



Including
Study Results
2016

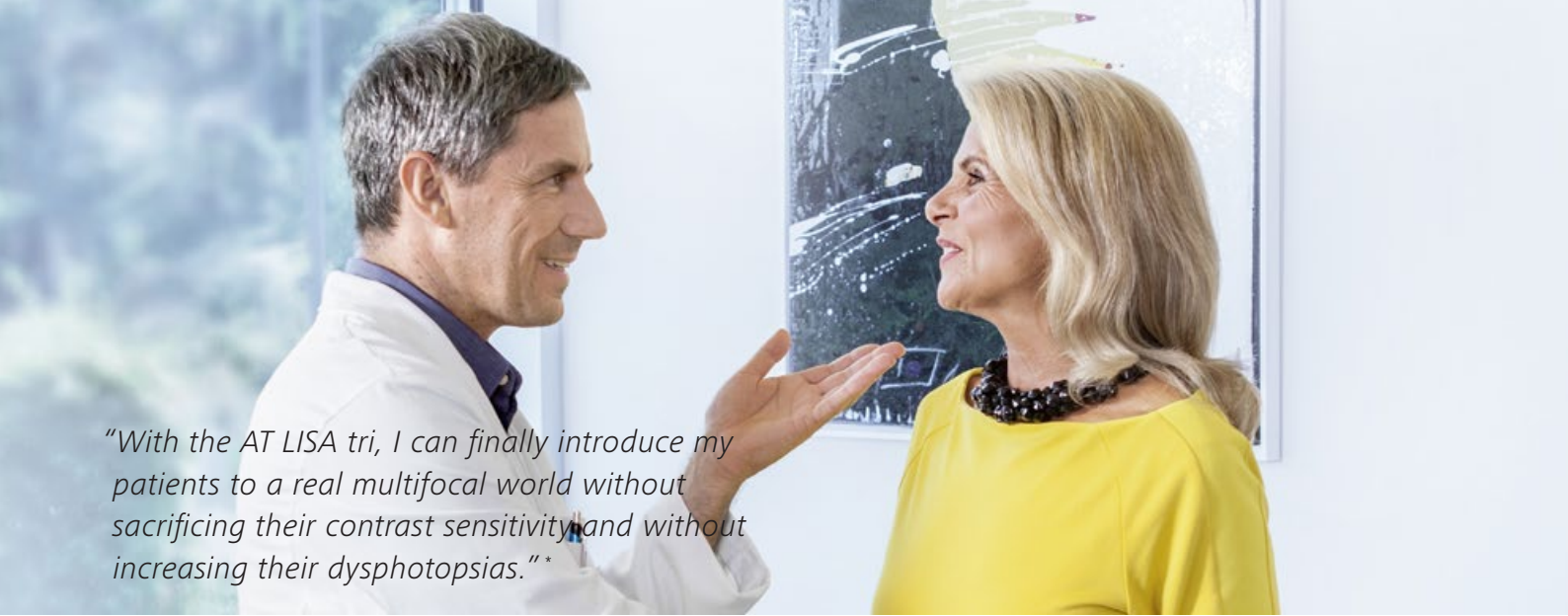
ZEISS AT LISA tri family

Clinical Leaflet

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Seeing beyond



*"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."**

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Introduction

Since their market introduction, AT LISA® tri 839MP and AT LISA tri toric 939MP from ZEISS have been included in numerous clinical studies, each one highlighting the strong performance of these gold standard trifocal MICS IOLs for restoring a full range of vision. The two members of the ZEISS AT LISA tri family are based on the successful ZEISS AT LISA platform and have proven to 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 AT LISA tri and AT LISA tri toric from ZEISS are +3.33 D and +1.66 D at the IOL plane, offering a comfortable reading and intermediate distance of approximately 40 cm and 80 cm respectively.

Clinical studies with ZEISS AT LISA tri 839MP

In the period from 2012 to today, several clinical studies have been conducted in Europe. The most recent publication results analyzing three to twelve months postoperative data are reviewed in this report (Table 1).



- Study A:** 76 eyes / 38 patients (3 months), prospective case series¹
- Study B:** 208 eyes / 104 patients (3 months), prospective study**
- Study C:** 60 eyes / 30 patients (3 months), prospective randomized trial²
- Study D:** 60 eyes / 30 patients (6 months), prospective case series³
- Study E:** 100 eyes / 50 patients (3 months), prospective study⁴
- Study F:** 100 eyes / 50 patients (3 months), prospective study⁵
- Study G:** 204 eyes / 102 patients (6 months), prospective study⁶
- Study H:** 120 eyes / 60 patients (12 months), prospective case series⁷
- Study I:** 54 eyes / 27 patients (3 months), prospective case series⁸

Table 1: Major studies on ZEISS AT LISA tri conducted from 2012 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 distance corrected near and intermediate visual acuity were measured at 33 to 40 cm

and 66 to 80 cm, respectively. The studies show strong results for uncorrected intermediate vision throughout, e.g. study C with logMAR 0.06 and 0.03 at 66 cm and 80 cm, respectively, confirming the broad range of functional intermediate vision with this lens.

