خبرنامه انجمن فوق تخصصی ویتره و رتین

آبان ماه ۱۳۹۳ – سال دوم – شماره ششم

اخبار ومطالعات جدید

۱. خطر گلوکوم بعد از جراحی ویترکتومی افزایش می یابد.

در یک Cross sectional prevalence Study بیمارانی که در طی شش سال در یک مرکز تحت جراحی ویترکتومی قرار گرفته و پیش از جراحی گلوکوم زاویه باز نداشته اند، ازنظر میزان بروز گلوکوم بررسی شدند.۳۱۲ چشم از ۱۵۶ بیمار(از هر بیماریک چشم در گروه درمان وچشم دیگر در گروه کنترل) وارد مطالعه شدند. درچشم های ویترکتومی شده ۱۵ مورد(۸,۹%) و در چشم های ویترکتومی نشده ۳ مورد(۲%) گلوکوم یافت گردید(P=0.02).فاکیک ویا سودوفاکیک بودن چشم ها تاثیری در شیوع گلوکوم زاویه باز نداشته است(P = 0.48, chi-square test) .

منبع: Retina, August 2014

۲. درمان انتیVEGF در بیماران AMDدر دنیای واقعی، منعکس کننده یافته های تحقیقات بالینی نمی باشد.

بررسی پرونده های ۴۵۹۲۳۷ بیماری که بعلت AMD تحت درمان با Anti VEGF بودند نشان میدهد که دفعات تزریق داروطی سال های اول و دوم پس از شروع درمان و تعداد ویزیت های پیگیری نسبت به انچه کارازمایی های بالینی بزرگ مثلCATT, HORIZON, SEVEN-UP توصیه کرده اند، کمتر می باشد.

منبع: Retina, September 2014

۳. تائیدیهFDAجهت استفاده از(Eylea(Aflibercept در درمان ادم ماکولامتعاقب انسداد ورید شبکیه (RVO) شرکت Regeneron اعلام کردکه FDAداروی Aflibercept را جهت درمان ادم ماکولا متعاقب BRVO تائید کرده است. قبلا FDA دارو را جهت درمان ادم ماکولا متعاقب CRVO تائید کرده بود. فلذا بدین ترتیب Eylea جهت درمان ادم ماکولا متعاقب RVO توسط FDA تائید شده است.

منبع: Retinal Physician e Update, 12 Oct 2014

۴. چشم دوم بیمارانی که بعلت Wet AMD تحت درمان قرارگرفته اند سرنوشت بهتری نسبت به چشم اول دارد.

براساس اطلاعات حاصل از سرویس بهداشت ملی انگلستان، محققان یافته های مربوط به چشم دوم را در بیمارانی که چشم اول انها بعلت Wet AMD تحت درمان با Ranibbizumab قرار گرفته بود، بررسی کردند. شانس درگیری چشم دوم ۱۴% در هر سال بوده است. چشم دوم در زمان شروع درمان میزان بینایی بیشتری داشته و اگرچه پس از شروع درمان بهبودی قابل توجهی در میزان بینایی نداشته ولی در هر زمان در یک پیگیری سه ساله نسبت به چشم اول بینایی بهتری داشته است.

منبع :Ophthalmology, October 2014

۵- با استفاده از اپلیکاتور (cotton swab)خطر افزایش فشار بعد از تزریق داخل چشمی را کاهش دهید.

48بیماری که تحت تزریق داخل ویتره 0.05 mlلوستنیس قرار گرفتند،از نظرروش بی حسی بطور تصادفی بدو گروه تقسیم شدند. در گروه اول قبل از تزریق، اپلیکاتوراغشته به لیدوکائین ۴% با فشار متوسط بر روی گلوب قرار گرفت و در گروه دوم ژل لیدوکائین ۳,۵% بدون فشاری برچشم برای بیحسی استفاده گردید. بیماران گروه اول پس از تزریق بطور معنی داری فشارچشم کمتری داشتند.همچنین بلافاصله پس ازتزریق IOP>50mmHgدرتعدادکمتری ازبیماران گروه اول دیده شد. (۱۰ % vs. 35%; P<0.001)

منبع:Journal of Glaucoma, October/November 2014

۶- پان رتینال فوتوکواگولاسیون سبب تغییرات معنی دار در سرعصب بینایی می گردد.

