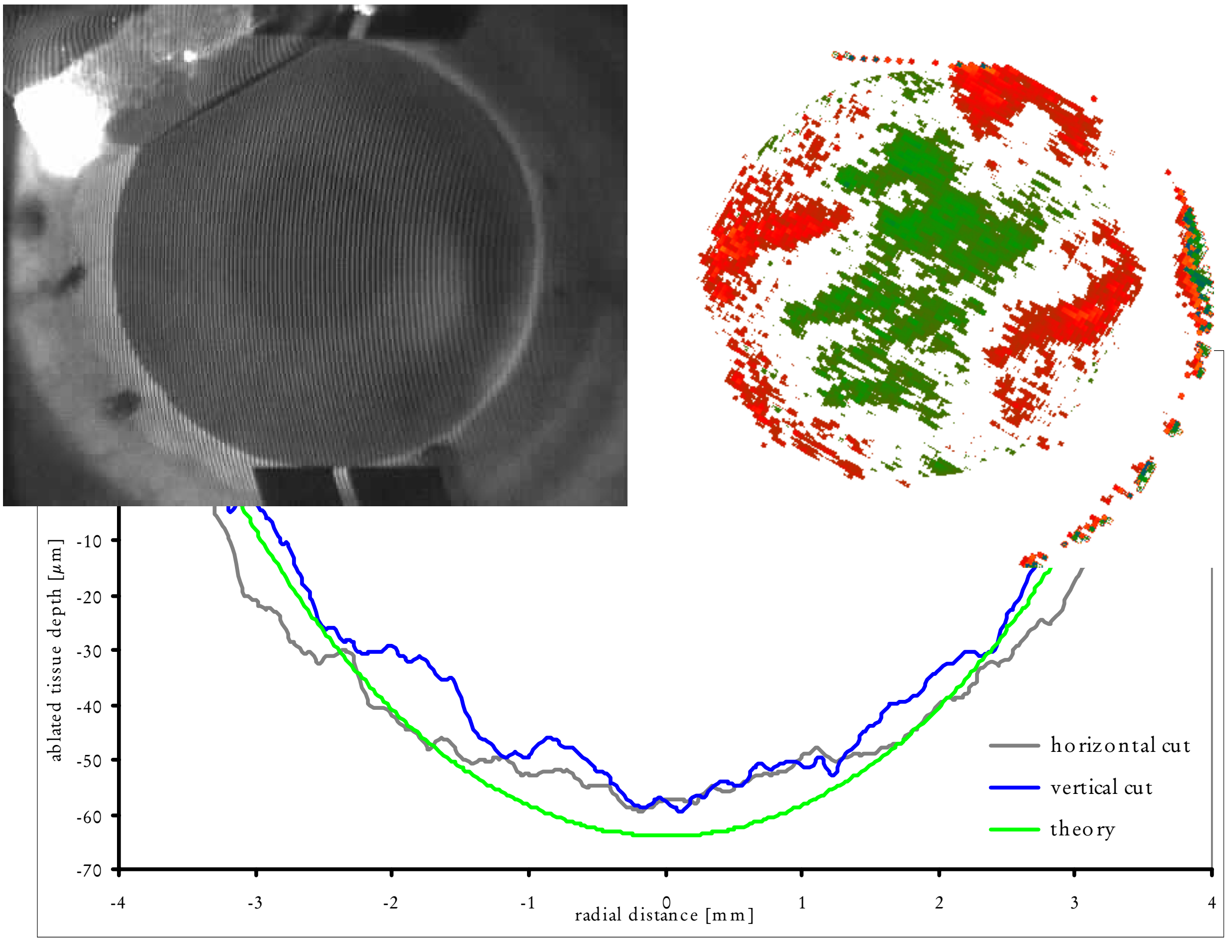

First results of intraoperative topometries during LASIK operations of

BioShape

VisuMed®

S.Schründer, MS and G.Fiedler, MD

September 2000

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1 Motivation

Today averaged results when considering a large number of LASIK treatments are quite excellent. Nevertheless there is still considerable scattering of the outcome. Depending on the location up to 10% of the patients require retreatments due to under/overcorrection or irregular ablation. One of the main reasons for the deviation can be found in the individual ablation rate of different patients' corneal tissues.

As the modification of nomogramms cannot cope for these individual variations, intraoperative topographies are mandatory to establish an online control of the ablation process which will thus enable an instantaneous adjustment of the excimer laser.

First clinical trials of an intraoperative monitoring of the ablation process during laser treatments for vision correction (LASIK) were done in August 2000. S. Schründer, MS, of Bioshape AG provided the apparatus for collecting the data. G. Fiedler, MD, performed the refractive procedures with a Bausch and Lomb Keracor 117 laser at the VisuMed AG laser center in Munich and also evaluated the pre- and postoperative clinical data of the patients.

The aim of the study is to evaluate this promising new method and to prove its potential to increase the safety and reliability of laser vision correction. VisuMed AG and all ophthalmic surgeons associated with this leading German supplier for refractive surgery have a vital interest in the method to improve the quality of the service offered to their patients. As they are directly confronted with correction problems they sre very interested in using the most recent and best technology. Thus exemplary cases of significant intraoperative topometries are presented in this report.

The company BioShape AG has invented the method and built a stand alone system to perform clinical trials. These trials have been the next logical step on the way to an incorporation of the method into a commercial laser system. Until the end of October further trials will increase the number of patients. These results will be presented at the ISRS conference and at the AAO show.

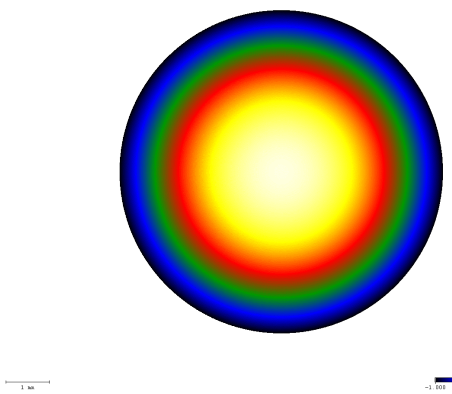
2 Introduction to elevation maps

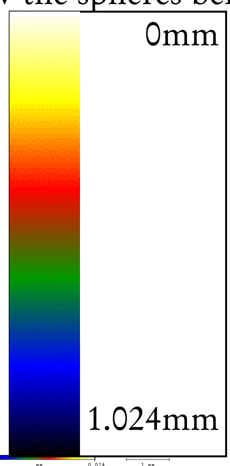
BioShape's intention is to give you an insight into what the laser does to the cornea while it is working. This is achieved by assessing the corneal topology during the treatment with extremely high precision. But our data differs from what you are used to from your placido ring based corneal topographer.

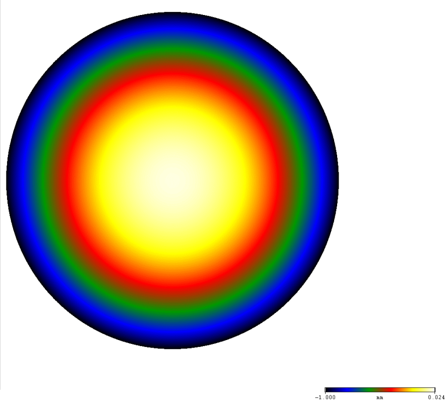
These corneal topographers display so called power maps. This makes sense as it is the refractive power of the outer surface which plays an important role when it comes to correcting visual errors with a laser. These machines help you to understand what the corneal curvature was before the treatment and what it is some time after the treatment. Unfortunately the machines require and actually measure the tear film which is absent during the operation. They also need to interpolate the data as their spatial resolution is very limited.

Rather than looking at the curvature or power of the cornea exact height data is required for a real time treatment control. The change in curvature is related to the change in height. Nevertheless height data will give you a direct feedback of what happens during the treatment as each laser pulse changes the height of the cornea. Let's look at an example:

Consider a spherical correction of -3 diopters starting with a sphere with 7.49mm radius (45 diopters). The correction increases the radius to 8.024mm (42 diopters). The following two images show the spheres before and after the correction.



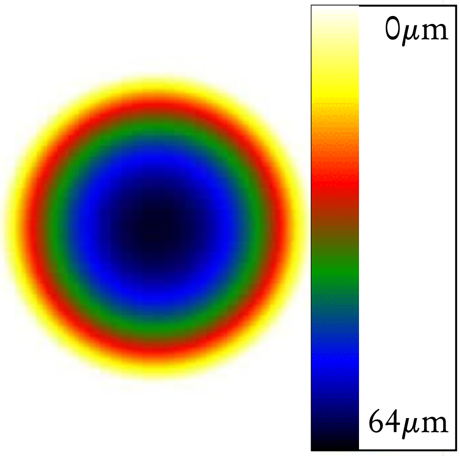




45D Sphere 42D Sphere

Each color represents a specific height in relation to a fixed horizontal plane. In these two images dark means approximately 1 mm below this plane whereas white is nearly in the plane. As the color scales are the same in both images the left sphere with the smaller radius appears slightly smaller in size as the dark colors are reached at a smaller radial distance..

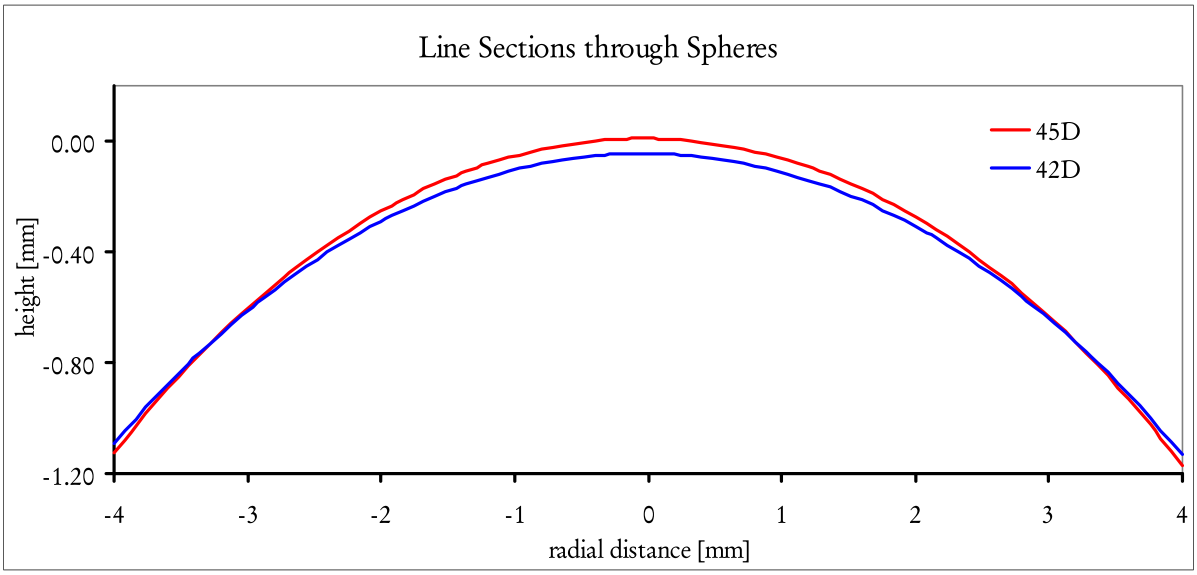
Let us take a look at the difference of these two spheres which would have to be taken off by the laser. It is shown in the next figure.



