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# Needling for encapsulated trabeculectomy filtering blebs (Review)

Feyi-Waboso A, Ejere HOD

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## [Intervention Review]

# Needling for encapsulated trabeculectomy filtering blebs

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# ABSTRACT

#### Background

Encapsulation of a filtering bleb following trabeculectomy may lead to elevation of intraocular pressure, prompting further medical or surgical intervention. It has been suggested that needling of an encapsulated bleb may be effective in re-establishing drainage and lowering intraocular pressure.

## Objectives

The objective of this review was to assess the effects of needling encapsulated blebs on intraocular pressure.

#### Search methods

We searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (*The Cochrane Library* 2012, Issue 1), MEDLINE (January 1950 to February 2012), EMBASE (January 1980 to February 2012), Latin American and Caribbean Literature on Health Sciences (LILACS) (January 1982 to February 2012), the *meta*Register of Controlled Trials (*m*RCT) (www.controlled-trials.com), ClinicalTrials.gov (www.clinicaltrials.gov) and the WHO International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/search/en). We did not use any date or language restrictions in the electronic searches for trials. The electronic databases were last searched on 14 February 2012.

#### **Selection criteria**

We included randomised and quasi-randomised in which bleb needling was compared with any form of antiglaucoma medication in people with encapsulated trabeculectomy blebs. The primary outcome was mean intraocular pressure measured in millimetres of mercury at day one, one week, one month and at last available follow-up.

#### Data collection and analysis

Two review authors independently assessed trial quality and extracted data. Study authors were contacted for additional information.

#### **Main results**

One trial, which randomised 25 eyes to either needling or medical treatment, met the inclusion criteria. At one day post-treatment, mean intraocular pressure was lower in the needling group (16.28 mmHg, standard deviation 5.9) than the medical group (19.45 mmHg, standard deviation 3.75). The difference was not statistically significant. At all other follow-up points, mean intraocular pressure was consistently higher in the needling group than the medical group, although the differences were not statistically significant. However, only one needled bleb remained successful at the end of follow-up compared to 10 out of the 11 blebs managed conservatively. This difference was statistically highly significant.



#### Authors' conclusions

Evidence from one small trial suggests that needling of encapsulated trabeculectomy blebs is not better than medical treatment in reducing intraocular pressure.

## PLAIN LANGUAGE SUMMARY

## Needling for encapsulated trabeculectomy filtering blebs

Trabeculectomy is an eye operation aimed at reducing intraocular pressure in people with glaucoma. A bleb usually forms at the site of operation, indicating aqueous drainage from the eyes. Trabeculectomy blebs can become encapsulated leading to poor drainage and high intraocular pressure. Some ophthalmologists needle encapsulated blebs in order to re-establish drainage and lower intraocular pressure. However, needling is invasive and can potentially be associated with higher risks of complications, such as anterior chamber collapse, infections, and cataract. This review included one trial conducted in Brazil which randomised 25 eyes. The trial compared needling using a 27-gauge needle to medical treatment with aqueous suppressants and digital massage. Outcome measures in the trial were mean intraocular pressure and successful intraocular pressure control (defined arbitrarily as IOP less than 20 mmHg). This review found no conclusive evidence that needling of encapsulated blebs results in better intra-ocular pressure control than antiglaucoma medication.



# BACKGROUND

## Introduction

Trabeculectomy (filtration surgery) is a surgical procedure that aims to reduce intraocular pressure (fluid pressure within the eye) (IOP) in people with glaucoma. This is achieved by creating a channel through which aqueous humour (fluid in the front of the eye) can drain out of the eye. A bleb (elevated conjunctiva) is formed at the site of surgery. This helps to regulate the amount of aqueous that drains from the eye and hence control the intraocular pressure. Aqueous leaving the eye in this way is gradually absorbed through the veins and lymphatics of the conjunctiva. Small amounts may pass directly into the tear film. The presence of a diffuse raised bleb with a reduction of IOP is regarded as indicative of adequate drainage and successful glaucoma surgery. Other signs of adequate drainage include microcysts.

Encapsulation of the filtering bleb may lead to elevation of IOP in the early postoperative period, prompting further medical or surgical intervention. Bleb encapsulation can occur in up to 13% of cases (Sherwood 1987). Encapsulated blebs have characteristic clinical features. They are often localised with an elevated or domeshaped appearance. The bleb has a thickened wall (Tenons cyst) often with dilated surface blood vessels and no microcysts. These features and a persistently raised IOP define an encapsulated bleb and distinguish it from a failed or scarred bleb.