محققین دربیمارانی که بعلت دیابتیک رتینوپاتی پرولیفراتیوتحت PRP قرار گرفتند، تغییرات سر عصب بینایی را بکمک Confocal Scanning Laser Ophthalmoscopy بررسی کردند.در پیگیری ۶ ماهه اگرچه تغییرات معنی داری در بهترین حدت بینایی اصلاح شده و فشار داخل چشم مشاهده نگردید، اما متغییرهایی همانندvertical C/D ratio, cup volume, mean cup depth, maximum cup depth

بطور معنی داری نسبت به یافته های اولیه افزایش پیدا کردند.

منبع: Glaucoma Journal, October 2014

۷– ایمپلانت دگزامتارون نتایج دراز مدت خوبی درادم ماکولای دیابتی دارد.

یافته های حاصل از ۲ مطالعه RCT ، شامل ۱۰۴۸ بیمار دچارادم ماکولای دیابتی که تحت درمان با ایمپلانت ۰,۷ mg ، 0.35mgو یا پلاسبو قرار گرفته وبمدت ۳۹ ماه پیگیری شدند، انالیز گردید.در گروه ایمپلانت ۰,۷mg، بیماران بیشتری ۱۵ حرف و یا بیشترافزایش در میزان بینایی داشتند .

(22.2% vs.18.4% in the 0.35 mg implant, and 12% of controls) بعلاوه میانگین ضخامت مرکزی شبکیه در گروه ایمپلانت ((−۱۱۱,۶μm and −107.9μmنسبت به گروه کنترل (−۴۱,۹ μmبطور معنی داری کاهش بیشتری را نشان داد. اما بهرحال میزان بروز و پیشرفت کاتاراکت دربیماران فاکیک در گروه ایمپلانت ۰,۷ mg ، 0.35mgوپلاسبو بترتیب ۶۷,۹% ، ۶۴,۱% و ۲۰,۴% بود.

منبع: Ophthalmology, October 2014

۸– متوترکسات ممکن است برتراز مایکوفنولات در درمان یووئیت باشد.

محققین طی یک مطالعه randomized, observer-masked اثرات متوترکسات و مایکوفنولات را در درمان یووئیت بینابینی غیر عفونی، یووئیت خلفی و پان یووئیت با یکدیگر مقایسه کردند. ۳۵ بیماری که هفته ای ۲۵ میلی گرم متوترکسات خوراکی دریافت می کردند با ۳۲ بیماری که ۱ گرم مایکوفنولات دو بار در روز دریافت می کردند مقایسه شدند. پس از ۶ ماه ،موفقیت درمانی در نسبت بیشتری از بیماران در گروه متوترکسات مشاهده گردید (۶۹ .(47% vs. %بهبودی ادم ماکولادرتعداد بیشتری ازبیماران در گروه متوترکسات رخ داد (۷۷(54% vs. %، اگرچه از نظر اماری معنی دار نبوده است.

منبع: Ophthalmology, October 2014

۹– تائیدیه جدید FDA برای استفاده از Ozurdexدردرمان ادم ماکولای دیابتی.

شرکت Allergan اعلام کرد که FDA ایمپلانت0.7mg ، Ozurdexرا برای درمان ادم ماکولای دیابتی در عموم بیماران دچار DME تائید کرده است. دارودر ماه ژوئن برای استفاده در بیمارانی که سودوفاکیک بوده و یا کاندید جراحی کاتاراکت بودند تائید شده بود.

منبع: Retinal Physician e Update 5 October 2014

۱۰ – COMRADE-B Retinal Vein Occlusion Trial

رانیبیزوماب با دوز ۰,۵ میلی گرم و ایمپلانت اهسته رهش دگزامتازون، هر دو برای درمان ادم ماکولا متعاقب انسداد شاخه ای ورید شبکیه تائید شده اند. دارای دو مکانیسم اثر متفاوت هستند ولی هر دو باعث بهبودی در BCVAمی شوند. دکتر تیلور نتایج اولین کارازمایی بالینی تصادفی که به مقایسه این دو درمان می پردازد را در کنگره AAO منتشر کرد. بر اساس این گزارش بیماران پاسخ بهتری به درمان با رانیبیزوماب در مقایسه با دگزامتازون می دهند. متوسط افزایش در BCVA در گروه رانیبیزوماب ۱۴,۹ حرف و در گروه دگزامتازون ۱۰,۱ حرف بود.

منبع: Retina Times, AAO Retina Subspecialty Day 2014

Friday's Retina Subspecialty Day, AAO

The American Academy of Ophthalmology (AAO) 2014 Annual Meeting, being held in conjunction with the European Society of Ophthalmology, began with Subspecialty Day on Friday, October 17, at McCormick Place in Chicago. Following are highlights of Friday's Retina Subspecialty Day sessions.

