College voor zorgverzekeringen

Onderwerp:	Plaatsing van torische lenzen bij cataract en astigmatisme
Samenvatting:	Bij patiënten met cataract en astigmatisme bestaat de gebruikelijke behandeling uit plaatsing van een spherische intraoculaire lens na cataractoperatie in combinatie met een bril. De vraag of behandeling van deze patiënten met een torische intraoculaire lens behoort tot de stand van wetenschap en praktijk wordt negatief beantwoord. Er zijn zeer weinig vergelijkende onderzoeksgegevens beschikbaar. De effectiviteit van het gebruik van de intraoculaire torische lens is niet aangetoond. Het College concludeert dat behandeling van cataract en astigmatisme door het plaatsen van een torische intraoculaire lens geen zorg is conform de stand van de wetenschap en praktijk.
Soort uitspraak:	SpZ = standpunt Zvw
Datum:	29 oktober 2010
Uitgebracht aan:	zorgverzekeraar
Zorgvorm:	Geneeskundige zorg

Onderstaand de volledige tekst.

De adviesaanvraag
U wilt advies omtrent de vraag of behandeling van cataract en astigmatisme door het plaatsen van een torische intraoculaire lens kan worden aangemerkt als een te verzekeren prestatie krachtens de Zorgverzekeringswet en aanverwante regelgeving (geneeskundige zorg).

Wet- en regelgeving
Met betrekking tot deze adviesaanvraag zijn de volgende bepalingen van belang.

- Artikel 10, onder a van de Zorgverzekeringswet. Hierin is omschreven dat het krachtens de zorgverzekering te verzekeren risico inhoudt de behoefte aan geneeskundige zorg, waaronder de integrale eerstelijnszorg zoals die door huisartsen en verloskundigen pleegt te geschieden.

- Artikel 11, derde lid van de Zorgverzekeringswet bepaalt dat bij algemene maatregel van bestuur de inhoud en omvang van de te verzekeren risico's nader kan worden geregeld. Deze algemene maatregel van bestuur vindt zijn uitwerking in het Besluit zorgverzekering.

- Artikel 2.1, eerste lid Besluit zorgverzekering regelt dat de zorg en overige diensten, bedoeld in artikel 11, eerste lid, onderdeel a, van de Zorgverzekeringswet de vormen van zorg of diensten omvatten die naar inhoud en omvang zijn omschreven in de artikelen 2.4 tot en met 2.15 van het Besluit zorgverzekering.

Artikel 2.4, eerste lid van het Besluit zorgverzekering omschrijft dat de zorg zoals onder meer medisch-specialisten deze plegen te bieden onder geneeskundige zorg valt.

- Artikel 2.1, tweede lid van het Besluit zorgverzekering bepaalt dat de inhoud en omvang van zorg of diensten mede wordt bepaald door de stand van de wetenschap en praktijk.

Stand wetenschap en praktijk
Behandeling van cataract en astigmatisme door het plaatsen van een torische intra-oculaire lens kan slechts worden aangemerkt als een te verzekeren prestatie indien het voldoet aan het criterium van de stand van de wetenschap en praktijk.

Werkwijze College
Het College volgt, ter bepaling van wat tot de stand van de wetenschap en praktijk gerekend dient te worden, de principes van evidence based medicine (EBM).
De methode van EBM integreert de medische praktijk en wetenschappelijke inzichten.
De methode houdt rekening met internationale literatuur, wetenschappelijke onderzoeken en gepubliceerde expert-opinies.

Evidence based wil niet zeggen dat voor alle geneeskundige interventies sprake moet zijn van harde bewijzen of harde eindpunten, maar wel dat de beschikbare evidence systematisch is geselecteerd en op gestructureerde wijze is gewogen en gebruikt.
Bij de beoordeling worden ook zachte eindpunten, zoals bijvoorbeeld kwaliteit van leven en patiënttevredenheid betrokken.
Kern van de methode is dat aan de medisch-wetenschappelijke informatie die is geselecteerd een niveau van bewijskracht wordt toegekend (het toekennen van "levels of evidence") waardoor een hiërarchie in evidence ontstaat. Kardinaal uitgangspunt bij EBM is verder dat sterke evidence in principe zwakkere evidence verdringt.

Uiteindelijk neemt het College een standpunt in over de vraag of de interventie al dan niet voldoet aan het criterium van de stand van de wetenschap en praktijk. Hierbij geldt als uitgangspunt dat er voor een positieve beoordeling medisch-wetenschappelijke gegevens voorhanden zijn met een zo hoog mogelijke bewijskracht.
Het College kan van dit vereiste afwijken, maar motiveert in dat geval waarom genoegen wordt genomen met bewijs van een lager niveau.
Alleen als de te beoordelen interventie gelijkwaardig is aan, of een meerwaarde heeft ten opzichte van de standaardbehandeling of gebruikelijke behandeling, concludeert het College dat er sprake is van zorg conform het criterium van de stand van de wetenschap en praktijk.

Voor een uitvoerige beschrijving van de wijze waarop het College beoordeelt of een interventie voldoet aan het criterium van de stand van de wetenschap en praktijk, verwijst het College naar zijn rapport *Beoordeling stand van de wetenschap en praktijk*. (CVZ 2007, 254).

Medische beoordeling
Na kennisneming van uw adviesaanvraag heeft het College deze voor een medische beoordeling voorgelegd aan zijn medisch adviseur. De medisch adviseur heeft onderzoek gedaan naar de stand van de wetenschap en praktijk van behandeling van cataract en astigmatisme door het plaatsen van een torische intraoculaire lens. Het volledige rapport is bijgevoegd. Onderstaand treft u een korte samenvatting en de conclusie aan.

Bij patiënten met cataract en astigmatisme bestaat de gebruikelijke behandeling uit plaatsing van een spherische intraoculaire lens na cataractoperatie in combinatie met een bril.
De vraag of behandeling van deze patiënten met een torische intraoculaire lens behoort tot de stand van wetenschap en praktijk wordt negatief beantwoord. Er zijn zeer weinig vergelijkende onderzoeksgegevens beschikbaar. De effectiviteit van het gebruik van de intraoculaire torische lens is niet aangetoond.
Het College concludeert dat behandeling van cataract en astigmatisme door het plaatsen van een torische intraoculaire lens geen zorg is conform de stand van de wetenschap en praktijk.

Juridische beoordeling
De vraag die beantwoord moet worden is of behandeling van cataract en astigmatisme door het plaatsen van een torische intraoculaire lens kan worden aangemerkt als een te verzekeren prestatie krachtens de Zorgverzekeringswet en aanverwante regelgeving.

Gelet op de toepasselijke regelgeving en het advies van de medisch adviseur, is het College van oordeel dat voornoemde behandeling niet voldoet aan de stand van de wetenschap en praktijk. Om die reden kan een dergelijke behandeling niet worden aangemerkt als een te verzekeren prestatie krachtens de Zorgverzekeringswet.

Advies van het College
Het College adviseert u bovenvermeld advies te betrekken in uw eventuele beslissing naar uw verzekerde(n).

Rapport

Achtergrondrapportage beoordeling stand van de wetenschap en praktijk torische intraoculaire lenzen

ICD-10 code: H52.2

Zorgactiviteit: 031241

Datum:29-10-2010

Uitgave

College voor zorgverzekeringen
Postbus 320
1110 AH Diemen
Fax (020) 797 85 00
E-mail info@cvz.nl
Internet www.cvz.nl

Volgnummer 2010116483
Afdeling ZORG-ZA

Auteurs dr. J. den Dekker
Doorkiesnummer Tel. (020) 797 85 43

Inhoudsopgave

Samenvatting

Bij patiënten met cataract en astigmatisme bestaat de gebruikelijke behandeling uit plaatsing van een spherische intraoculaire lens na cataract operatie in combinatie met een bril. De vraag of behandeling van deze patiënten met een torische intraoculaire lens behoort tot de stand van wetenschap en praktijk wordt negatief beantwoord. Er zijn zeer weinig vergelijkende onderzoeksgegevens beschikbaar. De effectiviteit, duurzaamheid, veiligheid en doelmatigheid van gebruik van de intraoculaire torische lens zijn niet aan getoond.

1. Inleiding

1.a. Aanleiding

Aanleiding voor dit rapport is de adviesaanvraag van een zorgverzekeraar. De zorgverzekeraar vraagt of er ruimte is om plaatsing van torische lenzen bij een cataract operatie te vergoeden op grond van de Zorgverzekeringswet. Een eerder CVZ advies heeft deze behandeling uitgesloten[1]. Wellicht zijn met het voortschrijden der tijd nieuwe inzichten beschikbaar gekomen. Volgens specialisten zou met een dergelijke ingreep het astigmatisme goed kunnen worden gecorrigeerd.

1.b. Achtergrond torische intraoculaire lenzen

Begrippen

Cataract is een vertroebeling van de ooglens waardoor het zien vermindert. Astigmatisme is een cylindrische oogaandoening waarbij de vorm van het hoornvlies niet rond, maar ovaal is. Daardoor is de breking van het licht binnen het oog niet in alle richtingen gelijk. Een monofocale kunstlens corrigeert alleen een sferische afwijking (bijziendheid en verziendheid). Een torische kunstlens corrigeert ook de cylindrische afwijking van het oog.

(Patho)fysiologie

Cataract of grijze staar is een vertroebeling van de ooglens die uiteindelijk tot blindheid kan leiden. De bekendste vorm van cataract is ouderdomsstaar (seniele cataract). Soms ontstaat cataract door ziekte (bijvoorbeeld diabetes), geneesmiddelengebruik (bijvoorbeeld langdurig gebruik van corticosteroïden) of een ongeval. In zeldzame gevallen is cataract aangeboren.

[1] Zaaknummer 26000585

	Cataract verloopt heel geleidelijk. Het kan in één of beide ogen voorkomen. Meestal gaat het om een normaal verouderingsproces.
Prevalentie	Cataract is de hoofdoorzaak van slechtziendheid boven de leeftijd van 55 jaar. Boven 75 jaar zou ongeveer 15% van de bevolking in meer of mindere mate aan cataract lijden. Schattingen van het voorkomen van astigmatisme lopen uiteen van enkele tot tientallen procenten van de bevolking.
Spontaan beloop	Bij cataract wordt het zicht troebeler en worden de kleuren minder intens. Er is een noodzaak om meer licht te gebruiken bij het lezen, het contrast tussen de letters en de achtergrond vervaagt, er treedt een vergeling van kleuren op, de omgeving wordt mistig. Veel patiënten worden gevoeliger voor licht en autorijden wordt gevaarlijk, vooral 's nachts. Cataract is niet te genezen. De aandoening is echter vrijwel altijd goed behandelbaar: de ondoorzichtig geworden lens wordt verwijderd en daarvoor in de plaats wordt een kunstlens geplaatst. Een oogarts voert deze ingreep uit. De ingreep vindt meestal onder plaatselijke verdoving plaats en heeft een lage kans op complicaties.
Standaard Behandeling/ Vergelijkende behandeling	Het gaat in dit rapport om implanteerbare lenzen ter behandeling van cataract bij patiënten die tevens lijden aan astigmatisme. De bestaande behandeling bestaat uit het plaatsen van een niet-torische (sferische) intraoculaire lens en een bril ter correctie van het astigmatisme.
(Nieuwe) interventie	Om astigmatisme te bestrijden kan een torische lens worden geplaatst. Een torische lens is een lens met extra functionaliteit, te weten cylindrische correctie. Vanwege deze eigenschap worden aan dergelijke lenzen hoge eisen gesteld voor wat betreft stabiliteit (voorkómen van rotatie).

1.c. Vraagstelling literatuuronderzoek

Vraagstelling	De vraagstelling van dit rapport luidt: voldoet behandeling van cataract en astigmatisme door het plaatsen van een torische intraoculaire lens aan de stand van wetenschap en praktijk?
Patiëntenpopulatie	Het betreft patiënten met zowel cataract als astigmatisme.
Relevante uitkomstmaten	Belangrijke uitkomstmaten zijn de zichtscherpte en het voorkomen van complicaties na plaatsing van torische lenzen in vergelijking tot de gebruikelijke behandeling.

