Visual quality improvement in refractive surgery
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Refractive surgery is a procedure for patients who are motivated not to use optical correction in the form of glasses or contact lenses.\textsuperscript{1-3} Satisfaction from the procedures is multi-factorial and sometimes difficult to gauge.\textsuperscript{1, 3-6} It is imperative to collect and analyze outcomes of different treatment modalities. The purpose of this thesis is manifold: 1. As a control of “how well we perform as surgeons”, do we deliver the results we think we do? 2. As an analysis of how new technologies or variations on other technologies are performing. 3. Evaluation of the severity of the side-effects of the technologies we use. 4. Assessing whether our technologies are acceptable in terms of benefit-risk ratio?

In terms of relatively simple parameters like Uncorrected Distance Visual Acuity (UDVA) we are achieving better than before.\textsuperscript{7-9} In the evaluation of the Advanced Personalized Nomogram we have shown that we can improve the uncorrected visual acuity post-operatively versus the best corrected visual acuity pre-operatively in 22\% of patients.\textsuperscript{10} We have shown that overcorrection with this form of wavefront guided ablations is reduced to 2.8\%.\textsuperscript{10} This is an improvement for those patients. The advantages are clear; more accurate post-operative outcomes, less over corrections, which means less enhancement procedures. The results are in agreement with other literature on the same nomogram\textsuperscript{11}, and we have independently shown that the newer laser nomogram assists in achieving better outcomes.\textsuperscript{12} Possibly, the improvement compensates for loss of vision that may have occurred as a result of the laser procedure in some of the other 78\%, that is, those who did not gain lines of vision, but did not lose lines. This is in line with the “under-promise – over-deliver” adage. One possible weakness of this study is the fact that we studied our results consecutively in the first 100 eyes. One might say that this is a small sample size. Common practice in refractive surgery is to continuously adjust laser nomograms to surgeon factors. Adjustments to nomograms are normally made after 20 to 30 eyes treated. In this aspect, we supplied data on a large enough sample. Is there another explanation for the improved visual acuity, besides the technology used? Detractors can say that the pre-operative visual acuity was biased to be less, while the post-operative visual acuity is biased to a better acuity. Contact lens wear could play a minor role, as our patients are required to come in after they have been ‘weaned’ of their contact lenses. In terms of visual acuity, this might have contributed to a slightly lower Corrected Distance Visual Acuity (CDVA). Testing was done independently by technicians, who are not involved with the analysis. Data analysis in refractive surgery is done continuously, and prospectively. There are official guidelines for the data set that needs to be recorded. As such we have complied with the rules of the profession. The fact that the data was analyzed retrospectively is thus not problematic, because the data we analyzed are the data that are in the standard of data collection. Missing data are a problem in the long term: satisfied patients return less often for follow up visits. This is well know, but not well described in the literature. The other issue is; are the improved outcomes for the myopic laser treatments only caused by the fact that a wavefront guided nomogram was used? I don’t think so. Together with each new nomogram, other software and hardware improvements are installed in the laser. Iris recognition has improved, and the
eyetracker technology is also advancing. Consistent with the literature, we improved our results, based on the combination of improved ablation nomograms, together with improved tracking and eye recognition technology. In the case of bioptics treatments, two factors are very important. One factor is the fact that the refractive error is usually small, and UCDA is usually acceptable in terms of legal vision for driving, but not as good as the patient wants it to be. The other factor is the fact that the refractive error is difficult to measure with our newer technology like the wavefront aberrometry. Setting indications for a refractive error that improves CDVA helps in deciding “how low do we go” in terms of the refractive error. The use of standard laser treatments, and ignoring wavefront aberrations on purpose, has permitted a mode of operation in which we usually achieve the target refraction and visual acuity that goes with it. In the article one can see that nearly 10% of patients do not achieve target refraction. This means that the most common side effect, that is, a residual refraction, occurs in nearly 10%. These errors are usually solved with a surgical enhancement procedure. The downside is a relative high incidence of a side effect, and the risk of incurring more complications, because another surgical procedure needs to be done in order to achieve the refractive goal. This is the most serious problem with bioptics. In due time, indications for doing bioptics will be better defined in the literature. Together with this, we do already see that newer intraocular lenses are being manufactured and used, that can pre-operatively address cylindrical refractive errors. The use of multifocal cylindrical lenses, will obviate the need for planned bioptics, and decrease the need for these procedures, by nearly 42.7% (in our hands). So, as we analyze our current practice and results, we see that technology advances outpace our current practice, by implementation of newer and usually better technology.