Signs of a failed bleb include a flat and injected conjunctiva often with subconjunctival fibrosis sometimes with thin walled cystic spaces. The IOP remains consistently elevated. Failure of the bleb by scarring usually occurs later although in one retrospective study, most blebs if they are going to fail will do so in the first 18 months (Lavin 1990). This review concerns the needling of encapsulated blebs only.

## **Treatment options**

The management of bleb encapsulation associated with elevated intraocular pressure is controversial. Bleb obstruction from encapsulation has been described as a transient phase requiring medical treatment to control IOP (Scott 1988). Others advocate digital massage associated with medical treatment as the initial management (Sherwood 1987; Van-Buskirk 1982). It has been suggested that needling of an encapsulated bleb (a form of surgical intervention) may be effective in re-establishing drainage and lowering IOP (Greenfield 1996). It has also been reported that the use of antimetabolites at the time of needling could improve results (Ewing 1990; Mardelli 1996; Shin 1993).

Bleb needling may be performed as an outpatient slit-lamp procedure or may be done in the operating theatre. It is essential to perform a gonioscopic examination before initial bleb needling to exclude mechanical blockage of the artificial channel of the trabeculectomy. The technique of bleb needling may vary slightly from surgeon to surgeon but basically involves introducing a 24 to 30 gauge needle under the conjunctiva about 10 mm from the assumed site of aqueous obstruction. Some surgeons advance the needle under the sclera flap and make sweeping motions of the needle tip to break down adhesions or remove obstructions at the drainage site until a raised conjunctiva bleb is formed. This procedure may be repeated, or followed by the injection of antimetabolites to reduce healing and scarring around the bleb site.

### **Rationale for a systematic review**

Successful needling of failed blebs makes it unnecessary to recommence patients on antiglaucoma medication. While bleb needling may re-establish drainage of aqueous, it is relatively invasive compared to medical treatment and may lead to complications such as over-drainage and anterior chamber collapse (collapse of the front of the eye). Other complications may include infection, cataract formation or progression. Despite these potential complications and disputed benefit, bleb needling is commonly performed.

#### OBJECTIVES

The objective of this review was to assess the effects of needling encapsulated blebs on intraocular pressure.

#### METHODS

#### Criteria for considering studies for this review

#### **Types of studies**

We included randomised and quasi-randomised controlled trials.

#### **Types of participants**

Participants in the trials were people with encapsulated trabeculectomy blebs.

#### **Types of interventions**

We included trials in which bleb needling was compared to any form of antiglaucoma medication.

## Types of outcome measures

#### **Primary outcomes**

The primary outcome for the review was:

(1) mean intraocular pressure (IOP) measured in millimetres of mercury at day one, one week, one month and at last available follow-up.

#### Secondary outcomes

Secondary outcomes were:

(2) proportion of participants with loss of at least two lines of bestcorrected visual acuity measured on the Snellen chart. Where visual acuity was measured in formats other than Snellen visual acuity, we converted to Snellen format;

(3) number of antiglaucoma medications;

(4) number of participants requiring repeat needling;

(5) number of participants requiring repeat trabeculectomy;

(6) proportion of participants presenting with any adverse event within one month of the intervention (subconjunctival haemorrhage; persistent conjunctival leak; flat anterior chamber; hypotony; new cataract or progression of pre-existing cataract; endophthalmitis; or choroidal detachment).



## Search methods for identification of studies

#### Electronic searches

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) 2012, Issue 1, part of *The Cochrane Library*. www.thecochranelibrary.com (accessed 14 February 2012), MEDLINE (January 1950 to February 2012), EMBASE (January 1980 to February 2012), Latin American and Caribbean Health Sciences (LILACS) (January 1982 to February 2012), the *meta*Register of Controlled Trials (*m*RCT) (www.controlledtrials.com), ClinicalTrials.gov (www.clinicaltrials.gov) and the WHO International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/search/en). We did not use any date or language restrictions in the electronic searches for trials. The electronic databases were last searched on 14 February 2012.