Relevante follow-up duur	Geïmplanteerde sferische lenzen vertonen neiging tot rotatie tot 24 maanden na plaatsing. Een follow-up van torische lenzen van 24 maanden is daarom gewenst.
Vereiste methodologische studiekenmerken	Goed opgezet, gerandomiseerd vergelijkend onderzoek. Dubbelblind onderzoek is praktisch niet mogelijk bij deze aandoening.

2. Zoekstrategie & selectie van geschikte studies

Zoektermen

Het CVZ heeft in augustus 2010 een literatuur search verricht met de zoektermen Toric AND lens OR lenses. De exacte zoekstrategie is weergegeven in bijlage 1.

Databases & websites

De literatuur search is doorgevoerd in Medline en de Cochrane Library voor de periode van mei 2006 tot augustus 2010.

De websites van de organisaties die zijn gescreend betreffende uitgebrachte standpunten en richtlijnen omtrent de toepassing van torische intraoculaire lezen staan eveneens in bijlage 1.

Selectiecriteria

In –en exclusie van de gevonden literatuur gebeurde op basis van abstracts. Indien artikelen niet op basis van de abstract konden worden geëxcludeerd zijn de gehele artikelen bekeken.

De volgende inclusie criteria zijn gebruikt bij de selectie van artikelen:

- Clinical trials/RCT's
- Reviews

Overige studies, waaronder ook medisch-technische verhandelingen zonder patiëntonderzoek, zijn uitgesloten.

3. Resultaten

3.a. Resultaten literatuursearch

Er zijn 39 artikelen gevonden (zie bijlage 1). Slechts twee studies vergeleken torische en sferische intraoculaire lenzen, waarvan één bij cataract-patiënten. Deze artikelen zijn geselecteerd (zie tabel 1).

3.b. Kwaliteit en beoordeling van de geselecteerde studies

Het betreft twee kleinschalige cohortonderzoeken met een zeer beperkte follow-up (6 maanden).

De kenmerken en resultaten van de geselecteerde studies zijn weergegeven in Tabel 1.

3.c. Effectiviteit

Op basis van de geselecteerde onderzoeken kan geen uitspraak worden gedaan over de effectiviteit van torische intraoculaire lenzen.

3.d. Standpunten en richtlijnen

Richtlijnen voor de toepassing van torische intraoculaire lenzen zijn niet gevonden. Wel gevonden is een standpunt van CIGNA (verzekeraar in de Verenigde Staten). Dit standpunt behelst het niet vergoeden van correctie van astigmatisme door intraoculaire, zoals torische, lenzen. (3)

Tabel 1 Overzicht geselecteerde studies

Eerste auteur, Jaar van publicatie	Type Onderzoek, follow-up duur	Aantal patiënten	Interventie en vergelijkende behandeling	Indicatie	Relevante uitkomstmaten	Resultaten	Commentaar[2]	Risk of bias[3]	Bewijs-klasse[4]
Lane (1)	Prospectief cohortonderzoek, 6 maanden	62 (40 vs 22); gem.lft. 69,1 vs 74,5 jr; mannen: 55,6 vs 41,7 %.	Torische IOL vs sferische IOL (bilateraal)	Cataract en astigmatisme	UCVA, BSCVA	UCVA: torische IOL gem. 1 lijn beter. BSCVA: geen verschil. Bril nodig: 24,3 vs 63,7%.	Kleine groep; vergelijkbaarheid twijfelachtig; beperkte rapportage methoden, korte follow-up.	onduidelijk	B
Statham (2)	Retrospectief cohortonderzoek, 6 maanden	12 vs 10	Torische IOL vs sferische IOL	Astigmatisme	Astigmatic Power Vector (APV), UCVA	Torische groep: APV gunstiger, UCVA beter.	Geen cataract, zeer kleine groep, rapportage zeer beperkt, korte follow-up.	hoog	B

[2] Inclusief opmerkingen over beoordeling van kwaliteit van de studie met name bij niet vergelijkende studies.

[3] Te bepalen aan de hand van vragenlijst/tabellen (volgnr. 2010019636). Kans op vertekening in de resultaten: hoog, laag, onduidelijk.

[4] Zoals gedefinieerd in rapport "Beoordeling stand van wetenschap en praktijk" (volgnr. 27071300):
A1: systematische review van tenminste twee onafhankelijk van elkaar uitgevoerde onderzoeken van A2-niveau;
A2: gerandomiseerd dubbelblind vergelijkend klinisch onderzoek van goede kwaliteit en voldoende omvang (RCT);
B : vergelijkend onderzoek, maar niet met alle kenmerken van A2;
C : niet-vergelijkend onderzoek;
D : mening van deskundigen.
Deze classificering is van toepassing op therapeutische interventies. Ongeacht het niveau moet het bewijs peer reviewed gepubliceerd zijn.

4. Bespreking

De vraag is of bij patiënten met cataract en astigmatisme het plaatsen van een torische intraoculaire lens leidt tot betere uitkomstmaten (gezichtsscherpte en complicaties) dan het plaatsen van een sferische lens in combinatie met een bril. Thans is onvoldoende evidence beschikbaar om deze vraag te kunnen beantwoorden. Er is hiernaar zeer weinig vergelijkend onderzoek gedaan. De effectiviteit van de intraoculaire torische lens is niet aangetoond.

5. Inhoudelijke consultatie

Gezien de beperkte beschikbare informatie is besloten af te zien van inhoudelijke consultatie.

6. Standpunt stand van wetenschap & praktijk

Bij patiënten met cataract en astigmatisme voldoet behandeling na cataract operatie met een torische intraoculaire lens niet aan de stand van wetenschap en praktijk.

7. Literatuurlijst

1. Lane SS, Ernest P, Miller KM, et al. Comparison of clinical and patient-reported outcomes with bilateral AcrySof toric of spherical control intraocular lenses. J Refract Surg 2009; 25(10): 899-901.

2. Statham M, Apel A, Stephensen D. Comparison of the AcrySof SA60 spherical intraocular lens and the AcrySof Toric SN60T3 intraocular lens outcomes in patients with low amounts of corneal astigmatism. Clin Experiment Ophthalmol 2009; 37(8): 775-9.

3. http://www.cigna.com/costumer_care/healthcare_professional/coverage_positions/medical/mm_0125_coveragepositioncriteria_intraocular_lens_implant.pdf.

Bijlage 1 Search torische intraculaire lenzen

Searchdatum: 31-08-2010
Zaaknr. 2010041757
Update van search uit 2006

Medline (PubMed)

Toric
AND
lens OR lenses

Limiet: vanaf 24-05-2006

Clinical trials/RCT's

1. Kwartz J and Edwards K. Evaluation of the long-term rotational stability of single-piece, acrylic intraocular lenses. Br J Ophthalmol 2010; 94(8): 1003-6.
Abstract: OBJECTIVES: To assess rotational stability beyond 3 months and compare the different designs and materials of two acrylic intraocular lenses (Akreos Adapt (Bausch & Lomb, Rochester, New York, USA) and AcrySof SA60AT (Alcon, Fort Worth, Texas, USA)). METHODS: Post hoc analysis of retro-illumination images from a previous multicentre, contralateral eye study was used to assess intraocular lens (IOL) position and rotational stability for up to 24 months postoperatively. The image of IOL and capsular bag enabled any rotation to be calculated by measuring the angle from the horizontal to an arbitrary point on the IOL edge. The difference between the angle at the first and subsequent visits was subtracted to give a measure of IOL rotational stability. RESULTS: Data were collected from 64 eyes fitted with the Akreos IOL and 58 eyes fitted with the AcrySof IOL. Mean (SD) absolute rotation values for the two IOLs were small over the 2-year period, ranging from 2.53 degrees (2.40 degrees) to 3.2 degrees (2.57 degrees) with Akreos Adapt and 2.67 degrees (2.22 degrees) to 3.33 degrees (3.06 degrees) with AcrySof SA60AT at 6 and 24 months, respectively. The differences were not statistically significant. Using the ANSI draft toric IOL standard, the percentage of lenses rotating < or =5 degrees was 90% at 6 months, 91% at 12 months and 80% at 24 months for the Akreos lens and 89% at 6 months, 75% at 12 months and 81% at 24 months for the AcrySof lens. CONCLUSION: Spherical, single-vision acrylic IOLs continue to show some tendency to rotate for up to 24 months postoperatively, although this is usually small. The Akreos Adapt lens may be a good platform for a toric lens product
Pub. type: Comparative Study
Journal Article
Multicenter Study
Randomized Controlled Trial
Research Support, Non-U.S. Gov't
ISSN: 1468-2079

2. Correia RJB, Moreira H, Netto SUL, et al. Visual performance after toric IOL implantation in patients with corneal astigmatism. Arq Bras Oftalmol 2009; 72(5): 636-40. (In het Portugees)
Abstract: PURPOSE: To analyze visual acuity without correction and rotational stability outcomes following toric IOL implantation. METHODS: Prospective study of 20 eyes of 13 patients that underwent phacoemulsification surgery indicated for cataract associated with regular keratomeric astigmatism, symmetrical, ranging from 1 to 4 diopters. Best corrected visual acuity, refraction, keratometry and computed topography were performed preoperatively. The calculation of cylindrical lens power and its placement were determined by the manufacturer. All lenses were implanted in the capsular bag by the same surgeon. The patients were examined by a second independent observer, at 1st, 10th, 20th, 30th, and 60th postoperative day. RESULTS: Visual acuity without correction ranged between 20/15 and 20/40. One eye achieved 20/15 (5%), 4 eyes 20/20 (20%), 6 eyes 20/25 (30%), 7 eyes 20/30 (35%) and 2 eyes 20/40 (10%). Best corrected visual acuity ranged between 20/15 and 20/40; two eyes with 20/15 (10%), 9 eyes 20/20 (45%), 7 eyes 20/25 (35%), 1 eye 20/30 (5%) and 1 eye 20/40 (5%). It is important to remember that the average spherical refraction was -0.05 SD (ranging from -0.50 to +0.75 SD). The mean cylindrical refraction was -0.63 CD

ranging from -0.50 to -1.25 CD. The IOL rotation in this study had an average of 3.2 masculine to 30 masculine, ranging from 0 masculine of rotation to a maximum of 13 masculine; 7 lenses (35%) suffered no rotation, 9 lenses (45%) suffered rotation between 1 masculine to 5 masculine, 3 lenses (15%) had rotation between 6 masculine to 10 masculine, and ultimately 1 lens (5%) had rotation between 11 masculine to 15 masculine. There was no significant rotation after the 30th postoperative day. DISCUSSION: The average of rotation of the IOL was 3.2 masculine, where 95% of IOLs presented rotation less than or equal to 10 masculine what means a very good rotational stability. In daily practice, a good visual acuity is directly related to IOL rotational stability and refractive predictability
Pub. type: Clinical Trial
Journal Article
ISSN: 1678-2925

3. Ruiz-Mesa R, Carrasco-Sanchez D, Diaz-Alvarez SB, et al. Refractive lens exchange with foldable toric intraocular lens. Am J Ophthalmol 2009; 147(6): 990-6, 996.
Abstract: PURPOSE: To assess visual and refractive outcomes, and rotational stability after refractive lens exchange (RLE) with toric intraocular lens (IOL) implantation to correct ametropia and preexisting astigmatism. DESIGN: Prospective, nonrandomized, observational case series (self-controlled). METHODS: This prospective, nonrandomized, and self-controlled study included 32 eyes of 19 consecutive patients with more than 1.00 diopter (D) of preexisting corneal astigmatism having RLE with AcrySof Toric IOL implantation (Alcon Laboratories Inc, Fort Worth, Texas, USA). Uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), refractive sphere, and keratometric and refractive cylinder were recorded preoperatively and 6 months after surgery. Toric IOL axis shift was also measured. A patient satisfaction, visual phenomena, and spectacle dependency questionnaire was also carried out. RESULTS: At 6 months postoperatively, UCVA was 20/32 or better in 100% of the eyes, with 84.3% achieving 20/25 or better. One hundred percent of eyes achieved 20/25 or better BCVA. No eye lost >or=2 lines, 1 eye lost 1 line, 16 eyes did not change, 4 eyes gained 1 line, and 11 eyes gained >or=2 lines of BCVA after the surgery. Mean refractive cylinder was reduced significantly after surgery from -2.46 +/- 0.99 D to -0.53 +/- 0.30 D (P < .001). Vector analysis to compare attempted vs achieved correction showed that 100% of eyes were within +/- 1.00 D for the spherical equivalent, and 100% of eyes were within +/-0.50 D for the astigmatic components (J(0) and J(45)). Mean toric IOL axis rotation was 0.90 +/- 1.76 degrees, being <or= 5 degrees in 96.8% of eyes evaluated. Patients were satisfied with their vision without reporting severe visual phenomena (from none to moderate). CONCLUSIONS: RLE with toric IOL implantation showed good visual and refractive outcomes for correcting spherical and cylindrical refractive errors
Pub. type: Controlled Clinical Trial
Journal Article
ISSN: 1879-1891

