



# Toric Intraocular Lenses in the Correction of Astigmatism During Cataract Surgery

## A Systematic Review and Meta-analysis

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**Topic:** We performed a systematic review and meta-analysis to evaluate the benefit and harms associated with implantation of toric intraocular lenses (IOLs) during cataract surgery. Outcomes were postoperative uncorrected distance visual acuity (UCDVA) and distance spectacle independence. Harms were evaluated as surgical complications and residual astigmatism.

**Clinical Relevance:** Postoperative astigmatism is an important cause of suboptimal UCDVA and need for distance spectacles. Toric IOLs may correct for preexisting corneal astigmatism at the time of surgery.

**Methods:** We performed a systematic literature search in the Embase, PubMed, and CENTRAL databases within the Cochrane Library. We included randomized clinical trials (RCTs) if they compared toric with non-toric IOL implantation ( $\pm$  relaxing incision) in patients with regular corneal astigmatism and age-related cataracts. We assessed the risk of bias using the Cochrane Risk of Bias tool. We assessed the quality of evidence across studies using the GRADE profiler software (available at: [www.gradeworkinggroup.org](http://www.gradeworkinggroup.org)).

**Results:** We included 13 RCTs with 707 eyes randomized to toric IOLs and 706 eyes randomized to non-toric IOLs; 225 eyes had a relaxing incision. We found high-quality evidence that UCDVA was better in the toric IOL group (logarithm of the minimum angle of resolution [logMAR] mean difference,  $-0.07$ ; 95% confidence interval [CI],  $-0.10$  to  $-0.04$ ) and provided greater spectacle independence (risk ratio [RR],  $0.51$ ; 95% CI,  $0.36$ – $0.71$ ) and moderate quality evidence that toric IOL implantation was not associated with an increased risk of complications (RR,  $1.73$ ; 95% CI,  $0.60$ – $5.04$ ). Residual astigmatism was lower in the toric IOL group than in the non-toric IOL plus relaxing incision group (mean difference,  $0.37$  diopter [D]; 95% CI,  $-0.55$  to  $-0.19$ ).

**Conclusions:** We found that toric IOLs provided better UCDVA, greater spectacle independence, and lower amounts of residual astigmatism than non-toric IOLs even when relaxing incisions were used. *Ophthalmology* 2016;123:275–286 © 2016 by the American Academy of Ophthalmology. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).



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During cataract surgery, the refractive status of the patient is changed. Some intraocular lenses (IOLs) correct spherical refractive errors, whereas others correct both spherical and astigmatic errors. Preoperative astigmatism 1.5 diopters (D) or greater is present in 20% of patients undergoing operation for age-related cataracts.<sup>1</sup> Residual postoperative astigmatism is an important cause for not obtaining planned emmetropia after cataract surgery.<sup>2</sup> Patients are 34 times more likely to use spectacles per diopter of astigmatic error in the better eye,<sup>3</sup> and residual postoperative astigmatism is an important reason for spectacle use even in patients with a spherical equivalent refraction  $\pm 0.5$  D. Correcting residual astigmatism results in significantly improved visual acuity at all contrast levels at both distance and near.<sup>4</sup>

Astigmatism can be corrected by implanting a toric IOL or by changing the corneal curvature by LASIK or similar procedures, or by placing relaxing incisions at the steepest meridian to flatten the corneal curvature.<sup>5</sup> Relaxing incisions

may correct up to 3 D of astigmatism, whereas toric IOLs can correct up to 8 D of astigmatism.<sup>6</sup> There are benefits and harms associated with toric IOLs and relaxing incisions. Toric IOLs can rotate. Small rotations do not affect the astigmatic power, but larger rotations will reduce the power of the IOL, for example, the correcting effect is eliminated if the IOL is rotated 30 degrees.<sup>7</sup> Thus, larger rotations, generally 10 degrees is used as a limit,<sup>8</sup> require surgical interventions to reposition the IOL. Relaxing incisions may be a site of infectious keratitis, and the refractive result may change over time as the cornea heals. Long-term stability studies of corneal-relaxing incisions are scarce, but it has been reported that the surgically induced astigmatism changes most in the first 10 weeks after surgery, with little change from 10 weeks up to 3 years after surgery.<sup>9</sup> Toric IOLs show the greatest rotation in the early postoperative period with little rotation after 1 week.<sup>10</sup>

We conducted the present systematic review and meta-analysis to evaluate the benefits and potential harms of toric implantation to correct preexisting corneal astigmatism in patients undergoing phacoemulsification for age-related cataracts. Toric IOLs were compared with (1) non-toric IOLs without further attempts to surgically correct astigmatism and (2) non-toric IOLs combined with a relaxing incision to correct astigmatism. The study was initiated by an initiative of the Danish Health and Medicines Authorities as part of providing evidence-based national guidelines on the treatment of age-related cataracts.

## Methods

We performed this systematic review and meta-analysis based on the principles described in the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) approach.<sup>11</sup> We chose to examine the effect of toric IOL implantation (I) versus non-toric IOL implantation (C) in patients with age-related cataracts and preoperative corneal astigmatism undergoing phacoemulsification (P) (PICO<sup>12</sup>). The effect (O) was evaluated as (1) number (in percentage) of patients who obtained postoperative spectacle independence at distance at all times, (2) uncorrected distance visual acuity (UCDVA) (in logarithm of the minimum angle of resolution [logMAR] or as a Snellen fraction as measured by included studies), (3) residual astigmatism (in diopters), and (4) number of operative and postoperative complications including reoperations for rotated IOL. The non-toric IOL could be combined with a relaxing incision. If included studies reported outcomes at more than 1 time point, the last reported time point was used in the analyses. The result of both toric IOLs and relaxing incision should be stable at 3 months, and none of the studies had a last reported time point earlier than 3 months postoperatively. We did not publish a protocol for the present review.

We conducted a systematic literature search on August 26, 2015, in the Embase, PubMed.gov, and Cochrane Central Library databases using the search term: (((cataract) AND surgery) AND toric iol) OR (((cataract) AND surgery) AND toric intraocular lens) OR (((cataract) AND surgery) AND toric intraocular lens). Two authors (L.K. and J.H.) evaluated the title and abstract of all search hits for eligibility. If there was any doubt as to the eligibility of a study, it was obtained and read in full by 2 authors (L.K. and J.H.). Eligibility criteria were randomized controlled clinical trials comparing the result after toric versus non-toric IOL implantation in patients with preoperative regular corneal astigmatism and cataract. References that reported only on outcome after toric IOL implantation in patients with corneal ectasia, such as keratoconus, or marginal pellucid degenerations were excluded. The implantation of non-toric IOLs could be combined with limbal or corneal-relaxing incisions.