Difference between 45D and 42D spheres

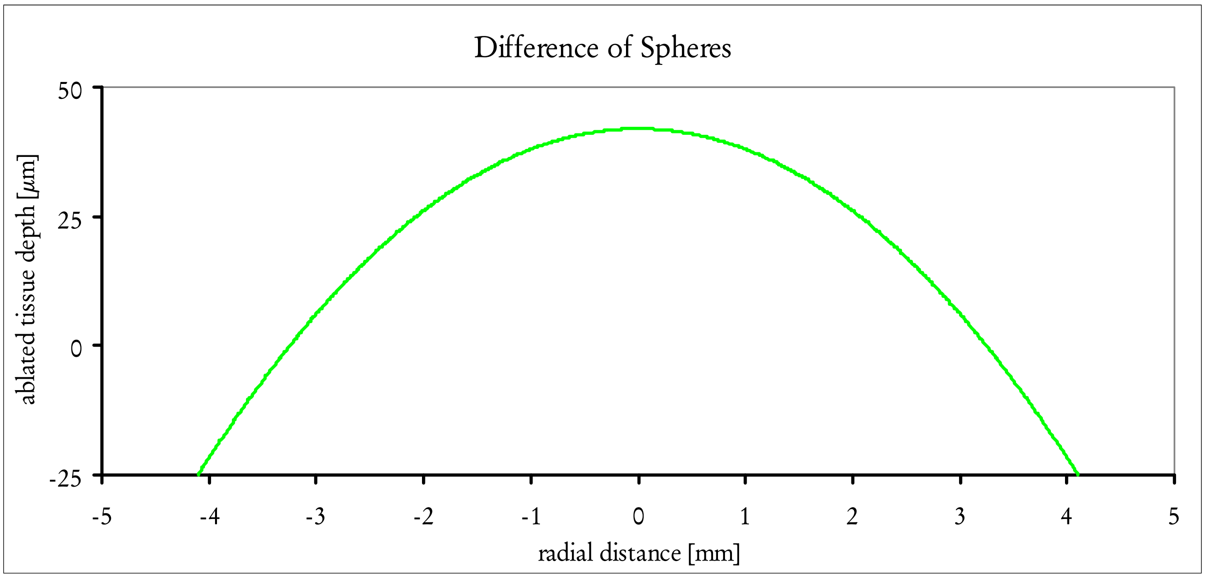
Please note that the color scale has decreased by a factor of 16. The height difference between white and black in this image is only 64 microns whereas it was 1024 microns in the images above. This difference is also given by Munnerlyn in his famous formula in the mid 80s. It means that in order to increase the radius of the sphere (as for correcting myopes) the center needs most tissue removal. This amount decreases towards the periphery. In other words the difference between the two spheres is again a sphere which has a much larger radius.

The situation becomes much clearer when looking at line sections through the spheres. This is done in the following images.



The two lines represent cuts through spheres with 42D and 45D. Please note that the scale of the vertical axis is twice that of the horizontal axis. This means that the difference between the two lines appears twice as large as it really is compared to the radial extension of the lines. To mimic a real treatment the 42D line is intersected by the 45D line at +3.25mm and −3.25mm yielding a 6.5mm treatment zone. Thus the difference between these curves would have to be taken off by a laser.

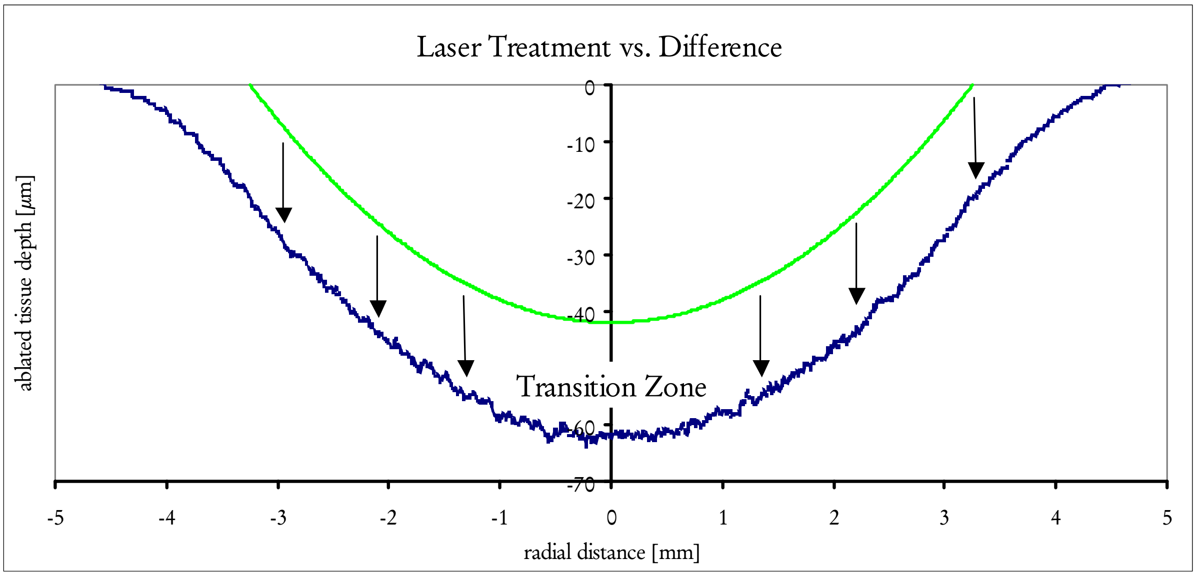
This difference is shown in the next graph:



Note that this time the vertical axis is in microns. Considering a 6.5mm optical zone of exact correction about 45 microns would have to be taken off in the center for the -3 D treatment. This corresponds well with the famous 12 microns per diopter rule. Outside the optical zone the difference becomes negative. This means that tissue would have to be added to reach the same sphere radius there. As this is impossible the correction outside the zone is not exact any more. Here the transition to the original radius starts.

How does a laser achieve this treatment? A broad beam laser is easily capable of reproducing the ablated sphere by using a diaphragm. Circles with different radii are superimposed to yield some sort of an amphitheater corresponding to the desired sphere. This is what the Visx laser does.

Flying spot lasers cannot do this as they apply smaller spots. They cannot reach the exact shape up to the border of the optical zone. Thus they require a transition zone. The following image shows the transition zone of a Bausch & Lomb Keracor 217 laser for the same treatment of –3 diopters at 6.5mm optical zone. The original difference sphere is also shown in green color to compare both.



The transition zone adds to the tissue amount that needs to be taken off for the –3 D correction in the optical zone of exact treatment. This means that the same treatment requires more tissue which is indicate in the figure by the arrows. In this example (6.5mm zone, -3 D) more than 60 microns will be ablated nominally. The same sort of shape would have to be expected from the clinical measurements.

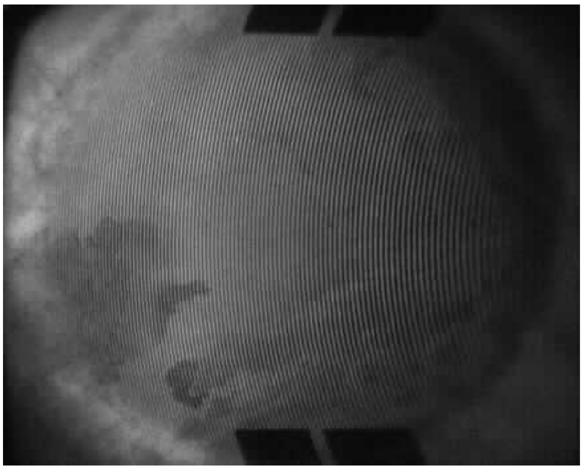
BioShape's first clinical trials were done on a Keracor 117 laser that exhibits the above mentioned transition zone. The optical zone of most patients was well above 6mm which resulted in treatments extending out to more than 9mm. The measurement system currently covers up to 9mm diameter. Thus nearly all of the treatment zone could be observed.

3 Clinical study

The study was performed on six eyes of six patients all receiving LASIK treatments by the same surgeon. The Keracor 117 Laser (Bausch & Lomb) was used. The following table gives the relevant patient data:

Patient #	Prescription D	Optical Zone [mm]	Transition Zone [mm]	Nominal Tissue Depth [μm]
1	-3.5 -1.5/0°	6.3	9.5	100
2	-3.75	6.5	9.5	77
3	-1.75	6.8	9.5	40
4	+2.25 +0.5/90°	6.0	9.5	53
5	-4.5	6.1	9.2	79
6	-5.0 -0.25/150°	6.3	9.5	103

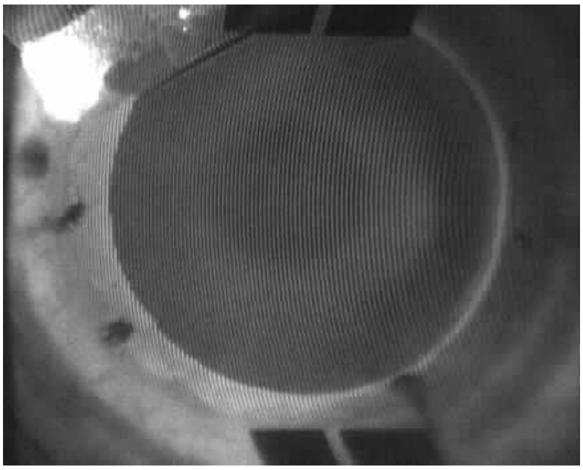
All patients were treated according to well established standardized procedures at the VisuMed Laser Center in Munich. Measurements were taken with an external, stand alone uv fringe projector with an excimer laser on board. Fluorescence fringe images were recorded before the LASIK cut, after the cut with closed and opened flap and immediately after the treatment. Here are some example images:



Before LASIK cut (plain epithelium)

After the LASIK cut

The epithelium exhibits some areas of lower fluorescence intensity which might be connected with touching it. Vessels in the sclera can be seen. After the cut the sponge on which the flap will be laid on is already in place. Also the ink marks to recognize the original position of the flap in case of an accident can be seen. There is also a reflex of a light bulb which was not switched of.



Before treatment (open flap with sponge)

After treatment

The fringe contrast is constantly high over a wide range under the flap. This makes the evaluation process easier. A slight downward shift of the eye in between the measurements can be observed. This shift is detected using the marks. It is accounted for in the evaluation process.

4 Results

To assess the tissue amount taken off by the laser the fringe images recorded before and after the treatment were evaluated. This was done using a specially developed software. All relevant geometrical data as magnification, projection angle and fringe period as well as thresholds to detect the fringes and several image processing features to enhance the stability need to be entered.

The resulting elevation maps of each individual image require a proper alignment to enable a meaningful subtraction of the height data. As a shift of the eye is always associated with a tilt that cannot be neglected sophisticated algorithms had to be found. Although the measurements extend beyond the optical zone we have limited the evaluation to this region as it is comparable to the theoretical data. We cannot compare the transition zone as its shape is not disclosed by the manufacturer of the laser.