4. Mendicute J, Irigoyen C, Ruiz M, et al. Toric intraocular lens versus opposite clear corneal incisions to correct astigmatism in eyes having cataract surgery. J Cataract Refract Surg 2009; 35(3): 451-8.
Abstract: PURPOSE: To compare toric intraocular lens (IOL) implantation with paired opposite clear corneal incisions (OCCIs) for astigmatism correction in patients having cataract surgery. SETTING: Ophthalmology Service, Donostia Hospital, San Sebastian, Spain. METHODS: This randomized prospective clinical study comprised eyes with more than 1.00 diopter (D) of preexisting corneal astigmatism. One group had AcrySof toric IOL implantation and the other, paired 2.75 mm/3.20 mm OCCIs in the steep axis with spherical IOL implantation. Uncorrected (UCVA) and best corrected (BCVA) visual acuity, refraction, corneal and total higher-order aberrations (HOAs), photopic and mesopic contrast sensitivity, and toric IOL axis were measured 3 months postoperatively. RESULTS: Forty eyes (40 patients) were evaluated. In the toric group, 95% of eyes achieved 20/40 or better UCVA and 70%, 20/25 or better. In the OCCI group, 80% of eyes achieved 20/40 or better UCVA and 50%, 20/25 or better. All eyes achieved 20/25 or better BCVA. Mean refractive cylinder decreased significantly from preoperatively to postoperatively (-1.75 +/- 0.71 to -0.62 +/- 0.46 D, toric group; -1.61 +/- 0.67 to -0.97 +/- 0.51 D, OCCI group) (P<.01). In the toric group, 95% and 100% of eyes were within +/-0.50 D for J(0) and J(45), respectively. In the OCCI group, the

percentages were 70% and 100%, respectively. No significant differences in HOA were found between groups (P>.1). Contrast sensitivity was similar except at the highest spatial frequency, being better in the toric group (P<.01). CONCLUSION: Toric IOL implantation achieved a slight enhanced effect over OCCIs in treating preexisting astigmatism
Pub. type: Comparative Study
Journal Article
Randomized Controlled Trial
ISSN: 1873-4502

5. Bauer NJC, de Vries NE, Webers CAB, et al. Astigmatism management in cataract surgery with the AcrySof toric intraocular lens. J Cataract Refract Surg 2008; 34(9): 1483-8.
Abstract: PURPOSE: To present clinical data from a single-center prospective clinical trial of the AcrySof toric intraocular lens (IOL). SETTING: Academic Hospital Maastricht, Maastricht, The Netherlands. METHODS: Fifty-three eyes (43 patients) had implantation of an AcrySof toric IOL. Three toric models were evaluated in cylinder powers of 1.50 diopters (D) (SN60T3; T3 group, n = 16), 2.25 D (SN60T4; T4 group, n = 14), and 3.00 D (SN60T5; T5 group, n = 23) at the IOL plane. The T5 group was subdivided into eyes that could be fully corrected (T5a, n = 13) and eyes that could be partially corrected (T5b, n = 10). RESULTS: Four months postoperatively, the mean uncorrected visual acuity (UCVA) was 0.77 +/- 0.23 in the T3 group, 0.93 +/- 0.23 in the T4 group, 0.82 +/- 0.15 in the T5a group, and 0.47 +/- 0.13 in the T5b group. More than 90% of the combined eyes in the T3, T4, and T5a groups achieved a UCVA of 20/40 or better, and almost 80% achieved a UCVA of 20/25 or better. Residual refractive astigmatism of less than 0.75 D was achieved in 74% of eyes and of less than 1.00 D in 91%. The mean IOL misalignment was 2.5 +/- 2.1 degrees in the T3 group, 3.5 +/- 2.3 degrees in the T4 group, and 4.1 +/- 3.5 degrees in the T5 group. CONCLUSION: Implantation of the AcrySof toric IOL proved to be an effective, safe, and predictable method of managing corneal astigmatism in cataract patients
Pub. type: Clinical Trial
Comparative Study
Journal Article
ISSN: 0886-3350

6. Schallhorn S, Tanzer D, Sanders DR, et al. Randomized prospective comparison of visian toric implantable collamer lens and conventional photorefractive keratectomy for moderate to high myopic astigmatism. J Refract Surg 2007; 23(9): 853-67.
Abstract: PURPOSE: To compare the Visian Toric Implantable Collamer Lens (TICL), a toric phakic intraocular lens (IOL), and photorefractive keratectomy (PRK) in the correction of moderate to high myopic astigmatism. METHODS: This prospective, randomized study consisted of 43 eyes implanted with the TICL (20 bilateral cases) and 45 eyes receiving PRK with mitomycin C (22 bilateral cases) with moderate to high myopia (-6.00 to -20.00 diopters [D] sphere) measured at the spectacle plane and 1.00 to 4.00 D of astigmatism. All patient treatment and follow-up occurred at the Naval Medical Center San Diego. Study follow-up was 1 day, 1 week, 1, 3, 6, and 12 months postoperative. RESULTS: Mean best spectacle-corrected visual acuity (BSCVA), change in BSCVA, proportion of cases with improvement of 1 or more lines of BSCVA, proportion of cases with BSCVA and uncorrected visual acuity (UCVA) 20/12.5 or better, proportion of cases with BSCVA and UCVA 20/16 or better (6 months, 88% vs 54%, P=.002), and predictability +/-1.00 D (6 months, 100% vs 67%, P<.001) were all significantly better in the TICL group than the PRK group at all time periods studied postoperatively. Similarly, contrast sensitivity, tested at both the 5% photopic level and the 25% mesopic level, was significantly better at all postoperative time points in the TICL group. Mean spherical equivalent refraction was closer to emmetropia (0.28+/-0.41 vs 0.76+/-0.86, P=.005), and predictability +/-0.50 D and stability of manifest refraction (+/-0.50 D and +/-1.00 D) were significantly better in the TICL group at all postoperative visits through 6 months. Mean astigmatism correction at 6 months was not significantly different between the two groups (0.52+/-0.33 vs 0.46+/-0.35, P=.450). CONCLUSIONS: The TICL performed better than PRK in all measures of safety (BSCVA), efficacy (UCVA), predictability, and stability in this comparison, supporting the TICL as a viable alternative to existing refractive surgical treatments
Pub. type: Comparative Study

Journal Article
Randomized Controlled Trial
ISSN: 1081-597X

7. Sanders DR, Schneider D, Martin R, et al. Toric Implantable Collamer Lens for moderate to high myopic astigmatism. Ophthalmology 2007; 114(1): 54-61.
Abstract: PURPOSE: To assess the efficacy of the Toric Implantable Collamer Lens (ICL) to treat moderate to high myopic astigmatism. DESIGN: Prospective nonrandomized clinical trial. PARTICIPANTS: Two hundred ten eyes of 124 patients with between 2.38 and 19.5 diopters (D) of myopia (spherical equivalent [SE]) and 1 to 4 D of astigmatism participating in the United States Food and Drug Administration clinical trial of the Toric ICL. INTERVENTION: Implantation of the Toric ICL. MAIN OUTCOME MEASURES: Uncorrected visual acuity (UCVA), refraction, best spectacle-corrected visual acuity (BSCVA), adverse events, and postoperative complications. RESULTS: At 12 months postoperatively, the proportion of eyes with 20/20 or better UCVA (83.1%) was identical to the proportion of eyes with preoperative 20/20 or better BSCVA (83.1%); 76.5% had postoperative UCVA better than or equal to preoperative BSCVA. The mean manifest refractive cylinder dropped from 1.93 D (+/-0.84) at baseline to 0.51 D (+/-0.48) postoperatively, a 73.6% decrease in astigmatism. Although only 21.0% of eyes had 1-D refractive cylinder preoperatively (none less), 91.4% of cases had < or =1 D of cylinder postoperatively. Furthermore, 65.6% had < or =0.5 D and 40.9% had < or =0.25 D of refractive cylinder postoperatively. Mean manifest refraction SE (MRSE) improved from -9.36 D (+/-2.66) preoperatively to 0.05 D (+/-0.46) postoperatively. A total of 76.9% of eyes were predicted accurately to within +/-0.5 D, 97.3% to within +/-1.0 D, and 100% to within +/-2.0 D of predicted MRSE. Postoperatively, 37.6% of eyes had a BSCVA of 20/12.5 or better, compared with a preoperative level of 4.8%. Furthermore, BSCVA of 20/20 or better occurred in 96.8% postoperatively, compared with 83.1% preoperatively. Mean improvement in BSCVA was 0.88 lines; there were 3 cases (1.6%) that lost > or =2 lines of BSCVA after 12 months postoperatively, whereas 18.9% of cases improved by > or =2 lines. A total of 76.4% of cases gained > or =1 lines of BSCVA, whereas only 7.5% of cases lost the equivalent amount. Three ICL removals were performed without significant loss of BSCVA, and 1 clinically significant lens opacity was observed. CONCLUSION: The results support the efficacy and predictability of Toric ICL implantation to treat moderate to high myopic astigmatism. Important safety concerns were not identified
Pub. type: Clinical Trial
Journal Article
Multicenter Study
Research Support, Non-U.S. Gov't
ISSN: 1549-4713

9. Dick HB, Krummenauer F, Trober L. [Compensation of corneal astigmatism with toric intraocular lens: results of a multicentre study]
Ausgleich des kornealen Astigmatismus mit torischer Intraokularlinse: Ergebnisse der Multicenterstudie. Klin Monbl Augenheilkd 2006; 223(7): 593-608.
Abstract: This clinical trial was conducted to evaluate visual acuity, refraction and rotation after implantation of the foldable toric intraocular lens (IOL) MicroSil Toric. PATIENTS AND METHODS: 68 eyes of 48 patients from four different surgical departments were examined over a follow-up of three months after cataract surgery. RESULTS: An individually produced IOL with cylindrical correction between 2.0 and 12.0 D was implanted in all eyes. Postoperatively, 68 % of the eyes achieved an uncorrected visual acuity (VA) of 0.5 or better, 12 % achieved 1.0 or better. A corrected VA of 0.5 or better was achieved by 85 %, 31 % achieved a corrected VA of 1.0 or better. Corrected VA improved by 3 (+/- 2) lines. The uncorrected VA improved by 6.0 lines in the mean. The increases in uncorrected and corrected VA were statistically significant ($p < 0.001$). The efficacy index amounted to 1.1 in the median and 1.3 (+/- 1.5) in the mean. Residual refraction (spherical equivalent) was 0.89 D (+/- 0.7 D) in the mean and was reduced by 5.14 D (+/- 4.78 D) in the mean. The total astigmatic error was reduced both in a statistically as well as in a clinically significant manner from 4.6 D (+/- 2.3 D) to 1.12 D (+/- 0.9 D) in the mean. 75 % of eyes needed a postoperative cylindrical correction of less than 1.5 D, 95 % less than 2.25 D. Corneal astigmatism was not changed significantly ($p = 0,435$). The surgically induced astigmatism (Naeser) amounted to 0.7 D in the median. In 85 % of the cases IOL rotation was less than 5

degrees. 15 % of the IOLs rotated more than 5 degrees, one IOL more than 10 degrees (max. 28 degrees). Patients ranked their surgical outcome on a scale from 1 (very good) to 6 (poor) which resulted in a mean score of 1.9 (+/- 1.0; min. 1.0; max. 5.0). No clinically relevant correlations of clinical parameters and satisfaction were detected. CONCLUSION: Implantation of the foldable, toric IOL with Z-haptics decreased the refractive error and improved postoperative visual outcome. This IOL was suitable for low as well as for high astigmatism. IOL rotation was low during the follow-up of three months resulting in sufficient correction of the pre-existing astigmatism
Pub. type: Clinical Trial
English Abstract
Journal Article
Multicenter Study
ISSN: 0023-2165

