

Abstracts

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Wavefront-guided ablation: evidence for efficacy compared to traditional ablation

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Adaptive optics was initially proposed almost 50 years ago as an attempt to improve telescopic visualization of stars. Later, advanced wavefront sensors with adaptive optics and deformable mirrors were designed to identify and correct the human eyes lower and higher order aberrations. Subsequent studies showed that adaptive optics facilitated a considerable increase in contrast sensitivity at high spatial frequencies because of correction of monochromatic aberrations.

These findings generated a surge of interest in wavefront technology, and its application to customized corneal laser treatment. Only a few years later, wavefront-guided ablation has become widely available for laser vision correction in humans. Thus, it is now routine to measure the optical aberrations of the eye beyond sphere and cylinder with the ultimate goal of achieving an ideal optical correction and improving the quality of the retinal image. According to recent statistics, approximately 55% of North American refractive surgeons have wavefront analyzers in their practice and routinely perform wavefront-guided ablations. But do custom results justify the intense promotion? Are we able to fulfill the promise of optimal vision through the application of wavefront data or is there at least evidence that wavefront-guided treatments provide major advantages over modern conventional laser treatments?

Nearly 3 years have passed since the FDA first approved wavefront-guided treatment in the United States, and multiple proprietary platforms for wavefront-guided ablation are now in use. Along with the rapid development of these systems and the accompanying marketing to both surgeons and patients, there has been a dramatic increase in expectations of what laser vision correction can achieve. However, several limitations persist and the goal of aberration free or "super" vision, at least for

most of the patients, is still far from reality. While wavefront-guided treatments are customized in the sense that treatment is directed at patient specific aberrations, the same treatments not infrequently lead to unpredictable visual outcomes at rates that are similar to conventional ablations attributable to factors such as variability in wound healing and biomechanical factors related to the cornea. Accordingly, a custom treatment does not guarantee a custom outcome for a given patient. However, when surgeons become more familiar with a particular wavefront-based platform and their personal nomograms are refined, very good visual results may be achieved in most of the patients. This, however, is also true of optimized conventional ablations.

The purpose of this study was to provide an evidence based overview of wavefront-guided refractive surgery outcomes, benefits, and limitations.

More than 400 reports investigating wave-front applications in refractive surgery exist, but studies comparing the outcomes of wavefront-guided treatment with conventional treatment are few in number. Available studies do not overwhelmingly demonstrate superior visual results attributable to a wavefront-guided approach.

While wavefront-guided refractive surgery provides excellent results, evidence is limited that it outperforms conventional laser in situ keratomileusis that incorporates broad ablation zones, smoothing to the periphery, eye trackers, and other technological refinements. However, it is evident that wavefront-customized ablation holds a promising future and merits ongoing investigation.

Topical ocular hypotensive medication and lens opacification: evidence from the ocular hypertension treatment study

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For decades, clinicians have questioned whether topical ocular hypotensive medication initiates or

accelerates cataract formation. An increased prevalence of lens opacities has been reported in some case control studies of participants with glaucoma or ocular hypertension. Furthermore, a recent large, well-defined population based sample and a recent clinical trial found a higher incidence of nuclear sclerosis among participants treated with topical ocular hypotensive medications. The Ocular Hypertension Treatment Study (OHTS) found a higher incidence of cataract extraction among participants randomized to topical ocular hypotensive medication compared with participants in the observation group.

To further investigate the possible role of topical ocular hypotensive medication in initiating or accelerating lens opacification in OHTS, authors compared the medication and observation groups during follow-up with regard to the rate of cataract extraction and combined cataract/filtering surgery and change from baseline in visual function, refraction, and visual symptoms. In addition, a one-time assessment of the lens of each eye of participants was completed by masked examiners using the Lens Opacities Classification System III (LOCS III).

The purpose of this study was to determine whether topical ocular hypotensive medication is associated with refractive changes, visual symptoms, decreased visual function, or increased lens opacification.

