Femto-LASIK: Assessment after 12 months of clinical experience

Should you be using the femtosecond laser in your own practice?

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Since the development of the femtosecond laser-assisted LASIK and the establishment of the first generation of devices for clinical applications in 2001, over 200,000 Femto-LASIK treatments to correct visual defects have already been performed in the USA. This laser technology has also been available in Germany since the end of 2004. Over a year ago, Omid Kermani, MD began replacing the mechanical microkeratome used with LASIK in favour of a femtosecond laser, and reports here on his experience with the new laser-assisted method.

Since 2001, our eye laser centre has been documenting all preoperative and postoperative refraction data and the laser parameters used electronically in a database (Datagraph, St. Pieger St. Wendelstein). Over the years, we have accumulated three-month data for an average of 58% (±6%) of our patients and 12-month data for 24% (±8%) of patients. With the aid of the database, retrospective investigations can now be retrieved with relative ease.

During the one-year period from October 2004 to October 2005, we treated 508 eyes of 260 patients with Femto-LASIK (Intralase, California, USA), accounting for approximately 70% of total LASIK procedures performed at our centre, proving the widespread acceptance of this new method.

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Of note is the fact that, in a time where "bargain prices" for treatments are advertised both in Germany and abroad, people have been willing to pay more money for Femto-LASIK treatment. The new procedure has been communicated with terms such as "Lasik without the knife", "Top laser technology from the USA", "Safer" and "Fewer complications."

Femto vs keratome: is the hype justified?

If we look at the refractive results in the majority of cases, i.e. myopias up to –6.0 D and cylindrical visual defects up to 2.5 cyl, we found that there has been no significant improvement in the three-month results following introduction of the femtosecond laser. In the past four years, there has only been one significant improvement in refractive outcome worthy of note and this occurred in 2002, following the introduction of a new generation of excimer lasers, which was accompanied by a myriad of innovations. Specifically, we were introduced to the use of aspheric ablation profiles, torsion error control and a rapid Eyetracker (200 Hz). From a previous figure of 81% (treated eyes) achieving refraction within ±0.5 D of the target result in 2001, 91% achieved the target result in 2002. We have been able to maintain this success rate with few minor deviations right up to the present day.

Upon closer inspection of the outcome with subgroups, such as hyperopia and astigmatism, along with eyes with particularly steep or particularly flat corneas, surgery success rates are still outstanding. The intra- and inter-individual variance in the curvature of the cornea is infinitely large. The keratometric value reflects only a very small proportion of the real picture and computer-assisted topography of the cornea is more suitable for displaying the aspheric and individual character of the human cornea.

Conventional, mechanical microkeratomes ideally feature three suction rings of varying sizes in order to take this situation into account. In critical cases, where there are very steep and very flat paracentral corneal radii, one can attempt to achieve a greater level of accuracy by selecting an applanation plate that is as thick as possible for the keratome head. The variance in the geometry of the corneal flap that can be generated mechanically is consequently very high. In the case of very steep (≤7.5 mm / ≥45 D) and very flat (8.0 mm / ≤42 D) corneas in particular, unpleasant surprises are becoming a more frequent occurrence. The hinge can be unexpectedly wide or narrow, thus reducing the available ablation zone, or the flap can lose its solid anchor to the cornea. In cross-section, after incision with the microkeratome, the lenticles have a clear meniscal shape. In extreme cases, a central perforation can occur. This phenomenon is known as a button-hole.

Hinges, flaps, thickness & lesions

According to our own measurements, the deviation in the central flap thickness with Femto-LASIK is less than with the conventional technique using the mechanical microkeratome.

Of significance is the difference in the context of "steep" and "flat" corneas mentioned above. On average, the deviation of the central lenticular thickness with Femto-LASIK is 12.3 µm, compared with 27.8 µm with the mechanically generated flap. In the case of "normal" corneas, i.e., those with a radius of between 7.5 mm and 8.0 mm, the difference is smaller. The femtosecond laser fares even better in terms of the variation in lenticular diameter (flap) and hinge length. Having measured corneal flaps in 50 eyes, we determined the average to be 0.2 mm for the flap diameter (1.2 mm mechanically) and 0.2 mm for the hinge (0.8 mm mechanically). The flap thickness is routinely determined sonographically with all LASIK procedures. However, the reason for the enhanced precision of the femtosecond laser in flap generation is the applanation technique that the laser adopts, which is independent of the corneal radius and diameter. During the laser process, virtually the entire cornea is applanated. There are no frictional errors of the type found with mechanical keratotomy, where the applanation plate progressively flattens the cornea and can lead to biomechanically related wavelike distortions.