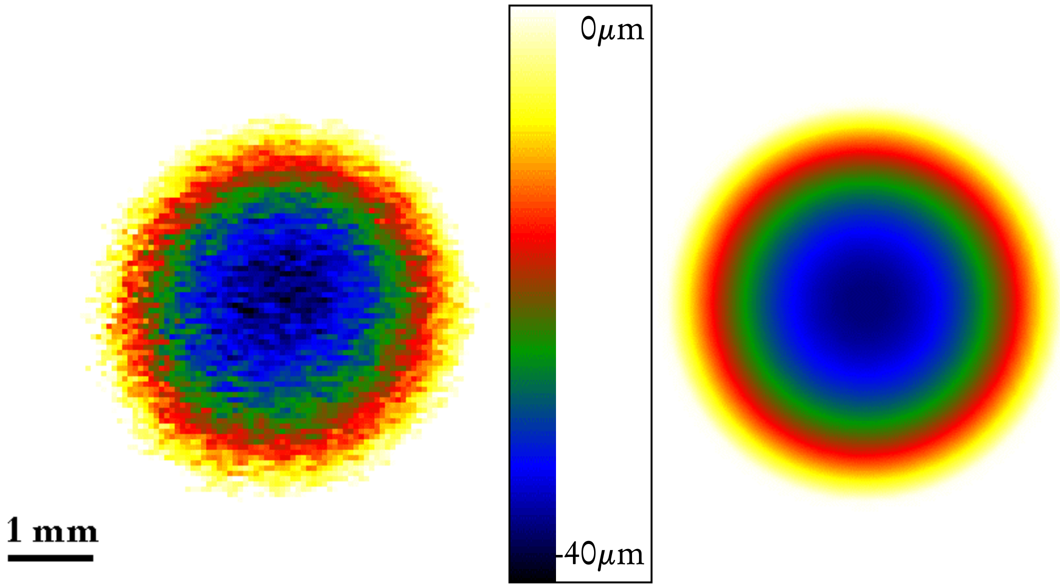
The following pages will show difference maps of a variety of patient treatments. They disclose how much tissue was ablated by the laser in which region of the cornea. These difference maps are compared to ideal treatments as derived from theory. The theoretical map was built such that its colors correspond well with the measurements. The deviation from this intended correction map is also given for better visualization purposes. Finally a horizontal and a vertical cut are displayed to reduce the findings to two dimensional representations. Here again differences are shown.

As these measurements have only recently been evaluated, the close connection to the patient data still has to be established. By the time of this writing there was preliminary data available from the patients.

The first example is a porcine cornea which serves somehow as a reference of an ideal treatment without any eye movements and decentration.

4.1 Porcine corneae

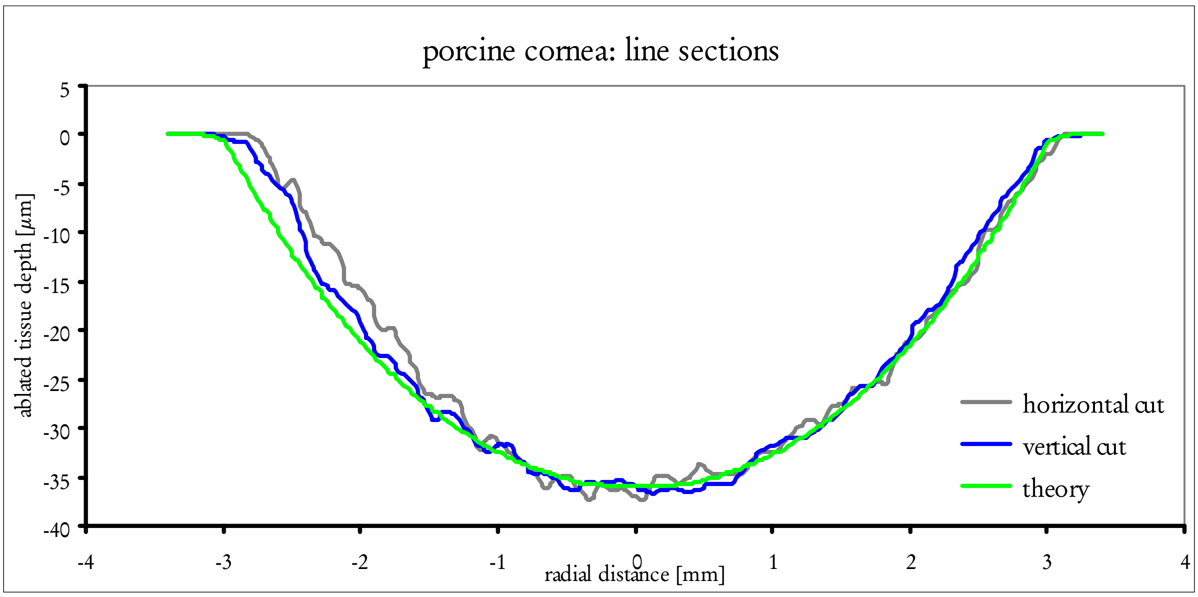
We first did measurements on porcine eyes. Here is an example for a –3D treatment:



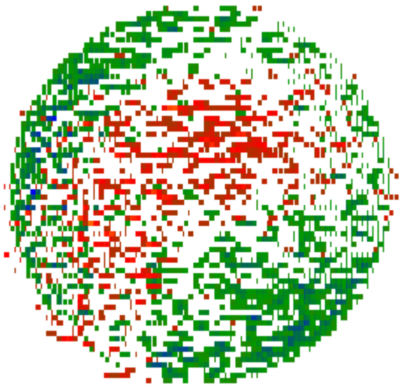
-3D porcine cornea treatment -3D simulation

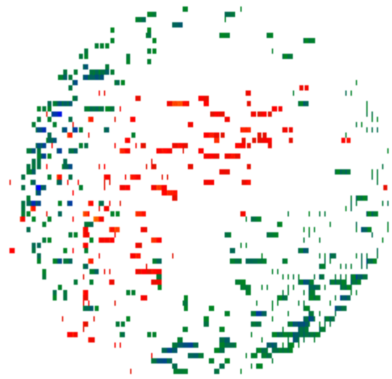
The color coding of the height values is identical in both images in covering 50 microns from bright to dark. This makes the colors of the two images comparable. The diameter corresponds to the optical zone of 6mm. The treatment is well centered and symmetric although the ablated surface is much rougher than in the simulation.

Here are two line cuts through the center of the treatment that are compared to the theoretically expected shape:



The difference between the treatment and theory color maps clearly reveals in which regions of the cornea the laser shape differs from the intended shape. Here are the resulting color coded images:

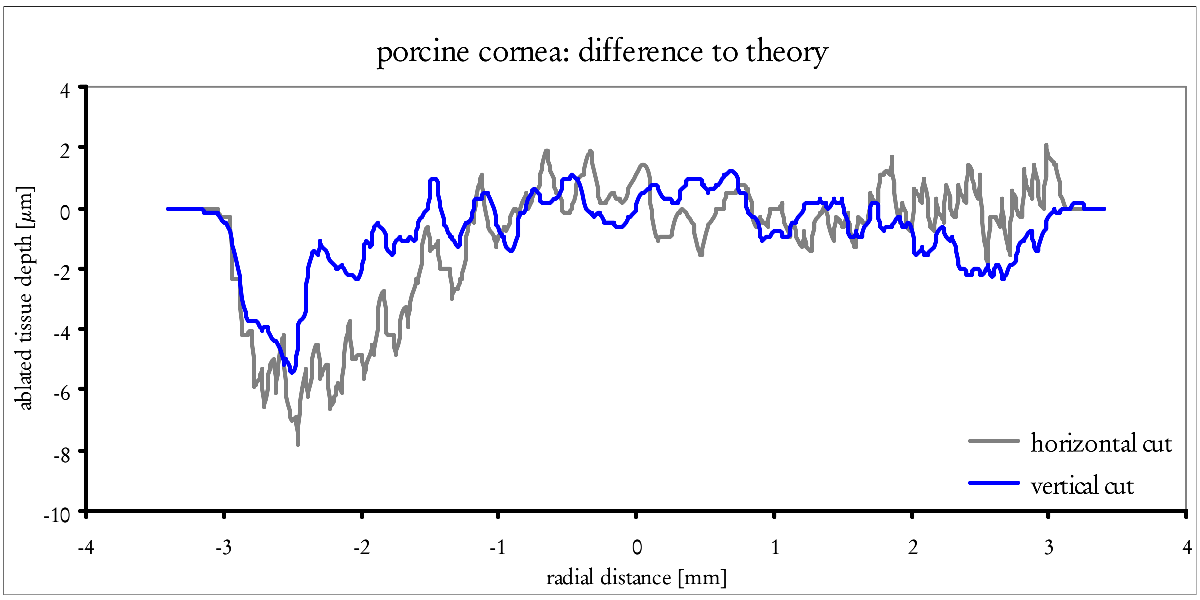




Difference with +/- 2 microns tolerance... ... and +/- 4 microns tolerance

In these images the red areas indicate regions in which too much tissue was taken off. The green regions still need further ablation to give the desired shape. White areas are within the tolerance range given below the images. In the left image the deviation from the optimum seems larger than in the right image. This is because the range of acceptance was increased from the left to the right image. As more false treated regions are accepted in the right image it is whiter than the left one. Similar images with a constant acceptance range of +/- 5 microns are given for all patients.

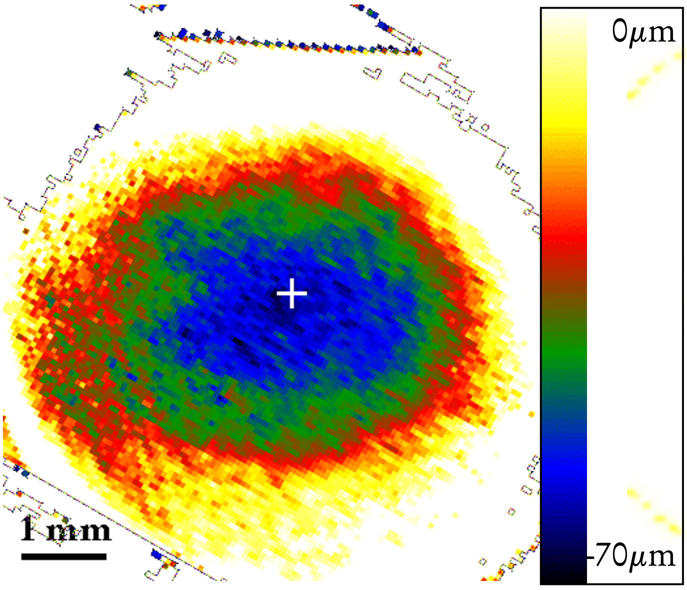
The difference between the central line cuts and the theory is shown in this graph:

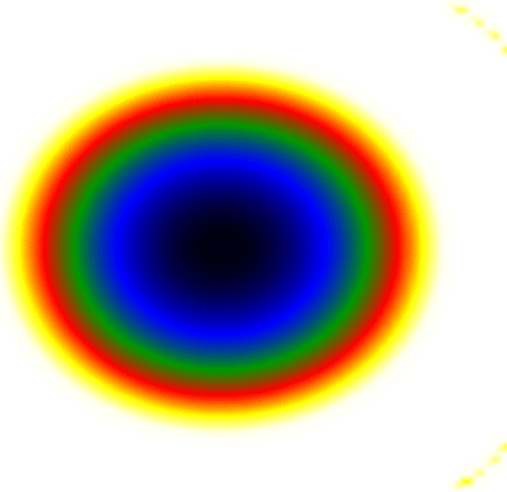


Some of the roughness below 2 microns can be attributed to the measurement itself. In this graph it is most important to have horizontal lines no matter at which height. The height is only an offset which does not influence the shape that is responsible for the refraction. So the more horizontally the curves are, the better the treatment was.

