Print Article

REFRACTIVE SURGERY

New treatment option for keratoconus

by Mark Tomalla, M.D.

view chart

Implantation of intracorneal ring segments with support from the femtosecond laser

In patients with keratoconus, a new surgical approach should enable better stabilization of the cornea as well as a reduction of astigmatism.
Method
Our first surgical experience with new femtosecond laser technology is reported, as well as post-op results of some cases.
All patients suffered from progressive keratoconus and were unable to wear contact lenses. They were treated with implantation of intracorneal ring segments. Tunnel preparation was realized with femtosecond laser technology.

Results

Stabilization of the cornea was successful in all treated eyes. Post-op astigmatism was significantly reduced and visual acuity improved more than 50% in all patients.
Femtosecond laser technology allows realization with very high accuracy of individualized shape and size of corneal tunnel depending on the surgical need. Intrastromal cuts from the inner to the outer parts of the cornea can be performed easily. During surgery, stress to the cornea is minimal, because only moderate pressure is exerted on the eye. The risk of infection is significantly reduced.
The technology of the femtosecond laser allows a new surgical approach for the treatment of keratoconus with implantation of corneal ring segments. Individualized treatment schemes can be realized with convincing first results. During post-op period, we observed a significant improvement of patients' visual acuity. At the moment, none of the participating patients needs to be treated by keratoplasty.
Femtosecond laser technology is a new treatment tool for the eye surgeon. We have been using the femtec (20/10 PERFECT VISION, Heidelberg, Germany) femtosecond laser in Duisburg, Germany at the Eye Clinic of Refractive and Ophthalmic Surgery since July 2004.
Beside preparation of flaps, the laser offers a new treatment option for patients with progressive keratoconus. The laser is very useful for precise preparation of ring tunnels before implantation of the intracorneal ring segments (ICRS).

Keratoconus

Keratoconus is characterized by generalized thinning and cone-shaped protrusion of the central cornea, which affects visual acuity. In the last stage, most cases need keratoplasty with all the risks associated with this procedure. Normally, this corneal disease affects both eyes but in different dimensions and at different times.

Symptoms of keratoconus are: changing visual acuity despite correction with glasses or contact lenses, perception of halos around light sources, as well as increased sensitivity to light and blinding.
Keratoconus affects one in 2,000 people. Causes for this disease are unknown. In families which are affected, it occurs more often, so the reason might be genetic predisposition. In addition, it affects people with trisomy 21 (Down's syndrome). Also, frequent and intense rubbing of the eyes for years, e.g., because of allergic reaction, is discussed as one possible reason for the development of keratoconus. There might be an existing relationship with extremely rare systemic diseases, where parts of the connecting tissues are destroyed, like Leber's congenital amaurosis, retinitis pigmentosa, and retinopathy of prematurity.
Differentiation is made between a "quiet" type of keratoconus ("forme fruste") and progressive keratoconus. "Forme fruste" occurs 10 times more often than progressive keratoconus. Normally it produces no symptoms and has only to be observed. If the condition remains stable, there is no need for treatment.
Progressive keratoconus is aggressive and can begin at a very early age. With progression of the disease, correction of visual acuity with glasses becomes more difficult because protrusion of the cornea develops unevenly. Hard contact lenses are a good solution because they put pressure on the cornea, thus correcting irregularities.
If protrusion of the cornea continues, there will come a point when the patient cannot wear contact lenses any longer and the cornea becomes continuously thinner. In the region of ectasia, it can break through and develop scars. Visual acuity will be permanently worse.
At the moment, there is no therapy that is successful in stopping or slowing the progression of the disease. Keratoconus cannot be healed. The only successful long-term treatment is keratoplasty, which means surgery with all included risks and complications. The patient regains an acceptable visual acuity often only months after surgery.
A lot of young people who suffer from keratoconus have the necessary corneal transplantation and have to live for many years with this transplant. This means the transplant has to function faultlessly for a very long time.
Each corneal transplant includes the risk of an immune reaction against the donor and causes a very high astigmatism after surgery as well. After surgery, the cornea is very weak and heals poorly. The cornea remains a weak point for the rest of the patient's life.
In the first months after transplantation, the patient's visual acuity changes very strongly. In theory, the "life" of the transplanted cornea after lamellar keratoplasty is unlimited; for perforating keratoplasty, it averages about 10 years.