Monocular and binocular visual acuity (logMAR)

Study	n	UDVA	CDVA	UIVA (80 cm) [°]	DCIVA (80 cm) [°]	UNVA (40 cm) [°]	DCNVA (40 cm) [°]
A monocular	76	0.10	–	66 cm: 0.15	–	0.1	–
A binocular	76	-0.05	–	66 cm: 0.05	–	0.05	–
B monocular	208	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	208	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	30	-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	60	0.03 ± 0.09	0.05 ± 0.08	66 cm: 0.08 ± 0.10	66 cm: 0.08 ± 0.10	33 cm: 0.20 ± 0.12	33 cm: 0.17 ± 0.11
F monocular	100	0.06 ± 0.08	0.04 ± 0.08	66 cm: 0.10 ± 0.09	–	0.06 ± 0.08	–
F binocular	100	0.04 ± 0.07	–	66 cm: 0.04 ± 0.08	–	0.01 ± 0.09	–
G binocular	204	0.02 ± 0.07 (3 months)	-0.02 ± 0.05 (3 months)	70 cm: 0.12 ± 0.11 60 cm: 0.13 ± 0.10 50 cm: 0.08 ± 0.11	70 cm: 0.11 ± 0.11 60 cm: 0.09 ± 0.08 50 cm: 0.07 ± 0.11	0.07 ± 0.11	0.06 ± 0.10
H monocular	120	0.03 ± 0.13	0.01 ± 0.11	66 cm: 0.12 ± 0.13 80 cm: 0.11 ± 0.13	66 cm: 0.11 ± 0.12 80 cm: 0.11 ± 0.13	33 cm: 0.23 ± 0.15 40 cm: 0.27 ± 0.15	33 cm: 0.21 ± 0.14 40 cm: 0.25 ± 0.14
I monocular	54	0.01 ± 0.10	-0.04 ± 0.08	0.06 ± 0.12	0.04 ± 0.11	0.09 ± 0.12	0.06 ± 0.13
I binocular	54	-0.06 ± 0.10	-0.10 ± 0.09	0.00 ± 0.12	-0.01 ± 0.10	0.04 ± 0.10	0.02 ± 0.11

[°] if not otherwise mentioned in table

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

In study F all patients had a binocular uncorrected visual acuity of logMAR 0.2 or better and 90 % had logMAR 0.1 or better at all distances (far, intermediate, near). Regarding monocular vision, still more than 90 % of the patients had an uncorrected visual acuity of logMAR 0.2 or better for all distances. UDVA was logMAR 0.1 or better in 90 % of the cases and UIVA and UNVA were logMAR 0.1 or better in 80 % of the cases.

Thanks to the continuously strong results at all three focal points, patients are able to enjoy a full range of vision, similar to a young phakic patient.

Visual acuity at various distances

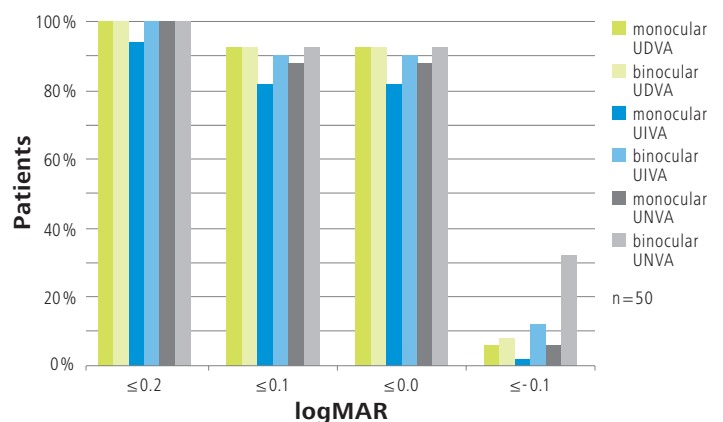


Figure 1. Monocular and binocular visual acuities at far, intermediate and near distances (Study F)

Mojzis et al.² compared the binocular defocus curve between bifocal and trifocal IOLs (Figure 2). Whereas the bifocal curve shows the typical valley in the intermediate range, the trifocal curve is much flatter between 0 D and -2.5 D, illustrating the very good intermediate visual acuity. The visual acuity is maintained below 0.10 logMAR (0.80 decimal) from distance vision up to a proximity of 40 cm (2.5 D), providing patients with a very smooth transition from near to distance vision and a continuous range of sharp vision.

