

The Rayner Line of Toric IOLs:
Highlights of Recently
Published Clinical Studies

Thanks to continuing advances in intraocular lens (IOL) technology, achieving spectacle-free vision post-cataract surgery has become the rule rather than the exception for many surgeons and their patients. While the ability of IOLs to correct the spherical equivalent of refractive error is regarded as a significant advantage of modern cataract surgery, surgeons increasingly recognise the importance of also correcting any pre-existing corneal astigmatism – estimated to affect around 20-30% of cataract patients.¹

Until relatively recently, pre-existing corneal astigmatism was managed with spectacles, contact lenses, or patients were required to undergo corneal curvature-altering procedures such as limbal relaxing incisions which can cause corneal damage and result in unsatisfactory refractive outcomes.² Consequently, since their conception in 1992³, toric IOLs have fast become the go-to solution for enhancing post-surgical uncorrected visual acuity in cataract patients with astigmatism.

Rayner Toric Solutions

Today, cataract surgeons have a number of toric IOL options which vary according to the material type, design, diameter, incision size, and spherical / cylindrical power (**Tables 1 and 2**). Rayner's toric IOL portfolio includes the T-flex Aspheric (a monofocal toric) and M-flex T (a multifocal toric).

T-flex Aspheric Toric IOLs offer a precise superior alternative to incisional methods for the treatment of pre-existing corneal astigmatism.⁴ Available in cylinders 1.0 D to 11.0 D in 0.5 D increments, T-flex IOLs offer a far greater range of cylinder and sphere combinations than most other toric IOLs, thus allowing the correction of significant levels of astigmatism.⁴ The technical specifications of the T-flex are summarised in **Table 1**.

M-flex T Multifocal Toric IOLs combine multifocal and toric optical components. This feature potentially offers reduced spectacle

dependence to be extended to patients with significant corneal astigmatism, i.e., above 1.5 D (for who standard multifocal IOLs are contraindicated);⁵ the technical specifications of the M-flex T are summarised in **Table 2**.

Clinical Evidence

The T-flex Aspheric Toric

Refractive Outcomes: Correction of Low to Moderate Astigmatism

Numerous studies have demonstrated the improvements in refractive outcomes afforded by the T-flex Aspheric Toric lens. For example, data from an ongoing prospective study found that the T-flex is an effective method of correcting low to moderate astigmatism. Data from 10 eyes of 6 patients showed that 2 to 4 months after surgery, median uncorrected distance visual acuity (UDVA) was 0.12 logMAR (range: -0.18 to 0.54 logMAR), and median corrected distance visual acuity (CDVA) increased from 0.20 logMAR (range: 0.02 to 0.44 logMAR) preoperatively to -0.10 logMAR (range: -0.26 to 0.16 logMAR) postoperatively. The median difference between achieved versus intended spherical equivalent was -0.18 D (range: -1.25 to +0.23 D), while median cylinder improved from -2.63 D (range: -6.50 to -0.25 D) preoperatively to -0.5 D (range: -1.25 to 0.00 D) after surgery.⁶

Refractive Outcomes: Treating Patients with More Severe Astigmatism

Findings from a prospective, observational study undertaken by Alberdi and colleagues also suggest that the T-flex is effective in patients with more severe astigmatism. Results from the study, which included 27 eyes with preoperative corneal astigmatism >1.5 D implanted with the T-flex (573T and 623T), demonstrated that the mean UDVA 3 months after surgery was 0.1042 ± 0.1290 , with 20/40 vision or better in 96% of eyes and 20/25 vision or better in 52% of eyes. Mean refractive postoperative sphere was 0.25 ± 0.37 D and mean refractive