Let us now take a closer look at the patient data. Again images of the treatments are compared to simulations with the same color scales for both of them. You will always find a cross in the treatment maps which represents the center of the pupil.

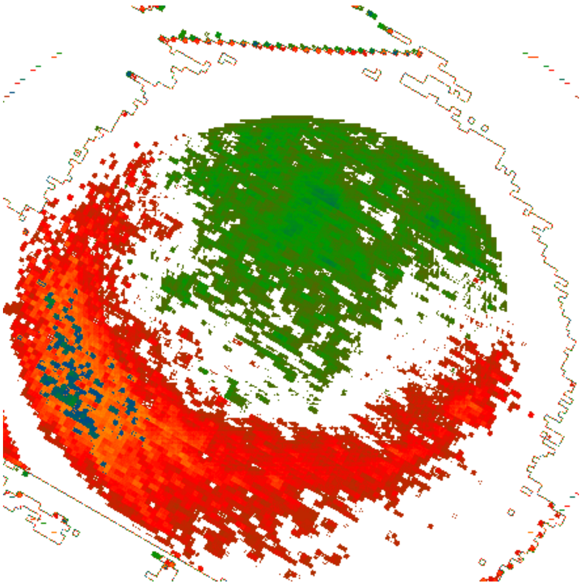
4.2 Patient 1:





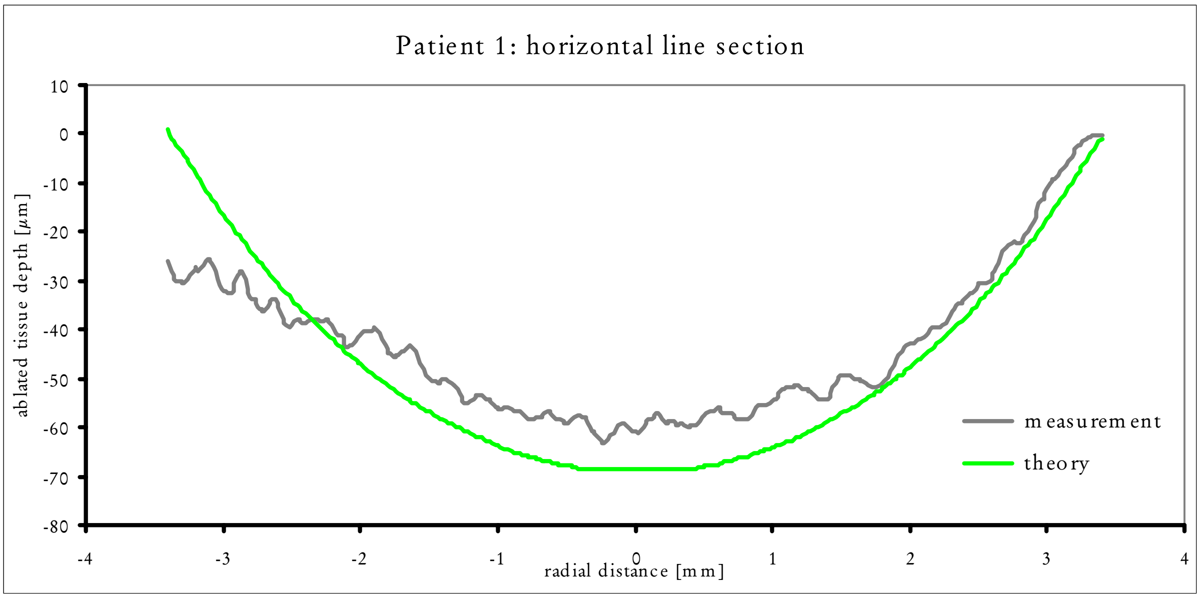
-3.5D ^ -1.5Dx0° treatment

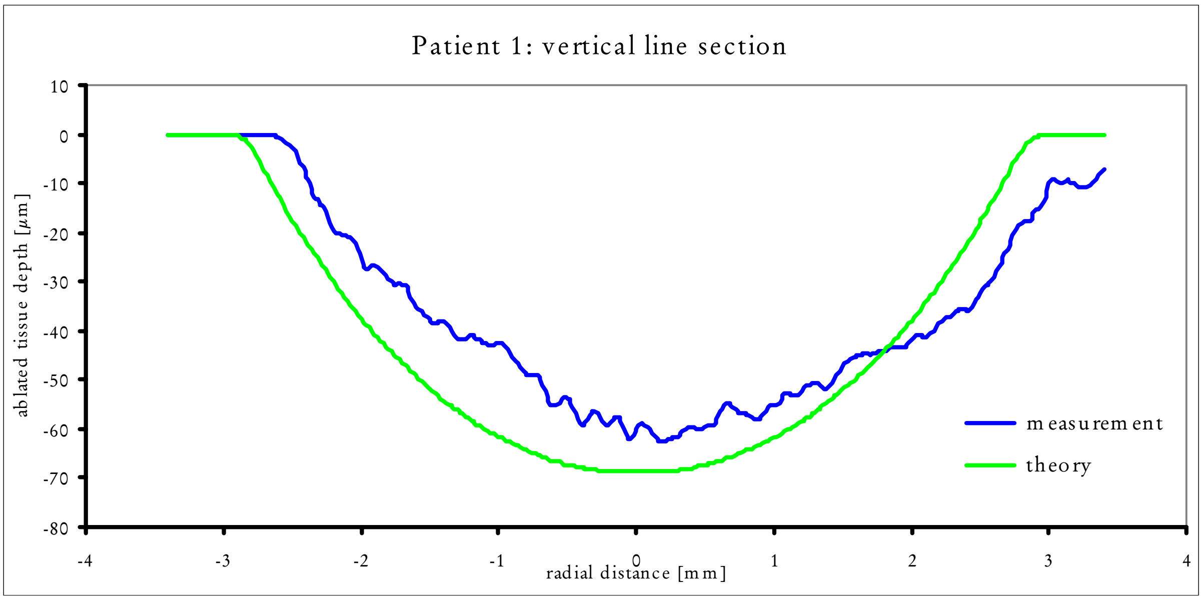
-3.5D ^ -1.5Dx0° simulation

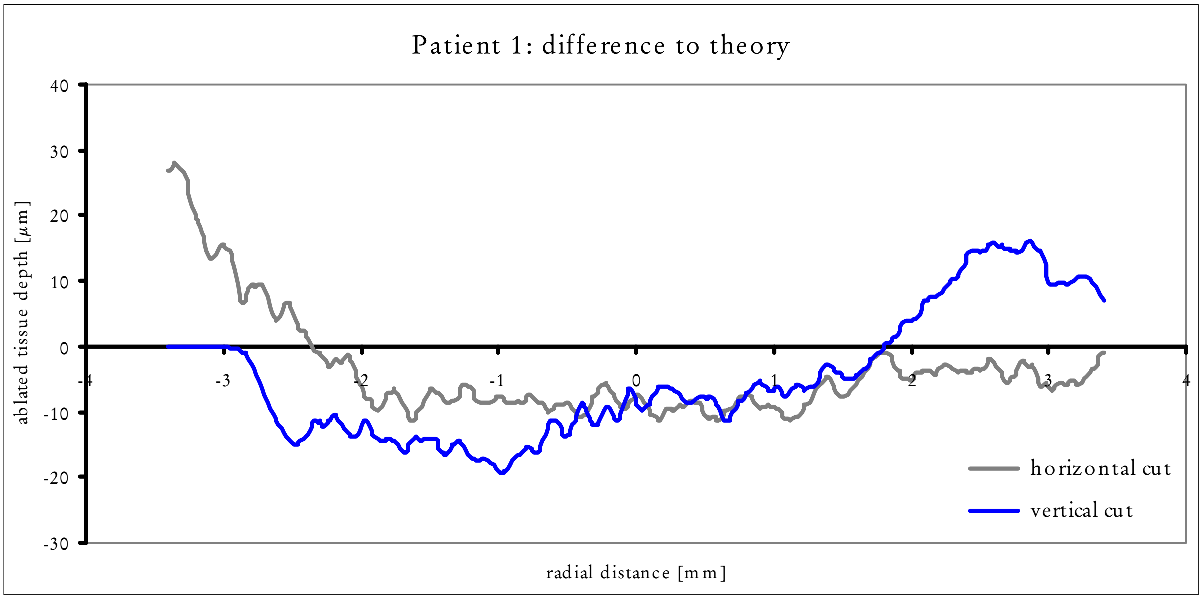


Difference map of Pat. 1

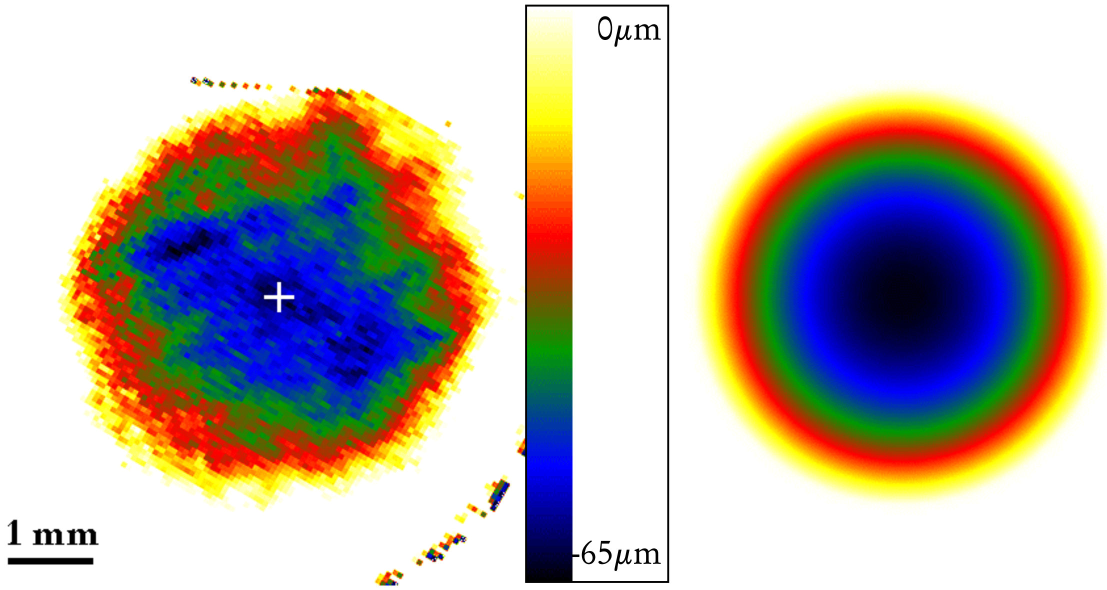
This patient received an astigmatic correction which is slightly decentered in relation to the pupil center (white cross). Thus the lower region appears overcorrected and the upper is undercorrected in the difference map. This finding is confirmed in the following line cuts. The upper two graphs show the treatments as compared to the theory. The decentration is below 0.5mm. It appears as a tilted blue line in the difference graph.


