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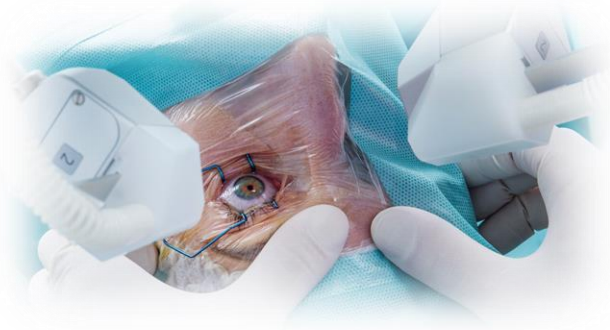

Cataract and Cataract Surgery

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Cataract and Cataract Surgery

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Investigator Initiated Trial

Effect on Early Ocular Blood Flow after Cataract Surgery with Different Fluidics System in High Myopia Cases

Jing Wang, Kaili Tang, Jinsong Zhang

Abstract Details

Objective

To investigate the early changes of ocular blood flow in patients with a history of high myopia after different intraocular pressure (IOP) with Active-sentry assisted CENTURION® Active Fluidics System phacoemulsification techniques.

Methods

A prospective, randomized and interventional clinical trial. 60 cataract patients with high myopia were enrolled and divided into 2 groups (IOP of 40mmHg, IOP of 70mmHg). All patients had examinations preoperative and 1 day after surgery. Postoperative hemodynamic parameters of OA, CRA and PCA vessels, subfoveal choroidal thickness and macular vessel density were major measurements, and postoperative IOP, BCVA were also examined and recorded in all patients.

Results

- There was no significant difference of intraocular pressure and BCVA between the two groups.
- Hemodynamic parameters variation of OA, CRA and PCA vessels were lower in IOP of 40mmHg group.
- The subfoveal choroidal thickness and macular vessel density change were also significantly lower in IOP of 40mmHg group.

Conclusion

Active-sentry assisted CENTURION® Active Fluidics System phacoemulsification techniques revealed more safety of ocular blood flow and IOP, especially in high myopia cataract patient.

Financial Disclosure

The study was funded by a research grant from Alcon (Investigator Initiated Trial) . All authors have no financial disclosure

LenSx®

Alcon Initiated Trial

Laser-Assisted vs. Conventional Clinical Outcomes and Surgical Technique with Torsional Modality Leading to Low Endothelial Cell Loss

Yoshitaka Oka, Val Injev, Noriyuki Sasaki

Abstract Details

Purpose

To compare effects of femtosecond laser assisted cataract surgery (FLACS) and manual phacoemulsification on cumulative dissipated energy (CDE), torsional amplitude (TA), and endothelial cell density (ECD).

Methods

This prospective randomized comparative study included patients scheduled to undergo cataract extraction using FLACS or conventional technique. The main outcome measures were CDE and ECD percent change and average TA.

Results

FLACS versus conventional method had significantly lower CDE (P<0.0001). Low endothelial cell loss (ECL) was achieved with both two groups (1.5±5.6% and 2.7±5.2%; P=0.260). TA was significantly lower for FLACS versus conventional method (P<0.0001).

Conclusion

FLACS achieved significantly lower CDE compared with the conventional method. Low ECL was achieved with both FLACS and conventional method when using low phacoemulsification energy and selecting an efficient ultrasound tip and modality.

LenSx®

Investigator Initiated Trial

Experimental study of using isolated capsulorhexis flap to protect corneal endothelial cells in femtosecond laser-assisted cataract surgery

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Abstract Details

Purpose

To evaluate effects of novel technique that using isolated capsule flap to protect corneal endothelium during femtosecond laser-assisted cataract surgery.

Methods

In this prospective, randomize, controlled animal research, the right eyes of 40 rabbits were equally divided into endothelium-protected (experimental) and control groups. In the experimental group, after femtosecond laser capsulotomy, the isolated capsule flap was lifted to the corneal endothelium by an ophthalmic viscosurgical device. Then, the endothelium was damaged for 1 minute with an ultrasonic energy (longitudinal phacoemulsification power:80%, phaco tip was placed 1.5-2.0mm from the endothelium). Irrigation/aspiration was used to remove the flap and residual lens material. The control group underwent the same surgery, except that the flap was removed immediately after capsulotomy. Corneal endothelioscopy was performed preoperatively and on postoperative days (PODs) 3 and 7 to observe endothelial cell density (ECD) and endothelial cell loss rate (ECL).

Results

There was no statistically significant difference in preoperative ECD between the two groups (2812 cells/mm2 and 2744 cells/mm2, respectively). At POD3, in the experimental group and control group, the ECD was 2711 cells/mm2 and 2421 cells/mm2, respectively. And the ECL was 3.59% and 13.26%, respectively. The difference of ECD was statistically significant (P<0.000). At POD7, the ECD of two groups was 2730 cells/mm2 and 2457 cells/mm2, respectively. And the ECL was 2.92% and 11.97%, respectively. The difference of ECD was also statistically significant (P<0.000).

Conclusion

The isolated capsulotomy flap technique significantly reduces damage to the endothelium caused by ultrasonic energy and protects corneal endothelial cells during phacoemulsification.

Financial Disclosure

This study is supported by a research grant from Alcon

NGENUITY®

Alcon Health Economics and Outcomes Research

Comparative Assessment of Ergonomic Experience Operating with Heads up Display and Conventional Surgical Microscope in Posterior Segment Surgeons

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Abstract Details

Purpose

Musculoskeletal pain issues are prevalent in ophthalmic surgeons, and can impact surgeons' well-being and productivity. Consideration is important for posterior-segment surgeons who hold non-neutral postures during lengthy surgeries that is known to result in cumulative strain. Heads-up displays (HUD) may reduce ergonomic stress compared to conventional microscopes. This study compared ergonomic experience between HUD and conventional optical microscope in the operating room (OR), as reported by a sample of posterior-segment surgeons in the United States.

Methods

An online questionnaire was distributed to a sample of surgeons with experience operating with HUD. The questionnaire captured surgeon-specific variables, the standardized Nordic Musculoskeletal Questionnaire, and custom questions comparing HUD and conventional microscope

Results

Descriptive analysis was conducted on responses from 37 posterior-segment surgeons with a mean 14.0 years of practice and 2.3 years using HUD. Most surgeons agreed or strongly agreed that HUD reduced the severity (64%) and frequency (63%) of pain and discomfort, improved posture (73%) and improved overall comfort (77%). 51% of respondents believed conventional microscope had a negative impact on their health. Of respondents who experienced headaches (n=14) or pain/discomfort during operation (n=29), 36% reported improvement in headaches and 76% reported feeling less pain/discomfort since using HUD in the OR, respectively.

Conclusion

This study indicates that heads-up display may be an important tool for wellness in the operating room as it can benefit posterior-segment surgeons across several ergonomic measures. Future studies with objective ergonomic assessment and larger sample size would be useful to further validate these findings.

NGENUITY®

Investigator Initiated Trial

Comfort Meets Class- A 3D Solution for your Surgical Experience

Naren Shetty, Aishwarya, Luci KAWERI, Ravi KRISHNA, P.Rohitha Nayak NAYAK

Abstract Details

Purpose

To compare cataract surgeon's comfort and ease of visualization while performing phacoemulsification using 2 different microscope systems, the NGENUITY® and the standard operating microscope (SOM).

Methods

Prospective, randomized controlled study. An interim analysis of 123 patients where 64 patients have been operated on using SOM and 69 patients using the NGENUITY® 3D Visualization System by 5 surgeons. All patients within the age of 40-70 with nuclear sclerosis grade 2 and above, undergoing cataract surgeries were included. Complicated and secondary cataracts were excluded. After routine surgery, the novel "Surgeon's Comfort Score" is filled and compared. Corneal edema, cells and flare, vision are compared on post-operative day 1.

Results

The brightness and illumination of the surgical field of SOM was higher compared to NGENUITY® as experienced by all the 5 surgeons ($p<0.0001$). Comfort of the surgical field of NGENUITY® was higher compared to SOM ($p<0.05$). Neck comfort was better after the surgery while operating on NGENUITY® ($p<0.05$ for 3 of 5 surgeons). Ease of visualization of the steps of surgery were better using NGENUITY® but not statistically significant presently. Post-operative vision, corneal edema, cells and flare were comparable.

Conclusion

The NGENUITY® system works accurately with lesser illumination providing better comfort to the cataract surgeon and patient. Ease of visualization is better with NGENUITY®. Increased distance between surgeon and patient with NGENUITY® makes it safer in COVID times. It is also found to be a better teaching tool.

Financial Disclosure

This study is supported by a research grant from Alcon

NGENUITY®

Alcon Initiated Trial

Advantages of A Three-Dimensional Heads-up Digital System Versus Standard Surgical Microscopes During Anterior Segment Surgery

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Abstract Details

Purpose

To present a laboratory modeling evaluation of a digital visualization system (NGENUITY® 3D Visualization System) mounted on three analog surgical microscopes, to compare total magnification, depth of field, and depth resolution.