This freedom from friction also means that other problems that we see quite frequently with the mechanical technique are no longer an issue with the laser technique. Epithelial lesions generally do not affect the subsequent progress of visual recovery, at least if they do not occur in the centre of the cornea. With mechanical keratotomy, according to our investigations, peripheral epithelial lesions occur in 5.6% of the cases. The incidence is probably even higher, because we only document such lesions statistically when a therapeutic contact lens is being fitted. Although the clinical relevance of peripheral epithelial lesions can be overlooked, occasionally extensive central epithelial dehiscences can occur that can also result in a delay of visual rehabilitation that should not be underestimated. Since we have been using the femtosecond laser, we have not had to fit a single therapeutic contact lens. The friction-free laser technique has an advantage here in terms of the integrity of the cornea being operated on.

Getting the position right

A further advantage that has become apparent from the applanation technique used with Femto-LASIK is the ability to re-centre the desired flap position in relation to the centre of the pupil. Hyperopic eyes in particular, frequently demonstrate an eccentric position of the pupil. The mechanical microkeratome must be centred in the middle of the cornea, regardless of the position of the pupil. In hyperopic eyes with eccentric pupils and a nasally eccentric visual axis (positive angle kappa), the available ablation zone can, in certain circumstances, be critically reduced. With Femto-LASIK, the position of the flap can be changed and optimized on the control interface (screen), even after applanation. The position of the flap hinge can also be custom-adjusted. If the astigmatism is with the rule, then the 12-o'clock position is selected for the hinge. If the astigmatism is against-the-rule, then a nasally oriented hinge is selected. The ablation zone can always be used to best effect.

Is the incision free of complications?

During the October 2004–2005 period, we have seen no incision-related complications in patients treated with Femto-LASIK. In actual fact, the complication rate in relation to incision errors is 0.0%. We have, however, seen some complications with the Femto-LASIK procedure. Folds in the flaps, sterile interface irritations, refractory sicca syndromes and ablation errors are just some examples. The frequency of these types of complications, which, in the long-term, do not affect the vision after treatment, stands at 3% for all cases attending our centre.

The frequency of irreversible, vision-affecting, incision-related complications from the traditional LASIK procedure stands at an average of 0.5%. Of note are incomplete incisions, button-holes, irregular incisions, decentred incisions and lenticular amputations. Half a per cent is really not much, one might argue. But when there are a thousand LASIK treatments per year in our eye laser clinic, 0.5% is still five eyes. And this is in just one year and just in our centre. Even based on conservative estimates, out of approximately 100,000 treatments in Germany per year, this would equate to five hundred eyes of around five hundred patients who would see worse after LASIK than before it. For an elective procedure that essentially is based on functional indications, this is a lot. It is therefore worthwhile to make efforts towards making this method safer. Femto-LASIK, in my opinion, is a step in this direction.

What about TLS?

But advances in medicine always have their price. There are new, different problems that did not affect us with conventional LASIK.

Transient light sensitivity (TLS), for example, is a syndrome that leads to varying degrees of photophobia developing days or weeks after treatment with Femto-LASIK. So far, I have only seen congress reports on this. The LASIK interface demonstrates no significant activity. In some cases, cells were also found in the anterior chamber but the retina is unremarkable, at least from an ophthalmoscopic perspective. Photophobia, on the other hand, and accompanying dysesthesia, can be very marked. There are no reliable figures on the incidence of this syndrome, which is probably a mild and transient anterior uveitis. Over the past year, we have seen two such cases. Although patients can generally be successfully treated for TLS with intensive topical treatment of prednisolone, with symptoms passing within a few days, it has been postulated that this irritated state is the consequence of a phototoxic insult. Phototoxic effects, however, are only described in the event of exposure to ultraviolet light (UV-B and UV-C). Short-wave UV light may interact with the intracellular structures and influence the reproductive and transcription activity of the affected cells. With Femto-LASIK, on the other hand, an infrared laser is used. In fact, the radiant beam that diverges behind the focus of the femtosecond laser is high in energy. So the only insult can be a thermal effect, rather than a toxic one. The path from the cornea to the retina is long and the diameter of the radiant beam that impacts on it is correspondingly large and the thermal effect, therefore, probably negligible. The iris is different, however. Its grid-like structure would be virtually transparent if it were not for the pigmented epithelium that is able to protect the retina like a light-blocking curtain. The distance between the cornea and the pigment of the iris is significantly less. This does not eliminate the possibility that, in individual cases, heating-up of the iris tissue may occur which then results in uveitic irritation. Thermal conduction via the network of iris vessels does not function during the incision process, because the circulation of blood is interrupted. The pigmented epithelium absorbs the radiation completely and could correspondingly be heated up. Other clinical references of potential thermal damage, however, are not available. Consequently, treatment of TLS is simple and effective.

