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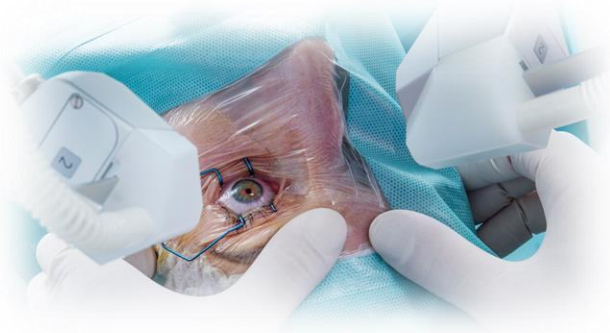

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Investigator Initiated Trial (India)

PP1-26: Comparison of Femtosecond Laser Assisted and Manual Phacoemulsification Cataract Surgery by Junior Surgeons: Randomized clinical trial

Shail Vasavada[1], Vandana Nath[1], Abhay Vasavada[1], Priyanka Patel[1], Vaishali Vasavada[1], Vineet Vaishnav[1]

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Abstract Details

Purpose

To compare intraoperative performance and postoperative outcomes following manual phacoemulsification(PE) versus femtosecond laser assisted cataract surgery(FLACS) in the hands of junior surgeons

Methods

Randomized, clinical trial in 320 patients(320 eyes) undergoing cataract surgery for uncomplicated cataracts in the hands of two junior surgeons at a single centre. Patients randomized to either: Group I(n=160 eyes)–FLACS performed on the LenSx® laser platform (Alcon Laboratories, USA) or Group II(n=160 eyes)–PE. Intraoperatively, cumulative dissipated energy(CDE) and fluid used were compared. Postoperative outcome measures evaluated over day 1, week 1, 1, 3 and 6 months postoperatively: central corneal thickness(CCT), corneal edema, anterior chamber inflammation, visual acuity, corneal endothelial morphology and macular thickness

Results

Preoperative demographics and nucleus density were comparable(P>0.005). CDE was significantly higher in PE group (5.41 + 2.73 in group I versus 8.83 + 4.28 in group II,P=0.001), and so was fluid used (79.33 +/- 33.46 versus 101.82 +/- 32.23 in groups I and II respectively, P<0.0001). The incidence of Descemet's folds on postoperative day 1 was higher in the PE group (60%) compared to the FLACS group (27%), the difference being statistically significant. CCT was significantly higher in the PE group on postoperative day 1 (550.96 + 33.64 versus 587.70 + 55.76 in groups I and II respectively, P<0.0001) and week 1 (527.94 + 30.78 versus 545.11 + 35.17 in groups I and II respectively, P=0.001). More patients in the FLACS group had >/=20/20 unaided visual acuity at 1 week and 1 month follow up. Anterior chamber cells and flare showed no significant difference between the groups on day 1 and week 1. No major intraoperative complications were noted in either group

Conclusion

In the hands of junior surgeons, both techniques are safe and effective. FLACS on the LenSx® platform led to lesser intraoperative CDE, fluid usage as well as clearer corneas and better UCVA in the early postoperative period.

Financial Disclosure

This study is supported by a research grant from Alcon Vision LLC and the authors have no financial interest related to this presentation

LenSx®

Alcon Health Economics and Outcomes Research

PP1-64: An umbrella review comparing the safety and effectiveness of femtosecond laser-assisted cataract surgery with manual cataract surgery

Hang Cheng[1], Margaret Ainslie-Garcia[2], Nicole Ferko[2], Carine Hsiao[1]

[1]Alcon Laboratories, Inc. Forth Worth, Texas; [2]EVERSANA, Burlington, Canada

Abstract Details

Purpose

Femtosecond laser-assisted cataract surgery (FLACS) automates corneal incision, capsulotomy, and lens fragmentation steps of manual cataract surgery (MCS) which may provide advantages in clinical and safety outcomes. A narrative umbrella review of systematic reviews and meta-analyses (MAs) was conducted to summarize the totality of evidence available for clinical and safety outcomes.

Methods

MEDLINE was searched using the terms “Femtosecond or femtolaser” and “cataract” from 2014-01-01 to 2019-11-01 for systematic reviews and MAs comparing FLACS and MCS.

Results

The search returned seven MAs that studied clinical or safety outcomes. All reviews assessing phacoemulsification time (3), mean phaco power (2), corneal thickness at one day (2), and corrected distance visual acuity (DVA) at 6-months (2) found significantly more favourable outcomes for FLACS compared with MCS. Results favored FLACS but were mixed (significant; trending towards significance) for better corrected DVA at 1-week (2;1), reduced endothelial cell loss overall (2;1), and lower corneal thickness overall (1;1). There was disagreement in the literature (FLACS significantly favored; no difference) for capsulorhexis circularity (3;1), mean absolute error (3;1) and cumulative dissipated energy (1;1). There was no difference in uncorrected DVA. Results were mixed for the rate of complications, but the majority of analyses found no difference in the rate of anterior and posterior capsular tears, edema, and intraocular pressure, including the review with the lowest heterogeneity.

Conclusion

Conclusions generally favored FLACS, with good alignment between reviews. This research area would benefit from consistent reporting of outcomes to increase comparability within meta-analyses.

CENTURION® Silver

Alcon Health Economics and Outcomes Research

PP1-37: Comparative clinical efficacy, safety, and economic outcomes of phacoemulsification, MSICS, And ECCE: A targeted literature review

Sarah Makari[1], Carine C.W. Hsiao[1], Sun-Ming Jessica Pan[1], Wendy Zhi Wang[2]; Elizabeth Persaud[2]

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Abstract Details

Purpose

A targeted literature search was conducted to compare the efficacy, safety, and economic outcomes of cataract surgery techniques including phacoemulsification, extracapsular cataract extraction (ECCE), and manual small incision cataract surgery (MSICS).

Methods

MEDLINE was searched in February 2021 with no date restriction. Search terms included phacoemulsification, extracapsular cataract extraction, small incision cataract surgery. Comparative clinical and economic studies were included. Efficacy, safety, quality of life (QoL), and economics outcomes were extracted.

Results

Twenty-six studies compared phacoemulsification, MSICS and/or ECCE (randomized =20, non-randomized=6). Phacoemulsification produced significantly lower surgically-induced astigmatism (n=3 vs. MSICS, n=1 vs. ECCE), more patients with uncorrected visual acuity 20/30 or better (n=2 vs. MSICS, n=1 vs. ECCE), and higher rate of patients with corrected visual acuity 20/30 or better (n=1 vs. MSICS, n=1 vs. ECCE). Phacoemulsification had similar rates of posterior capsular rupture (n=2) and endothelial cell loss (n=2) vs. MSICS, and significantly lower rate of posterior capsular opacification (n=1), and corneal edema (n=1) vs. ECCE. Phacoemulsification patients had faster recovery and fewer follow-up visits (n=3), earlier return-to-work and less government social assistance (n=1). Significant gains in QoL were reported after phacoemulsification at 4 weeks (vs. MSICS, n=1), and 1 week to 3 months (vs. ECCE, n=1). Phacoemulsification had higher total direct costs due to equipment and operating room costs (n=5).

