Rayner: Leading the Way to Offer More Patients a Trifocal Solution
Surgeon Panel Discussion on RayOne® Trifocal and the New Sulcoflex Trifocal
ESCRS Eurotimes Satellite Education Programme

Criteria of Selection and Indication, Results and Satisfaction, In Presbyopia Surgery with RayOne Trifocal premium lens

Fernando Llovet, MD, PhD
Clinica Baviera, Spain

VIENNA 2018
36TH Congress of the ESCRS
22–26 September
This Congress has been awarded 36 CME credits

NO FINANCIAL INTEREST

0. Two Questions, Two Ideas

Which patients are suitable for a MIOL?

"The main indication is the <u>presbyopic patient</u>"

Also in:

- Cataract surgery
- RLE for:
  - Dysfunctional Lens Syndrome
  - High ametropia (especially hyperopia)

When to implant a MIOL?

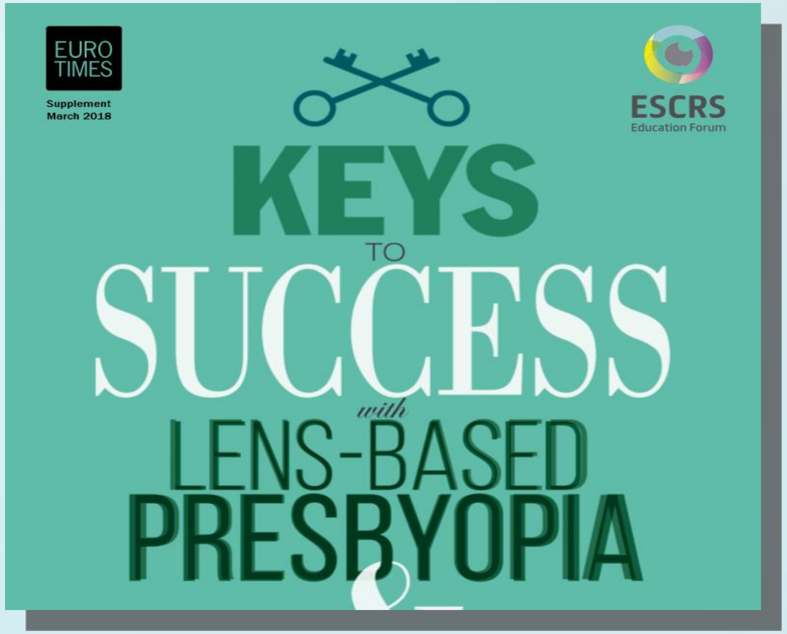
"When it is possible to obtain the emmetropia"

You need a <u>perfect surgery</u> but also:

- Select the <u>good</u> candidate
- Have <u>equipment</u> for after-surgery enhancements
- Be prepared to <u>manage</u> the unsatisfied patient

"If you can deliver a perfectly <u>emmetropic eye</u> at the end of surgery, you have no problem implanting a MIOL"

(Robert M. Kershner, MD)



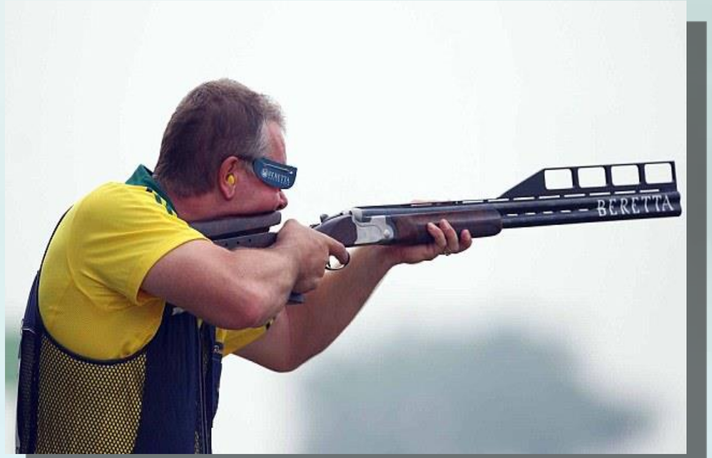
1. Patient selection

Before the operation: patient selection

1.1. Anamnesis

"The first contact establishes doctor-patient relationship…and obtain important data "

- Occupation and particular needs such as:
  - ✓ Professional driving
  - ✓ Intensive near vision using
  - ✓ Hunting, Olympic shooting…
- Personality and mental disorders:
  - ✓ High demand and expectations
  - ✓ Problems to be adapted, obsession
  - ✓ Medication (dilates pupil)
- General health problems:
  - ✓ Diabetes
  - ✓ Age: advanced senility?
  - ✓ Cataract old patients usually very pleased



1.2. Diagnosis and prognosis

Explain: "<u>What</u> happens, <u>why</u> it happens and <u>what</u> can we obtain"

- Diagnosis:
  - Presbyopia
  - Ametropia
  - Level
- Specific features:
  - Dry eye
  - Ambliopia
- Prognosis:
  - Near/Intermediate/Distance visions
  - Glasses independence
  - Dissatisfaction causes

1.3. Information and Informed Consent

“Exhaustive oral and written information”

- Information:
  - Custom explanation
  - Medical report
- Informed Consent:
  - Endorsed by Scientific Society
  - Personalized
- Attached Information:
  - “Multifocal vision”

1.4. Follow-up

"Establish a protocol and report on the post-op evolution"

- Immediate Post-op:
  - Inflammation, IOP, Lens position…
- Visual and refractive evolution:
  - Protocol: next day, 1 week, 1 month, 3 month
- End of surgical process:
  - Outcomes
  - Satisfaction
  - dissatisfaction causes
  - Medical report

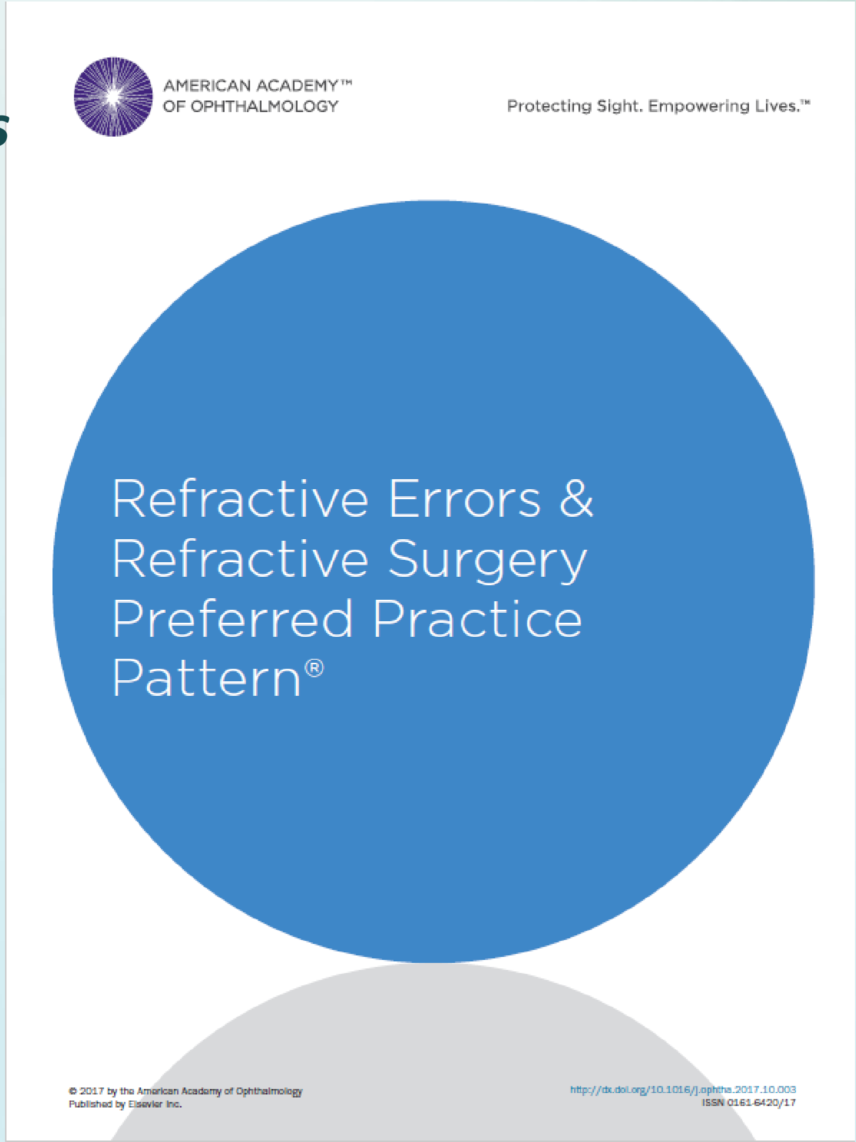
2. Pre-operative evaluation

Before the operation: standard patient evaluation and...

2.1. Standard exploration

"Lens surgery is also refractive surgery and it is necessary to perform the estandar exploration"

- Visual acuity (near, intermediate, distance)
- Refraction (near, intermediate, distance)
- IOP
- Biomicroscopy
- Ocular motility (Kappa angle, dominance)
- Pupillometry
- TBUT
- Pachimetry
- Corneal Topography
- Endothelial Count
- Fundus exploration (OCT)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Refractive Errors & Refractive Surgery Preferred Practice Pattern®

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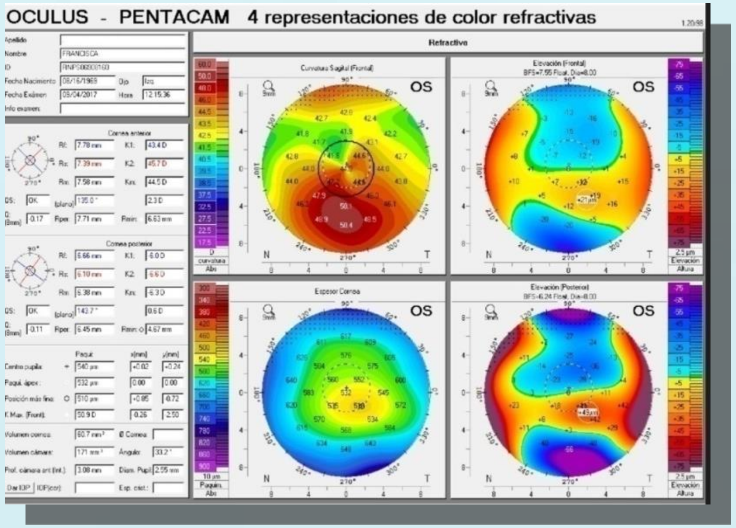
2.2. Surface disease

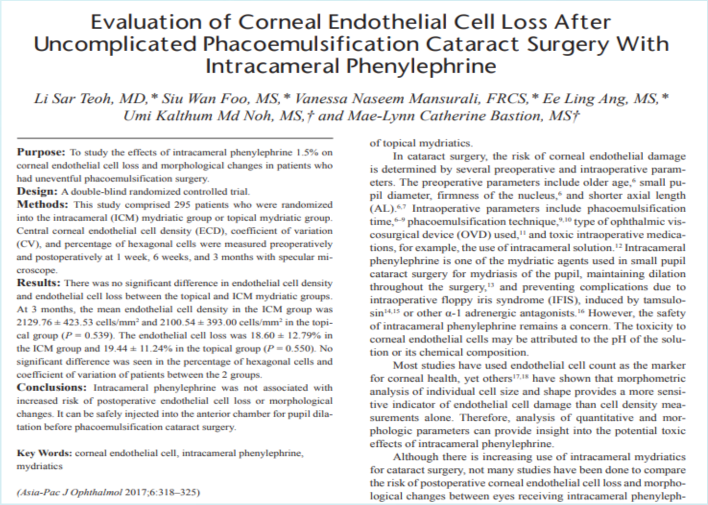
"It is essential to study of the ocular surface"

Rule-out:

- Corneal Fuchs dystrophy
- Severe dry eye
- Corneal scars, infiltrates
- Corneas non-suitable for laser correction (KC)

Corneal Topography and Endothelial Count are mandatory!





Evaluation of Corneal Endothelial Cell Loss After Uncomplicated Phacoemulsification Cataract Surgery With Intracameral Phenylephrine

Li Sar Teoh, MD, Siu Wan Foo, MS,* Vanessa Naseem Mansurali, FRCS,* Ee Ling Ang, MS,* Umi Kalthum Md Noh, MS,† and Mae-Lynn Catherine Bastion, MS†*

Purpose: To study the effects of intracameral phenylephrine 1.5% on corneal endothelial cell loss and morphological changes in patients who had uneventful phacoemulsification surgery.
Design: A double-blind randomized controlled trial.
Methods: This study comprised 295 patients who were randomized into the intracameral (ICM) mydriatic group or topical mydriatic group. Central corneal endothelial cell density (ECD), coefficient of variation (CV), and percentage of hexagonal cells were measured preoperatively and postoperatively at 1 week, 6 weeks, and 3 months with specular microscope.
Results: There was no significant difference in endothelial cell density and endothelial cell loss between the topical and ICM mydriatic groups. At 3 months, the mean endothelial cell density in the ICM group was 2129.76 ± 423.53 cells/mm² and 2100.54 ± 393.00 cells/mm² in the topical group ($P = 0.539$). The endothelial cell loss was 18.60 ± 12.79% in the ICM group and 19.44 ± 11.24% in the topical group ($P = 0.550$). No significant difference was seen in the percentage of hexagonal cells and coefficient of variation of patients between the 2 groups.
Conclusions: Intracameral phenylephrine was not associated with increased risk of postoperative endothelial cell loss or morphological changes. It can be safely injected into the anterior chamber for pupil dilatation before phacoemulsification cataract surgery.

Key Words: corneal endothelial cell, intracameral phenylephrine, mydriatics

(Asia-Pac J Ophthalmol 2017;6:318–325)

of topical mydriatics.