The latency time required with Femto-LASIK has completely changed the processes in our operating theatres

Increasing treatment time

The treatment time with Femto-LASIK is thought to be too long and, as a result, not without risk. Even with conventional LASIK using the mechanical microkeratome, the retinal circulation is interrupted as a result of the suction process. The time from the suction to the release of the vacuum, however, is relatively short at around 30 seconds. We document the entire docking time for all procedures involving the femtosecond laser and found that, on average, the duration of the period for which the retinal circulation is interrupted is 91 seconds (range 63 to 140 seconds). This is considerably longer than with conventional technology. With the intervening upgrade of the femtosecond laser from 15 kHz pulse frequency to 30 kHz, the docking time can now be reduced by around 15 to 20 seconds. We have not been able to observe any clinically detectable sequelae of this interruption to the circulation, and there are no references to such in the literature. Neurological damage is not very likely because, from clinical settings and experimental evidence, we know that the threshold of the revitalization time, even for the highly differentiated neurosensory tissue, is around three to five minutes of oxygen deprivation.

The introduction of the femtosecond laser in treatment processes involving LASIK has, regardless of the medical issues, brought with it a considerable number of disadvantages. The actual process involving Femto-LASIK is tissue dissection as a consequence of a cavitation bubble layer positioned intracorneally. With the 30 kHz version of the femtosecond laser, microtissue bridges, which can hamper the lifting of the flap, can be ignored. Nevertheless, it takes some time for the fine gas bubbles to diffuse out of the tissue. In worst-case scenarios, the fine gas bubbles can merge and form a white, opaque layer (OBL; opaque bubble layer). With the femtosecond laser, the surgeon should wait for at least 15 minutes after the 'incision' is made before the flap can be opened. By then, the gases will have diffused and the excimer laser can dock with the Eyetracker when the cornea is again transparent. The fine gas bubbles do not affect the ablation rate. We have, however, seen two extreme cases of OBL, in which the gas diffused via the iridocorneal angle into the anterior chamber and collected under the apex of the cornea. Laser ablation was only performed in this case on the following day.

Subsequently, the latency time required with Femto-LASIK has completely changed the processes in our operating theatres. We now treat two patients with the femtosecond laser at a time. The first is ablated after femtolasering of the second with the excimer laser. In the interim period, the second patient's cornea 'recovers'. It is a very complex procedure.

It must also be borne in mind that the femtosecond laser is significantly larger than the excimer laser. This could have implications on cost if a clinic must relocate in order to accommodate the larger laser. Further, the financial outlay for the service, with this sensitive, high-performance equipment, is higher than with the excimer laser.

We have, however, seen some progress made and steps taken towards addressing issues associated with the femtosecond laser when, at the 2005 American Academy of Ophthalmology (AAO) meeting in Chicago, a new generation of devices received their global premiere. A collaborative agreement between a German research centre (Laserzentrum Hannover e.V.) and a Swiss ophthalmological device manufacturer (Ziemer Group, Switzerland) has given birth to a compact femtosecond laser that produces much higher pulse rates and considerably less pulse energy with even shorter pulse times. 20/10 Perfect Vision GmbH is another German competitor in the field that harbours much potential. It remains to be seen, however, how these new systems will prove themselves in clinical practice.

Is it worth it?

The use of the femtosecond laser in LASIK is first and foremost a worthwhile investment in patient safety. From a cost-effectiveness perspective, its use is only justifiable if a correspondingly high volume of patients, i.e., at least 500 treatments a year, can be achieved. ■

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He was medical advisor on a research project commissioned by the German Ministry of Education and Science (BMBF) on the new laser technology[1] and, together with scientists from the Laserzentrum Hannover e.V. organization, headed by H. Lubatschowski, drew up the best laser pulse parameters for treating the human cornea.[2]

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