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COMPARISON OF VISUAL AND OPTICAL QUALITY OF MONOFOCAL VERSUS MULTIFOCAL INTRAOCULAR LENSES

--Manuscript Draft--

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Full Title: COMPARISON OF VISUAL AND OPTICAL QUALITY OF MONOFOCAL VERSUS MULTIFOCAL INTRAOCULAR LENSES

Short Title: Comparison between monofocal and diffractive multifocal intraocular lenses

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Section/Category: Lens/Cataract

Keywords: Intraocular lens; monofocal lens; multifocal intraocular lens; optical bench; optical quality

Corresponding Author: Irene Altemir
Hospital Universitario Miguel Servet
Zaragoza, SPAIN

Corresponding Author's Institution: Hospital Universitario Miguel Servet

Order of Authors:
Irene Altemir
PhD Maria S. Millan
PhD Fidel Vega
Francisco Bartol-Puyal
Galadriel Gimenez-Calvo
MD PhD Jose M. Larrosa
MD PhD Vicente Polo
MD PhD Luis E. Pablo
MD PhD Elena Garcia-Martin

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Abstract:
Objective: To compare visual quality in patients implanted with Tecnis® monofocal(ZCB00) and multifocal(ZMB00) intraocular lenses(IOL) taking into account their optical quality measured in vitro with an eye model.

Methods: 122 patients participated in this study: 44 implanted with monofocal and 78 with multifocal IOLs. Measurements of visual acuity(VA) and contrast sensitivity(CS) were performed. The optical quality of the IOLs was evaluated in three image planes (distance, intermediate and near) using an eye model on a test bench. The metric considered was the area under the curve of the modulation transfer function(AMTF).

Results: Optical quality at the far focus of the monofocal IOL(AMTF=66.97) was considerably better than with the multifocal lens (AMTF=32.54). However, no significant differences were observed between groups at Distance Corrected Visual Acuity(DCVA). DC near vision was better in the multifocal(0.15±0.200.43±0.21logMAR) than in the monofocal group(0.43±0.21logMAR,p<0.001), which correlated with the better optical quality at near reached by the multifocal IOL(AMTF=29.11) in comparison with the monofocal IOL(AMTF=5.0). In intermediate vision, VA was 0.28±0.16logMAR (multifocal) and 0.36±0.14logMAR (monofocal) with p=0.014, also in good agreement with the values measured in optical quality AMTF=10.69 (multifocal) and 8.86 (monofocal). The CS was similar in almost all frequencies. Pelli-Robson was slightly better in the monofocal (1.73) than in the multifocal group (1.64;p=0.023).

Conclusions: Patients implanted with multifocal ZMB00 achieved a distance VA similar to those implanted with monofocal ZCB00, but showed significantly better intermediate and near VA. A correlation was found between IOL's optical quality and patients' VA. CS was very similar between multifocal and monofocal groups.
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| Response to Reviewers: | November 16th, 2018  
Prof. Francesco Bandello  
Editor-in-Chief, European Journal of Ophthalmology  

Powered by Editorial Manager® and ProduXion Manager® from Aries Systems Corporation
Dear Prof. Bandello,

In reply to your e-mail dated 29th-October-2018 with the decision notification on our paper referenced above, please find below our point-by-point response to the questions, comments and suggestions outlined by the reviewers with indication of the changes we have made to the manuscript and their locations. A red-line version of the revised manuscript, with the changes made highlighted, has been submitted for your consideration.

We thank you for the opportunity to address the reviewers’ concerns. We are grateful to their valuable suggestions and recommendations that give us a chance for improving our manuscript.

The authors hereby transfer, assigns, or otherwise convey all copyright ownership to the European Journal of Ophthalmology in the event that such work is published by this journal. The authors certify that they have no commercial interest in any of the instruments and interventions mentioned in the manuscript.