See: Appendices for details of search strategies for CENTRAL (Appendix 1), MEDLINE (Appendix 2), EMBASE (Appendix 3), LILACS (Appendix 4), *m*RCT (Appendix 5), ClinicalTrials.gov (Appendix 6) and the ICTRP (Appendix 7).

#### Searching other resources

The reference list of the identified trial was searched to identify additional trials.

## Data collection and analysis

#### **Selection of studies**

Two review authors independently reviewed the titles and abstracts resulting from the searches. Full copies of potentially relevant trials were obtained. All full copies were assessed according to the 'Criteria for considering studies for this review'. Only trials meeting these criteria were assessed for methodological quality. Disagreements were resolved by discussion.

#### Data extraction and management

Data were extracted by two review authors independently using a form developed by the Cochrane Eyes and Vision Group. Discrepancies were resolved by discussion. All data were entered into Review Manager (Review Manager 2011) by one review author and checked by the second author.

#### Assessment of risk of bias in included studies

In the original version of this review, we assessed trial quality for allocation concealment, completeness of follow-up and intentionto-treat analysis. When we next update this review, we will assess trial quality according to The Cochrane Collaboration's risk of bias tool set out in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We contacted investigators of trials for clarification of any parameter graded as unclear. Masking of participants and providers and masking of outcome assessment were considered to be impractical or impossible since the comparisons involved a surgical procedure and medical treatment. We therefore did not use masking as a parameter of quality in this review.

### **Data synthesis**

We planned to calculate relative risks for outcome measures reported as dichotomous data and weighted mean difference for outcome measures reported as continuous data. We planned to combine individual study results in a meta-analysis if there were more than one trial. A fixed-effect model was to be used if there were fewer than three trials or a random-effects model if there were more than three trials to compare. If trials were not similar enough to be combined statistically, we planned to present the results of the trials in a tabular format.

# RESULTS

#### **Description of studies**

### **Results of the search**

The initial electronic searches revealed 596 reports of trials. We identified only one randomised controlled trial that met the inclusion criteria for the review (Costa 1997). An updated search was conducted in September 2006 which identified 24 new reports of trials but no trials met the inclusion criteria.

A further update search was done in September 2008 identifying 103 reports of trials, however, none were eligible for inclusion in the review.

Update searches were run in February 2012 which yielded a further 245 references. The Trials Search Co-ordinator scanned the search results and removed 207 references which were not relevant to the scope of the review. We screened the remaining 38 references and found one report of a study on the WHO International Clinical Trials Registry Platform (ChiCTR-TRC-09000647). We are unable to assess the study for potential inclusion in the review as the trial record contains insufficient information. We have contacted the lead investigator to ask for further information on the trial. We have not received a response but we will assess this study for potential inclusion in the review available.

#### **Included studies**

We included one trial that met our inclusion criteria (Costa 1997).

#### **Types of participants**

The trial recruited 25 eyes with encapsulated blebs from 282 eyes that had undergone filtering surgery. Bleb encapsulation was defined in the trial as a localised dome-shaped bleb, with prominent surface vessels, absence of conjunctiva microcysts, a patent sclerostomy on gonioscopy associated with an intraocular pressure (IOP) higher than 22 mm mercury (mmHg).

#### **Types of interventions**

The trial randomised eyes to either needling or medical treatment with aqueous suppressants and digital massage. Needling was carried out under local anaesthesia using a 27-gauge needle. Medical treatment was introduced if needling failed to control IOP below 20 mmHg. If this failed, surgical revision or further glaucoma surgery was performed. This was compared with medical treatment consisting of digital massage and non-specific betablockers, with or without systemic carbonic anhydrase inhibitor.

#### Types of outcome measures

Outcome measures were mean IOP and successful IOP control (defined arbitrarily as IOP less than 20 mmHg). Failure of IOP control was defined as equal to or greater than 20 mmHg or when further surgery was indicated. Other outcomes included visual acuity change of two or more Snellen acuity lines and mean number of antiglaucoma medications. Outcomes were reported at one day,

one week, one month, three months, six months and last available follow-up.

## **Risk of bias in included studies**

Randomisation was carried out using a randomisation table. Concealment of allocation was unclear. Analysis was not performed according to intention to treat principle. One eye was lost to followup at three months and four eyes at six months. It was not stated which of the groups these eyes belonged to. We have contacted the investigators to clarify these points.