In cataract surgery, the risk of corneal endothelial damage is determined by several preoperative and intraoperative parameters. The preoperative parameters include older age,[6] small pupil diameter, firmness of the nucleus,[6] and shorter axial length (AL).[6,7] Intraoperative parameters include phacoemulsification time,[6–9] phacoemulsification technique,[9,10] type of ophthalmic viscosurgical device (OVD) used,[11] and toxic intraoperative medications, for example, the use of intracameral solution.[12] Intracameral phenylephrine is one of the mydriatic agents used in small pupil cataract surgery for mydriasis of the pupil, maintaining dilation throughout the surgery,[13] and preventing complications due to intraoperative floppy iris syndrome (IFIS), induced by tamsulosin[14,15] or other α-1 adrenergic antagonists.[16] However, the safety of intracameral phenylephrine remains a concern. The toxicity to corneal endothelial cells may be attributed to the pH of the solution or its chemical composition.

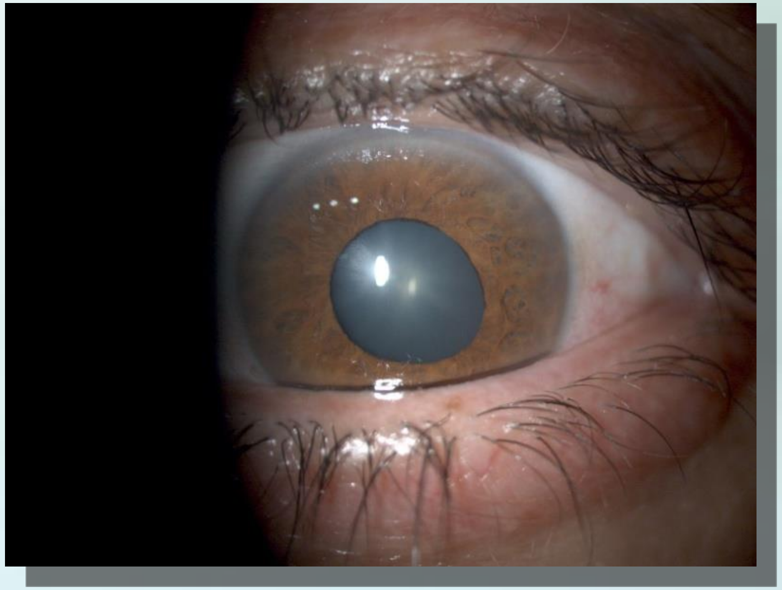
Most studies have used endothelial cell count as the marker for corneal health, yet others[17,18] have shown that morphometric analysis of individual cell size and shape provides a more sensitive indicator of endothelial cell damage than cell density measurements alone. Therefore, analysis of quantitative and morphologic parameters can provide insight into the potential toxic effects of intracameral phenylephrine.

Although there is increasing use of intracameral mydriatics for cataract surgery, not many studies have been done to compare the risk of postoperative corneal endothelial cell loss and morphological changes between eyes receiving intracameral phenyleph-

2.3. Pupil size

"Really is important the size and the pupillary function"

- You need a pupil that is small enough when accommodating and not very large by night to avoid halos and permit reading
- Evaluate pupil function, don't see the patient after dilation



CURRENT OPINION

Recent advances in small pupil cataract surgery

Boris E. Malyugin

Purpose of review
To highlight the existing and emerging cataract surgery trends in patients with insufficient mydriasis. Discuss the latest pharmacological approaches for pre and intraoperative pupil dilatation. Present the variety of newest pupil expansion devices; critically review their advantages and possible limitations to be considered by the surgeon.

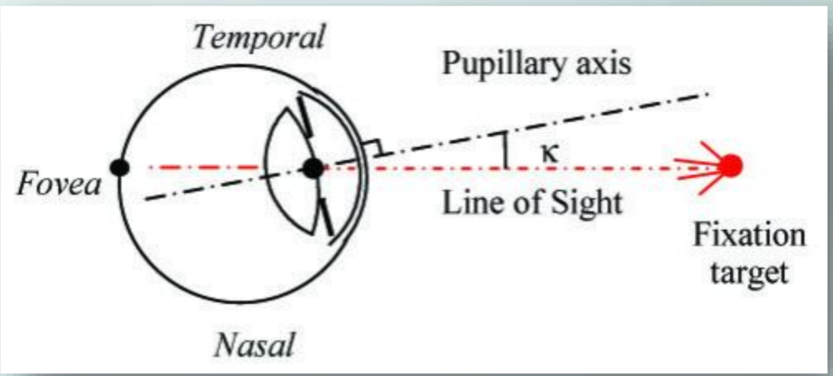
Recent findings
The intracameral use of various mydriatic combinations augmenting the preoperative mydriatic instillations is currently gaining popularity in cataract surgery. Two main options are available: bolus injection of pharmacological agent or its constant irrigation during the phacoemulsification procedure. The former is aimed to expand the pupil, whereas the latter is mostly preventing the pupil from constriction. Introduction of femtosecond-assisted cataract surgery, apart from some benefits was followed by a variety of adverse effects including prostaglandin release into the aqueous humor causing pupil constriction. Preoperative administration of nonsteroidal anti-inflammatory drugs at least 1 day prior to surgery significantly decreases the chance of pupil constriction after laser energy is applied to the eye. However, pupil expansion devices may be needed in up to 10% of cases. Following the success of the Malyugin ring (MicroSurgical Technology Inc., Redmond, Washington, USA) several manufacturers introduced pupil expansion devices of various designs. They are differing with materials, pupillary margin fixation mechanisms, and easiness of manipulations during implantation and removal.

Summary
Combination of proper use of pre and intraoperative pharmacological pupil dilatation protocols combined with pupil expander rings allow for well tolerated and effective cataract surgery in the vast majority of patients with insufficient mydriasis.

Keywords
intracameral mydriatic, iris hooks, Malyugin ring, phenylephrine, pupil ex

Curr Opin Ophthalmol 2018, 29:40–47
DOI:10.1097/ICU.0000000000000443

2.4. Kappa angle



- Diffractive lenses tolerate better the kappa angle than refractive lenses.
- In patients with a larger angle k, the choice to implant a trifocal IOL **should be carefully evaluated.**

Role of angle κ in visual quality in patients with a trifocal diffractive intraocular lens

Yingying Qi, MD, Jing Lin, MD, Lin Leng, MD, Guiqiu Zhao, MD, PhD, Qing Wang, MD, Cui Li, MD, Liting Hu, MD

Purpose: To evaluate the visual quality of patients with different angle κ sizes after a trifocal diffractive intraocular lens (IOL) implantation.

Setting: The Affiliated Hospital of Qingdao University, Qingdao, China.

Design: Prospective case series.

Methods: Patients who had phacoemulsification with the implantation of the trifocal IOL AT LISA tri 839MP were enrolled in the study. The patients were divided into 3 groups based on the size of the preoperative angle κ. Monocular far, intermediate, and near uncorrected visual acuities were measured during a 3-month follow-up. Other outcome measurements taken were the modulation transfer function (MTF) cutoff, the Strehl ratio, and objective scatter index. All the patients completed a subjective questionnaire survey.

Results: The study comprised 89 patients (89 eyes). The 3 groups showed statistically significant differences in the incidence of glare and halo after their surgery. There were no significant differences in the following variables: uncorrected far, intermediate, and near visual acuities, MTF cutoff, Strehl ratio, and spectacle independence. There was a significant difference in the MTF cutoff and Strehl ratio between the patients with the largest and the smallest angle κ.

Conclusions: The patients' postoperative far, intermediate, and near vision was not affected by their angle κ. However, when angle κ was greater than 0.4 mm, the incidence of glare and halo increased and when it was greater than 0.5 mm, patients' visual quality decreased. In clinical work, for patients with a larger angle κ, the choice to implant a trifocal IOL should be carefully evaluated.

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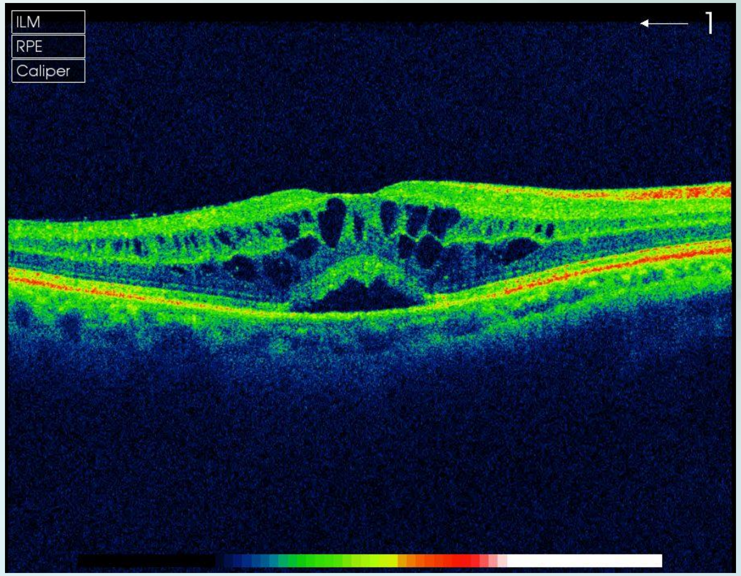
2.5. Fundus evaluation

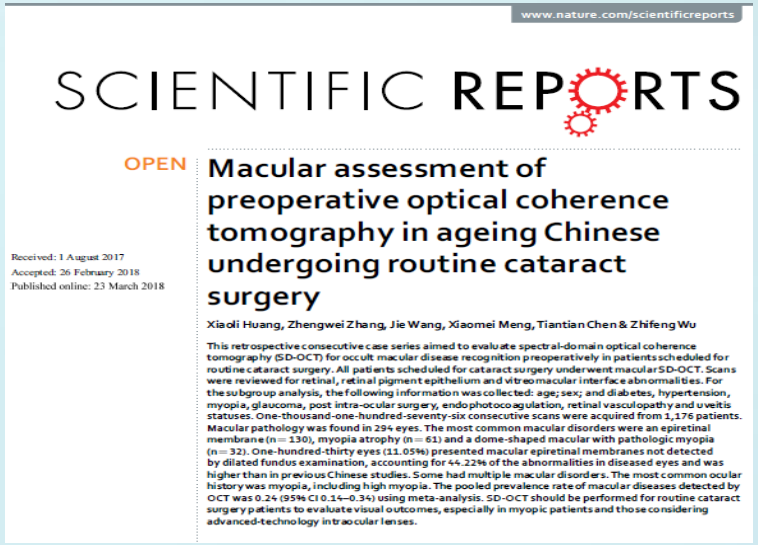
"Mandatory in intraocular surgery"

Perform routine macular OCT

(next to a good fundus examination)



- Epiretinal membranes: easy to overlook and can progress faster after surgery
- Patient with moderate stable macular disease: expect less distance and near VA and inform the patient accordingly



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Macular assessment of preoperative optical coherence tomography in ageing Chinese undergoing routine cataract surgery

Xiaoli Huang, Zhengwei Zhang, Jie Wang, Xiaomei Meng, Tiantian Chen & Zhifeng Wu

This retrospective consecutive case series aimed to evaluate spectral-domain optical coherence tomography (SD-OCT) for occult macular disease recognition preoperatively in patients scheduled for routine cataract surgery. All patients scheduled for cataract surgery underwent macular SD-OCT. Scans were reviewed for retinal, retinal pigment epithelium and vitreomacular interface abnormalities. For the subgroup analysis, the following information was collected: age; sex; and diabetes, hypertension, myopia, glaucoma, post intra-ocular surgery, endophotocoagulation, retinal vasculopathy and uveitis statuses. One-thousand-one-hundred-seventy-six consecutive scans were acquired from 1,176 patients. Macular pathology was found in 294 eyes. The most common macular disorders were an epiretinal membrane (n = 130), myopia atrophy (n = 61) and a dome-shaped macular with pathologic myopia (n = 32). One-hundred-thirty eyes (11.05%) presented macular epiretinal membranes not detected by dilated fundus examination, accounting for 44.22% of the abnormalities in diseased eyes and was higher than in previous Chinese studies. Some had multiple macular disorders. The most common ocular history was myopia, including high myopia. The pooled prevalence rate of macular diseases detected by OCT was 0.24 (95% CI 0.14–0.34) using meta-analysis. SD-OCT should be performed for routine cataract surgery patients to evaluate visual outcomes, especially in myopic patients and those considering advanced-technology intraocular lenses.

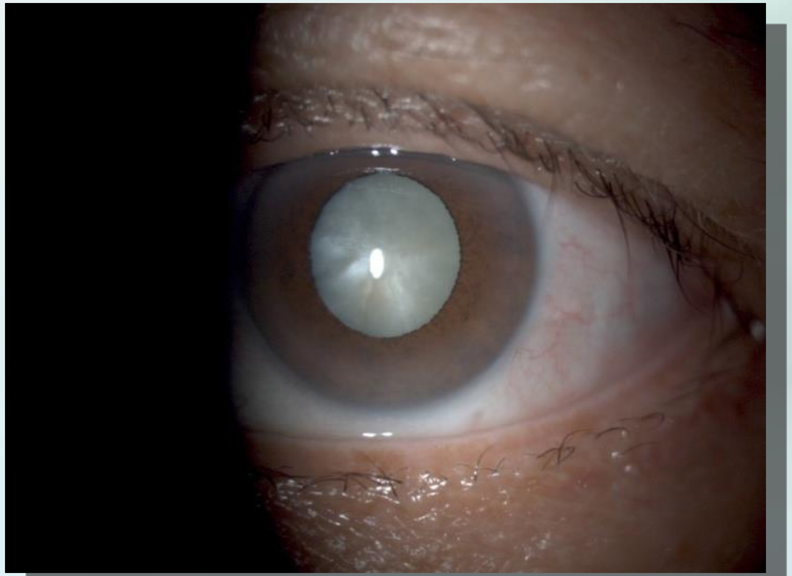
2.6. Accurate biometry

" Special attention to the IOL calculation"

- Use <u>optical interferometry</u>

  (if necessary: immersion biometry)

- **<u>Personalize lens constants</u>** by studying deeply your first cases with every new lens
- **<u>Recalculate</u>** lens power for the **<u>second eye</u>** if inaccurate first eye result (account for half the error)
- Use **<u>new generation</u>** formulae such as Haigis, Olsen and Barret. SRK-T preferred in myopic, Hoffer-Q in hyperopic



Accuracy of 8 intraocular lens calculation formulas in relation to anterior chamber depth in patients with normal axial lengths

Sabite Emine Gökce, MD, Ildamaris Montes De Oca, MD, David L. Cooke, MD, Li Wang, MD, PhD, Douglas D. Koch, MD, Zaina Al-Mohtaseb, MD

Purpose: To determine the effect of anterior chamber depth (ACD) on the accuracy of 8 intraocular lens calculation formulas in patients with normal axial lengths (ALs).

