



Abstract compendium of the

CROMA LUNCH SYMPOSIUM

SURPRISINGLY SIMPLE
SAFE, EFFICIENT & SMOOTH
CATARACT SURGERY SOLUTIONS

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Clinical and histology evaluation of two new absorbable Non-Penetrating Deep Sclerectomy implants in a rabbit model.

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Trabeculectomy has been the standard surgical approach for lowering IOP until NPDS was introduced. Although the reported efficacy of non-penetrating filtration surgery for open-angle glaucoma is widely different among the studies carried out over the past few years, all of them proved the effectiveness and safety of this procedure especially with the use of the collagen implant. Diverse materials have been used to reduce scar formation in order to enhance filtration and improve the longevity of NPDS including animal-based synthetics, chemical-based devices, and antimetabolites as Mitomycin C and 5-Fluorouracil with encouraging results. Crosslinked sodium hyaluronate-derived implant (SK-Gel) has demonstrated excellent biocompatibility as adjuvant tool in NPDS, polymer Chitosan has received particular attention as responsive ophthalmic delivery vehicle. We tested a newly modified Crosslinked Sodium Hyaluronate implant (cSHA) and Chitosan (CHI) implant in order to observe the clinical biocompatibility and by high resolution 50MHz ultrasound biomicroscopy (UBM) the rate of degrading of both material to determine the possibility of using them as adjuvant implants in NPDS.

Which IOL to choose

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There are many factors which influence which intraocular lens surgeons select for cataract surgery. These include data in journals, podium presentations and even commercial factors such as the premium IOL market in the USA.

Today I would like consider the fundamental elements which are important to lens design. There are three main components that constitute an intraocular lens (IOL) – The Material, Optic and Haptic. I would like to discuss the factors which influence IOL design under these headings as well as introduce a new lens to be released by Croma at the ESCRS meeting in Barcelona.

MATERIAL

Silicone, Hydrophobic and hydrophilic materials are suitable polymers for IOL manufacture. Unfortunately all materials implanted as IOLs have at some stage experienced problems

Late onset internal crazing described as “Snowflake degeneration” has been reported on several occasions with PMMA, yellow discoloration has occurred with certain silicone lenses and vacuoles or glistenings occur frequently with Hydrophobic Acrylic lenses

Although the glistenings do not appear to affect visual acuity in the majority of cases severe glistenings may affect contrast and there are reported cases of glistenings requiring IOL explantation.

Certain Hydrophilic Acrylic lenses have become opacified due to calcification and required explantation. The phenomenon has been reported to be a particular problem to certain manufacturers. In the one instance the problem was thought to be due to incompletely polymerized polymer blank or impurities, whilst the packaging was responsible for calcification with the Hydroview lens. David Apple has suggested that these specific instances can be considered as Primary calcification due to polymer problems as opposed to instances of secondary calcification due to an abnormal ocular environment. The latter can occur with hydrophilic acrylics or indeed any material. The earlier problems of primary calcification have been resolved and now millions of hydrophilic IOLs have now been implanted. Reported cases of calcification by manufacturers of hydrophilic acrylic IOLs are exceedingly rare and the material has several advantages as an IOL material.

Opacification of the posterior capsule varies with different lens designs and materials. The adhesive nature of different IOL materials is relevant although mechanical factors such as exerting pressure on the capsule and a square optic edge may be more important. A meta-analysis of randomized clinical trials indicated that acrysof and sharp-edged silicone IOLs are similarly effective in inhibiting PCO after cataract surgery.

OPTIC

Surgeons need to consider functional as well as structural factors when choosing the optic for their preferred IOL. Monofocal implants can be aspheric to improve contrast sensitivity or toric to reduce pre-existing contrast sensitivity. There is much discussion on the merits of neutral vs. negative asphericity but recent investigations suggest that simple contrast charts may lack sensitivity when comparing different clinical outcomes.

Multifocal implants are associated with contrast sensitivity which may be unacceptable in some patients whilst accommodative implants tend to be unpredictable. The evidence suggests that there is minimal forward translation and psycho visual data confirming efficacy has been lacking.

Although most manufacturers have incorporated UV absorbers to protect the retina the need to reduce blue light radiation is more controversial. Epidemiological studies demonstrating progression of macula degeneration are inconsistent and there is speculation that depriving individuals of blue light may be detrimental.

HAPTIC

Haptic design is a critical element in choosing an intraocular lens implant. Conventional J or C loop haptics distort the capsular bag and are not required with an intact capsulorhexis. A haptic that is sufficiently rigid to support the lens in the capsular bag is considered adequate. With single piece flexible IOLs, however, careful design is necessary to avoid distortion of the haptic and the ability to adapt to different dimensions of the capsular bag. Open loop haptics can be distorted by fibrosis of the capsule preventing fusion of the anterior and posterior capsule in the interval between the optic and haptic. Close looped soft haptics and plate haptics are rigid and resistant to fibrosis but are unable to adapt to the range of different capsular bag sizes encountered clinically. A strategy whereby the overall dimension of the IOL varies with axial length is used by several manufacturers to try and overcome this aspect of closed loop haptic behaviour.

An ideal haptic should be able to size automatically to different capsular bags without distortion whilst exerting posterior pressure on the posterior capsule with a broad arc of contact with the periphery of the capsular bag. A new haptic design for a single piece flexible lens incorporating these features has been developed by Croma as part of the new K1B IOL.

CROMA K1B IOL

The lens is a one piece mono bloc IOL manufactured from a hydrophilic acrylic material with a water content of 26%. The haptic is planar with an angulated haptic-optic junction which positions the optic posteriorly with an overall angulation of 5 degrees. The posterior radius at the haptic-optic junction also creates a 360 degree sharp edge designed to inhibit PCO and the anterior radius extends beyond the edge of the optic to reduce the centre thickness of the optic.