In terms of quality of vision there is still a lot of work to be done. We have found that straylight is not affected very much by LASIK and LASEK in myopes and hyperopes, when looking at the total group of patients. Interestingly we do find that some of our patients have an increase in straylight in one or both eyes. In some patients the slit lamp examination shows us clinical findings like flap striae, debris, or haze that explains to us why the straylight is increased. In others we still don’t have an explanation for the findings. In our myopic patient population we found a baseline increase of the straylight values, which is consistent with the literature. Because of our policy to measure straylight only after patients have not been wearing their contact lenses, and warpage of the corneal surface has been sufficiently addressed, we do not think that contact lens wear and weaning contribute to the overall small but significant decrease in straylight. We did find a trend that ablation thickness is possibly related to the decrease in straylight. Our sample size was not large enough to prove this. The hyperopic patient population actually showed data that is consistent with the above analysis: in the hyperopes there is no increase in straylight, but we did not find a decrease. The ablation profile is such, that the central corneal thickness is not affected. This is in accordance with the trend that a decrease in central corneal thickness is possibly a factor in the post-operative decrease in straylight that we found in the myopic population.
Refractive surgeons, and their patients, are fast adaptors to new technology. Such is also the case with concepts like straylight. Research of straylight evolved in the 1960-ies. After decades of research straylight is slowly becoming clinically relevant in ophthalmology. Technology is being invented that reliably and repeatedly measures straylight with an instrument clinicians can easily use. Although the technology has not been completely proven, with which I agree, I find, that understanding of the concept, and availability of the test helps to some degree to understand what is bothering the patient. Sometimes it may even help in the decision-process of whether or not to perform surgery. It is clear, that a lot of work still needs to be done, before straylight measurements will become an accepted part of the ophthalmic examination routine.

Complications remain part of surgery. The best way to deal with a complication is by prevention. This is largely done at the intake of the patient, by measuring and testing, and also by means of communicating with the patient – does the level of expectations correlate with our level of performance? Complications need to be charted and their treatment needs to be shared with peers. This in order to help the individual patients, but also to prevent future recurrence, and set guidelines on how to treat complications. In our case series on epithelial ingrowth removal, we have shown that the decrease in straylight is actually much larger than the improvement in Snellen visual acuity. Straylight will not soon become a sole reason for removal of ingrowth, as the indications for removal have been defined. Pre-operative risk assessment is probably the most important tool in reducing complications. The risk of reactivation of herpes keratitis after LASIK illustrates how sometimes, this cannot be done pre-operatively, and needs to be addressed when it occurs.

Is the risk of side-effect or complications worth the benefit of unaided vision? This question is answered by the millions of people who chose to have a procedure done. This is a very philosophical question, and I am unsure of the answer. I am aware however of the drive people have to undergo these procedures. It is imperative as a professional group to ensure safe implementation of the technologies. In the Netherlands, the Dutch Society of Refractive Surgeons has admirably developed clear guidelines and registration of refractive surgeons. This has developed out of the tension between a conservative environment in which ophthalmologists are educated and working, and the demand of the public to embrace new technologies. This tension is not going to be resolved, as long as technologies are being developed and implemented. This tension did bring about an environment in the Netherlands, in which the professional organization tries to ensure patient safety by actively producing, controlling adherence to, and updating those guidelines.

The wider view is to look where the development and implementation of the new technologies lead us to. In my understanding, all the improvements in technology and surgical results in refractive surgery slowly become accepted by cataract surgeons and our patients. We see increasing demand from our patients, to use newer technology, and to provide better vision after cataract surgery. Refractive surgery and cataract surgery are slowly converging to a single goal, of emmetropia without presbyopia,
with good visual quality in terms of straylight and patient satisfaction. The speed of this converging movement depends on environmental factors, such as insurance and government guided restrictions, speed of development of newer technologies, and maturation of the clinical practice of measuring visual acuity and visual quality, and the subjective assessment thereof.

REFERENCES