Methods

A theoretical assessment of system performance for a 3D heads-up digital visualization systems was compared with the standard oculars for three analog surgical scopes. For the comparisons between the systems, the NGENUITY® camera aperture was set at 30% of its full diameter; the surgeon would be 1.2m from the heads-up display; and the surgical scopes would be set-up per the manufacturer's instructions. Using the equipment specifications, the total magnification, depth of field, and depth resolution were calculated for each system. Total magnification was calculated purely as a function of system parameters. Depth of field and depth resolution incorporated other visual parameters (e.g., distance of the physician from the heads-up display).

Results

The 3D heads-up system provided 26–48% higher total magnification than the surgical microscope oculars. Setting the camera aperture at 30%, NGENUITY® provided up to 5-fold greater instantaneous depth of field than the total depth of field through the surgical scope oculars. Depth of field decreased at shorter viewing distances. NGENUITY® provided 11–42% better depth resolution than the surgical scope oculars, at the maximal system-specific total magnification.

Conclusion

An ocular-free, heads-up system has the potential to improve ergonomics, surgeon comfort and facilitate collaboration and teaching in the operating room. In this theoretical study, NGENUITY® improved total magnification, depth of field, and stereoscopic depth resolution versus standard surgical scope oculars.

ORA®

Alcon Health Economics and Outcomes Research

Comparing Intraoperative Aberrometry With Conventional Preoperative Planning An Economic Analysis in Japan

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Abstract Details

Purpose

The goal of this study was to assess the economic impact of intraocular lens (IOL) selection with IWA in cataract surgery in comparison to conventional preoperative planning in Japan.

Methods

A literature review was conducted to identify relevant studies published in peer-reviewed journals that reported clinical and refractive outcomes of IWA vs conventional planning for IOL power selection. The economic impact analysis was performed in Excel to evaluate the financial impact of IWA usage. The input of cost data was sourced from published literature or clinic charge to the patient.

Results

Nine studies reported less absolute prediction error (APE) (0.5 D or less) for eyes with IWA than those with preoperative evaluation. A large retrospective database with 32,189 eyes showed 6% significant reduction in APE (81.9% vs 75.9%, P<0.0001). Improved refractive outcomes not only provide better quality of vision but also reduce the risk of enhancement surgery (e.g. laser surgery, lens exchange or lens rotation) to correct the refractive error. On average, enhancement surgery can cost around JAN¥200,000 to JAN¥250,000 in Japan. Based on our evaluation, it may lead to JAN¥ 13,000 financial savings per patient.

Conclusion

IWA improves patient refractive outcomes and proves to be a very cost effective technology in our economic assessment conducted for the Japanese patients.

ORA®

Alcon Health Economics and Outcomes Research

A literature review to describe clinical efficacy of intraoperative aberrometer in challenging patient populations, versus standard of care

Sun-Ming Jessica Pan[1], Margaret Ainslie-Garcia[2], Nicole Ferko[2], Carine Hsiao[1]

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Abstract Details

Purpose

Intraoperative aberrometry (IA) provides real-time information during cataract surgery, and addresses several issues related to intraocular lens calculation to reduce prediction error. A literature review was conducted to compare IA with standard preoperative evaluation and planning (PEP) in patients with prior refractive surgery, astigmatism, or atypical axial length (AL).

Methods

MEDLINE and Google Scholar were searched from JAN-01-2004 to JUL-31-2020. Comparative studies published in English (randomized, non-randomized, meta-analyses) in patient populations of interest were included. Prediction error, postoperative astigmatism, and proportion of patients ±0.5 diopters (D) of refractive target were extracted.

Results

The search revealed studies across patients with prior refractive surgery (n=5 studies), pre-existing astigmatism (n=7), short (n=1) and long AL (n=1). In post-refractive populations, IA was reported to provide similar (n=1), numerical (n=2) or statistically significant improvements ($p<0.05$, n=2) in prediction error and proportion ±0.5D versus PEP with various formulas. All studies in patients with astigmatism that reported a p-value found significantly lower spherical equivalent (n=2) and residual astigmatism in IA compared with PEP (n=2), while three studies reported lower values in IA eyes (p-value not reported). In long eyes (>25.0mm), IA showed significantly lower mean numerical error (MNE) versus common formulas including Barrett-Universal-II and Hill-RBF and was comparable to AL-OPT Holladay-1. In short eyes (<22.1mm), IA had the lowest MNE of 4 common formulas but only achieved statistical significance versus Haigis.

Conclusion

IA appears to offer several advantages in accuracy and astigmatism-related outcomes, and may be an asset in addressing patient expectations for good postoperative visual outcomes in challenging populations.

AcrySof® IQ

Alcon Health Economics and Outcomes Research

Burden of Blindness in China - A Systematic Literature Review

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Abstract Details

Objectives

To collate and review published evidence in order to assess burden of blindness in China.

Methods

A systematic literature search was conducted in PubMed (period: January 2006 – May 2019) to collate and synthesized published evidence on burden of blindness in China.

Results

Overall, eight publications were included. Prevalence of blindness in China has been reported between 0.3% in people aged >40 years to 1.7% in people aged >50 years. Cataract remained the most frequent (36.7% to 52.6%) cause for blindness in the Chinese adults. Other leading causes of blindness in China included myopic retinopathy (24.8% to 36.4%), myopic macular degeneration (7.7% to 10.9%), glaucoma (6.25% to 9.1%) and corneal opacity (6.2% to 16.2%). In 2015, 111.7 million cataract cases were reported in China, of which 11.7 million suffered from blindness (BCVA<0.05). Further, it is projected that by 2050, cataract would affect 240.8 million Chinese people between 45-89 years of age. The Chinese Ministry of Health has reported that 45% of China's county hospitals do not offer cataract surgery services and most rural residents are unable to afford surgery in urban centers.

Conclusion

Chinese population is progressively ageing, resulting in an increasing burden of preventable blindness. There is a rural urban divide in access to surgery in China; lack of disease awareness and concerns about the quality of local services appear being the principal barriers in rural Chinese population.

AcrySof® IQ

Alcon Health Economics and Outcomes Research

Effect of IOL biomaterial on Posterior Capsule Opacification (PCO): Long-term real-world clinical practice evidence from large population based studies

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Abstract Details

Purpose

Posterior Capsular Opacification (PCO) involves lens epithelial cell proliferation and capsular fibrosis, resulting in visual obstruction. Nd:YAG laser capsulotomy treats PCO but leads to additional healthcare resource utilization. Longitudinal real world evidence (RWE) studies can provide long-term outcomes for large cohorts of patients and reflect routine clinical practice.

Methods

The present study is an overview of recently available RWE studies (N=3) on long-term PCO/Nd:YAG outcomes due to different IOLs.

Results

In Finland, a retrospective cohort study in Kotka region (Lindholm 2019) was conducted (2007-2016, N=10,044) and cumulative incidence of Nd:YAG laser posterior capsulotomy was estimated with competing risks survival analysis. Findings showed that AcrySof® IOLs were associated with a 38% reduction in Nd:YAG risk compared to Tecnis® ZCB00 (P<0.001). In the UK, a retrospective cohort study (Ursell 2018) was conducted using NHS cataract clinics data (2010-2016, N=52,162) and findings showed that 3-years Nd:YAG capsulotomy incidence was significantly lower for single-piece hydrophobic AcrySof® IOL vs. other hydrophobic as wells as hydrophilic IOLs (p<0.001). A healthcare claims data analysis (Kossack 2017) was conducted in Region Bavaria of Germany to assess impact of different IOLs on PCO (2010-2014, N=3025). Findings indicated statistically significantly lower risk of YAG capsulotomy in hydrophobic vs. hydrophilic IOLs (P<0.0001) up to 4 years post-cataract surgery.

Conclusion

Three robust RWE studies show that Hydrophobic IOLs are associated with a significantly lower risk of PCO requiring Nd:YAG capsulotomy vs. hydrophilic IOLs. In two studies, AcrySof® IOLs were associated with significantly lower YAG capsulotomy incidence vs. Tecnis® ZCB00.

AcrySof® IQ

Alcon Health Economics and Outcomes Research

Work productivity losses due to blindness in working Chinese adults aged ≥50 years and their caregivers

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Abstract Details

Objectives

To estimate the patient and caregiver burden resulting from productivity losses in working Chinese adults aged ≥50 years suffering from blindness.

Methods

A productivity loss estimator model was developed in Microsoft Excel. Input parameters: prevalence of blindness in the working Chinese adults aged ≥50 years was sourced from Zhao et al. epidemiology study. On average 50% loss of remaining working-age years per blind person was assumed after taking considering state retirement age-limit (5 and 2.5 years respectively men and women). World Bank data on Chinese Gross National Income per capita ($8,690) was used. Assuming one caregiver per blind person, caregiver productivity loss was set at 10% and number of years of lost productivity for caregivers were assumed at 3.75 years.

Results

An estimated 1.66 million Chinese men and 0.96 million Chinese women aged ≥50 years in the working age population suffered from blindness. Productivity loss due to blindness in working Chinese adults aged ≥50 years and their caregivers was estimated to be $102.4 billion ($72.1 billion for men, $21.6 billion for women, and $8.6 billion for their caregivers). Productivity losses in cataract related blindness, the cumulative burden for men, women and their caregivers was estimated at $53.9 billion (due to cataract) and $25.4 billion (due to retinal diseases).

