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OPHTHALMOLOGY

KERATOPLASTY PRESENTATION - 2021

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KERATOPLASTY

Meaning:

Corneal transplantation, also known as corneal grafting, is a surgical procedure where a damaged or diseased cornea is replaced by donated corneal tissue (the graft)

When the entire cornea is replaced it is known as penetrating (perforating) keratoplasty, PKP

When only part of the cornea is replaced it is known as lamellar keratoplasty, such as
DMEK = Descemet Membrane Endothelial Keratoplasty for the posterior lamellar area
DALK = Deep Anterior Lamellar Keratoplasty, as the name says, for the anterior lamellar area

Keratoplasty simply means surgery to the cornea. The graft is taken from a recently dead individual with no known diseases or other factors that may affect the chance of survival of the donated tissue or the health of the recipient.

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KERATOPLASTY

Indications, advantages and disadvantages:

Technique	Advantages	Disadvantages	Indications
PKP	Long-term experience, established and standardized procedure. So far mostly proceeded technique in Keratoplasty. Older than DALK or DMEK.	Slow visual rehabilitation Long aftercare Repeat graft is for sure	- Keratitis - Bullous keratopathy - Keratoconus - Repeat graft - Keratoplastik à chaud - Corneal stromal dystrophies - Trouble shooting when DALK n.s. - Etc.
DALK	Fast visual rehabilitation. Less rejection or graft failure. Anterior Keratoplasty only when having a healthy Descemet‘s membrane and endothelium.	Flat learning curve Higher expenditure on equipment Irregularity in the interface Risk of perforation of the DM	- Keratitis - Bullous keratopathy - Keratoconus - Corneal stromal dystrophies - Etc.
DMEK	Particularly fast visual rehabilitation and clearing of the cornea. Less rejection or graft failure. No irregular astigmatism. Proceeded when having a disfunction of only the Descemet‘s membrane or the endothelium.	Flat learning curve Higher expenditure on equipment Irregularity in the interface	- Fuchs-Dystrophie - Chronical lost of endothel-cells - Etc.

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KERATOPLASTY

Complications:

- Graft rejection
- Infection (intraocular and corneal)
- Wound leak
- Glaucoma
- Graft failure
- High refractive error (especially astigmatism, myopia, or both)
- Recurrence of disease (with herpes simplex or hereditary corneal stromal dystrophy)

So your technique has to be perfect and precise in order to avoid these complications.

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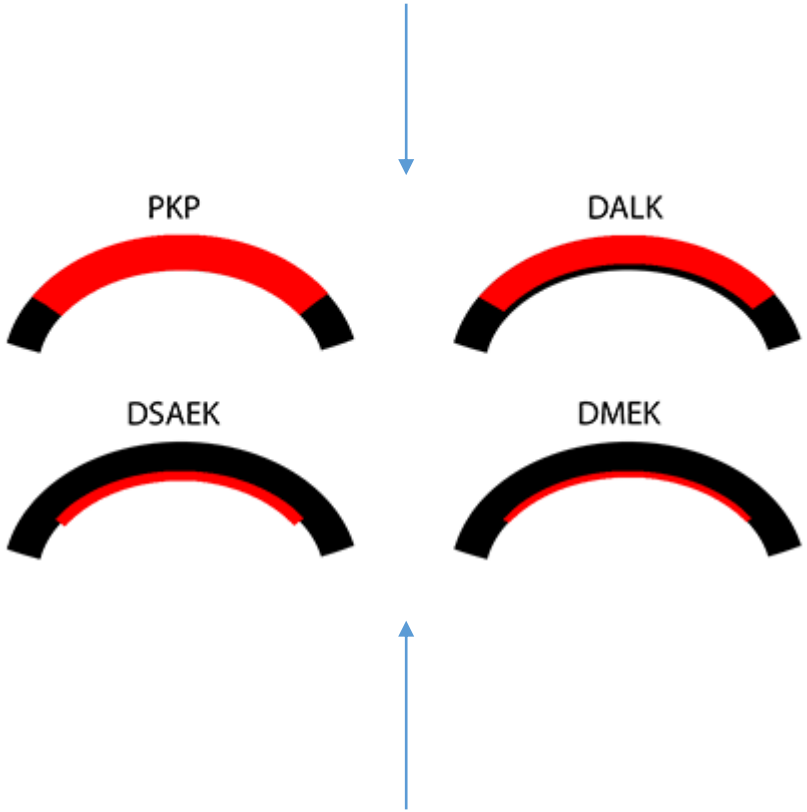
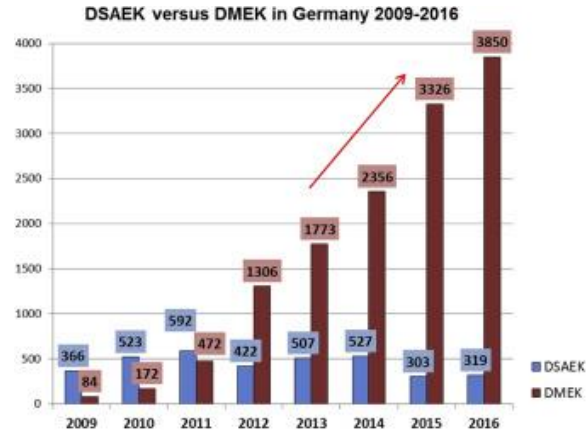
KERATOPLASTY

Anatomy of the possible procedures

Anterior, Epithelial side



Posterior, Endothelial side



The DSAEK technique is not supported by a1 medical, as DMEK od DALK do have more potential.

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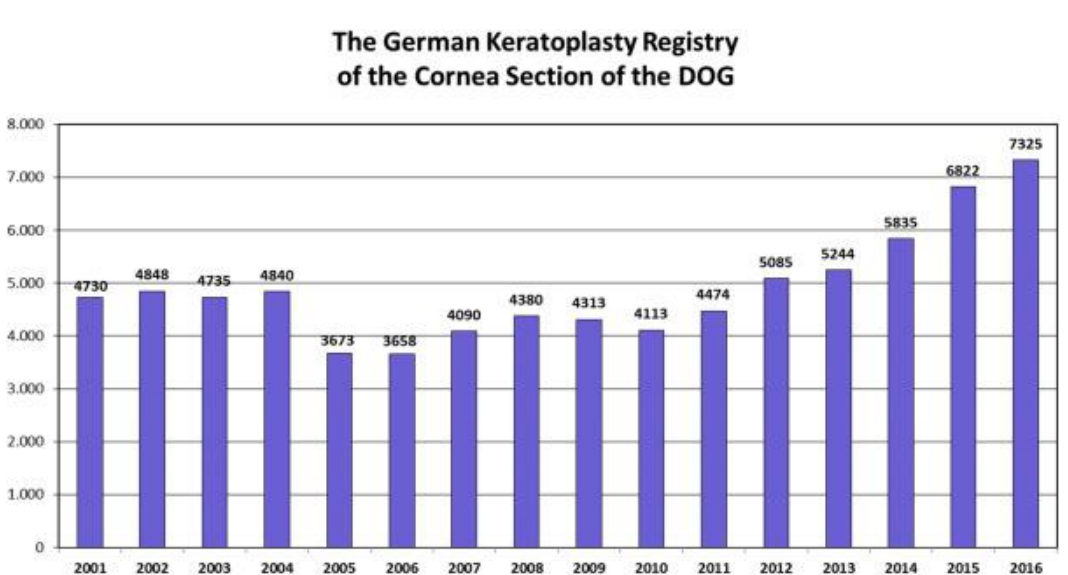
WHY KERATOPLASTY

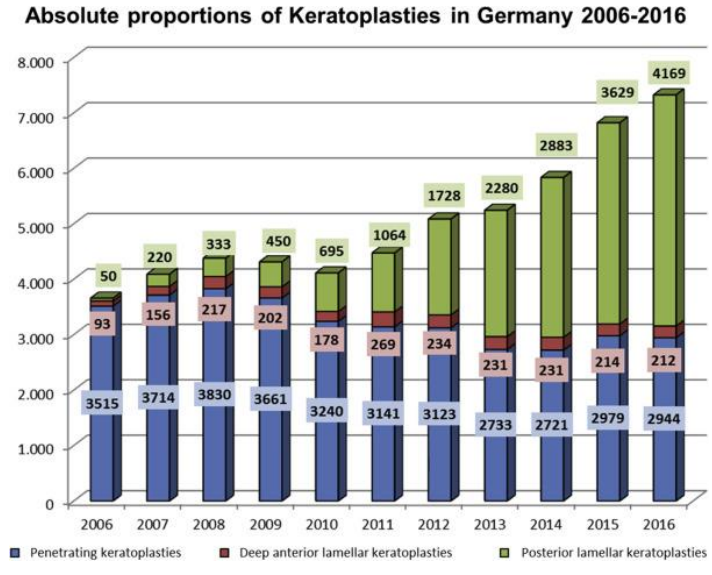
We are concentracting on Keratoplasty, because it is the most proceeded transplantation on human.

In Germany in 2018, 8.000 keratoplasties have been proceeded compared to Lung, Hart, Kidney, Liver, Pankreas, etc. in the last 5 years with all together a total of 2.800.

