

## Living FRIendly Summaries of the Body of Evidence using Epistemonikos (FRISBEE)

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# Is device-modified trabeculectomy better than classic surgery for treatment of glaucoma?

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## Abstract

Several techniques have emerged as complement or replacement for trabeculectomy, the standard surgery for glaucoma. Device-modified trabeculectomy is a recently developed technique whose results compared to the classical technique have not been fully defined. To answer this question, we used Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others. We identified eight systematic reviews including 34 studies overall. We extracted data from the systematic reviews, reanalyzed data of primary studies, conducted a meta-analysis and generated a summary of findings table using the GRADE approach. We concluded device-modified trabeculectomy probably leads to greater overall success rate and may decrease intraocular pressure more than classical surgery. In addition, this technique would probably have a better safety profile than standard trabeculectomy.

### Problem

Glaucoma is the second leading cause of blindness worldwide according to the World Health Organization. Among the known risk factors for the development of this disease is the increase in intraocular pressure (IOP). Trabeculectomy is the standard surgery for patients with uncontrolled glaucoma despite medical treatment. The use of devices has been recently added to the classical surgical technique, in order to promote the flow of aqueous humor from the anterior chamber and to avoid the post-trabeculectomy scarring by maintaining a continuous drainage of aqueous humor. In this line, the use of devices has been proposed as a technique that could improve surgical success and decrease the associated complication rate.

### Methods

To answer the question, we used Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others, to identify systematic reviews and their included primary studies. We extracted data from the identified reviews and reanalyzed data from primary studies included in those reviews. With this information, we generated a structured summary using a pre-established format, which includes key messages, a summary of the body of evidence (presented as an evidence matrix in Epistemonikos), meta-analysis of the total of studies, a summary of findings table following the GRADE approach and a table of other considerations for decision-making.

#### Key messages

- Device-modified trabeculectomy probably leads to greater overall success and decrease in intraocular pressure than standard surgery.
- Regarding to the safety of the technique, device-modified trabeculectomy probably decreases hypotonia and cataract surgery, and may decrease bleb leakage and narrow-chamber.
- It is not clear whether the technique reduces reintervention and hyphema.

## About the body of evidence for this question

<p>What is the evidence. See evidence matrix in Epistemonikos later</p>	<p>We found eight systematic reviews [1],[2],[3],[4],[5],[6],[7],[8] that include 48 primary studies reported in 54 references [9],[10],[11],[12],[13],[14],[15],[16],[17],[18],[19],[20],[21],[22],[23],[24],[25],[26],[27],[28],[29],[30],[31],[32],[33],[34],[35],[36],[37],[38],[39],[40],[41],[42],[43],[44],[45],[46],[47],[48],[49],[50],[51],[52],[53],[54],[55],[56],[57],[58],[59],[60],[61],[62].</p> <p>Thirty four correspond to randomized controlled trials, reported in 40 references [9],[10],[12],[13],[14],[15],[16],[18],[19],[20],[21],[22],[23],[25],[31],[32],[34],[36],[37],[38],[39],[42],[43],[44],[45],[46],[47],[48],[49],[50],[52],[53],[54],[56],[57],[58],[59],[60],[61],[62]. This table and this summary are based on the latter.</p>
<p>What types of patients were included*</p>	<p>The characteristics of included patients were:</p> <p>Regarding the type of glaucoma, 14 trials included patients with open angle glaucoma [12],[18],[19],[21],[25],[34],[38],[42],[43],[49],[50],[54],[56],[59], two trials included patients with angle-closure glaucoma [48],[61] and 13 trials included more than one type of glaucoma [13],[14],[15],[16],[32],[36],[37],[39],[45],[52],[57],[58],[60]. In five trials the type of glaucoma was not reported [10],[31],[44],[53],[62].</p> <p>Regarding the severity of glaucoma, 21 trials included patients with glaucoma refractory to medical treatment. [13],[14],[15],[16],[18],[19],[21],[32],[36],[37],[38],[39],[42],[43],[45],[49],[50],[52],[54],[56],[58] and one trial included patients with glaucoma refractory to surgical treatment [12]. In twelve trials the severity of glaucoma was not measured [10],[25],[31],[34],[44],[48],[53],[57],[59],[60],[61],[62].</p>
<p>What types of interventions were included*</p>	<p>Regarding the type of intervention, 18 trials used amniotic membrane [12],[13],[14],[25],[31],[32],[34],[36],[37],[48],[53],[54],[57],[58],[59],[60],[61],[62], nine trials used Ologen implants [16],[38],[39],[42],[44],[45],[49],[50],[52], five trials used ExPress mini glaucoma shunt [18],[19],[21],[43],[56], one trial used expanded polytetrafluoroethylene membrane implant (E-PTFE) [15], and one trial used absorbable gelatin film (Gelfilm) [10].</p> <p>Regarding the use of mitomycin C (MMC), 15 trials did not use MMC in any of their arms [13],[14],[19],[21],[25],[31],[32],[45],[48],[54],[57],[59],[60],[61],[62], 10 trials used MMC in both arms [10],[12],[15],[18],[36],[37],[43],[53],[56],[58] and nine trials used MMC only in the control arms (trabeculectomy + MMC) [16],[34],[38],[39],[42],[44],[49],[50],[52].</p> <p>All trials compared versus standard treatment (trabeculectomy).</p>
<p>What types of outcomes were measured</p>	<p>The systematic reviews grouped the outcomes as follows:</p> <ul style="list-style-type: none"> <li>• Post-operative intraocular pressure (IOP) in absolute numbers and percentage.</li> <li>• Drugs required during post-surgical care</li> <li>• Complete success (target IOP without associated medical treatment)</li> <li>• Qualified success (target IOP with associated medical treatment)</li> <li>• Adverse events (loss of visual acuity, hypotonia, re-intervention, hyphema, narrow chamber, bleb filtration, endophthalmitis, retinal detachment, corneal transplantation, need for cataract surgery, choroidal bleeding)</li> <li>• Improvement in visual acuity</li> <li>• Quality of life</li> <li>• Change in visual field</li> <li>• Cost/effectiveness</li> </ul>