Conclusion

Phacoemulsification may provide patients with improved visual outcomes, similar or better safety, and faster recovery. Solutions supporting implementation of phacoemulsification in developing countries may help reduce the burden of cataracts and improve patient visual outcomes.

CENTURION®

Investigator Initiated Trial (China)

PP1-49: 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 patients.

Financial Disclosure

The study was funded by a research grant form Alcon (investigator initiated trial). All authors have no financial disclosure.

CENTURION®

Alcon Health Economics and Outcomes Research

PP1-59: Comparative safety, efficacy and efficiency of phacoemulsification systems for cataract surgery: A systematic literature review

Hang Cheng[1], Megan Bourque[2], Sarah Kane[2], Daniel Son[2]

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Abstract Details

Purpose

Phacoemulsification (PKE) is the standard of care in cataract surgery. Advances in PKE technology aim to minimize iatrogenic effects, improve patient outcomes, and optimize procedural efficiencies. A systematic literature review (SLR) was conducted to evaluate recent clinical evidence comparing safety, efficacy, and efficiency of PKE systems.

Methods

PubMed and EMBASE/MEDLINE databases were searched in 03/2019. Observational and randomized controlled trials comparing ≥2 PKE systems were included. Searches were not limited by language and included articles published between 2009-2019. Article screening was performed in duplicate. Exclusion criteria encompassed studies involving femtosecond laser-assisted cataract surgery (FLACS), non-human studies, and non-comparative studies. Study and patient characteristics, clinical efficacy, procedural efficiency, and safety outcomes were extracted from all relevant articles.

Results

In total, 5,895 articles were screened. Data extracted from 27 relevant articles included the following PKE systems: WHITESTAR SIGNATURE® PRO, Legacy®, ACCURUS®, Stellaris®, CENTURION®, and INFINITI®. In total, 6,099 eyes were studied in the 27 articles, most of which underwent PKE using CENTURION® (n=2,022 eyes) and INFINITI® (n=3,114 eyes). In eight studies comparing CENTURION® and INFINITI®, safety outcomes were similar between the two systems; however, CENTURION® outperformed INFINITI® in cumulative dissipated energy (CDE, 8/8 studies), estimated fluid usage (EFU, 3/4 studies), and total aspiration time (TAT, 3/3 studies).

Conclusion

The CENTURION® and INFINITI® Vision Systems encompassed most of the comparative clinical data identified in this SLR. The CENTURION® Vision System outperformed the INFINITI® Vision System in CDE, EFU, and TAT. Superiority in these measures may result in reduced ocular trauma, quicker recovery, and superior visual outcomes.

CENTURION®

Alcon Health Economics and Outcomes Research

PP1-66: Benefits of torsional phacoemulsification and advanced fluidics in cataract surgery: A targeted literature search

Hsiao C[1], Pan SJ[1], Zhou A[2], Son D[2]

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Abstract Details

Introduction

Phacoemulsification systems aim to deliver optimal performance and safety during cataract surgeries. Several systems, including a gravity-based system, utilize torsional ultrasound energy and advanced fluidics to achieve those goals. A targeted literature search was conducted to identify the associated benefits of these systems.

Methods

PubMed was searched in February 2020 utilizing combinations of the following terms: phacoemulsification, torsional, Ozil, balanced tip, occlusion break surge, fluidics, gravity. The search was limited to 2010-2020. Studies (real-world or laboratory) published in English investigating the CENTURION® Vision System, CENTURION® Silver, and/or INTREPID® Balanced tip were included. Outcomes reported by ≥2 studies were summarized.

Results

Sixteen studies were identified (randomized controlled trial=2; randomized observational=7; nonrandomized=2; laboratory=5). While studies investigating an advanced gravity-based system were not identified, one laboratory study reported similar surge areas for both the CENTURION® Vision System's gravity and Active Fluidics™ settings. Active Fluidics™ and/or Balanced tip outperformed previous generation systems/tips: less cumulative dissipated energy (n=11; 14%-46%), less fluid usage (n=5, 9%-40%), reduced heat generation (n=2; 7%-84%), and shorter aspiration (n=4; 9%-34%) and ultrasound time (n=4; 19%-35%). Active Fluidics™ increased chamber stability, reducing post-occlusion break surge volume by 53%-75% (n=2).

Conclusion

Current literature suggests that Active Fluidics™ and Balanced tip may improve efficiency (eg, minimize heat generation) and surge protection, which may protect against serious complications (eg, corneal burns, posterior capsule rupture). Advanced gravity-based fluidics systems may share some of the same improvements, helping to reduce complications and/or improve outcomes. However, future research using real-world evidence is warranted to assess this.

ARGOS®

Alcon Health Economics and Outcomes Research

PP1-38: Time efficiencies associated with an innovative optical biometer in cataract surgery planning: A time-and-motion study

Lawrence Woodard, MD[1], Li-Chen Pan MPH[2], Manasi Datar PhD[2], Sun-Ming Pan, MPH[3], Chia-Wen Hsiao, MHS[3]

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Abstract Details

Introduction

Optical biometers offer greater success because of higher acquisition rates when acquiring data for power calculations, reducing the need to use ultrasound biometry (Manual A-Scan). We aimed to assess efficiencies gained by a swept-source optical-coherence-tomography biometer (ARGOS®) through its higher acquisition rate and integration with a digital image-guidance system (VERION™) compared to a standard biometer (LENSTAR®) in cataract evaluation.

Methods

A within-subjects, observational time-and-motion study with 22 patients undergoing cataract evaluation and surgery at a single US practice was conducted. A time-efficiency model was developed using inputs from this study and peer-reviewed literature. Data included time differences between optical biometry measurement for ARGOS® versus LENSTAR®, Manual A-scan measurement when acquisition failed, additional time from LENSTAR®'s inability to digitally integrate, walking time between instruments, and manual versus digital marking time. Two scenarios were developed, time difference between ARGOS® and LENSTAR® with VERION™ and ORA® (an intraoperative aberrometer) and time difference when ARGOS® and VERION™ were adopted at a practice using LENSTAR® (without VERION™) and when using digital versus manual marking.

Results

ARGOS saved up to 74-hours and 26-minutes per 1000 Advanced Technology IOL patients (4.5-mins/patient) in clinics using VERION™ and ORA®, driven by faster biometry measurement, A-scan avoided from higher acquisition rates and integration capabilities compared to LENSTAR®. Per patient, adopting ARGOS® and VERION™ exhibited 15-hours and 27-minutes of time-savings in clinics using LENSTAR®, with 7-hours and 29-minutes being saved from obviating manual marking.