Setting: Baylor College of Medicine, Alkek Eye center, Houston, Texas, USA.

Design: Retrospective case series.

Methods: Patients having cataract surgery with ALs between 22.0 mm and 25.0 mm were divided into 3 groups based on their preoperative ACD measurement. The mean prediction errors, mean absolute errors (MAEs), and median absolute errors for each group were calculated.

Results: For the ACD of 3.0 mm or less group and the ACD of 3.5 mm or more group, the Barrett Universal II, Holladay 2, Haigis, and Olsen ray-tracing formulas had mean prediction error values that were not significantly different from zero. For the ACD of 3.01 to 3.49 mm group, all formulas had mean prediction error values that were not significantly different from zero. For the ACD of 3.0 mm or less group, the Barrett Universal II formula had a smaller median absolute error than the Haigis, Hoffer Q, and Olsen optical low-coherence reflectometry (OLCR) (Lenstar) formulas and a smaller MAE than the Hoffer Q, Hill-RBF, and Olsen OLCR ($P < .05$). In the ACD of 3.5 mm or more group, the Barrett MAE was smaller than the Hoffer Q ($P < .05$); however, there were no significant differences between median absolute errors.

Conclusion: In eyes with normal ALs, taking preoperative ACD values into consideration might improve refractive outcomes.

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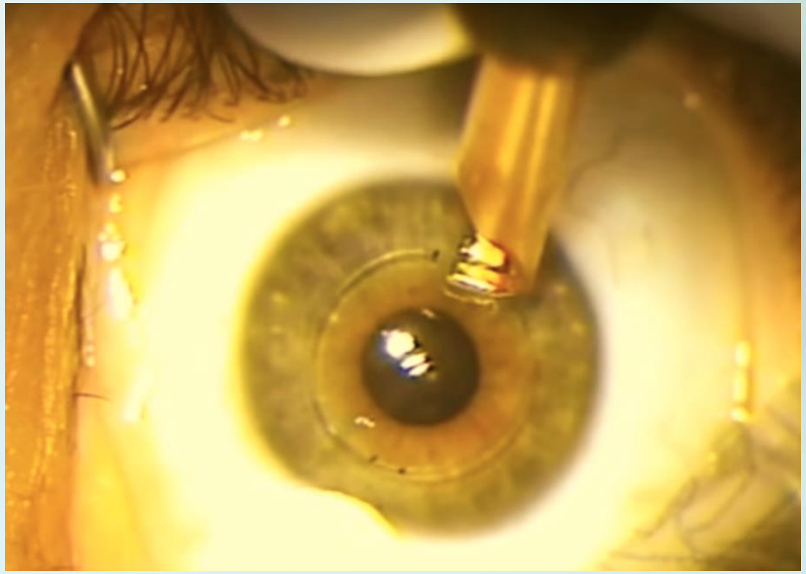
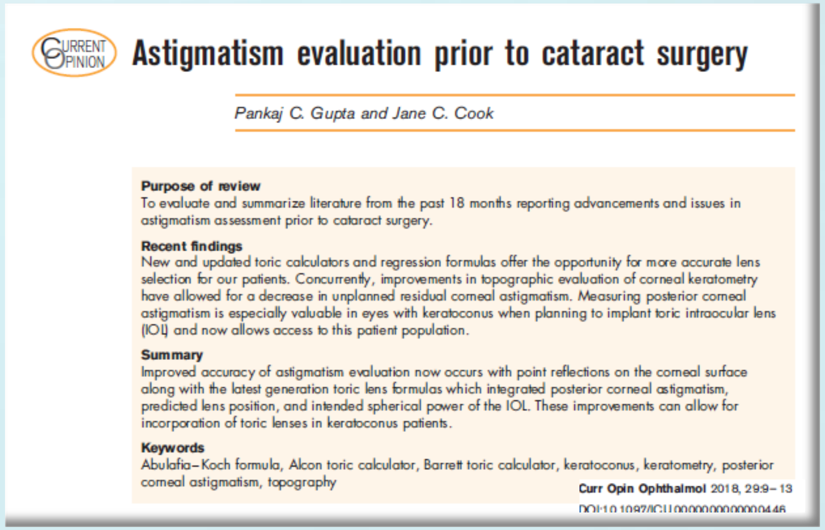
2.7. Astigmatism correction

"Always plan in advance the management of astigmatism"

- What to do with the previous or induced astigmatism (SIA & TIA)



- Skill one or more **techniques** and have them available: AK and LRI, (manual or femtosecond), Lasik, PRK, toric lenses
- **Consider corneal** astigmatism (anterior and posterior)
- **Consider toric implant**: >? D astigmatism



Astigmatism evaluation prior to cataract surgery

Pankaj C. Gupta and Jane C. Cook

Purpose of review
To evaluate and summarize literature from the past 18 months reporting advancements and issues in astigmatism assessment prior to cataract surgery.

Recent findings
New and updated toric calculators and regression formulas offer the opportunity for more accurate lens selection for our patients. Concurrently, improvements in topographic evaluation of corneal keratometry have allowed for a decrease in unplanned residual corneal astigmatism. Measuring posterior corneal astigmatism is especially valuable in eyes with keratoconus when planning to implant toric intraocular lens (IOL) and now allows access to this patient population.

Summary
Improved accuracy of astigmatism evaluation now occurs with point reflections on the corneal surface along with the latest generation toric lens formulas which integrated posterior corneal astigmatism, predicted lens position, and intended spherical power of the IOL. These improvements can allow for incorporation of toric lenses in keratoconus patients.

Keywords
Abulafia–Koch formula, Alcon toric calculator, Barrett toric calculator, keratoconus, keratometry, posterior corneal astigmatism, topography

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DOI:10.1097/ICU.0000000000000446

2.8. Refractive error

"Also want to remove glasses for far"

- Better: **hyperopic** that only wear glasses for reading
- Worse: **myopic** that take glasses off for reading

➢ **Attention to very myopic eyes**

➢ Be **careful in amblyopic or anisometropic** eyes

Refractive outcomes after multifocal intraocular lens exchange

Eric J. Kim, MD, Ahmar Sajjad, MD, Ildamaris Montes de Oca, MD, Douglas D. Koch, MD, Li Wang, MD, PhD, Mitchell P. Weikert, MD, Zaina N. Al-Mohtaseb, MD

Purpose: To evaluate the refractive outcomes after multifocal intraocular lens (IOL) exchange.

Setting: Cullen Eye Institute, Baylor College of Medicine, Houston, Texas, USA.

Design: Retrospective case series.

Methods: Patients had multifocal IOL explantation followed by IOL implantation. Outcome measures included type of IOL, surgical indication, corrected distance visual acuity (CDVA), and refractive prediction error.

Results: The study comprised 29 patients (35 eyes). The types of IOLs implanted after multifocal IOL explantation included in-the-bag IOLs (74%), iris-sutured IOLs (6%), sulcus-fixated IOLs with optic capture (9%), sulcus-fixated IOLs without optic capture (9%), and anterior chamber IOLs (3%). The surgical indication for exchange included blurred vision (60%), photic phenomena (57%), photophobia (9%), loss of contrast sensitivity (3%), and multiple complaints (29%). The CDVA was 20/40 or better in 94% of eyes before the exchange and 100% of eyes after the exchange ($P = .12$). The mean refractive prediction error significantly decreased from 0.22 ± 0.81 diopter (D) before the exchange to -0.09 ± 0.53 D after the exchange ($P < .05$). The median absolute refractive prediction error significantly decreased from 0.43 D before the exchange to 0.23 D after the exchange ($P < .05$).

Conclusions: Multifocal IOL exchange can be performed safely with good visual outcomes using different types of IOLs. A lower refractive prediction error and a higher likelihood of 20/40 or better vision can be achieved with the implantation of the second IOL compared with the original multifocal IOL, regardless of the final IOL position.

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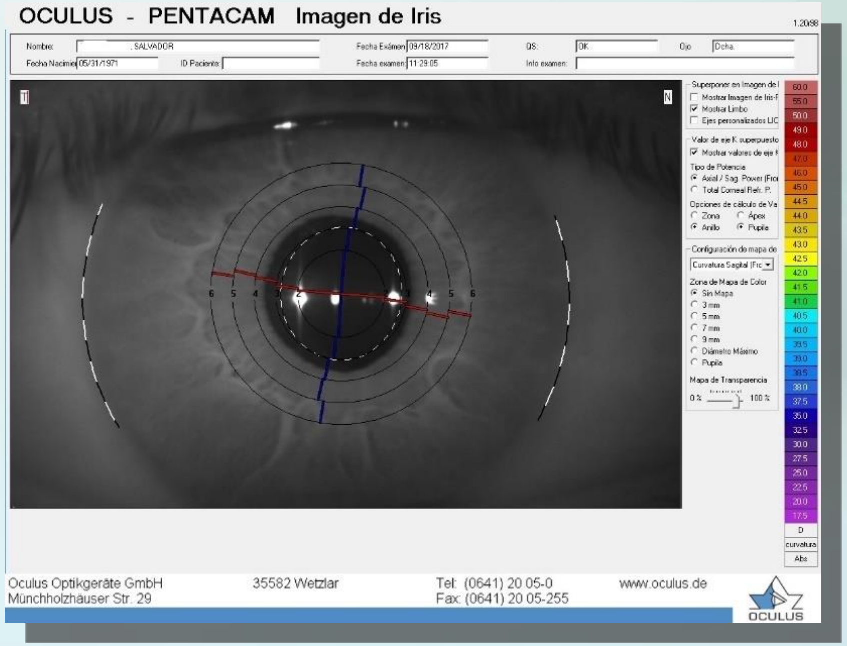
3. Implanting multifocal lenses

During the operation

3.1. Incision

"Be careful: do NOT induce astigmatism"

- Place it in the **correct axis** (ink-marks if needed at the slit lamp)
- Take **WTW** measurements into account
- If no astigmatism, make **anastigmatic** incisions (limbal-short-temporal)
- **Consider simultaneous** LRI or AK, or paired incisions

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ORIGINAL RESEARCH

Surgically induced astigmatism after phacoemulsification by temporal clear corneal and superior clear corneal approach: a comparison

This article was published in the following Dove Press journal:
Clinical Ophthalmology

Archana Sunil Nikose
Dhrubojyoti Saha
Pradnya Mukesh Laddha
Mayuri Patil

Department of Ophthalmology, N.K.P. Salve Institute and LMH, Nagpur, Maharashtra, India

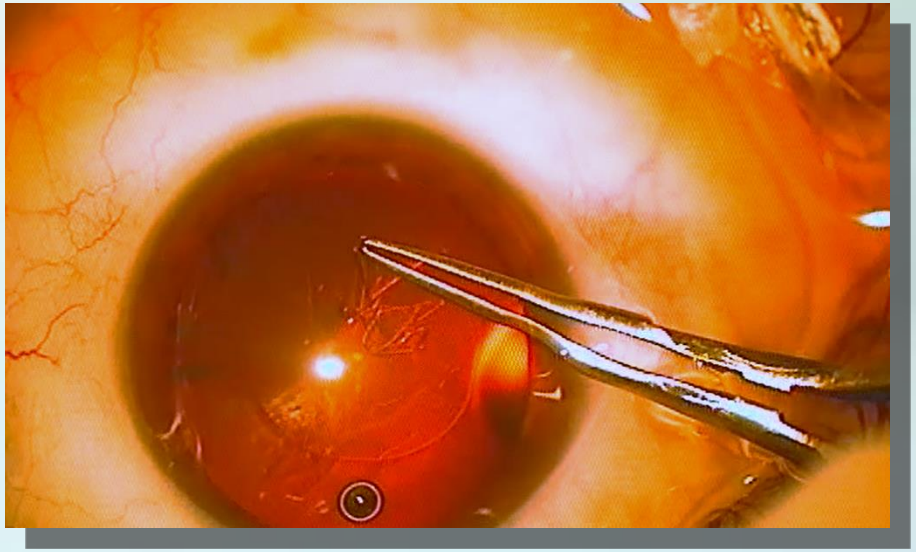
Introduction: Cataract surgery has undergone various advances since it was evolved from ancient couching to the modern phacoemulsification cataract surgery. Surgically induced astigmatism (SIA) remains one of the most common complications. The introduction of sutureless clear corneal incision has gained increasing popularity worldwide because it offers several advantages over the traditional sutured limbal incision and scleral tunnel. A clear corneal incision has the benefit of being bloodless and having an easy approach, but SIA is still a concern.
Purpose: In this study, we evaluated the SIA in clear corneal incisions with temporal approach and superior approach phacoemulsification. Comparisons between the two incisions were done using keratometric readings of preoperative and postoperative refractive status.
...thodology: It was a hospital-based prospective interventional comparative randomized control trial of 261 patients conducted in a rural-based tertiary care center from September 2012

Clinical Ophthalmology 2018:12 65–70

3.2. Capsulorhexis (CCC)

"Should cover the edge of the optics"

- Must be:
  - Perfectly **centred**
  - Perfectly **round**
  - Perfectly **sized**



New device for creating a continuous curvilinear capsulorhexis

Matthew A. Powers, BA, Malik Y. Kahook, MD

PURPOSE: To describe the evolution of a new device to facilitate continuous curvilinear capsulorhexis (CCC) creation.

SETTING: Department of Ophthalmology, University of Colorado School of Medicine, Aurora, Colorado, USA.

DESIGN: Experimental study.