We assessed all included studies for risk of bias using the Cochrane Risk of Bias tool.<sup>13</sup> The Cochrane Risk of Bias tool evaluates a study for risk of bias associated with patient selection (randomization procedure and allocation of patients), study performance (blinding of patients and personnel), outcome detection (blinding of outcome assessors), data attrition (e.g., patients lost to follow-up or otherwise not accounted for), and bias associated with the reporting of study findings or other types of bias. Two reviewers independently assessed risk of bias and extracted data from the included studies (L.K. and J.H.). Discrepancies were solved by discussion and consensus. We extracted data concerning prespecified outcomes (spectacle independence, UCDVA  $\geq 20/25$ , and rate of complications) from the included

studies and entered them into a meta-analysis using the Review Manager Software.<sup>14</sup>

We evaluated the quality of the evidence for each prespecified outcome across included studies using the GRADE system. We evaluated each outcome for factors that could affect the reliability of the outcome by looking at study limitations (risk of bias, e.g., lack of allocation concealment or lack of blinding of patients or outcome assessors, incomplete accounting of patients, selective outcome reporting, or other limitations),<sup>15</sup> inconsistency (different results between studies),<sup>16</sup> indirectness (was the study population and intervention comparable to the patient population and intervention that is relevant to the readers of the present meta-analysis, use of surrogate measures),<sup>17</sup> imprecision (large confidence intervals [CIs] or the lack of statistical strength by included studies to answer the posed question),<sup>18</sup> and risk of publication bias (small number of studies or small number of included patients, lack of reporting of negative findings).<sup>19</sup> We prepared a summary of findings and evidence tables using the GRADE profiler software.<sup>20</sup>

We analyzed dichotomous outcome data by calculating risk ratios (RRs) and continuous outcome data by using mean differences. We used the Review Manager 5 Software<sup>14</sup> for estimation of overall treatment effects. We calculated pooled estimates of effects by using random-effects models. When possible, we performed subgroup analyses of outcomes. A priori, we analyzed toric versus non-toric IOL and toric versus non-toric IOL in combination with relaxing incisions and multifocal toric versus multifocal non-toric IOL. According to Danish law, no institutional board review was required for this systematic review.

## Results

We identified 626 references after a systematic literature review. All references were screened for eligibility. After checking for duplicates and eliminating references that were deemed “not relevant” by title and abstract, we identified 25 potentially interesting references that were obtained in full and read thoroughly. We found 13 randomized clinical trials (RCTs) that fitted our inclusion criteria. These 13 RCTs compared the outcome after implantation of toric IOLs with non-toric IOL implantation in patients undergoing phacoemulsification for age-related cataract and with pre-existing, regular corneal astigmatism.<sup>21–33</sup> An overview of included studies and interventions is provided in Table 1. Risk of bias assessment of included studies is provided in Table S1 (available at [www.aaojournal.org](http://www.aaojournal.org)). Furthermore, 12 nonrandomized studies reporting the effect of toric IOL implantation were identified.<sup>34–45</sup> All nonrandomized studies and studies not comparing toric with non-toric IOLs were excluded from the analyses. A list of excluded studies with reasons for exclusion is provided in Table S2 (available at [www.aaojournal.org](http://www.aaojournal.org)). A diagram of the literature search is shown in Table S3 (available at [www.aaojournal.org](http://www.aaojournal.org)).

The included studies differed with respect to length of follow-up and types of IOLs used. Four studies compared toric IOL with non-toric IOL,<sup>24,29–31</sup> and 9 studies compared toric IOL with non-toric IOL plus relaxing incisions (limbal or corneal).<sup>21–23,25–28,32,33</sup> All relaxing incisions were performed manually. In one study, both the toric and non-toric IOLs were multifocal.<sup>22</sup> In total, 707 eyes were randomized to toric IOL implantation and 706 eyes were randomized to non-toric IOL implantation. Of those implanted with a non-toric IOL, 225 eyes received a relaxing incision and 481 eyes received a non-toric IOL only without surgical attempts to correct astigmatism. The included studies differed with respect to the type of toric IOLs used and nomograms used for planning the location, size, and depth of

Table 1. Overview of Interventions in Included Studies

Study ID	Intervention	Comparison Group	Follow-up	Preoperative Astigmatism	Study Population
Freitas et al 2014 <sup>21</sup>	Toric IOL in both eyes (AcrySof Toric TM, Alcon, Fort Worth, TX)	Non-toric IOL (AcrySof Natural, Alcon) + limbal-relaxing incisions in both eyes <sup>1</sup>	1+3+6 mos	0.75–2.5 D (both eyes)	Toric: 15 patients (30 eyes); age 65.7 yrs Non-toric: 16 patients (32 eyes); age 71.8 yrs
Gangwani et al 2014 <sup>22</sup>	Multifocal toric IOL (Mflex-T multifocal toric IOL, Rayner IOLs, East Sussex, UK) in 1 eye of a patient	Non-toric multifocal IOL (Mflex, Rayner IOLs) in the other eye + peripheral corneal-relaxing incisions <sup>1</sup>	3 mos	1.0–2.5 D	29 eyes in both groups; age 74.8 yrs (4.6)
Hirschall et al 2014 <sup>23</sup>	Rayner T-Flex toric IOL (Rayner) in 1 eye	C-Flex or Superflex non-toric IOL (Rayner) + 1 or 2 relaxing peripheral corneal incisions in the other eye <sup>1</sup>	1+6 mos	1.0–2.5 D	60 eyes (30 patients); age 71.0 yrs (8.4)
Holland et al 2010 <sup>24</sup>	Acrysof Toric (SA60T3-T5, Alcon)	Non-toric IOL (Acrysof SA60AT, Alcon)	1 yr	≥0.75 D with-the-rule astigmatism or ≥ 1.0 D against-the-rule astigmatism	Age 71 yrs Toric: 241 eyes Non-toric: 236 eyes
Lam et al 2015 <sup>32</sup>	TECNIS Toric IOL (Abbott Medical Optics (Santa Ana, CA))	TECNIS 1-piece IOL with limbal-relaxing incision	1+3 mos	≤3.0 D	Age: non-toric: 67.7 yrs (6.9), toric: 64.8 (10.3) Toric: 31 eyes of 31 patients Non-toric: 29 eyes of 29 patients
Liu et al 2014 <sup>33</sup>	Toric IOL (model and manufacturer not specified)	Non-toric IOL (model and manufacturer not specified) + peripheral corneal-relaxing incisions <sup>2</sup>	1+6 mos	Group A: 0.75–1.5 D Group B: 1.75–2.5 D	Age: non-toric: 70.5 yrs (8.0), toric: 67.3 yrs (10.3) Toric: 15 patients in Group A and 12 in group B Non-toric: 15 patients in Group A and 12 in group B
Maedel et al 2014 <sup>25</sup>	Aspheric toric IOL (Lentis Unico L-312T, Oculentis GmbH, Berlin, Germany)	Aspheric non-toric IOL (Lentis Unico L-312, Oculentis GmbH) + opposite clear corneal incisions <sup>3</sup>	1 hr, 1 wk, 3+9 mos	1.04–2.11 D (mean 1.69, SD 0.41)	Age 70.1 yrs (11.8) Toric: 18 eyes Non-toric: 21 eyes
Mendicute et al 2009 <sup>26</sup>	Toric IOL (Acrysof Toric SN60T3, SN60T4, SN60T5, Alcon)	Non-toric IOL (AcrySof SN60AT, Alcon) + opposite clear corneal incisions <sup>4</sup>	3 mos	1–3 D	Toric: 20 eyes; age 69.3 yrs (8.2) Non-toric: 20 eyes; age 71.9 yrs (6.8)
Mingo-Botin et al 2010 <sup>27</sup>	Toric IOL (Acrysof Toric, Alcon)	Non-toric IOL (Acrysof Natural, Alcon) + peripheral corneal-relaxing incisions <sup>5</sup>	3 mos	1–3 D	Toric: 20 eyes; age 71.5 yrs (11.1) Non-toric: 20 eyes; age 75.6 yrs (5.9)
Titiyal et al 2014 <sup>28</sup>	Toric IOL (AcrySof IQ Toric, Alcon)	Non-toric IOL (AcrySof IQ, Alcon) + astigmatic keratotomy <sup>6</sup>	1 day, 1 wk, 1+3 mos	1.25–3 D	Toric: 17 eyes; age 60.7 yrs (5.99) Non-toric: 17 eyes; age 62.23 yrs (3.29)
Visser et al 2014 <sup>29</sup>	Toric IOL (AcrySof aspheric toric, SN6AT3-T9, Alcon)	Non-toric IOL (AcrySof aspheric non-toric, Alcon, SN60WF)	1 wk, 1+3+6 mos	≥1.25 D	Age 74 yrs Toric: 41 patients (82 eyes) Non-toric: 45 patients (90 eyes)
Waltz et al 2015 <sup>30</sup>	Toric IOL (TECNIS toric ZTC150, Abbott Medical Optics)	Non-toric IOL (TECNIS 1-piece ZCB00 IOL, Abbott Medical Optics)	1 day, 1 wk, 1+3+6 mos	0.75–1.5 D	Toric: 102 patients; age 71.3 yrs (9.1) Non-toric: 95 patients; age 69.9 yrs (7.6)
Zhang et al 2011 <sup>31</sup>	Toric IOL (AcrySof Toric SN60T3-5, Alcon)	Non-toric (AcrySof non-toric SN60AT, Alcon)	1+3+6 mos	≥0.5–≤3 D in both eyes	Toric: 30 patients (60 eyes); age 67 yrs (10) Non-toric: 30 patients (60 eyes); age 65 yrs (12)

