DIOPTEX

THE FINE ART OF CORNEAL AND REFRACTIVE SURGERY

HISTORY OF DIOPTEX

innovation

2003

Dioptex was founded in 2003 by Dr. Albert Daxer as a research and developmental company. It is a spin-off of his scientific work at the Department of Ophthalmology, University of Innsbruck, Austria. Dr. Daxer introduced the Corneal Pocket Concept (CPC) as a general surgical principle into corneal surgery, and designed and developed the related tools and internationally patented high-end devices such as PocketMaker Ultrakeratome, PocketMaker Artificial Anterior Chamber, disposable Micro-CXL, MyoRing intra-corneal implant for the treatment of Keratoconus and Myopia as well as the related surgical procedures.

The PocketMaker, an internationally patented Ultrakeratome of incomparable precision and safety for the creation of corneal pockets is the starting point for many applications related to the new surgical concept. It can be considered as a revolutionary step in the development of corneal surgery. In contrast to conventional technologies such as mechanical LASIK microkeratomes and Femtosecondlasers, the PocketMaker Ultrakeratome marks the latest innovation step in the development of corneal cutting technology. The PocketMaker Ultrakeratome uses a new cutting principle based on a most innovative ultra-high precision diamond technology that guarantees incomparable quality of corneal cutting.

2007

CISIS (Corneal IntraStromal Implantation Surgery), the first surgical application of this revolutionary new corneal technology was introduced by Dr. Daxer in 2007 at ESCRS in Stockholm. CISIS combines the PocketMaker Ultrakeratome cutting of corneal pockets with the implantation of a new kind of corneal implant (MyoRing) into the corneal pocket for the treatment of Myopia, Keratoconus and post-LASIK Keratectasia.[1,2] In order to achieve the best possible result in every given case, the internationally patented MyoRing is an innovation designed to combine two a priori opposite qualities: It is rigid but also compressible to allow both, visual rehabilitation and implantation into a corneal pocket via a small incision.

2008

Dr. Haifa Mahmood of Bahrain and Prof. Jorge Alio of Alicante, Spain performed the first CISIS with MyoRing implantation using Femtosecondlaser technology.[3,4]

Dr. Daxer introduced a new surgical procedure for corneal crosslinking according to the CPC using the PocketMaker Ultrakeratome technology: Pocket CXL.[5]

[1] Daxer A. Corneal intrastromal implantation surgery for the treatment of moderate and high myopia. J Cataract Refract Surg 2008;34:194-198.
[2] Daxer A. Adjustable Intracorneal Ring in a Lamellar Pocket in Keratoconus. J Refract Surg 2010;26:217-221.
[3] Mahmood H, Venkateswaran RS and Daxer A. Implantation of a Complete Corneal Ring in an Intrastromal Pocket for Keratoconus. J Refract Surg 2011;27:63-68.
[4] Alio JL, Pinero DP and Daxer A. Clinical Outcome After Complete Ring Implantation in Corneal Ectasia using the Femtosecond Technology. Ophthalmology 2011;118:1282-1290.
[5] Daxer A, Mahmood H and Venkateswaran RS. Corneal Crosslinking and Visual Rehabilitation in Keratoconus in One Session Without Epithelial Debridement: New Technique. Cornea 2010;29:1176-1179.

In this new procedure Riboflavin is injected into the corneal pocket at 300 microns corneal depth for 2 minutes and then irradiated by UV-A light. This new approach avoids pain and healing problems of conventional treatment and reduces the time for surgery and UV-A exposure dramatically. In contrast to conventional epi-off crosslinking which requires 5.4 J/cm^2 total UV-A energy transferred to the cornea, the surgeon can achieve the same effect with only 2.1 J/cm^2 total UV-A energy transferred to the cornea when performing Pocket CXL. And the very best, this procedure can be combined with MyoRing implantation in the same surgical session to achieve not only stop of Keratoconus progression but also visual rehabilitation.