\* The information about primary studies is extracted from the systematic reviews identified, unless otherwise specified.

## Summary of findings

The information on the effects of device-modified trabeculectomy is based on 34 randomized trials including 1540 eyes.

Twenty-five trials measured absolute decrease in intraocular pressure (1164 eyes) [13],[14],[15],[16],[18],[21],[25],[31],[32],[34],[36],[37],[39],[42],[45],[48],[52],[53],[56],[57],[58],[59],[60],[61],[62], three trials assessed complete success (151 eyes) [18],[21],[56], six trials measured the need for reintervention (258 eyes) [18],[21],[39],[45],[49],[56], 14 trials measured hypotonia (695 eyes) [15],[18],[21],[34],[37],[42],[43],[45],[48],[49],[50],[52],[56],[62], 10 trials measured blebfiltration (521 eyes) [14],[16],[18],[21],[43],[48],[50],[52],[56],[62], 23 trials measured narrow chamber (1199 eyes) [14],[15],[18],[21],[25],[31],[32],[34],[36],[39],[42],[43],[48],[49],[50],[52],[56],[57],[58],[59],[60],[61],[62], 16 trials measured hyphema (818 eyes) [13],[14],[15],[16],[18],[21],[39],[43],[45],[49],[50],[52],[53],[56],[58],[60] and 3 trials measured the need for cataract surgery (264 eyes) [21],[43],[56].

The summary of findings is as follows:

- Device-modified trabeculectomy may decrease intraocular pressure more than standard surgery. The certainty of the evidence is low
- Device-modified trabeculectomy probably achieves greater complete success than standard surgery. The certainty of the evidence is moderate.
- It is not clear whether device-modified trabeculectomy decreases reintervention, because the certainty of the evidence is very low.
- Device-modified trabeculectomy probably decreases hypotonia. The certainty of the evidence is moderate.
- Device-modified trabeculectomy may decrease *bleb* leakage. The certainty of the evidence is low.
- Device-modified trabeculectomy may decrease narrow chamber. The certainty of the evidence is low.
- It is not clear whether device-modified trabeculectomy reduces hyphema, because the certainty of the evidence is very low.
- Device-modified trabeculectomy is likely to decrease cataract surgery. The certainty of the evidence is moderate.

