NKR 4 Grå Stær PICO 4a Toric IOLs for treatment of astigmatism (>2 dioptrier) in patients with cataract

Review information

Authors

Sundhedsstyrelsen¹

Citation example: S. NKR 4 Grå Stær PICO 4a Toric IOLs for treatment of astigmatism (>2 dioptrier) in patients with cataract. Cochrane Database of Systematic Reviews [Year], Issue [Issue].

Characteristics of studies

Characteristics of included studies

Holland 2010

Methods	RCT Compares UCDVA, spectacle independence and safety in patients receiving toric (AcrySof Toric) or non-toric (Acrysof) IOL
Participants	Country and clinic: multicenter study in USA Patients with age-related cataract and preexisting corneal astigmastism Demographics of study population: 55.1% female, mean age was 71 years Follow-up: 1 year postoperatively
Interventions	Group 1: toric IOL (Acrysof Toric) Group 2: spherical IOL (Acrysof SA60AT)
Outcomes	UCDVA at 1 year postoperatively was 20/25 or better in 154/243 in Group 1 and 98/237 in Group 2 Distance vision spectacle independence at 6 months postoperatively was 147/241 in Group 1 and 86/236 in Group 2 Safety: complications (e.g. macular edema, retinal detachment, additional surgical procedures) occured in 11/243 in Group 1 and 3/237 in Group 2
Notes	The study was sponsored by Alcon Laboratories Inc. Data from the study were considered during the approval process of the AcrySof Toric IOL by the United States Food and Drug Administration

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Each site had sealed randomization enveloped with IOL treatment assignments enclosed For each subject both an AcrySof Toric and a control IOL was available before beginning of surgery. After the surgical incision was performed, the envelope was opened and the assigned IOL was implanted"
Allocation concealment (selection bias)	Low risk	"Intraocular lens diopter and cylinder power were calculated for al subjects preoperatively, because IOL assignment was not revrealed until cataract surgery was in progress"
Blinding of participants and personnel (performance bias)	Unclear risk	"After the envelope was opened and the assigned IOL was implanted the investigators were no longer masked to IOL assignment, but the subject remained masked"
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Unclear risk	"Of the 541 enrolled subjects, 24 did not receive implants owing to preoperative or intraoperative exclusions; 517 received the AcrySof Toric IOL (n=256) or the control IOL (n=261). Results exclude subjects who received IOLs but discontinued (Toric n=4, control n=2) or were lost to follow-up (Toric n=9, control n=22)" Thus, 5% in the toric and 9% in the control group were lost after randomization. A comparison between the lost group and the analysed group is not provided and hence we cannot judge whether the high number of lost subjects were likely to affect the results
Selective reporting (reporting bias)	Low risk	Important outcomes are reported
Other bias	High risk	Industry sponsored study but not likely to affect the result

¹[Empty affiliation]

Visser 2014

Study design: Randomized controlled trial Study grouping: Parallel group
Baseline Characteristics Intervention
Included criteria: 21 years or older, bilateral age-related cataract, and bilateral regular corneal astigmatism of at leas 1.25D. Excluded criteria: Irregular corneal astigmatism, Fuchs endothelial dystrophy stage 2 or higher, glaucoma related extensive visual field loss, or and expected postoperative corrected distance visual acuity of less than 20/40 Pretreatment: Age, mean (range) intervention: 74 (50-88), male %: 49%Age, mean (range), kontrol: 74 (49-87), male %: 54%
Intervention Characteristics Intervention: • Description: Acrysof aspherical toric IOL (model SN6AT3-T9) • Duration of intervention: • Dose: • Follow-up time after EoT: 6 mdr Kontrol • Description: Acrysof aspehrical IOL model SN60WF • Duration of intervention: • Dose: • Follow-up time after EoT: 6 mdr
Brilleafhængighed Outcome type: DichotomousOutcome Reporting: Fully reported Direction: Lower is better Data value: Endpoint Antal patienter der ikke opnåede postop UCDVA 0.8 (snellen) eller bedre Outcome type: DichotomousOutcome Reporting: Fully reported Direction: Lower is better Data value: Endpoint Antal komplikationer
Outcome type: DichotomousOutcome Reporting: Fully reported Direction: Lower is better Data value: Endpoint Jesper Hjortdal on 28/04/2019 20:55 Select