Patient 1: horizontal line section
ablated tissue depth [µm]
radial distance [mm]
measurement
theory

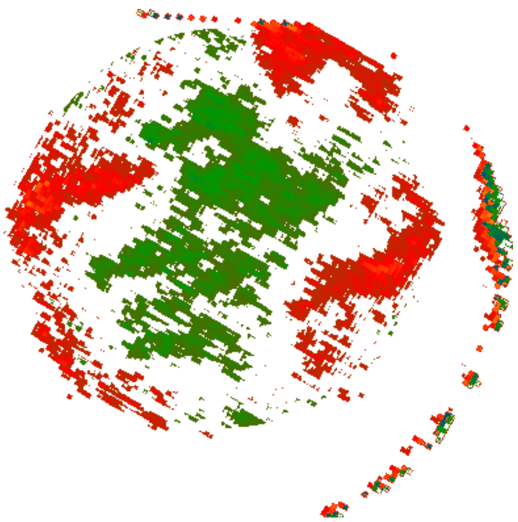

Patient 1: vertical line section
ablated tissue depth [µm]
radial distance [mm]
measurement
theory


Patient 1: difference to theory
ablated tissue depth [µm]
radial distance [mm]
horizontal cut
vertical cut

4.3 Patient 2:

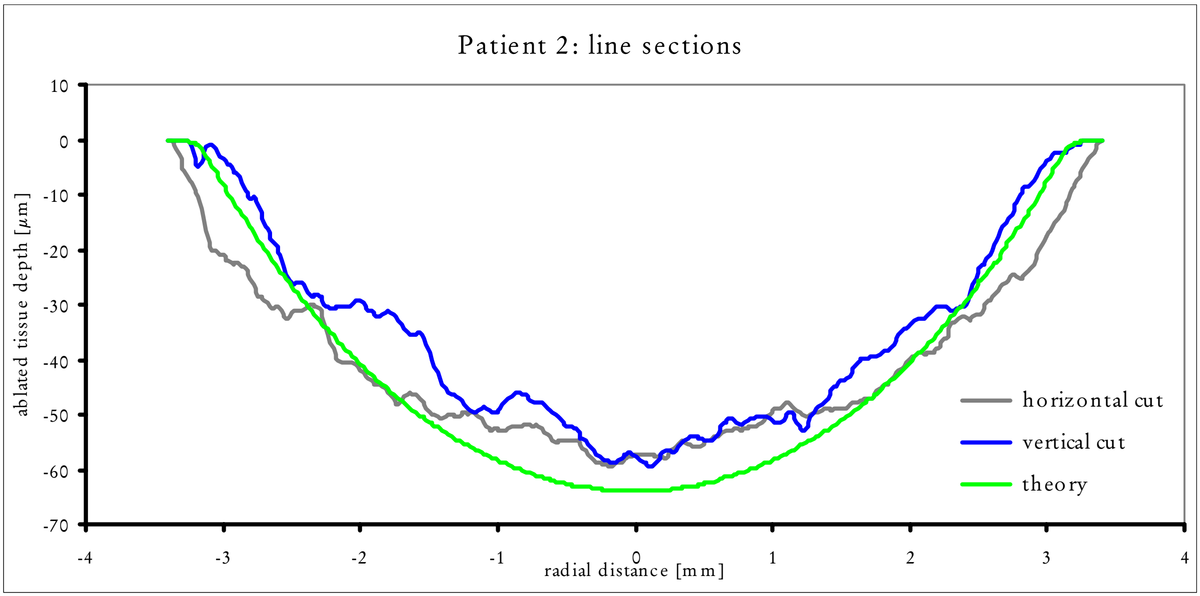


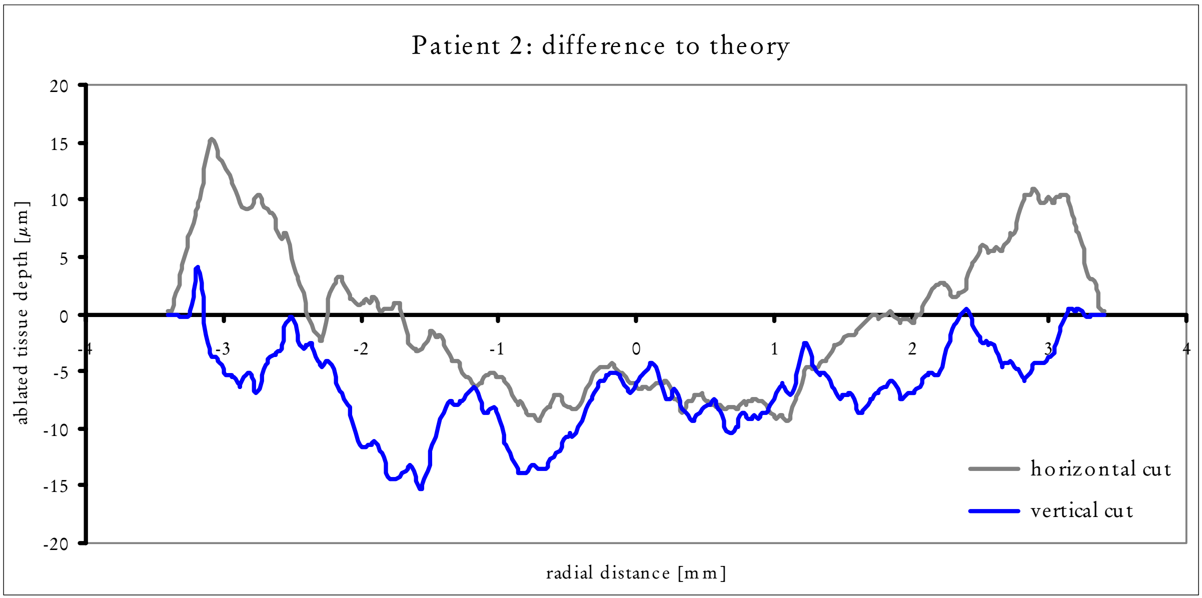
-3.75D treatment -3.75D simulation



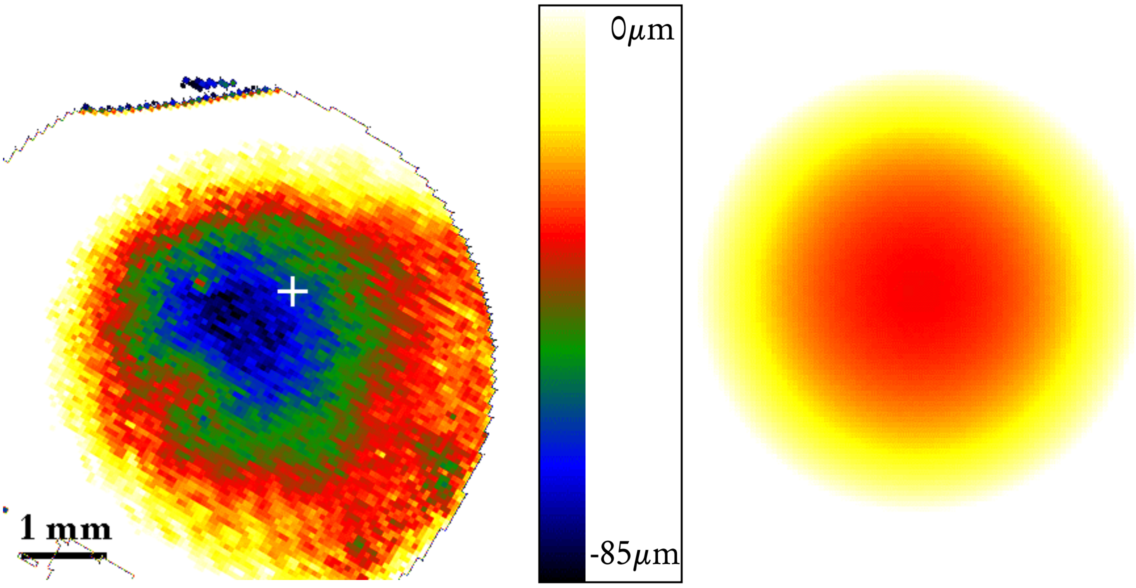
Difference map of Pat. 2

This treatment is well centered over the pupil. The treatment itself appear somewhat irregular which might be attributed to a non working eye tracker. This leads to a roughness exceeding 5 microns as confirmed in the graphs. The ablation depth corresponds quite well with the theoretically expected value.

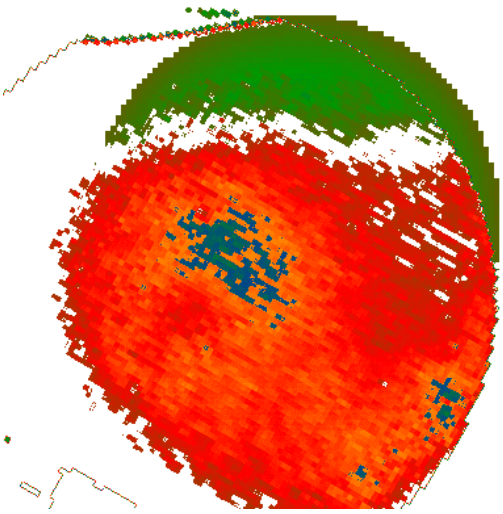

Patient 2: line sections
ablated tissue depth [µm]
10
0
-10
-20
-30
-40
-50
-60
-70
-4
-3
-2
-1
0
1
2
3
4
radial distance [mm]
horizontal cut
vertical cut
theory


Patient 2: difference to theory
ablated tissue depth [µm]
20
15
10
5
0
-5
-10
-15
-20
-4
-3
-2
-1
0
1
2
3
4
radial distance [mm]
horizontal cut
vertical cut