D = diopter; IOL = intraocular lens; SD = standard deviation.

All included studies were randomized clinical trials. All included patients had age-related cataract and regular astigmatism. Values are reported in mean (SD) or mean only if SD was not available. Age is reported in years. Nomograms used to plan size and location of incisions: (1) [www.lriccalculator.com](http://www.lriccalculator.com) according to Donnenfeld's nomogram; (2) surgeon's experience plus the method of Gill and Gayton; (3) not reported; (4) surgeon's personalized nomogram; (5) Nichamin's nomogram<sup>47</sup>; (6) no nomogram was used, paired 30-degree arcuate keratotomy incisions were made in the 7.0-mm optical zone on the steeper meridian. All incisions were performed manually.

relaxing incisions, but all studies compared the toric version of 1 IOL with the non-toric version of the same IOL from 1 manufacturer except 1 study that did not report the manufacturer or model of IOLs used.<sup>33</sup> The majority of studies used the AcrySof Toric IOL from Alcon (Fort Worth, TX),<sup>21,24,26–29,31</sup> 1 study used the Mflex-T multifocal IOL from Rayner (East Sussex, UK),<sup>22</sup> 1 study used the Lentis Unico from Oculentis GmbH (Berlin, Germany),<sup>25</sup> and 2 studies used the TECNIS toric IOL from Abbott Medical Optics (Santa Ana, CA).<sup>30,32</sup> Relaxing incisions were planned using the [www.lriccalculator.com](http://www.lriccalculator.com) software,<sup>46</sup> which is based on the nomograms by Donnenfeld and Nichamin in 3 studies,<sup>21–23</sup> 1 study<sup>27</sup> used Nichamin's nomogram,<sup>47</sup> and the remaining studies used a personalized method<sup>26,28,33</sup> or did not report<sup>25</sup> how relaxing incisions were planned. Preoperative astigmatism ranged from 0.75 D and generally up to 3 D.

Next, we focus on benefits (postoperative visual acuity and spectacle independence) and harms (perioperative and postoperative complications and residual astigmatism) associated with toric and non-toric IOL implantation.

### Postoperative Visual Acuity

Postoperative visual acuity was evaluated as UCDVA (logMAR in mean [standard deviation]) reported by included studies and by the number of patients who did not achieve an uncorrected postoperative visual of 20/25 or better (= 0.10 logMAR). Mean visual acuities were evaluated at the latest reported follow-up, which ranged from 3 months,<sup>22,25–28</sup> 6 months,<sup>21,23,29–31,33</sup> to 1 year.<sup>24</sup> There were no significant differences between visual outcomes at 3 or 6 months.

Postoperative UCDVA was significantly better in the eyes implanted with a toric IOL than in those implanted with a non-toric IOL (Fig 1). The mean difference (95% CI) for all eyes was  $-0.07$  logMAR ( $-0.10$  to  $-0.04$ ) better in patients implanted with toric IOLs. It was  $-0.10$  logMAR ( $-0.17$  to  $-0.04$ ) better when comparing eyes with toric IOLs with non-toric IOLs. For eyes implanted with toric IOLs, it was  $-0.06$  logMAR ( $-0.10$  to  $-0.02$ ) better than in eyes implanted with non-toric IOLs in combination with a relaxing incision. Each letter counts 0.02 units when visual acuity is tested using the logMAR chart at a distance of 20 feet. Thus, 2 to 5 more letters could be read correctly without glasses at a distance of 20 feet in eyes implanted with toric IOLs than in eyes implanted with a non-toric IOL. There was no significant difference between subgroups (toric vs. non-toric, toric vs. non-toric plus relaxing incision, multifocal toric vs. multifocal non-toric,  $P = 0.46$ ).

Mean visual acuities may be high, although some patients end up with a poor visual acuity. Therefore, we also evaluated postoperative visual acuity as the prevalence of patients not obtaining 20/25 (0.10 logMAR) UCDVA. For patients randomized to toric IOL implantation, 35.2% did not achieve 20/25 UCDVA versus 60.4% in patients randomized to non-toric IOL (both the groups including limbal-relaxing incisions and where no further attempts to correct astigmatism were included in this analysis). The difference between eyes randomized to toric or non-toric IOL was highly significant (RR, 0.59; 95% CI, 0.50–0.70;  $P < 0.00001$ ), but there was no difference among subgroups (toric vs. non-toric, toric vs. non-toric plus relaxing incision,  $P = 1.0$ ) (Fig 2).

### Distance Spectacle Independence

Spectacle independence was evaluated as the number of patients who reported that they used spectacles for distance viewing sometimes at 3 months<sup>27</sup> or 6 months<sup>24,29–31</sup> after surgery. The number of patients who required spectacles for distance viewing was significantly lower in patients randomized to toric IOL

implantation (29.7%) than in patients randomized to non-toric IOL implantation (53.2%) (RR, 0.51; 95% CI, 0.36–0.71) (Fig 3). In other words, in the toric IOL groups, 70.3% never required spectacles for distance viewing compared with 46.8% in the non-toric IOL groups even in combination with a relaxing incision. There was no difference between subgroups (toric vs. non-toric, toric vs. non-toric plus relaxing incision) ( $P = 0.67$ ) or at 3 or 6 months follow-up.