Conclusion

ARGOS® higher acquisition rate and integration capabilities demonstrates substantial time efficiencies in cataract evaluation and planning.

ARGOS®

Alcon Health Economics and Outcomes Research

PP1-68: Optical biometers: A review of published comparative evidence

Carine C.W. Hsiao, MS[1], Shantanu Jawla, MS[2]

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Abstract Details

Objectives

Optical biometry measures anatomical details of the eye that are critical for precise intraocular lens power calculation during cataract surgery. The objective of this study was to collate and report published comparative evidence for biometer versus IOLMaster 500®, IOLMaster 700® and LENSTAR® biometers.

Methods

A literature review identified published studies comparing ARGOS® to either IOLMaster 500®, IOLMaster 700® or LENSTAR®, for use in Cataract surgery. Embase, MEDLINE and Cochrane Library databases were searched via Ovid platform (period: database inception–14 May 2019). Search results were limited to English language, with no restrictions on study design/study type. Comparative data on following outcomes was collated: axial length (AL) measurements, acquisition rates (AR) (including dense cataract cases), predictive accuracy (PA) and Keratometry measurements.

Results

Nine publications were included. In 2 publications, ARGOS® showed numerically higher AR for ARGOS® (97.6%,99.4%) vs IOLMaster 700® (92.6%,97.1%). In 4 publications, AR for ARGOS® (99.4%,97.7%,98.2%, 96.0%) was numerically higher vs IOLMaster 500® (77.0%,80.7%,84.7%, 87.30%) and 1 publication comparing ARGOS® to LENSTAR® showed numerically higher AR for ARGOS® (96.0%) vs LENSTAR® (79.0%). In dense cataracts, 1 publication showed higher AR for ARGOS® (89.9%) vs IOLMaster 700® (63.6%). AL measurements (in 8 publications) and Keratometry measurements (in 3 publications) with ARGOS® showed good correlation with either of the three biometers. One publication found similar PA with ARGOS® and IOLMaster 500®

Conclusion

Findings from this literature search showed that ARGOS® had higher acquisition rates versus IOLMaster 500®, IOLMaster 700® and LENSTAR® biometers, with comparable outcomes in terms of AL measurements, predictive accuracy and Keratometry measurements.

NGENUITY®

Alcon Health Economics and Outcomes Research

PP1-39: Comparative Assessment of Ergonomic Experience Operating with Heads-Up Display and Conventional Surgical Microscope in Anterior-segment Surgeons

Sun-Ming PAN, Robert J Weinstock (MD)[1], Margaret H Ainslie-Garcia (MSc) [2], Nicole C Ferko (MSc)[2], Rana A Qadeer (MSc)[2], Leighton P Morris (BSc)[3], Hang Cheng (MSc)[3]

[1]Eye Institute of West Florida, FL, USA; [2]Eversana, Canada; Leighton P Morris, Hang Cheng- Alcon Vision LLC, Fort Worth, TX, USA; 3Alcon Vision LLC (Fort Worth, TX, USA)

Abstract Details

Purpose

Musculoskeletal pain issues can impact ophthalmic surgeons' well-being and productivity. Consideration is important for anterior-segment surgeons who experience movement repetition and time pressure due to surgical volume and intensity. Heads-up displays (HUD) may improve upon conventional microscopes by reducing ergonomic stress. This study compared ergonomic experience between HUD and conventional optical microscope in the operating room (OR), as reported by a sample of anterior-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 to compare HUD and conventional microscope.

Results

Descriptive analysis was conducted on responses from 25 anterior segment surgeons with a mean of 16.7 years of practice and 2.2 years of using HUD. Twenty-one (84%) surgeons agreed or strongly agreed that HUD reduced the severity and frequency of pain and discomfort, improved posture, and improved overall comfort. Eighteen (72%) respondents believed conventional microscope had a negative impact on their health. Of respondents who experienced headaches or pain/discomfort during operation, 6 (50%) reported improvement in headaches and 21 (88%) reported less pain/discomfort since using HUD.

Conclusion

This study adds to the limited body of literature of musculoskeletal issues in anterior-segment surgeons. Results suggest that heads-up display may be an important tool for wellness in the operating room as it can benefit anterior-segment surgeons across several ergonomic measures. Further research with a larger sample size is needed to validate these findings.

NGENUITY®

Alcon Health Economics and Outcomes Research

PP1-41: Advantages of A 3D Heads-up Digital System Versus Standard Surgical Microscopes During Anterior Segment Surgery

Robert J Weinstock, MD[1], *William F Wiley, MD[2], Lu Yin, PhD[3], Jyotsna Maram, PhD[3]*

[1]Eye Institute of West Florida, FL, USA; [2]Cleveland Eye Clinic, OH, USA; [3]Alcon Vision LLC, TX, USA

Abstract Details

Introduction

Three-dimensional (3D) heads-up digital visualization systems offer improvements over standard microscopes for anterior segment surgical procedures. We present a laboratory modeling evaluation of a new digital visualization system (NGENUITY® 3D Visualization System) mounted on three analog surgical scopes. By setting the camera aperture at 30% of its full diameter, NGENUITY® can provide up to five-fold greater instantaneous depth of field than the total depth of field through the microscope oculars

Results

At the suggested viewing distance to display of 1.2 m, the total magnification for cataract surgery is higher than the Alcon LuxOR® LX3, Leica Proveo 8, and Zeiss OPMI LUMERA® 700 by 45%, 26%, and 48%, respectively. Depth of field will decrease at shorter viewing distance. Based on user preference, the stereopsis effect (perceived depth magnitude) can be improved with longer viewing distance with NGENUITY®.

Conclusion

Compared with the analog surgical scopes, NGENUITY® has a greater advantage in total magnification for shorter viewing distance. The total magnification decreases as viewing distance to the 4K ultra-high-definition display increases. An ocular-free 3D heads-up system has the potential to provide procedural benefits by improving ergonomics and surgeon comfort, and by facilitating collaboration and teaching in the operating room.

NGENUITY®

Investigator Initiated Trial (India)

PP1-48: Comparison of Ease of Visualization and Comfort during Phacoemulsification using NGENUITY® 3D Visualization System versus Standard Operating Microscope

Dr. Naren Shetty, Dr. Aishwarya, Dr. Rohitha Nayak, Dr. Luci Kaweri, Dr. Ravi Krishna K

Abstract Details

Purpose

To compare ease of visualization and comfort of surgeon as perceived by surgeon while performing phacoemulsification using the NGENUITY ® system versus phacoemulsification on patients using the standard operating microscope (SOM)

Methods

Prospective, randomized, single treatment, single sequence study with an active control group. An interim analysis of 123 patients who have completed the study where 64 patients have been operated on using SOM and 69 patients have been operated using the NGENUITY® 3D Visualization System by 5 surgeons. Inclusion criteria of patients include all patients within the age of 40-70, undergoing cataract surgeries. After surgery, "Surgeon's Comfort Score" is filled. First postoperative day, the patient undergoes evaluation.