Device-modified trabeculectomy in glaucoma refractory to medical treatment				
<b>Patients</b>	Glaucoma refractory to medical treatment			
<b>Intervention</b>	Device-modified trabeculectomy			
<b>Comparison</b>	Trabeculectomy			
Outcomes	Absolute effect*		Relative effect (95% CI)	Certainty of the evidence (GRADE)
	WITHOUT device-modified trabeculectomy	WITH device-modified trabeculectomy		
	Difference: patients per 1000			
IOP (mmHg)	16.73	14.27	-	⊕⊕○○ <sup>1,2</sup> Low
	DM: 2.46 mmHg less (Margin of error: from 2.08 to 2.84 less)			
Complete success	595 per 1000	809 per 1000	RR 1.36 (1.1 a 1.69)	⊕⊕⊕○ <sup>1</sup> Moderate
	Difference: 214 more per 1000 (Margin of error: from 59 to 410 more)			
Reintervention	116 per 1000	83 per 1000	RR 0.71 (0.34 a 1.43)	⊕○○○ <sup>1,2,3</sup> Very low
	Difference: 33 less per 1000 (Margin of error: from 76 less to 50 more)			
Hypotonia	239 per 1000	165 per 1000	RR 0.69 (0.53 a 0.9)	⊕⊕⊕○ <sup>1</sup> Moderate
	Difference: 74 less per 1000 (Margin of error: from 112 to 24 less)			
Bleb leakage	123 per 1000	78 per 1000	RR 0.64 (0.38 a 1.07)	⊕⊕○○ <sup>1,4</sup> Low
	Difference: 45 less per 1000 (Margin of error: from 76 less to 9 more)			
Narrow chamber	192 per 1000	104 per 1000	RR 0.54 (0.41 a 0.71)	⊕⊕○○ <sup>1,4</sup> Low
	Difference: 88 less per 1000 (Margin of error: from 113 less to 56 more)			
Hyphema	102 per 1000	78 per 1000	RR 0.76 (0.5 a 1.15)	⊕○○○ <sup>1,2,4</sup> Very low
	Difference: 24 less per 1000 (Margin of error: from 51 less to 15 more)			
Cataract surgery	152 per 1000	48 per 1000	RR 0.32 (0.14 a 0.74)	⊕⊕⊕○ <sup>1</sup> Moderate
	Difference: 103 less per 1000 (Margin of error: from 130 less to 39 more)			

RR= Risk ratio.  
Margin of error = 95% confidence interval (CI).  
GRADE: evidence grades of the GRADE Working Group (see later in this article)

\* The risk **WITHOUT device-modified trabeculectomy** is based on the risk in the control group of the trials. The risk **WITH device-modified trabeculectomy** (and its margin of error) is calculated from relative effect (and its margin of error)

<sup>1</sup> The certainty of the evidence was downgraded by moderate risk of bias of included trials  
<sup>2</sup> The certainty of the evidence was downgraded for inconsistent results.  
<sup>3</sup> The certainty of the evidence was downgraded in two levels for imprecision.  
<sup>4</sup> The certainty of the evidence was downgraded for imprecision.

## About the certainty of the evidence (GRADE)\*

⊕⊕⊕⊕

**High:** This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

⊕⊕⊕○

**Moderate:** This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate

⊕⊕○○

**Low:** This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.

⊕○○○

**Very low:** This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

\*This concept is also called 'quality of the evidence' or 'confidence in effect estimates'.

† Substantially different = a large enough difference that it might affect a decision.

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## Other considerations for decision-making

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### To whom this evidence does and does not apply

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- The evidence presented in this summary applies to patients with glaucoma, mainly those with open angle type and refractory to medical treatment.
  - Most of the patients included in the trials were adults, so the pediatric population may not be well represented. Because of this, the evidence is not yet conclusive as to recommend the use of this technique in this population.
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### About the outcomes included in this summary

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- The outcomes of decreasing intraocular pressure and achieving complete success were chosen because they are critical for surgery outcome. In addition, events such as reintervention and complications of surgery were selected as safety parameters. This selection is based on the opinion of the authors of the summary, but generally agree with the outcomes reported in the systematic reviews.
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### Balance between benefits and risks, and certainty of the evidence

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- This new technique probably achieves greater overall success, associated with a likely decrease in complications, and may also be superior in other outcomes. However, it is important to keep in mind the limitations of existing evidence.
  - The incidence of complications reported in the control group (trabeculectomy) differs from what has been reported in other studies, so the benefit would be lower in absolute terms. For example, some studies [68],[69],[70] report an incidence of hyphema of 69 per 1000, bleb leakage of 20 per 1000, hypotonia of 9 per 1000 and narrow chamber of 130 per 1000, related to trabeculectomy surgery.
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### Resource considerations

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- Although the use of devices in trabeculectomy increases the costs, it achieves greater complete success and fewer complications, so the cost/benefit would favor device-modified trabeculectomy. These results have been studied in developed countries and are consistent with this conclusion [8]. However, in settings where this option is being considered it is reasonable to carry out a formal economic analysis.
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### What would patients and their doctors think about this intervention