Together with the compressible 26% hydrophilic material the design allows the lens to be inserted through incisions as small as 1.8 mm.

The optic of the lens is aspheric with a –ve asphericity designed to correct for the expected positive asphericity of the cornea. The theoretical modulation transfer of the aspheric optic design is less affected by minor degrees of decentration or tilt when compared to conventional spherical optics.

Initially the lens is supplied with a preloaded injector that can be inserted through a 2.65 mm incision. A similar preloaded injector is planned for a 2.2 mm incision. Optionally the lens can be inserted with a separate disposable injector through a 1.8 mm incision.

Studies of the K1B IOL performed by Philippe Sourdille and Lilian Werner in cadaver eyes have demonstrated that the lens produces minimal distortion or ovalization of the capsular bag and adapts with a broad arc of contact with the periphery of the capsular bag.

Clinical studies have begun with encouraging results,

The lens insertion is relatively easy with the preloaded injector system. The Z-flex haptic centers the lens immediately and allows early and stable fixation. Patients have achieved excellent unaided and corrected acuity with a provisional A constant of 119.4 using the SRK/T formula. The optic maintains contact with the posterior capsule with minimal wrinkles or striae. Longer follow –up will be required to determine the incidence of PCO.

In conclusion the K1B IOL produced by Croma fulfills the requirements discussed when considering the important criteria to consider when choosing a lens for cataract surgery.

New developments that await are the 2.2 mm incision preloaded injector and a toric version of the lens.

Tear film substitution with viscous eye lubricant to maintain optical clarity during ophthalmic surgery

Prof. Dr. Oliver Findl

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Surgical procedures may affect the surface of the cornea. The corneal epithelial cells have to be protected from drying out in order to avoid postoperative morbidity. Consequently, an eye lubricant has to be applied to exclude complications such as epithelial haze and edema, increased risk of infection and prolonged recovery.

In a recent study performed at the General Hospital Vienna the corneal moisturization and protection potential of several substances was investigated. 36 patient eyes received different lubricants of which the duration of corneal hydration and optical clarity were determined. The results showed that HPMC 2% was superior to BSS concerning hydration, intraocular visualization and retention time on the cornea. Further, the break-up time was highly prolonged when HPMC 2% was applied.

Hence, the use of HPMC 2% during cataract surgery for corneal protection and moisturization is suggested. As it protects the corneal surface for up to 20 min, generally only a single application per surgical procedure is required. Its uses as contact agent for therapeutic and diagnostic lenses or as lubricant for IOL injectors are only some further possible fields of application.

Bromfenac for Cataract Surgery

Prof. Leopold Schmetterer

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Only recently several new topical non-steroidal anti-inflammatory drugs (NSAIDs) have been introduced for ophthalmic use. Among these, bromfenac provides a particularly interesting pharmacological profile. Due to its high lipophilicity it provides excellent penetration through the cornea. In addition, bromination increases the duration of the anti-inflammatory action and provides enhanced inhibitory action on COX-2. The drug is indicated to reduce inflammatory processes and pain after cataract surgery. By providing comparable efficacy to other topical NSAIDs it is the only drug to offer twice a day instillation. Minimal stinging and burning provides excellent compliance as documented in several clinical trials. Clinical experience in more than 13 million users has confirmed this favorable side effect profile. Clinical trials have shown the efficacy of bromfenac in reducing inflammation and pain after cataract surgery, preventing intraoperative miosis during cataract surgery, treating allergic conjunctivitis, treating anterior uveitis and treating CME after cataract surgery. The present talk gives a short overview of the clinical characteristics of bromfenac.

Role of nutrients in the management of eye disease

Prof. Leopold Schmetterer

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The Age Related Eye Disease Study (AREDS) has shown that a combination of vitamin C (500 mg), vitamin E (400 IU), beta carotene (15 mg), zinc (80 mg) and copper (2 mg) is capable of reducing the progression of age related macular degeneration (AMD). Given the very high prevalence of the disease in the elderly population this is of major clinical and economical importance. In the recent years, however, a number of concerns over the composition of the AREDS medication have been raised. On the one hand the concentration of vitamin C and zinc used is very high and largely exceeds the suggestions for daily intake provided by the WHO. On the other hand high dose beta carotene has been blamed to increase the mortality in present and past smokers, preventing the use in this subgroup in patients. Moreover, the inclusion of beta carotene was a compromise, because at the time when the AREDS study was launched, the components of the macular pigment lutein and zeaxanthin could not yet be purified. There is, however, evidence that lutein and zeaxanthin can absorb damaging blue light and show potent antioxidative properties. In the recent years the focus was, however, also directed towards other substances. A specific interest is directed towards omega-3 free fatty acids. A number of epidemiological studies indicate that this class of drugs may be suitable to retard the progression of AMD, due to the potent anti-inflammatory properties. Gingko biloba, extracts of the leaves of the maidenhair tree, has been used in China for thousands of years. Several studies indicate that ginkgo biloba may improve microcirculation to the posterior pole of the eye indicating beneficial effects in eye diseases with a vascular component. The biological effects of flavonoids include antioxidant, anti-inflammatory, and a direct cytoprotective effect on the vascular system. Alpha lipoic acid is a potent free radical scavenger and provides protection to retinal ganglion cells from ischemia-reperfusion injuries. This makes alpha lipoic acid also an interesting treatment option in glaucoma. The present talk will give an overview of these different nutrients and their effects in the outer retina aiming to reduce the progression of the disease.