## **Effects of interventions**

## Intraocular pressure

At one day post-treatment, the mean intraocular pressure (IOP) in the needling group was 16.28 mmHg (standard deviation (SD) 5.91) compared to 19.45 (SD 3.75) in the medical group. The difference was not statistically significant (P = 0.132). At one week, the mean IOP in the needling group was 24.00 (SD 7.74) compared to 20.00 (SD 5.57). The difference was not statistically significant (P = 0.175). At last follow-up, mean IOP remained higher in the needling group (18.92, SD 6.39) compared to the medical group (16.09, SD 6.92). However, the difference was not statistically significant (P = 0.299). Details of mean IOP at all follow-up intervals are shown in Table 1.

When this outcome was reported as the proportion of eyes achieving an IOP less than 20 mmHg (defined as indicating a successful control), needling resulted in a success rate of 7.1% (1/14 eyes) compared to 90.9% (10/11 eyes) in the medical group. This difference was highly statistically significant (P = 0.00003). It is unclear from the trial at what point in the follow-up this outcome was observed.

## **Visual acuity loss**

There was no significant difference in visual acuity loss in the needling group (14.3%, 2/14 eyes) compared to medical treatment (18.2%, 2/11 eyes) at last follow-up (P = 1.000). It is unclear at what point in follow-up visual acuity loss occurred. Lens opacification was reported as the sole reason in all cases.

## Number of antiglaucoma medications

There was no significant difference in the mean number of antiglaucoma medications between the needling group and the medical group at one week (0.71, SD 0.72 versus 1.10, SD 0.31); one month (1.57, SD 0.51 versus 1.50, SD 0.52); and at last available follow-up (1.85, SD 0.36 versus 1.81, SD 0.40).

## **Repeat needling**

No eyes in the needling group underwent repeat needling.

## **Repeat trabeculectomy**

In the needling group 3/14 eyes required repeat trabeculectomy compared to 1/11 eyes in the medical treatment group. Two eyes in the needling group required bleb revision.

## Adverse event within one month of intervention

Apart from visual acuity loss already described above, no other adverse event was reported in the trial.

## DISCUSSION

## Intraocular pressure

The single trial in this study did not show a significant difference in the mean intraocular pressure (IOP) between the needling and medical groups at any follow-up interval. With the exception of day one, mean IOP was higher at all follow-up times in the needling group.

Although successful IOP control was not documented as an outcome in our protocol, we note that this outcome was reported in the trial included in this review. It is interesting that medical treatment resulted in a significantly higher success rate than needling given the fact that the difference in mean IOPs between the groups were not statistically significant at any intervals in the follow-up. The definition of success in this trial as IOP less than 20 mmHg could account for this paradox. For example, an eye with an IOP of 19 mmHg in the medical group would be regarded as achieving successful IOP control, whereas an eye with an IOP of 20 mmHg in the needling group would be regarded as unsuccessful, even though the difference between the two pressures is small and not statistically significant. Furthermore, eyes in the medical group also received a massage and this may have contributed to the higher 'success rate'. The effectiveness of massage in reducing IOP has not been quantified.

## Mean number of antiglaucoma medications

There was no statistically significant difference in the mean number of antiglaucoma drugs between the needling and medical groups. Again, this is surprising given the fact that the number of eyes in the needling group achieved significantly lower success rates compared to the medical group, and thus a higher mean number of additional antiglaucoma medications would be expected in the needling group. We have no explanation for this finding other than that due to the arbitrary definition of success in this trial as described above.

# Visual acuity loss and adverse effects

The cataractogenic effect generally believed to be associated with invasive eye procedures has not been demonstrated in this trial. There was no statistically significant difference in visual loss due to cataract between the needling and medical groups. Other potential adverse effects such as endophthalmitis, bleb leaks or shallow anterior chambers that can occur following needling were not reported in the trial. A larger sample size would have been needed to confirm the apparent safety of this procedure. No report is provided of patient perspective, particularly regarding discomfort of needling or intolerance of topical medication.

Although the trial in this review suggests a poor effect of bleb needling compared to antiglaucoma medication, doubt remains as to whether the trial had enough power to detect a significant effect given the small number of eyes randomised. Power calculations were not reported in the trial and attempts to contact the authors were unsuccessful. Scott 1988 suggests the beneficial effects of medical management of encysted blebs. In a retrospective review of 181 eyes, 18 developed encysted blebs and were managed without needling. His argument that this was a high bleb phase best managed by medical treatment would seem to support the findings of this trial. Richter 1988, however, observed in his series that 15 of 56 eyes (26.8%) with encapsulated blebs ultimately required

surgical revision because maximally tolerated medical therapy was insufficient to control IOP.