Reviews

1. Buckhurst PJ, Wolffsohn JS, Davies LN, et al. Surgical correction of astigmatism during cataract surgery. Clin Exp Optom 2010; aheadofprint Aug 24.
Abstract: High levels of corneal astigmatism are prevalent in a significant proportion of the population. During cataract surgery pre-existing astigmatism can be corrected using single or paired incisions on the steep axis of the cornea, using relaxing incisions or with the use of a toric intraocular lens. This review provides an overview of the conventional methods of astigmatic correction during cataract surgery and in particular, discusses the various types of toric lenses presently available and the techniques used in determining the correct axis for the placement of such lenses. Furthermore, the potential causes of rotation in toric lenses are identified, along with techniques for assessing and quantifying the amount of rotation and subsequent management options for addressing post-operative rotation
Pub. type: JOURNAL ARTICLE
ISSN: 1444-0938

2. Huang D, Schallhorn SC, Sugar A, et al. Phakic intraocular lens implantation for the correction of myopia: a report by the American Academy of Ophthalmology. Ophthalmology 2009; 116(11): 2244-58.
Abstract: OBJECTIVE: To review the published literature for evaluation of the safety and outcomes of phakic intraocular lens (pIOL) implantation for the correction of myopia and myopic astigmatism. METHODS: Literature searches of the PubMed and Cochrane Library databases were conducted on October 7, 2007, and July 14, 2008. The PubMed search was limited to the English language; the Cochrane Library was searched without language limitations. The searches retrieved 261 references. Of these, panel members chose 85 papers that they considered to be of high or medium clinical relevance to this assessment. The panel methodologist rated the articles according to the strength of evidence. RESULTS: Two pIOLs have been approved by the US Food and Drug Administration (FDA): one iris-fixated pIOL and one posterior-chamber IOL. In FDA trials of iris-fixated pIOLs, uncorrected visual acuity (UCVA) was >or=20/40 in 84% and >or=20/20 in 31% after 3 years. In FDA trials of posterior-chamber pIOLs, UCVA was >or=20/40 in 81% and >or=20/20 in 41%. Satisfaction with the quality of vision with both types of pIOLs was generally high. Toric anterior- and posterior-chamber pIOLs have shown improved clinical results in European trials compared with spherical pIOLs. Comparative studies showed pIOLs to provide better best spectacle-corrected visual acuity (BSCVA) and refractive predictability and stability compared with LASIK and photorefractive keratectomy and to have a lower risk of retinal detachment compared with refractive lens exchange. Reported complications and long-term safety concerns include endothelial cell loss, cataract formation, secondary glaucoma (pupillary block, pigment dispersion), iris atrophy (pupil ovalization), and traumatic dislocation. CONCLUSIONS: Phakic IOL implantation is effective in the correction of myopia and myopic astigmatism. In cases of high myopia of -8 diopters or more, pIOLs may provide a better visual outcome than keratorefractive surgeries and better safety than refractive lens exchange. The short-term rates of complications and loss of BSCVA are acceptable. Comprehensive preoperative evaluation and long-term postoperative follow-up examinations are needed to monitor for and prevent serious complications, and to establish long-term safety
Pub. type: Journal Article
Research Support, Non-U.S. Gov't

Review
ISSN: 1549-4713

3. Dick HB and Buchner SE. [Toric phakic intraocular lenses]
Torische phake Intraokularlinsen. Ophthalmologe 2007; 104(12): 1032-40.
Abstract: After more than 3 years of follow-up, the satisfactory results achieved with the toric iris-fixated phakic intraocular lens (IOL) mean we can regard implantation of this lens as a procedure with the potential to provide safe, predictable, effective and stable correction of astigmatic errors, providing patients are carefully selected and receive adequate preparation for surgery. The iris-fixated toric phakic IOL (Verisyse, Advanced Medical Optics; Artisan, Ophtec) is a PMMA lens with a total diameter of 8.5 mm and an optic diameter of 5 mm. It has a spherical anterior and a toric posterior surface. Its refractive power ranges from -2 dpt to -21 dpt for myopia and from +2 dpt to +12.5 dpt for the correction of hyperopia. Cylindrical correction is available from 2 dpt to 7.5 dpt. The Visian toric implantable Collamer lens (Staar) differs in that it is foldable and can be inserted through a very small incision of about 2.8 mm. It is placed in front of the natural lens in the ciliary sulcus. The aim of implanting these phakic IOLs is to correct the entire refractive error, meaning both the spherical and the astigmatic error, in a single step. Different lens models are available, and the selection depends on the direction of the cylinder axis and the anatomical situation, among other things
Pub. type: English Abstract
Journal Article
Review
ISSN: 0941-293X

4. Auffarth GU and Rabsilber TM. [Toric IOLs after cataract surgery and refractive lens exchange]
Torische Hinterkammerlinsen nach Kataraktoperation und refraktiven Linsenaustausch. Ophthalmologe 2007; 104(12): 1024-31.
Abstract: Patients with astigmatism (e.g. regular or keratoplasty-induced astigmatism) who undergo cataract surgery or refractive lens exchange with a standard monofocal IOL are often disappointed. Toric IOLs (T-IOLs) are, therefore, an excellent alternative for this condition. T-IOLs are now available from companies such as Alcon, Acri, Tec, Humanoptics, Wavelight, Rayner and Staar. Apart from Alcon and Staar who only produce T-IOLs with a fixed torus, all these produce customised lenses. The calculations needed for production of the T-IOLs are generally done by the companies and are based on the corneal astigmatism. T-IOLs have shown good rotational stability and good functional results. Corneal astigmatism can still be measured postoperatively, as it is corrected inside the eye. The referring ophthalmologist should exercise discretion when prescribing spectacles after surgery of this kind
Pub. type: English Abstract
Journal Article
Review
ISSN: 0941-293X

5. Horn JD. Status of toric intraocular lenses. Curr Opin Ophthalmol 2007; 18(1): 58-61.
Abstract: PURPOSE OF REVIEW: To provide an update on the status of toric intraocular lenses. These lenses can be used as an alternative or adjunct to corneal astigmatic incisions for correcting preexisting astigmatism in patients with cataracts. They are a particularly attractive option in those cases where limbal-relaxing incisions are not powerful or predictable enough. Other toric lenses may correct astigmatism in addition to spherical refractive errors in phakic patients. RECENT FINDINGS: Toric lenses have continued to gain popularity with the US Food and Drugs Administration (FDA) approval of the Acrysof Toric intraocular lenses. This lens is designed to be implanted in patients undergoing cataract removal and who have significant preexisting corneal astigmatism. In the FDA clinical trial, study patients received one of the three cylindrical powers, and control patients received a standard monofocal intraocular lenses. The study found that the Acrysof Toric intraocular lenses provided excellent visual outcomes and exhibited excellent rotational stability. With the Acrysof Toric intraocular lenses, the average lens rotation was less than 4 degrees from the lens' initial placement at 6 months after surgery. SUMMARY: Toric intraocular lenses provide

excellent vision for astigmatic cataract patients, and new designs are significantly improving visual acuity by minimizing the risk of rotation
Pub. type: Journal Article
Review
ISSN: 1040-8738

Overige studies

1. Ahmed II, Rocha G, Slomovic AR, et al. Visual function and patient experience after bilateral implantation of toric intraocular lenses. J Cataract Refract Surg 2010; 36(4): 609-16.
Abstract: PURPOSE: To evaluate the efficacy, stability, predictability, and patient-reported outcomes of bilateral toric intraocular lens (IOL) implantation in cases of cataract with preexisting astigmatism. SETTING: Fourteen universities, hospitals, or private practices, Canada. METHODS: Patients with cataracts and corneal astigmatism from 1.00 to 2.50 diopters (D) were included in a prospective study of bilateral AcrySof toric IOL implantation. Binocular uncorrected distance visual acuity (UDVA), manifest refraction, and IOL rotational stability were assessed 1 day and 1, 3, and 6 months postoperatively. Patients completed a questionnaire that assessed spectacle independence, visual disturbances, and satisfaction with vision (1 = completely unsatisfied; 10 = completely satisfied) preoperatively and 3 and 6 months postoperatively. RESULTS: The study included 117 patients (234 eyes). The binocular UDVA was 20/40 or better in 99% of patients and 20/20 or better in 63% of patients. The mean residual refractive astigmatism was 0.4 D +/- 0.4 (SD). The spherical equivalent was within +/-0.5 D of target in 77% of eyes. At last observation, IOL alignment was within +/-5 degrees in 91% of eyes and within +/-10 degrees in 99%. Sixty-nine percent of patients reported never using distance spectacles. The frequency and severity of halos and glare were significantly reduced from preoperatively to postoperatively. Satisfaction with vision was rated 7 or higher by 94% of patients. CONCLUSION: Bilateral implantation of toric IOLs yielded excellent and stable visual outcomes that patients rated as highly satisfactory. FINANCIAL DISCLOSURE: No author has a financial or proprietary interest in any material or method mentioned. Additional disclosures are found in the footnotes
Pub. type: Journal Article
Research Support, Non-U.S. Gov't
ISSN: 1873-4502

2. Alfonso JF, Baamonde B, Madrid-Costa D, et al. Collagen copolymer toric posterior chamber phakic intraocular lenses to correct high myopic astigmatism. J Cataract Refract Surg 2010; 36(8): 1349-57.
Abstract: PURPOSE: To assess the safety, efficacy, stability, and predictability after implantation of a toric intraocular copolymer (Collamer) lens (pIOL) to correct high myopic astigmatism. SETTING: Fernandez-Vega Ophthalmological Institute, Oviedo, Spain. METHODS: This study evaluated eyes that had implantation of a toric pIOL. Outcome measures were the uncorrected (UDVA) and corrected (CDVA) distance visual acuities (Snellen decimal), refraction, and postoperative complications. RESULTS: The study included 15 eyes of 12 patients (9 women). Preoperatively, the mean manifest spherical refraction was -1.98 diopters (D) +/- 1.32 (SD) (range -0.50 to -5.50 D) and the mean refractive cylinder, -4.85 +/- 0.83 D (range -6.50 to -4.00 D). At 12 months, the mean refractive cylinder was -0.55 +/- 0.52 D (range -1.50 to 0.00 D), with 93.3% of eyes having less than 1.00 D of cylinder. The mean spherical equivalent was -0.31 +/- 0.42 (range -1.00 to 0.75 D), with more than 70% of eyes within +/-0.50 D of the target. For the astigmatic components, 93.3% of eyes were within +/-1.00 D of J0 (r(2) = 0.98) and all eyes were within +/-1.00 D of J45 (r(2) = 0.98). The mean UDVA was 0.70 +/- 0.20 and the mean CDVA, 0.83 +/- 0.12. The overall efficacy index was 0.90. Postoperatively, all eyes had unchanged CDVA or gained 1 or more lines. CONCLUSION: The refractive outcomes and improvement in UDVA and CDVA were rapidly achieved and remained fairly consistent throughout the follow-up period, supporting the use of toric pIOLs in eyes with high astigmatism. FINANCIAL DISCLOSURE: No author has a financial or proprietary interest in any material or method mentioned
Pub. type: Journal Article
Research Support, Non-U.S. Gov't
ISSN: 1873-4502