As the corresponding author I confirm that I had full access to all the data in the study and I take responsibility for the integrity of the data and the accuracy of the data analysis as well as the decision to submit for publication. All procedures adhered to the tenets of the Declaration of Helsinki, and the experimental protocol was approved by the local Ethics Committee. All subjects gave informed consent to participate in the study.

As the corresponding author I also confirm that all authors have read the revision and agree with changes

Sincerely yours,
Irene Altemir

Responses to Reviewer 1
(We have copied their comments in cursive and our response is below each paragraph)

1. Page 2 Abstract results: instead of Best distance corrected (DC) VA, should be Distance Corrected Visual Acuity (DCVA)
   It has been modified in Page 2 in the Results section of the Abstract.

2. Page 2 Abstract conclusions: Should mention results of the contrast sensitivity between both groups
   A phrase related to the comparison of contrast sensitivity results between both groups has been included in Page 3, in the Conclusions section of the Abstract.

3. Page 5. This prospective randomized study must clearly state that an appropriate informed consent was signed
   We agree with the Reviewer that this is an important point that was missed in the former version of the manuscript. All the patients included in this prospective study signed an informed consent. An explicit explanatory phrase has been included in Methods Section, first paragraph (Page 5).

4. Page 8 "A noticeable decrease in distance VA, both corrected (DCVA) and uncorrected (UDVA), was reported in mesopic." the text should be: A noticeable decrease in distance VA, both corrected (DCVA) and uncorrected (UDVA), was reported in both groups (monofocal and multifocal) in mesopic conditions.
   This sentence has been modified to take into account the reviewer’s indications, in pages 8 and 9, Results Section, second paragraph.

Responses to Reviewer 2
(We have copied their comments in cursive and our response is below each paragraph)

Aim of this study is evaluation of clinical results: monofocal vs MIOL IOLs. This paper is very well designed and written, results; figures and graphs are presented and discussed clearly.

We thank the reviewer for their good appreciation of our work and suggestions on how to improve the manuscript.

In my opinion, it would be interesting to add PCO rate for each group and VF questionnaire. I recommend publishing this manuscript to this journal.

Thank you very much for your comments and suggestions. We agree with the reviewer that posterior capsular opacification (PCO) is an important issue, and it could be very
Interesting to evaluate posterior capsular opacity of patients operated depending on
the type of lens. Regrettably, the outcomes of the study were obtained 3 months after
surgery, a period of time short enough to expect a significant incidence of PCO in the
patients.

Following the recommendation of the reviewer, from now on we will include the
evaluation of PCO in the protocol of our studies dealing with outcomes obtained with
longer follow-up periods.

With regard to Visual Function (VF) questionnaire, we share the interest of the reviewer
on this point but decided not to include these results for two reasons:

1) To keep the article extension within the requested length by the European Journal of
Ophthalmology. We recall that the novelty of the paper was to compare visual quality in
patients implanted with either monofocal (ZCB00) or multifocal (ZMB00) intraocular
lenses (IOL) taking into account their optical quality measured in vitro with an eye
model.

2) We consider that a more complete and better interpretation of the VF questionnaire
results, especially those related with night driving and halo disturbances, would require
further work to objectively evaluate photic phenomena in these patients.

**Funding Information:**
TITLE

COMPARISON OF VISUAL AND OPTICAL QUALITY OF MONOFOCAL VERSUS MULTIFOCAL INTRAOCULAR LENSES

Short Title: Comparison between monofocal and diffractive multifocal intraocular lenses

Authors:

PhD Irene Altemir 1,2, PhD Maria S. Millan3, PhD Fidel Vega3, MD Francisco Bartol-Puyal FA,1 Galadriel Gimenez-Calvo2,4, MD PhD Jose M. Larrosa1,2, MD PhD Vicente Polo1,2, MD PhD Luis E. Pablo1,2, MD PhD Elena Garcia-Martin1,2

Affiliations:

1Miguel Servet University Hospital. Ophthalmology department. Zaragoza, Spain.
2Aragon Institute of Health Sciences (IIS Aragón). Zaragoza University. Zaragoza.
3Applied Optics and Image Processing Group (GOAPI), Faculty of Optics and Optometry of Terrassa, Universitat Politecnica de Catalunya, BarcelonaTech, Barcelona, Spain

Corresponding Author:

Irene Altemir-Gomez
C/ Padre Arrupe, Consultas Externas de Oftalmología, 50009- Zaragoza (Spain)
Email: irenealtemir@gmail.com
Telephone number: 0034.654.23.73.17
Word Count: 2424
ABSTRACT

Objective: To compare visual quality in patients implanted with Tecnis® monofocal (ZCB00) and multifocal (ZMB00) intraocular lenses (IOL) taking into account their optical quality measured in vitro with an eye model.

Methods: 122 patients participated in this study: 44 implanted with monofocal and 78 with multifocal IOLs. Measurements of visual acuity (VA) and contrast sensitivity (CS) were performed. The optical quality of the IOLs was evaluated in three image planes (distance, intermediate and near) using an eye model on a test bench. The metric considered was the area under the curve of the modulation transfer function (AMTF).

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Conclusions: Patients implanted with multifocal ZMB00 achieved a distance VA similar to those implanted with monofocal ZCB00, but showed significantly better intermediate and near VA. A correlation was found between IOL’s optical quality and patients’ VA. CS was very similar between multifocal and monofocal groups.

Key words: Intraocular lens; monofocal lens; multifocal intraocular lens; optical bench; optical quality
INTRODUCTION

Advances in cataract surgery techniques (1) and improvements in optics quality of intraocular lenses (IOL) have led to this kind of surgery attempting not only to improve patients’ vision but also to provide them with good visual quality.(2)

The appearance of multifocal lenses made a revolutionary change in kind of this surgery, allowing spectacle independence on a daily basis. (3,4)

Multifocal lenses were designed to provide good distance, intermediate and near vision, in such a way that a fixed-focus lens cannot meet. (5)

We could objectively measure the performance of IOLs through imaging quality metrics (for example, modulation transfer function based metrics) measured using a model eye on an optical bench (6,7) and study their correlation with visual performance of pseudophakic patients. By means of these correlated preclinical metrics (8) it would be possible to predict the relative change in the clinical outcomes given a change in the IOL design tested on optical bench.

In this study, the visual quality of implanted patients was tested by measuring their distance, intermediate and near VA and their contrast sensitivity (CS) in photopic and mesopic conditions. VA was related to the measured optical quality of the IOLs at the corresponding image distances, being the latter estimated from the area under the MTF (AMTF) curve measured in an optical bench. The AMTF has proved to be an efficient preclinical metric to predict average visual acuity outcomes in pseudophakic patients. (9,10)
METHODS

This study was undertaken in Miguel Servet Hospital (Zaragoza, Spain) where 122 patients with bilateral cataracts were recruited prospectively for the study. All of them underwent cataract surgery with posterior IOL in capsular bag. The lens implanted was randomly chosen between monofocal and multifocal, same type of lens in both eyes. All the patients enrolled in this study were informed about its nature and signed informed consent to undergo the clinical examination in accordance with the tenets of the Declaration of Helsinki. The study was approved by the hospital ethics committee.

Inclusion criteria were: aged less than 75, bilateral cataracts (VA higher than 0.6 in logMAR scale), corneal astigmatism less than 1 dioptre (D) and IOL power between +17 and +27 D. Exclusion criteria were: intraocular surgery, zonular-break risk factors, intraoperative problems, endophthalmitis, irregular astigmatism, deep amblyopia, systematic syndromes, glaucoma or corneal disorders.