### Harms Associated with Toric Intraocular Lens Implantation

The prevalence of postoperative complications was reported by 6 studies.<sup>21,24,26,27,29,30</sup> A summary of all complications encountered is shown in Table 2. A total of 23 of the 554 patients randomized to toric IOL implantation (4.2%) experienced a postoperative complication versus 11 of 478 patients randomized to non-toric IOL implantation (2.3%). There was no significant difference between the groups (RR, 1.73; 95% CI, 0.60–5.04) (Fig 4). In the toric group, 1 eye had a retinal detachment and 5 eyes received treatment for retinal tears postoperatively versus 1 eye with a posterior vitreous detachment without a retinal defect in the non-toric group. Twelve patients in the toric IOL group had to undergo a second procedure (including laser treatment for retinal tears and retinal detachment surgery and realignment of rotated IOL) versus 1 patient in the non-toric group; this difference was statistically significant ( $X^2 P = 0.013$ ). In the toric group, 7 patients had macular edema versus 4 patients in the non-toric group; this difference was not statistically significant ( $X^2 P = 0.72$ ).

On average, the toric IOLs rotated less than 5 degrees except for 1 IOL (Lentis Unico L-312T, Oculentis GmbH) that rotated approximately 20 degrees and was removed from the market shortly after the study (Table 2).

Residual astigmatism at 3 months<sup>22,25–28</sup> to 6 months<sup>23,29,30,33</sup> after surgery was on average 0.75 D lower in the toric groups than in the non-toric groups (mean difference, 95% CI,  $-1.46$  to  $-0.05$ ), and it was 0.37 D lower in the groups randomized to toric IOL implantation compared with non-toric IOL plus relaxing incision (mean difference, 95% CI,  $-0.55$  to  $-0.19$ ) (Fig 5). There were no significant differences between the amount of residual astigmatism at 3 and 6 months follow-up ( $P = 0.61$ ).

### Quality of the Evidence

Table 3 provides a summary of the evidence and a grading of quality of evidence according to the GRADE system. Generally, the quality of evidence was rated as high except for the prevalence of postoperative complications that was graded as moderate quality because a large number (5/13) of the included RCTs did not report or comment on perioperative or postoperative complications.

### Discussion

We performed a systematic review and meta-analysis to examine the effect of toric IOL implantation during cataract surgery in patients with age-related cataracts and regular corneal astigmatism. A total of 13 randomized trials were included in the meta-analysis comprising 707 eyes randomized to toric IOL implantation and 706 eyes randomized to non-toric IOL implantation.<sup>21–33</sup> In 225 eyes, the non-toric IOL was combined with a relaxing incision. We found high-quality evidence that toric IOL implantation provides better UCDVA and greater distance spectacle independence

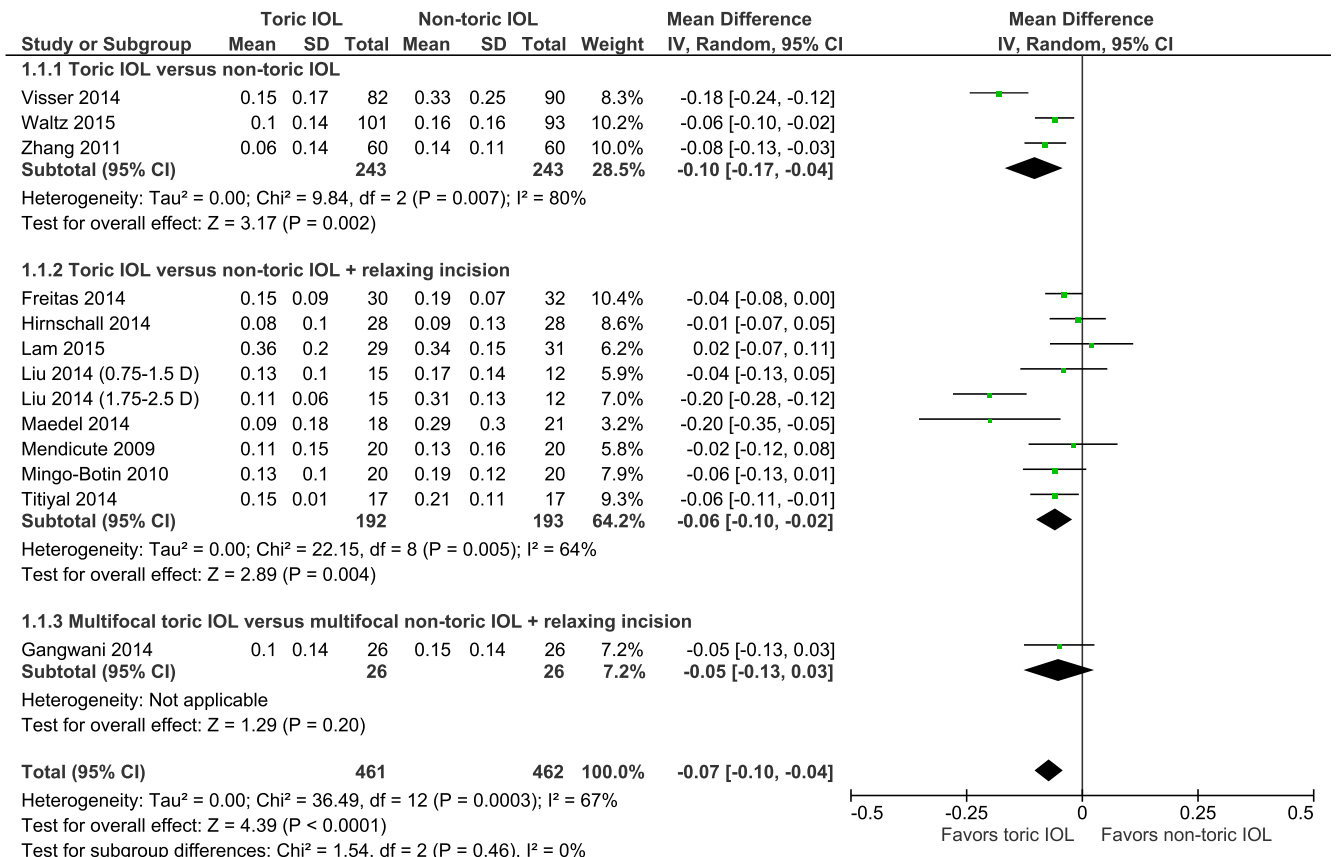


Figure 1. Forest plot comparing uncorrected distance visual acuity (UCDVA) in eyes randomized to implantation with a toric or non-toric intraocular lens (IOL). Visual acuity was 0.07 logarithm of the minimum angle of resolution (logMAR) better in the toric group compared with the non-toric groups. CI = confidence interval; IV = inverse variance; SD = standard deviation.