Additionally we have been able to observe that existing products and techniques are not giving the result that is needed. Techniques for the PKP, like manual non guided punching or other type of trephines, for DALK, like the big bubble or for DMEK, like the Descement's Stripping, are giving potential for improvments.

Then we have been luckily able to get in contact with two surgeons, both absolutely professionals and expirienced in Keratoplasty having decades of kowledge searching for the right partner to do the developments with. So that partner is now a1 medical.





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SURGEONS

a1 medical has developed with two different surgeons three techniques as well as instruments for those techniques and a system for the Keratoplasty.

The two surgeons are:

Dr. med. Jörg H. Krumeich
Bochum, Germany

and

Dr. Georg Gerten
Köln, Germany

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SURGEONS

With Dr. Krumeich we have been able to improve his former patented GTS (Guided Trephine System) and develope a better, more precise, more flexible trephine system called

C T S - CORNEA TRANSPLANT SYSTEM / Krumeich Trephine

With Dr. Gerten we have developed the instruments for his inventend techniqes for DMEK

the EASY LIQUD BUBBLE - DMEK

and for DALK

the CLEAR CORNEA FEMTO BUBBLE – DALK

a1 medical is thereby able to provide the most precise, easy, safe, reproduceable and sophisticated techniques, instruments and systems, compared to the our main competitors or old common techniques.

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PKP

CTS

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CTS

CTS – Cornea Transplant System

The new trephination system that revolutionizes corneal surgery

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HISTORY

Since the introduction of first corneal trephine (Arthur von Hippel 1877) several Improvments of Trephines had been introduced:

1948 Amsler 1966 Castroviejo 1971 Dräger Motor trephine	Handheld
1980 Hessburg 1982 Olson 1987 Hanna	Corneal suction
1987 Krumeich GTS	Perilimbal suction Lock-on trephine Unchanged IOP

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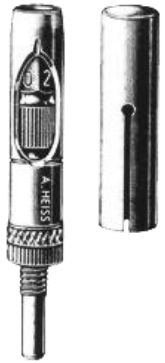
HISTORY

Handheld trephines

Francescetti

Castroviejo



Hessburg / Barron

Hanna

von Hippel

Krumeich Trephine (GTS)

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AIM

Aim of every PKP is not only to heal a disease but to get the best possible outcome regarding

- Difficulty of operation
- Duration of operation
- Costs

} Important for the surgeon

- Postoperative astigmatism
- Clear transplant

} Important for the patient and therefore the surgeon

- Postoperative irregular astigmatism is the main measurement, not if it comes to a successful operation by a skilled surgeon

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PROBLEMS

The main reasons for postoperative irregular astigmatism are:

- a transplant, that does not fit perfectly into the recipients bed
- a perfectly fitting transplant, that is not sewed evenly (suture).

- As the suture is completly dependent of the surgeons technique and skill, this presentation concentrates on the first reason

- To obtain a perfetly fitting transplant, you have to:

- Avoid trephine tilt
- Create identical dimensions meaning the transplant has to have the exact size of the hole, that is cut into the cornea by the trephine system

How to eliminate this reasons and how the solutions are implemented in the CTS is described in the following

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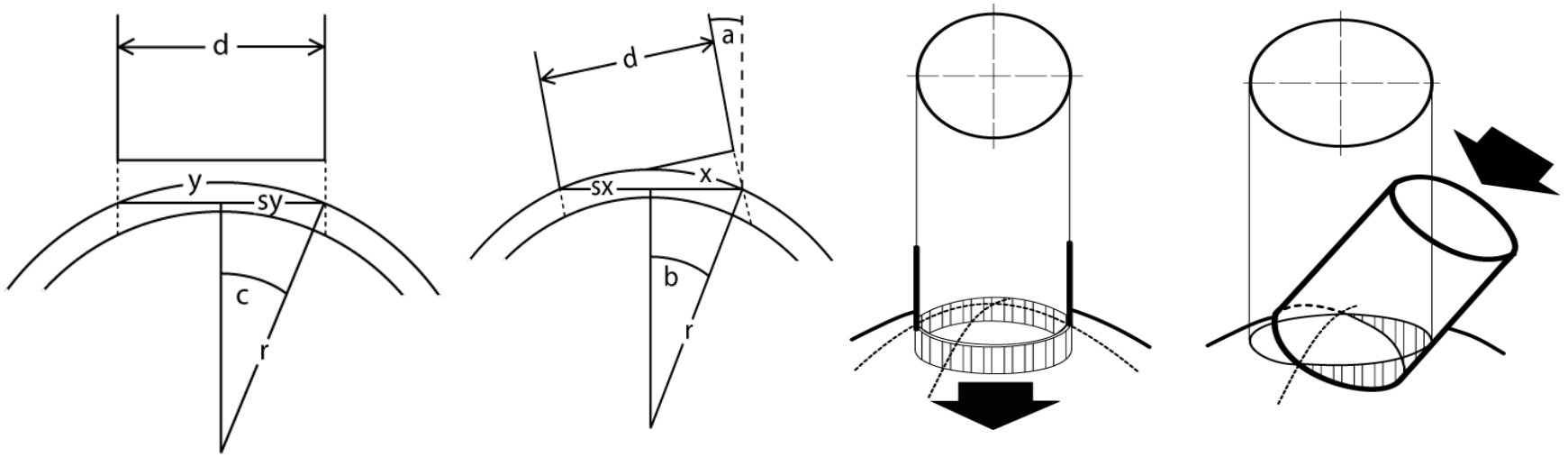
PROBLEMS

Trephine tilt, effect on the outcomes and how to avoid it



The trephine cannot be held perpendicularly to the Limbus when cutting

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PROBLEMS

Trephine tilt, **effect on the outcomes* and how to avoid it**

Tilt	2°	5°	10°	15°
x (mm)	8,00	8,03	8,12	8,28
y (mm)	8,00	8,00	8,00	8,00
rx (mm)	7,56	7,34	6,71	5,98
ry (mm)	7,60	7,60	7,60	7,60
Astigmatism (D)	0,26	1,58	5,90	11,99

To avoid trephine tilt, the trephine has to be fixated on the cornea while cutting, which is done by suction in most of the systems available

*Diameter, radii and resulting astigmatism for oblique trephination angles from 2° to 15°. The lenticule is cut in the flat state. The diameter of the trephine is 8,0 mm.

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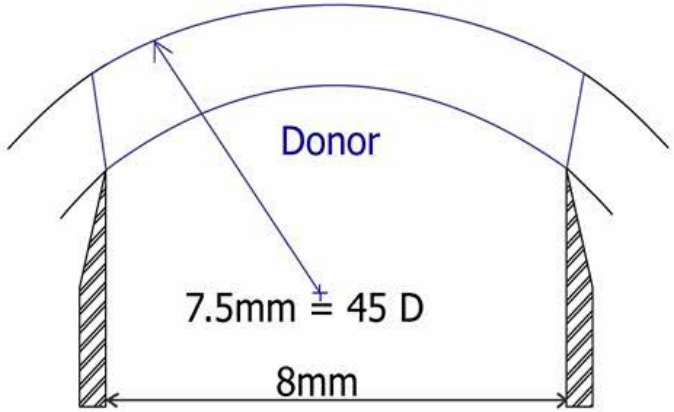
PROBLEMS

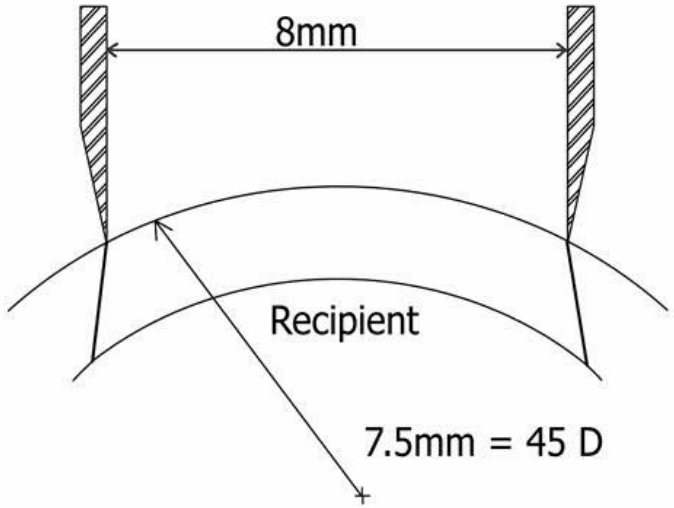
How to create identical dimensions between donor cornea and recipient bed – analysis of the market

Punch trephination

Punch trephination of donor tissue leads to different dimensions of donor and recipient due to a tissue gap on endothelial side and tissue squeeze of epithelial side. This is caused by cutting the button and the bed from different sides



epithelial side larger



tissue gap on endothelial side

Therefore systems that rely on punch trephination of the donor create undeterrable postoperative astigmatism

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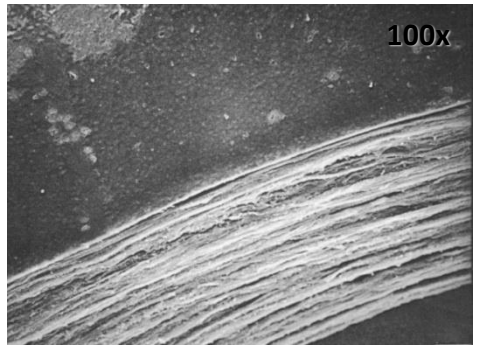
PROBLEMS