2010

Dr. G.M. Bikbova and Prof. M.M. Bikbov, Ufa Eye Research Institute, Ufa, Russian Federation, performed the first PocketMaker Endothelial Keratoplasty procedure.[6]

2011

Dr. Pavel Studeny of Czech Republic performed the first PocketMaker Keratoprothesis procedure.

2013

DIOPTEX launched the patented PocketMaker Artificial Anterior Chamber (AAC) at the ESCRS in Amsterdam. This superior technology, developed by Dr. Daxer is a revolutionary step in the development of safe and precise DALK and Endothelial Keratoplasty techniques as well as in modern eye-banking.

For optimal crosslinking results the revolutionary DIOPTEX Micro-CXL technology was developed and launched as disposable Mirco-CXL at the ESCRS in Amsterdam 2013. It uses a superior disposable Micro UV-A with many most innovative features.
DIOPTEX DISPOSABLE MICRO-CXL with the integrated MAGIC TOUCH technology can simply be called THE INNOVATION OF THE YEAR 2013!

A further revolutionary development based on the PocketMaker Ultrakeratome technology is ISKE (IntraStromal Keratectomy) for the removal of an intrastromal tissue lenticule without a flap for the treatment of high myopia.

[6] Bikbova G, Bikbov M and Daxer A. Descemet Stripping PocketMaker Endothelial Keratoplasty. Int J Kerat Ect Cor Dis 2012;1(2):125-127.

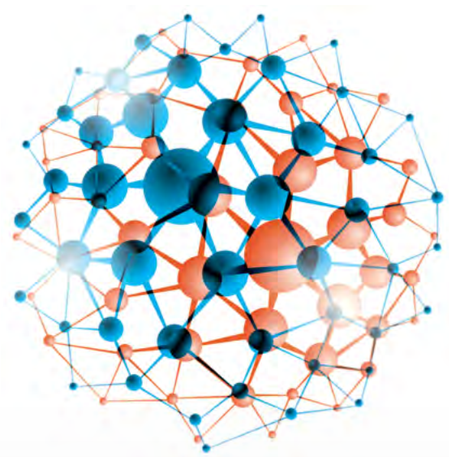
CORNEAL POCKET CONCEPT

Mother nature developed the cornea of the human eye according to the optical and biomechanical needs as a very regular ordered collagen tissue to achieve the right dipotic power, perfect transparency, immunological privilege and biomechanical strength.[7] In particular the structure and lamellar arrangement of the collagen is the basis of the biomechanical framework of the cornea. [8,9]

Therefore, the CORNEAL POCKET CONCEPT is the natural and most appropriate surgical approach to the lamellar nature of this particular tissue. The CORNEAL POCKET CONCEPT is based on the creation of a lamellar intra-corneal pocket without a significant alteration of the collagen lamellar structure.

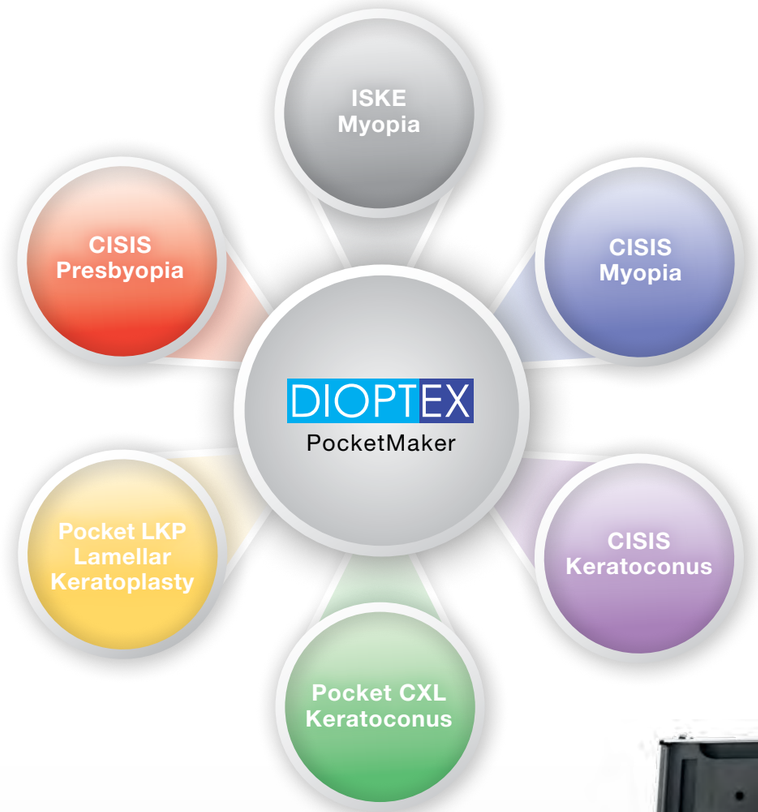
As a result of this biomechanical know-how a corneal pocket is the absolutely right structure in corneal surgery since it preserves the corneal biomechanics, independent of the pocket's dimension. This is in contrast to a non-lamellar surgery like e.g. a lasik flap, which definitely destroys biomechanics and weakens the cornea.

