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Science Brief

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Clinical evidence supporting the predictable refractive outcomes, efficient cylindric correction, and long-term stability of the Bi-Flex Toric IOL family

- Preoperative corneal astigmatism affects a remarkable proportion of cataract patients. Astigmatism-correction has not only become feasible in combination with the cataract surgery, but efficient cylindric correction has been shown to be essential for the best possible visual outcomes.

- We are very pleased to share that the predictable surgical results, efficient spherical and cylindric correction, high quality vision, and long-term refractive and rotational stability of our **Bi-Flex Toric** intraocular lenses have been confirmed by several clinical investigations released during the past few years.

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Efficient Astigmatism-Correction

Predictable refractive results – minimal residual spherical and cylindric refraction.

The majority of eyes result close to the refractive target (usually emmetropia), and also close to the pre-estimated residuals calculated prior to the surgery. These results confirm that the IOL sits in the effective lens position, and also approve the efficiency of the Medicontur IOL Optimizer IOL-calculation application.[1-6]

Residual astigmatism is close to zero.

Postoperative residual astigmastim is minimal, most of the eyes achieve a residual cylindric refraction within ±0.5 Dioptres from the refractive target. This confirms the efficiency of the Medicontur toric solutions in correcting astigmastism, and also support the validity of the optimized IOL-constants.[1-6]

Vector analysis confirms precise achievement of the refractive target.

Vector analysis helps you understand the astigmastim-correcting potential of toric IOLs, and helps the surgeon make correct decisions when choosing a toric lens. Postoeprative vector analyses confirm, that the Medicontur Toric lenses are able to correct preoperative cylindric error with high efficiency: TIA (Target Induced Astigmatism) and SIA (Surgical Induced Astigmatism) vectors are similar, the difference vector (DV) is close to zero, and the correction index (CI) tends to 1.0.[2,6]

Publications	Eyes / Patients	Calculation	Follow-up (months)	SEQ ± 0.5 D	SEQ ± 1.0 D	CYL ± 0.5 D	CYL ± 1.0 D
Bachernegg A, 2013, Austria[1]	20 / 30	Haigis	3	90%	100%	80%	97%
Bachernegg A, 2015, Austria[2]	20 / 30	Haigis	12	72%	93%	73%	86%
Harrisberg B, 2020, Australia[3]	115 / 97	Barrett + Total Corneal Astigmastim	1	85%	99%	97%	100%
Harrisberg B, 2020, Australia[4] *	29 / 17	Barrett + Total Corneal Astigmastim	1	96%	100%	100%	100%
Nemcova M, 2019, Czech Rep.[5]	35 / 22	Haigis + Total Corneal Astigmastim	3	89%	100%	80%	97%
Novacek L, 2020, Czech Rep.[6]	35 / 22	Haigis + Total Corneal Astigmastim	12	79%	97%	85%	100%

*Table 1. The majority of eyes (%) achieve a postoperative refraction close to the refractive target after Bi-Flex 677TA(Y) IOL-implantation. Residual refractive errors (SEQ= Spherical Equivalent Refraction; CYL= Cylindric Refraction) * Liberty 677MTY Trifocal IOL*

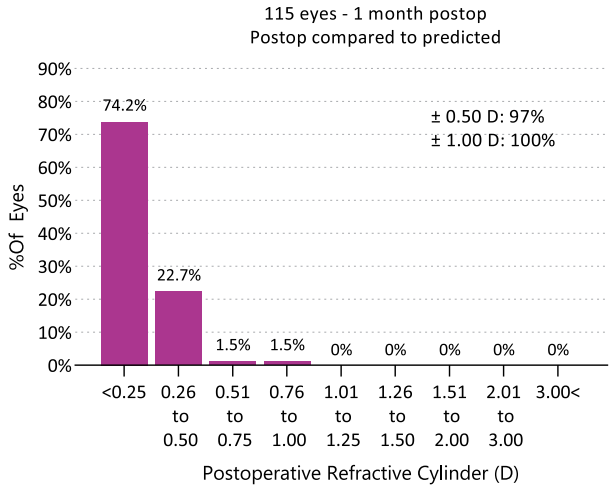

Figure 1. Residual cylindric refraction after Bi-Flex 677TAY-implantation 1 month postoperatively. (Harrisberg, 2020)