METHODS: Bench-side ex vivo testing of unique prototypes for guidance and assistance of CCC in bovine and human eyes was performed. Five designs were sequentially tested as follows: a flexible circular blade of nickel-titanium alloy (nitinol), a flexible nitinol guide wire, a flexible elastomeric suction device, a combination approach of a nitinol guide wire and flexible silicone ring, and a freestanding micropatterned silicone ring.

RESULTS: The first 3 designs were not amenable to insertion through a sub-2.4 mm corneal incision and failed to maintain adequate downward force to cut the capsule and/or prevent radial tears. The fourth design was successfully inserted through a 2.4 mm incision and maintained adequate downward pressure and contact to guide a manual CCC without radial tears. The final design was insertable through a 2.4 mm incision and exhibited self-adhesive characteristics after placement on the anterior capsule of an ophthalmic viscosurgical device–filled anterior chamber.

CONCLUSIONS: Given the steep learning curve of manual capsulorhexis and the high cost of capsulotomy-assistive devices, such as the femtosecond laser, an alternative approach for creating a CCC is desirable. Performance of a highly precise manual CCC through a small incision using a medical-grade silicone device with an adhesive micropatterned design is a viable and cost-effective option for use in cataract surgery across a wide range of user experience.

Financial Disclosure: All authors are named as the inventors in a patent filed by the University of Colorado covering the details in this report.

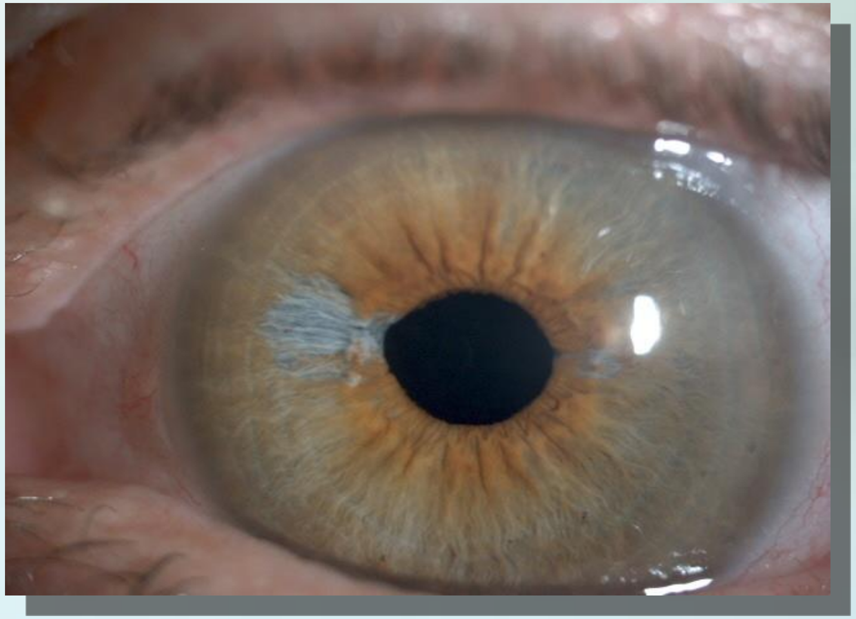
J Cataract Refract Surg 2014; 40:822–830 © 2014 ASCRS and ESCRS

3.3. Iris

"Take care of the iris"

ATTENTION to the IFIS

- Don't overstretch the pupil, consider using iris hooks if IFIS or small pupils
- Respect the iris with the phaco tip
- Avoid iris herniation
- Avoid postoperative high intraocular pressure



Effect of phenylephrine 1.0%–ketorolac 0.3% injection on tamsulosin-associated intraoperative floppy-iris syndrome

Steven M. Silverstein, MD, Viren K. Rana, MS, Robert Stephens, PhD, Larry Segars, PharmD, DrPH, Joseph Pankratz, MS, Shivani Rana, Mark S. Juzych, MD, MHSA, Nissiri Nariman, MD, MPH

Purpose: To determine the effect of phenylephrine 1.0%–ketorolac 0.3% injection (Omidria) on different components of intraoperative floppy-iris syndrome (IFIS).

Setting: Silverstein Eye Centers, Kansas City, Missouri, USA.

Design: Prospective case series.

Methods: Men treated with tamsulosin having standard cataract extraction surgery were placed in a treatment group that received phenylephrine 1.0%–ketorolac 0.3% injection in the irrigation solution and a control group) that received basic saline solution. Every procedure was video recorded using an endocyclophotocoagulation (ECP) probe and microscopic view. Pupil dilation, iris billowing, and iris prolapse were measured using a micrometer, ECP recording grading scale, and microscopic recordings, respectively.

Results: Each group (treatment and control) comprised 25 eyes of 25 patients. Although both groups had a decrease in pupil diameter before and after cataract extraction and before cataract extraction and after intraocular lens implantation, the changes were statistically significantly greater in the treatment group. Iris prolapse occurred in 3 patients (12.0%) in the treatment group and 14 patients (56.0%) in the control group ($P < .001$). Stage 3 (severe) pupil billowing occurred in 1 eye (4.0%) in the treatment group and 10 eyes (40.0%) in the control group ($P < .001$).

Conclusions: The use of the phenylephrine 1.0%–ketorolac 0.3% injection combination added to the irrigating solution during cataract surgery in patients at risk for IFIS led to significantly better prevention of miosis, less pupil billowing, and a reduced incidence of iris prolapse. A new grading scale for intraoperative iris abnormalities might be used for future evaluation.

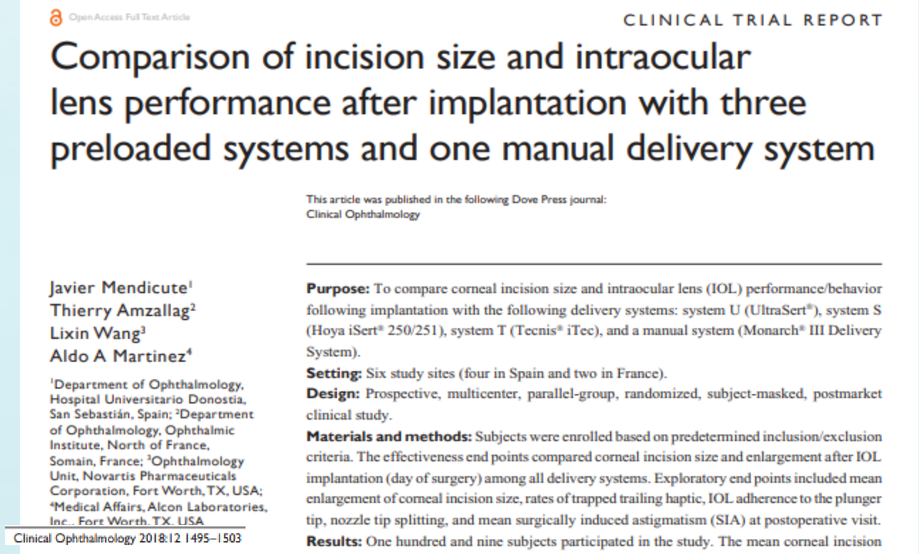
J Cataract Refract Surg 2018; 44:1103–1108 © 2018 ASCRS and ESCRS

3.4. IOL implant

"Implanting in-the-bag"

→ Caution

- Broken/very weak zonulae
- Broken/very asymmetric capsulorhexis
- Broken lens haptic
- Capsular rupture with vitreous loss



Open Access Full Text Article

CLINICAL TRIAL REPORT

Comparison of incision size and intraocular lens performance after implantation with three preloaded systems and one manual delivery system

This article was published in the following Dove Press journal:
Clinical Ophthalmology

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Clinical Ophthalmology 2018:12 1495–1503

Purpose: To compare corneal incision size and intraocular lens (IOL) performance/behavior following implantation with the following delivery systems: system U (UltraSert®), system S (Hoya iSert® 250/251), system T (Tecnis® iTec), and a manual system (Monarch® III Delivery System).
Setting: Six study sites (four in Spain and two in France).
Design: Prospective, multicenter, parallel-group, randomized, subject-masked, postmarket clinical study.
Materials and methods: Subjects were enrolled based on predetermined inclusion/exclusion criteria. The effectiveness end points compared corneal incision size and enlargement after IOL implantation (day of surgery) among all delivery systems. Exploratory end points included mean enlargement of corneal incision size, rates of trapped trailing haptic, IOL adherence to the plunger tip, nozzle tip splitting, and mean surgically induced astigmatism (SIA) at postoperative visit.
Results: One hundred and nine subjects participated in the study. The mean corneal incision

4. Post-operative management

Neuroadaptation !

No complications, good result → **Happy patient**

Problems:

1. ***Lens decentration***
2. ***Refractive residual error***
3. ***Dysphotopsias***
4. ***Blurred vision***
5. ***Dry eye***
6. ***Posterior capsule opacity***

→ ***Unhappy patient***

Dissatisfaction after multifocal intraocular lens implantation

Maria A. Woodward, MD, J. Bradley Randleman, MD, R. Doyle Stulting, MD, PhD

PURPOSE: To analyze the reasons for patient dissatisfaction after phacoemulsification with multifocal intraocular lens (IOL) implantation and the outcomes after intervention.

SETTING: Emory Eye Center, Atlanta, Georgia, USA.

METHODS: This retrospective review comprised eyes of patients dissatisfied with visual outcomes after multifocal IOL implantation. Outcomes analyzed included type of visual complaint, treatment modality for each complaint, and degree of clinical improvement after intervention.

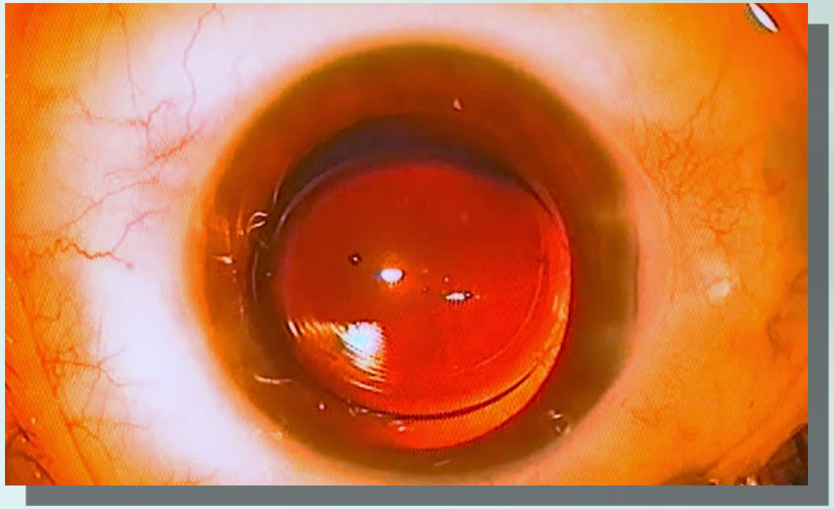
RESULTS: Thirty-two patients (43 eyes) reported unwanted visual symptoms after multifocal IOL implantation, including in 28 eyes (65%) with an AcrySof ReSTOR IOL and 15 (35%) with a ReZoom IOL. Thirty patients (41 eyes) reported blurred vision, 15 (18 eyes) reported photic phenomena, and 13 (16 eyes) reported both. Causes of blurred vision included ametropia (12 eyes, 29%), dry eye syndrome (6 eyes, 15%), posterior capsule opacification (PCO) (22 eyes, 54%), and unexplained etiology (1 eye, 2%). Causes of photic phenomena included IOL decentration (2 eyes, 12%), retained lens fragment (1 eye, 6%), PCO (12 eyes, 66%), dry-eye syndrome (1 eye, 2%), and unexplained etiology (2 eyes, 11%). Photic phenomena attributed to PCO also caused blurred vision. Thirty-five eyes (81%) had improvement with conservative treatment. Five eyes (12%) did not have improvement despite treatment combinations. Three eyes (7%) required IOL exchange.

CONCLUSIONS: Complaints of blurred vision and photic phenomena after multifocal IOL implantation were effectively managed with appropriate treatment. Few eyes (7%) required IOL exchange. Neodymium:YAG capsulotomy should be delayed until it has been determined that IOL exchange will not be necessary.

J Cataract Refract Surg 2009; 35:992–997 © 2009 ASCRS and ESCRS

5. Our study (methods)

5.1. Inclusion criteria



- **Prospective study**
  - Multicenter , Clinica Baviera, Spain
  - Multi surgeon
  - Performed in accordance with the principles of the Declaration of Helsinki
  - Approval from the Clınica Baviera Medico-Legal Committee
  - Information and Informed Consent

- Age < 70
- Refraction pre-op: sph. –6,00 to +6,00 D, corneal astigmatism < 2,50 D
- **Bilateral** implant
- **RLE or cataract** with **phacoemulsification**
- Target **emmetropia** in both eyes
- Follow-up ≥ 1 month

- **Exclusion criteria:** amblyopia, previous corneal surgery, clinically significant corneal endothelial dystrophy, history of corneal disease, history of retinal detachment, neuro-ophthalmic disease, pregnancy, and intraoperative or postoperative complications

5.2. Pre-op evaluation (*exaustive)*

- **Refractive status**
- Uncorrected distance visual acuity (UDVA) (**Snellen test**)
- Corrected distance visual acuity (CDVA)
- Uncorrected intermediate visual acuity (UIVA) at 80 cm (**Jaeger test**)
- Uncorrected near visual acuity (UNVA) at 40 cm (visual acuities were tested under photopic conditions, at approximately 85 cd/m2) (Jaeger test)

- Corneal topography
- Pupillometry
- Ocular surface (TBUT and Schirmer test)
- Slit-lamp and eye fundus evaluation
- Endothelial cell count analysis
- Optical biometry by partial coherence interferometry (PCI)
- OCT macular

5.3. Post-op evaluation

"Follow-up according to protocol"

- Follow-up assessment within 24 hours of the surgery, and then 5–7 days, 1 month, and 3 months postoperatively
- Ocular status and IOL position
- Visual acuity and refractive outcomes
  - UDVA mono & binocular
  - CDVA mono & binocular
  - UIVA mono & binocular
  - UNVA mono & binocular
  - CDIVA mono & binocular
  - CDNVA mono & binocular
- Contrast Sensitivity
- Defocus curve
- Aberrometry

5.4. Satisfaction evaluation

- Patient satisfaction data derived from the Clínica Baviera Satisfaction Questionnaire

Validation of the Spanish Catquest-9SF in patients with a monofocal or trifocal intraocular lens

Mats Lundström, MD, PhD, Fernando Llovet, MD, PhD, Andrea Llovet, MD, Mercedes Martinez del Pozo, MD, Blas Mompean, MD, José-Vincente González, OD, Konrad Pesudovs, PhD

PURPOSE: To validate the Spanish Catquest-9SF and study patient-reported visual function after implantation of a trifocal versus a monofocal intraocular lens (IOL).