Universal Screening for Pediatric Eye Disease

Darius M. Moshfeghi, MD

Twenty percent of newborns have fundus hemorrhages. These hemorrhages are more common in infants delivered vaginally than those delivered by C-section (odds ratio = 10.45).

Dr. Moshfeghi presented the initial results from his Newborn Eye Screen Testing (NEST) study and described universal screening as an emerging tool for pediatric eye disease. The study leveraged the infrastructure built for the Stanford University Network for Diagnosis of Retinopathy of Prematurity (SUNDROP), a large telemedicine

network.

The Workup of the Retinal Vein Occlusion Patient

J. Michael Jumper, MD

The workup of a patient with retinal vein occlusion should focus on atherosclerotic risk factors including hypertension, hyperlipidemia, and diabetes.

Retinal vein occlusion (RVO) can occur at any age, although advanced age is a risk factor. RVO is a multifactorial disease that shares risk factors with atherosclerosis. Thrombophilia testing is rarely necessary, although it may be useful for patients with a personal or family history of abnormal thrombosis.

Clotting disorders that act on both the venous and arterial system, namely hyperhomocysteinemia and the antiphospholipid antibody syndromes, have the greatest association with RVO.

A Retrospective Cohort Study in Patients with Tractional Diseases of the Vitreomacular Interface

Peter W. Stalmans, MD, PhD

Dr. Stalmans presented data from his observational study of 556 patients with vitreomacular interface (VMI) disorders with a follow-up of ~2 years. He reported that tractional disease of VMI is bilateral in 39% of patients. Spontaneous release of vitreomacular traction (VMT) is relatively rare (25% within a year).

Vitrectomy was eventually required in ~26% of eyes with VMT and ~5% of eyes with asymptomatic vitreomacular adhesion (VMA). Patients with VMT progressed from macular hole with VMT to a macular hole without VMT 15% of the time.

None of these holes closed spontaneously in contrast to the 40% closure rate seen in the ocriplasmin trials. Visual acuity outcomes in the VMT group were best when spontaneous release occurred, compared to those eyes with no release or surgically induced release.

BRIGHTER and CRYSTAL Studies

Jordi M. Monés, MD

BRIGHTER and CRYSTAL continue the investigation of ranibizumab as a treatment for branch retinal vein occlusion (BRVO) and central retinal vein occlusion (CRVO). The 2 trials were designed to evaluate flexible, stabilization criteria-driven PRN dosing of ranibizumab 0.5 mg in a broad population of patients.

Dr. Monés reported that such a dosing regimen was effective in improving visual acuity in an expanded population. Specifically, the BRIGHTER trial revealed that ranibizumab with or without laser was superior to laser alone over 6 months.

VIBRANT Trial

Robert E. Leonard II, MD

Patients with macular edema secondary to BRVO were twice as likely to gain ≥ 15 letters in BCVA if they received 6 monthly aflibercept injections (2 mg) compared to laser therapy for macular edema secondary to BRVO (53% vs 37%).

Complete data were obtained on 150 of the 183 patients enrolled in this phase 3, multicenter, randomized study. Aflibercept was significantly better than laser when comparing vision improvement and reduction in retinal thickness as measured by OCT.

Development of Atrophy in Neovascular AMD Treated with Anti-VEGF Therapy: Results of the HARBOR Study

SriniVas R. Sadda, MD

The HARBOR trial was designed to determine if anti-VEGF therapy can influence the development of atrophy in neovascular AMD. While the study was not able to completely address the question, the results do suggest that the risk of developing macular atrophy does not outweigh the benefits of ranibizumab therapy for wet AMD. Specifically, visual acuity gains do occur in the presence of atrophy, at least through 24 months of ranibizumab therapy.

Because atrophy developing in cases of treated wet AMD may differ from classically defined geographic atrophy, the HARBOR study uses the term "macular atrophy" to describe this phenomenon.

Sustained-Release Drug Delivery: Where Do We Stand?

Glenn J. Jaffe, MD

Local sustained drug delivery can be tailored specifically to the disease and appears to be a reasonable approach for the treatment of neovascular AMD. Sustained delivery can occur using multiple systems, different platforms, and various drugs.

Sustained-delivery platforms for neovascular AMD include encapsulated cell technology (ECT), nanostructured Tethadur (pSivida Corp, Watertown, MA), refillable reservoir/port delivery systems (PDS), and implantable, refillable, programmable pump delivery systems.