Vector analysis Parameter	Optimal value	Bachernegg, 2015	Novacek, 2020
TIA (Target Induced Astigmatism)	none	2.35 ± 0.66 0.60 D Ax180°	1.5 1.01 D Ax2°
SIA (Surgically Induced Astigmatism)	none	2.39 ± 0.73 D 0.80 D Ax177°	1.45 1.01 D Ax2°
DV (Difference vector)	0 (TIA-SIA)	0.41 ± 0.45 D 0.30 D Ax82°	0.17 0.09 D Ax158°
CI (Correction index)	1.0	1.02 ± 0.25	0.96
IOS (Index of Success)	0.0	0.22 ± 0.27	n.r.
Mean Magnitude of Error	0.0	0.08 ± 0.38	n.r.
Mean Angle of Error	0.0	2.72° ± 6.78°	n.r.

Table 2. Vector analysis parameters confirm efficient cylindric correction. n.r.= not reported. (Bachernegg, 2015; Novacek, 2020)

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Outstanding Visual Quality

Excellent visual acuity.

Significant improvement of visual acuity could be observed in all distances, even in the case of the monofocal toric IOL. There was only a 0.5-line difference between the UDVA and the CDVA postoperatively.[1-6]

Improvement of corrected visual acuities and near vision.

Due to the efficient astigmatism-correction, not only uncorrected, but also best corrected distance and near visual acuities improved significantly, compared to the preoperative status ($p<0.0001$).[7] Cylindric correction with a toric IOL helps in achieving the best possible visual outcomes, which is not feasible with conventional cylindric spectacles. [1-6]

Low level of dysphotopsia.

Visual disturbances are rarely reported, their severity is tolerable for the patients. Clinical results confirm the optical bench measurements which had shown that the seven diffractive rings of the Liberty IOLs provided sharp image on the retina without remarkable light scattering. Dysphotopic events are even less frequently reported by patients implanted with the Toric Liberty IOL-model, as cylindric correction further reduces light scattering deriving from the near focal point in low-light conditions or when focusing on distant objects.[4]

Highly satisfied patients.

The majority of the patients are highly satisfied with their vision and with their quality of life after their cataract surgery. Most common daily activities are performed easily, often regardless of the requirement of distance, intermediate or near vision skills.[1-6]

Spectacle independence with the Liberty Toric IOL.

The efficient cylindric correction helps in achieving the best possible visual outcomes, lowers the level of dysphotopic sensations, and enhances to achieve real spectacle independence.[4]

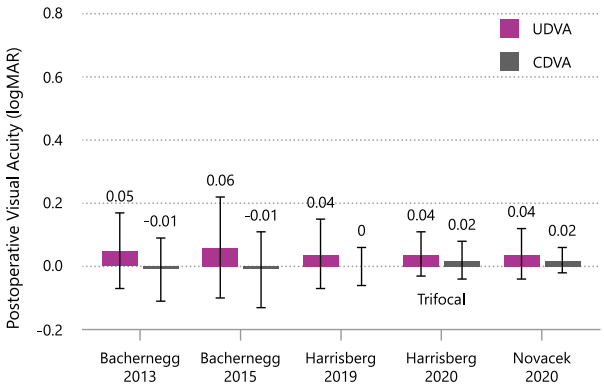

Figure 2. Postoperative monocular uncorrected and corrected distance visual acuities (logMAR) show excellent visual outcomes in various cohorts and patient populations

	Preoperative	Postoperative Month 3	Significance (p)
Distance			
UDVA (logMAR)	0.62 ± 0.40	0.04 ± 0.04	<0.0001
CDVA (logMAR)	0.22 ± 0.15	0.02 ± 0.03	<0.0001
Near			
UNVA (Jaeger)	8.46 ± 4.38	N/A	N/A
CNVA (Jaeger)	2.33 ± 1.76	1.09 ± 0.38	<0.0001

Table 3. Significant improvement of monocular uncorrected and corrected distance, and also near visual acuities could be observed, even after the implantation of the monofocal Bi-Flex 677TAY IOL (Novacek, 2020)

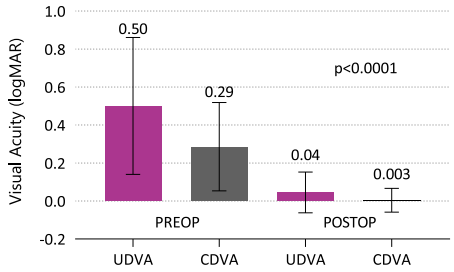

Figure 3. Both uncorrected and corrected monocular distance visual acuities improved significantly after cataract surgery and the correction of preoperative astigmastism (Harrisberg, 2020).