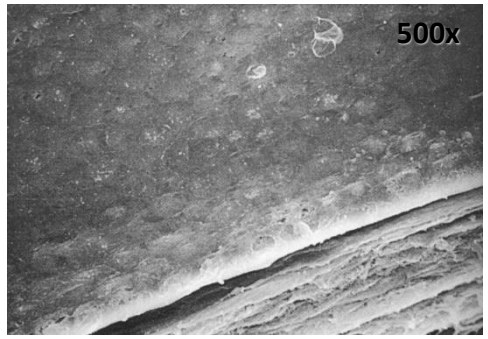
How to create identical dimensions between donor cornea and recipient bed – analysis of the market

Punch trephination

It is already known that punch trephination damages the endothelium

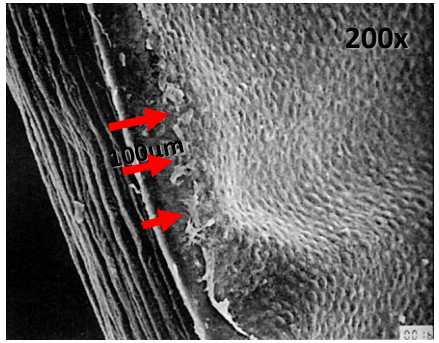
CTS cutting from epithelial side

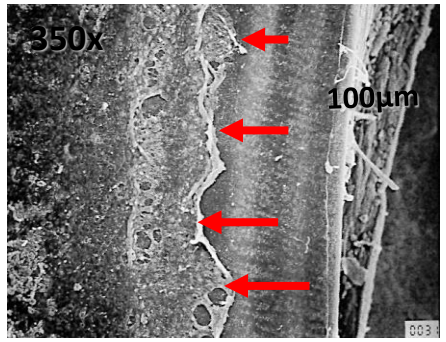




unaltered endothelium

Punch from endothelial side





Damaged cells

Retraction of endothelium

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PROBLEMS

How to create identical dimensions between donor cornea and recipient bed – analysis of the market

Fixture of the trephine on the eye

To avoid any manipulation of the cornea while cutting, it has to be fixated both on the anterior chamber bench and on the eye

While every anterior chamber bench works more or less the same – fixating the cornea at the limbus with a ring – fixating the trephine on the eye differs from system to system

Corneal suction	Limbal suction
Many systems, especially one-use systems, maintain suction on the cornea with a syringe	Some systems use limbal suction with a suction ring to avoid deformation of the cornea
But every suction on the cornea itself deforms it, because nearly all corneas, that have to be replaced are irregular in one form or another	**Problem with limbal suction**: the use of a Barraquer ring to fixate a trephine increases the intraocular pressure, leading to a limitation of thephination time

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PROBLEMS

How to create identical dimensions between donor cornea and recipient bed – analysis of the market

Fixture of the trephine on the eye

To avoid the increase of intraocular pressure, Jörg H. Krumeich presented the non-IOP suction ring with the GTS in 1987

This suction ring was modified to mount the CTS

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PROBLEMS

How to create identical dimensions between donor cornea and recipient bed – analysis of the market

Same diameter of donor button and recipient bed

First of all: An 8mm trephine does not create an 8mm button!

How is this possible? – The reasons are corneal curvature and elasticity

As every elastic material, the cornea returns to its original form after deformation. Thinking about a rubber band that is streched and that goes back to normal after releasing it.

This insight has wide-ranging consequences for corneal surgey, as no trephine system considers this.

All systems available, be it single-use, multi-use systems or Femto lasers rely on either a hollow trephine blade or a fix curvature to hold the cornea down

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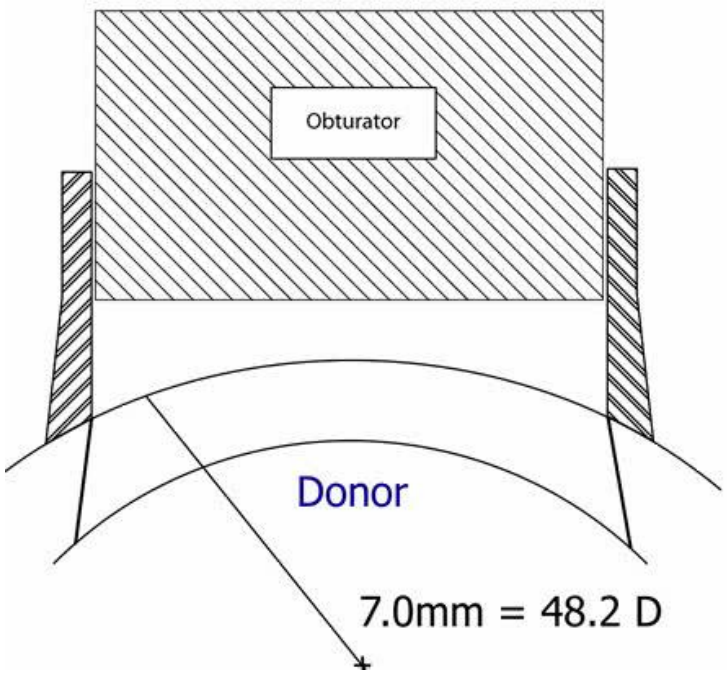
PROBLEMS

Case 1 – femto top-hat cut



Steps:

1. The cornea is applanated and cut
2. The applanation is removed and the cornea goes back to ist original form
3. That leads to a smaller diameter than set in the laser settings

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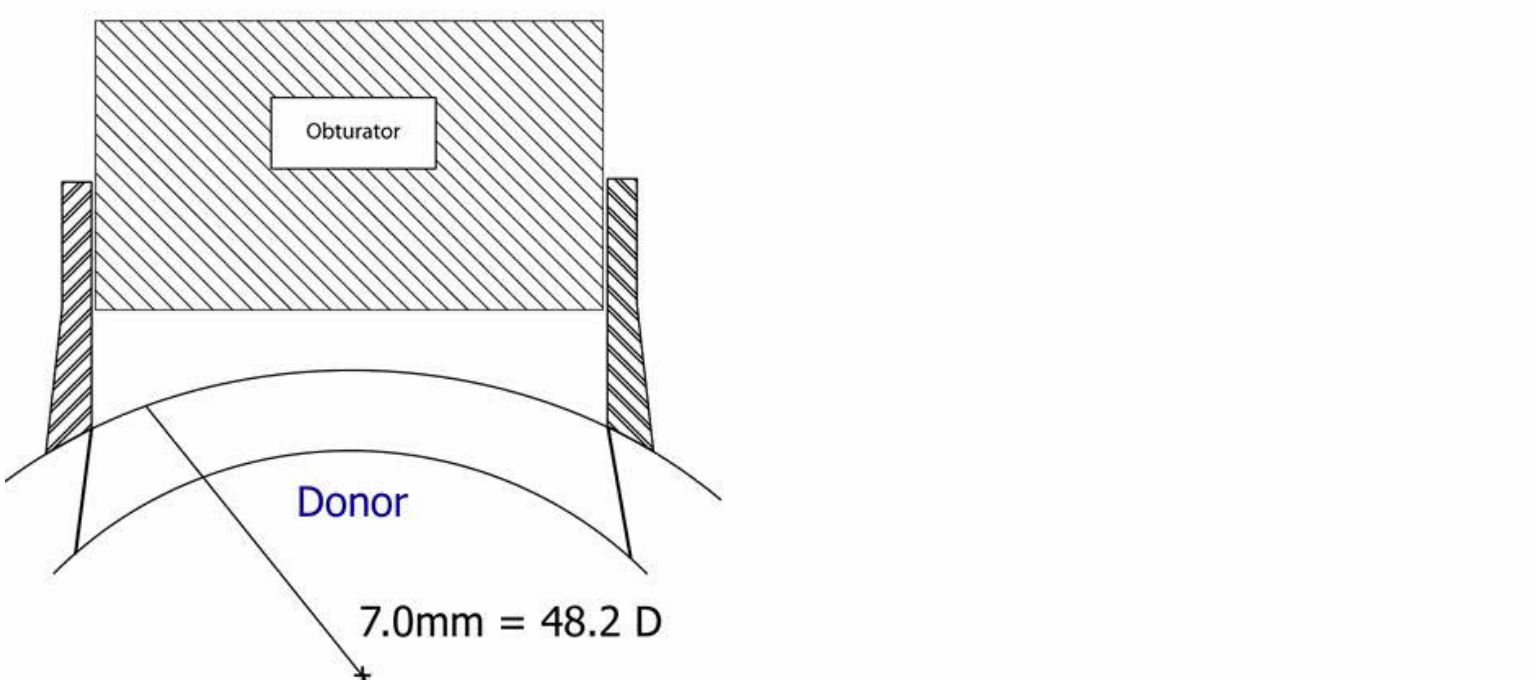
PROBLEMS

Case 1 – femto top-hat cut



Every femto user does know this problem but not the cause. Therefore it is common to chose a bigger diameter for the button

But it is never accurate. Every surgeon has a hand full of cases that they remember as cases, where the postoperative astigmatism was extremely low. But they don‘t know why.