Conclusion

Blindness affects 1.7% of China's population ≥50 years and it poses significant burden on society due to losses in work productivity. Health policy makers should aim to further improve access to vision care sand reduce the incidence and prevalence of preventable blindness in China.

Clareon® AutonoMe® **Alcon Health Economics and Outcomes Research**

A literature review of the clinical evidence on Nd:YAG laser capsulotomy incidence post-cataract surgery in eyes implanted with the Clareon intraocular lens

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Abstract Details

Purpose

Clinically significant posterior capsular opacification (PCO) is treated by Nd:YAG laser capsulotomy procedure. The purpose of this literature review was to collate and report Nd:YAG incidence post-cataract surgery in patients implanted with the Clareon® IOL.

Methods

A literature search was conducted using Pubmed, European and American Society for Cataract and Refractive Surgeons congress databases and internal clinical trial database (Jan 2010 to Mar 2021). Incidence of PCO requiring Nd:YAG with Clareon® IOL was extracted and reported.

Results

Five clinical trials reporting the incidence of PCO requiring Nd:YAG were identified. In a multi-center (Japan), single-arm study (N=110), at 14 months, Nd:YAG incidence was 0.0%. Among these subjects, 20 eyes were examined at 9 years, and 5.0% underwent Nd:YAG capsulotomy. In an open label, randomized, multicenter (US and Europe) prospective study (N=398) to evaluate the safety and effectiveness of Clareon®, 1.5% eyes underwent Nd:YAG capsulotomy at 15 months. In a prospective multicenter (US), single arm safety and performance clinical trial in cataract patients (N=350) with Clareon® IOL implantation, 4.6% eyes underwent Nd:YAG capsulotomy within 12 months. In an ongoing multicenter (UK and Spain), single-arm study assessing the long-term (3-year) safety and effectiveness of the Clareon® IOL (N=424), interim analysis at 24 months reported Nd:YAG incidence of 1.7%. While in a prospective observational study (Spain) Nd:YAG incidence for the Clareon® group (N=60), was 0.0% at 12 months.

Conclusion

Evidence from clinical studies demonstrates that the Clareon® IOL biomaterial and squared edge design provides a protective effect from PCO with low incidence of Nd:YAG capsulotomy being consistently reported.

Clareon® AutonoMe®

Investigator Initiated Trial

Clinical Evaluation of a New Hydrophobic Acrylic Preloaded Intraocular Lens with a Novel Delivery System

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Abstract Details

Background

Clareon® is a single piece hydrophobic intraocular lens (IOL) made from a new biomaterial and claims to have an enhanced manufacturing process that achieves unsurpassed optical clarity. It is packaged as a preloaded IOL with the AutonoMe™ which is the first automated disposable pre-loaded delivery device.

Purpose

To evaluate the clinical outcomes of patients implanted with the Clareon® monofocal IOL Model CNA0T0.

Methods

This is a multi-centre retrospective review of patients who underwent uneventful phacoemulsification cataract surgery and implantation with IOL Model CNA0T0. Visual outcomes were assessed at 1 month follow up. The primary outcome measures were the best corrected(BCDA) and uncorrected(UCDA) distance visual acuities. Secondary outcome measures include refractive stability and predictability, contrast sensitivity as well as wound stretch and surgically induced astigmatism(SIA)

Results

A total of 125 eyes had cataract surgery performed by 3 surgeons. Only 108 eyes completed at least 1 month follow up and were included for analysis. The mean logMAR BCDA and UCDA at 1 month was 0.06±0.08 and 0.18±0.17 respectively. 93.8% of eyes had BCDA of logMAR 0.18(Snellen 6/9) or better and all eyes had BCDA of logMAR 0.3(Snellen 6/12) or better. 80.9% of eyes had UCDA of 6/9 or better and 97.8% of eyes had UCDA of 6/12 or better. All eyes were within 0.75D of refractive target, 90.9% were within 0.5D and 68.7% were within 0.25D. The mean contrast values(logMAR) were 1.73±0.18 at 3cpd, 1.91±0.24 at 6cpd, 1.62±0.25 at 12cpd and 1.09±0.28 at 18cpd. Mean wound stretch and the centroid SIA for a 2.2mm incision was 0.04+0.05mm and 0.10D respectively. There was no wound stretch for a 2.4mm incision and centroid SIA was 0.23.

Conclusion

The Clareon® intraocular lens provided excellent visual outcomes and had good refractive predictability. Contrast sensitivity was better than aged match controls. The novel AutonoMe™ delivery system did not cause significant corneal wound stretch or surgically induced astigmatism.

Financial Disclosure

The authors have no financial interests related to this presentation. The authors received a grant from Alcon for this study.

Clareon® AutonoMe®

Alcon Initiated Trial

Post-market Clinical Study of the Clareon® AutonoMe® in an Indian Population

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Abstract Details

Purpose

To describe the interim clinical outcomes 1-month postoperatively, and IOL delivery performance of Clareon® AutonoMe® in an Indian population

Methods

Prospective, multicenter, single-arm study enrolled 151 eyes implanted with a Clareon® intraocular lens using the AutonoMe® delivery device (Alcon). Subjects were adult Indians with no ocular pathology other than cataract & pre-op corneal astigmatism of < 1.00D. Primary outcome measures were monocular BCDVA, UCDVA, MRSE at 1 month, the presence of IOL glistenings, all safety endpoints and surgeon questionnaire for AutonoMe® delivery device at 1 month.

Results

At 1-month(Interim analysis in a 12 month study), in the first eye, mean monocular BCDVA was 0.008 ± 0.1137 logMAR and mean monocular UCDVA was 0.1 ± 0.1494 logMAR. Similarly, in the second eye, monocular mean BCDVA was 0.014 ± 0.1041 logMAR and mean monocular UCDVA was 0.083 ± 0.1550 logMAR. All the eyes were within 1D of the refractive target at 1 month. 100% of surgeons reported "Very Easy or Easy" for the insertion of AutonoMe® into the incision site and "very controllable or controllable" during the IOL delivery. Grade 0 glistening and no surface haze were observed for all patients at 1 month.

Conclusion

In an Indian population, the visual performance of the Clareon® IOL showed optimal VA at 1 month and high surgeon satisfaction for the AutonoMe® delivery device. The mean MRSE was ≤0.25D, indicating that the surgeons optimized A-constant was well determined.

AcrySof® IQ PanOptix® **Alcon Health Economics and Outcomes Research**

Post-operative YAG capsulotomy rates with two trifocal intraocular lenses: Review of evidence

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Abstract Details

Objectives

To conduct a review of available evidence on post-operative YAG capsulotomy rates with two trifocal intra-ocular lenses.

Methods

European Society of Cataract & Refractive Surgeons (ESCRS) congress database was queried using trifocal IOL specific search terms to identify relevant presentations (e-posters, videos and webcasts) from 2015-2019, reporting on post-operative YAG capsulotomy rates two leading trifocal IOLs (PanOptix®, and AT LISA®).

Results

During the search period, 3 comparative studies were identified that reported Nd:YAG capsulotomy rates for PanOptix® vs. AT LISA®. In a matched cohort study from Czech Republic (N=56 each PanOptix® and AT LISA® eyes), YAG capsulotomy rate was reported at 19.6% for AT LISA® tri at 19.27 months and 3.5% for PanOptix® at 26.5 months. In a matched prospective comparative study from Czech Republic (N=200 each PanOptix® and AT LISA® eyes), YAG capsulotomy rate was reported at 6% for AT LISA® tri and 0.5% for PanOptix® at 6 months. In a matched prospective cohort study from Netherlands (N=28 each PanOptix® and AT Lisa® eyes), reported YAG capsulotomy rates was reported at 10.7% for AT LISA® tri and 14.3% for PanOptix® at 12 months (P=0.11).

Presented evidence from other non-comparative studies also favored PanOptix® with reportedly lower Nd:YAG capsulotomy rates observed with PanOptix® (studies duration: 3-9 months) compared to AT LISA® tri (studies duration: 3-24 months).

Conclusion

Published evidence indicates surgeons can experience favorable YAG capsulotomy outcomes with PanOptix® trifocal IOLs compared to AT LISA® trifocal IOLs, both at short and long-term post-operative follow-up periods.

AcrySof® IQ PanOptix®

Investigator Initiated Trial

A Prospective, Comparative Study of the Vision Outcomes between a Trifocal IOL and an Extended Depth of Focus IOL among Chinese Population

Guangbin ZHANG

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Abstract Details

Purpose

To compare whole range of visual outcomes, spectacle independence, and visual disturbances of PanOptix® IOLs (TIOL group) versus Symfony® IOLs (EDOF group) in a Chinese population.