In this concept, the corneal pocket, preferably created by the PocketMaker Ultrakeratome is the starting point for many new applications and surgical solutions.



[7] Fratzl P and Daxer A. Structural transformation of collagen fibrils in corneal stroma during drying: An x-ray scattering study. Biophys J 1993;64:1210-1214.
[8] Daxer A and Fratzl P. Collagen fibril orientation in the human corneal stroma and its implication in keratoconus. Invest Ophthalmol Vis Sci 1997;38:121-129.
[9] Daxer et al. Collagen fibrils in the human corneal stroma: structure and ageing. Invest ophthalmol Vis Sci 1998;39:644-648.

ONE POCKET - MANY APPLICATIONS



POCKETMAKER ULTRAKERATOME

precision & safety

The PocketMaker Ultrakeratome is an internationally patented device which sets a new standard in corneal cutting technology. It is in its precision, safety as well as number and kind of applications superior to all other existing corneal cutting technologies including mechanical Microkeratomes and Femtosecondlaser Microkeratomes.

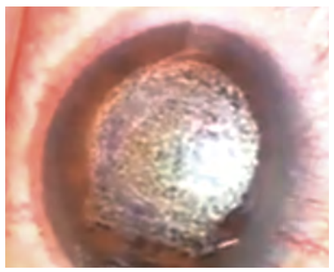
The PocketMaker Ultrakeratome is the core device for the surgical application of the CORNEAL POCKET CONCEPT. It allows the creation of almost entirely closed corneal pockets of up to 9 mm in diameter at any corneal depth.

The entire device fits into a case which is easy to carry. Among others this feature is the result of implementing the latest micro-technology into the system.

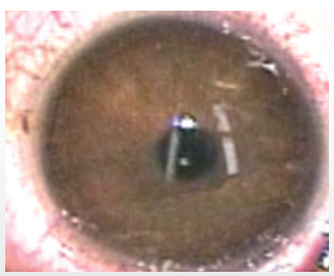
The creation of the pocket using the PocketMaker Ultrakeratome is a very safe procedure which is quick and easy to perform. It requires topical anesthesia only. The entry to the pocket is self-sealing and no suture is required.
The depth of the pocket is defined by the dimension of the disposable transparent applanator. The applanator has a magnification lens and, therefore, no surgical microscope is required. The PocketMaker Ultrakeratome gives the surgeon full visual and interventional control during the entire procedure.

The unique PocketMaker Ultrakeratome cutting technology uses an ultra-thin, on micron-level guided single-crystal diamond with cutting edges sharpened on atomic level even and driven by a unique, sterilizeable vibration micro-engine.
This superior corneal cutting technology guarantees the cutting of most perfect corneal pockets where the cutting interface is that smooth and of such a extraordinary quality that the corneal cut itself cannot even be easily recognized via a regular surgical microscope.