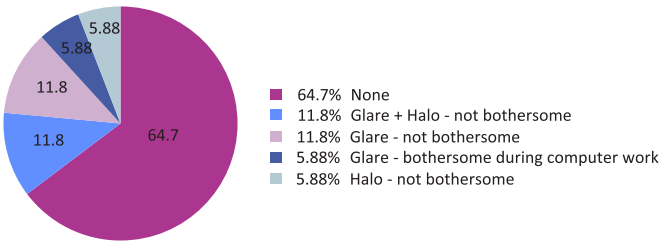

Figure 4. The majority of the patients do not report any dysphotopic phenomena. Those experiencing some rate them as usually not bothersome (Harrisberg, 2020)

Long-term Refractive and Rotational Stability

Refractive stability without significant shift.

Refractive outcomes achieved by the third postoperative month are shown to be stable in the long-term. No significant hyperopic or myopic shift could be observed. This also confirms that the Bi-Flex design of our toric IOLs ensures stability in the effective lens position, within the capsular bag.[2,6]

Stable visual outcomes.

Visual acuities measured later following IOL-implantation are similar to those obtained three months post-surgery.[2,6]

High rotational stability during the whole investigated period.

The magnitude of rotation (regarded as misalignment) could be seen within the first 24 hours, whereas only minimal rotation could be seen within the remaining follow-up between 1 day, 3 months, and 12 months. The Bi-Flex double-loop haptics ensure large contact angle (2 x 88.8°) with the wall of the capsular bag, which is the fundament of a good toric platform. No patient required a secondary procedure because of rotational instability or torus misalignment in any of the cohorts investigating the Medicontur Bi-Flex Toric IOLs. Off-axis rotation was within 5° in all eyes, in all relevant clinical studies.[2,6]

Low rate of PCO and Nd:YAG capsulotomy.

Thanks to the 360°continuous square edge design of the Bi-Flex lenses, the development of posterior capsule opacification could be efficiently reduced, and the majority of the patients did not need Nd:YAG laser capsulotomy within the first postoperative year.[2,7-12]

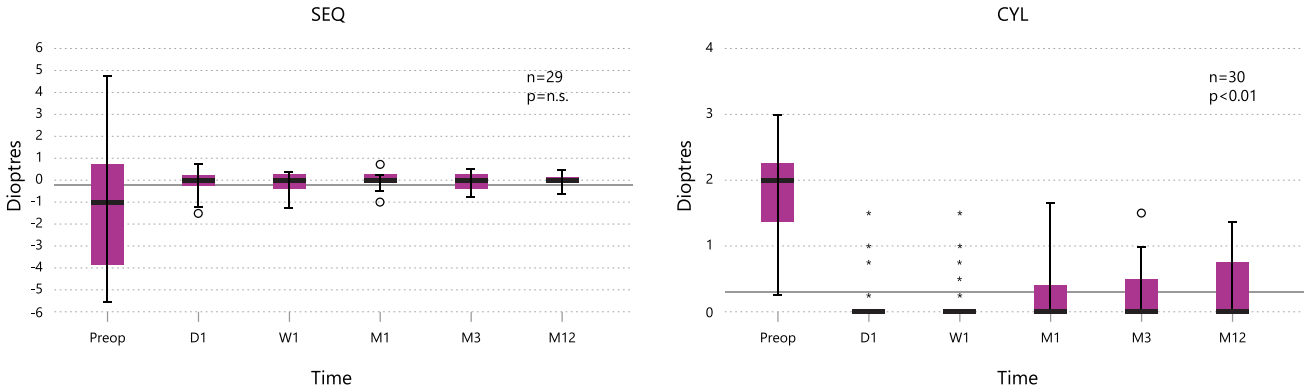

Figure 5. Stability of spherical equivalent (SEQ) and refractive astigmatism (CYL) over time after phacoemulsification and implantation of the Bi-Flex 677TAY toric IOL. The horizontal line in the SEQ-figure indicates the calculated mean postoperative target refraction. The dashed horizontal line in the CYL-figure indicates the calculated mean postoperative remaining refractive astigmatism. (Bachernegg, 2015)

