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Presbyopi-behandling, orientering fra ESCRS vintermøte

Dette års ESCRS´vintermøte ble holdt i Warsawa, Polen, 15-17 februar 2013. Her fikk 850 delegater fra 50 forskjellige land anledning til å møtes. Da antallet delegater var relativt få var det gode muligheter til å diskutere med forelesere etter presentasjonene. Dette gav ekstra utbytte av kongressen.

ESCRS (European Society of Cataract and Refractive Surgeons) arrangerer to møter årlig, et i februar og et i September og er dedikert til utvikling innen fremre segment kirurgi. Temaer som ble dekket var alt fra refraktiv kirurgi til hornhinnetransplantasjoner, Ocular Surface Disease, Cornea inflammasjoner, degenereasjoner og infeksjoner samt ferdighetstrening innen ulike operasjonsteknikker.

Hovedtemaene denne gang var Cross linking, diagnostisering og behandling av tørre øyne på et mer akademisk grunnlag og ikke minst Presbyopi behandling.

Innen Presbyopi behandling har linseoperasjoner vært i bruk lenge og resultater og komplikasjoner har vært presentert tidligere. Nyere var studiene av Supracor, presbyop laserbehandling av cornea. Denne teknikken har vunnet terreng i Finland og Frankrike, og er prøvd ut i et års tid ved en klinikk i Norge. Spennende var det også å høre om Flexivue og Kamra, begge corneal inleys som opereres inn i cornea ved hjelp av femtosecond laser, og som endrer corneas refraktive indeks.

Jeg hadde den ære av å få møte Dr. Pallikaris som hadde flere presentasjoner av sin nyeste patent, Flexivue, ved ESCRS og som gjerne ville presentere denne for Oftalmolog.

Ioannis Pallikaris har en lang karriære innen oftalmologi. Han startet studiene i Thessaloniki, Hellas og er nå professor ved Universitetet på Kreta siden 1996, og grunnlegger og direktør av Institute of Vision and Optics ved samme universitet.

Han er antagelig mest kjent for å være den refraktive kirurg som gjorde den første Lasik prosedyre på et menneske i 1989. Han var også mannen bak epi-LASIK (overflatebehandling) og PALM (photoablative lenticular modulation).

Han har, i tillegg til å ha utviklet mange patenter innen operativ behandling, skrevet en rekke bøker og et enormt antall artikler innen refraktiv kirurgi. Han var president i ESCRS fra 2006-2008.

Hans drivende kraft for å jobbe så hardt med innovasjon og utvikling innen oftalmologi har vært et ønske om å forbedre menneskers livskvalitet. Det rådet han gir til de som vil følge i hans fotspor lyder likt med et gammelt ordtak fra Kreta: ”return to there where you have lost and do not tarry where you have won”.

Her er Pallikaris' orientering vedrørende Flexivue for lesere av Oftalmolog:

Long-term results with Intracorneal inlay Flexivue MicroLens with Presbia using femtosecond laser for the treatment of presbyopia

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Nowadays, there has been an increasing interest in the field of refractive surgery regarding intracorneal inlays for the treatment of presbyopia in emmetropes, presbyopes aged between 45 and 60 years old.

The purpose of this study was to evaluate prospectively the efficacy and safety of a refractive intrastromal inlay (Flexivue Micro-Len™, Presbia Cooperatief U. A., Netherlands) for the corneal compensation of presbyopia using femtosecond laser for the creation of the pocket.

Flexivue Micro-Lens, (Presbia, Netherlands) is a transparent, hydrophilic concave-convex disc with a 3mm diameter and a thickness of approximately 15-20μm, depending on the additional power, which acts by changing the refractive index of the cornea.

The central 1.8mm diameter of the disc is plano in power and the peripheral zone has the appropriate addition power. The available inlay refractive power ranges from +1.25 diopters (D) to +3.50 D in 0.25 D increments. At the center of the disc there is a circular hole of 0.15mm diameter that allows flow of oxygen and nutrients to the cornea through the lens.

During far vision, the rays passing through the central zone of the implant and through the free peripheral corneal tissue without the lens added refractive effect, will be sharply focused on the retina, whereas the rays which pass through the refractive peripheral zone of the inlay will be focused in front of the retina. During near vision, the rays passing through the central zone of the implant will be out of focus behind the retina and the rays passing through the peripheral clear cornea will be blocked by the pupil. The rays passing through the peripheral refractive zone of the inlay will be focused on the retina.