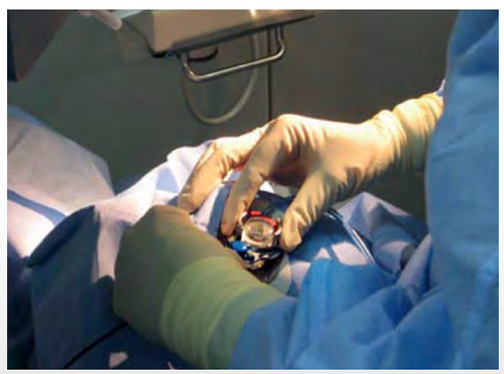
The photos show the situation immedatley after pocket creation.



corneal pocket using Femtosecondlaser technology



PocketMaker Ultrakeratome diamond technology.



MYORING INTRA-CORNEAL IMPLANT

The MyoRing is an internationally patented intra-corneal implant for the treatment of Keratoconus and Myopia. The MyoRing is a complete-ring shaped implant and a unique device since it combines two a-priori conflicting features which normally exclude each other:
The implant is rigid enough to maintain the stabilisation of the cornea and flexible (compressible) enough to be introduced into a corneal pocket via a small incision. It has also a shape-memory in order to reshape to the original shape within the pocket after implantation.

minimally invasive

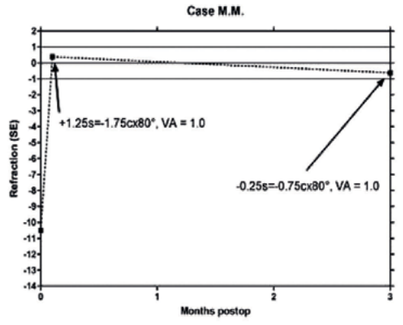
MYORING FOR MYOPIA

The MyoRing is particularly designed to cover the entire myopic range from -1 to -20 diopters.

The INDICATIONS for MyoRing treatment of Myopia are those not eligible for Excimer Laser treatment such as:

- high myopia
- thin cornea
- irregular corneal surface forme fruste
- forme fruste keratoconus
- the patient denies LASIK but wants a minimally-invasive and reversible myopia treatmen

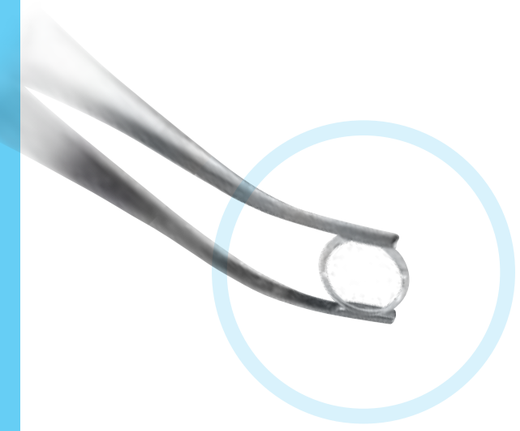
Since the alternatives to Excimer Laser surgery in these cases are intraocular procedures with significant side effects and long-term complications,[10]



CISIS (MyoRing implantation) for Myopia offers a minimal-invasive, reversible, safe and easy to perform alternative to the intraocular procedures.

The number of patients found to be not eligible for Excimer Laser surgery usually exceeds 15 % of the patients interested in Laser Vision Correction.
MyoRing implantation for Myopia, therefore, allows Laser Vision Centers to cover at least a significant number of this huge diagnostic drop-out rate.

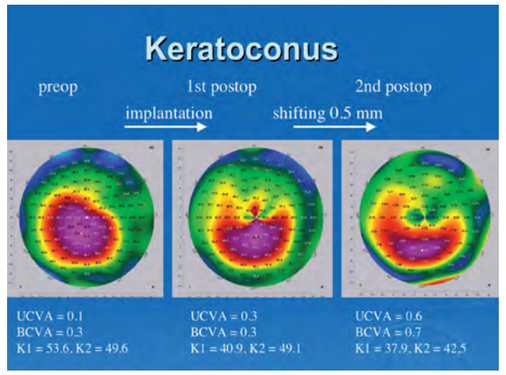
[10] Torun N et al. Posterior chamber phakic intraocular lens to correct myopia: Long-term follow-up. J Cataract Refract Surg 2013;39:1023-1028.