All subjects underwent an ophthalmologic evaluation: refraction, VA assessment, slit lamp examination, Goldmann tonometry, indirect funduscopy, endothelial-cell counting (SP-1P Topcon specular microscope). Optical coherence biometry (IOLMaster 500 Advanced Technology V.7.3 Carl Zeiss, Jena, Germany) was performed.

All patients were operated by the same surgeon using the same technique of phacoemulsification lens with 2.2 mm incisions. Each patient received the same type of lens in both eyes.

The postoperative revisions were performed at 1 day, 1 week, 1 month and 3 months after surgery. All patients underwent the postoperative evaluation of
their VA one month after the surgery of their second eye. VA was presented in LogMAR scale. The measurements included uncorrected and best-corrected distance visual acuity (UDVA and CDVA, respectively), best distance corrected intermediate visual acuity (CDIVA) and best distance corrected near visual acuity (CDNVA). The VA were measured at distance (6m, vergence +0.2 D), intermediate (63 cm, vergence +1.6 D) and near (33cm, vergence +3.0 D) using Early Treatment Diabetic Retinopathy Study (ETDRS) charts. We recall that it is essential to set cautiously near and intermediate distances in studies in which multifocal lenses are evaluated.

We take into account some other function besides VA; today, the most widespread and used in clinical treatment and investigation is CS.(11) We measured it in four frequencies: 3, 6, 12 and 18 cycles/degree (cpd) in photopic and mesopic conditions with CSV-1000 test. We also measured the CS with the Pelli-Robson test, which evaluates only one special frequency (1 cpd). This test was performed in photopic conditions with best far correction. These measurements were performed in all the patients three months after surgery.

**Intraocular lenses**

The intraocular lenses implanted were Tecnis ZCB00 as monofocal IOL and Tecnis ZMB00 as multifocal IOL (Fig. 1A).(12) Both IOLs are made of the same material (hydrophobic acrylic, refractive index 1.47) and share the same wavefront aspheric optics design that produces a maximum spherical aberration (SA) of -0.27 μm for a 6.0-mm eye pupil.
The Tecnis ZMB00 is a pupil independent, full aperture diffractive multifocal IOL of +4.00 D near addition (at the IOL plane). The lens has an anterior aspheric surface and a posterior spherical one with the diffractive profile. Theoretically, about 41% of the incident light energy would be directed to the near focus, another 41% to the distance focus and the remaining energy (approximately 18%) would be expended in higher diffraction orders. (13)

**Optical quality assessment**

Optical quality of distance, intermediate and near foci was determined with an optical test bench shown in Fig. 1B and described in detail elsewhere. (14) The setup included a model eye with an artificial cornea and it is consistent with the International Organization for Standardization (ISO) 11979-143 2:2014.2. (15) It was taken into consideration the recommendation of using an artificial cornea affected by spherical aberration, similar to the average human cornea. An iris diaphragm, with a variable aperture, was placed in front of the artificial cornea as the entrance pupil in order to control the size of the beam reaching the artificial cornea, and thus the level of spherical aberration introduced by the model eye (without the IOL). (16) To this extent, our artificial cornea provided +0.27 μm of spherical aberration (SA) for a 6.0 mm pupil diameter. A green light emitting diode (LED525E; Thorlabs GmbH, Munich, Germany), with emission centered at 525 nm and full-width at half-maximum spectral bandwidth of ±15 nm, was used to illuminate either a 1951 USAF (United States Air Force) resolution test or a four slit pattern test object for MTF measurement (Fig. 1C). The MTF curve was obtained in three image planes (distance, intermediate and near) from the Fourier transform of the line spread function of the slit pattern.
images. (6.8) The area under the MTF (AMTF) was determined by the integration of the MTF curve between 0 and 100 cycles per millimetre. The higher the AMTF values achieved, the better the optical quality of the IOL. For each IOL and focus, measurements were conducted with two pupil sizes at the IOL plane: a 3 mm lens aperture to compare with photopic pupils, and a 4.5 mm aperture to compare with mesopic light conditions.