ECT, refillable reservoirs, and programmable pump delivery systems have all successfully gone through proof-of-concept clinical trials.

Update on Gene Therapy for AMD

Jeffrey S. Heier, MD

Regular therapy delivers the best visual outcomes for patients with wet AMD; thus, gene therapy has been identified as having the potential to benefit these patients. And the human retina is ideally suited for gene-based therapies.

Dr. Heier described 2 gene therapy approaches for treating AMD: intravitreal injection of a fusion protein containing sFlt binding domain and subretinal injection of naturally occurring sFlt. The intravitreal method is undergoing study in a phase 1 clinical trial at recognized centers of excellence, and the subretinal approach is being studied in a phase 2 trial. The data indicate that both therapies are well-tolerated and biologically active.

An Easy Way to Save Money

George A. Williams, MD

By using the 0.3 mg dose of Lucentis (ranibizumab, Genentech, Inc, South San Francisco, CA) for conditions for which the 0.5 mg dose of Lucentis is indicated, significant savings could be achieved.

Dr. Williams reported that with the rapid increase of intravitreal injections in the United States (an estimated 4,500,000 injections in 2014), the cost of FDA-approved anti-VEGF agents has risen to ~$3 billion, a significant proportion of the entire Medicare Part D budget ($19.5 billion).

There is currently an effort by payers (including Noridian Healthcare Solutions, LLC, and Novitas Solutions, Inc) to expand the indicated use of the 0.3 mg dose of Lucentis. There is enough drug in the 0.3 mg Lucentis vial to give a full 0.5 mg dose. It is important to note that billing for the 0.5 mg dose and using the 0.3 mg dose is considered fraud and should be avoided.

The Future of Retina: A SWOT Analysis

David W. Parke II, MD

Retina is a subspecialty founded on medical knowledge as well as unique and complex surgical skills. Dr. Parke's SWOT (strengths, weaknesses, opportunities, and threats) analysis included a description of the retina specialty as resting at the top of the medical pyramid. While the position is inherently strong, it also has vulnerabilities.

Examples:

Strengths: Many of the core diseases managed by retina specialists have blindness as a frequent natural outcome. This makes it easy for the public and policy makers to prioritize the care provided by retina specialists.

Weaknesses: The retina specialty relies on a concentration of billing and procedure codes; this leaves retina specialists vulnerable should treatments of diseases such as age-related macular degeneration or diabetic retinopathy become markedly simplified.

Opportunities: New outcomes data from scientific innovation and the Academy's IRIS (Intelligent Research in Sight) clinical data registry will enable retina to develop hard numbers for aggregate and individual practice value.

Threats: New science can pose a threat to those unable to anticipate the need for change and to remain flexible. Practices need to be able to adapt to major shifts, such as if AMD treatment required only 1 treatment a year, or if macular surgery became largely a thing of the past.

Saturday's Retina Subspecialty Day, AAO

The American Academy of Ophthalmology (AAO) 2014 Annual Meeting, being held in conjunction with the European Society of Ophthalmology, began with Subspecialty Day at McCormick Place in Chicago. Following are highlights of Retina Subspecialty Day sessions on Saturday, October 18.

Does Genotype Affect Response to the AREDS Formulation?

While the genetics of AMD is an important area of research, its clinical application remains controversial, as shown in presentations by Carl Awh, MD, and Emily Chew, MD.

Genotype Group Determines Beneficial or Harmful Response to AREDS Components: Analysis of Data from AREDS Report Number 38

Carl C. Awh, MD

Dr. Awh reviewed his recently published subgroup analysis of 989 AREDS patients, which found that those with 2 complement factor H (CFH) and 0 age-related maculopathy susceptibility 2 (ARMS2) genetic risk alleles had markedly increased AMD progression if treated with the AREDS formulation compared to placebo.

Dr. Awh reviewed the statistical design of AREDS Report 38, a recently published analysis of 1237 AREDS patients that had found no association between CFH, ARMS2, and response to AREDS supplements, and stated that it was "statistically underpowered and incapable of finding an interaction" between treatment effect and genotype.

He then presented an analysis of genotyping and outcomes data published in AREDS Report 38. This revealed outcomes consistent with his recent Ophthalmology publication, confirming in this larger group of patients an adverse response to the AREDS formulation for those with 2 CFH and 0 ARMS2 risk alleles.