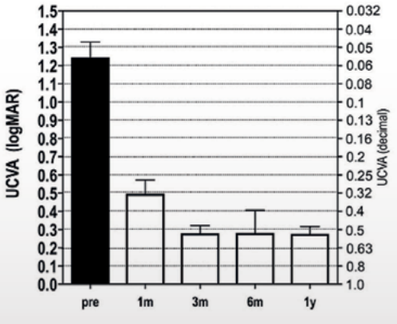
MYORING
FOR KERATOCONUS

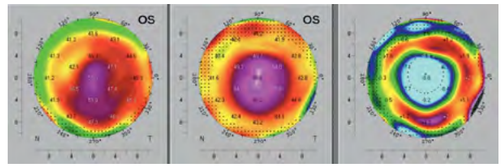
In contrast to conventional corneal implant techniques such as intra-corneal ring segments which are captured in corneal tunnels and which allow the surgeon access to only one degree of freedom (implant thickness), the MyoRing intra-corneal implant, implanted into a pocket which is usually larger in diameter than the diameter of the MyoRing, gives the surgeon access to all 3 theoretically possible degrees of freedom of corneal implant surgery (implant thickness, implant diameter and implant position). Therefore, this superior kind of surgery allows the surgeon to achieve the best possible result in every given case.

In particular the possibility to change the position of the MyoRing implant relative to the optical axis within the 9 mm corneal pocket is of outmost clinical importance for the following reason: A concentric preparation of a corneal tunnel around the postoperative optical axis is not possible since the postoperative optical axis is not known preoperatively and the postoperative optical axis is also different to the optical axis preoperatively. In other words, nobody knows the right placement of an intra-corneal implant preoperatively.[2] Shifting the MyoRing by only 0.5 mm can lead to a dramatic improvement of the result.[2]

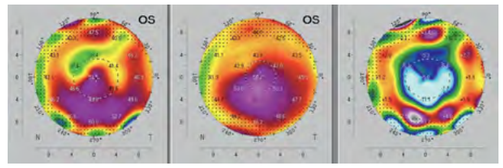


Without using these kinds of optimisation possibilities of CISIS the mean improvement of uncorrected visual acuity in moderate to advanced keratoconus cases using the regular nomogram is about 6 lines (logMAR).[11,12] These resutls can be significantly improved to more than 10 lines if a postoperative optimisation step, which can be necessary in up to 20 % of the cases, is performed.[2,11,12,13] The right analysis of the postoperative results and the related decision making in order to achieve the best results in every given case is part of an intensive training program for the surgeon at DIOPTEX. This particular training program consists of several steps including theoretical lectures, wetlab training, assisted surgery as well as preoperative and postoperative online consultation.
CISIS can be successfully applied to all grades of Keratoconus, especially if combined with Pocket CXL which increases the effect of the implant in advanced cases.
It can be used to treat central and non-central cones as well as post LASIK-Ectasia.[14]





central cone



non-central cone

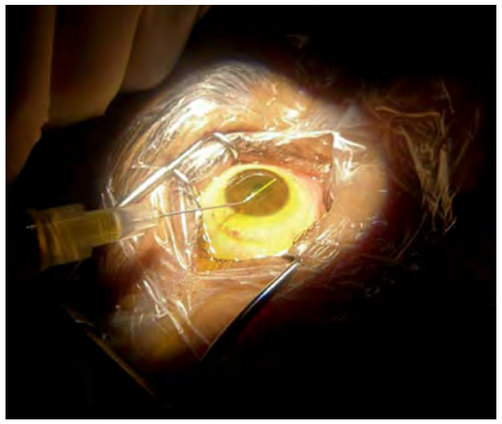
As the MyoRing is a full (360°) ring implant with no free ends, the extrusion rate is in contrast to ring segments almost zero.