**Statistical analysis**

Statistical analyses were carried out with the Statistical Package for the Social Sciences (SPSS 15.0, SPSS Inc., Chicago, IL). Mean values and standard deviations were calculated for every parameter. It was proved that samples adjusted to normality with the Kolmogorov-Smirnov test and the t-Student test was used accordingly.

**RESULTS**

The recruited patients (122) were divided into two groups according to the IOL implanted: monofocal (44) and multifocal (78). Mean age was 60.72±8.98 in the monofocal group and 63.27±6.42 years in the multifocal group. There were no differences between gender (Chi-square test, p=0.337) and age (t Student test, p=0.090) in both groups.

No relevant differences between IOL base powers were found: mean of +22.75±2.16 D (monofocal) and +22.65±2.22 D (multifocal) with p=0.817.

**Clinical measurements**
The results of VA in different light conditions are shown in Table 1 and Fig. 2A. In photopic conditions, no statistically significant differences between UDVA or DCVA were observed. A noticeable decrease in distance VA, both corrected (DCVA) and uncorrected (UDVA), was reported in both groups (monofocal and multifocal) in mesopic conditions. The largest differences in visual quality were found in near vision (DCNVA) ($p<0.001$). Smaller but statistically significant differences were also found in intermediate vision (DCIVA).

With regard to the postoperative CS, the monofocal group showed consistently slightly better results than the multifocal group, but these differences failed to reach the significance level except for the spatial frequency of 3 cpd under photopic conditions and with the Pelli-Robson test (Table 1 and Fig. 2B).

**Optical bench measurements**

Fig. 3 shows the images of the USAF test and the MTF obtained with a pupil of 3.0 mm in the optical test bench with the monofocal and multifocal IOLs in three image planes: distance (0.0 D), intermediate (+2.0 D) and near (+4.0 D) vergence with respect to the IOL plane. These vergences (or equivalently these image planes) are translated and referred to the glass plane. These planes approximated the planes at which VA was evaluated: 6m (0.17D), 63 cm (1.6D), 33cm (3.0D), although they did not exactly match. Good quality USAF images were obtained at distance with both lenses, although the image obtained with the monofocal lens had the best contrast. A reasonably good image at near was obtained only with the multifocal ZMB00 IOL. None of the lenses were able to produce a good image at the intermediate plane. Although the USAF images
allow a fast and qualitative comparison of the optical quality of the lenses, a quantitative assessment of the differences in optical quality was carried out by evaluating the area under the MTF between 0 and 100 cycles per mm (i.e. the AMTF, which corresponds to the shaded region below the MTF curves in Fig. 3). The four-slit pattern test was used in the optical bench to measure MTF in all IOLs. The AMTF values obtained with pupils of 3.0 and 4.5 mm are included in Table 2 and show that in every image plane, the larger the pupil, the lower the AMTF for both IOLs. Moreover, the monofocal ZCB00 had the largest AMTF (and thus, the best optical quality) at the distance focus, but fails at the near image plane. In contrast, the multifocal ZMB00 showed similar AMTF values (and thus, similar optical quality) at distance and near image planes. Finally, at the intermediate focus both IOLs decreased in their AMTF values.

**Relationship between clinical VA and laboratory AMTF**

The mean DCVA, DCIVA and DCNVA values for both IOLs were compared with their corresponding AMTF values. This is shown in Fig. 4 in the case of a pupil of 3.0 mm, showing an association between AMTF and VA in which, in general, larger values of AMTF correspond to better VA scores (lower logMAR values). However, this association can be thought to be compatible with a linear function only for relatively low values of AMTF. Thus, for AMTF values over a certain threshold (about 35), in the region shaded in grey on the right side of Fig. 3B, further improvement of the AMTF did not necessarily imply a significant gain in VA, and consequently, the VA values remained almost constant and good (values around 0.0 logMAR) even though the AMTF value overpassed the threshold.
DISCUSSION