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Judgement Comment: Patients were randomized using a online program. s. 1464
Allocation concealment (selection bias)	Low risk	Judgement Comment: computer generated. central allocation
Blinding of participants and personnel (performance bias)	Low risk	Judgement Comment: The patients and investigator performing the postoperative examinations were blinded.
Blinding of outcome assessment (detection bias)	Low risk	Judgement Comment: The investigator performing the postoperative examinations were blinded.
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: Intet frafald i kontrolgruppen og 4 der falder fra i interventinsgruppen (2 dør og 2 dropouts). men der er foretaget intention to treatanalyser
Selective reporting (reporting bias)	Low risk	Judgement Comment: Protokol på clinical trials. All primary and secondary outcomes of interest are reported
Other bias	Low risk	Judgement Comment: appears to be free of other sources of bias

Footnotes

Characteristics of excluded studies

Ahmed 2010

Reason for exclusion	Observational study describing the outcome after bilateral implantation with toric
	IOLs but did not compare to a group not receiving toric IOL implantation

Alberdi 2012

Reason for exclusion	Prospective observational study describing the rotational stability of Rayner
	T-flex. Does not compare visual function to patients not receiving toric IOL

Ale 2012

Reason for exclusion	Retrospective study comparing the outcome after implantation of two different
	types of IOLs (AcrySof Toric and AT-Torbi) but does not compare to patients not
	receiving toric IOL implantation

Alio 2010

Prospective, observational study describing the outcome after implantation of a toric IOL (Acri.Comfort 646 TLC) but does not compare to patients not receiving
toric IOL implantation

Alio 2011

Reason for exclusion	Prospective case series describing the outcome after implantation of a toric IOL
	(AcrySof) but does not compare to a group not receiving toric IOL implantation

Alio 2011b

Reason for exclusion	Prospective case series describing the outcome after implantation of a toric IOL
	(AT Lisa 909M) but does not compare to a group not receiving toric IOL
	implantation

Bachernegg 2015

Reason for exclusion Wrong study design	
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Bandeira 2018

Reason for exclusion	Wrong study design
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Bauer 2008

to	Prospective, observational studies describing the outcome after implantation of a toric IOL (AcrySof) but does not compare to a group not receiving toric IOL implantation
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Cervantes-Coste 2012

Reason for exclusion	Observational study describing the outcome after implantation of a toric IOL
	(AcrySof) but does not compare to a group not receiving toric IOL implantation

Chua 2012

Reason for exclusion	RCT comparing the outcome after implantation of an acrylic (AcrySof Toric SN60T3, SN60T4, and SN60T5) or a silicone (Staar AA4203-TF, AA4203-TL) toric IOL but does not compare to a group receiving a non-toric IOL
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Correia 2009

Reason for exclusion	Paper published in Portugese	
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Dardzhikova 2009

Reason for exclusion	Observational study describing the outcome after implantation of a toric IOL
	(AcrySof) but does not compare to a group not receiving toric IOL implantation

De Silva 2006

Reason for exclusion	Prospective, observational study describing the outcome after implantation of a
	toric IOL (MicroSil 6116TU) but does not compare to a group receiving a
	non-toric IOL

Dick 200	

Reason for exclusion	Observational study describing the outcome after implantation of a toric IOL (MicroSil Toric) but does not compare to a group receiving non-toric IOL implantation. Paper published in German
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Elhofi 2015

Reason for exclusion	Wrong study design
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Emesz 2015

Reason for exclusion	Wrong comparator
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Entabi 2011

Reason for exclusion	Cohort study describing the outcome after impantation of a toric IOL (T-flex
	623T) but does not compare to a group receiving a non-toric IOL

Ernst 2011

Reason for exclusion	Retrospective case series describing outcome after implantation of AcrySof Toric
	IOL