Table 1: Currently Available Monofocal Toric IOLs

Toric IOL	Material	IOL Design	IOL Diameter (mm)	Aspheric	Spherical Power (D)	Cylinder Power	Incision Size
T-flex (Rayner)	Hydrophilic Acrylic	Loop haptic	12.0/12.5	+	-10.0 to +30.0	1.0 to 11.0 (0.5 steps)	<2.0
AcrySof (Alcon)	Hydrophobic Acrylic	Loop haptic	13.0	+	+6.0 to +30.0	1.5 to 6.0 (0.75 steps)	2.2
AF-1 toric (Hoya)	Hydrophobic acrylic with PMMA haptic Tips	Loop haptic	12.5	+	+6.0 to +30.0	1.5 to 3.0 (0.75 steps)	2.0
Acri.Comfort/AT Tobi (Carl Zeiss Meditec)	Hydrophilic acrylic with hydrophobic surface	Plate haptic	11.0	+	-10.0 to +30.0	1.0 to 12.0 (0.50 steps)	<2.0
Lentis Tplus (Topcon)	Hydrophobic acrylic with hydrophobic surface	Loop/plate haptic	12.0/11.0	+	0.00 to +30.0	0.25 to 12.0 (0.75/0.01 steps)	2.6
Light-adjustable lens (Calhoun Vision)	Silicone with PMMA haptics	Loop haptic	13.0	+	+17.0 to +24.0	0.75 to 2.0	3.0
Microsil/Torica (HumanOptics)	Silicone with PMMA haptics	Loop haptic	11.6	-	-3.0 to +31.0	2.0 to 12.0 (1.0 steps)	3.4
Morcher 89A (Morcher GmbH)	Hydrophilic Acrylic	Bag-in-the-lens	7.5	-	+10.0 to +30.0	0.5 to 8.0 (0.25 steps)	2.5
Staar (Staar Surgical Company)	Silicone	Plate haptic	10.8/11.2	-	+9.5 to +28.5	2.0 or 3.5	2.8
Tecnis toric (Abbott Medical Optics)	Hydrophobic Acrylic	Loop haptic	13.0	+	+5.0 to +34.0	1.0 to 4.0 (0.5 to 1.0 steps)	2.2

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postoperative cylinder was 0.52 ± 0.63 . Vector analysis of attempted versus achieved visual correction showed that 100% of eyes were within ± 1.0 D and 87% of eyes were within ± 0.50 D. Further data showed the mean change in keratometric astigmatism was 0.54 ± 1.33 for J0 and -0.24 ± 1.17 for J45 ($p > 0.05$).⁷

Refractive Outcomes: Patients with >2.0 D Astigmatism

Similarly, data from a 46 eye study by Painter et al found that the T-flex improves refractive outcomes even in patients with > 2.0 D astigmatism. Postoperatively, 72% of patients had unaided vision of 6/9 or better, with 42% having < 0.25 D of residual cylinder and 78% having < 1.5 D of residual cylinder, compared with 6.9% preoperatively. Once astigmatism had been converted to power vectors, J0 reduced in magnitude from -0.81 D \pm 0.85 to 0.09 D \pm 0.42 ($p < 0.001$).⁸ An 84-eye study by Dr. Jacob Vos from the Pasteur Medical Centre in Bloemfontein, South Africa, also found that the T-flex was effective in patients with astigmatism > 2.0 D. Results showed that all patients experienced a significant improvement in UCVA. The author noted that 64 of 84 eyes (76%) had postoperative UCVA of 0.5 or better whereas pre-operatively only one eye had UCVA of 0.5 or better.⁹

Refractive Outcomes: T-flex to Treat Patients with a Pre-existing Corneal Astigmatism ≥ 3.0 D

Although the majority of commercially-available toric lenses typically correct astigmatism of ≤ 2.5 D, results from a small cases series study suggest that the T-flex might also be effective in patients with a pre-existing corneal astigmatism ≥ 3.0 D. Findings from the 12 eye (9 patient) study by Iovieno and colleagues, showed that at a mean follow-up of 3.75 months, there was a significant improvement in UDVA (1.0 ± 0.64 vs 0.39 ± 0.21 logMAR; $p < 0.05$), cylindrical refraction (-4.72 ± 1.13 vs -1.81 ± 1.10 D; $p < 0.01$), and refractive spherical equivalent (-4.56 ± 5.58 vs -0.36 ± 1.19 D; $p < 0.05$).