SETTING: Clinica Baviera, Valencia and Madrid, Spain.

DESIGN: Prospective case series.

METHODS: The Catquest-9SF was translated from English to Spanish according to a standard procedure. The Spanish version was validated through Rasch analysis. Patients completed the Catquest-9SF before cataract surgery and 3 months after the surgery. The change in patient-reported visual function caused by surgery, the level of achieved visual function, and satisfaction with vision after surgery were assessed for bilaterally implanted trifocal IOLs versus monofocal IOLs.

RESULTS: The Spanish Catquest-9SF showed very good psychometric properties. Patient-reported achieved visual function was significantly better for those with a trifocal IOL than for those with a monofocal IOL ($P < .001$). This was also true when the groups were matched for age and ocular comorbidity ($P = .006$). In multivariate analyses of all cases and matched cases (the same age and no comorbidity), the reported visual function was significantly better with trifocal IOLs than with monofocal IOLs ($P = .001$ and $P = .008$, respectively). There was greater improvement after trifocal IOL implantation in the matched cases, although not significant ($P = .103$).

CONCLUSIONS: Results show the Spanish version of Catquest-9SF is a valid patient questionnaire with good psychometric properties. Patients with a trifocal IOL implanted bilaterally reported better visual function than those with a monofocal IOL implanted bilaterally. The change in visual function after surgery was also greater in patients with a trifocal IOL.

Financial Disclosure: None of the authors has a financial or proprietary interest in any material or method mentioned.

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6. Our study (preliminary results)

6.1. Record and analysis

- ***The data is obtained from the central computerized medical file system***, Clínica Baviera

- Routine pre-op and post-op outcomes and complications were collected and analyzed

- Results are expressed as the mean ± standard deviation. A P value of less than .05 was considered statistically significant

- Statistical calculations were performed using R software version 3.2.1. Preoperative outcomes were compared with postoperative results using a paired test

6.2. Pre-operative Data

6.2.1. Pre-operative Data *(average age)*

Variable	N	Min	Max	Mean	SD	Median	Q25	Q75
Age (years)	74	36	70	**56.84**	7.48	56	52	62

6.2.2. Pre-operative Data *(refraction)*

Variable	N	Min	Max	Mean	SD	Median	Q25	Q75
Sphere (D)	148	-6.25	7	**1.51**	2.5	1.75	0.5	3
Cylinder (D)	148	-2.5	0	**-0.6**	0.49	-0.5	-0.75	-0.25
Spherical Equivalent (D)	148	-6.5	6.62	**1.22**	2.52	1.44	0.31	2.72

6.2.3. Pre-operative Data ***(AL, IOL power)***

Variable	N	Min	Max	Mean	SD	Median	Q25	Q75
AL (mm)	148	20.29	26.43	**22.97**	1.16	22.81	22.19	23.68
IOL power (D)	148	12.5	29.5	**22.92**	3.44	23	20.88	25

6.2.4. Pre-operative Data *(vision)*

Variable (logMAR)	N	Min	Max	Mean	SD	Median	Q25	Q75
UNVA (monocular)	148	0	0,7	**0,33**	0,25	0,15	0,15	0,52
UIVA (monocular)	148	0,7	0,7	**0,7**		0,7	0,7	0,7
UDVA (monocular)	148	0	1,7	**0,63**	0,47	0,52	0,3	0,8
CDVA (monocular)	148	-0,03	1,3	**0,06**	0,15	0,01	0	0,05

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6.2.5. Pre-operative Data *(vision)*

Variable (logMAR)	N	Min	Max	Mean	SD	Median	Q25	Q75
UNVA Binocular	74	0	0,7	**0,24**	0,23	0,15	0,15	0,3
UIVA Binocular	74	0,3	0,7	**0,5**	0,28	0,5	0,4	0,6
UDVA Binocular	74	0	1,7	**0,46**	0,41	0,4	0,21	0,7
CDVA Binocular	74	-0,08	0,52	**0,03**	0,09	0	0	0,01

6.3. Post-operative Data

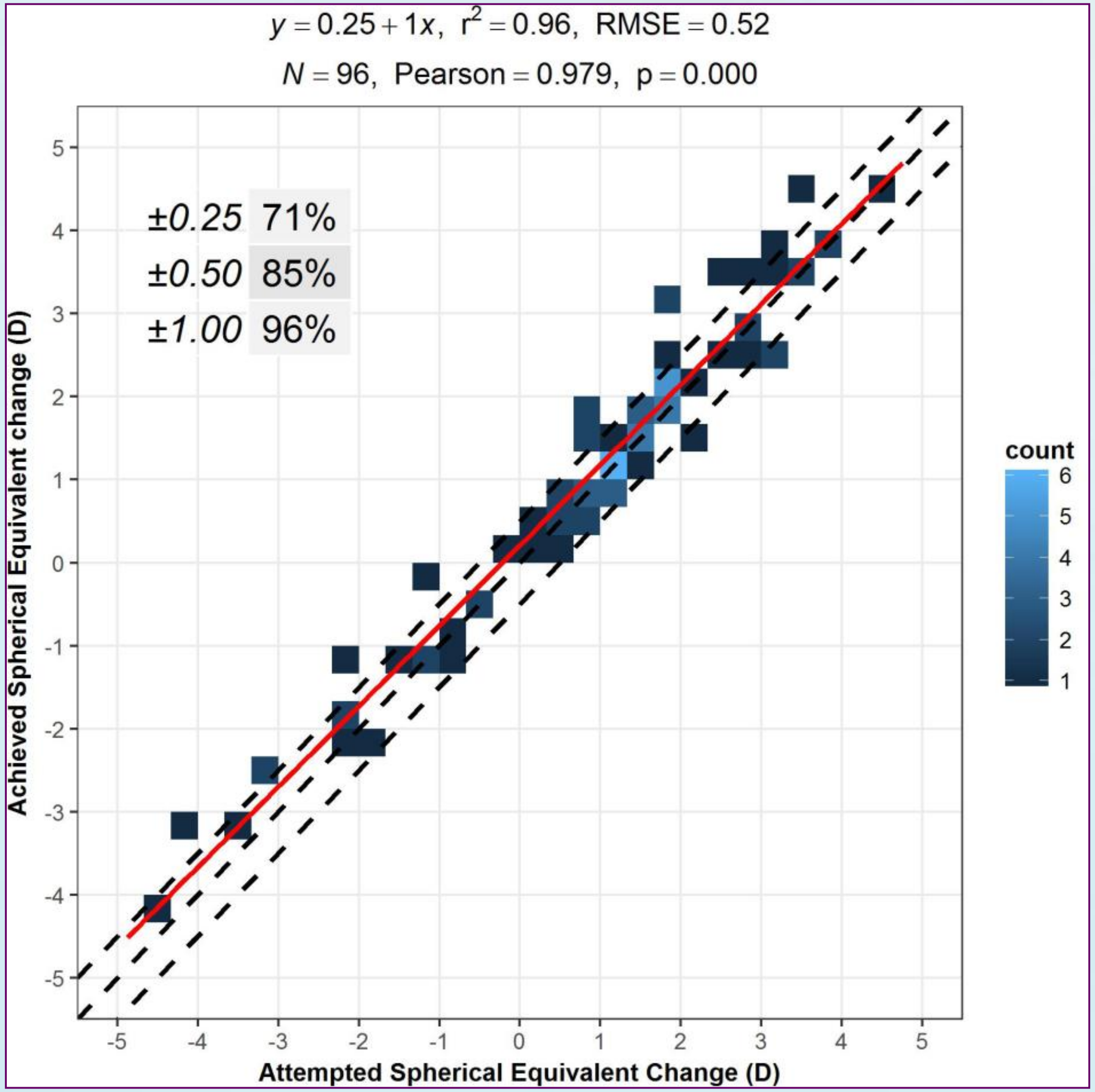
Visual and refractive results after surgery

6.3.1. Post-operative Data *(refractive)*

Variable	N	Min	Max	Mean	SD	Median	Q25	Q75
Sphere (D)	96	-2,5	1	**-0,06**	0,51	0	-0,25	0,25
Cylinder (D)	96	-1,75	0	**-0,38**	0,38	-0,25	-0,75	0
Spherical Equivalent (D)	96	-2,88	0,75	**-0,25**	0,52	-0,12	-0,5	0

Final spherical equivalent next to zero

6.3.2. Post-operative Data (**Spherical Equivalent**)



±0.25	71%
±0.50	85%
±1.00	96%

96 % the SE in plus minus one diopter

6.3.3. Post-operative Data *(visual acuity monocular)*

Monocular (n 96)	Min	Max	Mean	SD	Median	Q25	Q75
UNVA (LogMAR)	0	0,52	**0,12**	0,09	0,1	0,1	0,15
UIVA (LogMAR)	0	0,52	**0,23**	0,14	0,15	0,15	0,3
UDVA (LogMAR)	0	0,7	**0,06**	0,1	0,04	0	0,08
CDVA (LogMAR)	0	0,1	**0,02**	0,03	0	0	0,02

Excelent results in monocular visual acuity in the tree distances

6.3.4. Postoperative Data *(visual acuity binocular)*

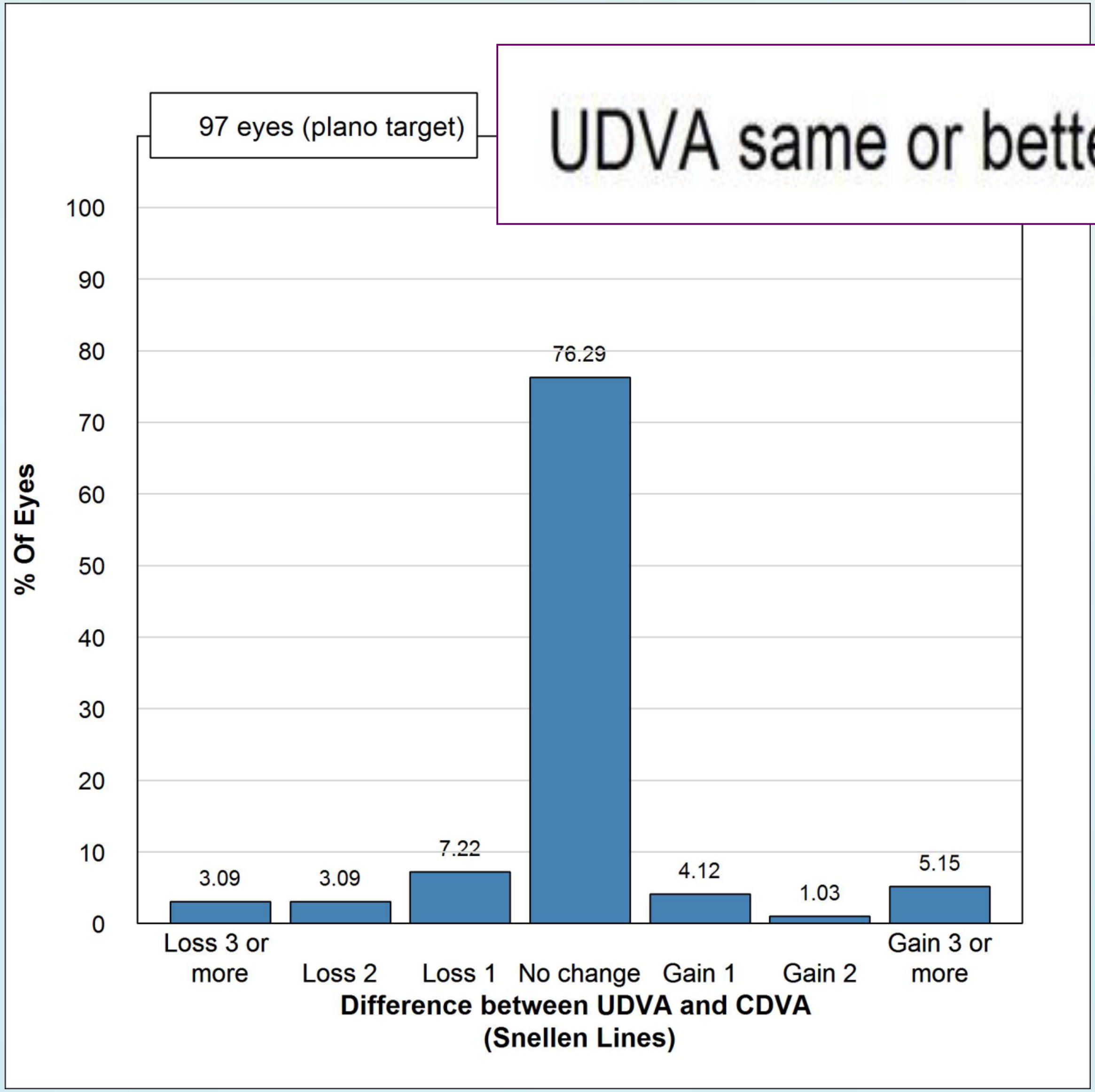
Binocular	Min	Max	Mean	SD	Median	Q25	Q75
UNVA (LogMAR)	0	0,15	**0,07**	0,06	0,1	0	0,1
UIVA (LogMAR)	0,1	0,52	**0,21**	0,13	0,15	0,15	0,3
UDVA (LogMAR)	-0,08	0,15	**0,01**	0,03	0	0	0,02
CDVA (LogMAR)	-0,08	0,05	**0**	0,02	0	0	0