3. Alfonso JF, Fernandez-Vega L, Fernandes P, et al. Collagen copolymer toric posterior chamber phakic intraocular lens for myopic astigmatism: one-year follow-up. J Cataract Refract Surg 2010; 36(4): 568-76.
Abstract: PURPOSE: To assess the predictability, efficacy, safety, and stability of collagen copolymer toric phakic intraocular lens (pIOL) implantation to correct moderate to high myopic astigmatism. SETTING: Fernandez-Vega Ophthalmological Institute, Oviedo, Spain. METHODS: This study comprised eyes that had implantation of a toric Intraocular Collamer Lens for moderate to high myopic astigmatism. The uncorrected (UDVA) and corrected (CDVA) distance visual acuities, refraction, pIOL vault, and adverse events were evaluated over 12 months. RESULTS: Preoperatively, the mean sphere in the 55 eyes was -4.65 diopters (D) +/- 3.02 (SD) (range -0.50 to -12.50 D) and the mean cylinder, -3.03 +/- 0.79 D (range -1.25 to -4.00 D). At 12 months, the mean Snellen decimal UDVA was 0.80 +/- 0.20 and the mean CDVA, 0.85 +/- 0.18; 62.0% of eyes had a CDVA of 20/20. More than 50.0% of eyes gained 1 or more lines of CDVA. The treatment was highly predictable for spherical equivalent (SE) (r(2) = 0.99) and astigmatic components J0 (r(2) = 0.97) and J45 (r(2) = 0.99). Of the eyes, 94.5% were within +/-0.50 D of the attempted SE and all were within +/-1.00 D. For J0, 94.5% of eyes were within +/-0.50 D and for J45, 98.2% of eyes; all eyes were within +/-1.00 D. The efficacy index was 0.95 at 3 months and 1.08 at 1 year. CONCLUSIONS: The UDVA and CDVA with toric pIOLs were good and highly stable over 12 months, confirming the procedure is safe, predictable, and effective for correction of moderate to high astigmatic
Pub. type: Journal Article
Research Support, Non-U.S. Gov't
ISSN: 1873-4502

4. Alfonso JF, Fernandez-Vega L, Lisa C, et al. Collagen copolymer toric posterior chamber phakic intraocular lens in eyes with keratoconus. J Cataract Refract Surg 2010; 36(6): 906-16.
Abstract: PURPOSE: To assess the safety, efficacy, stability, and predictability of collagen copolymer toric phakic intraocular lens (pIOL) implantation to correct myopia and astigmatism in eyes with keratoconus. SETTING: Fernandez-Vega Ophthalmological Institute, Oviedo, Spain. METHODS: This prospective study comprised keratoconic eyes that had implantation of a toric Intraocular Collamer Lens. Uncorrected (UDVA) and corrected (CDVA) distance visual acuities, refraction, and postoperative complications were evaluated 1, 3, 6, and 12 months postoperatively. RESULTS: Preoperatively, the mean spherical equivalent in the 30 eyes (21 patients) was -5.38 diopters (D) +/- 3.26 (SD) (range -13.50 to -0.63 D) and the mean cylinder, -3.48 +/- 1.24 D (range -1.75 to -6.00 D). At 12 months, 86.7% of the eyes were within +/-0.50 D of the attempted refraction and all eyes were within +/-1.00 D. For the astigmatic components J0 and J45, 83.3% of eyes and 86.7% of eyes, respectively, were within +/-0.50 D. The mean Snellen UDVA was 0.81 +/- 0.20 and the mean CDVA, 0.83 +/- 0.18; CDVA was 20/40 or better in 29 eyes 96.7% of eyes and 20/25 or better in 22 eyes (73.3%). No eyes lost more than 2 lines of CDVA; 29 eyes (96.7%) maintained or gained 1 or more lines. The efficacy index was 1.07 and the safety index, 1.16. There were no complications or adverse events. CONCLUSIONS: The results confirm that toric ICL implantation is a predictable, effective procedure to correct ametropia in eyes with keratoconus. Predictability and stability were achieved early and remained fairly stable up to 12 months
Pub. type: Journal Article
Research Support, Non-U.S. Gov't
ISSN: 1873-4502

5. Bhikoo R, Rayner S, Gray T. Toric implantable collamer lens for patients with moderate to severe myopic astigmatism: 12-month follow-up. Clin Experiment Ophthalmol 2010; 38(5): 467-74.
Abstract: PURPOSE: To report on the 12-month follow-up of 77 eyes with moderate to high myopic astigmatism implanted with toric implantable collamer lenses (ICLs). METHODS: Retrospective case-note review of 77 eyes from 42 patients undergoing toric ICL placement by one surgeon. Preoperative mean spherical equivalent -2.50 dioptres (D) to -15.00 D myopia and 1.00 D to 7.00 D astigmatism. RESULTS: At 12 months, mean manifest refractive cylinder (MRC) decreased 81% from 2.38 D to 0.44 D. MRC within 1.00 D occurred in 99% (76/77) of eyes, whereas 86% (66/77) had MRC

within 0.75 D. 99% (76/77) had postoperative best-corrected visual acuity (BCVA) better than or equal to preoperative values, whereas 78% (60/77) gained up to one line BCVA and 1% (1/77) lost one line BCVA. Uncorrected binocular vision of 6/6 or better occurred in 90% (38/42) of patients compared with binocular BCVA of 6/6 or better in 67% (28/42) preoperatively. One ICL was replaced due to low vaulting. Two eyes with astigmatism of 3.25 D and 3.50 D received subsequent laser in situ keratomileusis (LASIK) to reduce residual small refractive errors. Indications for ICL were: myopia too high for LASIK (73%), cornea too thin for LASIK (44%) and contact lens intolerance (33%). Night halos were reported in 10% (8/77) of eyes at 12 months. One ICL was removed due to unrecognized preoperative glaucoma. There were no cases of cataract formation, or endophthalmitis. CONCLUSION: This study is the largest reported series of toric ICL implantation in New Zealand. It supports the safety, efficacy and predictability of toric ICLs to treat myopic astigmatism
Pub. type: Journal Article
ISSN: 1442-9071

6. Buckhurst PJ, Wolffsohn JS, Naroo SA, et al. Rotational and centration stability of an aspheric intraocular lens with a simulated toric design. J Cataract Refract Surg 2010; 36(9): 1523-8.
Abstract: PURPOSE: To assess the stability of the Akreos AO intraocular lens (IOL) platform with a simulated toric design using objective image analysis. SETTING: Six hospital eye clinics across Europe. METHODS: After implantation in 1 eye of patients, IOLs with orientation marks were imaged at 1 to 2 days, 7 to 14 days, 30 to 60 days, and 120 to 180 days. The axis of rotation and IOL centration were objectively assessed using validated image analysis. RESULTS: The study enrolled 107 patients with a mean age of 69.9 years +/- 7.7 (SD). The image quality was sufficient for IOL rotation analysis in 91% of eyes. The mean rotation between the first day postoperatively and 120 to 180 days was 1.93 +/- 2.33 degrees, with 96% of IOLs rotating fewer than 5 degrees and 99% rotating fewer than 10 degrees. There was no significant rotation between visits and no clear bias in the direction of rotation. In 71% of eyes, the dilation and image quality was sufficient for image analysis of centration. The mean change in centration between 1 day and 120 to 180 days was 0.21 +/- 0.11 mm, with all IOLs decentering less than 0.5 mm. There was no significant decentration between visits and no clear bias in the direction of the decentration. CONCLUSION: Objective analysis of digital retroillumination images taken at different postoperative periods shows the aspheric IOL platform was stable in the eye and is therefore suitable for the application of a toric surface to correct corneal astigmatism
Pub. type: Journal Article
Research Support, Non-U.S. Gov't
ISSN: 1873-4502

7. Choi SH, Lee MO, Chung ES, et al. Comparison of the Toric Implantable Collamer Lens and Bioptics for Myopic Astigmatism. J Refract Surg 2010; aheadofprint Apr 28.
Abstract: PURPOSE:To compare results between toric implantable collamer lens (TICL) implantation and bioptics (ICL and excimer laser ablation) for the correction of myopic astigmatism. METHODS:A retrospective evaluation was performed in 29 eyes (20 patients) with TICL implantation and 26 eyes (17 patients) treated by bioptics. For eyes treated with bioptics, corneal ablation was performed at 1.5 to 5 months (mean 2.56 months) after ICL implantation by laser epithelial keratomileusis in 17 eyes, LASIK in 8 eyes, and photorefractive keratectomy in 1 eye. Uncorrected distance visual acuity (UDVA), corrected distance visual acuity, refraction, adverse events, safety, and efficacy were assessed preoperatively and 1, 6, and 12 months postoperatively. RESULTS:At 1 month postoperatively, UDVA in the TICL group was significantly higher than in the bioptics group (P=.02). However, the difference in UDVA at 12 months was not significant. At 12 months, mean spherical equivalent refraction was 0.33+/-0.21 diopters (D) in the TICL group and 0.29+/-0.41 D in the bioptics group (P=.07). Mean astigmatic error was higher in the TICL group (-0.42+/-0.32 D) than in the bioptics group (-0.32+/-0.38 D) (P=.10). In the bioptics group, the mean refractive cylinder at 12 months decreased from that reported at 6 months because of retreatment performed in two eyes. Safety and efficacy were not statistically different between groups. One eye with a TICL was treated to correct TICL decentration. Two crystalline lens opacities were observed after bioptics. CONCLUSIONS:This study demonstrates that TICL implantation provides reliable visual outcomes similar to bioptics. The

advantages of TICL implantation are a more stable visual outcome and the elimination of laser treatments and their inherent risks
Pub. type: JOURNAL ARTICLE
ISSN: 1081-597X

8. Elies D, Alonso T, Puig J, et al. Visian toric implantable collamer lens for correction of compound myopic astigmatism. J Refract Surg 2010; 26(4): 251-8.
Abstract: PURPOSE: To assess the safety, efficacy, predictability, and stability of a toric posterior chamber phakic intraocular lens for the correction of myopia with astigmatism. METHODS: A non-randomized, retrospective analysis of 63 eyes of 36 patients with a minimum follow-up of 6 months was performed. The STAAR Toric Implantable Collamer Lens (TICL) was implanted under topical anesthesia through a 3-mm temporal clear corneal incision. Mean preoperative spherical equivalent refraction was -10.71+/-3.55 diopters (D). Median preoperative best spectacle-corrected visual acuity (BSCVA) was 20/25, with a mean sphere of -8.78 D (range: -2.50 to -16.50 D) and mean cylinder of 3.60 D (range: 1.25 to 7.00 D). Postoperative parameters were analyzed at different time points, and vector analysis was performed to calculate surgically induced astigmatism. RESULTS: Fifty-nine (93.6%) eyes had a spherical equivalent refraction within +/-1.00 D and 52 (82.5%) eyes were within +/-0.50 D of emmetropia. Median postoperative uncorrected visual acuity was 20/25 and BSCVA was 20/20. Preoperative keratometric astigmatism was 1.99@178.2 vs 1.82@178.6 postoperative keratometric astigmatism, most likely due to the surgical incision. Preoperative refractive astigmatism was 2.17@93 whereas postoperatively it reduced to 0.38@99.6. No eye lost 2 or more lines of Snellen BSCVA. Twenty-two (34.9%) eyes gained 2 or more Snellen lines of vision. Preoperatively, 45 (71.4%) eyes had a BSCVA of 20/30 or better, whereas 60 (95.2%) eyes were within this range of BSCVA after surgery. The TICL demonstrated good rotational stability in this study. CONCLUSIONS: Implantation of the STAAR TICL was an effective, predictable, and safe method for correction of high myopia and myopic astigmatism as shown in this retrospective observational series
Pub. type: Journal Article
ISSN: 1081-597X