His conclusion: Although these were retrospective subgroup analyses, clinicians and researchers should consider the potential for harm from the AREDS formulation in patients with 2 CFH and 0 ARMS2 risk alleles.

Genetics and Risk of AMD

Emily Y. Chew, MD

Dr. Chew expanded on the data analysis of 1419 participants enrolled in AREDS who had available DNA. Rebutting Carl Awh's presentation, Dr. Chew discussed research showing that although treatment response to AREDS supplements may be affected by CFH genotype, all genotypes receive benefit, and no alternative interventions are yet available.

Dr. Chew emphasized that her group could not replicate Dr. Awh's findings when they analyzed a randomly selected residual cohort from AREDS, separate and independent of the cohort analyzed by Dr. Awh. She

noted that Dr. Awh's genotype groups were selected based on outcomes, ie, progression to AMD, and that choice created selection bias.

She stressed that the study results do not justify routine genetic screening at this time, and that prospective studies to corroborate these findings are needed. Dr. Chew advised retina specialists to continue recommending the AREDS supplements (a combination of antioxidants and zinc) as the treatment of choice for patients at risk of developing late AMD. She said there is no proof of treatment effects with antioxidants alone or zinc alone.

A Randomized Clinical Trial of Intravitreal Bevacizumab vs Intravitreal Dexamethasone for Diabetic Macular Edema: BEVORDEX

Mark C. Gillies, MD, PhD

Dr. Gillies presented the results from the small (n = 88) BEVORDEX trial comparing intravitreal bevacizumab treatment to intravitreal dexamethasone treatment in patients with diabetic macular edema (DME). The primary outcome of the trial was change in visual acuity from baseline.

Patients who were treated with dexamethasone (DEX) implant had a similar increase in visual acuity when compared to patients treated with bevacizumab. Treatment with DEX implant, however, resulted in better anatomic outcome and patients required fewer treatments (average = 2.7) compared to bevacizumab (average = 8.6).

Systemic Safety Concerns with Anti-VEGF Therapy: Pro and Con

Robert L. Avery, MD (Pro) and Usha Chakravarthy, MBBS, PhD (Con)

Dr. Avery presented data demonstrating that intravitreal anti-VEGF agents enter the systemic circulation and reduce systemic VEGF from hours to days. Previous research has shown a contralateral eye effect after intravitreal injection of anti-VEGF medications in both diabetic retinopathy and macular degeneration.

While no study has been powered to fully address the systemic safety of these medications, there have been concerning differences in the rate of systemic serious adverse events (SAEs) in the various comparison studies.

Dr. Chakravarthy countered by explaining that neither comparative effectiveness trials of different anti-VEGF inhibitors nor placebo-controlled trials of VEGF inhibitors have revealed consistent evidence of systemic adverse effects. While individual studies may provide hints of a systemic effect, the systemic effects disappear upon examination of the evidence in its totality.

Subthreshold Laser for Diabetic Macular Edema

N.H. Victor Chong, MD

Most ophthalmologists follow a modified-ETDRS protocol when performing laser treatment for diabetic macular edema (DME). Dr. Chong described the possible benefits of subthreshold laser for DME. He defined "subthreshold" as a lesion that was not visible clinically.

Research that he referenced suggests that the laser acts on the retinal pigment epithelium to increase absorption. Dr. Chong described recently published research suggesting a positive benefit of MicroPulse laser

(Iridex Corporation, Mountain View, CA)

COMRADE-B Retinal Vein Occlusion Trial

Simon R.J. Taylor, MA, PhD, FHEA, FRCOphth

Ranibizumab at 0.5 mg PRN and sustained-release biodegradable dexamethasone implant (DEX) are 2 established treatments for macular edema secondary to branch retinal vein occlusion (BRVO).

The 2 treatments have different mechanism of action, yet have both been shown to result in significant BCVA improvements. It has been difficult to directly compare the 2 treatments due to the distinctive patient groups enrolled in their respective phase 3 trials.

Dr. Taylor reported the results of the first study to compare the 2 treatments in a head-to-head randomized controlled trial. He reported that patients responded better to treatment with ranibizumab than to treatment with DEX. Patients demonstrated an average BCVA improvement of 14.9 letters in the ranibizumab group and 10.1 letters in the DEX group.

Study Assessing Double-Masked Uveitis Treatment (SAKURA) Phase 3 Trial

Sunil K. Srivastava, MD

Severe vision loss occurs in 25% to 35% of all uveitis cases, underscoring a significant unmet need for a new treatment for uveitis. Intravitreal sirolimus is a novel, noncorticosteroid, local immunoregulatory therapy that has now been shown to be a safe and effective treatment for noninfectious uveitis of the posterior segment.