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Case 2 – same curvature inside the trephine

PROBLEMS

This works the same way as applanation with the laser. The donor cornea is not pushed down horizontally by the trephine system but with a fix curvature, for example 44 Diopters.

If the cornea is steeper, it will be pushed down, leading to a button with a smaller diameter than the trephine

If the cornea is flatter, the cornea will be pushed into the trephine, leading to a button with a bigger diameter than the trephine

Both cases lead to a diameter, that does not fit perfectly into the bed – but why?

Because every cornea is different!

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PROBLEMS

Case 2 – same curvature inside the trephine

Facts and Figures

Radius of the cornea- Diopters	Radius the cornea - mm	Arc length / mm
38	8,84	8,30
40	8,40	8,34
42	8,00	8,38
44	7,64	8,42
46	7,30	8,47
48	7,00	8,52
50	6,72	8,57

This table explains the problem.

If the recipient has a radius of 38 Diopters but the donor cornea has 44 Diopters, there is a difference of 0,12mm material, which is transplanted. When the trephine does not adapt to that difference, it has to be either squeezed into the recipients bed or a tissue gap has to be closed – both leads to irregular astigmatism

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PROBLEMS

Case 2 – same curvature inside the trephine

There might be cases, where the donor cornea and the recipeint cornea have the same radii. This leads to that miraculous outcomes every surgeon knows.

But it is not miraculous…only the curvature needs to be changeable, which is implemented on the CTS via Obturators.

Obturators are glass bodies with a surface, that matches several corneas.

No other system available on the market is capable of preventing this astigmatism

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CTS

The CTS – Cornea transplant system

The CTS combines all of the above mentioned solutions for irregular astigmatism.

It implements the known solvings – such as the non-IOP suction ring and adds several new features

These new features are:

Adjustable trephine size –

the CTS is the only trephine system available, that is able to mount a 7.0mm, a 7.5mm and a 8.0mm trephine due to its unique trephine design

Both anterior and posterior Keratoplasties are possible –

The CTS is the only trephine system available, that not only works for PK and DALK but for DMEK due to a special central plug for the anterior chamber bench

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CTS

And of course the main feature:

The possibility to adapt to nearly every corneal curvature due to its set of obturators

R: 7.0 mm	R: 7.1 mm	R: 7.2 mm	R: 7.3 mm
D: 43.80	D: 43.23	D: 42.68	D: 42.14
C-1271+7.0	C-1271+7.1	C-1271+7.2	C-1271+7.3
C-1276+7.0	C-1276+7.1	C-1276+7.2	C-1276+7.3
C-1281+7.0	C-1281+7.1	C-1281+7.2	C-1281+7.3

R: 7.4 mm	R: 7.5 mm	R: 7.6 mm	R: 7.7 mm
D: 41.61	D: 44.39	D: 43.80	D: 43.23
C-1271+7.4	C-1271+7.5	C-1271+7.6	C-1271+7.7
C-1276+7.4	C-1276+7.5	C-1276+7.6	C-1276+7.7
C-1281+7.4	C-1281+7.5	C-1281+7.6	C-1281+7.7

R: 7.8 mm	R: 7.9 mm	R: 8.0 mm
D: 42.68	D: 42.14	D: 41.61
C-1271+7.8	C-1271+7.9	C-1271+8.0
C-1276+7.8	C-1276+7.9	C-1276+8.0
C-1281+7.8	C-1281+7.9	C-1281+8.0

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CTS HANDLING

The handling of the CTS has to be seperated in following main steps:

1. Setting up of the AC bench
2. Setting up of CTS Trephination-System
3. Trephination of the donor cornea
4. Trephination of the recipient‘s eye

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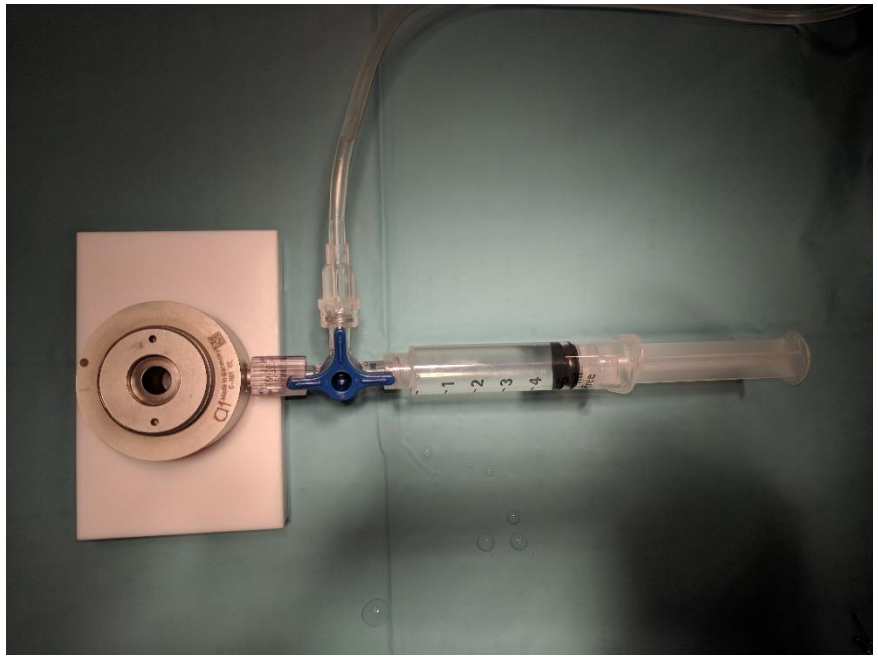
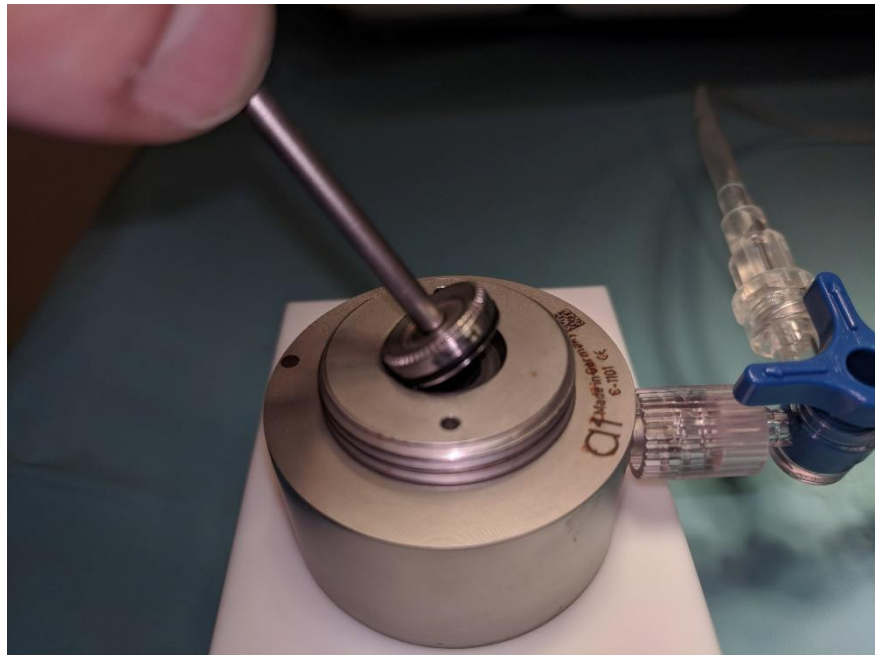
CTS HANDLING

1. The AC bench is connected via three-way-stopcock with an infusion of BSS and a syringe with BSS
2. The tubes and the AC bench is filled with BSS without air
3. The CTS Central Plug with o-ring is inserted with CTS T-screwdriver





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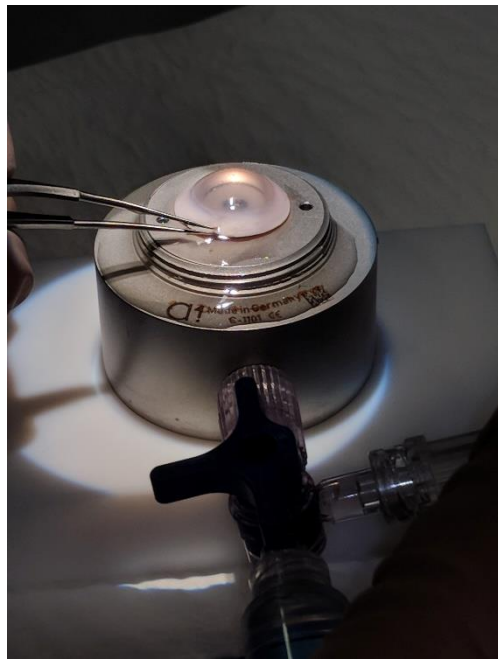
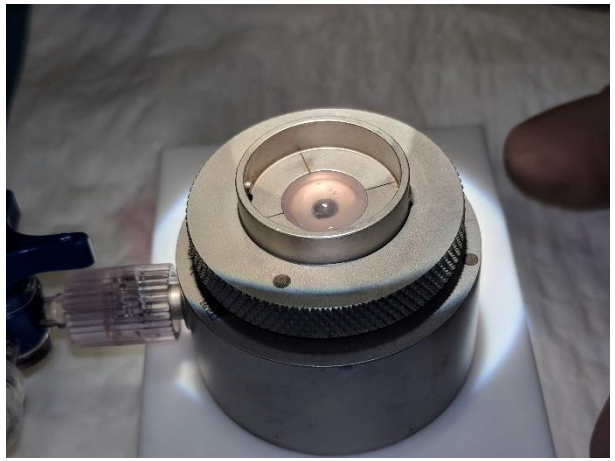
CTS HANDLING

