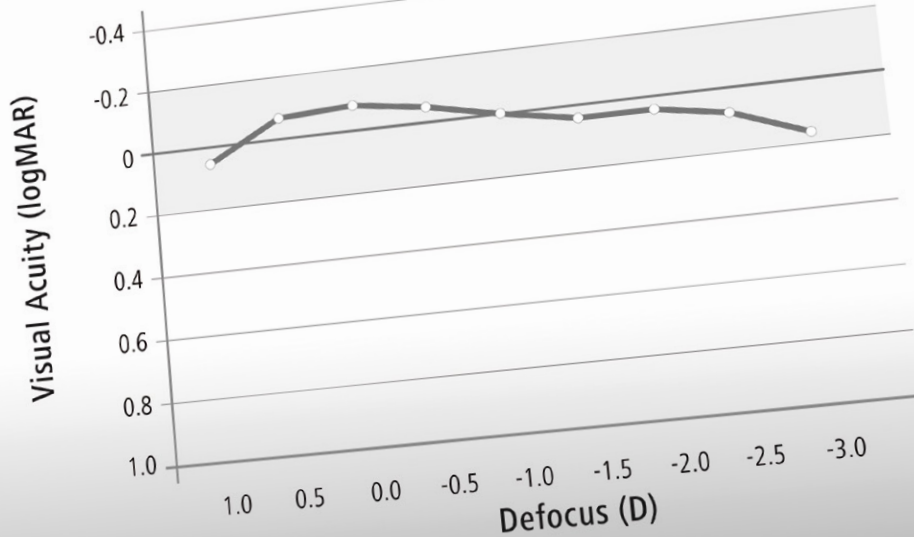


Defocus Curve (n = 30)



AT LISA tri 839MP /
AT LISA tri toric 939MP from ZEISS
Clinical Leaflet

NEW
Study
Results



We make it visible.



*“With the AT LISA tri, I can finally introduce my patients to a real multifocal world without sacrificing their contrast sensitivity and without increasing their dysphotopsias.”**

**Joaquín Fernández, MD
(Hospital Vithas Virgen del Mar, Almeria, Spain)*

Introduction

AT LISA® tri and AT LISA tri toric from ZEISS represent the next generation of ZEISS multifocal IOLs and are the first trifocal and trifocal toric preloaded true-MICS IOLs for True Living Vision. These two members of the ZEISS AT LISA tri family, based on the proven ZEISS AT LISA platform, provide excellent intermediate vision* without compromising distance and near vision due to

an optimized optic design with an additional dedicated focal point. The near and intermediate additions of the ZEISS AT LISA tri 839MP and ZEISS AT LISA tri toric 939MP are +3.33 D and +1.66 D, offering a comfortable reading and intermediate distance of approximately 40 and 80 cm respectively.

Clinical studies with ZEISS AT LISA tri 839MP

In the period from 2011 to today, several clinical studies (Table 1) have been conducted in Europe. Interim and final results analysing one to six month post-operative data are reviewed in this report.



- Study A:** 60 eyes/36 patients (1 month), German multicentric clinical data collection*
- Study B:** 208 eyes/104 patients (3 months), European prospective clinical trial*
- Study C:** 60 eyes/30 patients (3 months), prospective case series¹
- Study D:** 60 eyes/30 patients (6 months), prospective case series²
- Study E:** 60 eyes/30 patients (6 months), prospective case series³
- Study F:** 100 eyes/50 patients (3 months), prospective case series*
- Study G:** 86 eyes/44 patients (3 months), prospective case series*

Table 1: Major studies on ZEISS AT LISA tri conducted from 2011 until today

Visual acuity

Clinical results show that the ZEISS AT LISA tri 839MP provides excellent intermediate visual acuity in addition to very good far and near vision. The monocular uncorrected and best distance corrected near and intermediate visual acuity were measured at 33 to

40 cm and 66 to 80 cm respectively. Study C showed excellent results for uncorrected intermediate vision at 66 cm and 80 cm (logMAR 0.06 and 0.03, respectively) which confirm the broad distance range of functional intermediate vision with this lens.