Dr. Srivastava presented the results of the SAKURA study 1-a phase 3, randomized, multicenter, double-masked, international study. He revealed that intravitreal sirolimus 440 µg, when used as a monotherapy, is able to significantly reduce inflammation while preserving vision.

Stem Cell Trials

Allen C. Ho, MD

Dr. Ho began by explaining that while overall, there is only halting progress in stem cell therapy, there has been real progress in treating retinal diseases. Cell therapy sources include single-cell embryos, embryo blastocytes, and adult stem cells.

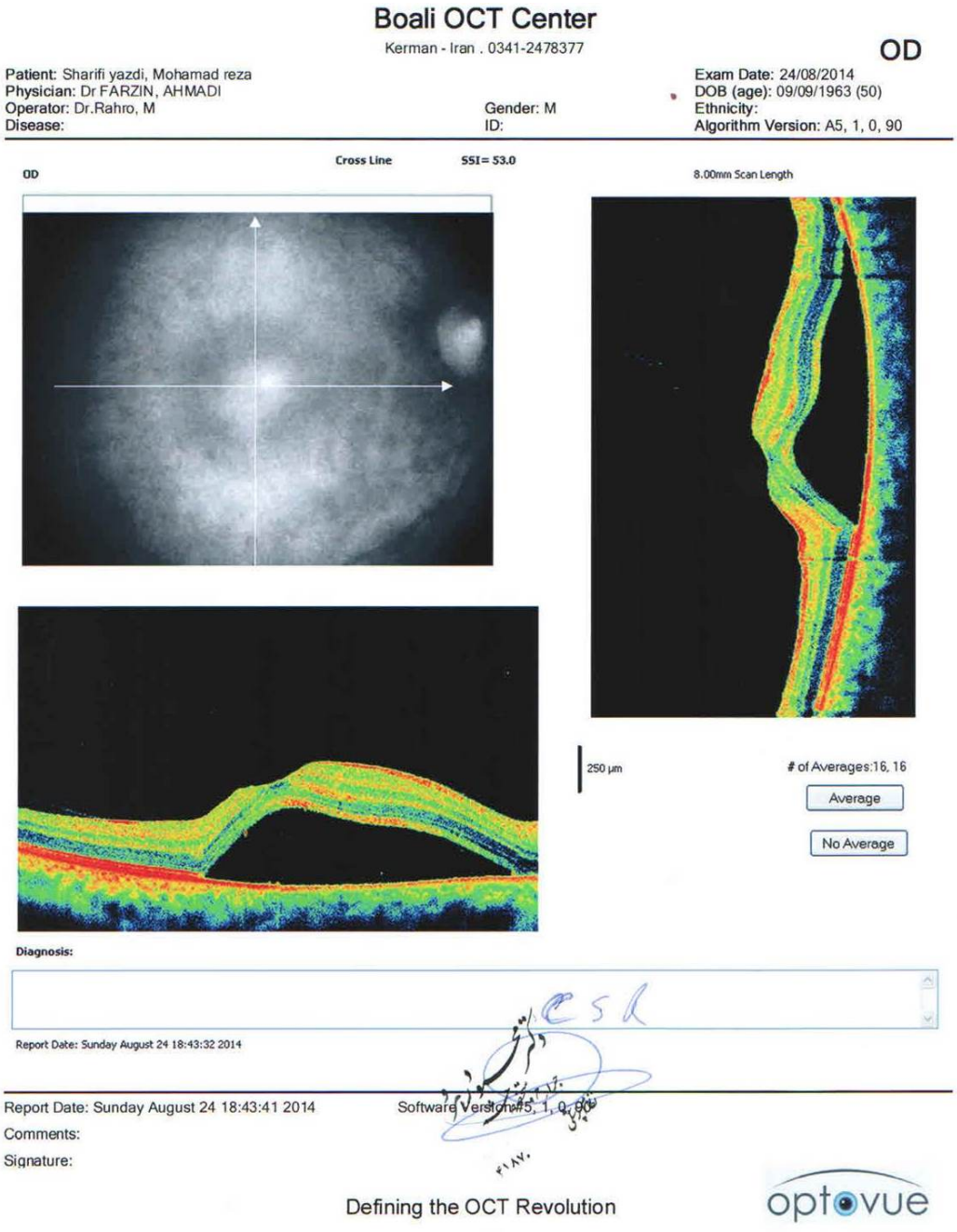
Multiple cell-based therapies (both stem cell and non-stem cell) are currently in clinical trial for the treatment of atrophic age-related macular degeneration (AMD). Data from phase 1 and phase 2 trials reveal that the cell lines are well-tolerated and do not stimulate an immune response or cause tumor formation.