4. The cornea is attached on the CTS Central plug (1) and fixated with CTS Fixation Ring Plate (2) and the CTS Tensioning Screw (3)



(1)

(2)



(3)

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CTS HANDLING

5. Set-up of CTS Trephination-System consisting of Trephine, Obturator (1) CTS Trephine Core (2), CTS Trephination-Guide (3),

(1)

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(3)

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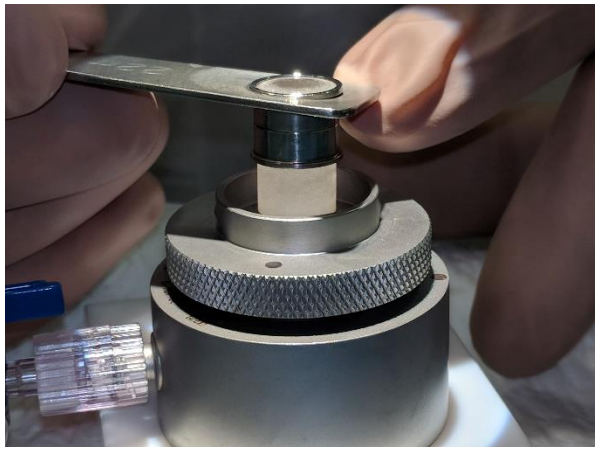
CTS HANDLING

6. Measuring of AC bench pressure (1), marking the startposition (2), apply the CTS Trephination Core to the AC Bench (3)



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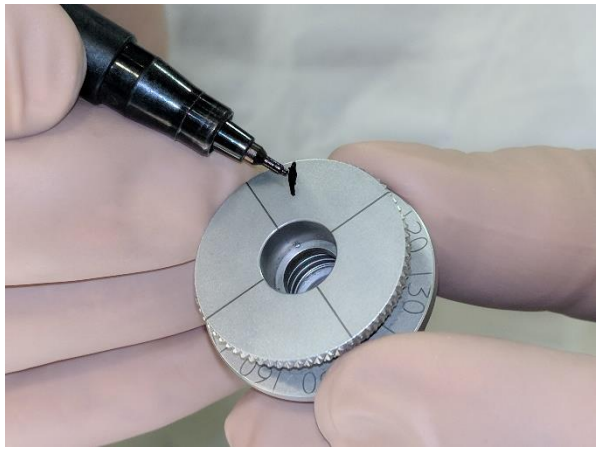

(2)

(3)

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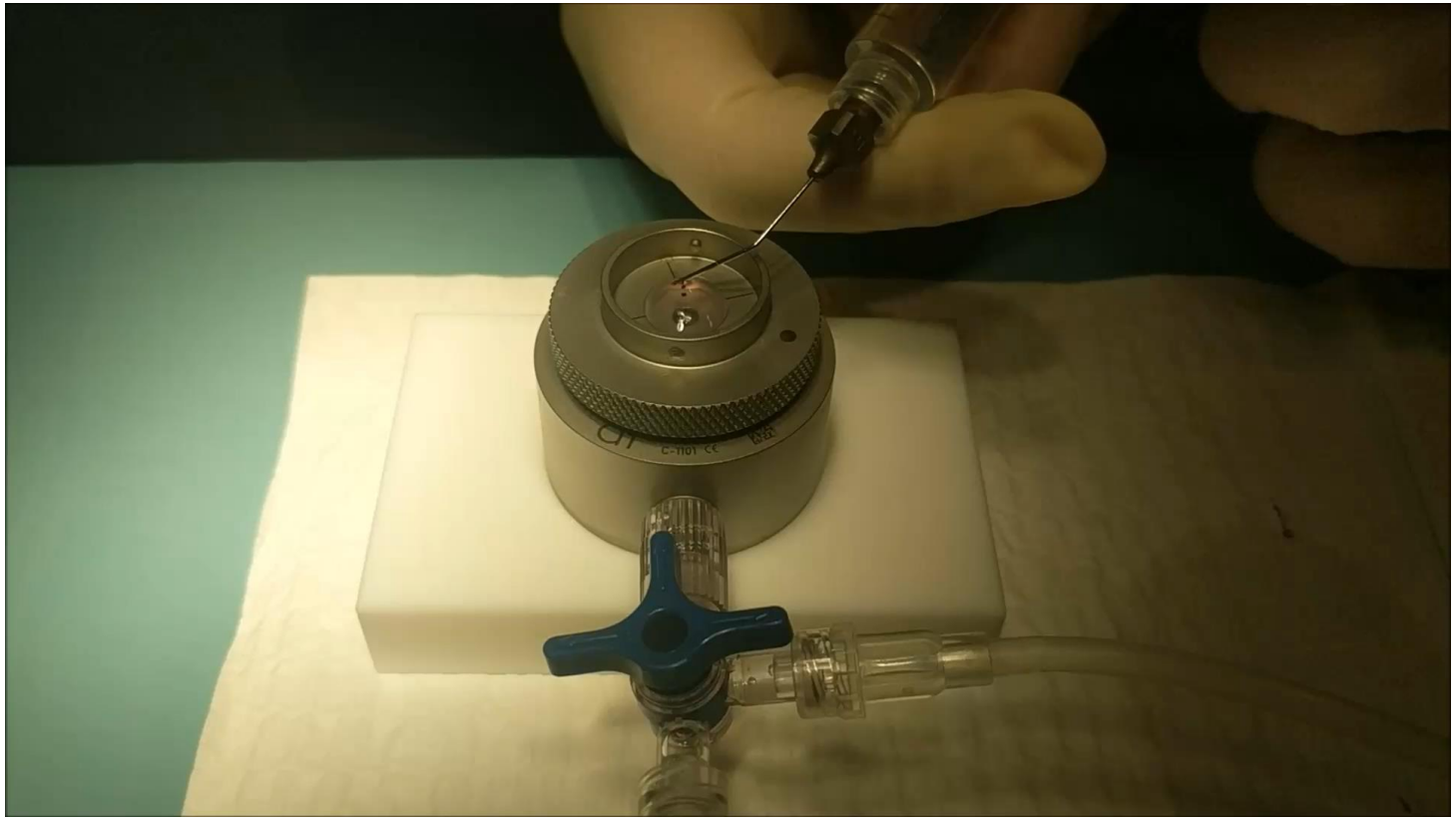
CTS
HANDLING

7. The trephination can now be performed



- A turn from one mark to another equals 100µm depth
- When you see the marks rotate through the microscope, the cut is done

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CTS
HANDLING

8. The trephination of the eye works exact the same way on the CTS suction ring

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DMEK

EASY
LIQUID
BUBBLE
DMEK

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EASY
LIQUID
BUBBLE
DMEK

Descemet's stripping is one of the currently proceeded techniques to gain the graft for the DMEK.

Stripping the Descemet's Membrane, as visible here below, is stressing the tissue and you are touching, grasping the edges with a forceps.

The result is that by touching the Endothelium you are damaging the cells, which are afterwards lost.

That can lead to rejections of the Graft and the procedure must be renewed.

The hospitals can also order already prepared grafts, but how is the graft prepared? Mostly also by stripping, with the difference that it is more expansive, being precut.

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EASY LIQUID BUBBLE DMEK

Dr. Gerten has taken, as the basis for his DMEK-technique, the liquid bubble DMEK from Dr. Melles for gaining the graft by himself.

The goal was to create a safe technique to get the graft, without touching the DM or Endothelium and damaging the DM while creating the bubble.

The result is the EASY LIQUID BUBBLE DMEK by Dr. Gerten.

Prior approach

courtesy of Dr. Gerten

Final technique

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EASY
LIQUID
BUBBLE
DMEK

The advantage is that the surgeon knows the status of the graft.

Using our instruments, designed and devloped together with Dr. Gerten, you can even avoid loosing the graft, which can happen when, for e.g. …

… cataract surgeries have been performed previously on the donner tissue. The incisions for the cataract surgeries leave scars. Those can rupture when creating the bubble. The circular peripheral sealing-ring prevents the tissue to be ruptured at the scars so you will not be loosing the graft.

Hospital is paying less for the donner tissue.

The surgery on patient-side is proceeded to standards.

But we have also here created special instruments for the iridectomy, which has to be done for the circulaiton of liquid within the chamber, and a special Descemeto-Rhexis Forceps as listed on the next page.

Show the videos to your customers and they will directly recognize why this technique is better or even the best at the moment.