In this multi-center clinical trial authors compared the medication and observation groups of the Ocular Hypertension Treatment Study (OHTS) during 6.3 years of follow-up with regard to the rate of cataract and combined cataract/filtering surgery, and change from baseline in visual function, refraction, and visual symptoms. A one-time assessment of lens opacification was done using the Lens Opacities Classification System III (LOCS III) grading system.

An increased rate of cataract extraction and cataract/filtering surgery was found in the medication group (7.6%) compared with the observation group (5.6%) (hazard ratio [HR] 1.56; 95% confidence interval [CI] 1.05 to 2.29). The medication and observation groups did not differ with regard to changes from baseline to June 2002 in Humphrey visual field mean deviation, Humphrey visual field foveal sensitivity, Early Treatment of Diabetic Retinopathy Study (ETDRS) visual acuity, refraction, and visual symptoms. For the medication and observation groups, LOGS III readings were similar for nuclear color, nuclear opalescence, and cortical opacification.

There was a borderline higher mean grade for posterior subcapsular opacity in the medication group (0.43 ± 0.6 SD) compared with the observation group (0.36 ± 0.6 SD) ($P = .07$).

Authors noted an increased rate of cataract extraction and cataract/filtering surgery in the medication group as well as a borderline higher grade of posterior subcapsular opacification in the medication group on LOCS III readings. Authors found no evidence for a general effect of topical ocular hypotensive medication on lens opacification or visual function.

Modulation transfer function and pupil size in multifocal and monofocal intraocular lenses in vitro

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Multifocal intraocular lenses (IOL) are designed to increase depth of field and to enhance near vision for cataract patients. The effectiveness of multifocal IOLs in enhancing quality of vision has been shown in many clinical studies. The refractive design of the Array SA-40N IOL (Allergan), a typical multifocal IOL, has a beneficial effect on near vision. However, many problems, including loss of corrected visual acuity at near distance and contrast sensitivity, glare, halos, and dependence on pupil size have been reported. Pupil size affects the relative power distributions of the light generated by the zonal-progressive design of the Array IOL, whose concentric zones of progressive aspheric surfaces provide repeatable distributions of the power. Furthermore, controls of optical aberration, diffraction, retinal illuminance, pupil centration, and the Stiles-Crawford effect are affected by pupil size. Therefore, pupil size is expected to have an effect on the modulation transfer function (MTF), which is defined as the amplitude of the image contrast divided by the amplitude of the object contrast and is a function of spatial frequency.

The aim of this study was to investigate the relationship between pupil size and near and far MTFs in a multifocal IOL in vitro. The results were used to predict the visual performance of patients with a multifocal IOL.

A refractive multifocal IOL (Array SA-40N, Allergan) and a monofocal IOL (PhacoFlex SI-40NB, AMO) were evaluated using the OPAL Vector system

and a model eye with a variable effective aperture. With effective pupil diameters of 2.1, 3.0, 3.4, 3.9, 4.6, 5.1, and 5.5 mm, the in-focus and defocus MTFs were measured in the multifocal and monofocal IOLs.

With increases in effective pupil diameter, the far MTF progressively decreased at all spatial frequencies. In contrast, the near MTF began to increase at effective pupil diameter 2.1 mm, showed a peak at 3.4 mm, and decreased at diameters greater than 3.4 mm. The ratio of near MTF to far MTF showed an increase with larger effective pupil diameters and at lower spatial frequencies.

The authors concluded with remarks that with a zonal progressive multifocal IOL, the pupil size effected a trade-off between the far and near MTFs: The near MTF increased at the expense of the far MTF at large pupil sizes (effective pupil diameter >3.4 mm). To enhance near vision with a multifocal IOL, the desirable effective pupil diameter should be 3.4 mm or larger.

First safety study of femtosecond laser photodisruption in animal lenses: Tissue morphology and cataractogenesis

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The problem of presbyopia is a universal one that is believed to affect more than 130 million people in North America currently. The condition of presbyopia is described as the gradual loss of the accommodative response of the lens with age. That accommodative response, described by von Helmholtz as the release of resting tension in the natural crystalline lens to induce a more spherical lenticular shape, is subject to an age-related loss of function beginning in the mid 40s, primarily caused by a loss of the elastic properties of the natural crystalline lens.