11 Daxer B, Mahmood H, Daxer A. MyoRing Treatment for Keratoconus: DIOPTEX PocketMaker vs. Ziemer LDV for Corneal Pocket Creation. Int J Kerat Ect Cor Dis 2012;1(3):151-152.
12 Jabbarvand M et al. Continous intracorneal ring implantation for keratoconus using femtosecond laser. J Cataract Refract Surg 2013;39:1081-1087.
13 Daxer A, Mahmood H and Venkateswaran RS. Intracorneal continous ring implantation in Keratoconus: One-year follow-up. J Cataract Refract Surg 2010;36:1296-1302.
14 Daxer A. MyoRing for Central and Noncentral Keratoconus. Int J Kerat Ect Cor Dis 2012;1(2):117-119.

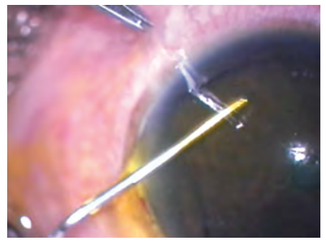
POCKET CROSSLINKING (POCKET CXL)

Pocket Crosslinking means corneal crosslinking by applying Riboflavin to the cornea via a PocketMaker corneal pocket at preferably 300 microns depth to bypass the epithelium.[5]

After creation of the corneal pocket using the PocketMaker Ultrakeratome Riboflavin is injected into the corneal pocket via the small entry tunnel for anly 2 minutes. This most effective procedure avoids postoperative pain and discomfort since the epithelium is not touched.



Riboflavin injection

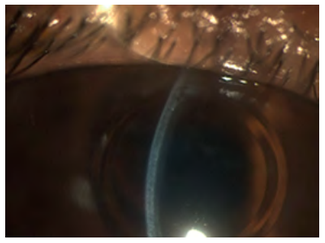


The optimal depth for the placement of the corneal pocket was found to be 300 microns since this placement reduces the required total UV-A energy transfer to the cornea to about 2.1 J/cm² compared to 5.4 J/cm² of the conventional epi-off technique.
For this particular kind of treatment the UV-A exposure time can be significantly reduced according to the **Daxer-Formula**