Methods

37 subjects who underwent binocular cataract surgery were assigned to TIOL group (18 with 36 eyes) and EDOF group (19 with 38 eyes). Binocular uncorrected (UDVA) and best-corrected (BCDVA) distance visual acuities (5m), uncorrected intermediate (UIVA, 60cm) and near (UNVA, 40cm) visual acuities, distance-corrected intermediate (DCIVA, 60cm) and near (DCNVA, 40cm) visual acuities, modulation transfer function (MTF), spectacle independence, defocusing curve, photopic contrast sensitivity and Chinese version validated Questionnaire for Visual Disturbance (QUVID) were evaluated 3 months postoperatively. Standardized logarithm of the minimum angle of resolution (logMAR) charts were used for VA measurement

Results

Post-operative 3 months UDVA, BCDVA, UIVA-60cm, DCIVA-60cm, photopic contrast sensitivity, and MTF were not significantly different between groups (both $P > 0.05$). The TIOL group achieved significantly better UNVA-40cm (0.11±0.13 Vs 0.22±0.08), DCNVA-40cm (0.08±0.08 Vs 0.22±0.08) (both $P < 0.05$) and higher proportion of patients reporting never using spectacles for near vision than the EDOF group (83.33% Vs 47.37%, $P < 0.05$). QUVID questionnaire showed incidence of severe starbursts, halos, and glare were comparable in 2 groups 3 months after surgery ($P > 0.05$).

Conclusion

Compared to EDOF IOL, PanOptix® IOL achieve better near-vision and higher spectacle independence, which resulted in superior whole range of visual outcomes with comparable visual quality in a Chinese population.

Financial Disclosure

This study is supported by a research grant from Alcon

AcrySof® IQ PanOptix®

Investigator Initiated Trial

Clinical outcome of PanOptix® trifocal IOL implantation in Chinese elder cataract patients aged 60-79 years old

Chi Xiao, Haiyan He, Kexing Hu, Xiaoting Ye, Daxian Wang
China

Abstract Details

Purpose

To evaluate visual performance after implantation of a diffractive trifocal IOL (AcrySof® IQ PanOptix®, Alcon) in Chinese elder cataract patients 60-79 years old.

Methods

Retrospective case series study. Cataract patients aged 60-79 years old that underwent cataract phacoemulsification extraction combined with AcrySof® IQ PanOptix® IOLs implantation from July 2020 to January 2021 have been included. Pre-op baseline data and 3 months post-op clinical data of all subjects were recorded. Post-op binocular uncorrected (UDVA) and best-corrected (BCDVA) distance visual acuities (5m), uncorrected intermediate (UIVA, 60cm) and near (UNVA, 40cm) visual acuities, distance-corrected intermediate (DCIVA, 60cm) and near (DCNVA, 40cm) visual acuities, total intraocular aberration, total intraocular high order aberration, modulation transfer function (MTF), Strehl ratio, VF-14 visual function questionnaire, spectacle independence were evaluated. Standardized logarithm of the minimum angle of resolution (logMAR) charts were used for VA measurement.

Results

39 patients with 45 eyes, including 10 males (11eyes) and 29 females (34 eyes), aged 69.93±8.50 years old have been analyzed. Post-op 3 months UDVA, UIVA and UNVA have significantly improved compared with pre-op visual acuity (0.08±0.11 Vs 0.77±0.26; 0.03±0.18 Vs 0.72±0.21; 0.15±0.22 Vs 0.62±0.18, all $p < 0.05$). Total intraocular aberration, coma and trefoil significantly decreased, while MTF and Strehl ratio increased postoperatively. Spectacle independence were reported in all of the patients.

Conclusion

AcrySof® IQ PanOptix® IOL provides good far, intermediate and near visual acuity in elder (aged 60-79 years) Chinese cataract patients.

Financial Disclosure

The study was funded by a research grant from Alcon (investigator initiated trial).

AcrySof® IQ PanOptix® **Investigator Initiated Trial**

Evaluation of short-term visual outcome of a diffractive trifocal intraocular lens in Chinese high myopic cataract patients

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Abstract Details

Purpose

To evaluate the short-term visual performance after implantation of a diffractive trifocal intraocular lens (AcrySof® IQ PanOptix®, Alcon) in high myopic cataract patients.

Methods

According to axial length (AL), 74 eyes of 39 patients were divided into two subgroups: subgroup 1（high myopic group，AL≥26.0 mm) and subgroup 2（age-matched control group，AL＜26.0mm). Logarithm of the minimum angle of resolution (logMAR）visual acuity of uncorrected distance (UDVA), intermediate (UIVA) and near (UNVA), defocus curve, postoperatively spherical equivalent (SE) , photopic and mesopic contrast sensitivity were evaluated 1 month postoperatively.

Results

72.98% patients postoperative SE refraction were within ± 0. 5 D of target refraction in each group. Postoperative SE is -0.25±0.37D in subgroup 1 and -0.10±0.44D in subgroup 2. In both groups, 93.48% and 92.86% patients achieved 0.1 LogMAR for UDVA and UIVA, while 86.96% patients in subgroup 1 and 78.57% patients in subgroup 2 achieved 0.1 LogMAR in UNVA respectively. Each subgroup showed the similar defocus curve in which the best corrected distance visual acuity reached at a vergence of 0.00 D (far focus) at peak, then dropped slightly at -1.00 D, ascended from -1.50D (intermediate focus) and peaked again at -2.50 D (near focus) similarly. Subgroup 1 showed significantly better visual acuity at +2.00,+1.50,+0.50,0.00, −0.50, and −3.00 diopters compared to subgroup 2 ($P < 0.05$). Contrast sensitivity value under photopic and mesopic conditions were similar in both subgroups.

Conclusion

AcrySof® IQ PanOptix® intraocular lens provides good visual outcome, including good full range of vision with non-compromised visual quality in high myopic cataract patients at 1 month postoperatively.

Financial Disclosure

This study is supported by a research grant from Alcon

AcrySof® IQ Vivity™ **Alcon Health Economics and Outcomes Research**

A Cost-effectiveness Analysis of AcrySof® IQ Vivity™ Intraocular Lens from Private Health Fund Perspective in Australia

Chandra Bala , PhD, MBBS[1]; Paul Athanasiov, MD, MBBS[2]; Jason Holland, B.App.Sci[3]; Mukesh Dhariwal, MPH, MBBS[4]; Amit Gupta, MSc[5]; Hemant Rathi, MSc[6]

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Abstract Details

Purpose

AcrySof® IQ Vivity™ is the first and only Extended Depth of Focus (EDoF) intraocular lens (IOL) with the Wavefront-Shaping X-WAVE technology and a clinically proven monofocal visual disturbance profile. This study estimates the cost-effectiveness of AcrySof® IQ Vivity™ IOL vs. standard aspheric monofocal IOL, from a private health fund perspective in Australia.

Methods

A Markov model was developed using the following health states: well, need for spectacles (near/distance/varifocal), severe visual disturbances (glare/haloes/starbursts) – with/without spectacles, and death. Model inputs were sourced from a randomized clinical study (NCT03010254), published literature, and expert opinion. IOL costs (AcrySof® IQ Vivity™ - AU$651, and AcrySof® SN60WF- AU$290) were derived from the published prostheses list. A lifetime time horizon (30 years) was considered, and cost and health outcomes were discounted at 5% per annum. Model outcomes included incremental cost-effectiveness ratio (ICER) per quality adjusted life year (QALY) gain. Sensitivity and scenario analyses were also conducted.

Results

Bilateral implantation of AcrySof® IQ Vivity™ IOL provided greater vision related quality of life (QALY gain of 0.16) at an incremental lifetime cost of AU$384 vs. monofocal IOL leading to ICER of AU$2,383/QALY, which is well below the medical technology cost-effectiveness thresholds (range: AU$45,000-AU$75,000) recommended by the Australian authorities. Results were most sensitive to the cost of IOL prosthesis, post-operative spectacle dependence, and disutility due to wearing glasses. The robustness of results was further confirmed by probabilistic sensitivity analysis, and scenario analyses.

Conclusion

AcrySof® IQ Vivity™ IOL is a highly cost-effective treatment strategy with improved vision-related quality of life outcomes for patients undergoing cataract surgery.

AcrySof® IQ Vivity™

Alcon Initiated Trial

Multi-country Registry Assessment of Real-world Visual Performance and Patient Satisfaction Outcomes of a Novel Non-diffractive Presbyopia-correcting IOL

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Abstract Details

Purpose

To report real world visual and patient satisfaction outcomes with the non-diffractive design, AcrySof® IQ Vivity™ (DFT015) and AcrySof® IQ Vivity™ Toric IOL (DFT315, DFT415, and DFT515).

Settings

An international, ambispective registry study conducted in Europe, the UK and Australia and evaluated through routine clinical practice.

Methods

After a minimum of 3 months follow-up per local practice standards, subjects bilaterally implanted with AcrySof®IQ Vivity™ (DFT015) or AcrySof®IQ Vivity™ Toric IOL (DFT315, DFT415, and DFT515) underwent visual acuity assessments at distance, intermediate (66 cm) and near (40 cm). Subject satisfaction was collected via validated questionnaires. This is the first interim analysis.

Results

To date, 129 subjects aged 66.6±10.25 years were enrolled. Binocular mean±SD UCDVA was 0.009±0.088 logMAR, UCIVA was 0.094±0.118 logMAR, and UCNVA was 0.255±0.157 logMAR. Binocular mean±SD BCDVA was -0.030±0.077 logMAR, DCIVA was 0.075±0.116 logMAR, and DCNVA was 0.251±0.143 logMAR. At study entry, the average manifest refraction (MRSE) was -0.146±0.387 D in first eyes and -0.167±0.321 D in second eyes. Initial patient satisfaction with sight was high, with 94% reporting "Satisfied". Further, 74.8% of patients reported no difficulty with sight during everyday life and 72.6% reported no difficulty to engage in activities or hobbies of interest. There were no unanticipated AEs.