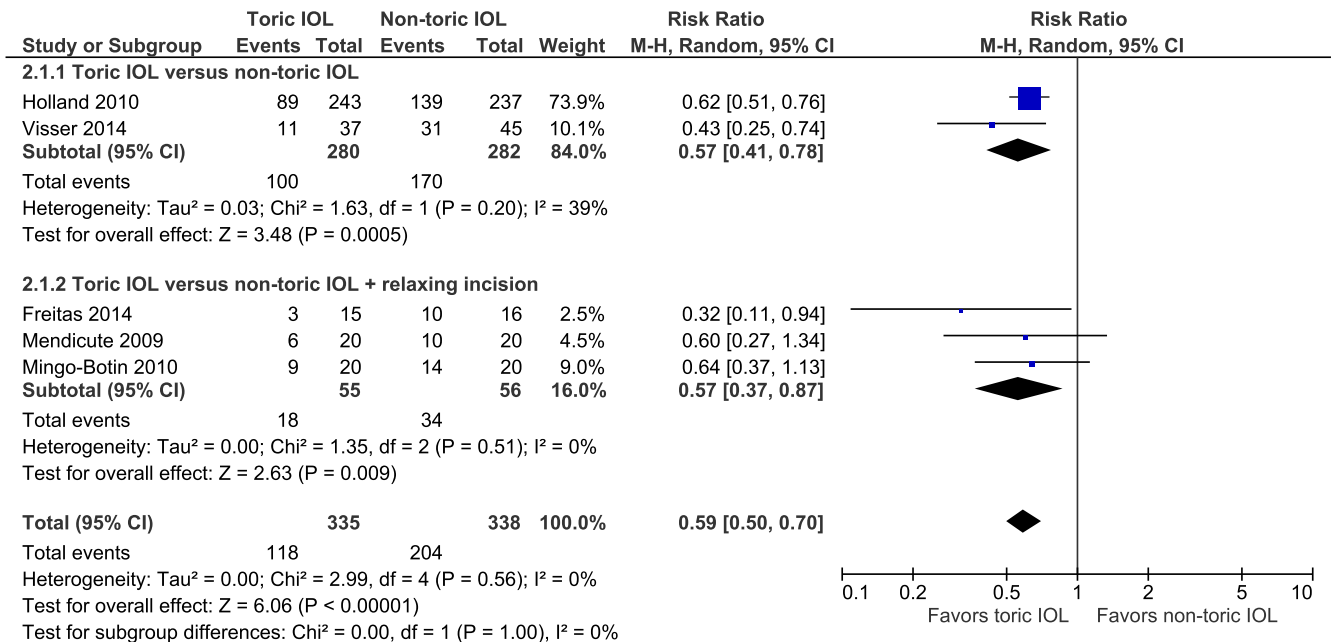
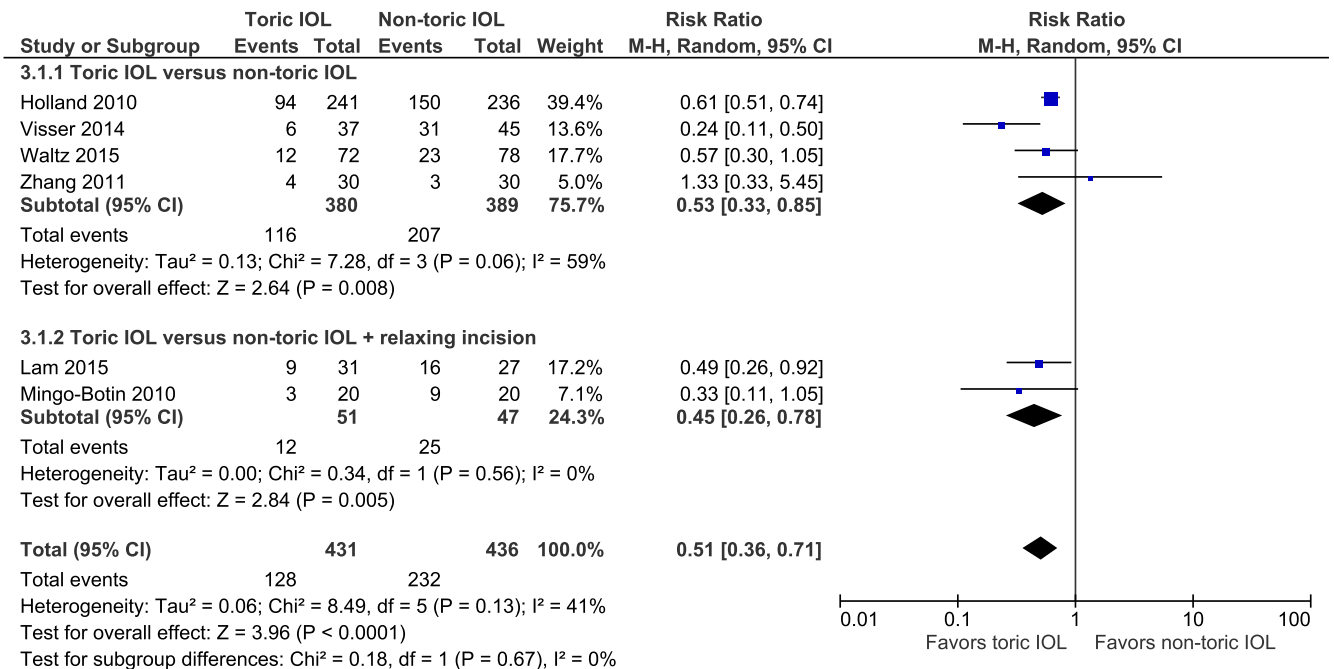


Figure 2. Forest plot showing the number of patients who did not achieve 20/25 UCDVA and the risk ratios (RRs) for not obtaining 20/25 UCDVA. A significantly greater number of patients did not achieve 20/25 UCDVA in the non-toric groups. CI = confidence interval; IOL = intraocular lens; M-H = Mantel-Haenszel; SD = standard deviation.



**Figure 3.** Forest plot showing the number of patients who reported that they required spectacles for distance viewing, as well as the RRs for needing spectacles for distance viewing. Spectacle independence was significantly greater in the toric group. CI = confidence interval; IOL = intraocular lens; M-H = Mantel–Haenszel.

than implantation of non-toric IOL or non-toric IOLs combined with a relaxing incision. We found moderate-quality evidence that toric IOL implantation was not associated with increased harms, and we found high-quality evidence that the residual astigmatism was lower in patients who received a toric IOL than in patients implanted with a non-toric IOL combined with a relaxing incision.

### Study Strengths and Limitations

The present study has strengths and weaknesses. It is an inherent part of the design of systematic reviews that they rely on published findings by other authors and on how those authors chose to report their findings. For the present review, we included randomized trials that compared toric with non-toric IOL implantation ± relaxing incisions. The majority of studies were small with an included number of approximately 20 eyes in each group. However, the strength of a systematic review and meta-analysis is that information from many studies is combined, and with the total number of randomized patients in the included studies we can say with confidence that UCVA is better, spectacle independence is greater, and residual astigmatism is lower in patients implanted with toric IOLs than in patients implanted with non-toric IOLs regardless of whether it is in combination with a relaxing incision or not. When it comes to the risk of complications and harms associated with the procedure, we did not find an overall difference between the groups, but we may not have sufficient power to say there is no difference between the groups. Thus, if more randomized trials comparing toric with non-toric ± relaxing incisions are

to be conducted, the emphasis should be on reporting harms and complications associated with the procedure.

The level of preoperative corneal astigmatism was approximately 0.75 to 3 D in the included RCTs. The studies did not report findings in a way that allowed for subgroup analysis of different degrees of preoperative astigmatism except for 1 study that included only 27 eyes in both the low (0.75–1.5 D) and high astigmatism (1.75–2.5 D) groups.<sup>33</sup> Thus, we cannot conclude from the present study at which degree of astigmatism toric IOLs should be used or which level of astigmatism the outcome after toric IOL implantation exceeds that of relaxing incisions. After cataract surgery, 60% of patients report they wear glasses for distance viewing sometimes or always when the postoperative astigmatism exceeds 0.75 D in the better eye.<sup>3</sup> Thus, it may seem advisable to inform the patient of the potential for astigmatism correction during cataract surgery if the surgeon expects that the postoperative astigmatism will exceed 0.75 D.