In our study, photopic conditions of the UDVA and CDVA were similar. The UDVA results were remarkable in this study: +0.04±0.11 in the monofocal IOL group and +0.02±0.10 in the multifocal IOL group. With the best DCVA, the values slightly improved: -0.02±0.06 (monofocal) and -0.02±0.08 (multifocal). A reduction of the distance in VA was found in both groups under mesopic light conditions. Our results are in good agreement with those obtained by Chang DH, who evaluated VA in 32 patients implanted with the multifocal ZMB00 IOL. (17) He found -0.02±0.08 and -0.09±0.08 values for UDVA and CDVA respectively in photopic conditions. In agreement with our results, they also found a reduction of patients’ VA in mesopic conditions.

Furthermore, there was a significant improvement in near vision of the multifocal group in comparison with the monofocal one. We found values of +0.43±0.21 (monofocal) and +0.15±0.20 (multifocal) in DCNVA. Chang DH (17) reported better values while Ye et al. (18) found DCNVA of +0.025±0.11 in patients with multifocal ZMA00 (+4.0D) and +0.55±0.12 with the monofocal ZA9003. These results confirm that the multifocal ZMB00 IOL improves the near visual function of the patients with respect to a monofocal implant.

Regarding the intermediate visual outcomes, the DCIVA worsened in both groups with regard to their own scores in distance vision. Moreover, the intermediate vision in the monofocal group was worse than in the multifocal one (+0.36±0.14 versus +0.28±0.16; p=0.014 respectively). The values of DCIVA in the multifocal group are similar or slightly worse than the results reported in previous studies with Tecnis Multifocal IOLs and other diffractive multifocal
IOLs.\(^{(17,18)}\) In fact, some limitations have been reported after the implantation of multifocal IOLs with high addition, which has motivated the clinical evaluation of new IOLs with lower addition \(^{(19,20)}\).

Regarding CS, our study supports the premise that this function is not seriously compromised in the multifocal group in comparison with the monofocal one, since we only found slightly higher CS in eyes with the monofocal IOL, with the Pelli Robson test and the low frequency of 3cpd in the CSV-1000 test. This is consistent with results reported in previous studies. \(^{(21)}\) Packer et al. compared CS values between patients implanted with Tecnis multifocal ZM900 IOLs and monofocal and reported worse CS with Tecnis ZM900, but, similarly to our study, these differences were not clinically significant.\(^{(22)}\)

Finally, the relationship between VA and optical quality of the IOLs was evaluated. The largest differences of VA between the two groups are reported for near vision, in which, consistently with the bifocal design of the ZMB00 IOL, the VA results of the multifocal group were much better than those achieved by the monofocal one (DCNVA of \(+0.15\pm0.20\) in multifocal versus \(+0.43\pm0.21\) in monofocal, \(p<0.001\)). This result correlated well with the large differences in AMTF (AMTF\(_{\text{multifocal}}=29.11\) versus AMTF\(_{\text{monofocal}}=5\)).

In the case of distance vision, both groups had similar values of DCVA despite the fact that the AMTF of the multifocal ZMB00 was noticeable smaller than the AMTF of the monofocal ZCB00 (AMTF\(_{\text{multifocal}}=32.54\) vs AMTF\(_{\text{monofocal}}=66.97\)). The fact that this difference in optical quality does not imply an improvement in VA at the clinical level can be justified taking into account that once patients have reached the level of optical quality for which VA
is already good (around 0.0 logMAR), additional improvements in the optical quality of the IOLs did not produce any detectable improvement in their VA. These results are in agreement with the findings of Felipe et al. (23) who showed that a decrease in the average modulation value of at least 24-25% is necessary in order to cause a significant decrease in VA. (9)

Intermediate vision (DCIVA) worsened in both groups regarding their respective scores in distance vision. The AMTF reported in intermediate image plane was very similar for both IOLs (AMTmonofocal=10.69 versus AMTFmultifocal=8.86 respectively), although the DCIVA were slightly but significantly better in the multifocal group (+0.36±0.14 monofocal versus +0.28±0.16 multifocal, with p=0.014).