Conclusion

In this real world assessment of patients bilaterally implanted with AcrySof® IQ Vivity™ and/or AcrySof® IQ Vivity™ Toric Extended Vision IOLs, we have observed very good distance, intermediate, and near visual acuity outcomes and high percentages of visual satisfaction. Enrollment continues.

Constellation®

Alcon Initiated Trial

Intraocular Pressure Compensation Performance for 25 Gauge Dual-Cutting and Single-Cutting Beveled Vitrectomy Probes Comparison

Val Kolesnitchenko, MD, Vara Wuyyuru, MS, Ying Zhu, MS
Alcon Vision LLC, Fort Worth, TX, USA

Abstract Details

Purpose

To understand intraocular pressure (IOP) compensation performance for 25 Gauge (Ga) dual- and single-cutting beveled vitrectomy probes under different system settings.

Methods

25 Ga 20K cuts-per-minute (cpm) and 10K cpm vitrectomy probes were driven by a vitrectomy system with IOP control to aspirate in an eye model. Six samples were tested under core duty cycle and varying vacuums. Both system IOP compensation enabled and disabled settings were used.

Results

Different from results of 10K probes without IOP compensation, changing the cut rate did not generate a significant difference for 20K probes. 20K probes' IOP at maximum cut rate was 21.96 ± 0.6 mmHg for 250 mmHg, and 7.47 ± 0.98mmHg for 650 mmHg. When IOP control was enabled, IOP levels for 20K probes and 10K probes were similar and not significantly influenced by cut rate changes. 20K probes' IOP at maximum cut rate increased to 32.32 ± 1.07 mmHg(47% improvement) for 250 mmHg, and 37.12 ± 4.04 mmHg (397% improvement) for 650 mmHg compared to result without IOP compensation.

Conclusion

25 Ga dual-cutting 20K cpm vitrectomy probes have a more constant IOP when cut rate changes without IOP control compared to the previous generation single-cutting 10K cpm vitrectomy probes. Using IOP compensation can help surgeons to keep the eye at stabilized IOP ranges during aspiration of 25 Ga dual-cutting 20K cpm vitrectomy probes and maintain the efficiency of aspiration.

Constellation®

Alcon Initiated Trial

Comparison of the Intraocular Pressure Control Performance with 27 Gauge Dual-Cutting and Previous Generation Single-Cutting Beveled Vitrectomy Probes

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Alcon Vision LLC, Fort Worth, TX, USA

Abstract Details

Purpose

To evaluate intraocular pressure (IOP) control performance of 27 Gauge (Ga) dual- and single-cutting beveled vitrectomy probes under different settings

Methods

27 Ga dual-cutting 20K cuts-per-minute (cpm) and single-cutting 10K cpm beveled vitrectomy probes were driven by a dual-pneumatic vitrectomy system with IOP control to aspirate solution in an eye model. Six samples were tested under core duty cycle and vacuums of 250 mmHg and 650 mmHg. Cut rates ranged from 2,500 cpm to 10,000 cpm for 10K probes and from 2,500 cpm to 20,000 cpm for 20K vitrectors

Results

Without IOP compensation, 27 Ga 20K probes' IOP was similar for all cut rates. IOP ranged from 22.71 ± 0.30 mmHg to 22.81 ± 0.37 mmHg for 250 mmHg, and 7.93 ± 0.46 mmHg to 8.33 ± 0.32 mmHg for 650 mmHg. 10K probes' IOP ranged from 25.47 ± 0.38 mmHg to 27.46 ± 0.43 mmHg for 250 mmHg and 16.14 ± 0.77 mmHg to 19.30 ± 0.77 mmHg for 650 mmHg. When IOP control was enabled, IOP levels for 10K and 20K probes were similar and both had no significant difference under different cut rate. IOP of 20K probes at maximum cut rate obviously increased to 29.24 ± 0.75 mmHg for 250 mmHg, and 27.42 ± 2.64 mmHg for 650 mmHg compared to result without system's IOP intervention.

Conclusion

27 Ga dual-cutting 20K cpm vitrectomy probes provide a more constant IOP level compared to single-cutting 10K cpm vitrectors under different cut rates without IOP compensation

HYPERVIT®

Alcon Health Economics and Outcomes Research

An Economic Analysis of Vitrectomy Probe Utilization in Vitreoretinal Procedures: A United States Provider Perspective

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Abstract Details

Purpose

Current vitrectomy probes on the market are associated with inefficient vitreous removal and long vitrectomy times. This economic analysis modeled how the introduction of the HYPERVIT® Dual Blade Vitrectomy Probe impacts procedure time and costs from a US hospital perspective.

Methods

A 1-year economic model assumed 252 procedure days per year and 10 vitrectomy procedures per day. In current practice, probe utilization was 50% for a 7,500 cuts per minute (CPM) probe and 50% for a 10,000 CPM probe. In future practice, utilization was 100% for the optimized 20,000 CPM probe. Analyses for 25+ and 27+ gauge probe options were included. Average vitrectomy procedure durations were estimated from literature, and probe vitrectomy time was estimated from flow rates. Utilization of scissors was estimated from observational data. Costs from an outpatient provider perspective included devices (vitrectomy probe, scissors), labor (anesthesia technician, nurse/technician), and facility overhead costs. Device costs were based on 2020 list prices, and other costs were informed by national data or literature. Costs from literature were inflated to 2020 US dollars.

Results

HYPERVIT® reduced procedure time by 10.9% to 14.5%, and potentially allowed 309 to 427 additional procedures to be performed per year, depending on probe gauge. Scissor use was reduced by 33%. Cost savings of $81 to $136 per procedure or $204,753 to $341,560 over 1 year were predicted.

Conclusion

The gains in procedure time and associated cost savings (reduced scissor, labor, and facility costs) were predicted to offset the cost of the optimized probe.

HYPERVIT®

Alcon Initiated Trial

Flow Dynamic Comparison of 25G Dual Blade vs. Single Blade Vitrectomy Cutters

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[*]Affiliation at the time of the study

Abstract Details

Purpose

Leverage micro-particle image velocimetry (PIV) experiments and computational fluid dynamics (CFD) simulation models to define and compare sphere of influence (SOI) extent and pulsatile motion around vitrectomy probes.

Methods

The micro-PIV experiments and simulation models of three probes, namely, 25+™ Advanced UltraVit™ 10,000 cuts per minute (cpm), 25+™ HyperVit™ 20,000 cpm flat and beveled tips were used to compare flow velocity around the probe tip at applied vacuum of 650 mmHg and 50/50 duty cycle settings. Further CFD simulations were conducted with matched flow rates to compare performance.

Results

The micro-PIV results indicate higher fluctuation magnitude for the 10K single blade bevel probes as compared to the 20K dual blade probes. Both 20K probes, beveled and flat tips, demonstrated a similar behavior. The intensity of velocity fluctuations in CFD simulations was significantly reduced for both for 20K dual blade compared to 10K single blade cutters. In addition, under matched-flow, the maximum SOI size of 20k dual cutting probes was smaller compared to that of 10K single blade probes.

Conclusion

Micro-PIV experiments and CFD simulations were used to compare flow dynamics in nearfield of the vitrectomy probe tip. The flow performance of 25 gauge dual cutting 20K probes had more stable aspiration. The 20K probes showed a smaller SOI compared to 10K probes under matched-flow conditions. Simulations may help surgeons better understand differences in probe performance and optimize instrument selection.

ULTRAVIT®

Investigator Initiated Trial

Mechanism and Prognostic Indicators for Explosion-related Eye Trauma: Eye Injury Vitrectomy Study

Kang Feng, Zhi-zhong Ma, MD

Peking University Third Hospital, Peking University Eye Center, Bejing Key Laboratory of Restoration of Damaged Ocular Nerve

Abstract Details

Purpose

To explore the clinical features, surgical interventions, prognosis of injured eyes following explosion, and to develop the risk factors for poor prognosis.

Methods

A nested case-control study. To the date of December 31st, 2018, 99 explosion-related eye-globes were selected from the Eye Injury Vitrectomy Study database, which is a multicenter prospective cohort study and began in 1990s. All cases selected underwent vitreoretinal surgery or enucleation, and were followed up for at least 6 months. Clinically meaningful preoperative variables and outcomes were used to develop logistic regression models.

Results

The unfavorable outcomes were defined as silicone oil-filled eyes, phthisis bulbi, enucleation, and anatomically restored eyes whose final BCVA is worse than initial vision after 6 months of follow-up. The proportion of unfavorable outcomes were 92.0%, 60.9%, and 66.7% in large festive fireworks, detonator, and beer bottle groups respective. The anatomic and visual outcome of injured eyes with combined injury of blast wave and projectile were worse than that of ruptured eyes (Fisher's exact = 0.041). The extrusion of iris/lens (OR = 3.20, P = 0.015), PVR-C (OR = 6.08, P = 0.036), and choroid damage (OR = 5.84, P = 0.025) are independent risk factors of unfavorable prognosis for explosion-related eye trauma.

Conclusion

The extrusion of iris/lens, PVR-C, and choroid damage are the independent risk factors for unfavorable outcomes in explosion-related eye trauma. There is a unique injury mechanism in explosion-related eye trauma.