6.3.4. Post-operative Data *(Efficacy and safety monocular)*

Monocular (n 96)	Min	Max	Mean	SD	Median	Q25	Q75
Efficacy	0,2	18	**1,22**	1,79	1	0,92	1,04
Safety	0,82	19	**1,34**	1,9	1	1	1,07

Excellent efficacy and safety indexes

6.3.6. Post-operative Data (efficacy)



UDVA same or better than CDVA:86.60%

High eficcacy results

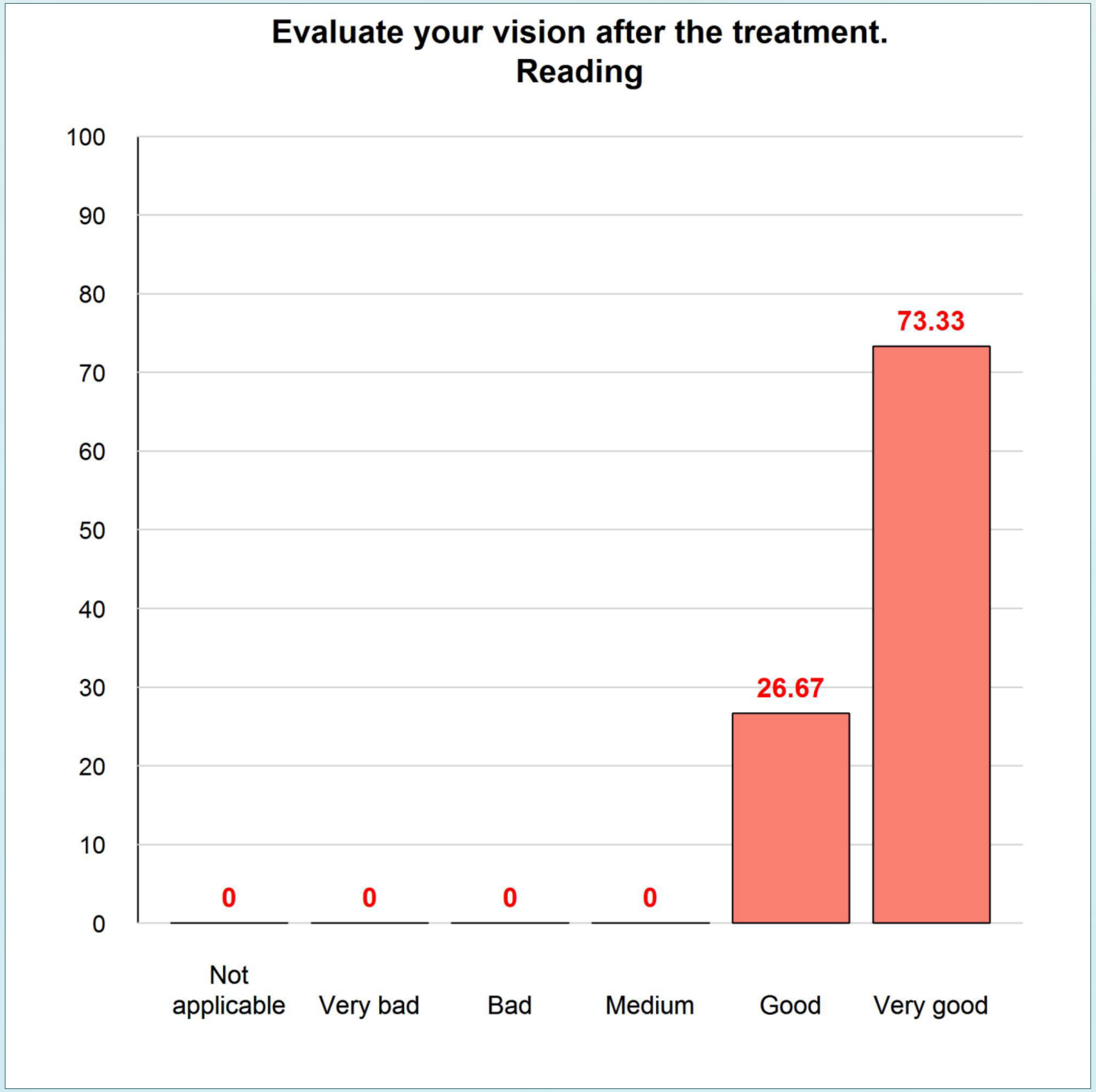
6.3.7. Post-operative Data (safety)

High safety results

6.4. Satisfaction Data

Subjective results

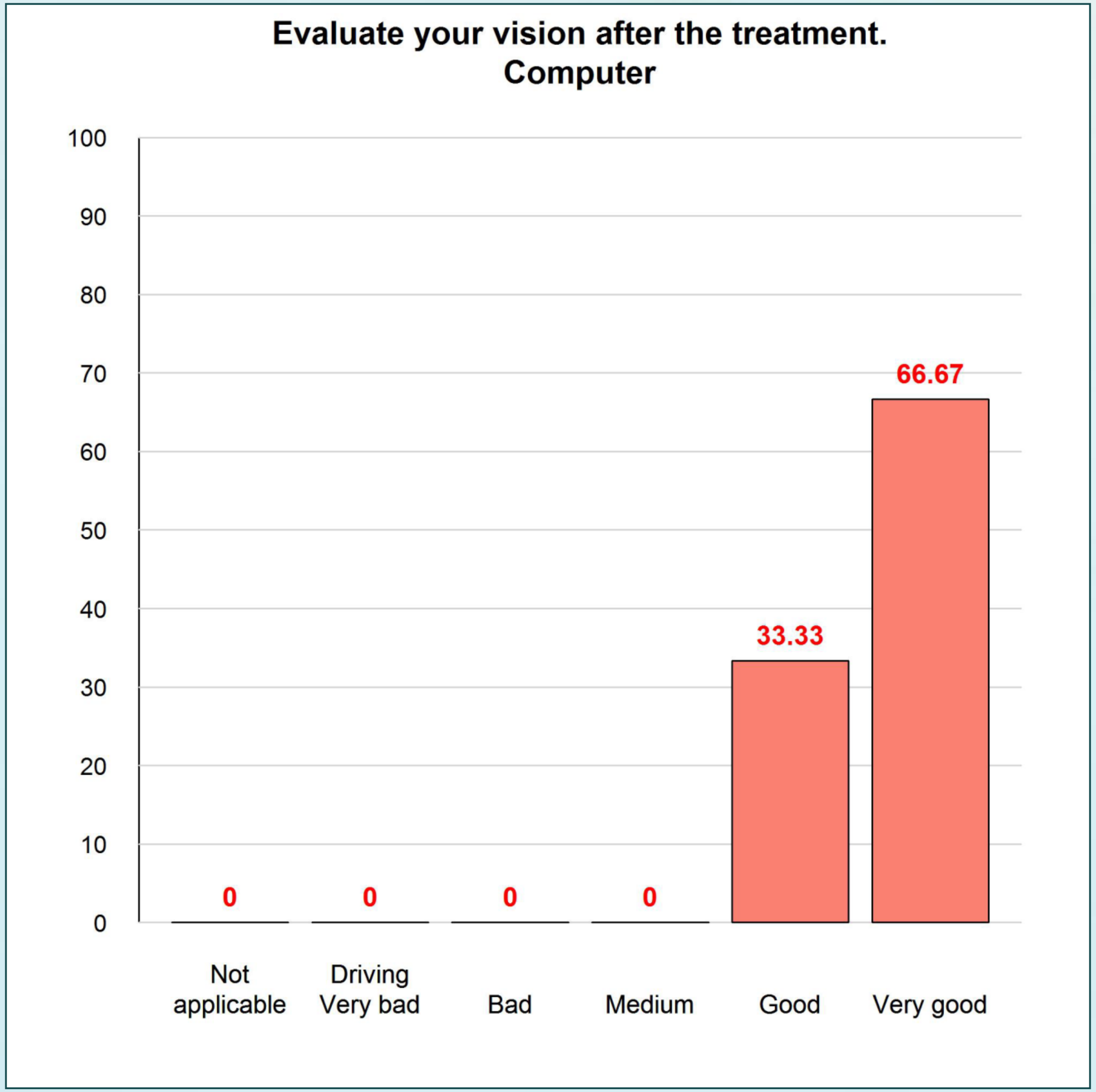
6.4.1. Satisfaction Data (reading)



Very good:	**73.33** %
Good:	**26.67** %

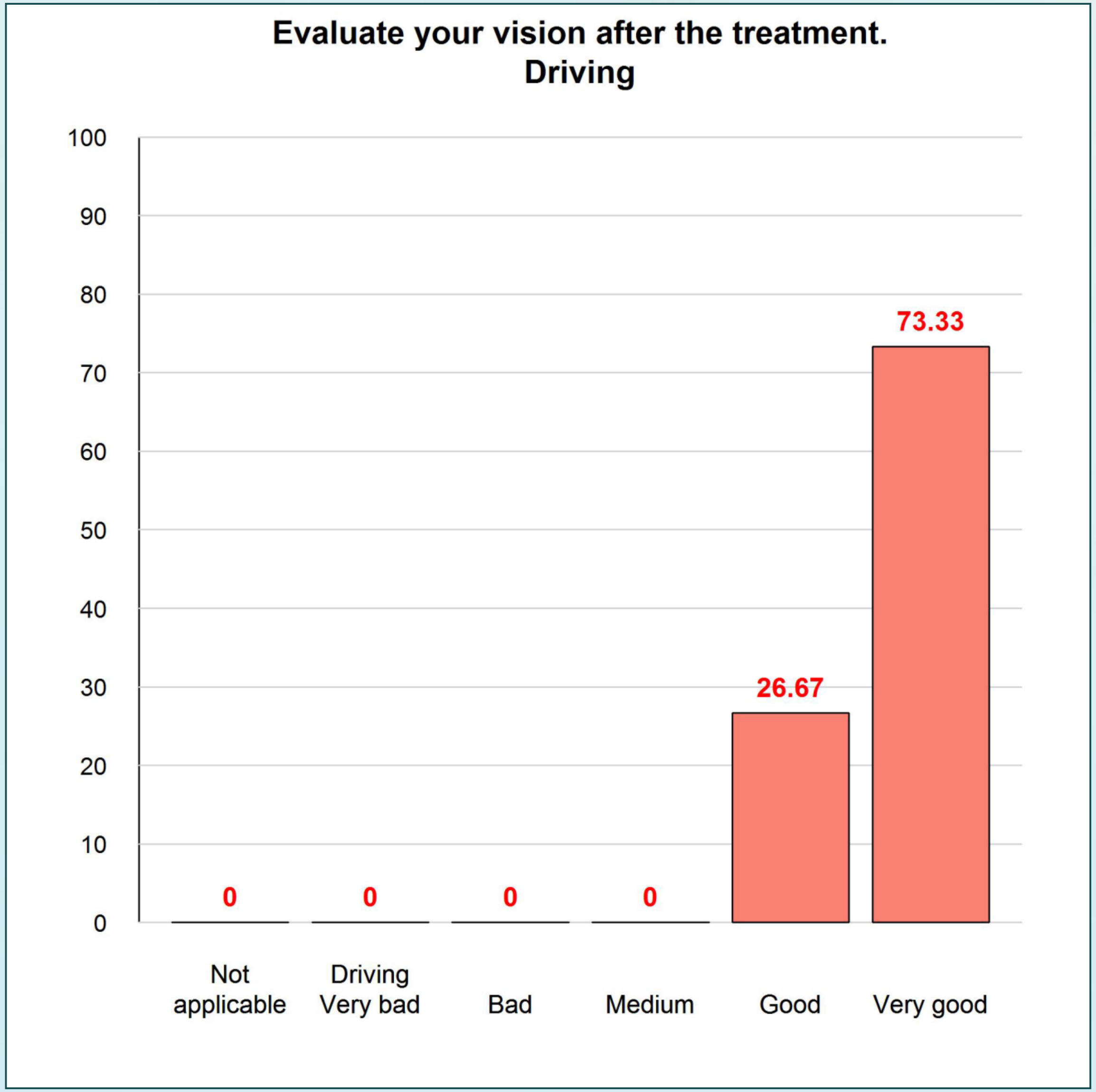
All the pacients reported reading well or very well

6.4.2. Satisfaction Data (computer)



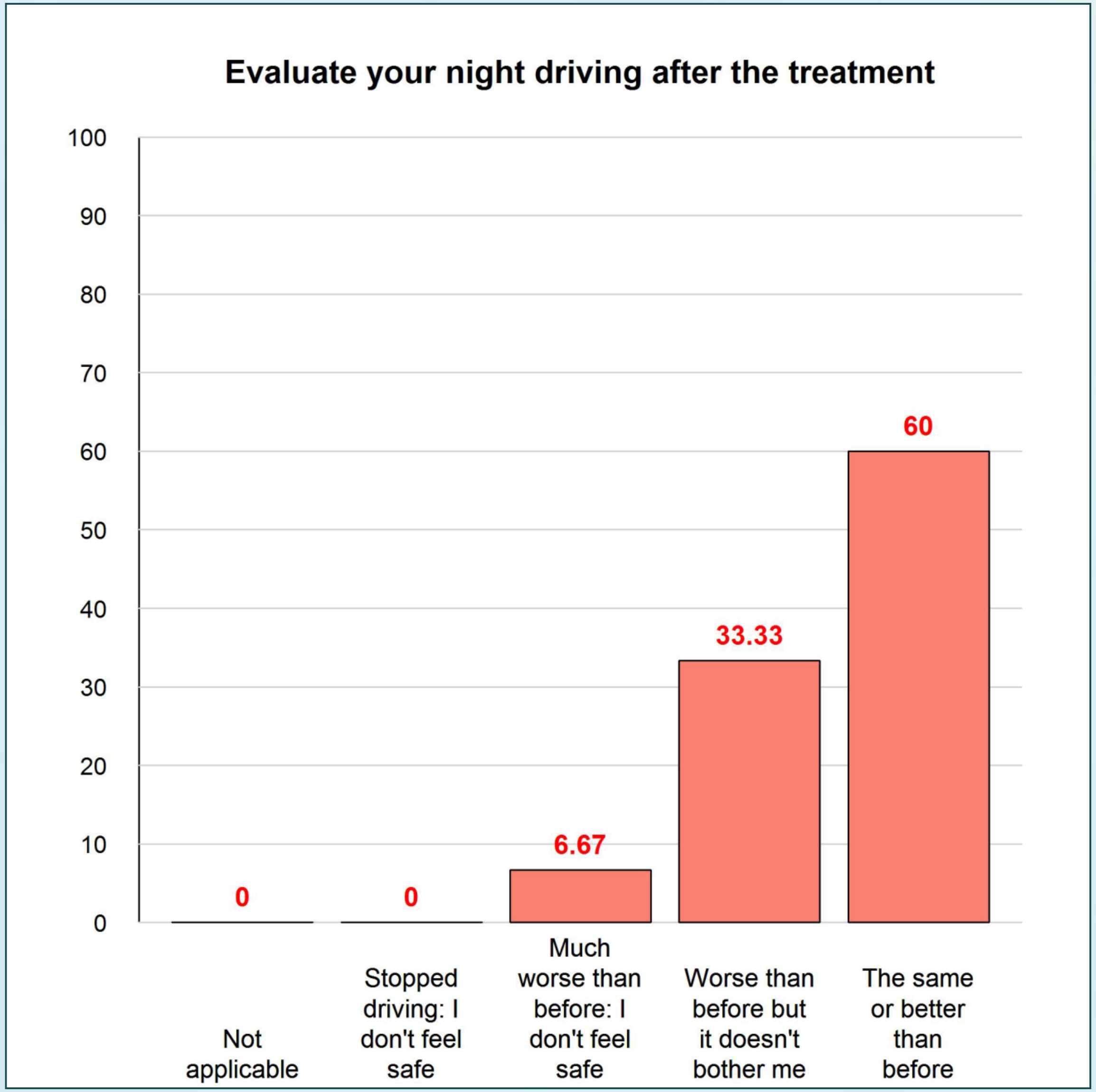
Very good: **66.67** %
Good: **33.33** %