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EASY
LIQUID
BUBBLE
DMEK

Steps on Donner side:

1. Fixing the donner tissue on the CTS – Artificial Chamber using the DMEK-Teflon-Central Plug, Epithelium downwards.
2. Creating suction/ vakuum on the Artificial Chamber for fixing the donner tissue
3. Incision
4. First preparation by using the Gerten thin spatula
5. Second preparation by using the Gerten thik spatula
6. Inserting the Gerten-DMEK Cannula for creating the bubble
7. Placing the Gerten circular peripheral sealing-ring, keeping the cannula inside the incision
8. Creating the bubble
9. Trephination of the tissue
10. Separation of graft from tissue in liquid
11. Transportation of the graft to the patient

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EASY
LIQUID
BUBBLE
DMEK

Steps on Patient side:

1. Clear Cornea Incisions
2. Placing the AC-Cannula
3. Iridectomy by using the Gerten Iridectomy Forceps and Scissor
4. Descemeto-Rhexis by using Marker, Sinskey, Spatula and Gerten Descemeto-Rhexis-Forceps
5. Taking out the DM
6. Putting in the new DM
7. Rolling out as usual
8. Air bubble below the graft for better attachment to strome. Re-bubbling if necessary.

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EASY
LIQUID
BUBBLE
DMEK

Instrument Set:

DMEK - SET

Item-No.	Item-Description	Qty
MIS-0611	Steriliz. tray with lid, stainl. steel, electrop., 270x175x30mm, 4 lower & 2 upper instr. sup., for use in autoclave	1
MIS-0154	Metal Bowl Ø 61.0mm height 30.0mm, 0.07 Liter, with sandblasted inside	2
ES-0392	Kershner Eye speculum, fenestrated blades, for nasal and temporal placement	1
F-4640	Halsted Mosquito Forceps, straight, length 14.5cm	2
F-0280	Corneal Colibri Utility Forceps, Corneal Colibri Utility Forceps, 45° angle, length 7.5cm	2
F-1861	Gerten Descemet Forceps, curved, disc shaped & smooth jaws, length 10.5cm	1
F-1500	Kremer Corneal Fixation Forceps, straight, U-shaped, 13.0mm spread, 1x2 teeth, 0.12mm, with lock, length 10.5cm	1
VR-0520-23TDT	Gerten DMEK Rhexis Forceps, 23G, Titanium Handle with changeable Tip in a Storage- and Steriliz.-Box	1
HS-0691	Sinskey Lens Manipulating Hook, Ø 0.2mm, blunt tip, angled, 180° reversed	1
HS-2040	Membran-Peeler, blunt, angled 110°, length 13.0cm	1
HS-0450	Manipulator, Spatula 0.50mm x 0.25mm, round, Ø 0.25mm, angled	1
HS-1950	Bores Optic Zone Marker, 8.0mm	1
VR-0500-23TDT	Gerten Iridectomy Forceps, angled, horiz., 23G, Titanium Handle + chang. Tgip in a Storage- and Steriliz.-Box	1
VR-0510-23TDT	Gerten Iridectomy Scissor, angled, horiz., 23G, Titanium Handle + chang. Tip in a Storage- and Steriliz.-Box	1
C-0723	Gerten Iridectomy Punch, Titanium Handle, etc.	1
C-0550	Universal Trephine Handle	1
C-0560+8.0	Trephine Blade „short model“ 8.0mm Ø	1
C-0560+8.25	Trephine Blade „short model“ 8.25mm Ø	1
L-0730	Air Injection Cannula, angled, 7.0mm, 30G	1
L-0980	Heslin Anterior Chamber Maintaining Cannula, 25G	1
HS-0005TS	Gerten Dilator for the Easy Liquid Bubble DMEK, 0.15/0.5 con., angled, straight 11.0mm, blunt, grad. graduated from 1.0 - 4.0mm distal to proximal in 1mm intervals	1
HS-0007TS	Gerten Dilator for the Easy Liquid Bubble DMEK, 0.15/0.3/0.5 mm, con., angled, straight 11.0mm, blunt, grad. graduated from 1.0 - 4.0mm distal to proximal in 1mm intervals	1
L-1309	Gerten Easy Liquid Bubble DMEK Cannula, 27G, 0.3mm Port above, straight, conc., self-sealing	1
HS-0008TS	Gerten Easy Liquid Bubble DMEK circular peripheral sealing-ring, Ø 10.0mm	1
C-1101	CTS Anterior Chamber, only	1
C-1108	CTS DMEK-Teflon-Central Plug for Anterior Chamber	1

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EASY
LIQUID
BUBBLE
DMEK

Instruments:

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DALK

CLEAR CORNEA FEMTO BUBBLE DALK

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CLEAR
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FEMTO
BUBBLE
DALK

The currently most proceeded technique is the Big Bubble technique, developed by Anwar, Krumeich, etc. and improved by Tan, etc.

Thereby the surgeon is trying the preparate a tunnel into the anterior cornea for inserting a cannula to create the air filled bubble.

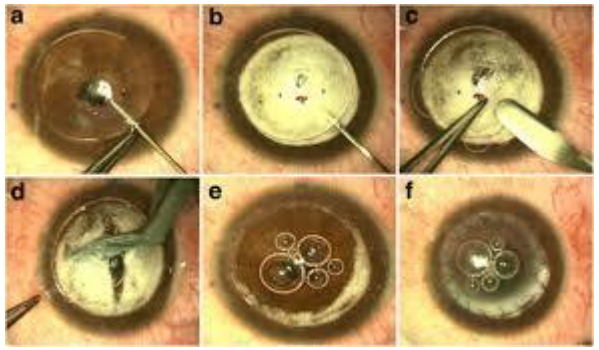
Once the bubble has been successfully created the preparation starts.

The goal is to remove the anterior lamellar part of the cornea down to the Descemet‘s Membrane.

Challenging is …

DM should not be ruptured when inserting the cannula
-> Finding the right level
DM should not be ruptured when removing anterior lamellar parts
DM should not be ruptured when doing preparation on the edges
DM should not be ruptured when doing preparation down to DM
NO stromal parts should remain on the DM

So risk of perforation as well as stromal remnants with inferior optical results is high. In case of a perforation surgeons are trouble shooting by PKP.



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CLEAR CORNEA FEMTO BUBBLE DALK

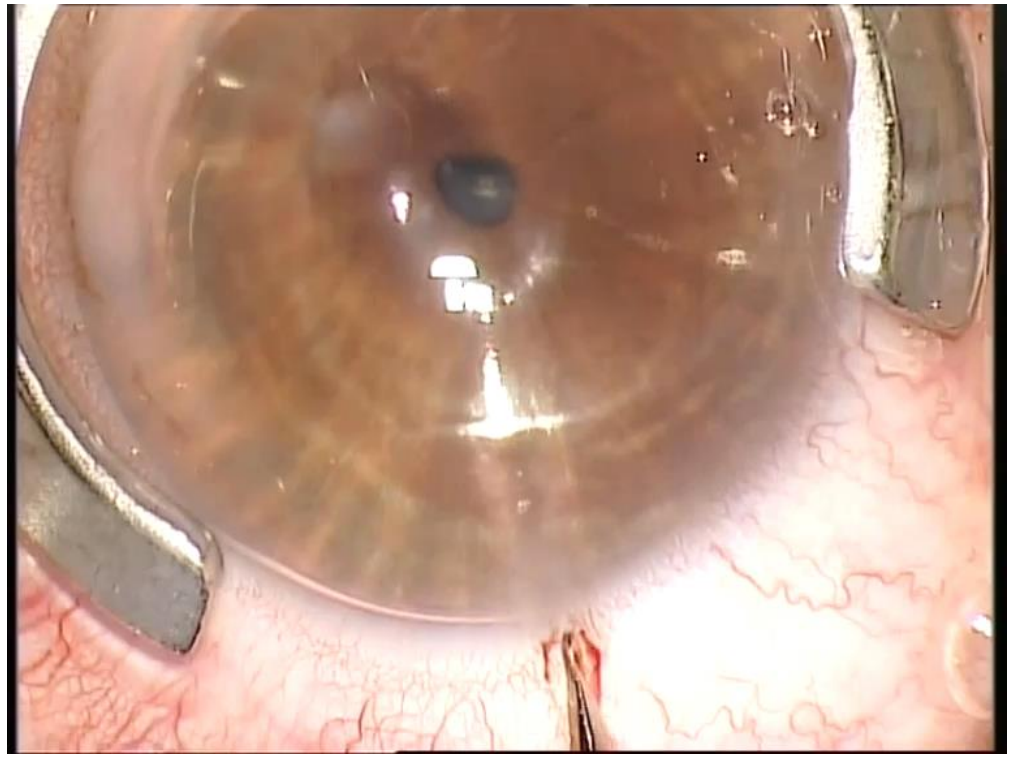
Dr. Gerten has taken, as the basis for his DALK technique also the Big Bubble but considering the following challenges:

- How can the preparation on the patient be done, in a safe, precise and reproducable way?
- Without perforating the DM
- Without Stromal remnants
- Having permanent perfect vision instead of a milky cornea

The goal was to create a safe technique to get the preparation on the patient done without perforations and to get a graft of the donner and the bed at the patient that are perfectly fitting together.

The result is the Clear Cornea Femto Bubble DALK by Dr. Gerten.

courtesy of Dr. Gerten



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CLEAR CORNEA FEMTO BUBBLE DALK

The advantage for the surgeon is, when preparing the tunnel, by the Clear Cornea Entrance, to enter the level between DM and Stoma. Which is then separated by the Cannula.