Plaza-Puche and Alio analyzed the defocus curves of different multifocal IOLs.⁹ A comparison of the defocus curves of ZEISS AT LISA tri and PhysIOL's FineVision showed statistically significant differences in the intermediate range, with better results for ZEISS AT LISA tri. A comparison to Alcon's ReSTOR +3.0 highlighted the difference in intermediate VA with statistically superior results for ZEISS AT LISA tri at distances between 66 cm and 1 m (corresponding to a defocus range of -1.5 D to 1.0 D).

Defocus Profile

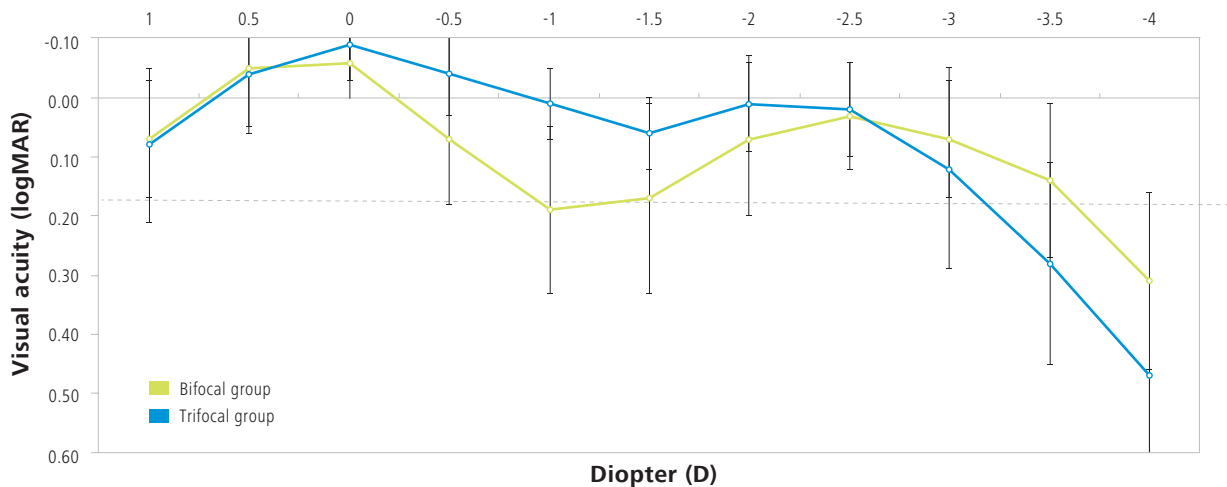


Figure 2. Mean binocular defocus curve in the bifocal (green) and trifocal (blue) groups

Refraction

Clinical results show that the ZEISS AT LISA tri 839MP provides very good postoperative refractive results. Several studies confirm the high refractive predictability with the ZEISS AT LISA tri IOL (Table 3).

Postoperative refraction

Study	n	SE ± SD (D)	Sphere ± SD (D)	Cylinder ± SD (D)	Follow up
A	76	-0.08 ± 0.25	0.05 ± 0.25	-0.1 ± 0.18	3 months
B	208	0.14 ± 0.41	0.34 ± 0.42	-0.43 ± 0.37	3 months
C	60	-0.29 ± 0.33	-0.19 ± 0.35	-0.20 ± 0.21	3 months
D	60	-0.12 ± 0.39	-0.02 ± 0.38	-0.28 ± 0.28	6 months
E	100	-0.08 (-1.38 to 0.75)	+0.20 (-0.75 to 1.00)	-0.58 (-1.75 to 0.00)	3 months
G	204	n/a	-0.06 ± 0.21	-0.09 ± 0.21	6 months
H	120	–	0.1	-0.34	12 months
I	54	0.05 ± 0.32	–	0.32 ± 0.33	3 months

Table 3: Mean postoperative refraction

Mojzis et al.¹⁰ plotted the spherical equivalent of their 60 patients before and 3 months after surgery in the below radial chart, demonstrating the refractive accuracy in their study. Whereas before surgery, patients had refractive deviations in the range

of 5 to -11.5 D (blue curve), after surgery all patients were within ± 1 D (shaded area and orange curve), with many along the black line, representing 0D residual refraction.