Results

The brightness of the surgical field of SOM was higher compared to NGENUITY® surgical field experienced by all the 5 surgeons {(<0.0001), (<0.0001), (0.0001), (0.0001), (0.0001)}.Comfort of the surgical field of NGENUITY® was higher compared to SOM {(0.0082), (0.0007), (0.0466), (0.0043), (0.0041)}.Illumination of surgical field measured for SOM was more compared to NGENUITY® but Neck comfort was better after the surgery while operating on NGENUITY®.

Discussion

Use of "surgeons comfort score" highlights steps and parameters where surgeons rate their comfort level with the viewing modality and rate their difficulty if they find it difficult to visualize a surgical step.

Conclusion

Study shows that NGENUITY® system works well with lesser illumination providing better neck comfort to the operating surgeons, and more comfortable surgical field illumination as compared to surgeries done under SOM.

Financial Disclosure

This study is supported by a research grant from Alcon Vision LLC and the authors have no financial interest related to this presentation.

Hybrid Tip

Alcon Health Economics and Outcomes Research

PP1-69: Clinical and economic burden associated with posterior capsule rupture in cataract surgery - A targeted literature review

Carine C.W. Hsiao, MS[1], Hang Cheng, MS[1], Divyesh Thakker[2], Javed Shaikh[2], Amanda Henry[3]

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Abstract Details

Purpose

Despite advances in cataract surgery, posterior capsule rupture (PCR) remains a serious complication. PCR may require additional surgical interventions, leading to an additional burden on healthcare systems. The purpose of this study was to review published scientific evidence on clinical and economic burden associated with PCR.

Methods

A targeted literature search using Medline® (including Medline In-process), Embase® and Cochrane databases using a predefined search strategy was conducted (search period: 2000 to 22nd February 2019). Additionally, a grey literature search was also performed. Studies reporting on incidence of PCR during cataract surgery, complications of PCR, and the costs and resource use associated with PCR were included.

Results

PCR incidence varied across regions: UK (0.53-5.10%), USA (0.36-3.05%), Canada (0.45%), Europe (2.09-10.71%), Egypt (23.30%) and Asia (0.19-8.00%). Reportedly, 40-70% of PCR cases suffer from vitreous loss requiring unplanned vitrectomy. Unplanned vitrectomies add significant cost to healthcare system and increased risk for complications. Reportedly, ~23% of PCR cases failed to achieve post-operative visual acuity of ≤0.30 logMAR, and 31% cases suffer from visual loss. PCR cases had higher post-operative follow-up visits, longer follow-up duration, higher number of secondary surgeries required versus uncomplicated cataract surgeries, leading to incremental cost burden on healthcare systems.

Conclusion

Cataract surgeries complicated by PCR pose a significant clinical and economic burden, with increased risk of developing complications such as Cystoid Macular Edema, Retinal Detachment, Endophthalmitis, and impaired visual outcomes leading to additional burden on the healthcare systems worldwide.

ORA®

Alcon Health Economics and Outcomes Research

PP1-70: Clinical outcomes for intraoperative aberrometry compared with conventional preoperative management: A literature review

Paul Delatore[1], Margaret Ainslie-Garcia[2], Nicole Ferko[2], Carine Hsiao[1], Hang Cheng[1]

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Abstract Details

Purpose

Intraoperative aberrometry (IOA) provides real-time information during cataract surgery, and addresses several issues related to intraocular lens (IOL) calculation to reduce prediction error. A literature review was conducted comparing IOA with preoperative biometry and planning (PBP).

Methods

A literature review of MEDLINE and Google Scholar was undertaken over the last 15 years. Study inclusion was limited to randomized and non-randomized comparative studies and systematic reviews in the English. Articles where IOA procedure were not followed or did not have sufficient detail to understand how IOA was used were excluded. Outcomes were absolute prediction error (APE) and postoperative astigmatism (PA). Values of <0.5 diopters (D) and <1.0D were considered as good and acceptable levels, respectively.

Results

Thirteen studies compared IA to PBP used in conjunction with a variety of formulas. Absolute prediction error ranged from 0.24D – 1.19D for IA, and from 0.31D – 1.69D with PBP. The proportion of patients within ±0.5D of target was significantly or numerically higher in the IA group in 5/15 and 9/15 comparisons, respectively. Only PBP used with the AL-optimized Holladay 1 formula was numerically higher than IA. Results were similar when considering the proportion of patients within ±1.0D. For postoperative astigmatism outcomes, IA consistently showed significant or numerical improvement compared with PBP for mean error, and proportions within ±0.5D or ±1.0D refractive cylinder.

Conclusion

The use of IOA appears to offer several advantages in accuracy and astigmatism-related outcomes, and may be an asset in addressing heightened patient expectations for excellent postoperative visual outcomes.

AcrySof®

Alcon Health Economics and Outcomes Research

PP1-71: Effect of IOL Biomaterial on Posterior Capsule Opacification: Long-term real-world clinical practice evidence from large population-based studies

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Abstract Details

Objectives

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 United Kingdom, a retrospective cohort study (Ursell 2018) was conducted using NHS (National Health Service) 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=3,025). 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.

Clareon® AutonoMe®

Alcon Initiated Trial

PP2-06: Interim Analysis of a Post-market Clinical Study of the Clareon® AutonoMe® in an Indian Population

D Ramamurthy[2] , Jeewan S Titiyal[1] , Naren Shetty[3], Samar Basak[4], Umang Mathur[5]

[1]Professor & Head, Cornea, Cataract & Refractive Surgery Services, RP Centre for Ophthalmic Sciences, All India Institute of Medical Sciences, New Delhi; [2]Chairman, The Eye Foundation, Coimbatore; [3]Head of Cataract and Refractive Lens Services, Narayana Nethralaya, Bengaluru; [4]Director, Disha Eye Hospital, Kolkata; [5]Director, Dr Shroff's Charity Eye Hospital, New Delhi

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.

Clareon® AutonoMe® **Investigator Initiated Trial (Malaysia)**

PP2-13: 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

PP2-21: Interim Analysis of Post-market Clinical Study of the New Hydrophobic Acrylic IOL (CNA0T0) and Delivery System with Korean Population

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Abstract Details

Purpose

To provide interim 1-month real-world experience of Korean surgeons and clinical outcomes of Clareon® AutonoMe®.