Advantages of preparation ring tunnels with femtosecond laser:

- Enables intrastromal cuts from inner parts to outer ones;
- Different, depths, widths and diameters, defined in advance, can be created resulting in different shapes of ring tunnels
- Centric as well as eccentric laser cuts can be performed;
- Because of the patented patient interface, the cornea remains nearly in normal shape (with about 35 dpt.);
- Cornea stress is minimal, because only moderate pressure is exerted on the eye during Surgery; and
- Risk of infection is significantly reduced.

Implantation of intracorneal ring segments for treatment of progressive keratoconus

With implantation of intracorneal ring segments (ICRS, Intacs, Addition Technology, Des Plaines, Ill.), the conus should be stabilized and the time point for necessary keratoplasty delayed or totally avoided. This surgery is performed when the cornea is clear in the central part. If later transplantation of the cornea becomes necessary, it can be performed at any time without problems.
In 2000, Colin et al. (2) reported on correction of keratoconus (with clear,

central corneas) with ICRS. They described successful reduction of astigmatism and flattening of the cornea after surgery.
One year later, the group reported the one-year results. Post-op visual acuity of all patients especially improved significantly because of this surgery. Also, topographical examination of the cornea's condition (size and height of the conus) confirmed the improvement in all patients (3).
Ruckhofer (7) reported his long-term results (five years post-op) after implantation of ICRS. He also confirmed that in certain cases of early keratoconus, the implants can improve the geometry of the cornea as well as the visual acuity.
Siganos et al. (8) reported on one-year results (average follow-up 11.3 months) in patients with keratoconus who were treated with ICRS. Most patients showed improved UCVA as well as BCVA after surgery.
Boxer Wachler et al. (1) performed an asymmetric implantation of ICRS for the treatment of keratoconus. The thicker ring segment was placed inferiorly, the thinner ones superiorly. The UCVA as well as BCVA were improved after surgery. Irregular astigmatism was reduced in eyes with clear corneas as well as in eyes with scarred corneas.
Two-year results of treatment with ICRS of asymmetric astigmatism of patients with keratoconus were published by Tunc et al. (9). Results of the surgery were flattening of the central cornea and a significant reduction of irregular astigmatism in all patients.
A newer publication about treatment of keratoconus by Colin et al. (4) underlines the fact that implantation of ICRS in clear corneas improves patients' visual acuity and can in some cases prevent the need for corneal transplantation.
Intacs were approved by the Food and Drug Administration in July 2004 for the treatment of keratoconus. During surgery, there is no removal of the patient's tissue, existing astigmatism is reduced or regulated through implantation of ring segments. Clear improvement of visual acuity can be observed directly after surgery.