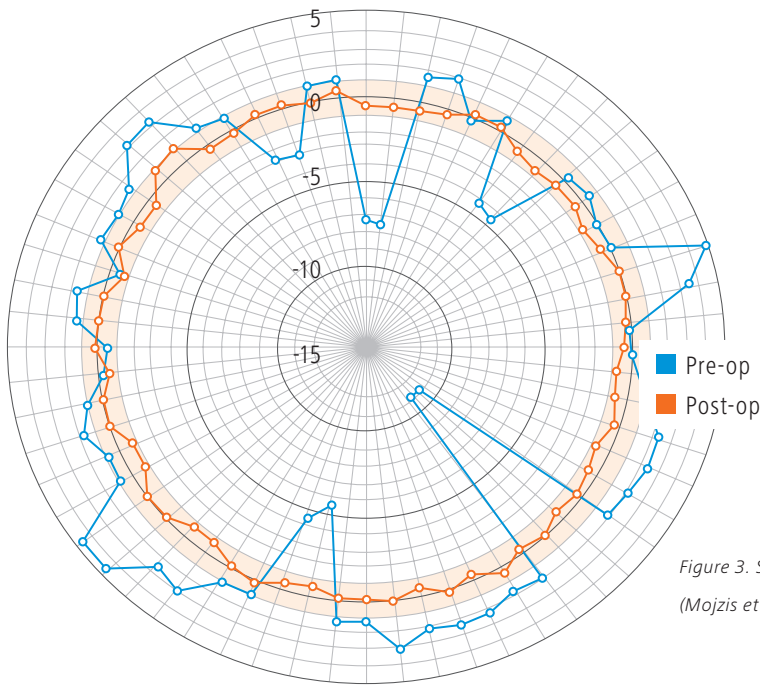


Figure 3. Spherical equivalent before and 3 months after surgery (Mojzis et al.¹⁰)

Figure 4 shows a stable refraction after implantation of the AT LISA tri IOL over 12 months in study H.

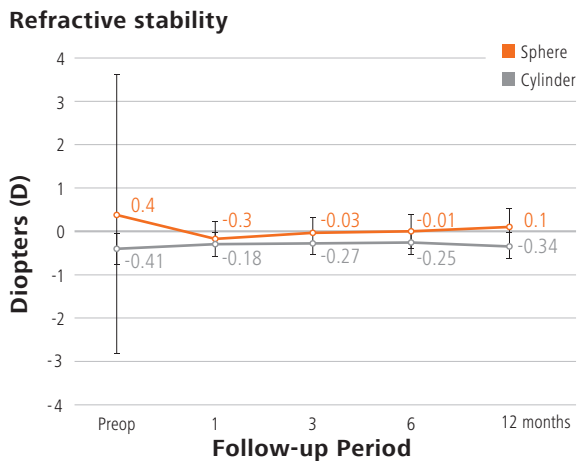


Figure 4. Changes in the manifest sphere and cylinder during the 12 months follow-up period (Study H)

Study I showed 80% of all eyes with a spherical equivalent accuracy within ± 0.5 D 3 months after surgery (see Figure 5). In study A the SE of all patients was within ± 1.0 D and 90% of the patients had a SE within ± 0.5 D after 3 months.

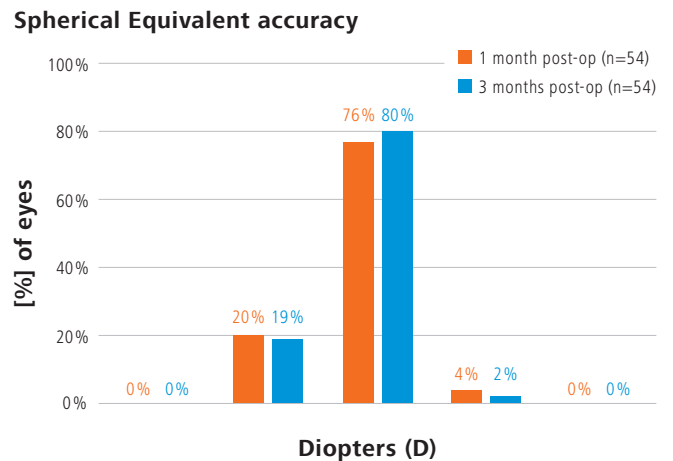


Figure 5. Monocular postoperative achieved accuracy of spherical equivalent (SE) after implantation of an AT LISA trifocal intraocular lens (Study I)



Patient satisfaction

All studies investigating patient satisfaction yielded very high ratings for ZEISS AT LISA tri. The following section summarizes these findings, highlighting patient satisfaction feedback for different daily activities as well as spectacle independence scores. In study D 30 patients were asked to rate their vision in certain situations. For typical activities at various distances including reading, the average rating was in the range of satisfied to very satisfied (Figure 6).