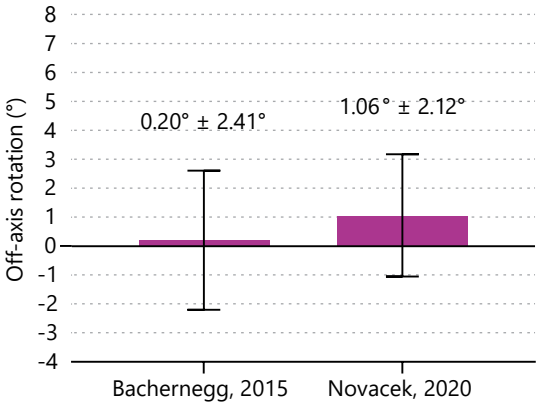

Figure 6. The Bi-Flex Toric IOLs maintain surgical position. Off-axis rotation is minimal. (Bachernegg, 2015; Novacek, 2020)

Study	Eyes / Patients	Follow-up (years)	PCO (eyes)	PCO (%)
Dexl, 2015	50 / 25	0.5	0	0
Bachernegg, 2015	30 / 20	1	0	0
Győry, 2019	100 / 50	1	0	0
Nagy, 2020	Liberty: 48 / 24 ReStor: 46 / 23	2	11 13	22.9 28.3
Gerbec, 2014	856 / 642	2.5	9	1.05
Vámosi, 2010	176 / 151	5	15	14.4
Győry, 2020	82 / 41	5	18	21.9

Table 4. Incidence of PCO following Medicontur Bi-Flex IOL-implantation.

Further reading **1. Bachernegg A,** Rückl T, Riha W, Grabner G, Dexl AK. Rotational stability and visual outcome after implantation of a new toric intraocular lens for the correction of corneal astigmatism during cataract surgery. J Cataract Refract Surg. 2013 Sep;39(9):1390-1398. **2. Bachernegg A,** Rückl T, Strohmaier C, Jell G, Grabner G, Dexl AK. Vector Analysis, Rotational Stability, and Visual Outcome After Implantation of a New Aspheric Toric IOL. J Refract Surg. 2015 Aug;31(8):513-520. **3. Harrisberg B.** Predictability of refractive and clinical outcomes after astigmatism correcting intraocular lens implantation. Presented as an e-poster at the virtual WOC Congress, 2020. **4. Harrisberg B.** Visual outcomes with supplementary multifocal sulcus IOLs. Presented at the RANZCO Congress in 2020, in Brisbane, Australia **5. Němcová M.** Clinical outcomes, astigmatism-correction and rotational stability after the implantation of the Medicontur Bi-Flex 677TAY toric intraocular lens. Presented at the Congress of Czech Cataract and Refractive Surgery (ČSRKCH), in Hradec Králové in 2019, **6. Nováček LV,** Němcová M, Tyx K, Lahodová K, Rejmont L, Rozsíval P, Studený P. Evaluation of astigmatism-correcting efficiency and rotational stability after catacract surgery with a double-loop haptic toric intraocular lens - a one-year follow-up. [Under peer-review] **7. Dexl A.** Visual outcome, patient satisfaction and spectacle independency after implantation of progressive Bi-Flex M. Final Result of a Multicentric study. Presented at the ESCRS 2014 Congress, in London, UK. **8. Győry JF.** Győry JF, Madár E, Srinivasan S. Implantation of a diffractive-refractive trifocal intraocular lens with centralized diffractive rings: Two-year results. J Cataract Refract Surg. 2019 May;45(5):639-646. **9. Nagy ZZs,** Kiss H, Juhász É, Sándor GL, Kránitz K, Dunai ÁF. The impact of intraocular lens design on refractive stability and long-term visual outcome – a comparative evaluation of two different presbyopia-correcting IOLs. [Under publication]. **10. Gerbec H.** First results with Medicontur Bi-Flex 677AB 1.8 hydrophilic aspheric IOL. Presented at the WESCRS Congress in 2014, in Ljubljana, Slovenia. **11. Vámosi P.** Nd:YAG-laser capsulotomy rates in 176 eyes 5 years after phacoemulsification. Presented at the ESCRS Congress in 2010, Paris, France.. **12. Győry JF,** Madár E, Balla L, Srinivasan S. Evaluation of the long- term performance of the trifocal intraocular lens with centralized diffractive rings: five-year results. [Under publication].

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