The amount of residual astigmatism was significantly lower in the toric group compared with the non-toric and non-toric in combination with relaxing incisions. The mean amount of postoperative astigmatism was in the range of 0.18 to 0.77 D in the groups randomized to toric IOL and 0.48 to 1.32 D in the groups randomized to non-toric IOL plus relaxing incision. The average difference between the groups was 0.75 D for patients randomized to toric versus non-toric IOL and 0.37 D for patients randomized to toric versus non-toric plus relaxing incisions. Thus, although the differences were significant and toric IOLs are better at compensating for astigmatism than relaxing incisions, some

Table 2. Overview of Harms in Included Studies

Study ID	Rotation*	Perioperative Complications	Postoperative Complications	Second Surgical Procedures
Freitas et al 2014 <sup>21</sup>	—	None encountered	None encountered	None encountered
Gangwani et al 2014 <sup>22</sup>	2.52 (1.97)	Not reported	Not reported	Not reported
Hirschall et al 2014 <sup>23</sup>	2.5 (1.8)	Not reported	Not reported	Not reported
Holland et al 2010 <sup>24</sup>	<4	Not reported	Toric group: 6 eyes with macular edema Non-toric group: 2 eyes with macular edema	Toric group: 1 eye had retinal detachment; 1 eye had IOL repositioning because of rotation, followed by second surgery for IOL replacement; 1 eye had paracentesis for elevated postoperative IOP; 1 eye underwent focal laser treatment for diabetic macular edema; 1 eye had laser photocoagulation for treatment of a retinal tear Non-toric group: 1 eye had crystalline lens fragment removal
Lam et al 2015 <sup>32</sup>	7.67 (4.04)	None encountered	None encountered	None encountered
Liu et al 2014 <sup>33</sup>	Not reported	None encountered	None encountered	Not reported
Maedel et al 2014 <sup>25</sup>	19.90 (14.48)	Not reported	Not reported	Not reported
Mendicute et al 2009 <sup>26</sup>	3.53 (1.97)	Not reported	None encountered	None encountered
Mingo-Botin et al 2010 <sup>27</sup>	3.65 (2.96)	Not reported	Toric group: none encountered Non-toric group: 1 eye with central de-epithelialization requiring bandage contact lens treatment	None encountered
Titiyal et al 2014 <sup>28</sup>	4.8 (1.2)	Not reported	None encountered	None encountered
Visser et al 2014 <sup>29</sup>	3.6 (3.2)	Toric group: 1 eye with small anterior capsule tear. Non-toric group: 1 eye with zonulolysis; 1 eye with large anterior to posterior capsule tear.	Toric group: 1 eye with high IOP; 1 eye with cystoid macular edema; 1 eye with macular pucker. Non-toric group: 2 eyes with high IOP; 2 eyes with cystoid macular edema; 1 eye with anterior uveitis; 1 eye with posterior vitreous detachment without retinal defect	Toric group: 1 eye had IOL repositioning; 1 eye with posterior vitreous detachment with a retinal defect Non-toric group: none encountered
Waltz et al 2015 <sup>30</sup>	2.7 (5.51)	Not reported	Not reported	Toric group: 1 eye with a rotated IOL (that was not repositioned) had a retinal tear and received treatment; 4 eyes had IOL repositioning; 2 eyes had retinal repair procedures Non-toric group: none reported
Zhang et al 2011 <sup>31</sup>	-	Not reported	Not reported	Not reported

IOL = intraocular lens; IOP = intraocular pressure.

\*The IOL rotation is reported in degrees as mean (SD). Complications are reported as number of eyes.

surgeons may find the difference to be too small to be clinically significant.

The present review was focused on the effect of toric IOL implantation in patients with regular corneal astigmatism and age-related cataract. Toric IOLs are used for wider indications; however, evidence-based evaluation of toric IOLs for these purposes is beyond the scope of this review. Positive results have been demonstrated in patients with high degrees of irregular astigmatism after penetrating keratoplasty,<sup>48,49</sup> in patients with pellucid marginal degeneration,<sup>50</sup> and in astigmatic patients undergoing refractive lens exchange.<sup>51,52</sup>

Toric IOLs are more expensive than non-toric IOLs, but economic analyses have shown that the lifetime costs are reduced if toric IOLs are implanted in patients with

preoperative corneal astigmatism because of the reduced need for postsurgical spectacles.<sup>53</sup> Relaxing incisions are cheaper than toric IOLs, but as we have demonstrated in the meta-analyses presented in this study, relaxing incisions are inferior to toric IOLs in regard to postoperative UCVA and residual astigmatism, at least in the patients in the included studies who had preoperative astigmatism in the range of 0.75 to 3.0 D. This information should be conveyed to patients when they decide, in collaboration with the surgeon, which surgical approach should be used.

We chose spectacle independence for distance viewing at all times as an important outcome. Nearly all patients will require spectacles for reading and near vision tasks after surgery unless multifocal IOLs are implanted or monovision is planned. If patients require distance spectacles, sometimes

Table 3. Quality of Evidence and Summary of Findings

Outcomes	No. of Participants (Studies)	Quality of the Evidence (GRADE)	Relative Effect (95% CI)	Anticipated Absolute Effects	
				Risk with Non-Toric IOL	Risk Difference with Toric IOL (95% CI)
UCDVA (logMAR)					
Toric IOL vs. non-toric IOL	486 (3 studies)	⊕⊕⊕⊕ High			The mean UCDVA was 0.10 better (0.17–0.04 better) in the toric group
Toric IOL vs. non-toric IOL + relaxing incision	385 (9 studies)	⊕⊕⊕⊕ High			The mean UCDVA was 0.06 better (0.10–0.02 better) in the toric group
Multifocal toric IOL vs. multifocal non-toric IOL + relaxing incision	52 (1 study)	⊕⊕⊕⊖ Moderate* due to imprecision			The mean UCDVA was 0.05 better (0.13 better to 0.03 worse) in the toric group
UCDVA $\geq 20/25$					
Toric IOL vs. non-toric IOL	562 (2 studies)	⊕⊕⊕⊕ High	RR 0.57 (0.41–0.78)	603 per 1000	259 fewer per 1000 patients in the toric group did not obtain UCDVA $\geq 20/25$ (from 133 fewer to 356 fewer)
Toric IOL vs. non-toric IOL + relaxing incision	111 (3 studies)	⊕⊕⊕⊕ High	RR 0.57 (0.37–0.87)	607 per 1000	261 fewer per 1000 patients in the toric group did not obtain UCDVA $\geq 20/25$ (from 79 fewer to 383 fewer)
Spectacle independence at distance at all times					
Toric IOL vs. non-toric IOL	769 (4 studies)	⊕⊕⊕⊕ High	RR 0.53 (0.33–0.85)	532 per 1000	250 fewer per 1000 patients in the toric group required spectacles for distance viewing (from 80 fewer to 357 fewer)
Toric IOL vs. non-toric IOL + relaxing incision	98 (2 studies)	⊕⊕⊕⊕ High	RR 0.45 (0.26–0.78)	532 per 1000	293 fewer per 1000 patients in the toric group required spectacles for distance viewing (from 117 fewer to 395 fewer)
Prevalence of postoperative complications					
Toric IOL vs. non-toric IOL	921 (3 studies)	⊕⊕⊕⊖ Moderate <sup>†</sup> due to publication bias	RR 2.1 (0.66–6.72)	24 per 1000	26 more per 1000 patients in the toric group experienced a postoperative complication (from 8 fewer to 136 more)
Toric IOL vs. non-toric IOL + relaxing incision	111 (3 studies)	⊕⊕⊕⊖ Moderate <sup>†</sup> due to publication bias	RR 0.33 (0.01–7.72)	18 per 1000	12 fewer per 1000 patients in the toric group experienced a postoperative complication (from 18 fewer to 120 more)
Residual astigmatism					
Toric IOL vs. non-toric IOL	364 (2 studies)	⊕⊕⊕⊕ High			The mean residual astigmatism was 0.75 D lower in the toric group (1.46–0.05 lower)
Toric IOL vs. non-toric IOL + relaxing incision	327 (8 studies)	⊕⊕⊕⊕ High			The mean residual astigmatism was 0.37 D lower in the toric group (0.55–0.19 lower)
Multifocal IOL vs. non-toric multifocal IOL + relaxing incision	58 (1 study)	⊕⊕⊕⊕ High			The mean residual astigmatism was 0.27 D lower in the toric group (0.55 lower to 0.01 higher)