Financial Disclosure

The study was funded by a research grant from Alcon (Investigator Initiated Trial).

ULTRAVIT®

Investigator Initiated Trial

Prognostic Factors and Long-term Outcomes of Eye-globe Perforation: Eye Injury Vitrectomy Study

Kang Feng, Zhi-zhong Ma, MD

Peking University Third Hospital, Peking University Eye Center, Bejing Key Laboratory of Restoration of Damaged Ocular Nerve

Abstract Details

Purpose

To delineate anatomic and visual outcomes of injured eye globes with perforating, and to develop the prognostic indicators for perforating eyes.

Methods

The case series study, from a multicenter prospective cohort database. To the date of December 31st, 2018, of 63 perforating globes were selected. All cases underwent vitreoretinal surgeries or enucleations, and were followed up for at least 6 months. Demographic characteristics, basic examination for traumatized eyes, and intraocular tissue damages were recorded by surgery-in-chief. At the follow-up visit, best corrected VA, intraocular pressure, the intraocular tamponade material, retinal anatomic outcome of eye-globes, and phthisis or enucleation were evaluated.

Results

Fifty injured eyes (79%) were caused by sharp objects and 13 eyes (21%) were injured by a missiles. Twenty-two injured eyes can be anatomically restored with final vision of more than 4/200 through vitreoretinal surgery. The PVR-C (OR = 5.67, P = 0.01), area of retinectomy more than 2 times of optic disk (OR = 5.16, P = 0.04), and macular damage (OR = 6.38, P = 0.01) were correlated with unfavorable outcomes.

Conclusion

The injured eyes with perforation can be saved through vitreoretinal surgery, the PVR-C, retinectomy more than 2 times of optic disk, and macular damage were independent risk factors for poor long-term prognosis.

Financial Disclosure

The study was funded by a research grant from Alcon (Investigator Initiated Trial).

WAVELIGHT®

Investigator Initiated Trial

Comparison of Clinical Outcomes of Two Corneal Topography-guided Platforms on Virgin Eyes

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Abstract Details

Purpose

To compare and analyze the differences in visual and aberrated outcomes between corneal-wavefront-guided (CWG) LASIK by AMARIS® 1050S (Schwind eye-tech-solutions GmbH & Co. K8G) and corneal topography-guided (CTG) LASIK by WAVELIGHT® EX500 (Alcon Laboratories, Fort Worth, TX)

Methods

This prospective and pseudo-randomized study included 266 patients who received binocular similar LASIK surgery, and only data relating to right eyes were selected for analysis. A total of 134 patients underwent CWG-LASIK to correct ametropia (myopia or myopic astigmatism) and whole corneal high-order aberrations using the AMARIS® ORK-CAM platform (AMARIS® group). A total of 132 patients received CTG-LASIK using the WaveLight® EX500 platform (EX500 group). Visual acuity, refractions, and corneal higher order aberration (HOA) were assessed preoperatively and 3 months postoperatively.

Results

After 3 months of operation, a total of 75.6% patients gained more than 1 line of Snellen uncorrected distance visual acuity (UDVA) compared to preoperative corrected distance visual acuity (CDVA) of the EX500 group; the rate of the AMARIS® group was 70.1% (P=.43). Postoperative spherical aberration and vertical coma of the EX500 group were lower than those of the AMARIS® group. Increases of spherical aberration and coma in the EX500 group were lower than those of the AMARIS® group. Postoperative contrast sensitivity was higher than preoperative contrast sensitivity in both groups.

Conclusion

Both WaveLight® EX500 corneal topography-guided LASIK and AMARIS® 1050S corneal wavefront-guided LASIK showed excellent refractive and visual outcomes, while the EX500 group showed minimal changes in wavefront aberrations compared to the AMARIS® group.

Financial Disclosure

This study is supported by a research grant from Alcon

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Rebound tonometry measurements over extended-wear bandage contact lenses

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Abstract Details

Purpose

The aim of this study was to assess the validity of rebound tonometry measurements obtained over eyes wearing extended-wear bandage contact lenses with the highest oxygen transmissibility (Dk/t) value of 175 @ -3.00 D.

Methods

A total of 151 normal eyes were included in this prospective pretest-posttest study. A rebound tonometer (iCare PRO) was used to collect three measurements each of the intraocular pressure readings from “naked” eyes (eyes without contact lenses) and the same eyes wearing extended-wear lotrafilcon A bandage contact lenses (Alcon Air Optix ® Night & Day® Aqua Contact Lenses). The mean pre- and post-application values were pooled and compared using the paired t-test.

Results

The application of extended-wear lotrafilcon A contact lenses over normal eyes did not cause a statistically significant change in the intraocular pressure measurements obtained using an iCare PRO tonometer (13.74 + 2.15 mm Hg vs. 13.77 + 2.26 mm Hg, p-value = 0.6506).

Conclusion

iCare PRO rebound tonometry measurements obtained over extended-wear bandage lotrafilcon A contact lenses are acceptable for clinical use.

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Financial Disclosure

Contact lenses were sponsored by Alcon Research, Limited. The iCare probes were provided by Medilight, Incorporated. Dr. Romeo C. dela Cruz is a key opinion leader of Alcon; he did not participate in data collection and was blinded during data analysis.

DAILIES TOTAL1®

Alcon Initiated Trial

Patient and practitioner satisfaction with a new Water Gradient daily disposable contact lens in Asia

Timothy Grant[1], Bena Pak[2],Colette Parkinson[3]

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Abstract Details

Purpose

A satisfaction survey to soft contact lens wearers and practitioners in Australia, China, Hong Kong, Korea, New Zealand, Singapore and Taiwan to determine acceptability of a water gradient daily disposable contact lens (WGDD).

Methods

Satisfaction outcome surveys were completed by soft contact lens wearers and practitioners. Demographic information, pre-survey lens brand, dryness/discomfort and lens wear experience were collected from patients. Participants were fit with WGDD and provided 1 week supply. Lens wearing experience with the WGDD lens was collected at a follow up office visit. Practitioners completed a satisfaction survey before and after the fitting period.

Results

A total of 968 patient and 96 practitioner surveys were collected. Average age of the patients was 34 years with 71% being female. All patients were contact lens wearers with 65% wearing DD lenses and 52% of patients reported prior dryness and/or discomfort with their lenses. At the 1 week follow-up, the percentage who agreed or strongly agreed with the survey statements indicated a high level of satisfaction with WGDD: 83% agreed or strongly agreed the lenses were comfortable all day, 79% agreed their vision was clear at the end of the day and 9 out of 10 patients preferred WGDD to their habitual lenses. After fitting WGDD, 96% practitioners agreed the lens was easy to fit, 90% were likely/very likely to recommend WGDD to their colleagues, and 86% agreed WGDD technology is extraordinary and results in excellent clinical performance.

Discussion

The survey obtained a large, geographically diverse sample regarding acceptance of WGDD contact lenses. Patients and practitioners indicated a high level of satisfaction with the new water gradient daily disposable lens.

PRECISION1®

Alcon Initiated Trial

Characterization of the surface properties of a novel daily disposable, silicone hydrogel contact lens

Bob Tucker[1], Ethan Leveillee[1], Erich Bauman[1], Lakshman Subbaraman[1]

[1]Alcon Research, LLC, USA

Abstract Details

Purpose

A novel surface modified silicone hydrogel (SiHy) material, verofilcon A, was recently developed incorporating surface science advancements resulting in a lens material with "SMARTSURFACE®" technology. This study was conducted to characterize the aqueous film stability on these lenses evaluating water break up time (WBUT) using an *in vitro* model.

Methods

To determine the WBUT on contact lenses under fully hydrated conditions, the iDDrop method was employed. After overnight lens soaking in PBS to eliminate influence of packaging solution additives, the iDDrop instrument trough was filled with a phosphate buffered saline solution and the lens sample was submerged on its lens mount. The lens was then raised out of the fluid at a controlled rate. High resolution videos of the fluid thinning on the lens surface were then recorded. The WBUT was defined as the time of first break when the fluid thickness reaches zero once out of the fluid. Each lens was submerged between recordings to ensure the lens was fully rewetted. Each experimental group had 10 lenses, and three measurements per lens were conducted, resulting in 30 total measurements.

Results

The average WBUT on verofilcon A was 30±6 seconds, whereas on etafilcon A, somofilcon A and stenfilcon A WBUT was found to be 7±3 sec, 6±3.5 sec and 5±2.6 sec respectively. Based upon Student's t-test, the WBUT of verofilcon A was statistically higher than the other lenses ($p<0.05$).

Conclusion

Surface modification techniques can create novel, ultra-soft surface gels on silicone hydrogel core materials. The surface modification process improved aqueous film stability on verofilcon A contact lenses as demonstrated with a longer WBUT.

PRECISION1®

Alcon Initiated Trial

Clinical comparison of Verofilcon A and Etafilcon A daily disposable contact lenses

Lakshman Subbaraman[1], Jason Miller[2], Bradley Giedd+

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Abstract Details

Purpose

To compare the subjective performances of verofilcon A daily disposable silicone hydrogel contact lenses, which have a core with 51% and a surface with >80% water content, with etafilcon A hydrogel contact lenses, which have a 58% water content.