Methods

Prospective, multicenter, single-arm study in which 125 eyes were implanted with the Clareon® IOL(CNA0T0) delivered with the AutonoMe® delivery device. The study endpoints are monocular BCDVA, UCDVA, the difference between target refraction and manifest refraction, surgeon satisfaction with the AutonoMe® delivery system via a questionnaire, the presence of glistenings, and all safety endpoints at 1 month

Results

In the interim result, 93.6% of eyes achieved monocular BCDVA of 0.2 logMAR or better. In the first eye, monocular BCDVA was 0.029 ± 0.1137 logMAR and monocular UCDVA was 0.107 ± 0.1453 logMAR at 1 month. In the second eye, monocular BCDVA was 0.015 ± 0.1015 logMAR and monocular UCDVA was 0.108 ± 0.1240 logMAR 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 glistenings and no surface haze were observed for all patients at 1 month.

Conclusion

In a Korean population, the visual performance of the Clareon® IOL showed good VA at 1 month and high surgeon satisfaction for the AutonoMe® delivery system.

Clareon® AutonoMe®

Alcon Initiated Trial

PP2-31 Two-year Multinational Evaluation of a New Aspheric Hydrophobic Monofocal Intraocular Lens

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Abstract Details

Purpose

To report visual acuity, refractive, and safety outcomes of the Clareon® aspheric, hydrophobic, monofocal, intraocular lens (IOL) 2 years after implantation.

Settings

Conducted at study centers in Australia (n = 3), France (n = 2), Germany (n = 2), Italy (n = 2), the Netherlands (n = 2), Spain (n = 5), and the United Kingdom (n = 3).

Methods

Prospective, multinational, single-arm trial assessing long-term (3-year) safety and effectiveness of the Clareon® IOL implanted bilaterally in adults. Subjects attend 12 study visits with primary objectives to demonstrate long-term visual acuity and adverse event (AE) outcomes of the IOL, one-year visual acuity, and AE outcomes compared to historical safety and performance endpoint rates as reported in EN ISO 11979-7:2014. We present the 2 year interim results.

Results

245 subjects enrolled; 215 implanted. At 2-years, postoperative mean corrected distance visual acuity (CDVA) was 0.03 logMAR in first and second eyes, and >96% of eyes had CDVA 20/25 or better. Mean manifest refractive spherical equivalent was within target (emmetropia) by 1-week and maintained at 0.06 D in first and second eyes at 2 years. There were no unanticipated AEs. Clinically significant posterior capsule opacification (PCO) was reported for 3 first (1.4%) and 5 second (2.4%) eyes, and clinically significant PCO requiring Nd:YAG laser capsulotomy was reported for 3 first (1.4%) and 5 second (2.4%) eyes.

Conclusion

The 2-year visual outcomes were excellent and had stable refractive results. There were no unanticipated AEs, and very low rates of PCO and Nd:YAG capsulotomies

AcrySof® IQ Vivity™

Alcon Initiated Trial

PP2-11 - Multi-country Clinical Outcomes of a New Non-diffractive Extended Vision Intraocular Lens

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Abstract Details

Purpose

To characterize the clinical outcomes following bilateral implantation of a novel non-diffractive extended depth of focus intraocular lens (IOL) with wavefront shaping X-WAVE™ technology, AcrySof® IQ Vivity™ (model DFT015), versus an aspheric monofocal IOL (model SN60WF) from two large confirmatory multicountry studies.

Settings

Post-operative clinical outcomes obtained at 6-months from a combined 30 global investigational sites located in Australia (3), Canada (6), Spain (6), United Kingdom (4) and United States (11).

Methods

These prospective, multi-center, randomized, parallel group, assessor and patient masked studies included (study 1, OUS) 273 bilaterally implanted patients, of whom 268 completed the study (DFT015, n=151; SN60WF, n=117) and (study 2, US) 219 bilaterally implanted patients, of whom 217 completed the study (DFT015, n=106; SN60WF, n=111).

Binocular best-corrected distance visual acuity (BCDVA; 4 m), distance-corrected intermediate visual acuity (DCIVA; 66 cm), and distance-corrected near visual acuity (DCNVA; 40 cm) were assessed at Month 6. Defocus curve and quality of vision (QoV study 1; QUIVID) study 2 were also assessed.

Results

Distance VA was similar between the groups (mean binocular BCDVA < 0.0 logMAR) while the observed means for binocular DCIVA indicated an improvement of > 1-line with DFT015. The observed means for binocular DCNVA indicated ~1-line improvement (OUS), and greater than 1-line improvement (US) favoring DFT015. DFT015 demonstrated a > 0.5 D extended mean binocular defocus range over SN60WF at 0.2 logMAR. The OUS rates of reporting not at all severe glare, halos, or starbursts were similar (<10% difference) between groups. Rates of US patients reporting "not at all bothered" by starbursts, halos, and glare were similar (<10% difference) between groups.

Conclusion

In comparison with an aspheric monofocal IOL, these two large-scale, independent confirmatory trials indicate that the DFT015 non-diffractive presbyopia correcting IOL improves near and intermediate vision without reducing distance vision. Patients bilaterally implanted with the DFT015 IOL reported low rates of visual disturbances comparable to an aspheric monofocal.

AcrySof® IQ Vivity™ Toric **Alcon Initiated Trial**

PP2-14: Real-world Outcomes of a Novel Non-diffractive Presbyopia Correcting Toric IOL—A multi-country registry study

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Abstract Details

Purpose

To report the first real-world performance and safety outcomes with the AcrySof®IQ Vivity™ Toric IOL (Models DFT315, DFT415, and DFT515).

Settings

International, ambispective registry study conducted in routine clinical practices in Europe, the UK, and Australia.

Methods

This is a sub-analysis of subjects enrolled and implanted with AcrySof® IQ Vivity™ Toric IOLs to date. After a minimum of 3 months post-op and up to 6 months follow-up per local clinical practice standards, subjects implanted with bilateral AcrySof® IQ Vivity™ Toric IOLs underwent performance assessments of visual acuity at distance, intermediate (66 cm), and near (40 cm). Subject satisfaction and spectacle independence were recorded via validated questionnaires. AEs were collected. We present an interim analysis of outcomes observed at the enrollment visit

Results

To date, of 129 subjects enrolled, 21 subjects were implanted with AcrySof® IQ Vivity™ Toric IOLs. Binocular mean (SD) UCDVA was 0.022 (0.082) logMAR; UCIVA was 0.080 (0.113) logMAR, and UCNVA was 0.244 (0.150) logMAR. All eyes had ≤ 0.50 D of manifest refractive cylinder after surgery. 95.3% of subjects reported rarely or never wearing glasses at arm's length and 93.2% of subjects were satisfied with their sight. No halos, glare, or starbursts were reported by 76.2%, 76.2%, and 95.2% subjects, respectively. There were no unanticipated AEs.

Conclusion

Initial real-world assessment of patients implanted with the AcrySof® IQ Vivity™ Toric IOL suggests very good visual outcomes, high levels of patient satisfaction with their sight, and a low need to wear spectacles for distance and intermediate activities. Study enrollment is ongoing.