Patient Satisfaction Evaluation

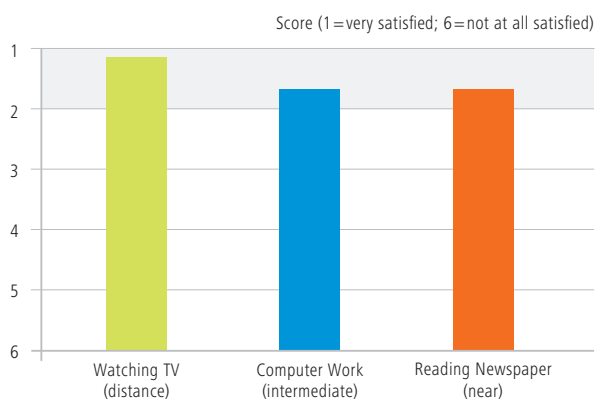


Figure 6. Average ratings for patient satisfaction for distance, intermediate and near vision (Study D), 6 months post-op

A scale from 1 (very good) to 6 (very bad) was used in study I to evaluate patients' uncorrected vision quality for the different daily tasks. The average score was 1.98 ± 1.07 . Moreover, 92% patients would choose the same IOL again and recommend it to others.

High patient satisfaction with ZEISS AT LISA tri is further reflected in study B, in which 96% of patients stated that they would choose a multifocal lens again. Low levels of halos (15%) and glare (10%) were found after 6 months in a study with 34 patients¹¹, contributing to the high level of patient satisfaction in this study. In study A, 90% of the patients reported to perceive halos at 1 month after surgery, however, 80% of these patients described these halos as not disturbing. At 3 months after surgery, the perception of halos decreased to 50%.

Spectacle independence

Spectacle independence is the predominant goal of patients when they opt for a multifocal IOL. The trifocal design of ZEISS AT LISA tri 839MP provides 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 7).

Spectacle Independence (Study B)

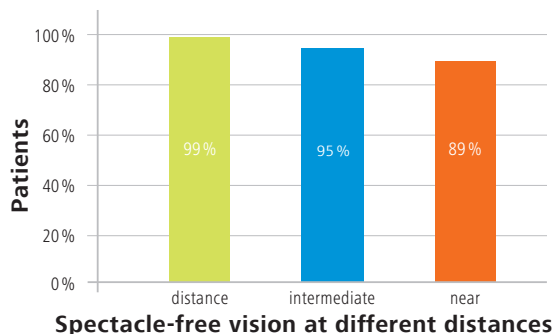


Figure 7. Level of spectacle independence 3 months after surgery (Study B)

These results are confirmed by study I with 100 % of the patients being spectacle-free at far and intermediate distances and only 12 % of the patients needing a near correction occasionally.

In a study by Kretz et al.¹² the DATE (Daily Tasks Evaluation) score – a questionnaire developed at the International Vision Correction Research Centre (IVCRC) of the University of Heidelberg, Germany – was used to provide a quick method for evaluating the patients’ satisfaction and ability to perform daily tasks.

Less than 10 % of the 52 patients in the study needed glasses to read newspapers or a book or to do computer work and only 15 % needed glasses to perform precision work. Study E confirmed these findings, reporting that 96 % of the patients could perform their daily activities without problems. Specifically, the mean spectacle independence scores for reading, doing computer work, and for activities requiring distant vision were 10.33 ± 12.47 , 5.71 ± 11.90 , and 3.92 ± 9.77 , respectively (Scale used: 0 = no spectacles needed; 40 = spectacles always needed), showing that most patients could perform these tasks without the use of spectacles.

Contrast sensitivity

The clinical results from a European randomized trial** measured with an Optec 6500 device demonstrated that contrast sensitivity is maintained within the normal range (Figure 8). This is achieved by the higher light energy transmittance and optimization of the diffractive ring design.

Analyzing specifically the contrast sensitivity performance of IOLs in low mesopic conditions, Plaza-Puche et al. confirmed that the third focus point does not adversely affect the low mesopic contrast sensitivity of ZEISS AT LISA tri.¹³