The authors noted that astigmatism on the target axis was reduced by an average of 5.0 D ($p < 0.01$).¹⁰

The T-flex's ability to provide excellent, stable visual outcomes in patients with astigmatism has also been demonstrated in a large study. Data from a retrospective analysis encompassing 507 eyes that underwent cataract surgery over a 5-year period revealed that while there was a wide range of preoperative spherical errors (range, -10.5 D to $+9.0$ D), post T-flex implantation, the mean absolute error was only 0.35 D (standard deviation [SD], 0.46 D). Patients included in the study also had wide range of refractive astigmatism (from 0.0 D to 7.25 D), while keratometric astigmatism ranged from 0.67 D to $+7.86$ D, and keratometry values from values from 33.35 to 59.00mm. The mean postoperative cylinder from all these cases was 0.26 D (SD, 0.35 D), with 90% of patients having 0.5 D or less of astigmatism post-T-flex implantation. In terms of postoperative residual astigmatism, 6% of patients had $+1.0$ D, 7 patients had more than $+1.0$ D and no patient had more than $+2.0$ D of residual astigmatism. The rate of complications was also low. Two patients had radial tears in the continuous curvilinear capsulorrhexis and 1% of patients had cystoid macular oedema (all cases were resolved with topical steroid and ketorolac treatment). There were no returns to theatre for IOL misalignment.¹¹

Refractive Outcomes: Improving Visual Acuity and Astigmatism in Post-Keratoplasty

The efficacy of the T-flex in improving visual acuity and astigmatism in post-keratoplasty (PK) patients has also been demonstrated in a retrospective analysis by Stewart and McAlister. Results from the study, which included 14 non-PK and 8 PK patients who underwent cataract surgery and astigmatism correction with the T-flex showed that best spectacle-corrected visual acuity improved from preoperative values in both PK and non-PK groups, and that there was no statistically significant difference between groups. However, postoperatively

Table 2: Currently Available Multifocal Toric IOLs

Toric IOL	Material	IOL Design	IOL Diameter (mm)	Multifocal Technology	Near Addition (D)	Aspheric	Spherical Power (D)	Cylinder Power (D)	Incision Size (mm)
M-flex T (Rayner)	Hydrophilic acrylic	Loop	12.0/12.5	Refractive	+3.0 or +4.0	+	+14.0 to +32.0	1.0 to 6.0 (0.5 steps)	<2.0
AcrySof IQ Restor toric (Alcon)	Hydrophobic acrylic	Loop	13.0	Diffraction + refractive	+3.0	+	+6.0 to +34.0	1.0 to 3.0 (0.5/0.75 steps)	2.2
Acri.LISA toric (Carl Zeiss Meditec)	Hydrophilic acrylic with hydrophobic surface	Plate	11.0	Diffraction	+3.75	+	-10.0 to +32.0	1.0 to 12.0 (0.5 steps)	<2.0
Lentis Mplus (Topcon)	Hydrophilic acrylic with hydrophobic surface	Plate	11.0	Sector-shaped refractive segment tor-shaped refractive segment	+3.0	-	0.0 to C36.0	0.25 to 12.0 (0.75/0.01* steps)	2.6

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only 50% of patients in the PK group had a best uncorrected visual acuity of 6/12 or better, versus 93% in the non-PK group. Postoperative refractive spherical error decreased in both groups to a mean of -0.857 D in the non-PK group and -1.438 D in the PK group; there was no statistically significant difference between the groups. Mean postoperative cylindrical refractive error decreased from preoperative values by approximately 50% for both groups (non-PK 57.3%, PK 53.5%). Further, an analysis of the postoperative astigmatic power vector (APV) demonstrated a statistically significant reduction (as compared with preoperative values) within each group (non-PK, $p=0.0075$; PK, $p=0.0043$). There was also a statistically significant difference between the mean of both groups preoperatively and postoperatively with the difference of the APV between PK and non-PK groups decreasing from 2.05 D to 0.992 D, a difference of 50%. These findings led the authors to conclude that the T-flex is an effective method of treating both regular corneal-based astigmatism and cataract in both PK and non-PK patients.¹²

de Sanctis et al also evaluated the T-flex in 3 patients with high PK astigmatism (range 6.75 to 8.75 D), and found that 12 months postoperatively, UDVA improved from 20/200 to 20/30 in Patient 1, from 20/400 to 20/40 in Patient 2, and from 20/200 to 20/25 in Patient 3; CDVA was 20/25 or better in all 3 patients. Additional data showed that the sphere equivalent was within ± 0.50 D of the intended value, and that the refractive astigmatism was <1.00 D in all eyes. The authors also observed that the rotation of the T-flex was less than 5 degrees.¹³



T-flex® Aspheric (Rayner)