AcrySof® IQ Vivity™

Alcon Initiated Trial

PP2-15: Real World Outcomes of a Novel Presbyopia-correcting IOL with Non-diffractive Design Implanted in Patients with Altered Corneas

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Abstract Details

Purpose

To report Real-World clinical visual outcomes of a non-diffractive designed, AcrySof® IQ Vivity™ Extended Vision IOL (model DFT015, DFT315-515) implanted in a subgroup of subjects with altered corneas. This is a sub-analysis of a multi-country, ambispective registry study.

Settings

Study centers in Australia (3), Germany (4), The Netherlands (2) and Spain (8)

Methods

After a minimum of 3-months follow-up, visual performance was evaluated based on visual acuity at distance, intermediate (66 cm) and near (40 cm) distances. Refractive residual error, subject satisfaction, and spectacle independence was also reported via validated questionnaires. This is the first interim analysis of the post-refractive surgery subjects.

Results

To date, 17 subjects with altered corneas have been enrolled. Altered corneas include post-LASIK (n=5), Corneal Dystrophy (n=4) or Dry Eye (n=10). Binocular mean (SD) (logMAR) BCDVA was 0.018 (0.062); DCIVA 0.143 (0.123) and DCNVA 0.202 (0.194). Binocular mean (SD) UCDVA was 0.060 (0.082); UCIVA 0.134 (0.113) and UCNVA 0.228 (0.205). No halos, glare and starburst were reported by 88.9%, 83.3% and 88.9% of subjects. There are no unanticipated AEs to-date.

Conclusion

In this Real-World assessment, patients with altered corneas and bilaterally implanted with the AcrySof® IQ Vivity™ or AcrySof® IQ Vivity™ Toric Extended Vision IOL, have shown good distance, intermediate and functional near visual outcomes and very low levels of visual disturbances. The study enrollment continues.

AcrySof® IQ Vivity™

Alcon Initiated Trial

PP2-16: 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.

AcrySof® IQ Vivity™

Alcon Initiated Trial

PP2-30: Clinical Outcomes of a New Extended Vision Intraocular Lens Implanted at Vision Eye Institute

Uday Bhatt[1]

[1]*Vision Eye Institute Footscray*

Abstract Details

Purpose

To evaluate the visual outcomes of subjects implanted with a new non-diffractive extended vision intraocular lens (Alcon DFT015) at a surgical site in Australia.

Settings

Multicenter clinical trial sponsored by Alcon

Methods

Bilaterally implanted 13 subjects with the DFT015 IOL and 9 with the monofocal control IOL (SN60WF) as part of a prospective, randomized, subject and assessor masked trial*. At 6 months after the second eye implant, the binocular defocus curve, binocular distance corrected visual acuities (VAs) at distance (CDVA, 4 m), intermediate (DIVA, 66 cm) and near (DNVA, 40 cm), and visual disturbances of halos, glare and starbursts (QoV, McAlinden) were assessed.

*Inclusion criteria: ≥22 years of age, Bilateral cataract requiring surgery, Preoperative regular astigmatism of <1.0 D, IOL power 18.0 to 25.0 D targeting emmetropia (0.0±0.5 D)

Results

The DFT015 IOL binocular defocus curve demonstrated >0.5 D of extension over the SN60WF IOL at 0.2 logMAR. Binocular CDVA was better than 0.0 logMAR for both groups. At intermediate and near, the improvement in binocular distance corrected VA for the DFT015 IOL over the SN60WF IOL was ≥ 0.1 logMAR. In the DFT015 IOL group, 100% of subjects were not at all bothered by halos, starbursts and glare; while 67% or more subjects were not at all bothered by these visual disturbances with the SN60WF IOL.

Conclusion

Compared with the SN60WF IOL, bilateral implantation of this new non-diffractive extended vision IOL provided subjects with an extended range of vision from distance to near, while maintaining the same quality of vision and visual disturbance profile as an aspheric monofocal.

AcrySof® IQ PanOptix®

Investigator Initiated Trial (Hong Kong)

PP2-02 - Early Clinical Outcome of AcrySof® IQ PanOptix® Trifocal Intraocular Lens in Asian Eyes

John Chang

Abstract Details

Methods

In this prospective study, subjects implanted with bilateral AcrySof® IQ PanOptix® Trifocal IOLs were included. Postoperative assessments included photopic and mesopic VA at distance, intermediate (60cm) and near (40cm); photopic and mesopic contrast sensitivity; defocus curve; questionnaire on dysphotopsia, satisfaction and spectacle independence.

Results

Nineteen patients were included. Mean binocular uncorrected VA at distance, intermediate (60 cm), and near (40 cm) were -0.05±0.07, 0.04±0.09, and 0.04±0.06 in logMAR, respectively. Across the defocus powers from +0.50D to -3.00D, vision was satisfactory and the mean VA was equal to or better than 20/25. No eye lost ≥ 1 line of corrected distance VA. Contrast sensitivity was within normal range at 3, 6 and 12 cpd, but slightly worse than the age norm at 18 cpd. Mean halo, glare, and starburst scores were 2.3, 0.2, and 1.6 (0 = none; 5 = very severe) respectively. The mean satisfaction score was 4.3 (0 = very dissatisfied; 5 = very satisfied). One-hundred percent of spectacle independence was achieved. No IOL exchange was required.

Conclusion

In conclusion, our results showed that bilateral implantation of AcrySof® IQ PanOptix® Trifocal IOLs was safe and provided satisfactory vision at various distances with acceptable CS and minimal dysphotopsia. Complete spectacle independence and high satisfaction score were achieved. All patients achieved bilateral VA of at least 20/25 or better at distance and near (40 cm), and 20/40 or better at intermediate (60 cm). The visual outcomes in the current study were consistent with those reported in other studies.

Financial Disclosure

Financial support was received for this investigator-initiated trial from Alcon Laboratories

AcrySof® IQ PanOptix® **Investigator Initiated Trial (China)**

PP2-17: 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 AcrySof® IQ PanOptix® IOLs (TIOL group) versus TECNIS 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 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, 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, AcrySof® IQ 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

The study was supported by the grant from Investigator-Initiated Trials grant (grant number: 60043935) funded by Alcon Inc. The authors have no conflicting relationships.