CI = confidence interval; D = diopter; IOL = intraocular lens; logMAR = logarithm of the minimum angle of resolution; RR = risk ratio; UCDVA = uncorrected distance visual acuity. The basis for the assumed risk (e.g., the median control group risk across studies) is provided in the footnotes. The corresponding risk (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

\*Too few patients were included to ascertain whether there was any difference between the 2 groups.

<sup>†</sup>Thirteen RCTs were included, but the prevalence of complications/risks associated with toric IOL implantation or relaxing incisions was described by only 6 of the included RCTs.



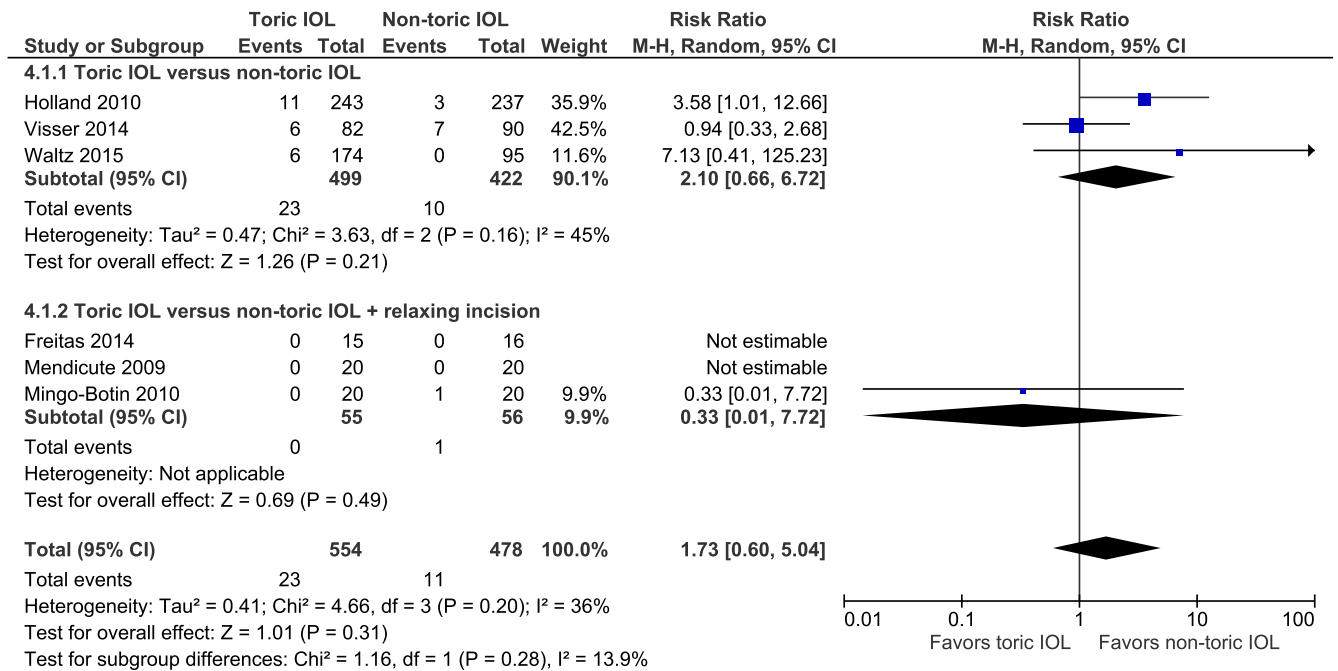


Figure 4. Forest plot demonstrating the RR of postoperative complications in patients randomized to toric or non-toric IOL implantation. There were no overall statistically significant differences between the toric and non-toric groups. CI = confidence interval; IOL = intraocular lens; M-H = Mantel-Haenszel.