Although a number of potential options for the surgical correction of presbyopia exist, there is no widespread accepted method for restoring accommodation that does not also involve invasive lens exchange surgery with experimental materials or mechanisms. As a result, a new intralenticular strategy has been proposed in which focused light energy is directed into the substance of the lens to change the modulus of elasticity in aging lenses (photo-phaco modulation) or reduce the lens volume in locations

that can change the refractive error or accommodation ability (photophaco reduction).

The purpose of this study was to determine through safety studies the tissue effects and potential cataractogenesis of laser modification of the crystalline lens (photophaco modulation).

Six fresh porcine lenses and 6 living rabbit eyes (with the contralateral eye as a control) were radiated with a low-energy femtosecond laser to induce lens fiber disruption. After 3 months, the rabbit eyes were extracted and tested for light scatter and lens function and fixed for histology and ultrastructure.

After laser treatment, all lenses displayed a tightly packed array of intralenticular bubbles, which resolved with time. In the porcine eyes, the bubbles coalesced unless spacing of 9 μm or greater was applied at an energy of 2 μJ . In the rabbit eyes, an energy of 1 μJ and spacing of 10 μm was chosen for transcorneal delivery, showing minimum bubble coalescence. After 3 months, the rabbit lenses showed good transparency, with only 1 rabbit having cataract formation unrelated to the laser. Laser scanning studies show essentially identical values for the back focal length and sharpness of focus (variability of back focal length). Ultrastructurally, the rabbit eyes showed a 0.5 μm electron dense border layer with adjacent normal lens architecture.

Femtosecond laser photodisruption of the ocular lens yields a self-limited lesion with bubbles that resolve with time. In living animal eyes, no cataract formation was found with no loss of lens function or induced light scatter after 3 months. These results suggest that use of a low-energy femtosecond laser might be safe when modifying the lens for presbyopia correction.

Smoking and cataract: Review of causal association

Kelly SP, Thornton J, Edwards R, Sahu A, Harrison R
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Age related cataract is usually a gradual, progressive opacification of the crystalline lens resulting in impaired visual function. The 1998 World Health Report estimated that there were over 19 million people blind from cataract, which represented 43% of global blindness. The definitive management for cataract is surgical extraction with intraocular lens implantation. As yet, no medical treatment has proven to prevent, delay, or reverse the development of

cataract in otherwise healthy human eyes. Cataract causes major visual impairment among affected individuals and results in significant health resource consumption for populations and society. Identifying modifiable risk factors for cataract is thus important and may help establish preventative measures.

Increasing age is the most important risk factor for cataract, possibly because of the accumulation of lens damage with age together with an age-related decline in protection against oxidative damage in the eye. Other risks for cataract include environmental factors, for example exposure to ultraviolet radiation.¹ Systemic diseases have an important role in cataract formation. In some studies, high alcohol consumption was associated with increased risk for cataract, but no association was found in other studies. There has been considerable interest in the possible protective role of dietary antioxidants and supplements in age-related cataract, but evidence of effectiveness to date is equivocal. In 2 clinical trials, high-dose antioxidant supplementation did not delay cataract formation, but in a third study, supplementation did delay progression.

Several risk factors for the development of cataract have been identified. This review evaluates epidemiologic literature that has examined tobacco smoking as a risk factor for cataract formation using established causality criteria. Twenty-seven studies were included in this review. Evidence suggests that smoking has a 3-fold increase on the risk for incident nuclear cataract development. There was also evidence of dose response, temporal relationship, and reversibility of effect. There was limited evidence of an association between smoking and posterior subcapsular cataract, but little or no association with cortical cataract. Thus, the literature review indicated a strong association between smoking and the development of cataract, particularly nuclear cataract. The association fulfills the established criteria for causality. The association between smoking and other types of cataract is less distinct and requires further evaluation.