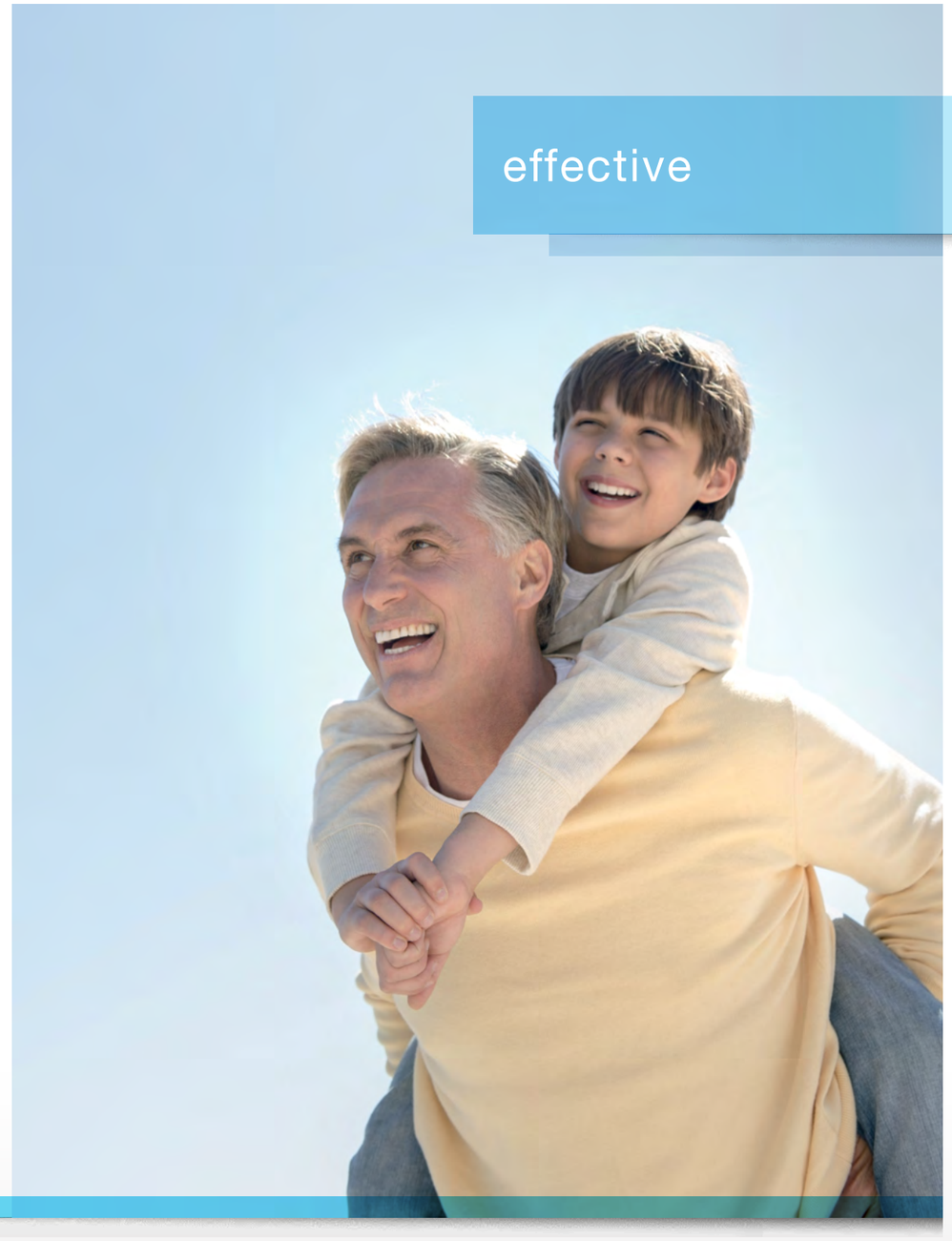
$$UV-A\ exposure\ time\ (minutes) = \frac{36}{UV-A\ intensity\ \left(\frac{mW}{cm^2}\right)}$$

Pocket CXL can (or should) be combined with Myo Ring implantation by placing both into the same corneal pocket, Riboflavin and MyoRing.[5]

Pocket-CXL combined with MyoRing implantation can achieve both in one surgical session: stop of progression and visual rehabilitation. And all this without postoperative pain and significantly reduced UV-A energy transfer.



One day after combined surgery



DIOPTEX
DISPOSABLE
MICRO-CXL

This most innovative patented device is the first CXL system based on integrated micro technology. It is a disposable single use system with many fundamental advantages over existing systems and marks the beginning of a new era in corneal crosslinking: So far Corneal Crosslinking (CXL) was the field of large, expensive and heavy UV-A sources. DIOPTEX disposable Micro-CXL is the latest UV-A technology for Corneal Crosslinking. The device is smaller than a tiny pen even and it can be placed directly on the eye to avoid any effect of eye movement.

INNOVATION OF THE YEAR 2013

It can be carried simply in a pocket of a trousers or a shirt. This device uses latest integrated micro technology and follows a „pay per procedure“ – philosophy. It is a single use disposable device and comes in 2 versions:
1. a version with 5.4 J/cm^2 total energy transfer for conventional epi-off Crosslinking.
2. a version with 2.1 J/cm^2 total energy transfer for the most effective Pocket Crosslinking technique.

The system is very easy to use with its MAGIC TOUCH technology but it is also adjustable according to the individual needs.