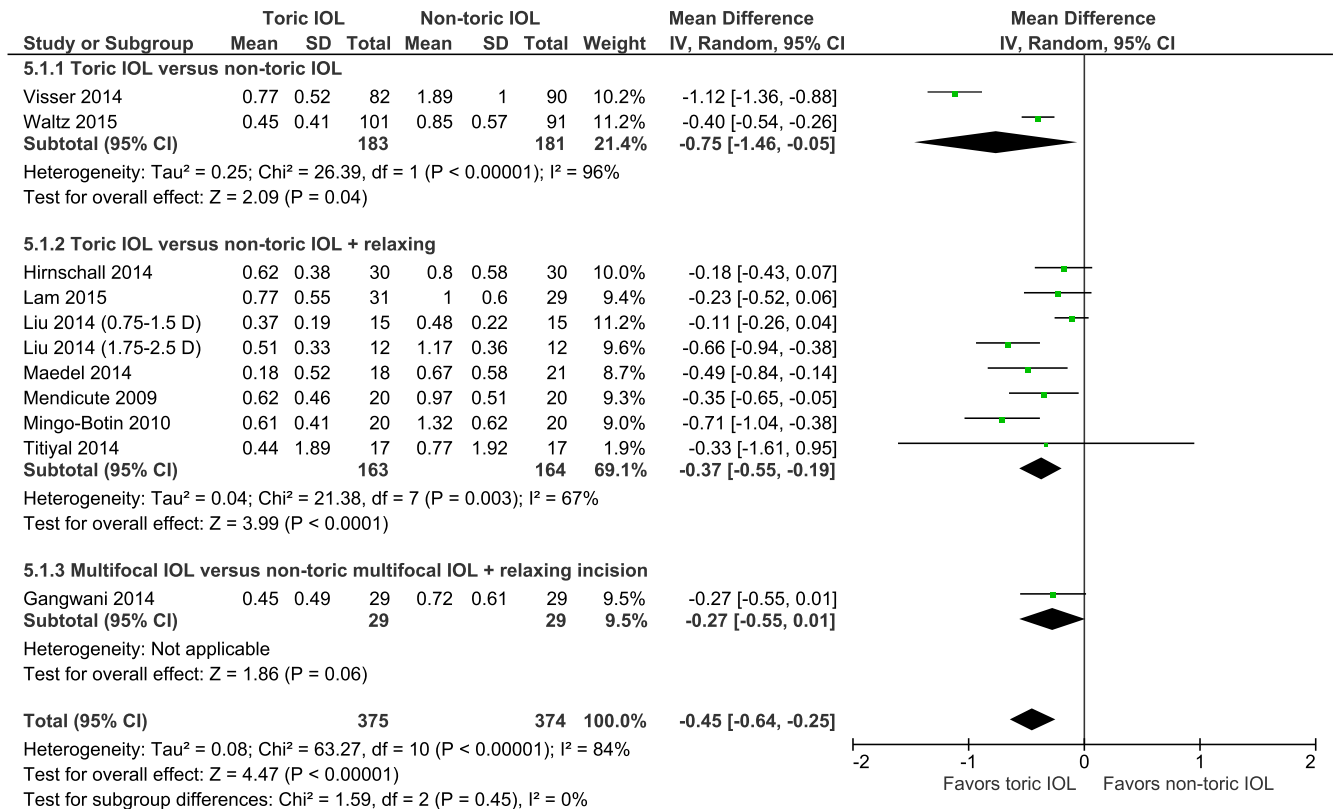


Figure 5. Forest plot demonstrating the residual astigmatism in patients randomized to toric or non-toric IOL implantation. Residual astigmatism was on average 0.5 diopters (D) lower in the toric group. CI = confidence interval; IOL = intraocular lens; IV = inverse variance; SD = standard deviation.

they will have to buy new spectacles after surgery, and the benefit of perioperative astigmatism correction is lost. We found that 70.3% of patients reported that they never required spectacles for distance viewing after toric IOL implantation compared with 46.8% in both the non-toric IOL and the non-toric plus relaxing incision groups. Thus, in terms of the decision to purchase or not to purchase distance glasses after cataract surgery, there is little benefit for patients who receive a relaxing incision compared with patients who receive no surgery to correct the astigmatism.

Precise preoperative biometry and IOL calculation are prerequisites for optimum refractive outcome after cataract surgery. The toric IOL and relaxing incisions both counteract the corneal component of total ocular astigmatism, whereas the astigmatic component from the lens disappears when the lens is removed during phacoemulsification. Corneal astigmatism is composed of contributions from the anterior and posterior corneal surface. The axis orientation changes with age from a with-the-rule dominance in younger years to against-the-rule dominance in older age groups; the change is most dominant for the anterior corneal curvature.<sup>54</sup> Thus, the ratio between anterior and posterior corneal curvature is not constant throughout life. Although the contributions from the posterior corneal curvature are small, they are significant<sup>55</sup> and the main cause for astigmatic refractive errors after toric IOL implantation.<sup>56</sup> This calls for individual preoperative evaluation of the posterior corneal curvature. Swept-source optical coherence tomography in combination with autokeratometry has been demonstrated to be superior to topography and Scheimpflug imaging in predicting toric IOL outcome because of the information from the posterior corneal surface.<sup>57</sup>

The benefits of toric IOL implantation are improved uncorrected distance visual outcome, greater spectacle independence, and lower residual astigmatism, but it is also important to examine whether toric IOL implantation is as safe as the other options. We did not find any differences in terms of the total number of perioperative or postoperative complications between the groups of patients randomized to toric IOL or non-toric IOL  $\pm$  relaxing incisions. However, patients randomized to toric IOL implantation had to undergo significantly more secondary surgical procedures because of rotated IOLs and retinal tears. Retinal tears could be related to toric IOL implantation if the surgeon has to manipulate the IOL to place it at the correct axis. The need for manipulation is expected to decrease with increasing surgeon experience. If the eyes were manipulated more, this may be reflected in increased postoperative inflammation, but we did not find any significant differences in the number of patients who had cystoid macular edema.

The astigmatic correcting effects of toric IOLs is reduced if the IOL rotates. A retrospective study found that the axis changed on average 1.36 degrees 2 weeks after YAG-laser capsulotomy, but the changes were within measurement error.<sup>58</sup> Axis rotation leads to less correction of astigmatism than expected preoperatively and may induce a hyperopic shift.<sup>59</sup> The astigmatic correcting effect is eliminated if the IOL is rotated 30 degrees.<sup>7</sup> In general, mean rotation was <5 degrees in the studies included in the present review. Only 1 toric IOL (Lentis Unico L-312T, Oculentis GmbH)

was found to be associated with significant rotation, and it was removed from the market shortly after conclusion of that study.<sup>25</sup> In our meta-analysis, 6 of 554 patients (1.1%) randomized to toric IOL implantation required a second surgical procedure to realign a rotated toric IOL. However, evaluation of mean rotations may hide high degrees of rotation despite low mean values. Pooled estimates of toric IOL rotation were reported by Visser et al,<sup>8</sup> who found that rotation greater than 10 degrees occurred in 3% with the AcrySof Toric IOL, 20% with the Staar Toric IOL (Staar Surgical Co, Monrovia, CA), 9% with the MicroSil toric IOL (HumanOptics, Erlangen, Germany), and 13% with the Rayner toric IOL.<sup>8</sup> Confidence intervals were not provided, and thus we do not know if the different types of toric IOLs are statistically significantly different. The way findings were reported in our included studies did not allow for an evaluation of the prevalence of toric IOLs that had rotated 10 degrees or more.

## Conclusions

Toric IOLs are superior to non-toric IOLs even in combination with a relaxing incision in reducing the amount of postoperative astigmatism and increasing postoperative uncorrected visual acuity, but more patients have to undergo a second procedure to realign the IOL and to treat retinal tears or detachments. These conclusions are limited to the range of preoperative astigmatism reported in included studies (generally 0.75–3.0 D) and the duration of follow-up (3–6 months). We recommend that patients with regular corneal astigmatism receive a toric IOL if they are to undergo cataract surgery for age-related cataracts and they want postoperative spectacle independence for distance viewing.

**Acknowledgments.** The authors thank information specialist Karine Korsgaard at Rigshospitalet, Glostrup, Denmark, for assistance in the literature search.

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## Footnotes and Financial Disclosures

Originally received: April 15, 2015.

Final revision: October 1, 2015.

Accepted: October 1, 2015.

Available online: November 18, 2015. Manuscript no. 2015-615.

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Financial Disclosure(s):

The author(s) have made the following disclosure(s): L.K.: Personal fees from Danish Health and Medicines Authorities during the conduct of this study.

The study was initiated and funded by the National Danish Health and Medicines Authorities, but the sponsor had no role in the design or conduct of this research.

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Obtained funding: Not applicable

Overall responsibility: Kessel, Andresen, Tendal, Erngaard, Flesner, Hjortdal

Abbreviations and Acronyms:

**CI** = confidence interval; **D** = diopter; **IOL** = intraocular lens; **logMAR** = logarithm of the minimum angle of resolution; **RCT** = randomized clinical trial; **RR** = risk ratio; **UCDVA** = uncorrected distance visual acuity.

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