6.4.3. Satisfaction Data (**driving**)



Very good: **73.33** %
Good: **26.67** %

6.4.4. Satisfaction Data (<u>night driving</u>)

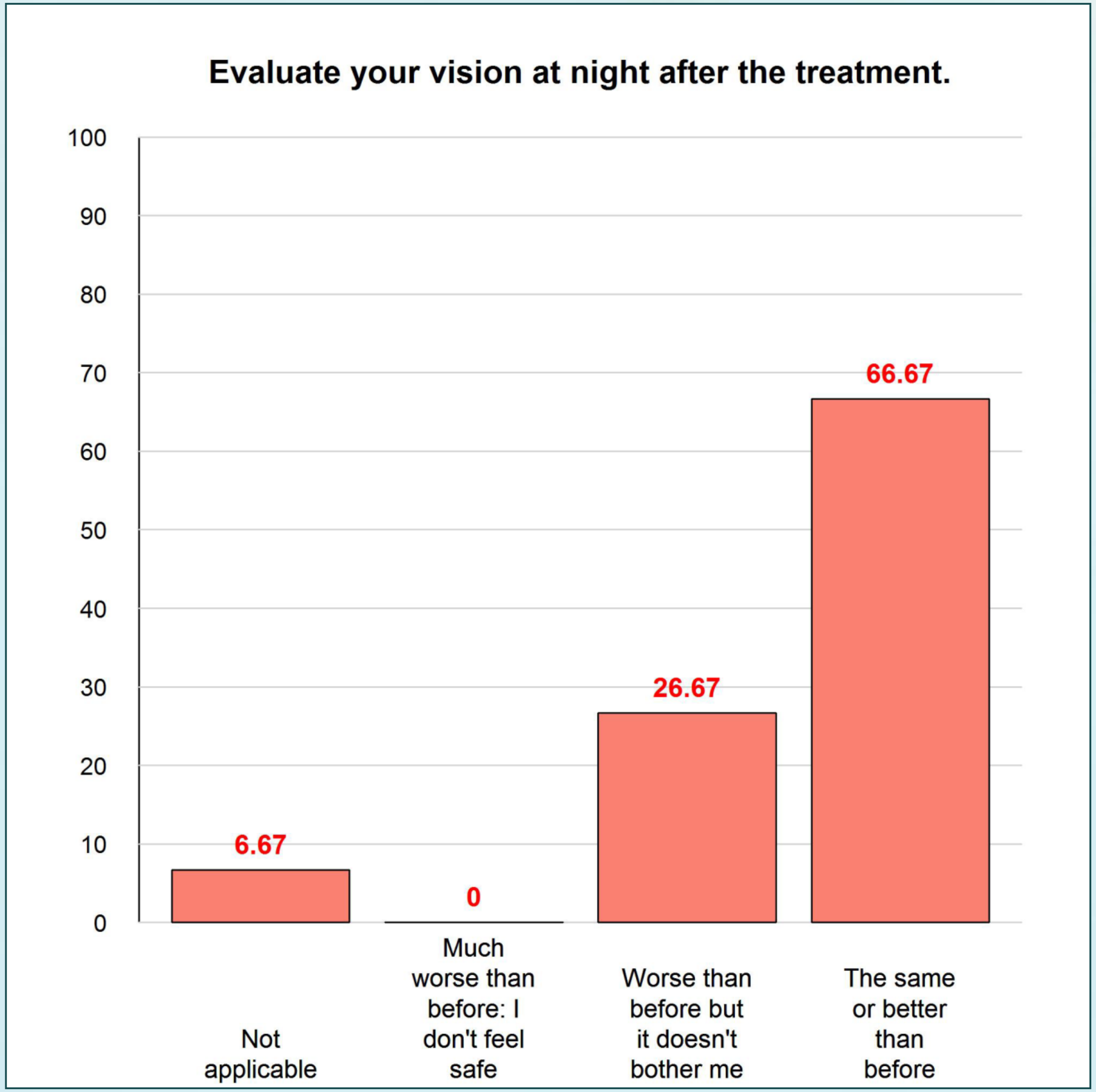


Insecurity: 6.67 %
Stopped: 0 %

A high percentage of patients felt driving at night was the same or better than before surgery

No patient stopped driving

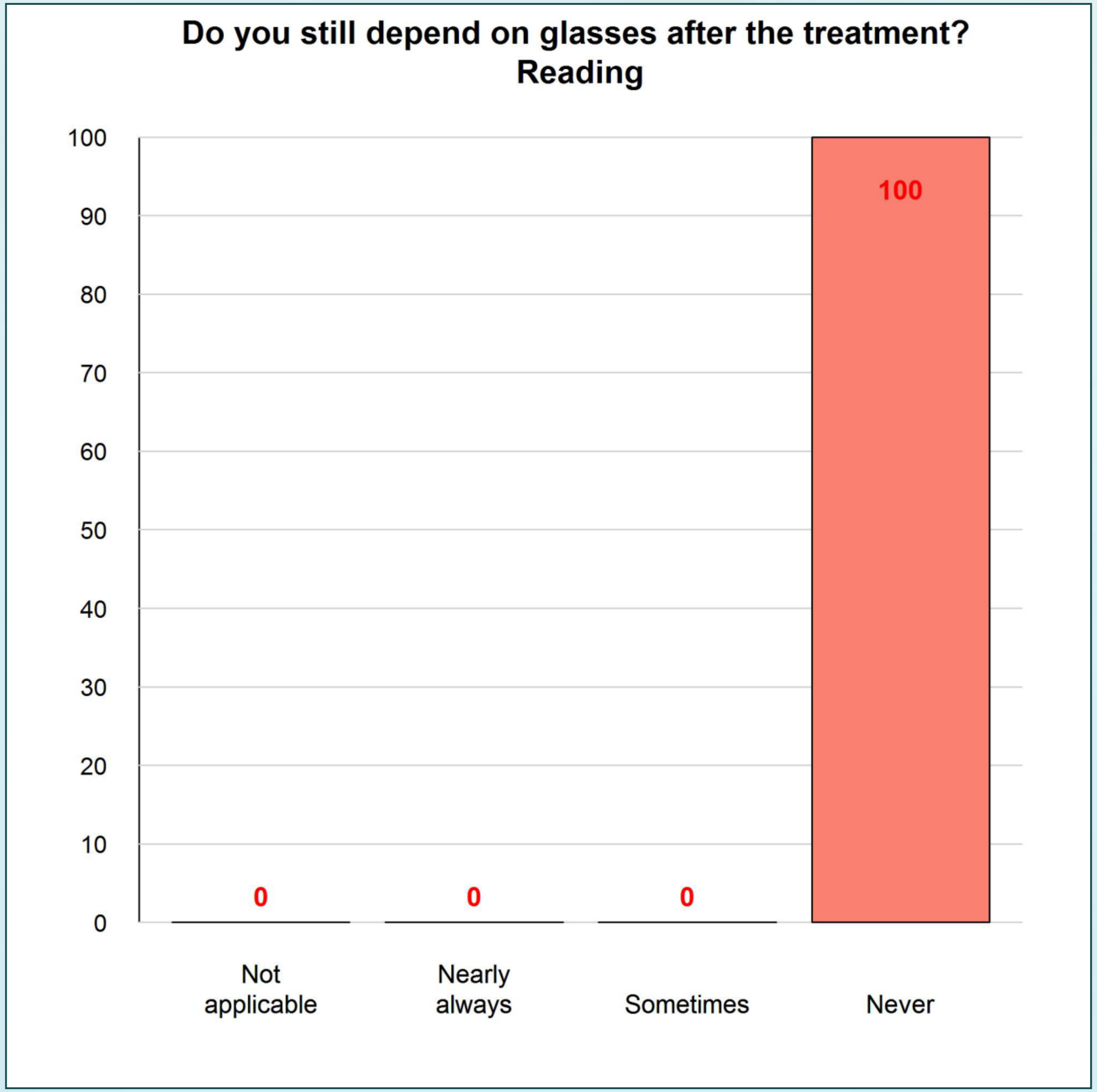
6.4.5. Satisfaction Data (<u>night vision</u>)



Same or better
66.67 %

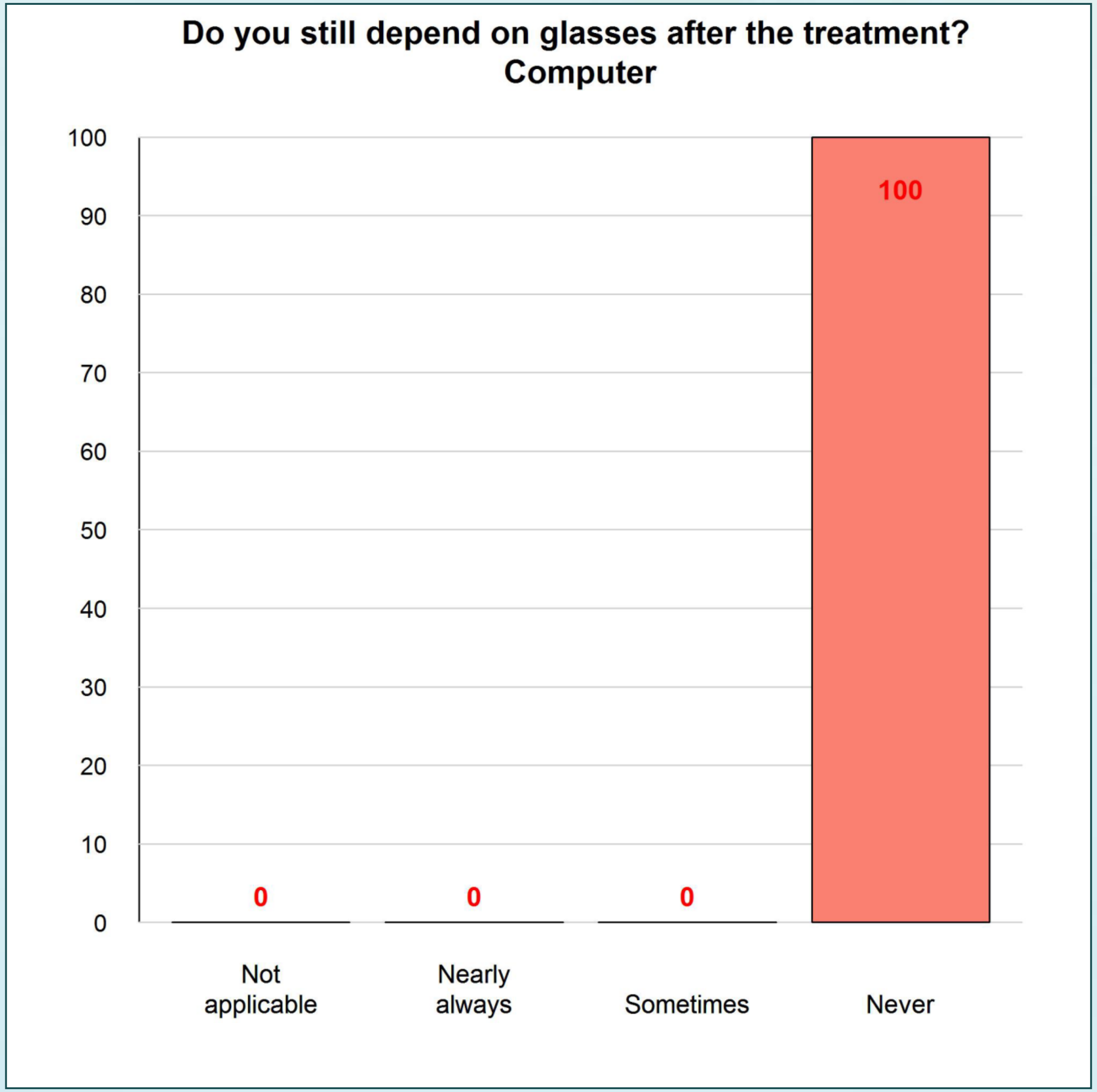
A high percentage of patients had equal or better night vision