For instance, even the beam profile of the UV-A light can be varied individually, if needed.
The particular main beam profile results in a shortening of the corneal lamellae anterior to the pocket and the MyoRing.

Therefore, the system can either be used for the stop of keratoconus progression only or as a refractive procedure in combination with MyoRing implantation in order to achieve incomparable excellent visual results in advanced keratoconus cases even.

LAMELLAR KERATOPLASTY

Another important application of the CPC and the PocketMaker Ultrakeratome technology is the use of corneal pockets as a starting point for lamellar anterior and endothelial keratoplasty.

The patented PocketMaker Lamellar Keratoplasty System (PMLKP) is a revolutionary development which uses

1. the superior PocketMaker Ultrakeratome cutting technology,

2. a most precise stop-delimited trephination technology for the host cornea in order to limit the trephination at the pocket level and

3. a PocketMaker Ultrakeratome artificial anterior chamber (PMAAC) in order to apply the superior cutting technology of the PocketMaker Ultrakeratome to the donor corneal button.

The fact, that the technology allows to safely cut large pockets with perfect smooth interfaces as close as 50 microns to the Endothelium will change Lamellar Keratoplasty to a very safe, effective and easy to perform procedure with a very low conversion rate. Since the PocketMaker technology allows the surgeon to perform a corneal cut of any shape it is also possible to cut even parallel to the posterior corneal surface – an important feature to avoid peripheral transplant steps in Endothelial Keratoplasty.

A main problem when creating corneal pockets with Femtosecondlaser technology as a starting point for CISIS, keratoplasty or keratoprothesis is that the corneal tissue is usually scary or turbid or may have folds at least in a limited area. In such cases incomplete Femtosecondlaser pockets are not rare. The PocketMaker technology, however, is not sensitive to such limitations and incomplete cutted pockets are usually not seen since scars, turbidity or folds do not affect the safety and effectiveness of the PocketMaker Ultrakeratome cutting process. A further problem in this kind of applications when using the Femtosecondlaser technology is the fact, that the localized tissue rupture of the laser shots during tissue cutting have often to be applied deep in the corneal stroma. However, the deeper the Femtosecondlaser application the more imprecise is the cutting and the more uncertain the result. In contrast, the precision and quality of cutting of the PocketMaker Ultrakeratome technology is independent of the cutting depth. Moreover, the PocketMaker is so precise that it can cut safely at least 50 microns close to the Endothelium with a most perfect cutting interface.

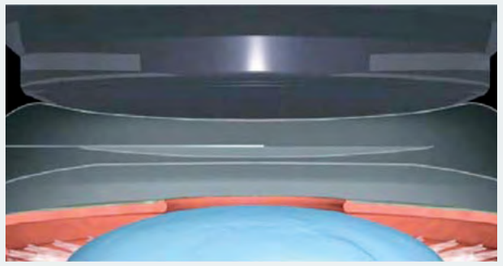
PRESBYOPIA

As a result of the so far unreached corneal pocket cutting quality, the PocketMaker Ultrakeratome is the best choice for creating corneal pockets for presbyopia inlay implantation.

In contrast to similar Femtosecondlaser approaches, where incomplete cuts are a risk for irreversible postoperative irregular astigmatism,[15] the PocketMaker Ultrakeratome technology avoids such complications since it allows perfect smooth cutting interfaces as a result of the particular lateral diamond technology.

ISKE

ISKE (Intrastromal Keratectomy) is a revolutionary technology. The internationally patented system uses the ultra-high precision and unique cutting quality of the PocketMaker Ultrakeratome which allows the cutting of two overlapping corneal pockets to separate an intrastromal tissue lenticule from the remaining corneal stroma which can be removed easily by a forceps via a small corneal tunnel. The fact that no flap is needed preserves the biomechanical stability of the cornea in comparison to LASIK.



[15] Zixian D and Xingtao Z. Irregular astigmatism after femtosecond laser refractive lenticule extraction. J Cataract Refract Surg 2013;39:952-954.

future

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