9. Gayton JL and Seabolt RA. Clinical Outcomes of Complex and Uncomplicated Cataractous Eyes After Lens Replacement with the AcrySof Toric IOL. J Refract Surg 2010; aheadofprint Apr 14.
Abstract: PURPOSE:To compare outcomes for uncomplicated versus complex eyes after implantation of AcrySof toric intraocular lenses (IOLs) (Alcon Laboratories Inc) in a retrospective series of cataractous astigmatic eyes. METHODS:Toric IOLs were implanted in 230 eyes of 162 adult patients. Approximately half (52%, n=120) the eyes had no complications (uncomplicated group). The other 110 (48%) eyes (complex group) had a variety of complexities, including retinal or macular problems (eg, age-related macular degeneration), angle or pressure problems (eg, glaucoma), or high astigmatism that required adjunctive limbal relaxing incisions (LRIs). Outcomes were retrospectively assessed approximately 6 weeks after surgery. RESULTS:Preoperative corneal astigmatism was 1.60+/-1.20 diopters (D) overall (1.40+/-0.70 D in the uncomplicated group and 1.90+/-1.60 D in the complex group). Residual cylinder was 0.40+/-0.60 D overall (P<.01 compared to baseline) and was significantly lower (P<.01) for the uncomplicated group (0.30+/-0.40 D) than for the complex group (0.50+/-0.80 D), which contained the adjunctive LRI subgroup (residual cylinder 0.80+/-0.70 D). A larger percentage of uncomplicated eyes (26%) than complex eyes (16%) had at least 20/20 uncorrected distance visual acuity (UDVA) (P=.05). Excluding eyes with intentionally targeted myopic postoperative spherical equivalent, no eyes lost Snellen lines of UDVA, and the average improvement in UDVA was 0.8+/-0.6 logMAR. Corrected distance visual acuity of the retinal/macular subgroup was poorer than the uncomplicated group pre- and postoperatively but was significantly improved by the surgery (P<.001; average improvement ~3 Snellen lines). CONCLUSIONS:AcrySof toric IOLs reduced cylinder and improved UDVA in both complex and uncomplicated eyes with cataractous astigmatism
Pub. type: JOURNAL ARTICLE
ISSN: 1081-597X

10. Kamiya K, Shimizu K, Aizawa D, et al. One-Year Follow-up of Posterior Chamber Toric Phakic Intraocular Lens Implantation for Moderate to High Myopic Astigmatism. Ophthalmology 2010; aheadofprint July 1.
Abstract: OBJECTIVE: To assess the 1-year clinical outcomes of toric Visian Implantable Collamer Lens (ICL; STAAR Surgical, Nidau, Switzerland) implantation for moderate to high myopic astigmatism. DESIGN: Prospective, observational case series. PARTICIPANTS: Fifty-six eyes of 32 consecutive patients, with spherical equivalent errors of -4.00 to -17.25 diopters (D) and cylindrical errors of -0.75 to -4.00 D, who underwent toric ICL implantation. METHODS: Before and 1 week and 1, 3, 6, and 12 months after surgery, the safety, efficacy, predictability, stability, and adverse events of the surgery were assessed in eyes undergoing toric ICL implantation. Ocular higher-order aberrations (HOAs) and contrast sensitivity (CS) function also were evaluated before and 1 year after surgery. MAIN OUTCOME MEASURES: Uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), safety index, efficacy index, predictability, stability, adverse events, HOAs, and CS function. RESULTS: The logarithm of the minimum angle of resolution (logMAR) UCVA and logMAR BSCVA were -0.11 (corresponding to Snellen equivalent 20/16)+/-0.12 and -0.19 (corresponding to 20/12.5)+/-0.08 1 year after surgery, respectively. The safety and efficacy indices were 1.17+/-0.21 and 1.00+/-0.29. At 1 year, 91% and 100% of the eyes were within 0.5 and 1.0 D, respectively, of the targeted correction. Manifest refraction changes of -0.07+/-0.27 D occurred from 1 week to 1 year. For a 4-mm pupil, fourth-order aberrations were changed, not significantly, from 0.05+/-0.02 mum before surgery to 0.06+/-0.03 mum after surgery (P = 0.38, Wilcoxon signed-rank test). Similarly, for a 6-mm pupil, fourth-order aberrations were not significantly changed, merely from 0.20+/-0.08 mum before surgery to 0.23+/-0.11 mum after surgery (P = 0.15). The area under the log CS function was significantly increased from 1.41+/-0.15 before surgery to 1.50+/-0.13 after surgery (P<0.001). No vision-threatening complications occurred during the observation period. CONCLUSIONS: In the authors' experience, the toric ICL performed well in correcting moderate to high myopic astigmatism during a 1-year observation period, suggesting its viability as a surgical option for the treatment of such eyes. FINANCIAL DISCLOSURE(S): Proprietary or commercial disclosure may be found after the references
Pub. type: JOURNAL ARTICLE
ISSN: 1549-4713

11. Kim MH, Chung TY, Chung ES. Long-term efficacy and rotational stability of AcrySof toric intraocular lens implantation in cataract surgery. Korean J Ophthalmol 2010; 24(4): 207-12.
Abstract: PURPOSE: To evaluate the long-term efficacy and rotational stability of the AcrySof toric intraocular lens (IOL) in correcting preoperative astigmatism in cataract patients. METHODS: This prospective observational study included 30 eyes from 24 consecutive patients who underwent implantation of an AcrySof toric IOL with micro-coaxial cataract surgery between May 2008 and September 2008. Outcomes of visual acuity, refractive and keratometric astigmatism, and IOL rotation after 1 day, 1 month, 3 months, and long-term (mean, 13.3+/-5.0 months) follow-up were evaluated. RESULTS: At final follow-up, 73.3% of eyes showed an uncorrected visual acuity of 20/25 or better. The postoperative keratometric value was not different from the preoperative value; mean refractive astigmatism was reduced to -0.28+/-0.38 diopter (D) from -1.28+/-0.48 D. The mean rotation of the toric IOL was 3.45+/-3.39 degrees at final follow-up. One eye (3.3%) exhibited IOL rotation of 10.3 degrees, the remaining eyes (96.7%) had IOL rotation of less than 10 degrees. CONCLUSIONS: Early postoperative and long-term follow-up showed that implantation of the AcrySof toric IOL is an effective, safe, and predictable method for managing corneal astigmatism in cataract patients
Pub. type: Journal Article
ISSN: 1011-8942

12. Qasem Q, Kirwan C, O'Keefe M. 5-year prospective follow-up of Artisan phakic intraocular lenses for the correction of myopia, hyperopia and astigmatism. Ophthalmologica 2010; 224(5): 283-90.
Abstract: AIM: To determine the efficacy and safety of Artisan phakic intraocular lenses (IOLs) for refractive error correction. METHODS: A prospective study was conducted on patients undergoing Artisan phakic IOL implantation for myopia, hyperopia or astigmatism from 2002 to 2008. Visual acuity, manifest refractive spherical equivalent

(MRSE), endothelial cell counts and higher order aberrations were recorded pre- and postoperatively. RESULTS: One hundred and fifty-one (84 patients) myopic (mean MRSE -11.2 +/- 4.1 D) and 14 (7 patients) hyperopic eyes (mean MRSE 7.1 +/- 1.3 D) were treated. Twenty eyes (11 patients) had toric IOLs to correct astigmatism (mean MRSE -9.05 +/- 6.13 D, mean astigmatism 4.06 +/- 1.26 D). Three months postoperatively, mean MRSE in 37.6% of eyes was within +/-0.5 D, 61.8% within +/-1.0 D and 91.4% within +/-2.0 D. 18.5% underwent keratorefractive surgery to correct residual refractive error. A 1.56-fold increase occurred in 4th order spherical aberration. Endothelial cell loss was 1.45% at 1 year and negligible at 5 years. Fifty-four eyes (29.2%) gained one or more lines of best corrected visual acuity and no eye lost a line. CONCLUSION: Artisan phakic IOLs are safe and effective for refractive error correction
Pub. type: Journal Article
ISSN: 1423-0267

13. Schallhorn S, Tanzer D, Sanders DR, et al. Night driving simulation in a randomized prospective comparison of Visian toric implantable collamer lens and conventional PRK for moderate to high myopic astigmatism. J Refract Surg 2010; 26(5): 321-6.
Abstract: PURPOSE: To compare changes in simulated night driving performance after Visian Toric Implantable Collamer Lens (TICL; STAAR Surgical) implantation and photorefractive keratectomy (PRK) for the correction of moderate to high myopic astigmatism. METHODS: This prospective, randomized study consisted of 43 eyes implanted with the TICL (20 bilateral cases) and 45 eyes receiving conventional PRK (VISX Star S3 excimer laser) with mitomycin C (22 bilateral cases) for moderate to high myopia (-6.00 to -20.00 diopters[D] sphere) measured at the spectacle plane and 1.00 to 4.00 D of astigmatism. As a substudy, 27 eyes of 14 TICL patients and 41 eyes of 21 PRK patients underwent a simulated night driving test. The detection and identification distances of road signs and hazards with the Night Driving Simulator (Vision Sciences Research Corp) were measured with and without a glare source before and 6 months after each procedure. RESULTS: No significant difference was noted in the pre- to postoperative Night Driving Simulator in detection distances with and without the glare source between the TICL and PRK groups. The differences in identification distances without glare were significantly better for business and traffic road signs and pedestrian hazards in the TICL group relative to the PRK group whereas with glare, only the pedestrian hazards were significantly better. A clinically relevant change of Night Driving Simulator performance (>0.5 seconds change in ability to identify tasks postoperatively) was significantly better in the TICL group (with and without glare) for all identification tasks. CONCLUSIONS: The TICL performed better than conventional PRK in the pre- to postoperative Night Driving Simulator testing with and without a glare source present
Pub. type: Journal Article
Research Support, U.S. Gov't, Non-P.H.S
ISSN: 1081-597X

14. Tsinopoulos IT, Tsaousis KT, Tsakpinis D, et al. Acrylic toric intraocular lens implantation: a single center experience concerning clinical outcomes and postoperative rotation. Clin Ophthalmol 2010; 4, 137-42.
Abstract: PURPOSE: To present clinical results of toric intraocular lens (IOL) implantation for preexisting astigmatism correction and determine the time of any postoperative rotation. PATIENTS AND METHODS: Twenty-nine eyes of 19 patients underwent uncomplicated phacoemulsification and were implanted with an Acrysof ((c)) toric IOL. Uncorrected visual acuity, residual astigmatism, and postoperative rotation of the IOL were estimated one and six months after the operation. RESULTS: Uncorrected visual acuity was >/=0.5 in 26 of 29 eyes (89.7%) and >/=0.8 in 19 of 29 patients (65.5%). The mean toric IOL axis rotation was 2.2 +/- 1.5 degrees (range 0.6-7.8 degrees) one month postoperation and 2.7 +/- 1.5 degrees (range 0.9-8.4 degrees) six months postoperation. CONCLUSION: Implantation of one-piece hydrophobic acrylic toric IOLs appears to have acceptable stability, which encourages visual outcome and emerges as an attractive alternative for correction of refractive astigmatism
Pub. type: Journal Article
ISSN: 1177-5483

15. Dardzhikova A, Shah CR, Gimbel HV. Early experience with the AcrySof toric IOL for the correction of astigmatism in cataract surgery. Can J Ophthalmol 2009; 44(3): 269-73.
Abstract: OBJECTIVE: The AcrySof toric IOL (tIOL) became available in Canada in 2006, thereby giving surgeons another option in the correction of astigmatism during cataract surgery. The purpose of this paper is to report the early experience of the acrylic AcrySof tIOL. DESIGN: Observational clinical study. PARTICIPANTS: One hundred eleven eyes, including 41 bilateral patients. METHODS: Patients were implanted with the AcrySoftIOL by 1 surgeon between April and September 2007. The eyes were followed for 6 months and pre- and postrefractive outcomes were summarized. RESULTS: Preoperatively, the mean refractive cylinder was -1.25 D compared with -0.32 D postoperative. At 6 months, 95.5% of eyes remained within 10 degrees of planned axis. Two eyes of 1 patient (1.8%) required bilateral repositioning at 2 weeks postoperative for significant rotation off axis. CONCLUSIONS: Based on our early postoperative experience, we have found the AcrySof tIOL to be successful in reducing moderate levels of astigmatism
Pub. type: Comparative Study
Journal Article
ISSN: 0008-4182