Contrast sensitivity

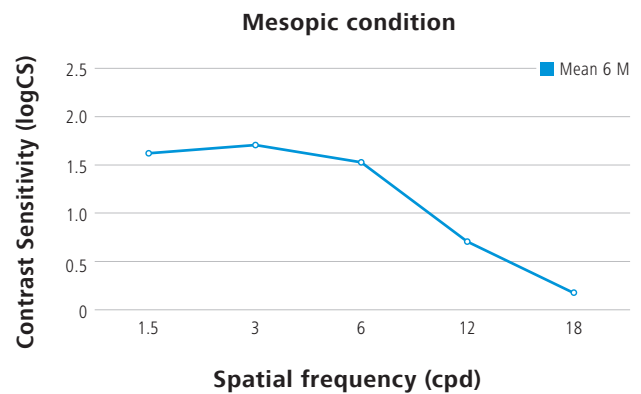
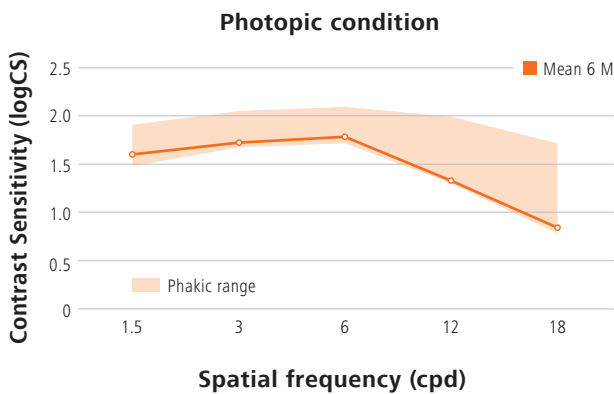


Figure 8. Mean-6 months postoperative contrast sensitivity function**

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, including patients with astigmatism. Clinical investigations with ZEISS AT LISA tri toric have confirmed an outstanding performance of this IOL.

Study J: 220 eyes / 110 patients (12 months multicentered study)**

Study K: 56 eyes / 28 patients (3 months), prospective case series¹⁴

Study L: 40 eyes / 20 patients (12 months), prospective case series¹⁵

Study M: 40 eyes / 20 patients (6 months), prospective case series¹⁶

Study N: 40 eyes / 20 patients (3 months), prospective case series¹⁷

Study O: 56 eyes / 28 patients (3 months), prospective case series¹⁸

Study P: 23 eyes / 12 patients (1 month), prospective case series¹⁹

Study Q: 30 eyes / 16 patients (3 months), prospective study²⁰

Table 4: Studies with the ZEISS AT LISA tri toric 939MP IOL

Visual acuity and refraction

As for the ZEISS AT LISA tri 839MP, an excellent visual performance was found for all distances with the ZEISS AT LISA tri toric 939MP.

Study	n	UDVA	CDVA	UIVA (80 cm) [°]	DCIVA (80 cm) [°]	UNVA (40 cm) [°]	DCNVA (40 cm) [°]
J monocular	220	0.10 ± 0.14 (n=210)	0.02 ± 0.11 (208)	–	–	–	–
J binocular	220	0.02 ± 0.10 (208)	-0.02 ± 0.09 (206)	0.06 ± 0.16 (204)	0.06 ± 0.15 (204)	0.16 ± 0.14 (208)	0.15 ± 0.13 (204)
K monocular	56	0.13 ± 0.15	0.00 ± 0.09	66 cm: 0.08 ± 0.15	66 cm: 0.05 ± 0.17	0.13 ± 0.18	0.02 ± 0.07
K binocular	56	0.05 ± 0.10	-0.04 ± 0.08	66 cm: 0.08 ± 0.19	66 cm: -0.03 ± 0.11	0.10 ± 0.16	-0.03 ± 0.11
L monocular	40	0.14 ± 0.18	0.00 ± 0.07	66 cm: 0.04 ± 0.07	–	0.16 ± 0.10	–
L binocular	40	0.10 ± 0.11	0.00 ± 0.08	66 cm: 0.00 ± 0.05	–	0.09 ± 0.07	–
M monocular	40	0.05	–	0.05	–	0.12	–
N monocular	40	0.00	-0.05±0.04	<0.1	–	<0.20	–
O monocular	56	-0.08	-1.0	-0.12	-0.12	0.00	-0.06
Q binocular	30	0.03 ± 11	0.00 ± 0.09	0.08 ± 0.11	0.07 ± 0.11	-0.10 ± 0.30	0.15 ± 0.09

[°] if not otherwise mentioned in table

Table 5: Monocular and binocular visual acuity results with the AT LISA tri toric IOL

* The information contained in this clinical leaflet is based on clinical studies conducted on AT LISA tri toric 939MP/M. The AT LISA tri toric 949MP/M, the version in SE notation, is equivalent in lens design; the statements in this clinical leaflet can therefore be considered applicable. Please note that refractive outcomes may vary slightly depending on the calculation method and constants chosen.