*Data on file

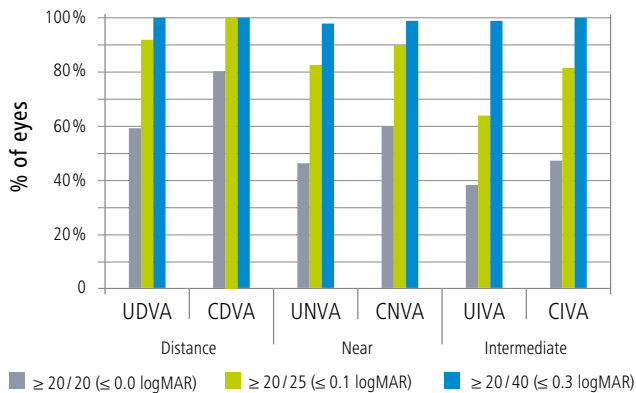
Monocular and binocular visual acuity

Study	UDVA	CDVA	UIVA	DCIVA	UNVA	DCNVA
A monocular	0.05±0.08	0.01±0.04	0.18±0.16	0.15±0.17	0.16±0.19	0.09±0.09
B monocular	0.08±0.13	0.03±0.14	0.17±0.16	0.15±0.15	0.21±0.16	0.13±0.14
B binocular	0.03±0.09	0.00±0.13	0.10±0.15	0.08±0.15	0.15±0.14	0.08±0.12
C monocular	-0.05±0.08	-0.06±0.07	66 cm: 0.06±0.07 80 cm: 0.03±0.08	66 cm: 0.06±0.07 80 cm: 0.03±0.08	33 cm: 0.07±0.09 40 cm: 0.15±0.09	33 cm: 0.07±0.09 40 cm: 0.14±0.10
D monocular	-0.03±0.09	-0.05±0.08	0.08±0.10	0.08±0.10	0.20±0.12	0.17±0.11
E monocular	0.05±0.07	-0.02±0.05	–	–	–	–
E binocular	–	-0.06±0.04	–	0.16±0.07	0.16±0.07	0.12±0.07
F monocular	0.06±0.08	0.04±0.08	0.10±0.09	–	0.06±0.08	–
F binocular	0.04±0.07	–	0.04±0.08	–	0.01±0.09	–
G monocular	0.05±0.08	0.02±0.05	0.11±0.11	0.06±0.11	0.07±0.11	0.05±0.09
G binocular	-0.01±0.07	-0.03±0.04	0.03±0.10	0.00±0.11	0.02±0.09	0.01±0.08

Table 2: Monocular and binocular visual acuities for distance, intermediate and near vision in logMAR (mean ± SD)

In general the studies show a remarkable improvement in patients' visual acuity with binocular implantation of ZEISS AT LISA tri 839MP when compared with the monocular visual acuity results. (Figure 1)

Monocular Visual Acuity



Binocular Visual Acuity

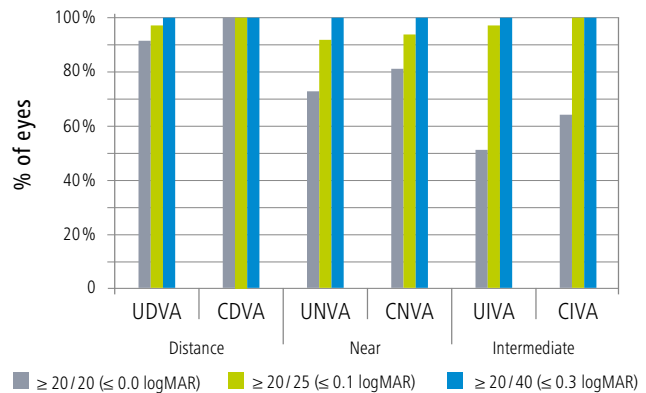


Figure 1: Monocular and binocular visual acuities at various distances (study F)

In study C a binocular defocus curve was measured three months post-operatively. The visual acuity is maintained below 0.10 logMAR (0.80 decimal) within a defocus diopter range of +1.0 D to -2.5 D (Figure 2). The defocus diopters from -1.0 D to -2.0 D illustrate the very good intermediate visual acuity. The defocus curve shows a very smooth transition for patients from near to distance vision over the complete defocus diopter range, in contrast to bifocal IOLs.