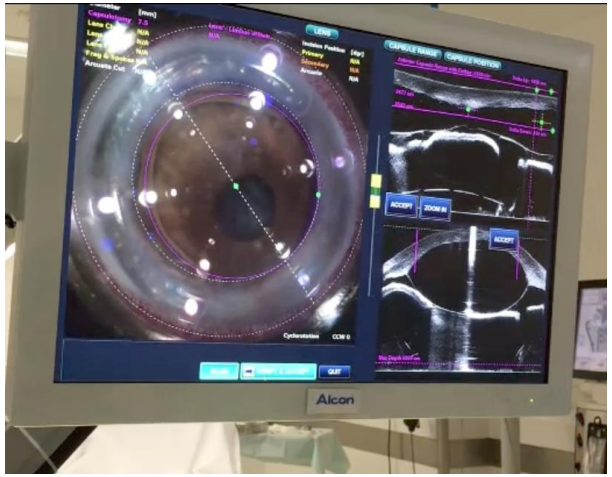
The surgeon has a permanent control and vision to the DM.

Instead of creating a anterior bubble, he is creating a posterior bubble, which is perfectly separating DM from Stroma. So thereby he has already eliminated some challenges that surgeons are still facing and which is leading them to proceed PKP instead of DALK.

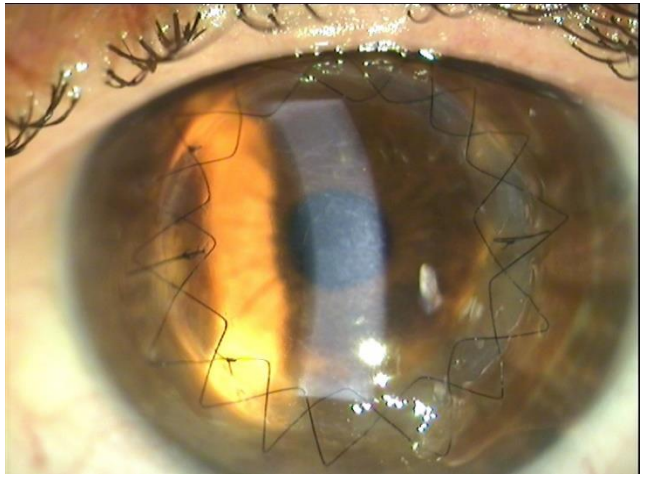
By this technique teaching and learing DALK is going to be much easier so we believe that even the cases will rise.

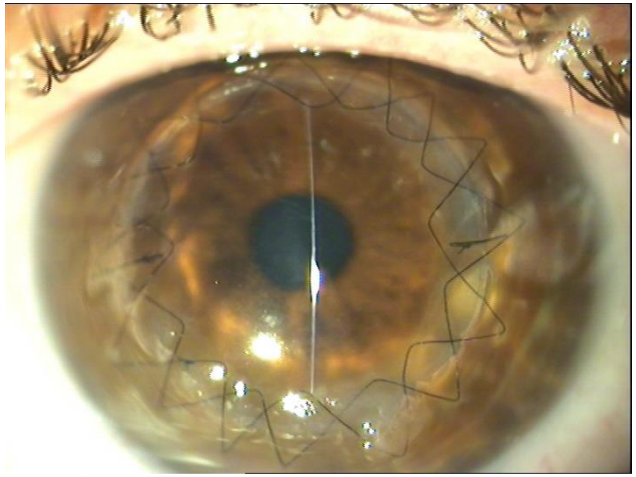
The trephination of the graft can either be proceeded, as visible in the video, by the laser, or by using our CTS.

Stroma and DM during surgery/ laser



Split-lamp diagnosis 1 day after surgery





courtesy of Dr. Gerten

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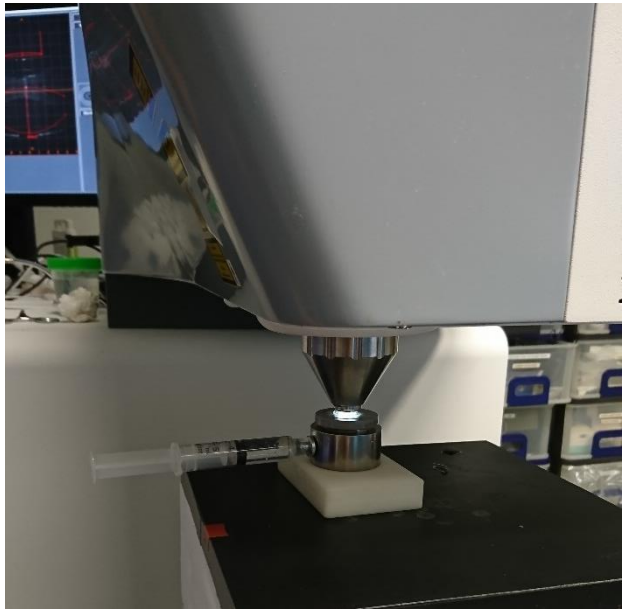
CORNEA
FEMTO
BUBBLE
DALK

Steps on the Donner side:

1. Fixing the donner tissue on the CTS – Artificial Chamber unsing the complete unit. Endothelium downwards.
2. Putting liquid inside until reaching 22mm/Hg vor creating the artificial chamber
3. Lasering the graft
4. Removing DM from graft
5. Graft is ready for transplantation.

courtesy of Dr. Gerten



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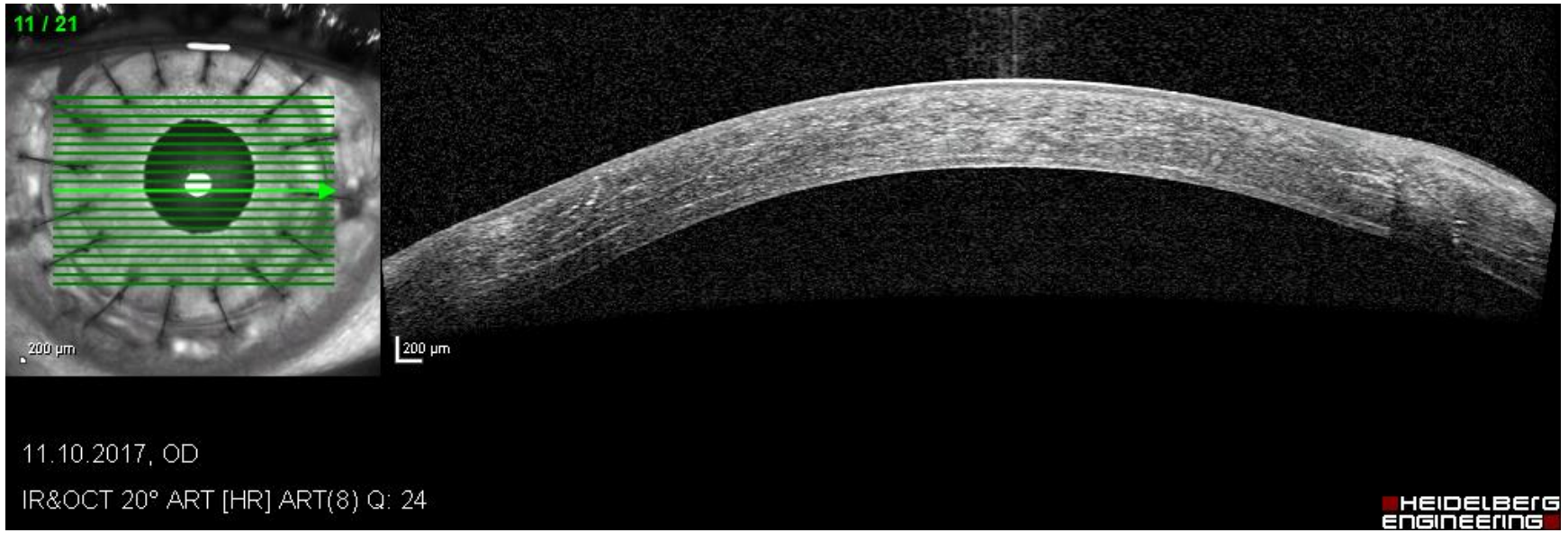
Steps on Patient side:

1. Clear Cornea Incisions until reaching DM
2. Side port incisions for the release of preasure creating the bubble
3. Using the Gerten trifaced spatula for preparing the tunnel
4. Inserting the cannula
5. Injecting air
6. Trephination by laser
7. Removing the cornea
8. Placing in the new graft
9. Double-barelled cross seam
10. Preasure control

courtesy of Dr. Gerten



OCT 3 months after surgery

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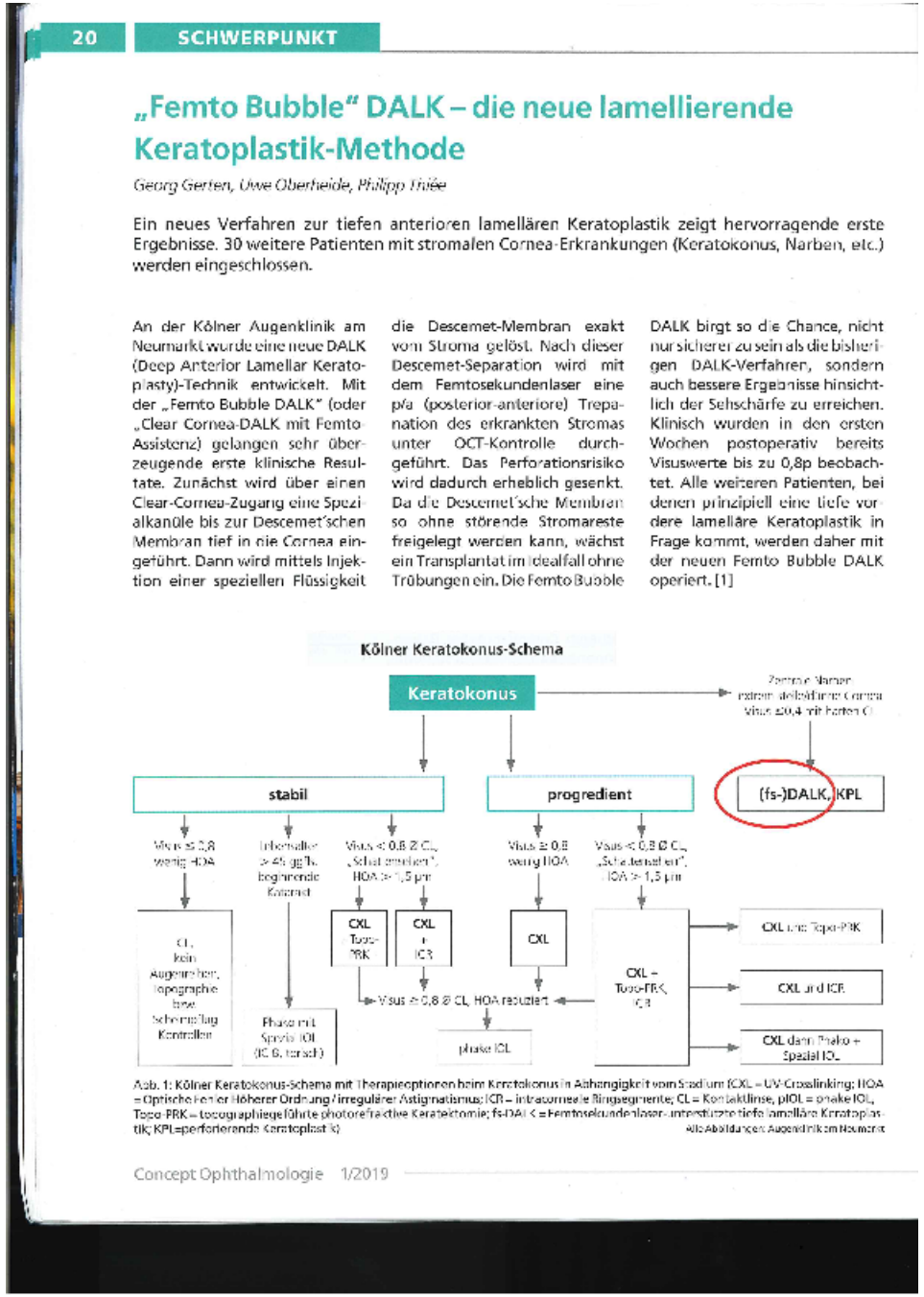
CLEAR CORNEA FEMTO BUBBLE DALK



20 SCHWERPUNKT

„Femto Bubble" DALK – die neue lamellierende Keratoplastik-Methode

Georg Gerten, Uwe Oberheide, Philipp Thiée

Ein neues Verfahren zur tiefen anterioren lamellären Keratoplastik zeigt hervorragende erste Ergebnisse. 30 weitere Patienten mit stromalen Cornea-Erkrankungen (Keratokonus, Narben, etc.) werden eingeschlossen.

An der Kölner Augenklinik am Neumarkt wurde eine neue DALK (Deep Anterior Lamellar Keratoplasty)-Technik entwickelt. Mit der „Femto Bubble DALK" (oder „Clear Cornea-DALK mit Femto-Assistenz) gelangen sehr überzeugende erste klinische Resultate. Zunächst wird über einen Clear-Cornea-Zugang eine Spezialkanüle bis zur Descemet'schen Membran tief in die Cornea eingeführt. Dann wird mittels Injektion einer speziellen Flüssigkeit die Descemet-Membran exakt vom Stroma gelöst. Nach dieser Descemet-Separation wird mit dem Femtosekundenlaser eine p/a (posterior-anteriore) Trepanation des erkrankten Stromas unter OCT-Kontrolle durchgeführt. Das Perforationsrisiko wird dadurch erheblich gesenkt. Da die Descemet'sche Membran so ohne störende Stromareste freigelegt werden kann, wächst ein Transplantat im Idealfall ohne Trübungen ein. Die Femto Bubble DALK birgt so die Chance, nicht nur sicherer zu sein als die bisherigen DALK-Verfahren, sondern auch bessere Ergebnisse hinsichtlich der Sehschärfe zu erreichen. Klinisch wurden in den ersten Wochen postoperativ bereits Visuswerte bis zu 0,8p beobachtet. Alle weiteren Patienten, bei denen prinzipiell eine tiefe vordere lamelläre Keratoplastik in Frage kommt, werden daher mit der neuen Femto Bubble DALK operiert. [1]

Abb. 1: Kölner Keratokonus-Schema mit Therapieoptionen beim Keratokonus in Abhängigkeit vom Stadium (CXL = UV-Crosslinking; HOA = Optische Fehler Höherer Ordnung / irregulärer Astigmatismus; ICR = intrastromale Ringsegmente; CL = Kontaktlinse, pIOL = phake IOL, Topo-PRK = topographiegeführte photorefraktive Keratektomie; fs-DALK = Femtosekundenlaser-unterstützte tiefe lamelläre Keratoplastik; KPL=perforierende Keratoplastik)

Alle Abbildungen: Augenklinik am Neumarkt

First clinical results are already published.

More clinical results in process.

The CCFemtoBubble-DALK is promising to be the perfect technique, eliminating the prior known challenges, making it reproducable.

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CLEAR CORNEA FEMTO BUBBLE DALK

Instrument Set:

DALK - SET

Item-no.	Item-Description	Qty
MIS-0611	Steriliz. tray with lid, stainl. steel, electrop., 270x175x30mm, 4 lower & 2 upper instr. sup., for use in autoclave	1
MIS-0154	Metal Bowl Ø 61.0mm height 30.0mm, 0.07 Liter, with sandblasted inside	2
ES-0392	Kershner Eye speculum, fenestrated blades, for nasal and temporal placement	1
HS-0450	Manipulator, Spatula 0.50mm x 0.25mm, round, Ø 0.25mm, angled	1
F-0280	Corneal Colibri Utility Forceps, Corneal Colibri Utility Forceps, 45° angle, length 7.5cm	2
F-0940	Suture Forceps (Tuebingen model), with 5.0mm tying platform, very delicate, length 8.5cm	1
N-0330	Barraquer Needle Holder, curved, 9.0 x 0.5mm, smooth jaw, without lock, length 12.0cm	1
S-0400	Troutman-Katzin Corneal Transplant Scis. strong cvd, right, point. tips&small bl. cutting length 6.0mm, length 10.0cm	1
S-0410	Troutman-Katzin Corneal Transplant Scis. strong cvd, left, point. tips&small bl. cutting length 6.0mm, length 10.0cm	1
HS-1665	Green Cornea Marker, 4 Blades, Inner-Ø: 3.0mm, Outer-Ø: 12.0mm	1
HS-1666	Neuhann Cornea Marker, 8 Blades, Inner-Ø: 3.0mm, Outer-Ø: 12.0mm	1
HS-0691	Sinskey Lens Manipulating Hook, Ø 0.2mm, blunt tip, angled, 180° reversed	1
HS-0004TS	Gerten Spatula for the Clear Cornea DALK, triangular, slim, angled, 11.0mm, blunt	1
L-1308	Gerten Clear Cornea DALK Cannula, 25G, 0.5mm Port below, conical, angled, self-sealing	1
L-0730	Air Injection Cannula, angled, 7.0mm, 30G	1
HS-1620	Globe Fixation Ring	1
HS-1811	Gerten Cornea Zone Marker, 6.0mm, with Marking of the Cornea-Center	1
HS-1831	Gerten Cornea Zone Marker, 8.0mm, with Marking of the Cornea-Center	1

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DALK

Instruments:

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KERATOPLASTY
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Positioning statement:

Keratoplasty by a1 medical is promising to be the first choice for each Cornea-Surgeon.
The CTS together with the two techniques are very unique and unbeatable at the moment.

Target customers:

Cornea Surgeons and Eye Banks

Main selling points:

Unique, precise, eliminating challenges, improving surgery, etc. Only available at a1 medical.
In addition it is a one time investment for a system and two instruments sets, and the hospital can cover all Keratoplasty-Surgeries with it.

Handling common market objections:

Yes, there are also other tequniques but all of them have risks, that can be eliminated by switching to our system and techniques.

Product superiorities versus competition:

No one has those systems and instruments sets. Comparable products, like for trephination are all not serving with the result of our CTS. DMEK and DALK Instruments, i mean the Gerten Instruments are available only with us. A customer entering the Keratoplasty by a1 medical will be able to perfomr Keratoplasty at its highes profession, without a need of any other additional company.

Supportive promotional tools:

CTS brochures available now. DMEK and DALK within short time.

https://youtu.be/gAOlpFuu5YE

at min. 16:12

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THANKS

THANK YOU FOR YOUR ATTENTION!