Methods

In this prospective, multicenter, study, successful wearers of spherical soft contact lenses for distance correction were randomized to wear verofilcon A or etafilcon A lenses for 8 (-1/+2) days. After washout, subjects were dispensed the alternative lenses. Exploratory endpoints included subjective overall lens preference (5-point scale [strongly or somewhat prefer lens 1; no preference; strongly or somewhat prefer lens 2]) and subjective ratings (10-point scale) of end-of-day (EOD) vision, overall handling, insertion comfort, EOD comfort, lens handling at insertion, overall comfort, overall quality of vision, vision throughout the day, and lens handling at removal.

Sample size calculation was based on a prior clinical study, which evaluated the performance of verofilcon A and three other marketed soft contact lenses, including etafilcon A lenses.

Results

Ninety-two subjects were enrolled, with 46 each initially randomized to verofilcon A and etafilcon A lenses and subsequently crossed over to the other lens type. Of these subjects, 68 (73.9%) preferred/strongly preferred verofilcon A lenses, whereas 21 (22.9%) preferred/strongly preferred etafilcon A lenses ($p < 0.0001$). Mean ± SD ratings of EOD vision, overall handling, insertion comfort, EOD comfort, lens handling at insertion, overall comfort, overall quality of vision, vision throughout the day, and lens handling at removal were all significantly higher for verofilcon A than for etafilcon A lenses.

Conclusion

These results demonstrate that verofilcon A lenses performed better than etafilcon A lenses with respect to overall preference and other subjective endpoints evaluated in this study.

PRECISION1®

Alcon Initiated Trial

Clinical performance of a new daily disposable spherical contact lens

Stacie Cummings[1], Brad Giedd[2]; Christopher Pearson[3]

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Abstract Details

Purpose

To evaluate the clinical performance of a new daily disposable contact lens (verofilcon A), including its distance visual acuity (VA), subjective acceptance and lens fit characteristics

Methods

In this US multisite study, 69 subjects wore the new verofilcon A contact lenses, which were provided at a power of -1.00 D to -6.00 D in 0.25 D increments. Lens performance was assessed in a subject-masked, randomized, parallel group safety and efficacy study with bilateral lens wear for 3 months (-2/+5 days). Subjective ratings were recorded at the follow-up visits on a 10 point continuous scale with extreme anchors (1= poor/difficult to 10 = excellent/easy). Lens fit characteristics were recorded by determining centration and overall fit

Results

At 3 months, >95% of the eyes wearing verofilcon A contact lenses had distance VA of 20/20 or better. Subjective overall comfort was very good, with a mean overall comfort rating of 9.5. Overall handling (9.2) and vision (9.4) were also rated highly. Lens fit/movement was assessed as optimal in 89.9% of subjects and never rated as unacceptably tight or loose, and lens centration was assessed as optimal in 95.7% of subjects

Conclusion

The unique material features, advanced surface technology, and optimal lens fitting characteristics of the new verofilcon A lenses contribute to a high level of satisfaction by lens wearers in visual acuity, comfort and ease of handling

OPTI-FREE® Puremoist® **Alcon Initiated Trial**

Antimicrobial efficacy of contact lens solutions assessed by ISO standards

Paul Shannon, Cindy McAnally, Rhonda Walters, Arlie Jaurigue, Monica Crary

Abstract Details

Purpose

The purpose of these studies was to assess the antimicrobial activity of two commercially available MPS by ISO 14729 and ISO 18259 methods.

Methods

Two commercially available MPS, containing dual-preservative systems, polyaminopropyl biguanide 0.00013%/polyquaternium 0.0001% (PHMB/PQ) and polyquaternium-1 0.001%/ myristamidopropyl dimethylamine (PQ/ALDOX) 0.0006%, were evaluated. PHMB/PQ and PQ/ALDOX solutions, prepared in compatible test tube materials and manufacturer's recommended lens cases, were inoculated with known concentrations (105-106) of ISO panel of microorganisms as well as *Acanthamoeba* trophozoites per ISO 14729 and ISO 18259. At the recommended product disinfection time (DT), ISO organisms were recovered using validated media and recovery methods.

Results

The preservative system in PHMB/PQ was less efficacious than PQ/ALDOX against *F. keratoplasticum* in both tubes (2.1 vs 3.7 LR) and lens cases (1.8 vs 4.4 LR). Similarly, PHMB/PQ was less efficacious than PQ/ALDOX against *C. albicans* in tubes (3.2 vs 4.8 LR) and cases (1.4 vs 4.5 LR). PHMB/PQ was also less efficacious against *S. marcescens* in cases (3.8 vs 5.0 LR). PQ/PHMB had less efficacy than PQ/ALDOX against *Acanthamoeba* trophozoites ATCC 30461 (1.2 vs 3.2 LR) and ATCC 50370 (0.4 vs 2.2 LR). PHMB/PQ was less efficacious in the lens case vs test tubes for two organisms.

Conclusion

PQ/ALDOX was more effective against five of seven organisms, including two strains of *Acanthamoeba*. EN ISO 14729 and EN ISO 18259 standards evaluate the impact of testing materials on antimicrobial efficacy of MPS against microorganisms known to cause microbial keratitis.

OPTI-FREE® Puremoist® **Alcon Initiated Trial**

Impact of Material Incompatibilities on Multipurpose Solution Efficacy

Cindy McAnally, Monica Crary, Rhonda Walters, Elise Miller, Valerie Harris, Jamie King, Megan Thomas, Manal Gabriel, Sameer Chaudhari, Paul Shannon

Abstract Details

Purpose

ISO 18259 requires MPS manufacturers to evaluate the impact of contact lenses on MPS efficacy. The purpose of this study was to evaluate the impact of four commercially available contact lenses on the efficacy of six marketed MPS using the manufacturer recommended lens cases.

Methods

Six MPS (PQ/ALDOX: polyquaternium-1 0.001%/myristamidopropyl dimethylamine 0.0006%, PQ/PHMB: polyquaternium 0.0001%/polyaminopropyl biguanide 0.00013%, PQ/ALEX: polyquaternium-1 0.0003%/alexidine dihydrochloride 0.00016%, PQ/ALEX/PHMB: polyquaternium 0.00015%/alexidine dihydrochloride 0.0002%/polyaminopropyl biguanide 0.00005%, PHMB-1: polyhexamethylene biguanide 0.0001%, and PHMB-2: polyhexanide 0.0001%) were evaluated with four types of contact lenses per ISO 18259.

Results

PQ/ALDOX, PQ/ALEX, PQ/ALEX/PHMB, and PQ/PHMB exhibited ≥4.0 log kill of *S. marcescens* at DT across all lenses. PHMB-1 and PHMB-2 were least effective against *S. marcescens* with ≤3.1 log kill at DT across all lenses. The efficacy of all MPS against *C. albicans* was reduced across all lenses at DT compared to the control. PQ/ALDOX was most effective against *Fusarium keratoplasticum* at DT with >4.3 log kill across all lenses. PQ/ALEX demonstrated ≥4.0 log kill for 2 lenses at DT. PQ/PHMB and PQ/ALEX/PHMB were less effective with ≤3.0 and ≤2.4 log kill at DT, respectively, for all lenses. PHMB-1 and PHMB-2 MPS were least effective against *F. keratoplasticum* with ≤1.2 log kill at DT and were the only MPS with survivors at 7d.

Conclusion

PQ/ALDOX was the only MPS that maintained *Fusarium* efficacy across all lens types. This organism is of particular importance in light of previous outbreaks of *Fusarium* keratitis related to a previously marketed MPS containing alexidine.

SYSTANE®

Alcon Initiated Trial

Comparative Efficacy and Safety of Ocular Lubricants Containing Hydroxypropyl Guar

Richard Kara[1], Sruthi Srinivasan[2], Margaret Ainslie-Garcia[3], Nicole Ferko[3], Elizabeth Persaud[3]

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Abstract Details

Purpose

Artificial tears (ATs) are often the first line of treatment for dry eye disease, but an array of ingredients makes it challenging for patients and clinicians to select a product that best meets their needs. A literature review was completed to determine the comparative efficacy and safety of artificial tears containing hydroxypropyl guar (HPG).

Methods

MEDLINE and Embase were searched for the period Jan-01-2004 to Aug-08-2019. The clinicaltrials.gov database was also reviewed. Search terms included “Hydroxypropyl guar” as well as “ocular lubricant” or “artificial tear”. No language restrictions were applied to search criteria. Clinical studies that compared HPG-containing ATs and another AT were included. Clinical (ocular staining, tear break-up time [TBUT]), safety (adverse events [AEs]), or patient-reported outcomes (PROs) were extracted.

Results

Thirty studies compared HPG-containing drops with a variety of other ingredient types. HPG drops significantly improved ocular staining in 5/15 comparisons. HPG provided an advantage over carboxy methylcellulose (CMC) for ocular staining in 2/5 comparisons, but was statistically outperformed in 1 comparison. No comparator demonstrated a statistical advantage over HPG drops for TBUT. AEs were comparable across all artificial tears, with no serious safety issues identified. Assessments of PROs were extremely diverse, with over 15 surveys, scales, or questions used for measurement across 20 studies.

Conclusion

Artificial tears containing HPG may offer advantages in the objective clinical signs of dry eye versus a variety of comparators, with similar safety. Future studies should consider consistency in comparators and PRO measures.