AcrySof® IQ PanOptix® **Investigator Initiated Trial (Thailand)**

PP2-20: Digital Reading Performance with Diffractive Multifocal Intraocular Lenses: One month interim analysis

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Abstract Details

Introduction

Cataract surgery with multifocal intraocular lenses (MF-IOLs) is a common presbyopia correction with promising outcomes. Digital devices become an essential part of the modern human lifestyle. Digital reading performance (DRF) is different from conventional paper reading in many ways, such as screen illumination, display polarity, glance-like reading, digital eye strain. We conduct this study to evaluate DRF and propose the optimized critical-print-size (CPS) and screen polarity recommendation for MF-IOLs implanted patients

Purpose

To evaluate DRF of patients bilaterally implanted with a difference MF-IOLs, AcrySof® IQ PanOptix®

Methods

Twenty-four eyes (12 cases) of bilateral MF-IOLs implantation, in the same day. The primary outcome in binocular uncorrected reading acuity measure with MNREAD® iPad App at 1 month. Secondary outcomes included distance binocular uncorrected visual acuity (BUCVA), intermediate (at 60 cm) BUCVA, near (at 40 cm) BUCVA at post-operative at day 1, 1 week, and 1 month, CPS with uncorrected acuity (at 60cm and 40 cm) at 1 month on MNREAD® iPad App.

Results

LogMAR BUCVA measure with MNREAD® iPad App at 1 month at 60 cm and 40 cm with positive display polarity (black-on-white background) and negative polarity (white-on-black) are -0.09, -0.04, -0.06, and 0.08, respectively. The mean digital CPS at 40 cm is 0.26.

Summary

Bilateral implanted AcrySof® IQ PanOptix®, shown rapid visual recovery and excellent DRF at 60 cm and 40 cm. Setting of display screen on digital device(s) as positive display polarity (black-on-white) with font size 7 pt or larger increase the likelihood of digital reading satisfaction in bilateral implanted MF-IOLs.

Financial Disclosure

Financial support was received for this investigator-initiated trial from Alcon Laboratories (Thailand) Ltd

AcrySof® IQ PanOptix® **Investigator Initiated Trial (Australia)**

PP2-25: Alcon PanOptix Intraocular Lens (IOL) in a Large Real-world Cohort

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Abstract Details

Introduction

The advances in intraocular lens (IOL) design over the previous two decades have resulted in increasing desire of spectacle independence after cataract surgery in patients as well as their surgeons, albeit with minimal compromise to visual quality. Trifocal intraocular lenses (IOL) are the advanced 21st century IOLs that provide good visual acuity at all distances without significantly compromising patient's quality of vision.

Purpose

The purpose of the study was to evaluate and report the real world visual and refractive outcomes of patients implanted with PanOptix® IOL at Vision Eye Institute between the year 2019 and 2020.

Methods

773 consecutive eyes of 580 patients were assessed at 6 months following implantation with PanOptix® IOL. Uncorrected and corrected visual acuity at far, intermediate and near distances and the mean absolute difference to refractive target values were analysed. Relevant adverse events were also recorded.

Results

580 consecutive patients (773 eyes) receiving Alcon PanOptix IOL were included. Mean age was 66.1 ± 10.4 years and 58.5% female. Two thirds (60.3%) of eyes required a toric IOL. Preoperatively 46.7% of eyes were 6/6 with correction. Postoperatively 62.1% of eyes were 6/6 unaided, 66.8% and 86.5% of eyes achieved N6 or better unaided for intermediate and near vision respectively. The mean absolute difference to refractive target was 0.21 ± 0.22D. 8.3% of eyes underwent a YAG laser up to 2 years following surgery.

Conclusion

The PanOptix® IOL is an effective choice following cataract or lens exchange surgery to provide functional spectacle independence at all distances without compromising the general quality of life.

Financial Disclosure

UB: Alcon, Bausch & Lomb and Johnson and Johnson; ML: Alcon and Zeiss.

CONTOURA®

Investigator Initiated Trial (China)

PP3-01: Comparison of Clinical Outcomes of Two Corneal Topography-guided Platforms on Virgin Eyes

Li LI, Zheng WANG

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

The study was supported by the Science Research Foundation of Aier Eye Hospital Group (AM169D04), Changsha, China. The study was also funded by Alcon Laboratories Pvt. Ltd (IIT # 52058705).
The authors declare that they have no financial conflict of interest

CONTOURA®/Phorcides **Investigator Initiated Trial (India)**

PP3-17: Comparing Visual Outcomes of CONTOURA® LASIK with Topoguided LASIK using Phorcides Analytical Software Performed in Eyes with Myopic Astigmatism

Ramamurthy Dandapani, Soundarya B, Shreyas Ramamurthy, Gitansha Shreyas Sachdev

Abstract Details

Purpose

To compare the differences in astigmatism treatment between CONTOURA® LASIK and Topo guided LASIK using the Phorcides analytical software.

Settings

Prospective, single centre, randomized, observer masked contralateral eye study at a tertiary eye care hospital.

Methods

60 eyes of 30 patients over the age of 18 years who underwent refractive correction using Femto-assisted LASIK for -0.5 to -8.0 D sphere and -1.0 to -5.0 D cylinder were included. Analysis of intra operative correction and post operative parameters like uncorrected and corrected distance visual acuity(UDVA/CDVA), manifest refractive cylinder, spherical equivalent (MRSE), higher order aberrations and contrast sensitivity was done with follow up visits at 1 week, 1 month and 3 months.

Results

At the end of 3 months, UDVA was LogMAR 0.04+/-0.07 in the CONTOURA® group and LogMAR 0.06+/-0.1 in the Phorcides group (p=0.784). Similarly there was no statistically significant difference in the CDVA (p=0.661) between the two groups. The manifest cylinder and MRSE were -0.16+/-0.27 D and -0.12+/-0.22 D respectively in the CONTOURA® group and -0.16+/-0.30 D (p=0.876) and -0.06+/-0.20 D (p=0.272) respectively in the Phorcides group, with no statistically significant difference between the two groups. Vector analysis showed no statistically significant difference between the groups with a median Target Induced Astigmatism(TIA) of 2.02+/-0.82 D and 2.17+/-1.02 D (p=0.515) , Surgically Induced Astigmatism(SIA) of 2.2+/-1.01 and 2.42+/-1.05, Difference Vector(DV) of 0.35+/-0.5 D and 0.72+/-0.64 D (p=0.015) and Correction Index(CI) of 1.07+/-0.11 and 1.21+/-0.58 (p=0.213) in both the groups respectively. Visual quality analysis based on contrast sensitivity and higher order aberrations were also not statistically different between the groups.

Conclusion

Laser vision correction treatments using both CONTOURA® LASIK and topoguided LASIK using Phorcides Analytical software showed equally good results in terms of quantity and quality of vision at the end of three months.

Financial Disclosure

Received grant from Alcon Laboratories for conducting the study.

General

Alcon Health Economics and Outcomes Research

PP5-71: Cataract, Glaucoma, Vitreoretinal, and Laser Refractive Surgery Hospital Costs in the Asia-Pacific Region: A comprehensive literature review

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Abstract Details

Purpose

To conduct a literature review of hospital costs associated with cataract, glaucoma, vitreoretinal, and laser refractive surgeries.