4.4 Patient 3:



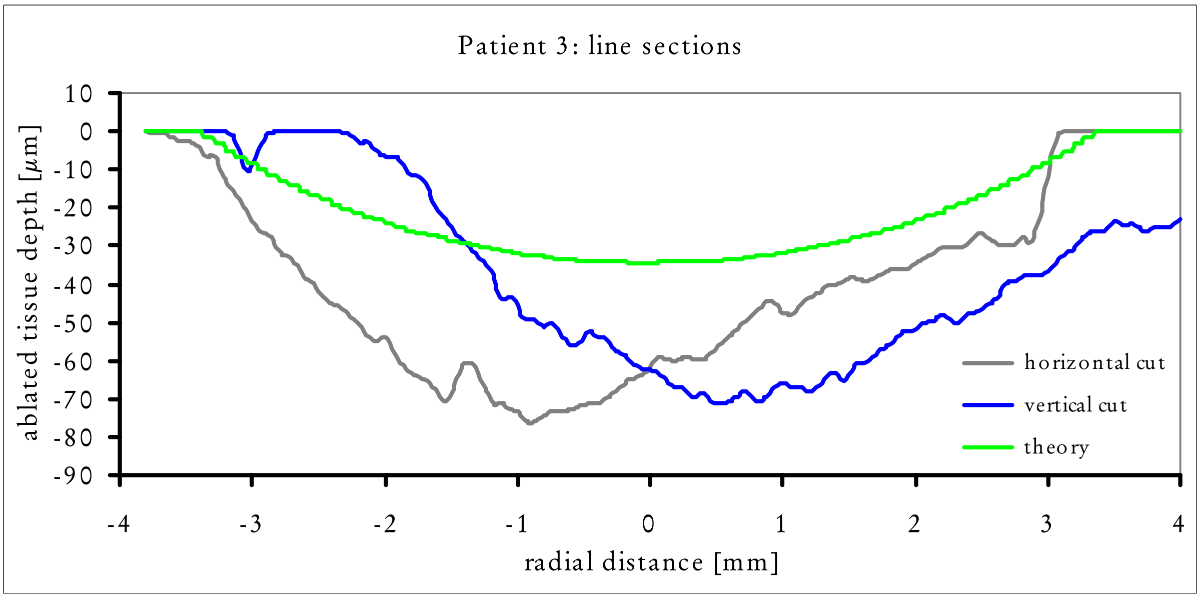
-1.75D treatment -1.75D simulation

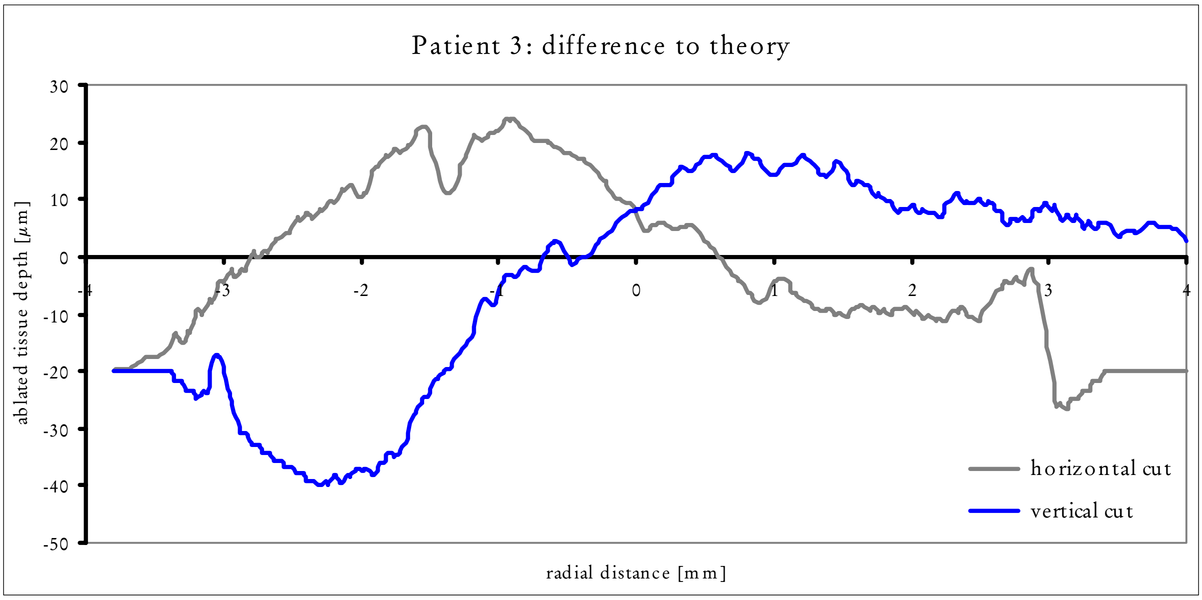


Difference map of Pat. 3

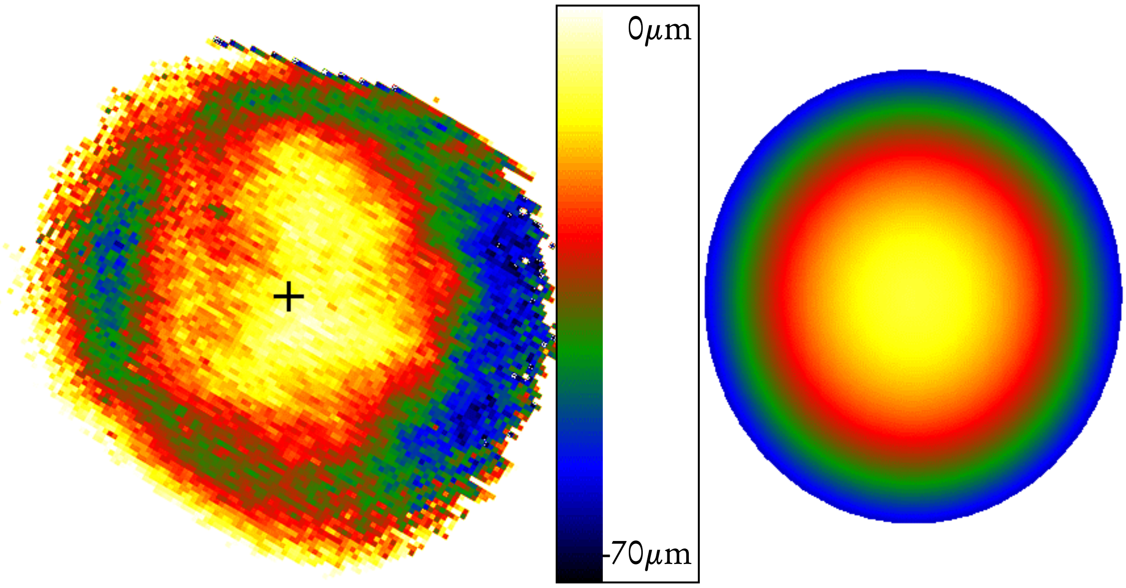
This treatment zone seems to be decentered by approximately 1mm. The decentration is also well visible in the difference map. It shows severe overcorrection in the lower part of the cornea and some undercorretion in the upper regions. These findings are confirmed by the line cuts. The difference cuts are strongly tilted due to the decentration. Also the total amount of ablated tissue seems well beyond the intended ablation depth of 40 microns. It reaches up to 70 microns which could be a strong indication for an extremely high individual ablation rate for this patient.

The patient is actually complaining of severe vision problems which will most probably be connected with the measurements.

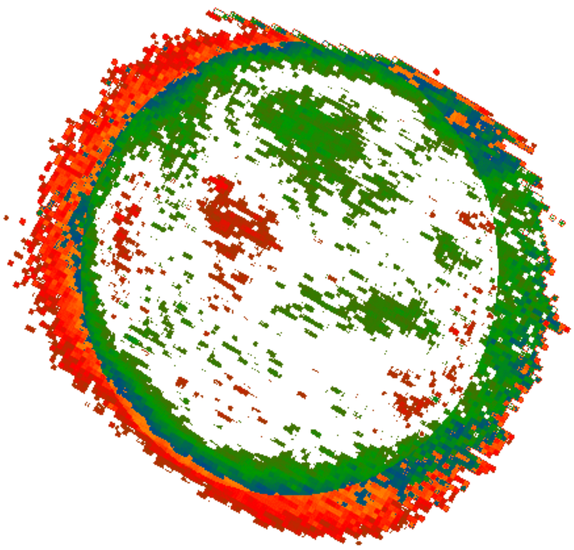




4.5 Patient 4:



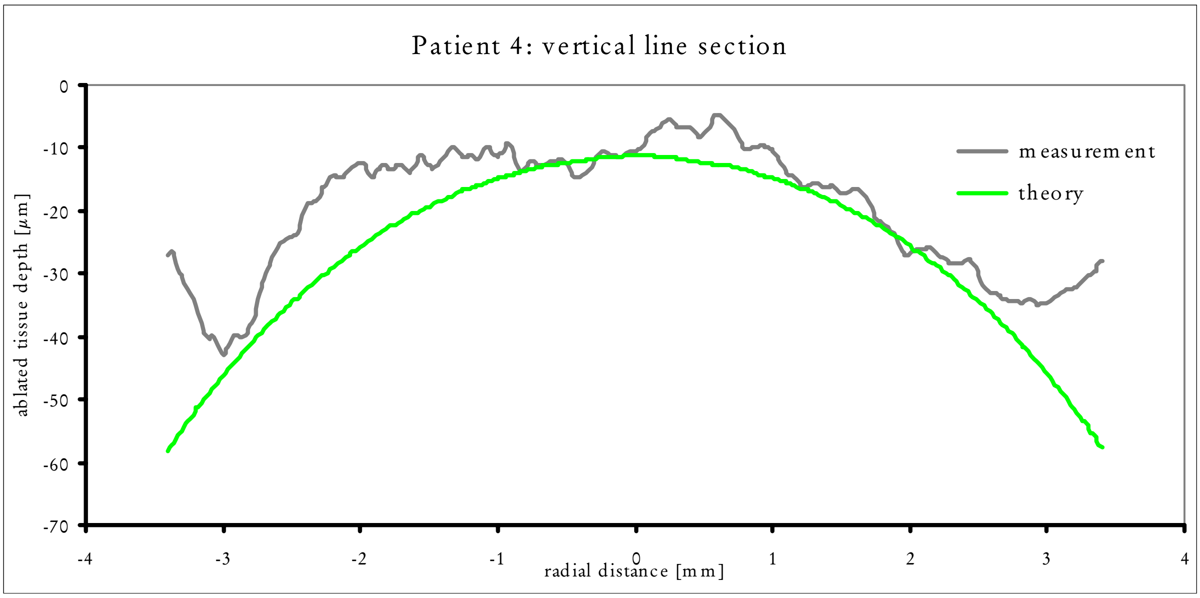
+2.25D ^ +0.5D x 90° treatment +2.25D ^ +0.5D x 90° simulation