Anecdotal evidence of the apparent usefulness of bleb needling may be due to the concomitant use of antimetabolites during and after needling. This may improve IOP control as some reports have suggested (Shin 1993). Other studies report the need to repeatedly needle encapsulated blebs to achieve a satisfactory IOP control. Variation in technique of needling may also influence IOP control. The use of larger needles for needling and the technique of subscleral flap needling can affect IOP outcomes. Variable success rates have been reported for needling of blebs that have failed for reasons other than encapsulation although there are no reported randomised controlled studies in this group.

This review was limited by the fact that only one trial was included. A meta-analysis of several good quality randomised controlled trials would have allowed for a more precise and meaningful estimate of the effect of needling of encapsulated blebs.

## AUTHORS' CONCLUSIONS

## Implications for practice

The single trial in this review suggests that a single needling procedure of encapsulated blebs offers no better intraocular pressure control than medical management. Clinicians must weigh up the potential risk to benefit ratio when deciding to needle encapsulated blebs.

#### Implications for research

Despite the lack of evidence for the effect of bleb needling the procedure is commonly performed. Best available evidence is limited to the outcome from a single randomised trial. There is a need for more randomised controlled trials to validate the findings of this single trial and provide more information on the role and safety of needling in the management of encapsulated blebs. The adjuvant use of antimetabolite with needling requires examination. The role of digital massage in bleb remodelling needs further evaluation.

# ACKNOWLEDGEMENTS

Richard Wormald conceived the idea for this review. We are grateful to Mark Wilkins for peer review comments on this review. The electronic searches were prepared and executed by the Cochrane Eyes and Vision Group editorial team.

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## REFERENCES

#### References to studies included in this review

Costa 1997 {published data only}

Costa VP, Arcieri E, Freitas TG. Long-term intraocular pressure control of eyes that developed encapsulated blebs following trabeculectomy. *Eye* 2006;**20**(3):304-8.

Costa VP, Correa MM, Kara-Jose N. Needling versus medical treatment in encapsulated blebs. A randomized, prospective study. *Ophthalmology* 1997;**104**(8):1215-20.

#### **References to studies awaiting assessment**

## ChiCTR-TRC-09000647 {published data only}

ChiCTR-TRC-09000647. A randomised controlled trial to compare the clinical outcomes of needle revision of trabeculectomy bleb vs repeat trabeculectomy in managing failed trabeculectomy. www.chictr.org/en/proj/show.aspx? proj=753 (accessed 1 June 12).

## **Additional references**

#### Ewing 1990

Ewing RH, Stamper RL. Needle revision with and without 5fluorouracil for the treatment of failed filtering blebs. *American Journal of Ophthalmology* 1990;**110**(3):254-9.

#### Glanville 2006

Glanville JM, Lefebvre C, Miles JN, Camosso-Stefinovic J. How to identify randomized controlled trials in MEDLINE: ten years on. *Journal of the Medical Library Association* 2006;**94**(2):130-6.

#### Greenfield 1996

Greenfield DS, Miller MP, Suner IJ, Palmberg PF. Needle elevation of the scleral flap for failing filtration blebs after trabeculectomy with mitomycin C. *American Journal of Ophthalmology* 1996;**122**(2):195-204.

#### Higgins 2011

Higgins JPT, Altman DG, Sterne JAC (editors). Chapter 8: Assessing risk of bias in included studies. In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from www.cochranehandbook.org.

## CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

#### Costa 1997

Lavin 19	<b>39</b> 0

Lavin MT, Wormald RP, Migdal CS, Hitchings RA. The influence of prior therapy on the success of trabeculectomy. *Archives of Ophthalmology* 1990;**108**(11):1543-8.

#### Mardelli 1996

Mardelli PG, Lederer CM, Murray PL, Pastor SA, Hassanein KM. Slit-lamp needle revision of failed filtering blebs using mitomycin C. *Ophthalmology* 1996;**103**(11):1946-55.

#### Review Manager 2011 [Computer program]

The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). Version 5.1. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011.