Function of femtosecond laser

The femtosecond laser femtec is an infrared laser, which works with a wavelength of 1052 nm. It sends ultrashort laser pulses with a diameter of 0.001 mm. A femtosecond is equivalent to a trillion seconds (10-15 sec).
With the femtosecond laser, tissue can be cut very precisely and nearly without any development of heat. In eye surgery, the laser is used primary for cuts in the inner part of the cornea, e.g. for preparation of tunnels for ICRS.
Contrary to the excimer laser, the laser pulses do not develop their energy on the surface of the cornea, but at an exactly-defined depth in the inner part of the cornea.
Each laser pulse produces a micro gas bubble that separates the tissue (photodisruption). With the help of thousands of computer-positioned laser pulses, three-dimensional, highly-precise laser cuts in the inner part of the cornea have become a reality.
During surgery, the laser energy is focused precisely at a defined depth of corneal tissue. Thus, micro plasma is created, which evaporates corneal tissue of about 1 micrometer in diameter.
A microbubble consisting of carbon dihydrate and water (diameter 5-12 micrometers) is created. It expands and separates the surrounding corneal tissue. This mixture is sucked off by the endothelial pump function. Thousands of these laser pulses separate the corneal tissue intrastromal during preparation of ring tunnels(10).
The technology of femtosecond laser femtec is very innovative and is used at the moment only in selected study centers in Europe. Only a few publications are available.
The experimental study by Rabsilber et al. (6) confirmed very precise stromal cuts with sharp edges when femtosecond laser femtec was used for preparation of LASIK flaps.
Durrie et al. (5) used a different femtosecond laser technology for a different indication (flap preparation during LASIK surgery), but they

confirmed better post-op values of astigmatism when femtosecond laser technology was used.
There are no earlier reports about the treatment of keratoconus patients with ICRS using femtec?s femtosecond laser technology for tunnel preparation.
Preparation of implantation tunnels with femtosecond laser technology
Compared to mechanical techniques, an advantage of using a femtosecond laser is that intrastromal cuts can be performed from inside the cornea to the outer parts. The risk of infection is reduced significantly for each operation. Centric as well as eccentric fixations of the tunnels can be realized. The shape of the cornea remains arced during surgery, which means it only has to be flattened minimally to about 35 D (because of the patented femtec patient interface).
Thanks to innovative laser technology, intrastromal preparation of the cornea in 70% of depth has become reality. An exactly-defined tunnel of 1-mm width is created.
Distance between laser pulses is 8 micrometers, resulting in a very precise laser cut. No remaining connecting tissue is the consequence of this technique. Afterward, intrastromal ring segments can be implanted very well.

The patients

The following case reports describe our practical experience with this surgery.
In November 2004, a 42-year-old man (L.B.) visited our clinic with keratoconus in both eyes. He was not able to wear contact lenses. The BCVA in the left eye, which was to undergo surgery, was pre-op plane −2.25/0o = 0.2. Pachymetry of the cornea showed 320 microns at the weakest point.
In December 2004, a 41-year-old woman (S.F) visited our clinic with keratoconus in her right eye. The BCVA was 0.2, and the patient was not able to wear contact lenses.
Eight years ago, a keratoplasty was performed in her left eye. This eye had an astigmatism of 12 D and a BCVA of 0.03.
Pachymetry of the cornea of the right eye showed 293 microns at the weakest point. K-values were 57.0 dpt. in 48o and 51.1 dpt. in 138o (6 D astigmatism).
In January 2005, a 35-year-old man (S.K.) visited our clinic. He had keratoconus in both eyes and was not able to wear contact lenses. BCVA in his left eye, which was to undergo surgery, was pre-op −6.25 −5.25/150o= 0.25. Pachymetry of the cornea showed 414 micrometers at the weakest point.
In March 2005, a 46-year-old woman (E.B.) visited our clinic. She had keratoconus in both eyes and was not able to wear contact lenses. Pre-op refraction of the left eye was +0.5 -8.25/160o = 0.2. Pachymetry of the cornea showed 442 microns at the weakest point.
Because of these conditions, we decided to implant Intacs (Addition Technology Inc., Des Planes, Ill.) after preparation of ring tunnels with femtosecond laser.
Implantation of ICRS is performed to maintain the patient’s cornea as long as possible and to improve visual acuity. Regular pressure and draw forces that affect the cornea after surgery should stabilize the condition of the cornea and be an effective treatment for keratoconus.

The surgery

Before surgery, we measured the following parameters with the corneal topography system Orbscan from Bausch & Lomb (Rochester, N.Y.):
• thickness of the cornea,
• localization of the keratoconus, and
• difference in height.
These values are necessary parameters for the femtosecond laser, which we used to prepare the ring tunnels.
The entry for each patient varies depending on the location of the conus.