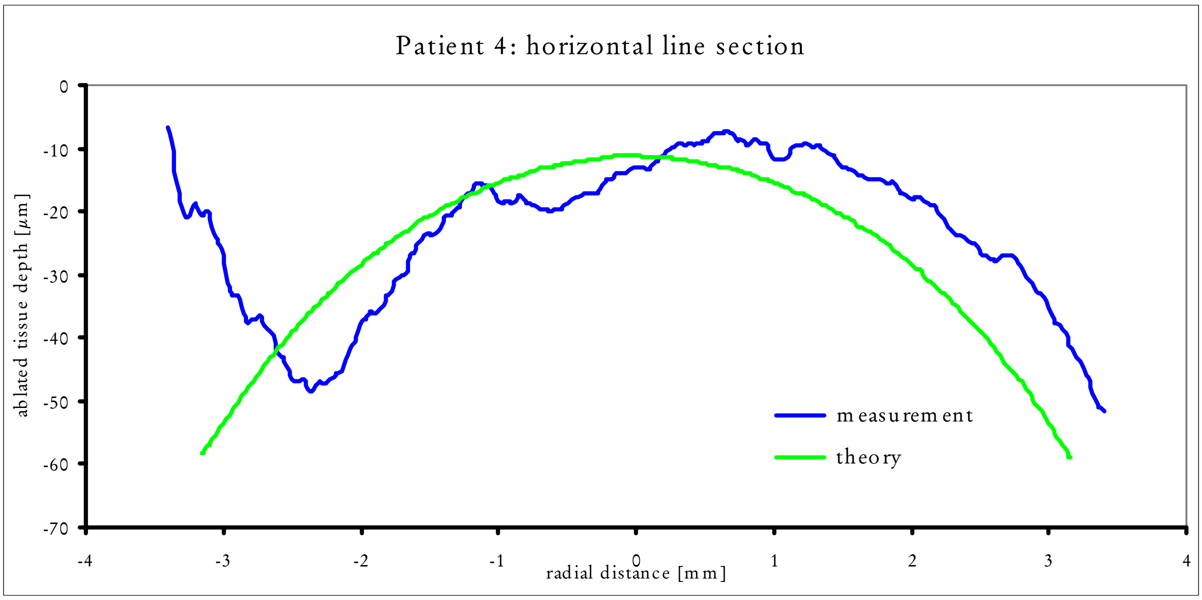


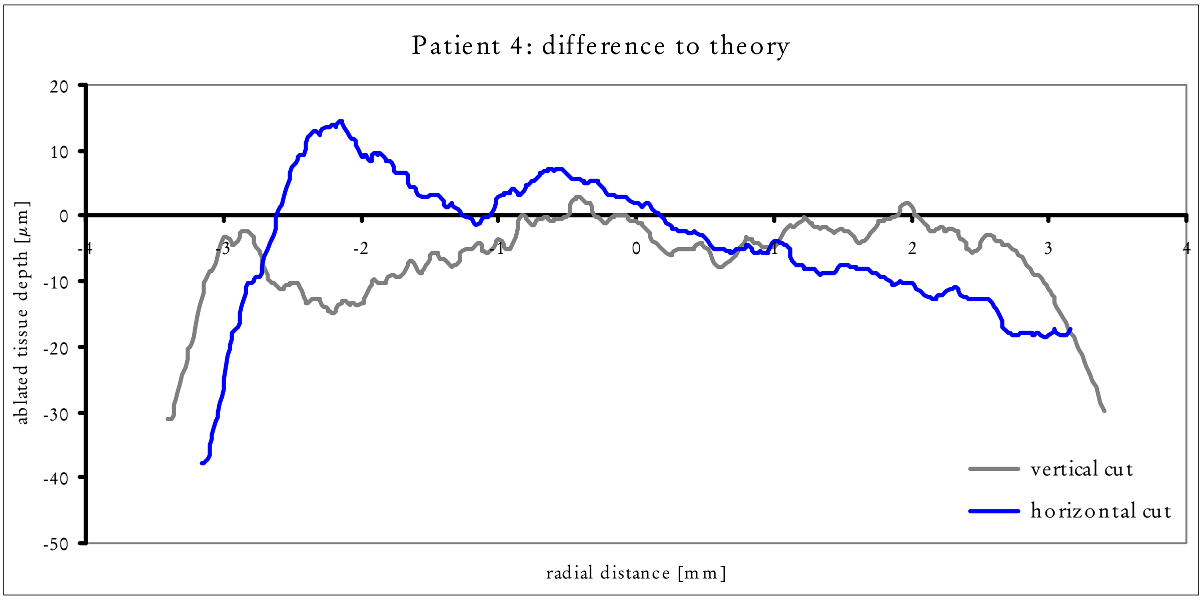
Difference map of Pat. 4

Here a hyperopic astigmatism was treated. From the colors of first map it is obvious that there was more tissue being taken off in the periphery than in the center, as required for hyperopic treatments. Also the asymmetry according to the astigmatism is well visible. The difference between the treatment and the theory shows a fairly good performance.

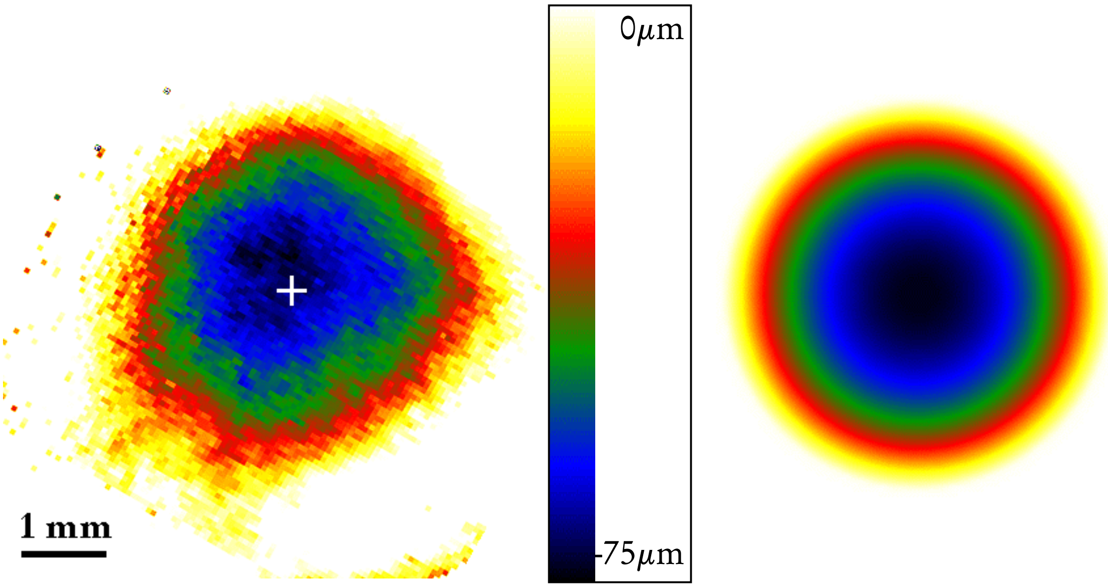
Nevertheless the line cut representations shows a minor vertical decentration of less than 0.5mm. This results in a tilted difference cut for this direction.


Patient 4: vertical line section
measurement
theory
ablated tissue depth [µm]
radial distance [mm]
0
-10
-20
-30
-40
-50
-60
-70
-4
-3
-2
-1
0
1
2
3
4

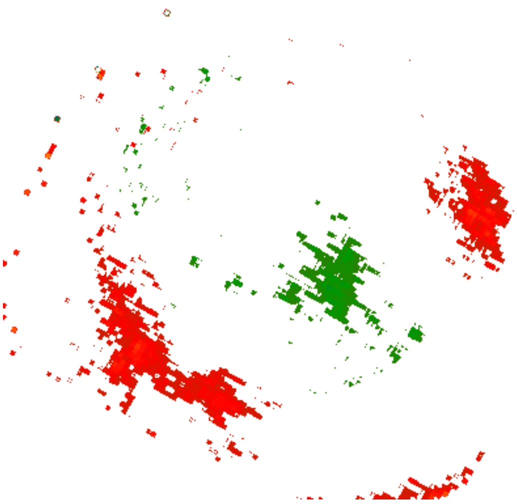

Patient 4: horizontal line section
measurement
theory
ablated tissue depth [µm]
radial distance [mm]
0
-10
-20
-30
-40
-50
-60
-70
-4
-3
-2
-1
0
1
2
3
4


Patient 4: difference to theory
vertical cut
horizontal cut
ablated tissue depth [µm]
radial distance [mm]
20
10
0
-10
-20
-30
-40
-50
-4
-3
-2
-1
0
1
2
3
4

4.6 Patient 5:

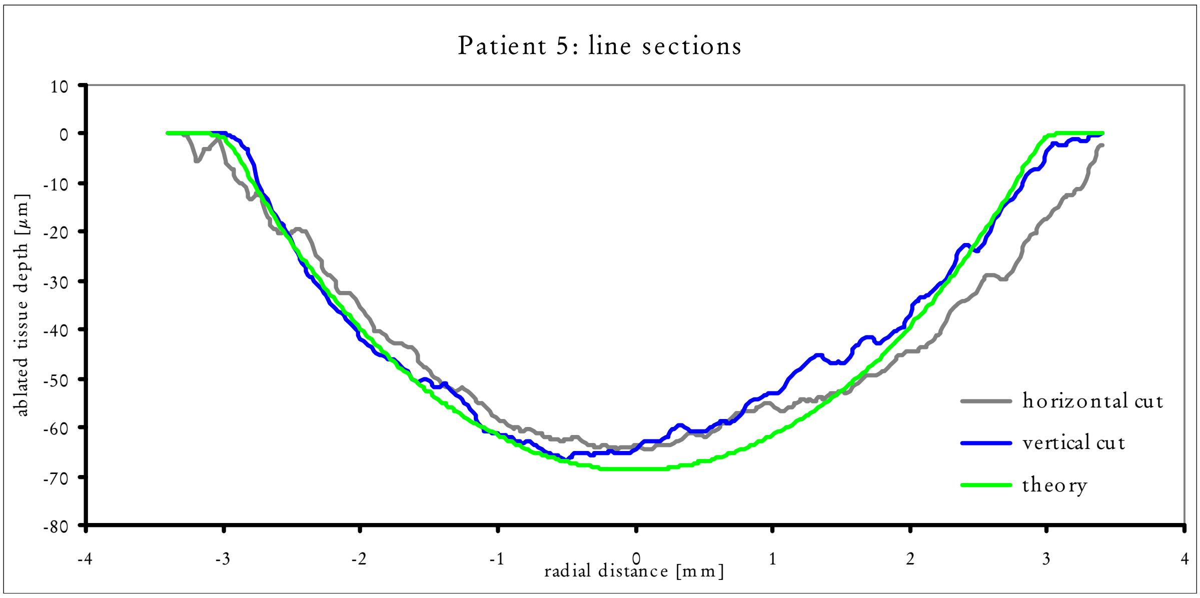


-5.0D ^ -0.25D x 150° treatment -5.0D simulation

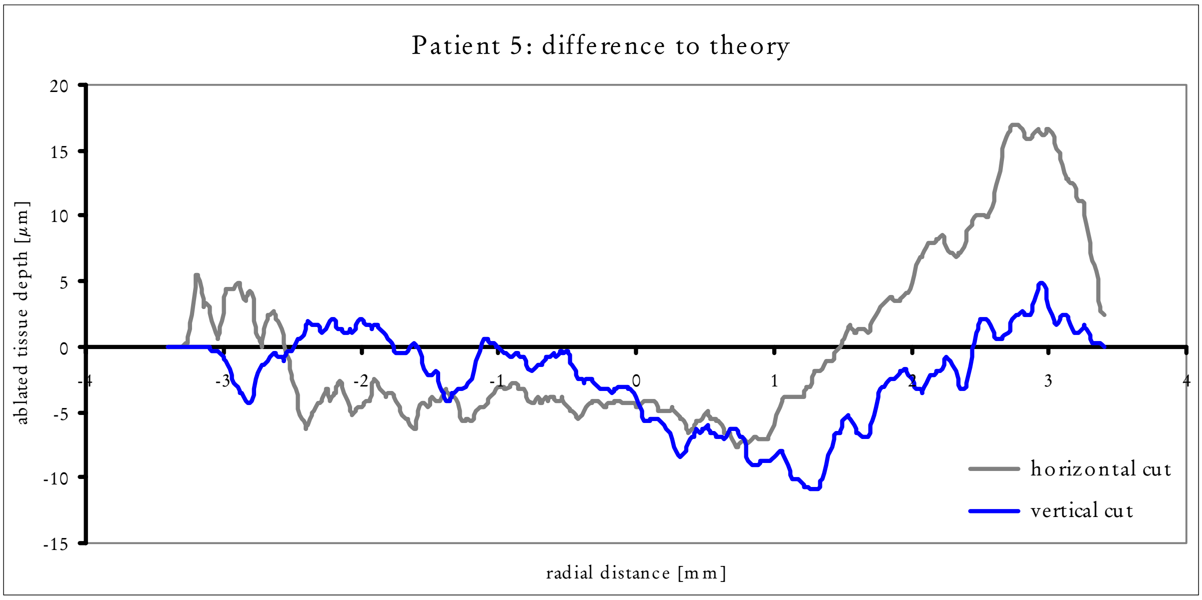


Difference map of Pat. 5

This patient received the most accurate treatment of all included in the study. This is well confirmed in the graphs of the line cuts (note the small scale of difference cut). Still there is some residual tissue in the lower right region that would have to be taken off instead of the red regions for an optimum. These errors do not appear in the cuts as they are located at 45 degrees.