#### Richter 1988

Richter CU, Shingleton BJ, Bellows AR, Hutchinson BT, O'Connor T, Brill I. The development of encapsulated filtering blebs. *Ophthalomology* 1988;**95**(9):1163-8.

#### Scott 1988

Scott DR, Quigley HA. Medical management of a high bleb phase after trabeculectomies. *Ophthalmology* 1988;**95**(9):1169-73.

## Sherwood 1987

Sherwood MB, Spaeth GL, Simmons ST, Nichols DA, Walsh AM, Steinmann WC, et al. Cysts of Tenon's capsule following filtration surgery. Medical management. *Archives of Ophthalmology* 1987;**105**(11):1517-21.

## Shin 1993

Shin DH, Juzych MS, Khatana AK, Swendris RP, Parrow KA. Needling revision of failed filtering blebs with adjunctive 5fluorouracil. *Ophthalmic Surgery* 1993;**24**(4):242-8.

#### Van-Buskirk 1982

Van-Buskirk EM. Cysts of Tenon's capsule following filtration surgery. *American Journal of Ophthalmology* 1982;**94**(4):522-7.

#### References to other published versions of this review

## Feyi-Waboso 2004

Feyi-Waboso A, Ejere HOD. Needling for encapsulated trabeculectomy filtering blebs. *Cochrane Database of Systematic Reviews* 2004, Issue 1. [DOI: 10.1002/14651858.CD003658.pub2]

Methods	Random allocation using randomisation table Mean follow up for both groups 9.6 months Outcome assessors not masked	
Participants	25 eyes with encapsulated blebs	



Costa 1997 (Continued)	Male or female Mean age: needling group 59.71 years (SD 10.8); medical group 57 years (SD 16.36) Setting: Brazil		
Interventions	Intervention: Bleb needling using a 27 gauge needle Control: Medical treatment consisting of digital massage and non-selective beta-blocker drops as first choice with or without systemic carbonic anhydrase inhibitor. Dose of treatment not specified.		
Outcomes	Mean intraocular pressure (IOP) Failure of IOP control (equal to or greater than 20 mmHg) Visual outcome Number of antiglaucoma medications		
Notes	Instrument for IOP measurement not stated		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence genera- tion (selection bias)	Low risk	Randomisation table used	
Allocation concealment (selection bias)	Unclear risk	Not reported	

# Characteristics of studies awaiting assessment [ordered by study ID]

## ChiCTR-TRC-09000647

Methods	Randomised, parallel groups	
Participants		
Interventions	Needle revision of trabeculectomy bleb versus repeat trabeculectomy	
Outcomes Primary outcomes		
	IOP reduction in intraocular pressure by 2 criteria (< 22 mmHg or > 30% reduction)	
	Number of IOP-lowering medications	
	Secondary outcomes	
	Complications of treatment	
	Progression of disc changes and/or visual field loss	
	Need of subsequent surgical intervention	

Notes

# ADDITIONAL TABLES



## Table 1. Mean intraocular pressures (mm Hg) with standard deviations

Follow-up intervals	Needling (SD)	Medical (SD)	P (student's t test)
Baseline (n=25)	28.14 (4.01) n=11	25.72 (5.23) n=14	0.201
1 day (n=25)	16.28 (5.91) n=11	19.45 (3.75) n=14	0.132
1 week (n=25)	24.00 (7.74) n=11	20.00 (5.57) n=14	0.175
1 month (n=25)	20.64 (5.31) n=11	19.60 (6.39) n=14	0.670
3 months (n=24)	17.35 (4.03) n=?	17.60 (3.40) n=?	0.872
6 months (n=21)	18.00 (6.39) n=?	14.66 (4.84) n=?	0.205
Last follow-up (n=25)	18.92 (6.39) n=11	16.09 (6.92) n=14	0.299

## APPENDICES

## **Appendix 1. CENTRAL search strategy**

#1 MeSH descriptor Glaucoma
#2 MeSH descriptor Filtering Surgery
#3 MeSH descriptor Intraocular Pressure
#4 glaucom\* or filter\* or filtrat\* or drain\*
#5 IOP or trabeculectom\*
#6 ((intraocular or intra-ocular) near pressure\*)
#7 (#1 OR #2 OR #3 OR #4 OR #5 OR #6)
#8 MeSH descriptor Blister
#9 bleb\*
#10 (#8 OR #9)
#11(#7 AND #10)