One of the strengths of this study is the correlation of the results obtained in the laboratory in optical bench with the clinical results in patients. However, the conclusions of this study should be taken into consideration according to the limitations thereof, since the sample size is relatively small. Further prospective studies could be needed.

ACKNOWLEDGEMENTS

The authors have no proprietary interest.

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No conflicting relationship exists for any author.

No supplementary data to the manuscript.

Conflict of interest disclosures: None.
REFERENCES


Table 1. Visual acuity (LogMAR) and contrast sensitivity for multifocal and monofocal IOLs groups. Bold letters indicate statistically significant differences.

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<td>±0.20</td>
<td>1.46</td>
</tr>
<tr>
<td>CSV1000 12cpd mesopic</td>
<td>0.99</td>
<td>±0.32</td>
<td>0.86</td>
</tr>
<tr>
<td>CSV1000 18cpd mesopic</td>
<td>0.48</td>
<td>±0.34</td>
<td>0.46</td>
</tr>
</tbody>
</table>

Abbreviations: UDVA, uncorrected distance visual acuity; DCVA, distance corrected visual acuity; DCIVA, distance corrected intermediate visual acuity; DCNVA, distance corrected near visual acuity; SD, standard deviation; CS,
contrast sensitivity; CSV, contrast sensitivity vision; cpd, cycles per degree; VA, visual acuity.
Table 2. AMTF values obtained with the monofocal ZCB00 and multifocal ZMB00 at each image plane with pupils of 3.0 and 4.5 mm.

<table>
<thead>
<tr>
<th>Pupil Size</th>
<th>Distance</th>
<th>ZCB00 lens</th>
<th>ZMB00 lens</th>
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<tr>
<td>3 mm pupil</td>
<td>Distance</td>
<td>66.97</td>
<td>32.54</td>
</tr>
<tr>
<td></td>
<td>Intermediate</td>
<td>10.69</td>
<td>8.86</td>
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<tr>
<td></td>
<td>Near</td>
<td>5.0</td>
<td>29.11</td>
</tr>
<tr>
<td>4.5 mm pupil</td>
<td>Distance</td>
<td>56.95</td>
<td>28.11</td>
</tr>
<tr>
<td></td>
<td>Intermediate</td>
<td>7.15</td>
<td>6.03</td>
</tr>
<tr>
<td></td>
<td>Near</td>
<td>5.0</td>
<td>24.63</td>
</tr>
</tbody>
</table>
FIGURE LEGEND

Figure 1: A- Optic characteristics of monofocal (ZCB00) and multifocal (ZMB00) intraocular lenses (IOLs). B- Model of artificial eye in optical bench. C- Representation of USAF test (a), and 4-slit pattern test (b).

Figure 2: Bar graphs with the mean and standard deviation of A: visual acuity (logMAR scale) and B: contrast sensitivity for multifocal and monofocal groups.

Figure 3: Images of the USAF test obtained with the monofocal ZCB00 and multifocal ZMB00 IOLs in the optical bench at distance, intermediate and near image planes. The associated MTF at each image plane is shown below. The shadowed regions of the MTF curves are integrated, from 0 to 100 c/mm, to calculate the area under the MTF (AMTF values in Table 2).

Figure 4: Distance, intermediate and near visual acuity values (mean ± standard deviation) versus the area under the MTF (AMTF). The squares represent monofocal ZCB00 parameters and the circles represent multifocal ZMB00 parameters. The solid line is a linear fit of data with AMTFs values lower than 35.
Figure 2

Visual Acuity (LogMar scale)

Contrast Sensitivity

Spatial Frequency (cycles per degree)