Rotational Stability and Lens Centration

One of the challenges associated with toric IOL implantation lies in ensuring that the lens remains in position and demonstrates rotational stability. Results from a 27-eye prospective, observational study found that mean rotation of the T-flex was minimal and remained stable at 3 months postoperatively with the greatest rotation found in the immediate postoperative period. Rotation $<10^\circ$ was noted in 92.6% of eyes, and no statistically significant differences were found between the rotations of the two T-flex lens models (573T and 623T). Decentration did not prove to be clinically significant in any patient and was in line with findings observed in a study with the AcrySof toric IOL (Alcon Laboratories).⁷

Additional data from a 33-eye study published in the *Journal of Refractive and Cataract Surgery* in 2011 also highlights the excellent rotational stability of the T-flex. Specifically, Entabi et al found that all eyes were within 15 degrees of the intended axis and 91% were ± 10 degrees at 4 months post-surgery. Additional findings showed that T-flex also produced a statistically-significant reduction in the preoperative mean cylinder at 4 months post-surgery.¹⁴ Further data from a 15-eye study by Steinwender and colleagues also confirmed the rotation stability of the T-flex. During the first postoperative month, the mean absolute IOL rotation was 5.60 degrees ± 3.21 , similar to that of the iSert toric (HOYA Surgical Optics).¹⁵

Circumventing the Need for LRIs

Cataract patients with a low to moderate degree of corneal astigmatism (<2.5 D) who desire reduced spectacle dependency have a number of treatment options available to them including incisional keratotomy, or a combination of limbal relaxing incisions (LRIs) with implantation of a monofocal IOL. Findings from a study undertaken by Hirschschall and colleagues that included 60 eyes of 30 patients (with 30 eyes being implanted with the T-flex), with corneal astigmatism ranging from 1.0 to 2.5 D found that patients who were implanted with the T-flex demonstrated a statistically significant reduction ($p=0.042$), in the mean astigmatism vector; 1.74 ± 0.64 (SD) in the toric IOL group 1.27 ± 0.76 D compared with the LRI group. Furthermore the study highlighted the predictability of toric IOLs over LRIs, as astigmatism in the LRI group showed a statistically significant increase ($p<0.001$), in the astigmatism vector from the 1 month to the 6 month postoperative visit.¹⁶

The M-flex T Multifocal Toric

Multifocality in astigmatic patients

The effectiveness of the T-flex lens when compared to LRIs, was also seen when the M-flex T was compared with the M-flex and LRIs. Findings from a study undertaken by Findl and colleagues that included 30 eyes of 30 patients with corneal astigmatism ranging from 1.0 to 2.5 D bilaterally, found that patients who were implanted with the M-flex T had similar visual outcomes as those who received LRI and non-toric IOL implantation.¹⁷

Specifically, the mean refractive astigmatism with the toric IOL was 0.4 D 3 months after implantation, compared with 0.8 D in the eyes treated with an LRI and multifocal IOL. The uncorrected distance and near visual acuities were similar in both groups, but there was a trend toward slightly better, although not significant, results in the eyes with the M-flex T. Additionally, rotational stability was excellent and patients' satisfaction with their visual outcomes was high.¹⁷ These findings are echoed by results from a single-centre, randomized, contralateral eye controlled clinical trial reported by Vinod Gangwani MRCOphth, at the XXIX Congress of the ESCRS.

The trial, which enrolled 30 patients with 1.0 to 2.5 D of astigmatism in each eye, compared outcomes following implantation with the M-flex T in one eye, and the M-flex multifocal only IOL combined with LRI in the other eye. An analysis of data 3-months post-surgery revealed that the M-flex T was associated with better refractive and functional outcomes than multifocal IOL implantation with LRIs. Eyes with the M-flex T also had significantly less mean manifest residual cylinder, and well as significantly greater mean reduction in astigmatism compared with the M-flex/LRI group. Further, a higher proportion of eyes with the M-flex T had less than 0.5 D of residual cylinder than the eyes with the M-flex/LRIs (59 % versus 47%). Distance and near UCVA outcomes also were slightly better in the

M-flex T group compared with M-flex/LRIs group. The study also investigated rotational stability of the M-flex T, and found that after 3 months, the mean absolute rotation was 2.9 ± 2.3 D.¹⁸



M-flex T® (Rayner)