SYSTANE®

Investigator Initiated Trial

Therapeutic efficacy of lipid and non-lipid eye drops for dry eye disease management

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Abstract Details

Purpose

To evaluate the six-month therapeutic efficacy of a lipid and a non-lipid based artificial tear supplement for the management of dry eye disease (DED).

Methods

Ninety-nine participants (64% females; aged 44±16 years) with DED were enrolled in a prospective, multicentre, double-masked, parallel-group, randomised controlled trial, and self-administered either a lipid-based (Systane® Complete) or a non-lipid-based (Systane® Ultra) drop four times daily for six months. Symptoms and tear film and ocular surface parameters were assessed monthly against global consensus diagnostic criteria. Patient compliance was determined by returned bottle weight.

Results

Significant improvements were noted, in both study groups, in symptoms after one month (all $p<0.05$), lid wiper epitheliopathy after two months ($p\leq0.01$), and non-invasive tear film breakup time (NIBUT) and ocular surface staining after four months ($p<0.05$). By six months, one in five participants no longer met the diagnostic criteria for DED. By one month, 70% of participants had responded favourably to their allocated treatment (with an improvement of >4s in NIBUT and/or ≥4.5 points in OSDI from baseline), with a mean improvement in OSDI symptomology score of 16.6 ± 12.8 points, and 4.5 ± 5.6 s in NIBUT.

Conclusion

Lipid and non-lipid based tear supplements offer rapid symptomatic relief after one month of regular, daily use. Further profound, structural improvements in tear film and ocular surface integrity become apparent after continued use for several months, suggesting that patient compliance with regular, repeated application may help restore tear film and ocular surface homeostasis, to achieve a therapeutic, rather than solely palliative effect.

Financial Disclosure

Financial support was received for this investigator-initiated trial from Alcon Laboratories (Australia) Pty Ltd. The funding source had no role in the design and conduct of the study; the collection, management, analysis, and interpretation of the data or the preparation of the poster

SYSTANE®

Alcon Initiated Trial

Impact of Dry Eye Disease on Patient Quality of Life

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Abstract Details

Purpose

The prevalence of dry eye disease (DED) is increasing, due to environmental triggers, the aging population, and increasing use of digital displays. DED is a chronic, progressive, and symptomatic condition, but its impact is largely under recognized. A literature review was conducted to understand the impact of DED on patient quality of life (QOL).

Methods

MEDLINE was searched for the period Jan-01-2004 to Jul-05-2019. Search terms included DED and QOL, humanistic burden, and utility. Reference lists from relevant articles were also scanned. No language restrictions were applied to search criteria. Non-interventional studies reporting the quantitative or qualitative impact of DED on QOL were retained.

Results

The search returned 15 relevant articles. Three main themes emerged including decreased quality of vision, activity restriction, and symptom-related pain. Tear film instability can cause blurry vision which can reduce visual function, correlated with QOL. Patients with DED were three times more likely to report difficulties in activities than those without DED. DED was associated with a 12-34% impairment in daily activities and 11-35% impairment in productivity, and was found to be significantly higher with severe DED. Seven articles reported a correlation between severity of DED and impaired QOL or activities. One study reported moderate DED had similar QOL to angina, while severe DED had QOL similar to disabling hip fracture.

Conclusion

The area of dry eye and MGD is one of growing research and development, and is much needed to understand the serious impact of DED on patient QOL.

SYSTANE® COMPLETE **Alcon Initiated Trial**

Assessment of tolerability and ocular comfort following propylene glycol/hydroxypropyl guar-based lubricant eye drop use

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Abstract Details

Purpose

To evaluate tolerability drop profile and improvement in ocular discomfort after SYSTANE® COMPLETE (propylene glycol/hydroxypropyl-guar [PG-HPG]) nano-emulsion lubricant eye drops use in dry eye disease (DED).

Methods

DED patients (aqueous-deficient (ADE), lipid-deficient (EDE) and mixed dry eye (MDE) were included in phase IV, multicenter, open-label, single-arm, interventional study. Patients received 1 drop of PG/HPG, twice daily for 28 days. Tolerability scores (burning, stinging, blurry vision and foreign body sensation (FBS)) were assessed on Day 1, immediately following first dose and was assessed on a 0–10 scale (0=no symptoms; 10=worst symptoms). Change from baseline in global ocular discomfort visual analogue scale (OD-VAS) score (0 to 100) at Day 14 was assessed.

Results

Of 134 patients treated (59 years, female 75.4%; ADE [n=41]; EDE [n=44]; MDE [n=49]), >92% reported tolerability scores in 0–5 category (burning 97%; stinging 96.3%; blur 92.5% and FBS score 94.8%) after drop instillation at Day 1. The proportion of patients reporting 0–5, for burning, stinging, blurring and FBS lessened, 90.2%–100% in ADE, 93.2%–95.5% in EDE, and 91.8%–98% in MDE, respectively. Overall, mean (range) OD-VAS score decreased from 46.7 (25–67.8) at baseline to 29.3 (10.5–47.0) at Day 14 (−17.3 from baseline). Subtype analysis showed change from baseline in OD-VAS of −22.0 (−65–21) for ADE, −17.6 (−59–61) for EDE, and −13.1 (−78–45) for MDE at Day 14.

Conclusion

PG/HPG lubricant in nano-sized droplets provided effective symptomatic relief in in all dry eye subtypes and was well tolerated.

SYSTANE® COMPLETE **Alcon Initiated Trial**

Improvement in symptom relief following a single dose of PG/HPG-based lubricant eye drops in patients with dry eye disease

Sruthi Srinivasan[1], Joseph Tauber[2],Elizabeth Yeu[3], Steven Silverstein[4], Manoj Venkiteshwar[1]

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Abstract Details

Purpose

To evaluate symptom relief improvement following single dose of SYSTANE® COMPLETE (propylene glycol/hydroxypropyl-guar [PG-HPG]) nano-emulsion lubricant eye drop in dry eye patients.

Methods

Multicenter, open-label, interventional study, 134 adult dry eye patients (subtyped aqueous-deficient, lipid-deficient and mixed dry eye) instilled 1 drop of PG-HPG BID for 28 days. Patient-reported outcome assessment of dry eye symptoms (DES) and soothing profile performed using 0 (no symptoms/eyes feeling good) −10 (worst symptoms/no feeling at all) visual analog scale, 4 time points on Day 1 (baseline, 0 (immediate), 4(±1), and 8(±1) hours post-drop instillation. Ratings categorized 0–5 and 6–10 and analyses of change in scores from baseline Day 1 were performed by dry-eye subtype.

Results

At baseline, 45.5% (61/134) patients (mean age: 59 years) reported baseline DES score 6–10. Of these, 67.2%, 77.0%, and 70.5% reported shift to 0–5 at 0, 4, 8 post-single dose, respectively. Corresponding change from baseline in median (95% CI) DES scores was: −1 (−3,−1), −2 (−3,−2), and −2 (-2,−1). Soothing sensation of 0–5 observed in 82.1%, 81.3%, and 82.1% at 0, 4 and 8 hours post drop with median scores of 3 (0–10), 3.0 (0–10), and 3.5 (0–10) at 0, 4, and 8 hours. Reduction in DES from baseline and good soothing sensation were noted across all subtypes at post-dose time points.

Conclusion

Treatment with a single dose of PG-HPG provided instant relief, improved dry eye symptoms, sustained symptom relief, and soothing sensation (up to 8 hours) across dry-eye subtypes.

SYSTANE® HYDRATION UD **Investigator Initiated Trial**

A prospective study on the impact of hydroxypropyl guar, borate and hyaluronate matrix on protecting the ocular surface in glaucoma patients with dry eye disease – A 3-month interim analysis

Christopher Leung, Poemen Chan, Wing Ki Gilda Lai, Vivian Sm Chiu

Abstract Details

Purpose

Dry eye disease is prevalent among glaucoma patients. This study aims to investigate the impact of topical application of a lubricant containing hydroxypropyl guar, borate and hyaluronate matrix for treatment of dry eye disease in patients with glaucoma who were taking at least one form of topical intraocular pressure (IOP) lowering medications.

Methods

In this prospective study, changes in symptoms and signs of dry eye before and after topical application of preservative free Systane® Ultra Hydration 6 times/day were evaluated in 33 glaucoma patients with dry eye disease. All patients had an Ocular Surface Disease Index (OSDI) between 21 to 80 at the eligibility-confirmation visit. OSDI (primary outcome measure) was measured at baseline, 3 months, and 6 months. Changes in corneal staining score, tear break-up time, and the result on Schirmer's test were measured at baseline and 6 months.

Results

At the baseline, the mean (SD) visual field MD was -10.0 (7.5) dB, the corneal staining score was 2.82 (1.19); the tear break-up time was 4.86s (3.86s), and the Schirmer's test result was 10.3mm (7.8mm). The OSDI was 48.8 (14.3) at the screening visit and 50.1 (17.1) at the eligibility-confirmation visit. The OSDI decreased to 42.2 (19.7) at 3 months (P=0.005, paired t-test).

Conclusion

Topical application of hydroxypropyl guar, borate and hyaluronate matrix relieved dry eye symptoms in glaucoma patients taking IOP-lowering medications.

Financial Disclosure

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