Feng 2017

Reason for exclusion	Wrong intervention

Ferreira 2012

Reason for exclusion	RCT. Compares Tecnis and AcrySof Toric IOLs. Does not compare to a group	ı
	not receiving a toric IOL	

Freitas 2014

Reason for exclusion	Wrong study design
reason for exclusion	Wrong study design

Frohn 1999

F	Reason for exclusion	Case report of a single patient receiving a toric IOL	ı
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Gangwani 2014

Reason for exclusion	Wrong comparator
Reason for exclusion	Wrong comparator

Gayton 2011

Reason for exclusion	Retrospective study describing the outcome after implantation of a toric IOL
	(AcrySof toric) but does not compare to a group receiving a non-toric IOL

Gerl 2017

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Reason for exclusion	Wrong study design	

Gil 2014

	Reason for exclusion	Wrong intervention
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Gills 2002

Reason for exclusion	Case report describing management of astigmatism with 2 toric IOLs
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Gills 2002b

Reason for exclusion	Prospective study describing the outcome of combined toric IOL implantation
	(Staar) and relaxing incisions in reducing high preexisting astigmatism

Gills 2003

Reason for exclusion	Case report describing the management of astigmatism with 2 toric IOLs
Reason for exclusion	Jase report descripting the management of astigmatism with 2 tone roles

Goggin 2011

Reason for exclusion	Observational study describing the outcome after implantation of a toric IOL
	(SN60TT AcrySof Toric) but does not compare to a group receiving a non-toric
	IOL

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Reason for exclusion	Same study population as Goggin 2011, describes the outcome after implantation of a toric IOL (SN60TT Acrysof Toric) but does not compare to a group receiving a non-toric IOL
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Gundersen 2012

Reason for exclusion	Observational study describing the outcome after implantation of a toric IOL
	(AcrySof Toric) but does not compare to a group receiving a non-toric IOL

Hatch 2015

Peacon for exclusion	Wrong intervention	
iteason for exclusion	Wrong intervention	

Hirnschall 2014

Reason for exclusion Wrong intervention	Reason for exclusion
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Hoffmann 2011

Reason for exclusion	Case series describing the outcome after implantation of a toric IOL (AcrySof	
	Toric) but does not compare to a group receiving a non-toric IOL	

Jampaulo 2008

Reason for exclusion	Retrospective, interventional, case series describing the rotational stability of a
	toric IOL (Staar Toric) but does not compare visual outcome/spectacle indepence
	in patients receiving/not receiving a toric IOL

Jin 2010

Reason for exclusion	Partly observational and partly theoretical study evaluating the effect of axis	
	misalignment on postoperative refraction	

Jung 2018

Reason for exclusion Wrong study design	
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Kasthurirangan 2015

Reason for exclusion	Wrong outcomes
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Kersey 2007

Reason for exclusion	Case series describing the outcome after implantation of a toric IOL in patients
	who had previously undergone penetrating keratoplasty

Kessel 2016

Reason for exclusion	Wrong study design
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Kim 2010

Reason for exclusion	Prospective, observational study describing the rotational stability of a toric IOL	
	(AcrySof Toric) but does not compare visual outcome or spectacle independece	
	in patients receiving/not receiving a toric IOL	

Koshy 2010

Reason for exclusion	Prospective, observational study describing the rotational stability of a toric IOL
	(AcrySof SN60TT) but does not compare visual outcome or spectacle
	independece in patients receiving/not receiving a toric IOL

Lam 2016

Reason for exclusion	Wrong study design
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Lane 2009

Reason for exclusion	Prospective non-randomized study comparing outcome after implantation of
	AcrySof Toric or AcrySof spherical IOL