16. Lane SS, Ernest P, Miller KM, et al. Comparison of clinical and patient-reported outcomes with bilateral AcrySof toric or spherical control intraocular lenses. J Refract Surg 2009; 25(10): 899-901.
Abstract: PURPOSE: To compare clinical and patient-reported outcomes with bilateral implantation of AcrySof toric or spherical control (Alcon Laboratories Inc) intraocular lenses (IOLs). METHODS: Patients with cataract and corneal astigmatism who previously received either an AcrySof toric IOL or an AcrySof spherical control IOL were offered implantation of the same IOL in the fellow eye. Six-month assessments included visual acuity, refractive cylinder, spectacle use, and patient satisfaction. RESULTS: The study included 62 patients (toric, n=40; control, n=22). All corneal incisions were temporal, with final mean incision sizes of 3.0 mm for the toric IOL and 3.1 mm for the spherical control IOL. A significantly greater proportion of patients with toric IOLs achieved spectacle independence for distance vision and did not require prescription glasses for near or distance vision (P=.0190). Patients with toric IOLs had significantly less residual refractive cylinder (P<.0001) and better binocular distance uncorrected visual acuity (UCVA) (P=.0014) than those with spherical control IOLs. CONCLUSIONS: Patients with bilateral AcrySof toric IOLs achieved superior spectacle freedom, residual refractive cylinder, and distance UCVA compared to patients with bilateral spherical control IOLs
Pub. type: Comparative Study
Journal Article
Research Support, Non-U.S. Gov't
ISSN: 1081-597X

17. Park SC, Kwun YK, Chung ES, et al. Postoperative astigmatism and axis stability after implantation of the STAAR Toric Implantable Collamer Lens. J Refract Surg 2009; 25(5): 403-9.
Abstract: PURPOSE: To evaluate the efficacy, safety, and rotational and footplate stability of the STAAR Toric Implantable Collamer Lens (TICL; STAAR Surgical Co) for correction of myopic astigmatism. METHODS: In this prospective, consecutive, interventional case series, a TICL was implanted uneventfully in 30 consecutive eyes of 20 patients with myopia and astigmatism. The uncorrected visual acuity, best spectacle-corrected visual acuity, refraction, and astigmatism were measured preoperatively and at last follow-up. To evaluate postoperative axis deviation from the intended axis and footplate displacement, a digital anterior segment photograph was taken after full mydriasis and ultrasound biomicroscopy for the four footplates of the TICL in each eye at last follow-up. Possible risk factors for TICL rotation were analyzed through correlation analysis. RESULTS: After mean follow-up of 7.6 months, the mean refractive astigmatism decreased from 2.43 +/- 1.24 diopters (D) preoperatively to 0.73 +/- 0.47 D postoperatively, and the mean difference between intended and achieved TICL axes was 4.03 +/- 3.39 degrees. The absolute value of TICL rotation had significant correlation with the spherical power of the TICL (P = .037). The footplates of all TICLs were in situ in the ciliary sulcus except for one case in which one of the four footplates was located below the ciliary sulcus. CONCLUSIONS: Implantation of the STAAR TICL appears to be an effective and safe method for correction of myopic

astigmatism. No clinically significant rotation or footplate displacement of the TICLs was detected postoperatively during mean follow-up of 7.6 months
Pub. type: Journal Article
Research Support, Non-U.S. Gov't
ISSN: 1081-597X

18. Statham M, Apel A, Stephensen D. Comparison of the AcrySof SA60 spherical intraocular lens and the AcrySof Toric SN60T3 intraocular lens outcomes in patients with low amounts of corneal astigmatism. Clin Experiment Ophthalmol 2009; 37(8): 775-9.
Abstract: BACKGROUND: Toric intraocular lenses (IOLs) have been reported to be an effective method of reducing postoperative refractive astigmatism and spectacle dependence following cataract surgery. This study compares a series of patients with low corneal astigmatism implanted with either the AcrySof SA60 spherical IOL or the AcrySof Toric SN60T3 IOL in a quantitative fashion to establish the merit of toric IOLs in these cases. METHODS: A retrospective chart audit was undertaken of 12 patients receiving the AcrySof Toric SN60T3 IOL (1.5 DC, Alcon, Fort Worth) and 10 patients receiving the AcrySof SA60 IOL (Alcon, Fort Worth). Preoperative corneal astigmatism and postoperative refractive astigmatism were recorded and converted into a non-signed Astigmatic Power Vector for statistical analysis. Postoperative vision (uncorrected visual acuity, UCVA) was also recorded for both groups. A statistical analysis was performed to examine for differences in outcomes between groups. RESULTS: The mean magnitude of the preoperative corneal Astigmatic Power Vector was not significantly different between the groups. The mean magnitude of the postoperative refractive vector was significantly smaller in the AcrySof Toric group. The mean UCVA was significantly better in the AcrySof Toric group compared with the AcrySof group. CONCLUSION: The AcrySof Toric IOL provides a significant improvement in postoperative astigmatism and UCVA when compared statistically with its spherical counterpart for patients with low degrees of corneal astigmatism
Pub. type: Comparative Study
Journal Article
ISSN: 1442-9071

19. Guell JL, Morral M, Gris O, et al. Five-year follow-up of 399 phakic Artisan-Verisyse implantation for myopia, hyperopia, and/or astigmatism. Ophthalmology 2008; 115(6): 1002-12.
Abstract: PURPOSE: To report long-term results of Artisan-Verisyse phakic intraocular lenses (PIOLs) to correct myopia, hyperopia, and/or astigmatism and the percentage of additional keratorefractive surgery to eliminate residual refractive errors. DESIGN: Retrospective, nonrandomized, interventional case series. PARTICIPANTS: From January 1996 to January 2003, 399 Artisan-Verisyse PIOLs were consecutively implanted. To correct myopia, 101 5-mm optic Verisyse PIOLs (group 1) and 173 6-mm optic Verisyse PIOLs (group 2) were implanted. Forty-one were PIOLs for hyperopia (group 3), and 84 were toric (group 4). METHODS: Manifest refraction, uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), biomicroscopy, tonometry, funduscopy, and central endothelial cell count (ECC) were determined before surgery, at 3 months, and at yearly intervals up to 5 years. MAIN OUTCOME MEASURES: Refraction, UCVA, BSCVA, efficacy and safety indexes, enhancements' rate with keratorefractive surgery, central ECC, and complications. RESULTS: Mean follow-up was 4.05 years. Mean preoperative spherical equivalent (SE) and that at last follow-up were, respectively, -19.8+/-3.23 and -0.5 +/- 0.89 diopters (D) (group 1), -11.27+/-3.11 and -0.64+/-0.8 D (group 2), +4.92+/-1.7 and +0.02+/-0.51 D (group 3), and -6.82+/-8.69 and -0.09+/-0.64 D (group 4). Group 4 had a mean preoperative cylinder of -3.24+/-1.02 D, which decreased to -0.83+/-0.74 D postoperatively. Additional keratorefractive surgery was performed in 60.39% of eyes (group 1), 19.6% (group 2), 41.4% (group 3), and 5.95% (group 4). Mean preoperative central ECC and that at last follow-up were, respectively, 2836+/-398 and 2514+/-529 cells/mm(2) (group 1), 2755+/-362 and 2454+/-588 cells/mm(2) (group 2), 2735+/-355 and 2560+/-335 cells/mm(2) (group 3), and 2632+/-543 and 2537+/-615 cells/mm(2) (group 4). Main complications were 3 explantations due to an unacceptable drop in ECC, 3 lenses' repositioning (2 ocular trauma and 1 unappropriate iris capture), 3 lenses' exchange due to refractive errors, 1 macular hemorrhage, 1 retinal detachment, and 2 cataracts. CONCLUSIONS: According to our experience, implantation of iris-claw PIOLs is a reversible, effective, stable, safe procedure in the first 5 years of follow-up

Pub. type: Comparative Study
Journal Article
ISSN: 1549-4713

20. Kamiya K, Shimizu K, Igarashi A, et al. Comparison of Collamer toric implantable [corrected] contact lens implantation and wavefront-guided laser in situ keratomileusis for high myopic astigmatism. J Cataract Refract Surg 2008; 34(10): 1687-93.
Abstract: PURPOSE: To compare the postoperative visual outcomes after implantation of a Collamer toric implantable contact lens (ICL) and after wavefront-guided laser in situ keratomileusis in high myopic astigmatism. SETTING: Department of Ophthalmology, Kitasato University, Kanagawa, Japan. METHODS: This study comprised 30 eyes (18 patients) having toric ICL implantation and 24 eyes (17 patients) having wavefront-guided LASIK (Technolas 217z) to correct high myopic astigmatism (manifest spherical equivalent [SE] <or=-6.0 diopters [D]; manifest refractive cylinder >or=1.0 D). The safety, efficacy, predictability, stability, and adverse events were assessed preoperatively and 1 week and 1, 3, and 6 months postoperatively. RESULTS: At 6 months, the mean safety index was 1.28+/-0.25 (SD) in the ICL group and 1.01+/-0.16 in the LASIK group and the mean efficacy index, 0.87+/-0.15 and 0.83+/-0.23, respectively. All eyes in the ICL group and 71% of eyes in the LASIK group were within +/-1.00 D of the targeted SE correction at 6 months. The mean change in manifest refraction from 1 week to 6 months was -0.04+/-0.24 D in the ICL group and -0.60+/-0.49 D in the LASIK group. There were no significant complications in the ICL group; 2 eyes (8.3%) in the LASIK group required enhancement ablations. CONCLUSION: Toric ICL implantation was better than wavefront-guided LASIK in eyes with high myopic astigmatism in almost all measures of safety, efficacy, predictability, and stability, suggesting that toric ICL implantation may become a viable surgical option to treat high myopic astigmatism
Pub. type: Comparative Study
Journal Article
ISSN: 0886-3350

21. Sanders DR and Sanders ML. Comparison of the toric implantable collamer lens and custom ablation LASIK for myopic astigmatism. J Refract Surg 2008; 24(8): 773-8.
Abstract: PURPOSE: To compare the results of wavefront-guided custom LASIK and the Toric Implantable Collamer Lens (TICL) in the correction of myopic astigmatism. METHODS: This observational, non-randomized study compared clinical efficacy results from the TICL's US Food and Drug Administration Clinical Trial and published Summaries of Safety and Effectiveness of two wavefront-guided lasers: STAR S4 CustomVue excimer laser system (VISX Inc) and LADARVision4000 CustomCornea excimer laser system (Alcon Laboratories Inc). Preoperative myopic refractive error was divided into two groups: -3.00 to -7.00 diopters (D) and -7.00 to -11.00 D. RESULTS: The percentage of eyes with uncorrected visual acuity (UCVA) of 20/20 and 20/40 and predictability of manifest refraction spherical equivalent within +/- 0.50 and +/- 1.00 D in the three groups was similar with only one statistically significant difference (TICL versus Alcon within +/- 1.00 D: 97% versus 82%; P = .008). The TICL had significantly better postoperative best spectacle-corrected visual acuity (BSCVA) compared to preoperative BSCVA than both the VISX CustomVue and Alcon CustomCornea (P < .001). The TICL postoperative UCVA outcomes compared to preoperative BSCVA were significantly better than Alcon CustomCornea outcomes (P < .001). Additionally, almost half (48%) of the TICL cases had improvement in postoperative UCVA compared to preoperative BSCVA, whereas only 23% of the Alcon CustomCornea eyes showed improvement. CONCLUSIONS: Although comparable in clinical efficacy outcomes, the TICL had a significantly better postoperative improvement in BSCVA and significantly better postoperative UCVA than preoperative BSCVA. The TICL can be considered as an alternative to LASIK through the full range of use
Pub. type: Comparative Study
Journal Article
Research Support, Non-U.S. Gov't
ISSN: 1081-597X

22. Zuberbuhler B, Signer T, Gale R, et al. Rotational stability of the AcrySof SA60TT toric intraocular lenses: a cohort study. BMC Ophthalmol 2008; 8, 8.