Defocus Curve (n = 30)

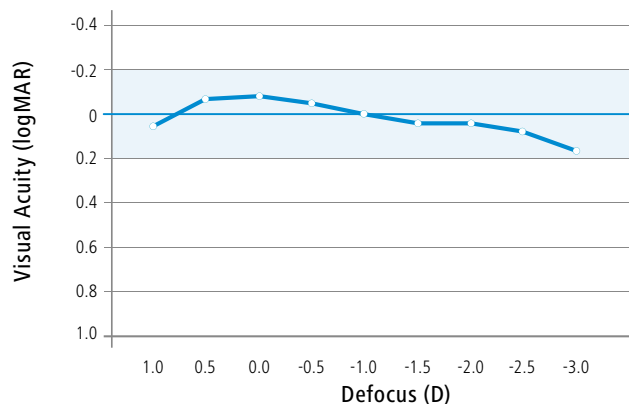


Figure 2: Defocus curve (study C)

Refraction

Clinical results show that the ZEISS AT LISA tri 839MP provides very good post-operative refractive results (Table 3).

The predictability of the refractive results of the ZEISS AT LISA tri 839MP is excellent. In all patients (100%) participating in study A, a post-operative spherical equivalent (SE) of ± 0.75 D or less was measured. In this study, results after one month reported 88% of eyes with a SE ± 0.50 D, and 72% achieved a SE ± 0.25 D (Figure 3).

Post-operative Spherical Equivalents

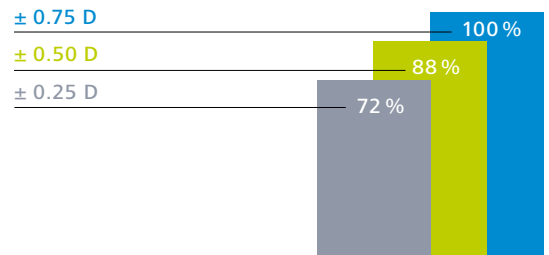


Figure 3: Percentages of Residual Spherical Equivalents from 51 eyes 1 month post-operatively (study A)

Study	Eyes	SE \pm SD (D)	Sphere \pm SD (D)	Cylinder \pm SD (D)	Follow up
A	51	0.10 \pm 0.29	0.22 \pm 0.35	-0.24 \pm 0.24	1 month
B	203	0.14 \pm 0.41	0.34 \pm 0.42	-0.43 \pm 0.37	3 months
C	60	-0.29 \pm 0.33	-0.19 \pm 0.35	-0.20 \pm 0.21	3 months
D	60	-0.12 \pm 0.39	-0.02 \pm 0.38	-0.28 \pm 0.24	6 months
E	60	0.09 \pm 0.20	0.31 \pm 0.22	-0.40 \pm 0.24	6 months
F	100	-0.08 \pm 0.40	0.20 \pm 0.39	-0.58 \pm 0.32	3 months
G	86	0.15 \pm 0.39	0.26 \pm 0.43	-0.23 \pm 0.30	3 months

Table 3: Mean post-operative refraction

Patient satisfaction

The very good refractive outcomes are reflected in the results of the patient satisfaction evaluation in study E. After 6 months, 100% of the patients were satisfied with their distance and intermediate vision and 93% with their near vision. High satisfaction scores were found in all studies and 96% of the patients of study B stated that they would choose a multifocal lens again. A high level of patient satisfaction was also reported in study D. Thirty patients were asked to rate their vision in certain situations. Most patients stated to be satisfied or very satisfied with their vision at all distances (Figure 4).

Low levels of halos (15%) and glare (10%) were found after 6 months in a study in 34 patients. This might contribute to the high level of patient satisfaction in this study by Dr. Fernandez, Almeria, Spain (presented at the ESCRS 2012, Milan, Italy).