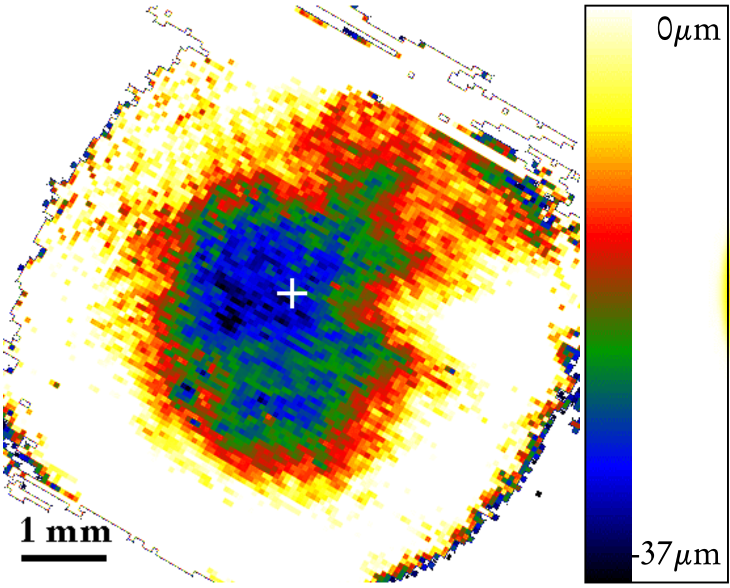


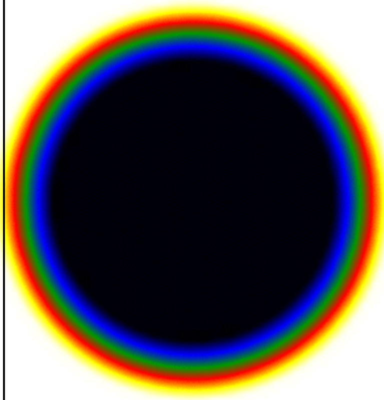
Patient 5: line sections
ablated tissue depth [µm]
10
0
-10
-20
-30
-40
-50
-60
-70
-80
-4
-3
-2
-1
0
1
2
3
4
radial distance [mm]
horizontal cut
vertical cut
theory



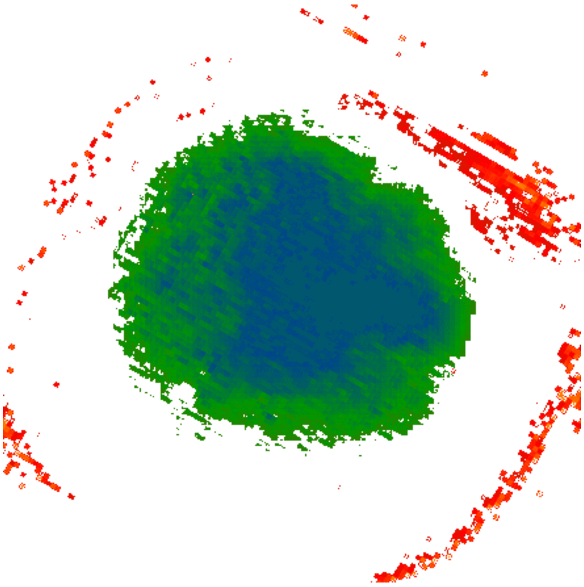
Patient 5: difference to theory
ablated tissue depth [µm]
20
15
10
5
0
-5
-10
-15
-4
-3
-2
-1
0
1
2
3
4
radial distance [mm]
horizontal cut
vertical cut

4.7 Patient 6:



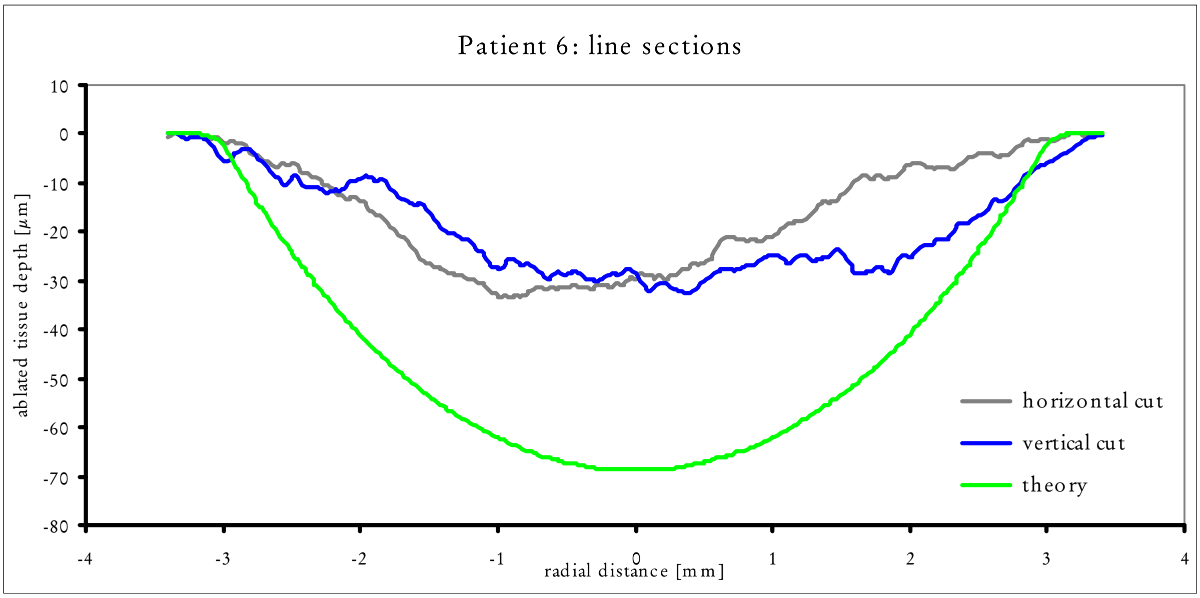


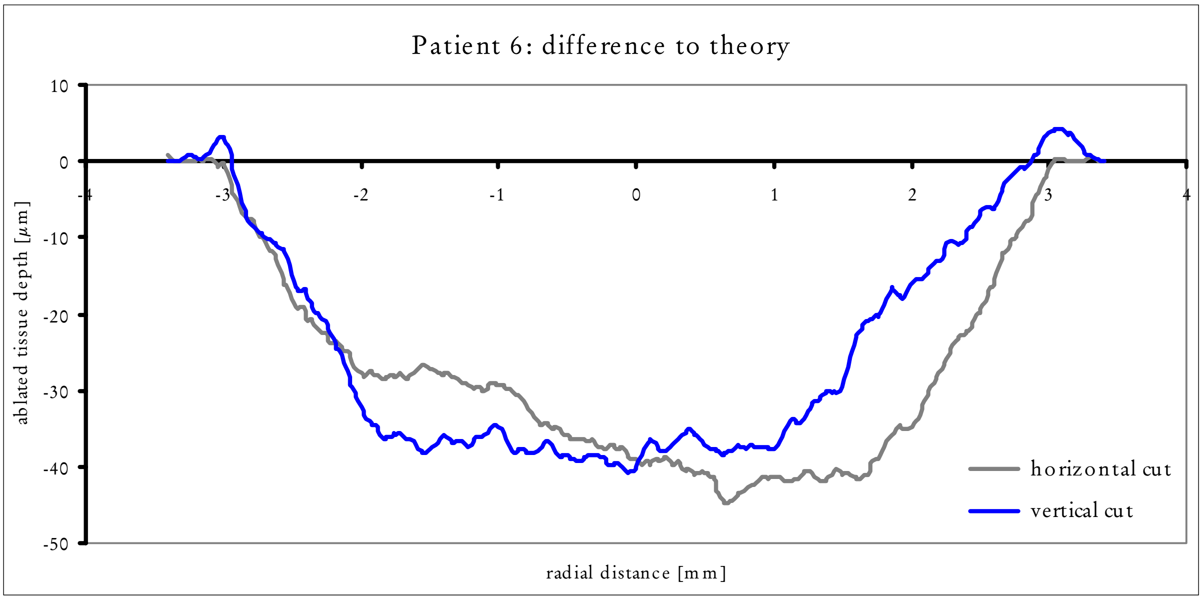
-4.5D treatment -4.5D simulation



Differenz map of Pat. 6

The treatment is rather well centered over the pupil. The difference map reveals a very large region that still needs ablation in the center. This is confirmed in the following line sections. But there is also an additional finding. The difference cut shows a horizontal line for both cutting directions. The curvature compares favorably with the intended treatment. Nevertheless this region is only 4mm in diameter. It means that this patient should get night vision problems as soon as his pupil increases above 4mm in diameter. This could be a good example for a too small ablation rate at the end of the treatment that still gives satisfactory results initially. Still the treatment was not executed according to the settings as the totally ablated tissue depth is only less than 40microns compared to the intended 70microns. These measurements still have to be compared to clinical findings and conventional topometry.





5 Discussion and conclusion

In the results six exemplary patients were presented that received different corrections. The small number of patients prevents a statistical analysis of the data. Nevertheless some indications are already provided.

The following table summarizes the results:

Patient	Decentration	Undercorrected tissue depth			Overcorrected tissue depth		
	mm	is	should be	%	is	should be	%
1	0.5	60	70	14			
2		55	65	15			
3	1				75	35	114
4	0.5						
5							
6		30	70	57			
total	**3 of 6**	**3 of 6**			**1 of 6**		

The bottom line indicates the incidence of deviations from the intended ablation. There is a total of 4 patients at which a difference between the calculated and the measured ablation occurred, 2 of them with a very large difference. Half of the patients treatments seemed decentered. In how far these results affect the vision of the patients remains to be seen for 5 of them. One is already known to suffer from problems. Most of the others may have received a better surgery with online-control.

These first measurements strongly emphasize the power of the method. It was the first time that the whole amount of ablated tissue within a range of more than 8mm diameter was observed intraoperatively. The accuracy of the method was proven to provide a sufficient resolution to reach a reliable refractive surgery without considerable misscorrections. The measurements would have altered the treatments if access to the laser had been given in due time.

There are currently two other methods being tested worldwide. Both of them have significant drawbacks that currently exclude their broad application in realtime measurements for a laser control:

An optical sensor that continuously monitors the thickness within the most central part of the cornea is currently used in Switzerland (Prof. Seiler, Prof. Boehnke). It was already adapted to the Schwind laser and is built by Haag Streit. One year follow ups indicate a strong correlation between the intraoperative measurements and the final visual outcome of the patients. Unfortunately the system only measures one point instead of the whole surface as the presented system does. This is completely insufficient when considering complicated asymmetric treatments. It also cannot account for inhomogenities in the ablation rate over the whole cornea.

In the USA there is another system currently being tested at Dr. Dishler's. It is a fiberoptic interferometer which is scanned over the surface. The device is capable of measuring the whole cornea but it needs time for the scanning process. It remains to be shown in how far the system can be adapted to an eye tracker to compensate for the movements. The presented system does not suffer from this ambiguity as it takes one measurement within nanoseconds. During this short time period there are no motion artefacts.

In conclusion BioShape together with G. Fiedler, MD, have presented the first worldwide intraoperative topometries during corneal laser surgery. The results have indicated a strong need for an online monitoring system to enhance the visual outcome of patients already during the treatment process.