The intracorneal pocket was created using femtosecond laser (Intralase 150, AMO, Irvine, CA). Using appropriate software, a full lamellar cut was created at 280 microns depth with a diameter of 9.00 mm and a line-spot separation of 2-2 microns.

One year after the operation, mean UNVA was significantly

improved from 0.68±0.03 logMAR preoperatively (range: 0.40 to 1.00) to 0.14 ± 0.09 logMAR (range: -0.02 to 0.36), (p<0.001) in operated eyes and from 0.53 ± 0.13 logMAR (range: 0.34 to 0.73) preoperatively to 0.13 ± 0.13 logMAR (range: 0.00 to 0.38) binocularly (p<.001). UNVA of the operated eyes was 20/32 or better in 75% of the patients 12 months after the inlay implantation.

Mean UDVA in operated eyes was significantly decreased from 0.06 ± 0.09 logMAR (range: -0.08 to 0.26) preoperatively to 0.38 ± 0.15 logMAR (range: 0.12 to 0.8), (p<0.001) 12 months postoperatively, whereas binocularly did not change significantly (p=0.516).

At last follow up, mean spherical equivalent of the operated eyes was significantly changed from 0.66 ± 0.35 (range: 0 to -1.25) diopters preoperatively to -1.95±1.32 (range: -3.88-0.25) diopters (p<0.001).

At last follow-up, 37% (17 patients) had lost 1 line of CDVA (0.1 logMAR) in operated eye, whereas no patient lost two or more lines in CDVA in the operated eye. CNVA of the operated eyes, as well as binocularly, remained unchanged during the follow-up period (p=0.8).

Mean central corneal pachymetry of the operated eyes did not change significantly postoperatively (p=0.132) from 546.5±22.4 μm (range: 508 to 599) preoperatively.

Corneal topographic astigmatism was -0.72±0.33 D (range: from -0.12 to -1.40) preoperatively and changed to -1.23±0.31 D (range: from–0.70 to-1.81), (p=0.005). Mean surgically induced astigmatism was -0.44±0.19 D (range: from -0.18 to -0.83) at mean axis (degrees) of 169±22.

Endothelial cell counts in operated eyes were not significantly (p=0.776) altered 12 months after surgery from preoperative measurement of 2536±224.54cells/mm2 (range: 2104 to 2899).

Twelve months after the refractive lens implantation, 81.25% of the patients perceived their UNVA in the operated eye as excellent, while 93.75% were independent of their near glasses with 6.25% of the patients using glasses for near tasks for less than half of their everyday use. None of the patients was using glasses for distant vision.

During the last follow up visit, 81.25% of patients perceived their binocular UDVA as excellent compared to 53.33% one month postoperatively, and 18.75% described it as good. As for the UDVA of the operated eye, one year after surgery, 18.75% of the patients perceived it as excellent and 81.25% as good.

One year after the procedure 12.50 % of patients still experienced haloes always or very frequently and 12.50% still experienced glare.

Mean intraocular pressure of the operated eyes was not statistically significantly altered (p=0.452) from 14.51±3.44 mmHg (range: 10 to 19) preoperatively, twelve months after the inlay implantation.

During the study, general conclusions regarding patient selection for the implantation of the intracorneal inlay Flexivue Microlens to treat presbyopia were that the best candidates proved to be emmetropic, presbyopic patients aged 50 – 60 years old with clear lens, while better outcomes were succeeded with patients having scotopic pupil diameter between 5 – 7 mm. Larger pupils tend to lead to glare phenomena during night driving.

Three inlay exchanges in order to enhance the additional power of the inlay were performed one year after the first implantation, one removal followed by re-implantation of an intracorneal inlay of the same power was performed due to development of corneal ingrowth (resolved after the exchange) and one removal of the intracorneal inlay Flexivue Microlens was performed because of night driving difficulties.

During this particular study implantation of the intracorneal inlay Flexivue Microlens proved to be an efficient and safe method to treat presbyopia in post refractive emmetropes presbyopes as well, expanding the inclusion criteria of the surgical treatment.

Flexivue Microlens inlay implantation does not interfere with the preoperative evaluation and biometry prior to a potential cataract operation because the material of the inlay is transparent.

Intraoperatively during a cataract surgery, transparent Flexivue Microlens® intracorneal inlay provides good visibility through operating microscope and also permits common surgical manipulations during a routine phacoemulsification under topical anesthesia. Moreover, transparency of Flexivue Microlens intracorneal inlay will also permit femtosecond laser cataract surgery without the need of the inlay removal.