Leon 2015

Reason for exclusion	Wrong study design
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Leyland 2001			
Reason for exclusion	Case series describing the outcome and rotational stability of a toric IOL (Staar Toric AA-4203TF) but does not compare to a group receiving a non-toric IOL		
Liu 2014			
Reason for exclusion	Wrong study design		
Maedel 2014			
Reason for exclusion	Wrong study design		
Mairot 2016			
Reason for exclusion	Wrong study design		
Mayer 2017			
Reason for exclusion	Wrong study design		
Mencucci 2013			
Reason for exclusion	Prospective, non-randomized, observational study comparing the outcome after implantation of AcrySof Toric and AcrySof spherical IOL		
Mencucci 2013a			
Reason for exclusion	Wrong study design		
Mendicute 2008			
Reason for exclusion	Prospective, observational study describing the outcome after implantation of AcrySof toric IOL but does not compare to a group receiving non-toric IOL		
Mendicute 2009			
Reason for exclusion	Wrong study population		
Mingo-Botin 2010			
Reason for exclusion	Wrong study population		
Mohammad Rabei 2016			
Reason for exclusion	Wrong study design		
Mojzis 2011			
Reason for exclusion	Retrospective study evaluating the outcome after multifocal toric IOL implantation		
Mozayan 2014			
Reason for exclusion	Wrong study design		
Nagpal 2015			
Reason for exclusion	Wrong study design		
Nanavaty 2017			
Reason for exclusion	Wrong study design		
Osher 2011			
Reason for exclusion	Observational study describing the outcome after combined toric IOL implantation and astigmatic keratotomy. Does not compare to a group not receiving toric IOL implantation		
Ouchi 2011			
Reason for exclusion	Prospective study evaluating the effect of toric IOL implantation combined with limbal relaxing incisions. Does not compare to a group not receiving toric IOL implantation		

Review Manager 5.3 6

Packer 2018		
Reason for exclusion	Wrong comparator	
Park 2011		
Reason for exclusion	Prospective study comparing toric and non-toric IOL implantation in patients undergoing simulataneous phacoemulsification and 23-gauge vitrectomy. All patients had vitreoretinal disease	
Pepose 2015		
Reason for exclusion	Wrong comparator	
Poll 2011		
Reason for exclusion	Retrospective study comparing outcome after toric IOL or peripheral corneal relaxing incisions	
Pouyeh 2011		
Reason for exclusion	Retrospective case series describing the outcome after implantation of a toric IOL (AcrySof Toric) in a teaching hospital. Does not compare to a group receiving a non-toric IOL	
Roensch 2012		
Reason for exclusion	Case series describing the outcome after toric IOL (AcrySof Toric) or multifocal IOL (AcrySof Restor) implantation. Does not compare to a group receiving a non-toric, monofocal IOL	
Ruhswurm 2000		
Reason for exclusion	Observational study describing the outcome after toric IOL (Staar AA4203T) implantation. Does not compare to a group receiving a non-toric IOL	
Sambhara 2017		
Reason for exclusion	Wrong study design	
Sasaki 2012		
Reason for exclusion	Prospective, non-randomized study comparing outcome after implantion of a toric (AcrySof Toric) or spherical (AcrySof) IOL	
Scialdone 2013		
Reason for exclusion	Wrong comparator	

Seth 20	018			

Wrong study design

Sheppard 2013

Reason for exclusion

Reason for exclusion	Multicenter cohort study describing the outcome after implantation of a toric IOL
	(Tecnis Toric) but does not compare to a group receiving a non-toric IOL

Stanwood 2002

Reason for exclusion	Case series describing the outcome after implantation with a toric IOL (Staar
	AA4203TF or AA4203TL) but does not compare to a group receiving a non-toric
	IOL

Statham 2009

Reason for exclusion	Retrospective chart review comparing outcome after AcrySof Toric or AcrySof
	spherical IOL

Stewart 2010

Reason for exclusion	Retrospective study describing the outcome after toric IOL implantation (Rayner T models) in patients who had previously undergone penetrating keratoplasty
	compared to non-keratoplasty patients. Does not compare to a group receiving a non-toric IOL

Sun 2000

Reason for exclusion Retrospective study describing the outcome after implantation of a toric IOL (Staar AA4203TF) or a non-toric IOL (unknown model). The study included both patients who underwent cataract surgery and clear lens extraction

Swiatek 2012

Reason for exclusion	Retrospective case series reporting the outcome after implantation of a toric IOL
	(AcrySof T3-T9) but does not compare to a group receiving a non-toric IOL