## Appendix 2. MEDLINE (OVID) search strategy

1 randomized controlled trial.pt. 2 (randomized or randomised).ab,ti. 3 placebo.ab,ti. 4 dt.fs. 5 randomly.ab,ti. 6 trial.ab,ti. 7 groups.ab,ti. 8 r/1-7 9 exp animals/ 10 exp humans/ 119 not (9 and 10) 12 8 not 11 13 exp glaucoma/ 14 exp filtering surgery/ 15 exp trabecular meshwork/ 16 (glaucom\$ or filter\$ or filtrat\$ or drain\$).tw. 17 (intra?ocular adj3 pressure\$).tw. 18 IOP.tw. 19 trabeculectom\$.tw. 20 or/13-19 21exp blister/



22 bleb\$.tw. 23 or/21-22 24 20 and 23 25 12 and 24

The search filter for trials at the beginning of the MEDLINE strategy is from the published paper by Glanville et al (Glanville 2006).

# Appendix 3. EMBASE (OVID) search strategy

1 exp randomized controlled trial/ 2 exp randomization/ 3 exp double blind procedure/ 4 exp single blind procedure/ 5 random\$.tw. 6 or/1-5 7 (animal or animal experiment).sh. 8 human.sh. 97 and 8 10 7 not 9 116 not 10 12 exp clinical trial/ 13 (clin\$ adj3 trial\$).tw. 14 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj3 (blind\$ or mask\$)).tw. 15 exp placebo/ 16 placebo\$.tw. 17 random\$.tw. 18 exp experimental design/ 19 exp crossover procedure/ 20 exp control group/ 21exp latin square design/ 22 or/12-21 23 22 not 10 24 23 not 11 25 exp comparative study/ 26 exp evaluation/ 27 exp prospective study/ 28 (control\$ or prospectiv\$ or volunteer\$).tw. 29 or/25-28 30 29 not 10 31 30 not (11 or 23) 32 11 or 24 or 31 33 exp glaucoma surgery/ 34 exp intraocular pressure/ 35 (glaucom\$ or filter\$ or filtrat\$ or drain\$).tw. 36 (intra?ocular adj3 pressure\$).tw. 37 IOP.tw. 38 trabeculectom\$.tw. 39 or/33-38 40 exp blister/ 41 bleb\$.tw. 42 or/40-41 43 38 and 42 44 32 and 43

# Appendix 4. LILACS search strategy

glaucom\$ OR intraocular pressure OR trabeculectom\$ AND bleb\$

# Appendix 5. metaRegister of Controlled Trials search strategy

trabeculetomy and bleb

# Appendix 6. ClinicalTrials.gov search strategy

Trabeculectomy AND Bleb

# Appendix 7. ICTRP search strategy

Trabeculectomy AND Bleb

# WHAT'S NEW

Date	Event	Description
12 June 2012	New search has been performed	Issue 8, 2012: Electronic searches were updated.
12 June 2012 New citation required but conclusions have not changed		Issue 8, 2012: One potential new trial was identified but further information is needed before it can be included/excluded.

# HISTORY

Protocol first published: Issue 2, 2002 Review first published: Issue 2, 2004

Date	Event	Description
23 April 2009	New search has been performed	Issue 3, 3009: updated searches yielded no new trials to include in review.
21 August 2008	Amended	Converted to new review format.
19 September 2003	New citation required and conclusions have changed	Substantive amendment

# CONTRIBUTIONS OF AUTHORS

Data collection for the review: AFW, HE Screening search results: AFW, HE Screening retrieved papers against inclusion criteria Appraising quality of papers: AFW, HE Abstracting data from papers: AFW, HE Writing to authors of papers for additional information Data management for the review Entering data into RevMan: AFW, HE Analysis of data: AFW, HE Writing the review: AFW, HE

# DECLARATIONS OF INTEREST

None known.

# SOURCES OF SUPPORT

## **Internal sources**

• Royal Gwent NHS Trust, UK.



## **External sources**

• No sources of support supplied

# INDEX TERMS

# Medical Subject Headings (MeSH)

Blister [\*therapy]; Filtering Surgery; Glaucoma [drug therapy] [\*surgery]; Intraocular Pressure; Needles; Paracentesis [\*methods]; Randomized Controlled Trials as Topic; Trabeculectomy [\*adverse effects] [methods]

## **MeSH check words**

Humans