In a case series (Study P) with 23 eyes 75 % reached an uncorrected monocular distance visual acuity (decimal) of 1.0 (corresponding to 0.0 logMAR) or better and 91 % of 0.8 (0.1 logMAR) or better after 1 month. Uncorrected monocular intermediate visual acuity was better than 0.8 (0.1 logMAR) in 83 % of the cases and 78 % of the eyes reached an uncorrected monocular near visual acuity of 0.8 (0.1 logMAR) or better. Binocular uncorrected near visual acuity was better than 0.8 (0.1 logMAR) in 100 % of the patients.

In study K, 98.2 % of the patients had a postoperative cylinder within ± 1.0 D and 78.6 % had a manifest cylinder of ± 0.5 or less. The spherical equivalent was within ± 1.0 D and ± 0.5 D in 89.3 % and 71.4 % of eyes, respectively. All patients had a target refraction within ± 1.0 D in study L. The data confirms that the toric model of the AT LISA tri provides consistently excellent refractive outcomes for patients with astigmatism. This is further supported by the defocus curve of the trifocal toric AT LISA tri (Figure 9) which shows the same continuous range of vision as the defocus curve of the non-toric model (Figure 2).

Defocus curve of the AT LISA tri toric IOL

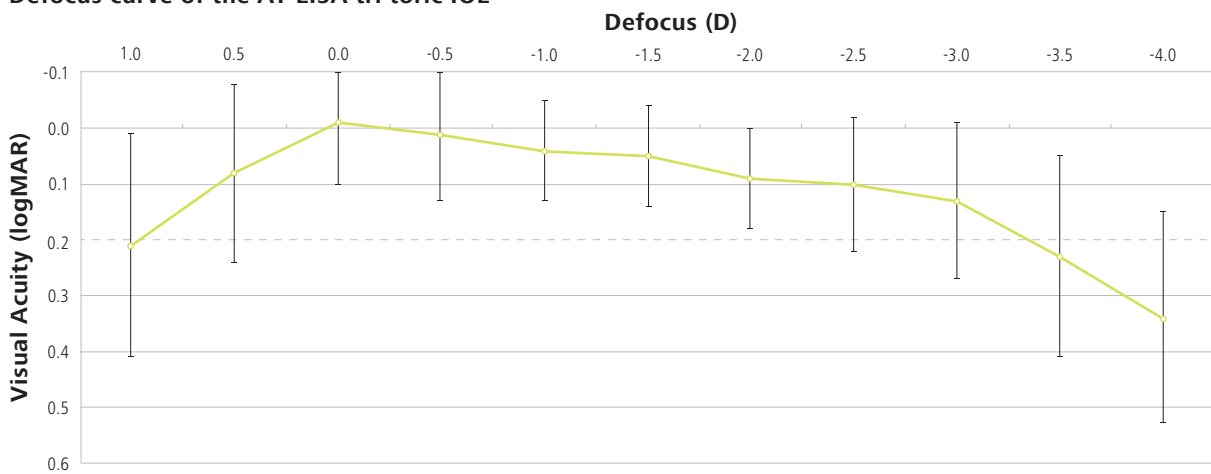


Figure 9. Binocular defocus curve with the AT LISA tri toric (Study Q)

Contrast sensitivity

Contrast sensitivity was measured with the CSV-100 device in study Q. Figure 10 shows the photopic and mesopic results as well as the normal range of a phakic eye.

Contrast sensitivity of the AT LISA tri toric IOL

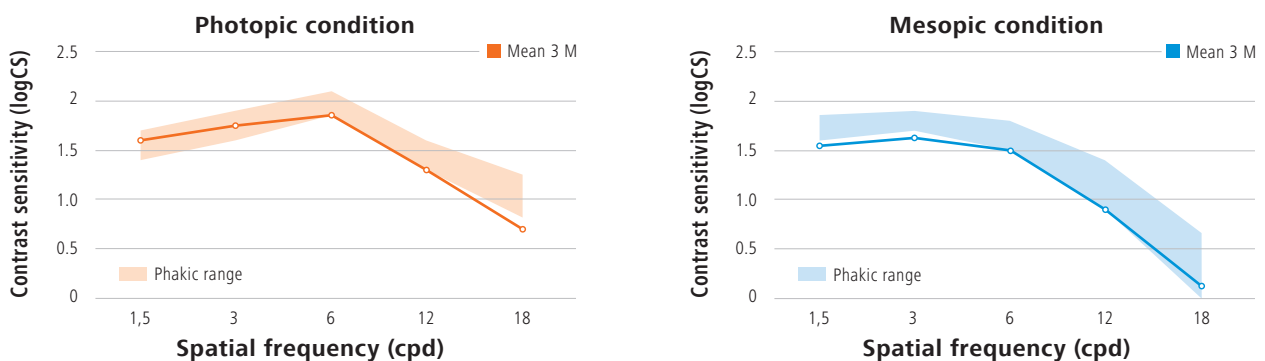


Figure 10. Contrast sensitivity with the AT LISA tri toric IOL (Study Q) 3 months postoperatively