Tassignon 2011

Reason for exclusion	Observational study describing the outcome after spherotoric IOL implantation
	(Morcher BIL IOL). Does not compare to a group receiving a non-toric IOL

Thomas 2018

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	Reason for exclusion	Wrong study design

Titiyal 2014

Reason for exclusi	Mrong study design	
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Vasavada 2013

Reason for exclusion	Wrong study design
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Vickovic 2012

Reason for exclusion	Observational study evaluating the outcome after implantation of AT TORBI toric
	intraocular lens. Does not compare to a group not receiving a toric IOL

Visser 2011

Prospective, observational study describing the outcome after implantation of
different types of toric IOLs (AcrySof SN60T6, SN60t7, SN60T8 or SN60T9) but
does not compare to a group that did not receive toric IOL implantation

Visser 2011b

Reason for exclusion	Cohort study describing the outcome after implantation of a multifocal IOL (AT
	Lisa). Does not compare to a group receiving a non-toric or non-multifocal IOL

Visser 2012

Reason for exclusion	Observational study describing the outcome after implantation of different types of toric IOLs (AcrySof Toric) or toric phakic IOL (Artiflex pIOL, Artisan Toric pIOL) implantation. Does not compare to a group receiving a non-toric IOL
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Waltz 2015

Reason for exclusion	Wrong patient population
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Webers 2017

Reason for exclusion	Wrong study design
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Woo 2015

Reason for exclusion	Wrong study design
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Zuberbuhler 2008

Reason for exclusion	Retrospective study describing the outcome after implantation of a toric IOL				
	(AcrySof SA60T3, SA60T4, SA60T5) but does not compare to a group receiving				
	a non-toric IOL				

Zukaite 2019

Reason for exclusion	Wrong study design
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Footnotes

References to studies

Included studies

Holland 2010

[Empty]

Visser 2014

Visser, Nienke; Beckers, Henny J. M.; Bauer, Noel J. C.; Gast, Sacha T. J. M.; Zijlmans, Bart L. M.; Berenschot, Tos T. J. M.; Webers, Carroll A.; Nuijts, Rudy M. M. A.. Toric vs aspherical control intraocular lenses in patients with cataract and corneal astigmatism: a randomized clinical trial.. JAMA Ophthalmology 2014;132(12):1462-1468. [DOI:]

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Ahmed 2010

[Empty]

Alberdi 2012

[Empty]

Ale 2012

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Alio 2010

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Alio 2011

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Bachernegg 2015

Bachernegg, Alexander; Ruckl, Theresa; Strohmaier, Clemens; Jell, Gerlinde; Grabner, Gunther; Dexl, Alois K.. Vector Analysis, Rotational Stability, and Visual Outcome After Implantation of a New Aspheric Toric IOL.. Journal of Refractive Surgery 2015;31(8):513-520. [DOI:]

Bandeira 2018

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Bauer 2008

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Cervantes-Coste 2012

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De Silva 2006

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Elhofi 2015

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Emesz 2015

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Entabi 2011

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Feng 2017

Feng K.; Guo H.K.; Zhang Y.L.; Wu, Z.. Visual quality comparison after multifocal toric intraocular lens or monofocal toric intraocular lens implantation.. [Zhonghua yan ke za zhi] Chinese journal of ophthalmology 2017;53(4):274-280. [DOI:]

Ferreira 2012

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Freitas 2014

Freitas, Giuliano Oliveira; Boteon, Joel Edmur; Carvalho, Mario Jose; Pinto, Rogerio Melo Costa. Treatment of astigmatism during phacoemulsification.. Arquivos Brasileiros de Oftalmologia 2014;77(1):40-46. [DOI:]

Frohn 1999

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Gangwani 2014

Gangwani, Vinod; Hirnschall, Nino; Findl, Oliver; Maurino, Vincenzo. Multifocal toric intraocular lenses versus multifocal intraocular lenses combined with peripheral corneal relaxing incisions to correct moderate astigmatism.. Journal of Cataract & Refractive Surgery 2014;40(10):1625-1632. [DOI:]