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- Faced with the evidence presented in this summary most clinicians should lean in favor of this technique.
  - However, in resource-constrained settings, the decision may vary. The limited certainty of existing evidence may also be a factor leading to variations in decision making.
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### Differences between this summary and other sources

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- Most systematic reviews reached conclusions similar to the ones presented here. However, the reviews are generally cautious with respect to these results because of the limitations of the primary studies and their risk of bias. Among the systematic reviews evaluated, it is important to highlight the review by Wang (2015) [7], because it evaluates 33 of the 34 randomized trials used in this analysis.
  - No clinical guidelines were found making a recommendation about these techniques.
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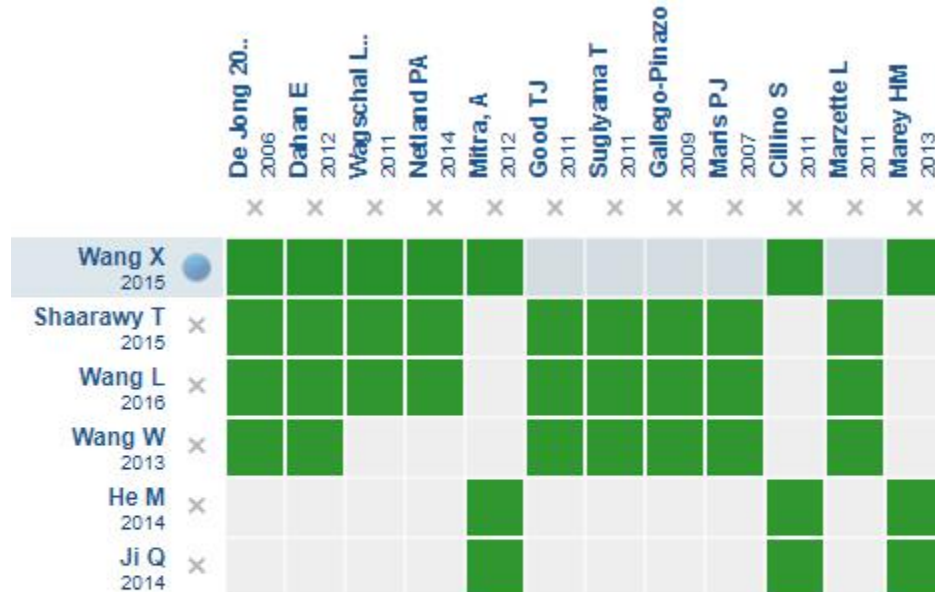
### Could this evidence change in the future?

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- The probability that future research changes the conclusions of this summary is high, particularly for outcomes where there is greater uncertainty.
  - There are at least three ongoing studies (two randomized trials [63],[64] and an observational study [65]) in the International Clinical Trials Registry Platform of the World Health Organization evaluating the use of device-modified trabeculectomy. In addition, there are at least two ongoing systematic reviews [66],[67] which could provide relevant information.
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## How we conducted this summary

Using automated and collaborative means, we compiled all the relevant evidence for the question of interest and we present it as a matrix of evidence.



Starting from any systematic review, Epistemonikos builds a matrix based on existing connections in the database.

The author of the matrix can select relevant information for a specific health question (typically in PICO format) in order to display the information set for the question.

The rows represent systematic reviews that share at least one primary study, and columns display the studies.

The boxes in green correspond to studies included in the respective reviews.

Follow the link to access the **interactive version**: [Device modified trabeculectomy in glaucoma](#)

## Notes

The upper portion of the matrix of evidence will display a warning of “new evidence” if new systematic reviews are published after the publication of this summary. Even though the project considers the periodical update of these summaries, users are invited to comment in *Medwave* or to contact the authors through email if they find new evidence and the summary should be updated earlier. After creating an account in Epistemonikos, users will be able to save the matrices and to receive automated notifications any time new evidence potentially relevant for the question appears.

The details about the methods used to produce these summaries are described here <http://dx.doi.org/10.5867/medwave.2014.06.5997>.

Epistemonikos foundation is a non-for-profit organization aiming to bring information closer to health decision-makers with technology. Its main development is Epistemonikos database ([www.epistemonikos.org](http://www.epistemonikos.org)).

These summaries follow a rigorous process of internal peer review.

### Conflicts of interest

The authors do not have relevant interests to declare.

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