Rotational stability

To achieve good visual results in astigmatic patients, precise alignment and postoperative rotational stability of the toric IOL is of critical importance. AT LISA tri toric from ZEISS proved to consistently provide very good rotational stability in studies: In all cases of study P the lenses were stable and within 5° of the intended axis one month after surgery. No IOL rotations were noted in studies N and O. In study L, in 95% of the eyes the achieved IOL axis was within 5° of the intended axis. After 12 months the achieved axis was within 5° of the target axis in 96.6% of the eyes of study J.

Reading acuity

Subjective reading acuity, measured with the Salzburg Reading Desk was 0.11 logRAD at an average preferred distance of 38.9 cm. Subjective intermediate acuity was 0.03 logRAD at an average preferred distance of 78.2 cm (Study N). Study J revealed a reading acuity of 0.15 ± 0.13 logRAD at a mean preferred distance of 37.40 cm and a reading speed of 163.57 ± 41.08 words per minute (wpm). These results are better than those found for other diffractive, apodized and refractive multifocal IOLs (Diffractive IOLs: reading acuity 0.27 ± 0.13 logRAD; reading speed 139 ± 32 wpm; Apodized: 0.29 ± 0.15 logRAD; 147 ± 35 wpm; Refractive: 0.40 ± 0.16 logRAD; 152 ± 40 wpm) using the same method to assess reading acuity and speed.²¹

Patient satisfaction

12 months after surgery, all patients of study J were highly satisfied with their postoperative vision. On a scale from 0 to 10 (with 0 standing for very satisfied and 10 for not satisfied at all) the mean satisfaction scores were 0.6 ± 0.6 for distance, 0.7 ± 0.7 for intermediate and 0.7 ± 0.8 for near vision.

Figure 11 shows the high patient satisfaction at far, intermediate and near distance, resulting in more than 98.1% of the patients who would choose the same lens again.

Patient satisfaction with the AT LISA tri toric IOL

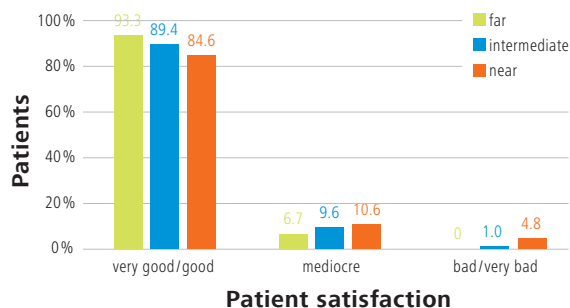


Figure 11. Patient satisfaction after 3 months with the AT LISA tri toric at various distances (Study J)

Spectacle independence

12 months after surgery, 87.5% of the patients reported to never use reading glasses or to do it only occasionally. Only one patient reported to always wear spectacles for near vision. Figure 12 shows how often patients wore glasses for far, intermediate and near distances 12 months after bilateral implantation of the ZEISS AT LISA tri toric IOL. Strong spectacle independence scores further led to high patient satisfaction, with 95.2% of the patients being happy with their spectacle-free distance and intermediate and 83.7% with their near vision.

Use of spectacles after implantation of the AT LISA tri toric IOL

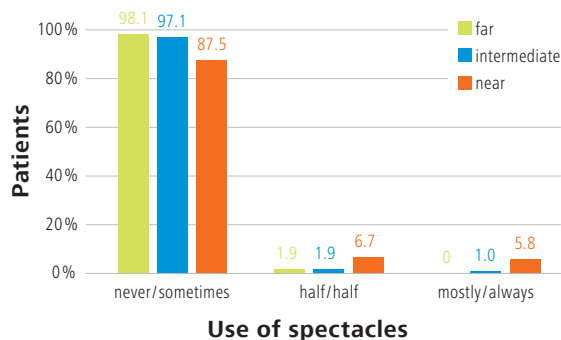



Figure 12. Use of spectacles 3 months after implantation of the AT LISA tri toric (Study J)



*"The 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)

Conclusion

These clinical results highlight the advantages of the ZEISS trifocal optic design represented by the AT LISA tri family. It provides patients with True Living Vision: an excellent vision at all distances. AT LISA tri and AT LISA tri toric are ideal for patients who are looking for a high level of spectacle independence and comfortable vision while performing their daily activities.

** Unpublished European studies performed between 2012 and 2016 at various sites. Data on file

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