Correction of hyperopia by intracorneal lenses Two-year follow-up

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Intracorneal implants or inlays have been investigated for the past 40 years, starting with Barraquer in 1964.

He used flint glass, but anterior stromal necrosis occurred followed by extrusion of the implant. Dohlman et al. recognized the importance of water and nutrient movement across the cornea from the aqueous humor. This led McCarey and Andrews to use hydrogel hydroxyethyl methacrylate (HEMA) to increase the solute permeability of the intracorneal implant material. Later, McDonald et al. reported excellent tissue biocompatibility in non-human primates with hydrogel lenses (Permalens) with a water content of 71%. In a 5-year follow-up, they observed persistent clarity, lack of inflammatory reaction, absence of vascularization, and normal endothelium. However, glucose transport decreased significantly with greater implant thickness; to obtain the desired refractive effect, the authors determined the implant should be 270 to 340 μm . Clinical results of intracorneal hydrogel implants were promising, but the main limitations were the surgical instruments and the thickness of the implant. With the recent advances in automated microkeratome technology, hinged lamellar flap dissections are simpler and more reliable. This has led to the popularity of laser in situ keratomileusis (LASIK) for the treatment of refractive errors. Additionally, it is well established that the corneal flap can be lifted and repeated ablation can be performed for enhancements. However, for hyperopia, LASIK presents a significant number of complications, including decentration, regression, and undercorrection.

Fenestrated hydrogel intracorneal implants (Permavision, Anamed Inc.) were developed to address the limitations reported with the earlier, relatively thick hydrogel lenses. They are composed of more than 78% water content and a refractive index that is substantially close to the refractive index of corneal tissue (1.376). The thickness ranges from 15 to 45 μm according to dioptric power. The lens is designed to correct hyperopia up to +6 diopters (D). In a previous study, confocal microscopy follow-up of several animals implanted with Permavision lenses was conducted. Excellent compatibility was seen, but with relative keratocytic proliferation around only the lens. This study assessed the safety and efficacy of this lens in a controlled clinical study in human sighted eyes.

The purpose of this study was to assess the safety and efficacy of intracorneal lenses as a surgical alternative for the correction of hyperopia.

Twenty-three eyes of 21 patients who had a mean hyperopia of 4.3 diopters (D) \pm 0.71 (SD) (range +2.5 to

+6.0 D) received PermaVision lenses (Anamed Inc.), which are made of a highly permeable hydrogel with a water content of 78% and a refractive index close to that of corneal tissue (1.376). The Moria M2 microkeratome was used to make a 160 μ m corneal flap with a diameter of \pm 8.5 mm. The intracorneal lens was placed beneath the flap after minimal interface irrigation.

Clinical examination showed mild corneal edema and a myopic shift during the first week postoperatively. In 17 eyes (73.9%), the postoperative uncorrected visual acuity was similar to the preoperative best corrected visual acuity (BCVA); 1 eye (4.3%) lost 1 line of preoperative BCVA. In 5 eyes (21.7%), various degrees of lens opacification with some degree of corneal haze were seen after uneventful follow-up. Decentration of 0.5 to 1.0 mm was seen in 2 eyes (8.6%), 1 of which had the lens

explanted because of significant opacification. Induced astigmatism was evident in 1 eye (-1.5 D). A total of 16 eyes (69.6%) were within +0.5 D of target, and 20 eyes (86.9%) were within +1.0 D (87%). No flap melting or extrusion of the lens was recorded in 24 months of follow-up. Night halos and glare were reported in 3 eyes; all had a lens diameter of 5.0 mm.

Authors concluded that intracorneal hydrogel lenses were tolerated relatively well by stromal tissue, providing a reasonably stable and predictable way to correct moderate hyperopia. However, induced astigmatism, stromal opacification, decentration, and night halos and glare occurred in a significant number of eyes. To ensure safety, deep flap cuts are preferred and these eyes should be watched carefully to avoid decentration of the lens in the early postoperative period.