Patient Satisfaction Evaluation

Score (1 = very satisfied; 6 = not at all satisfied)

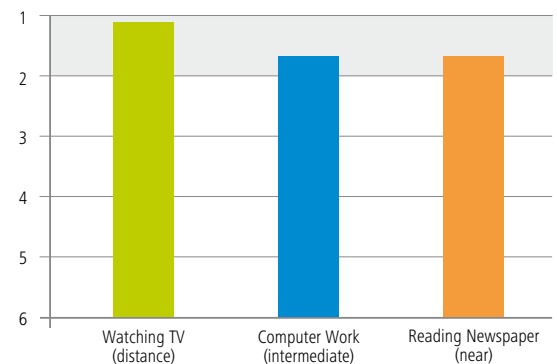


Figure 4: Patient satisfaction for distance, intermediate and near vision (study D), three months post-operative



Spectacle Independence (study B)

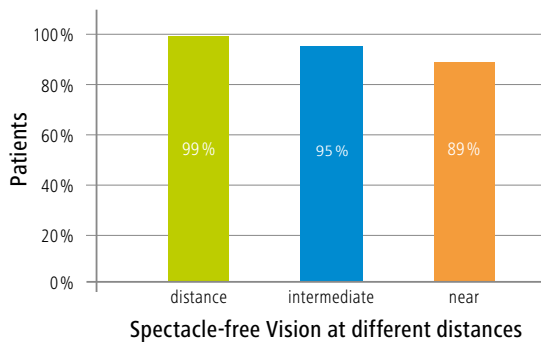


Figure 5: Level of spectacle independence

Contrast sensitivity

In study D, monocular photopic contrast sensitivity of 60 eyes was measured without best distance correction after six months using the CSV-1000 test. The clinical results demonstrate that photopic contrast sensitivity is maintained within the normal range (Figure 6). This is achieved due to the higher light energy transmittance and optimization of the diffractive ring design.

Spectacle independence

Spectacle independence is the major expectation and demand of patients if they opt for a multifocal IOL. The trifocal design of ZEISS AT LISA tri 839MP delivers three focal points covering a broad range of distances with practically no gaps. This is reflected in the high levels of spectacle independence in study B (Figure 5).

Photopic Contrast Sensitivity (n = 60)

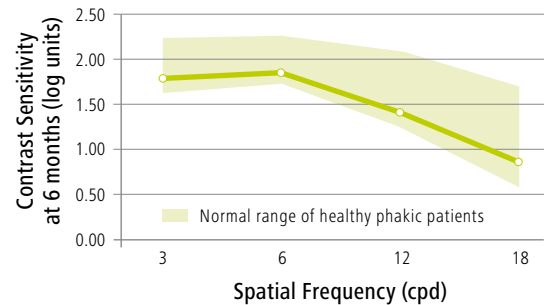


Figure 6: Monocular contrast sensitivity of ZEISS AT LISA tri 839MP under photopic conditions (study D)

Ocular Aberrations

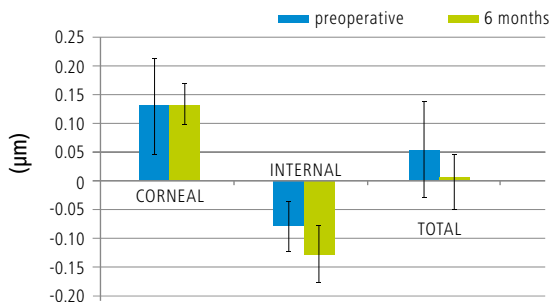


Figure 7: Changes in spherical aberration (Z4 coefficient) at corneal, internal, and ocular levels

Ocular Aberrations

Total ocular aberrations were significantly reduced after surgery, as shown in study D. There was also a statistically significant improvement of the ocular Strehl ratio (from 0.11 ± 0.03 preoperatively to 0.14 ± 0.04 at 6 months postoperatively, $p=0.019$).

Clinical experience with ZEISS AT LISA tri toric 939MP



The toric trifocal IOL is designed to make spectacle-free vision available to a broader group of patients. First clinical experiences with ZEISS AT LISA tri toric have confirmed an outstanding performance of this IOL.

In an ongoing study of a small series of patients*, excellent visual acuity results for all measured distances were reported one month after surgery (Table 4).