گزارش موردی

آقای ۵۱ ساله با شکایت از کاهش دید چشم راست ازحدود۴ هفته پیش مراجعه کرده است. بینایی چشم راست با اصلاح ۱۰/۸و چشم چپ بدون اصلاح ۱۰/۱۰ می باشد.

مردمک مارکوس گان منفی است. تصاویرOCT و انژیوگرافی را مشاهده می کنید.

تشخیص های افتراقی و درمان؟



Boali OCT Center

Kerman - Iran . 0341-2478377

OD

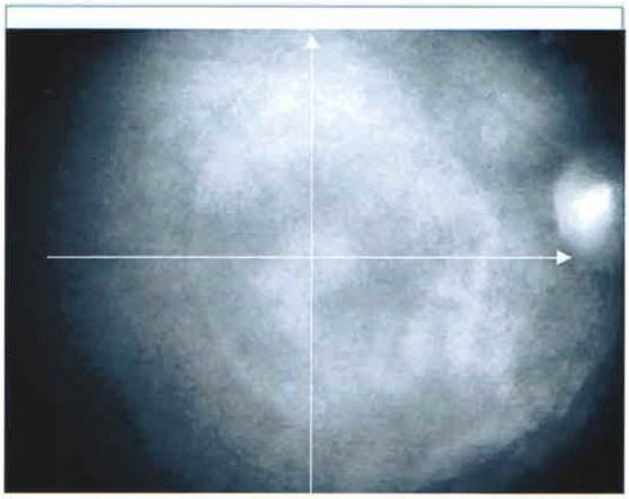
Patient: Sharifi yazdi, Mohamad reza
Physician: Dr FARZIN, AHMADI
Operator: Dr.Rahro, M
Disease:

Gender: M
ID:

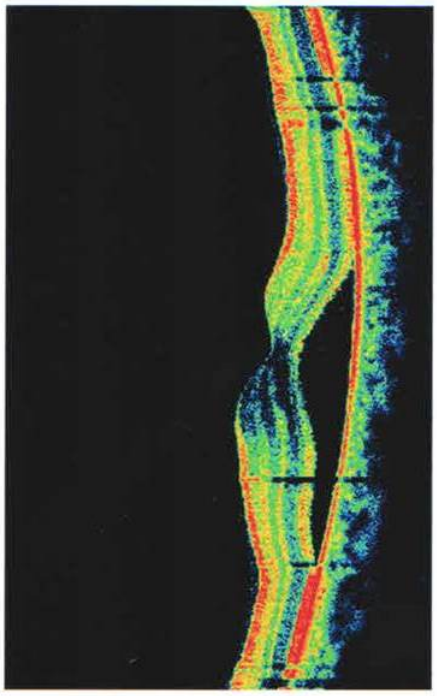
Exam Date: 20/09/2014
DOB (age): 09/09/1963 (51)
Ethnicity:
Algorithm Version: A5, 1, 0, 90

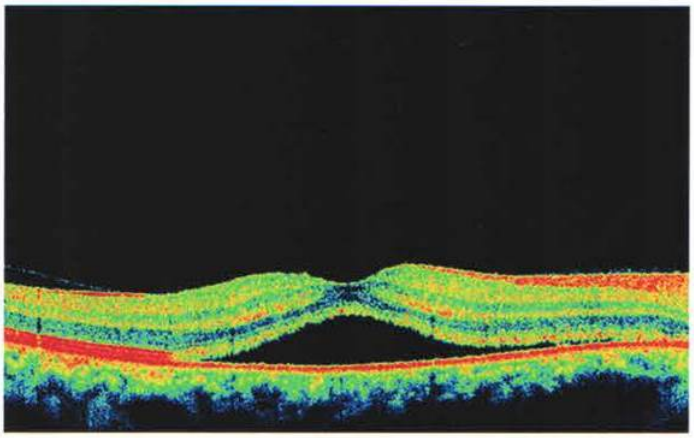
OD

Cross Line SSI= 57.7



8.00mm Scan Length





250 µm

# of Averages:16, 14

Average

No Average

Diagnosis:

CSR (استرچل همراه پارگی RPE)

Report Date: Saturday September 20 10:04:42 2014

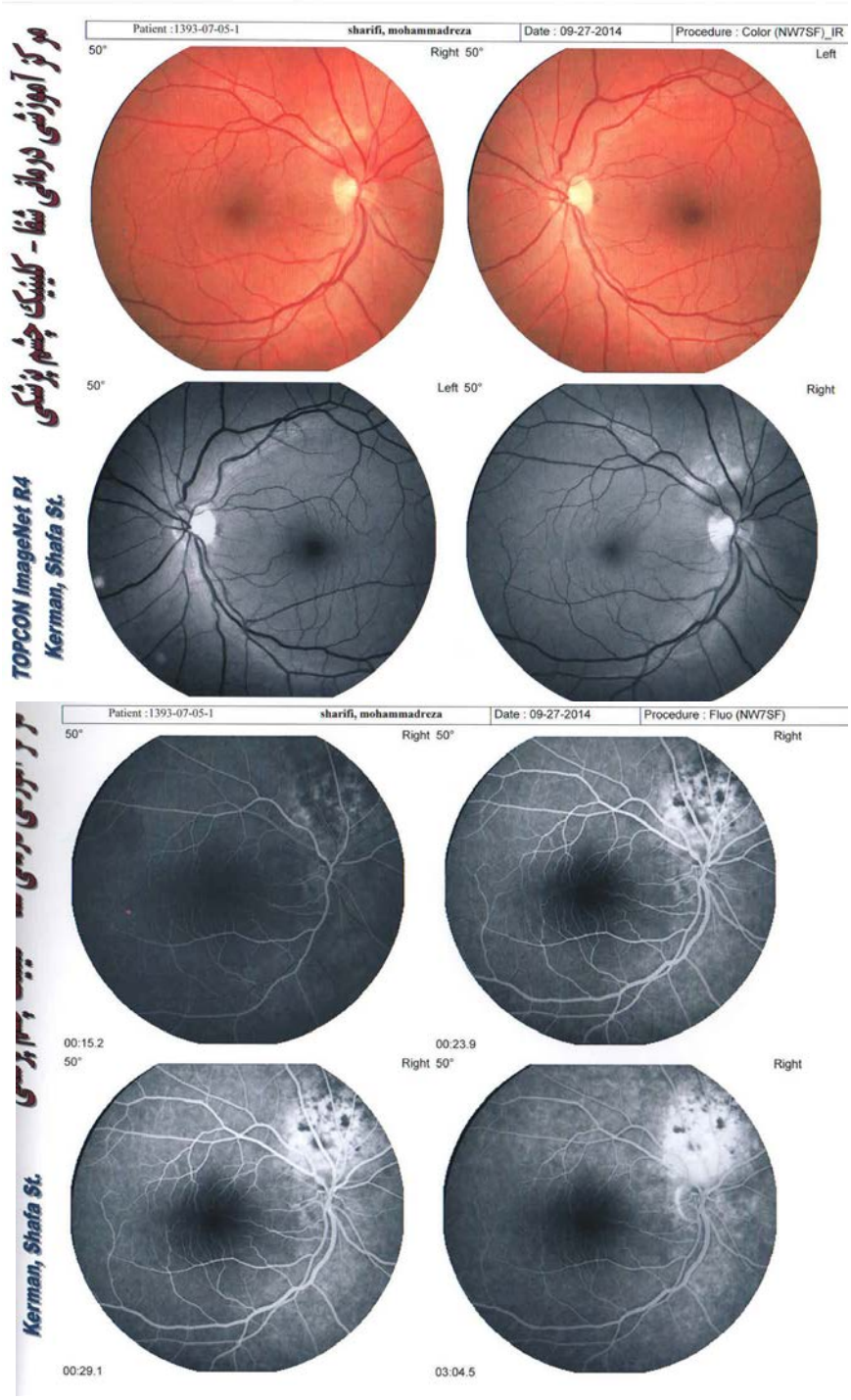
Report Date: Saturday September 20 10:04:50 2014 Software Version #5, 1, 0, 90

Comments:

Signature:

Defining the OCT Revolution

optovue



انجمن جراحان ویتره و رتین ایران

گردآوری : دکتر همایون نیکخواه

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انجمن چشم پزشکی ایران

آدرس: تهران، خیابان کارگر شمالی، نرسیده به خیابان فاطمی،کوچه فردوسی، پلاک ۳، طبقه اول

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