Gayton 2011

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Gerl 2017

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Gil 2014

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Gills 2002

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Gills 2002b

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Gills 2003

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Goggin 2011

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Goggin 2011b

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Gundersen 2012

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Hatch 2015

Hatch, Kathryn M.; Woodcock, Emily C.; Talamo, Jonathan H.. Intraocular lens power selection and positioning with and without intraoperative aberrometry.. Journal of Refractive Surgery 2015;31(4):237-242. [DOI:]

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Jung 2018

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Liu, Zhiping; Sha, Xiangyin; Liang, Xuanwei; Wang, Zhonghao; Liu, Jingbo; Huang, Danping. Toric intraocular lens vs. peripheral corneal relaxing inci- sions to correct astigmatism in eyes undergoing cataract surgery.. Eye Science 2014;29(4):198-203. [DOI:]

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Mairot 2016

Mairot A.; Dot C.; El Chehab H.; Agard, E.. Interest of low power toric intra ocular lenses in cataract surgery, about 80 eyes Apolline Mairot; Corinne Dot; Hussam El Chehab; Emilie Agard.. Investigative Ophthalmology and Visual Science.Conference: 2016 Annual Meeting of the Association for Research in Vision and Ophthalmology, ARVO 2016.United States 2016;57(12):1315. [DOI:]

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Mendicute 2008

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Mendicute 2009

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Mohammad Rabei 2016

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Osher 2011

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Park 2011

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Pepose 2015

Pepose, Jay S.; Hayashida, Jon; Hovanesian, John; Davies, James; Labor, Phillips Kirk; Whitman, Jeffrey; Carter, Harvey; Colvard, Michael; Buckhurst, Phillip J.; Khodai, Omid; Mittleman, David; Feinerman, Gregg. Safety and effectiveness of a new toric presbyopia-correcting posterior chamber silicone intraocular lens.. Journal of Cataract & Refractive Surgery 2015;41(2):295-305. [DOI:]

Poll 2011

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Pouyeh 2011

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Roensch 2012

[Empty]

Ruhswurm 2000

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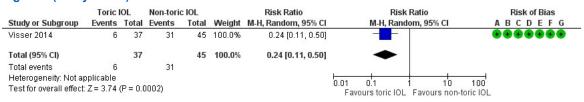
Data and analyses

1 Torisk IOL vs Non-torisk IOL

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Spectacle dependence.	1	82	Risk Ratio (M-H, Random, 95% CI)	0.24 [0.11, 0.50]
1.3 No of patients not obtainingUCDVA 20/25 or better	2	194	Risk Ratio (M-H, Random, 95% CI)	0.47 [0.34, 0.64]
1.4 Number of complications.	1	82	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.35, 2.39]

Figures

Figure 1 (Analysis 1.1)

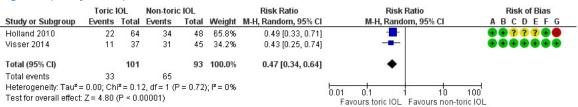


Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Forest plot of comparison: Torisk IOL vs Non-Torisk IOL, outcome: 1.1 Spectacle dependence..

Figure 2 (Analysis 1.3)

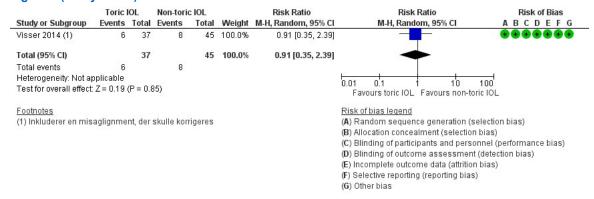


Risk of bias legend

- (A) Random sequence generation (selection bias)
 (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

Forest plot of comparison: 1 Torisk IOL vs Non-torisk IOL, outcome: 1.3 No of patients not obtaining UCDVA 20/25 or better.

Figure 3 (Analysis 1.4)



Forest plot of comparison: 1 Torisk IOL vs Non-torisk IOL, outcome: 1.4 Number of complications...