6.4.6. Satisfaction Data (**depend on glasses: reading)**



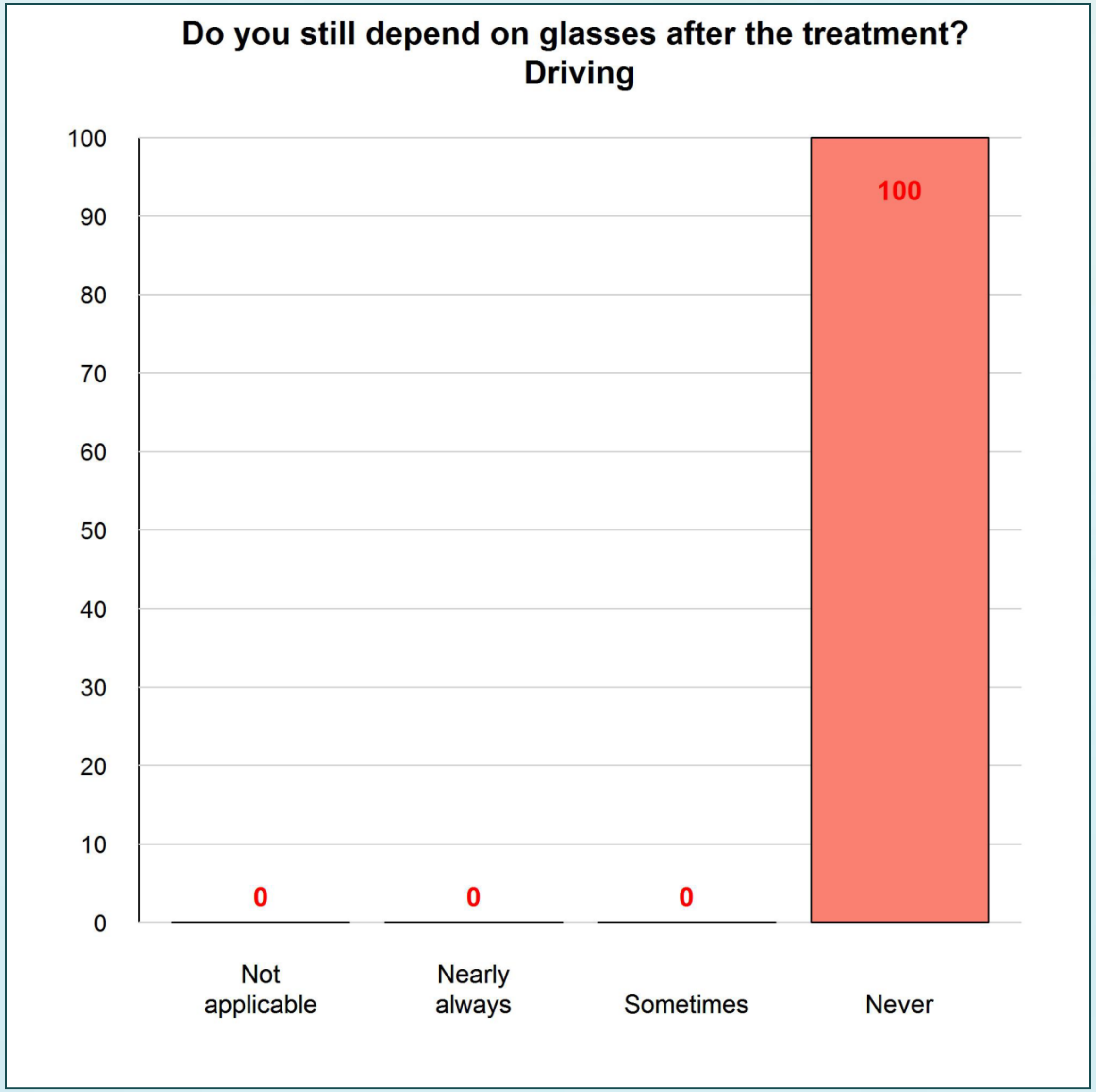
None of the patients needed glasses for reading

6.4.6. Satisfaction Data (depend on glasses: computer)

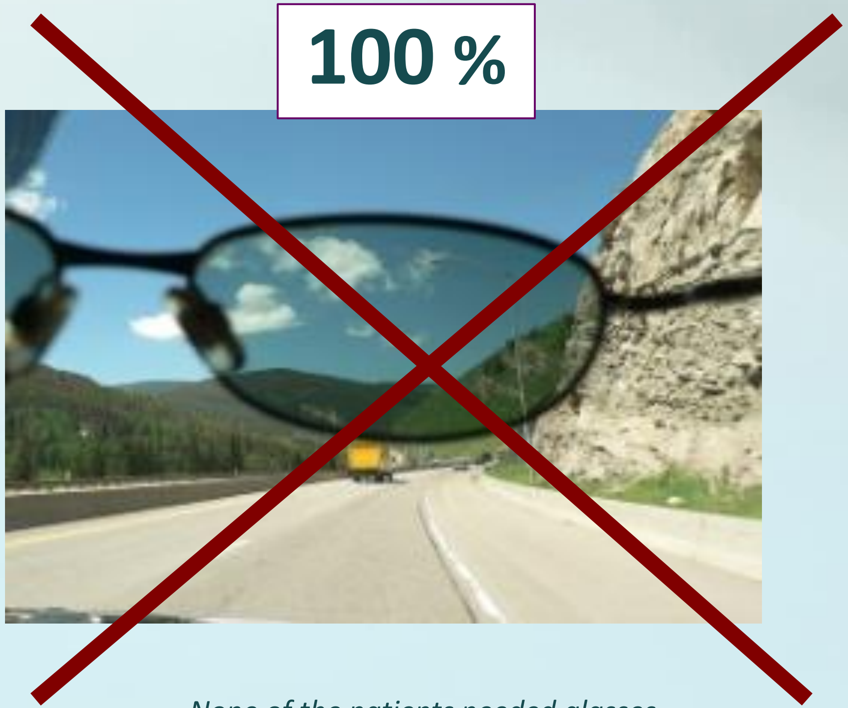


None of the patients depend on glasses for computer

6.4.6. Satisfaction Data (**depend on glasses: driving**)

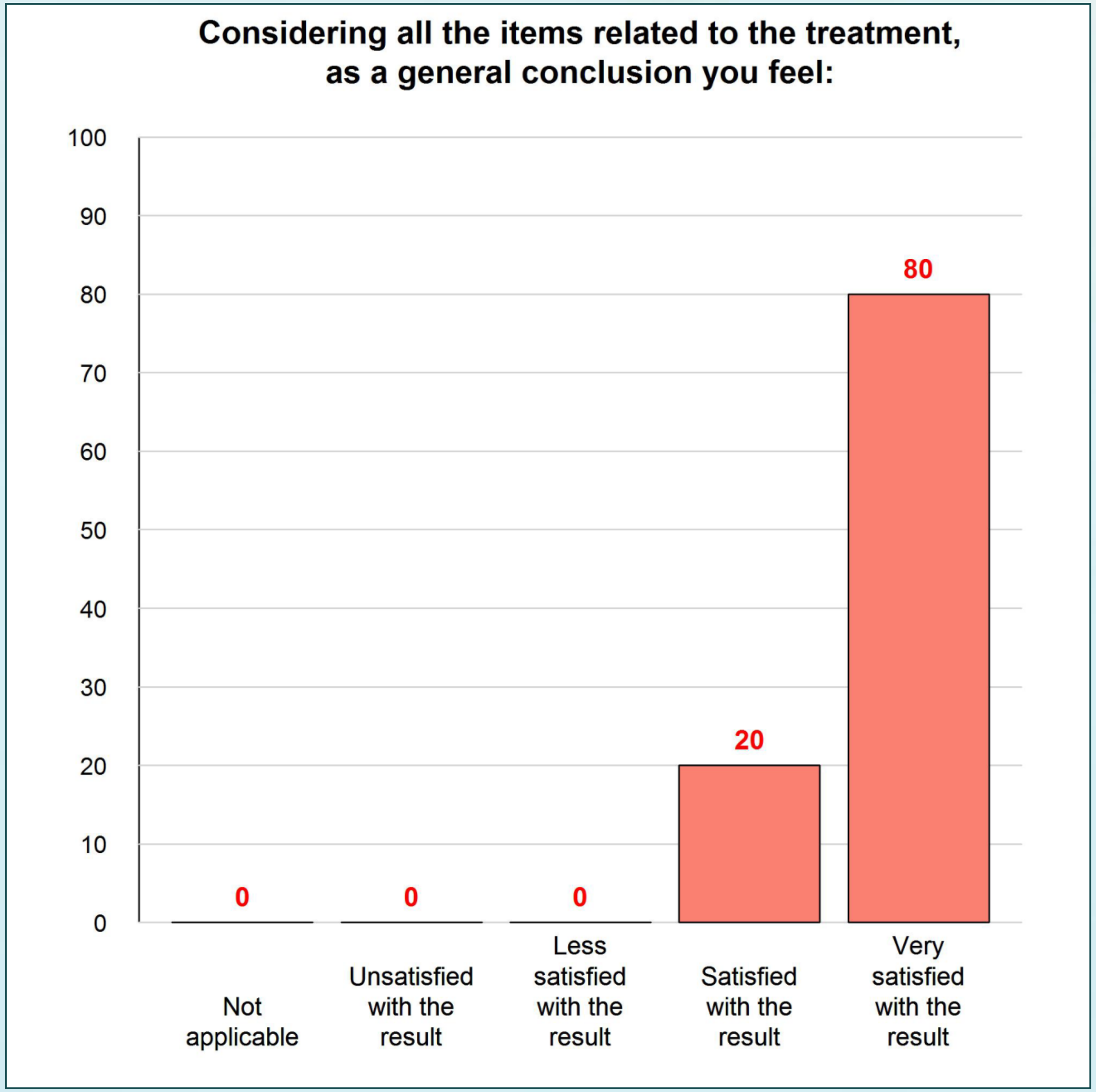


100 %



None of the patients needed glasses for driving

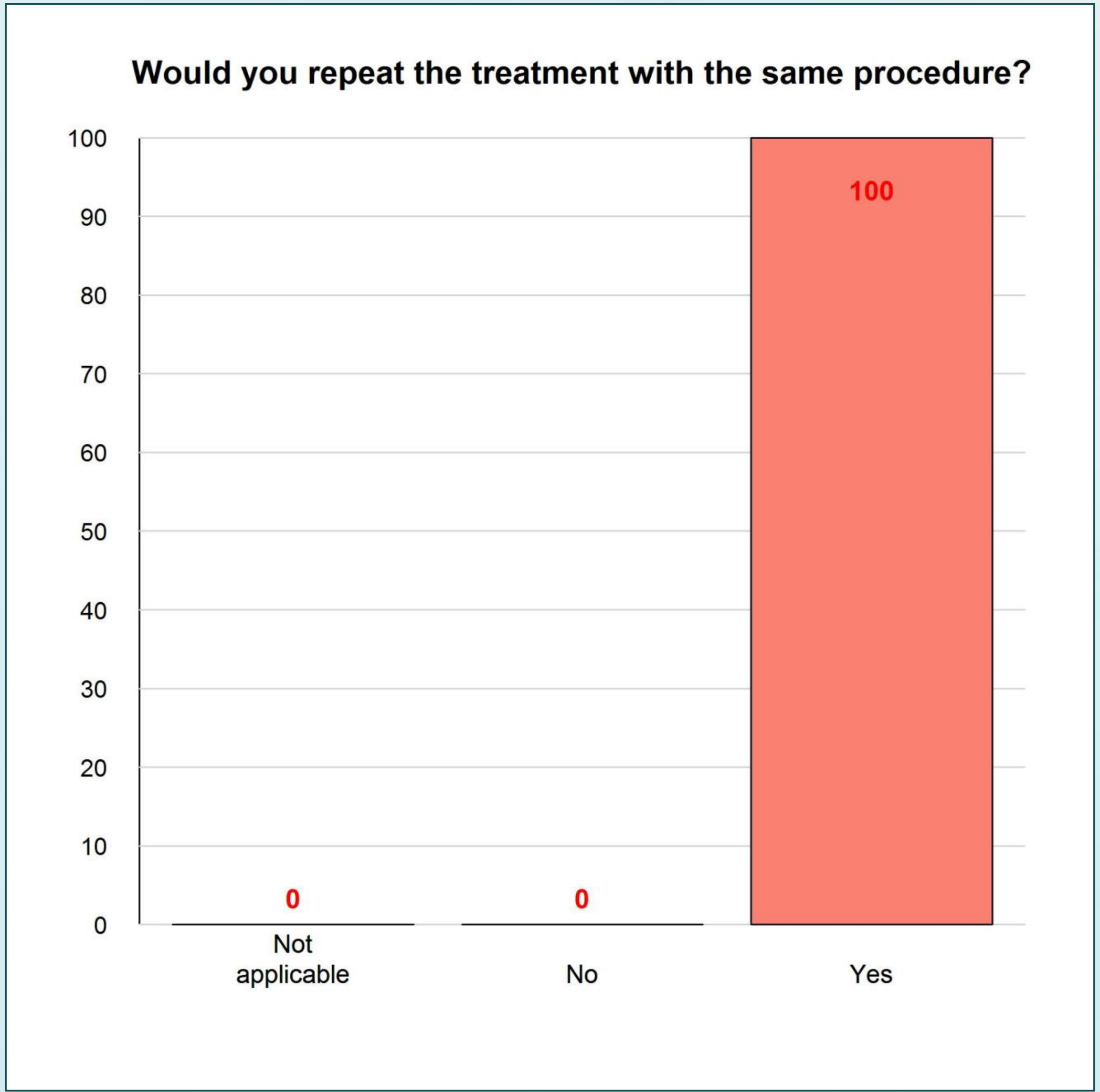
6.4.7. Satisfaction Data (subjective outcomes: **general feel**)



Dissatisfaction: 0 %

The general satisfaction was very high

6.4.8. Satisfaction Data (subjective outcomes: **repeat**)



Repeat: 100 %

All the patients would repeat

7. Preliminary conclusions

The RayOne® trifocal allows good visuals results in the 3 distances, with great independence of glasses and a high degree of satisfaction.

Thank you very much!

¡Muchas gracias!