Improving Visual Acuity – and Quality of Life

Published data also shows that, like the T-flex, the M-flex T affords significant improvements in visual acuity. Data from a 50-eye study by Kwitko and colleagues found that 100% and 95.3% of patients achieved a UDVA of 20/40 and 20/30, respectively. All patients achieved an uncorrected near visual acuity (UNVA) of J4, with 96.9% and 92.3% attaining J3 and J2, respectively. Post-operatively, all patients were within 0.22 D (or better) of their intended cylindrical correction.¹⁹

The results of a 30 eye study by Mrukwa-Kominek and colleagues also suggest that the M-flex T is able to increase quality of life (QoL) by improving visual outcomes in patients with a corneal astigmatism of >1.5 D. Before surgery the mean UDVA was 0.33 ± 0.11 , and the mean BCDVA best-corrected distance visual acuity was 0.61 ± 0.091 . Post-operatively, the mean UDVA was 0.99 and 85% of eyes attained a UNVA of J2; intermediate vision was satisfied in 91% of eyes. The authors noted that the improvement in visual acuity paralleled improvements in quality of life as assessed by the VF-14 QoL Questionnaire.^{20, 21}

Expert View

As noted previously, cataract surgeons have a number of pseudophakic toric IOLs available to them. In addition to the T-flex, examples of currently available monofocal toric IOLs include: the AcrySof (Alcon Laboratories); the AF-1 toric (HOYA Surgical Optics); the Acri.Comfort/AT Torbi (Carl Zeiss Meditec); the light-adjustable lens (LAL, Calhoun Vision), the Microsil/Torica (Human Optics); the Morcher 89 A (Morcher GmbH); the Staar (Staar Surgical Company); the Lentis Tplus (Topcon); and, the Tecnis toric (Abbott Medical Optics). The availability of multifocal toric IOLs is somewhat more limited, and in addition to the M-flex T include the AcrySof IQ Restor (Alcon Laboratories), the Acri.LISA (Carl Zeiss Meditec), and the Lentis Mplus (Topcon). The technical specifications of each of the aforementioned toric IOLs are described in **Tables 1 and 2**.

While post-operative outcomes (which may in turn be influenced by factors including lens design, the biomaterial used, and the diameter of the IOL¹) undoubtedly drive toric IOL choice, the surgeon's experience and personal preferences may also influence IOL selection.

For Dr. Julián Cezón, MD, Medical Director at Clinica CIMO in Seville, Spain, what sets the T-flex aspheric toric lens apart from its competitors is that it offers a far greater range of cylinder and sphere combinations than most other toric IOLs. "In my experience, the T-flex toric IOL is also safe, stable, and efficient," he adds.

Other advantages of the T-flex toric IOL compared with other monofocal torics include the ease of implantation. According to Sanjay Mantry MBBS, FRCOphth, an ophthalmic surgeon in practice at the Gartnavel General Hospital, Glasgow, UK, implanting the Rayner T-Flex IOL for the correction of astigmatism is a very simple procedure. "I have achieved excellent results with this lens from the get-go, and over time, my results have only improved," he says.

Thomas Kohnen MD, PhD, Professor of Ophthalmology at Goethe University in Frankfurt, Germany, believes that the T-flex supersedes other IOLs on the market in several ways. “When we look at the published data in the scientific literature, and based on our own clinical experience, it is clear that the T-flex compares very favourably with other toric IOLs on the market in terms of key criteria such as uncorrected distance visual acuity, residual astigmatism, misalignment and ease of use,” he explains.

The M-flex T multifocal toric also rates highly among key opinion leaders. According to Sérgio Kwitko, MD, based at Hospital de Clínicas in Porto Alegre, Brazil, while there are a number of options for correcting vision in the cataract patient with astigmatism and presbyopia, such as a combination of multifocal IOL and limbal relaxing incisions, he prefers to address these issues in a single procedure – something he is able to do with the M-flex T. “For these patients, my lens of choice is the Rayner M-flex T multifocal toric IOL because it is precise, can be easily implanted in one surgery and it offers excellent stability over time,” he says.

Conclusions

Recently published data highlights the safety and efficacy of the Rayner range of toric IOLs. With regards to the T-flex, results from several clinical studies suggest that this IOL has good rotational stability and affords excellent refractive outcomes in cataract patients with pre-existing corneal astigmatism. Similarly, the M-flex T offers improved unaided distance and near vision in patients with varied degrees of corneal astigmatism. Furthermore both lenses provide astigmatic patients with options which avoid less stable methods of astigmatic correction.

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EC201454 07/14