For the first patient, L.B., temporal entry was chosen; for patient S.F., at 12:00 pm; and for patients S.K. and S.B., temporal also was chosen. Laser energy was 3.0 µJ and spacing was 8/10 for all treated patients. During treatment with femtosecond laser, we were especially careful with complete vacuum between the patient interface and the cornea. It is extremely important that no shear forces occur. High sensitive pressure measurement of the laser controls this carefully. Because pressure can remain low, surgery occurs with minimal stress for the eye.
The tunnel was prepared in 70% depth of the cornea. According to the individual condition of the patient, the outer diameter was prepared between 8.0 mm and 8.8 mm, the inner diameter was prepared between 7.0 mm and 7.8 mm. We chose 1 mm for the width of the tunnel. Because of these precise values, we were able to prepare a very narrow tunnel, which suits the ICRS ideally without leaving any unnecessary space.
After preparation of the tunnels with femtosecond laser, the ICRS were implanted with the help of a standard microscope.

Implantation of intracorneal ring segments

The eye was stabilized and afterwards opened with a diamond knife to 70% depth of the cornea. For the future, this mechanical cut will be replaced by the femtosecond laser. Then, a bougienage is performed in the tunnel with a curved probe.
In using the femtosecond laser, corneas that are sometime over 50 D steep have to be reduced to 35 D during preparation of the tunnel. After this procedure, the cornea will return to its natural steep shape. It is therefore sometimes difficult to ensure that the ring segment will follow the natural shape of the cornea.
New instruments are being manufactured at present. With their support, implantation of the ICRS should be possible at 35 D.
Consequently, working with patient interface and implantation of ICRS will be performed under equal conditions for the cornea. A safe implantation will be possible without worrying about differences of pressure height during implantation.
Meanwhile, adequate instruments are available to facilitate the implantation of ICRS. The tunnel is kept open with gripping forceps and the first ring segment is moved forward while the cornea is flattened. Because the tunnel is prepared as narrow as possible, this surgical step is difficult to perform. Then the second ring segment is implanted analogue to the first one in the opposite direction.
The tunnel is sealed with the help of balanced salt solution and fixed with an interrupted suture in the entry region.

Post-op results

After surgery, all patients showed stable position of the ICRS as well as a significant improvement of vision.
Post-op, patient L.B. had a visual acuity 0.4 and astigmatism was reduced to 1.25 D.
Post-op visual acuity of patient S.F. was 0.4 without correction.
On discharge from the hospital, vision with refraction was +1.5 -2.0 ‘65, with mean 0.5.
Our measurements confirmed reduction of astigmatism of 4 D.
Post-op visual acuity of patient S.K. was 0.5 without correction.
On discharge from the hospital, we measured -1.5 -1.0 ? 160o = 0.8 of refraction and an astigmatism reduction of 4.25 D.
Post-op refraction of patient S.B. was -2.0 -4.0 ?170o= 0.32, and reduction of astigmatism was 4.25 D.
Thanks to the implantation of ICRS supported by femtosecond laser, there is a new option for the treatment of progressive keratoconus with a clear central cornea. Visual acuity improved significantly in all treated patients.
The advantages of femtosecond laser surgery are that the cuts can be performed intrastromally, from the inner parts to outer ones. Risk of infection is significantly reduced. Depending on the cornea’s thickness, the

cuts can be performed in different levels, centric as well as eccentric.
With this new technology, we are able to perform personalized treatment in all depths and widths and to realize optimal draw and pressure conditions.
The patient interfaces of the femtec femtosecond laser can be used easily, enabling us to perform soft surgery.
This kind of surgery cannot be realized with a mechanical instrument. The technology of femtosecond laser has to be considered as very innovative.
Because of its versatility, there are additional indications for this very precise laser, such as astigmatic keratotomy, lamellar and perforating keratoplasty, and correction of eccentric ablation after LASIK.

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