Study H: 40 eyes / 20 patients (6 months), prospective case series⁴
Study I: 40 eyes / 20 patients (3 months), prospective case series⁵
Study J: 56 eyes / 28 patients (3 months), prospective case series⁶
Study K: 23 eyes / 23 patients (1 month), prospective case series⁷

Table 4: Ongoing studies on ZEISS AT LISA tri toric

Study	Eyes	UDVA	CDVA	UIVA	DCIVA	UNVA	DCNVA	Follow-up
H	40	0.05		0.05		0.12		6 months
I	40	0.00		0.05		<0.20		3 months
J	56	-0.08	-0.10	-0.12	-0.12	0.00	-0.06	3 months

Table 5: Monocular visual acuity results with AT LISA tri toric at various distances

In a case series (study K) with 23 eyes 75 % reached an uncorrected distance visual acuity (decimal) of 1.0 or better and 91 % of 0.8 or better after 1 month. Uncorrected intermediate visual acuity was better than 0.8 in 83 % of the cases and 78 % of the eyes reached an uncorrected near visual acuity of 0.8 or better. Binocular uncorrected near visual acuity was better than 1.0 in 100 % of the patients.

Contrast sensitivity

Contrast sensitivity was measured with the Optec 6500 device in 15 patients (data on file). Figure 8 shows that the results were within the normal range of this age group under photopic conditions. Figure 9 shows the results under mesopic conditions.

Photopic Contrast Sensitivity (n = 15)

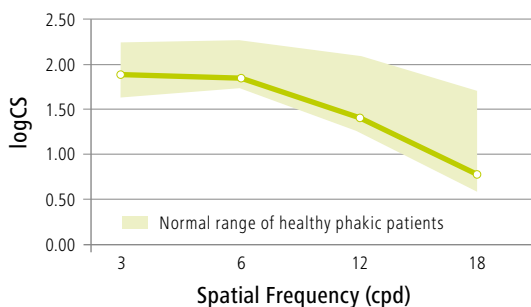


Figure 8: Contrast sensitivity of ZEISS AT LISA tri toric 939MP under photopic conditions

Mesopic Contrast Sensitivity (n = 15)

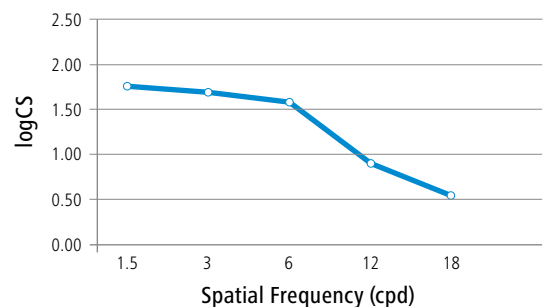



Figure 9: Contrast sensitivity of ZEISS AT LISA tri toric 939MP under mesopic conditions

*Data on file



*“The new AT LISA tri toric from ZEISS delivers excellent, predictable visual results at all distances and enables accurate astigmatism correction. Easy to implant and align, the IOL guarantees a stable position in the eye.”**

* Patrick Versace, MD
(Vision Eye Institute, Sydney, Australia)

Reading acuity

Subjective reading acuity, measured with the Salzburg Reading Desk was 0.11 logMAR at a preferred distance of 38.9 cm. Subjective intermediate acuity was 0.03 at a preferred distance of 78.2 cm (study I).

Rotational stability

In all cases of study K the lenses were stable and within 5 degrees of the intended axis one month after surgery. No IOL rotations were noted in studies H and I.

Conclusion

These clinical results highlight the advantages of this next generation trifocal optic design that provides patients with True Living Vision and lets them experience excellent vision at all distances with real intermediate vision. It is ideal for patients who are looking for a high level of spectacle independence and comfortable vision while performing most of their daily activities.

1. Mojzis P et al. *J Refract Surg* 2014; 30:666–672; 2. Mojzis P et al. *J Cataract Refract Surg* 2014; 40:60–69; 3. Law EM, Aggarwal RH, Kasaby S. *Eur J Ophthalmol.* 2014; 24:501–508; 4. Faria-Correia F et al. Presented at the ASCRS 2015, San Diego; 5. Kaymak H et al. Presented at the ASCRS 2015, San Diego; 6. Kretz FT et al. Presented at the ASCRS 2015, San Diego; 7. Daya SM, Espinosa M, Khan S. Presented at the ASCRS 2015, San Diego



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