Abstract: BACKGROUND: To evaluate the rotational stability of the three types of AcrySof SA60TT toric intraocular lenses (Alcon, Switzerland) in cataract surgery after the first postoperative week. METHODS: A retrospective study of 44 eyes in 33 patients. All patients underwent similar uncomplicated phacoemulsification cataract surgery. Seven eyes with corneal astigmatism of less than 1.5 D were implanted with the AcrySof SA60T3 intraocular lens. Seventeen eyes with astigmatism between 1.5 D and 2.25 D received the SA60T4 intraocular lens, and 20 eyes with more than 2.25 D of corneal astigmatism received the SA60T5 intraocular lens. Intraoperatively, the axis of the toric lens was aligned to the steepest axis of the corneal astigmatism. Main outcome measure was the postoperative position of the lens, assessed at 1 week and 3 months, using a specially designed angle measuring eyepiece for the slit lamp. RESULTS: There was no significant difference in the rotational stability of the three types of toric intraocular lenses. Overall, the postoperative rotation was within 5 degrees in 95% and within 2 degrees in 68% of eyes. The mean absolute rotation was 2.2 +/- 2.2 degrees. No lens showed more than 9 degrees of rotation, and no lens required secondary repositioning. There was no trend for either clockwise or anti-clockwise rotation. The surgical procedure did not change the corneal astigmatism. CONCLUSION: Once placed to it's position, each of the three types of the AcrySof SA60TT toric intraocular lenses demonstrate rotational stability in the capsular bag
Pub. type: Evaluation Studies
Journal Article
ISSN: 1471-2415

23. Tehrani M and Dick HB. Iris-fixated toric phakic intraocular lens: Three-year follow-up. J Cataract Refract Surg 2006; 32(8): 1301-6.
Abstract: PURPOSE: To evaluate the 3-year safety, efficacy, predictability, and stability of iris-fixated toric phakic intraocular lens (pIOL) implantation for the correction of myopia or hyperopia with astigmatism. SETTING: Department of Ophthalmology, Johannes Gutenberg University, Mainz, and Department of Ophthalmology, University Clinic, Bochum, Germany. METHODS: A prospective clinical trial of 40 eyes of 23 patients with high ametropia and astigmatism was conducted. Best spectacle-corrected visual acuity (BSCVA), uncorrected visual acuity, refraction, astigmatism, intraocular pressure, slitlamp biomicroscopy, and indirect ophthalmoscopy were measured preoperatively and postoperatively. RESULTS: Of the 40 eyes, 28 were myopic and 12 were hyperopic. Three years postoperatively, 70% of eyes were within +/-1.00 diopter (D) of the targeted refraction. In the myopic group, mean preoperative BSCVA was 20/40 and improved postoperatively to 20/25. Sixty-six percent of eyes gained 1 or more lines from the preoperative BSCVA. The mean cylinder decreased from -3.58 D +/- 1.26 (SD) preoperatively to -1.15 +/- 1.01 D postoperatively. In the hyperopic group, preoperative BSCVA was 20/25 and improved to 20/20 postoperatively. Thirty-six percent of eyes gained 1 or more lines from the preoperative BSCVA. The mean cylinder decreased from -3.37 +/- 0.88 D to -1.53 +/- 0.69 D postoperatively. The correction was stable in all eyes 3 years after surgery. No potentially sight-threatening complications occurred. CONCLUSION: The 3-year follow-up showed the iris-fixated toric pIOL was effective in correcting high ametropia and astigmatism
Pub. type: Journal Article
ISSN: 0886-3350

24. Tahzib NG, Cheng YYY, Nuijts RMMA. Three-year follow-up analysis of Artisan toric lens implantation for correction of postkeratoplasty ametropia in phakic and pseudophakic eyes. Ophthalmology 2006; 113(6): 976-84.
Abstract: PURPOSE: To determine the 3-year follow-up of efficacy and safety of Artisan toric iris-fixated lens implantation after penetrating keratoplasty (PK) to correct high ametropia and astigmatism. DESIGN: Prospective noncomparative case series with a minimum follow-up of 1 year. PARTICIPANTS: Artisan toric lens implantation was performed in 36 eyes of 35 patients who were contact lens intolerant or unable to wear glasses due to anisometropia and/or high astigmatism. INTERVENTION: Thirty-six eyes of 35 consecutive patients received Artisan toric lens implantation for postkeratoplasty astigmatism and/or anisometropia. MAIN OUTCOME MEASURES: Manifest refraction, uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), and corneal topography were determined or performed before surgery and at 3, 6, and 12 months and yearly intervals up to 4 years after surgery. Efficacy, safety, percent reduction of refractive astigmatism, anisometropia of defocus, and the astigmatism

correction index were determined. A patient satisfaction questionnaire and specular microscopy were assessed. RESULTS: The mean +/- standard deviation of preoperative refractive cylinder was -7.06+/-2.01 diopters (D) (range, -3.0 to -11.0), which was reduced to -1.73+/-1.25 D, -1.69+/-1.15 D, -1.94+/-1.68 D, -2.02+/-1.93 D, and -2.00+/-1.53 D at 6 months (n = 36), 1 year (n = 36), 2 years (n = 29), 3 years (n = 15), and the last follow-up examination (28.5+/-12.5 months, n = 36), respectively (P<0.001 for all time points, paired t test). The spherical equivalent was reduced from -3.19+/-4.31 D (range, +5.5 to -14.25 D) preoperatively to -1.03+/-1.20 D (range, +1.0 to -5.25 D) at the last follow-up. The UCVA and BSCVA were > or =20/40 in 31.6% and 80.6%, respectively. There was a loss of BSCVA of >2 lines in 8.3% of eyes and a gain of at least 2 lines in 8.3% of eyes. Percent reductions in refractive astigmatism and anisometropia of defocus were 88.8%+/-29.5% and 77.8%+/-19.3%, respectively. The astigmatism correction index was 96.0%+/-24.2%. Satisfaction increased from 3.6 to 8.0 (scale, 0-10) after implantation. The endothelial cell loss as compared with preoperatively was 13.8%+/-18.7% (n = 34), 21.2%+/-21.8% (n = 33), 29.6%+/-27.3% (n = 26), 30.4%+/-32.0% (n = 18), and 34.8%+/-26.3% (n = 6) at 6 months (P = 0.001), 1 year (P<0.001), 2 years (P<0.001), 3 years (P = 0.001), and 4 years postoperatively (P = 0.1), respectively. In 2 patients, irreversible graft rejections occurred, and in 1 patient, gradual endothelial decompensation occurred. CONCLUSION: Artisan toric lens implantation after PK was effective for reduction of refractive astigmatism and ametropia. All patients were suitable for spectacle correction after implantation. There was continuing endothelial cell loss from 6 months to 3 years postoperatively. In 3 cases, corneal graft failure developed
Pub. type: Journal Article
ISSN: 1549-4713

Kosten-studies

1. Pineda R, Denevich S, Lee WC, et al. Economic evaluation of toric intraocular lens: a short- and long-term decision analytic model. Arch Ophthalmol 2010; 128(7): 834-40.
Abstract: OBJECTIVE: To assess the economic value of improved uncorrected visual acuity among patients with cataract and preexisting astigmatism treated with toric intraocular lenses (IOLs) compared with conventional monofocal IOLs. METHODS: We developed a decision analytic model of hypothetical patients with preexisting astigmatism. We examined costs and outcomes among patients 65 years and older with cataract and preexisting astigmatism (1.5-3.0 diopters) who were receiving either toric or conventional IOLs with and without intraoperative refractive correction (IRC). Data were obtained from the literature and from a survey of 60 US ophthalmologists. Total medical costs of bilateral treatment were calculated for the first posttreatment year and remaining lifetime. Cost-effectiveness and cost-utility outcomes were computed. Future costs and utilities were discounted by 3%. RESULTS: A larger proportion of patients receiving toric IOLs achieved distance vision spectacle independence (67%) and uncorrected visual acuity of 20/25 or better OU (53%) compared with conventional IOLs with (63% and 48%, respectively) or without IRC (53% and 44%, respectively), resulting in fewer future vision corrections. Toric IOLs provided an additional 10.20 quality-adjusted life years (QALYs) compared with conventional IOLs with (10.14 QALYs) and without IRC (10.10 QALYs). Higher first-year costs of the toric IOL ($5739) compared with the conventional IOL with ($5635) or without ($4687) IRC were offset by lifetime cost savings of $34 per patient, $393 per patient achieving uncorrected visual acuity of 20/25 or better, and $349 per QALY compared with the conventional IOL without IRC. CONCLUSIONS: Toric IOLs reduce lifetime economic costs by reducing the need for glasses or contact lenses following cataract removal. These results can inform physicians and patients regarding the value of toric IOLs in the treatment of cataract and preexisting astigmatism
Pub. type: Journal Article
Research Support, Non-U.S. Gov't
ISSN: 1538-3601

2. Laurendeau C, Lafuma A, Berdeaux G. Modelling lifetime cost consequences of toric compared with standard IOLs in cataract surgery of astigmatic patients in four European countries. J Med Econ 2009; 12(3): 230-7.

Abstract: OBJECTIVE: To compare the lifetime costs of freeing astigmatic patients from spectacles after bilateral cataract surgery implanting toric intraocular lenses (IOLs: i.e., Acrysof Toric) versus monofocal IOLs, in France, Italy, Germany and Spain. METHODS: A Markov model followed patient cohorts from cataract surgery until death. Prevalence rates of patients not needing spectacles and the types of spectacles prescribed for those requiring them were obtained from clinical trials and national surveys. The economic perspective was societal. Mortality rates were incorporated into the model. Discount rates were applied. A sensitivity analysis was performed on non-discounted costs. RESULTS: Fewer patients with toric IOLs needed spectacles for distance vision than patients with monofocal IOLs. With monofocal IOLs more than 66% of patients needed complex spectacles compared to less than 25% implanted with toric IOLs. In France and Italy, toric IOLs reduced overall costs relative to otherwise high spectacle costs after cataract surgery. Savings were 897.0 euros (France), 822.5 euros (Germany), 895.8 euros (Italy) and 391.6 euros (Spain), without discounting. On applying a 3% discount rate the costs became 691.7 euros, 646.4 euros, 693.9 euros and 308.2 euros, respectively. CONCLUSIONS: Bilateral toric IOL implants in astigmatic patients decreased spectacle dependence for distance vision and the need for complex spectacles. The economic consequences for patients depended on the national spectacle costs usually incurred after cataract surgery
Pub. type: Journal Article
Research Support, Non-U.S. Gov't
ISSN: 1369-6998

Overige bronnen

1. **NICE**. Intraocular lens insertion for correction of refractive error, with preservation of the natural lens. 2009. Geraadpleegd in Sept 2010 via http://www.nice.org.uk/nicemedia/live/11984/43341/43341.PDF
Deze richtlijn is gebaseerd op een literatuuroverzicht uit mei 2008, beschikbaar via http://www.nice.org.uk/nicemedia/live/11984/42465/42465.pdf

2. **Medical Advisory Secretariat**. Phakic intraocular lenses for the treatment of refractive errors: an evidence-based analysis . 2009. Geraadpleegd in Aug 2010 via http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_pIols_20090929.pdf.
Literatuur tot januari 2009.

3. **CIGNA**. Intraocular Lens Implant. 2009. Geraadpleegd in Aug 2010 via http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0125_coveragepositioncriteria_intraocular_lens_implant.pdf.
CIGNA does not cover ANY of the following premium intraocular lens implants, because each is intended to reduce the need for reading glasses and thus considered a convenience item and not medically necessary (This list may not be all inclusive):
· presbyopia correcting IOL (i.e., multifocal, accommodating IOL)
· astigmatism correcting IOL (i.e., toric IOL)
· clear lens extraction IOL

Clinical trials
Voor een overzicht van trials klik hier

Geraadpleegde bronnen
Zoektermen: toric, astigmatism, cataract

Bibliographische databases	Websites van Overheidsinstellingen	Websites Verzekeraars	Richtlijnen en systematische reviews	Clinical trials
Cochrane library (Wiley) HTA Databases TRIP-database UptoDate	CKS (UK) CTAF (CA) G-BA (D) HAS (F) HTAi-Vortal INHATA IQWIG (D) KCE (B) LBI (A) MAS (CA) NHS evidence (UK)	AETNA ANTHEM Premera Medicaid (CMS) CIGNA Regence Group	GAIN GIN National Guideline Clearinghouse New Zealand guidelines group (NZGG) NICE SIGN TRIP-database	Clinical trials.gov