Methods

Four targeted searches (one for each surgery type) were conducted in Ovid EMBASE and MEDLINE for studies published between November 2014 and November 2019. Articles published in English that reported hospital costs (for diagnostics, monitoring, staff, facility, medications, anesthesia, consumables, complications, and administration/overhead) from the Asia-Pacific region were included. Costs are reported in 2020 USD.

Results

We identified seven articles with 59 relevant costs: 50 related to cataract surgeries from India, Malaysia, Sri Lanka, and China; eight related to vitreoretinal surgeries from Indonesia; and one related to laser refractive surgery from Nepal. No studies reported glaucoma surgery costs.

We identified cataract surgery costs for hospital stays, staff, consumables, facilities, medications, and overhead. Large variations were observed in the overall procedure-related cost of cataract surgeries: $19.39-$189.98 for manual small-incision cataract surgery, $22.41-$1,266.04 for extracapsular cataract extraction, and $53.24-$1,647.95 for phacoemulsification. Pre-surgery, surgery-specific, and post-surgery vitrectomy costs were reported in one study, with the sum ranging from $233.71-$341.36. A single cost for the equipment required to establish a laser refractive surgery unit was also obtained ($684,059.90). No diagnostics-, anesthesia-, or complications-related hospital costs were identified for any procedure.

Conclusion

Our review captured a variety of hospital costs for cataract, vitreoretinal, and laser refractive surgeries from six Asian countries. However, with the rise of health technology assessments and economic evaluations in the Asia-Pacific region, robust collection and standardization of region-specific hospital costs should be emphasized.

AcrySof® IQ

Alcon Health Economics and Outcomes Research

PP5-112: 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

PP5-113: 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.

Vision Care

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Alcon Initiated Trial

PP5-90: Clinical comparison of Verofilcon A and Etafilcon A daily disposable contact lenses

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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.

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

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

PP5-91: Clinical performance of a new daily disposable spherical contact lens

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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

SYSTANE®

Alcon Health Economics and Outcomes Research

PP5-63: Impact of Dry Eye Disease on Patient Quality of Life

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Abstract Details

Introduction

The prevalence of dry eye disease (DED) is increasing, due to environmental triggers, the aging population, and use of digital displays. DED is a chronic, progressive, and symptomatic condition, but its impact is largely underrecognized. 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 may 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 is one of growing research and development, and much needed to understand the serious impact of DED on patient QOL.

Financial Disclosure

RK and SS are employees of Alcon. MAG and NF are employees of EVERSANA, contracted by Alcon to conduct the literature review

SYSTANE®

Alcon Health Economics and Outcomes Research

PP5-87: Comparative Efficacy and Safety of Ocular Lubricants Containing Hydroxypropyl Guar

Richard Kara[1], Sruthi Srinivasan[1], Margaret Ainslie-Garcia[2], Nicole Ferko[2], Paul Delatore[1]

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Abstract Details

Introduction

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.

Financial Disclosure

RK and SS are employees of Alcon. MAG and NF are employees of EVERSANA, contracted by Alcon to conduct the literature review.

SYSTANE® Complete

Alcon Initiated Trial

PP5-94: Sustained symptom relief in subjects with dry eye disease following a single dose of PG/HPG-Nanoemulsion

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Abstract Details

Purpose

To evaluate symptomatic improvement following a single dose of PG/HPG-Nanoemulsion (SYSTANE® Complete) in subjects with dry eye disease (DED)

Methods

This phase IV, multicenter, open-label, single-arm, interventional study included 54 adults, 40 women and 14 men, with DED administered a single dose of PG/HPG-Nanoemulsion. Dry eye symptom scores were recorded before (baseline) and immediately after instillation, and 4 (±1) and 8 (±1) hours later, on a scale of 0 (no symptoms) to 10 (worst imaginable symptoms). Soothing sensation scores, ranging from 0 (eyes feeling good) to 10 (no feeling), were determined at the same post-instillation times, and tolerability profiles, consisting of burning, stinging, foreign body sensation and blur, all on scales of 0-10, were recorded immediately after instillation

Results

Subjects were grouped into those with scores of 0-5 (no/minimal symptoms) and 6-10 (moderate-to-severe symptoms). Dry eye symptom scores were significantly lower at all three post-instillation time points than at baseline ($p<0.001$). At baseline, 61% (33/54) subjects reported moderate-to-severe symptoms, compared with 24% (12/54), 15% (8/54), 20% (11/54) at 0, 4, and 8 hours, respectively ($p<0.001$). Soothing sensation was maintained over the 8-hour follow-up period with 87%, 85% and 89% of subjects reporting scores of 0-5 at 0, 4 and 8 hours, respectively. Eye drops were well tolerated, with 94%, 92%, 94% and 96% reporting no or minimal burning, stinging, blur and foreign body sensation, respectively

Conclusion

A single application of the PG/HPG-Nanoemulsion provided instant/immediate and sustained symptom relief for 8 hours and was well tolerated by most study subjects

SYSTANE® Complete, SYSTANE® Hydration

Investigator Initiated Trial (ANZ)

PP5-96: Comfort and Vision Effects of Post-lens Lubrication during Mini-scleral Contact Lens Wear

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Abstract Details

Purpose

To compare the effect on subjective responses up to 6 hours post-lens insertion, when two different lubricating eye drops are instilled in mini-scleral contact lenses prior to lens insertion, compared to filling with saline alone.

Methods

Experienced soft contact lens wearers were enrolled in this prospective, randomized, double-masked study. Subjects were custom fitted with KATT 16.5mm Boston XO miniscleral lenses. Subjects attended visits on separate days and were randomized to receive an hydroxypropyl guar (HPG)/nanoemulsion (test #1) or an HPG/sodium hyaluronate (test #2) eye drop into the mini-scleral lens prior to filling with saline, or filling with saline alone (control). Subjective responses were collected 5 mins, 2, 4 and 6 hours post-lens insertion.

Generalized linear mixed model was applied to compare the rate that subjects' responses improved post-lens insertion for the different treatments. Statistical significance was set at $p \leq 0.05$.

Results

Eleven males and 13 females, average age 29.3 ± 5.4 years completed the study. Dryness symptoms improved at a slower rate post-lens insertion with saline alone compared to the addition of test eye drop #1 ($p = 0.005$) or test eye drop #2 ($p = 0.049$). Test eye drop #1 was more effective than saline alone in improving symptoms of fluctuating vision ($p = 0.011$), grittiness/burning/stinging ($p = 0.001$) and foreign body sensation ($p=0.006$) more quickly.

Conclusion

Instillation of the two commercially available test eye drops prior to filling mini-scleral contact lenses with saline is beneficial for improving lens comfort in wearers new to scleral lenses.

Financial Disclosure

This study was funded by Alcon Laboratories

NOTE: Centurion® Silver is not currently registered in Singapore

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