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[Intervention Review]

Types of materials for frontalis sling surgery for congenital ptosis

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ABSTRACT

Background

Congenital ptosis is a drooping of one or both eyelids at birth, often due to poor development of the levator palpebrae superioris muscle. This can result in amblyopia, astigmatism, and ocular torticollis and therefore may necessitate surgical intervention in early childhood if visual development is compromised. Patients may have varied levels of levator function. Those with moderate to good function may elect to first attempt ptosis repair with external levator advancement or mullerectomy/Fasanella–Servat procedures. For those with poor function, those procedures are less likely to be effective, so they may undergo frontalis sling surgery, in which the tarsal plate is coupled to the frontalis muscle, so that movement of the brow and forehead result in movement of the eyelid. The optimal material to use in this surgery is unknown.

Objectives

To evaluate the comparative effectiveness and safety of various materials used in frontalis sling surgery for congenital ptosis.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (which contains the Cochrane Eyes and Vision Trials Register) (June 2018), Ovid MEDLINE, Ovid MEDLINE E-pub Ahead of Print, Ovid Medline In-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily (January 1946 to 20 June 2018), Embase (January 1947 to 20 June 2018), PubMed (1948 to 20 June 2018), Latin American and Caribbean Health Sciences Literature Database (LILACS) (1982 to 20 June 2018), ClinicalTrials.gov (www.clinicaltrials.gov) and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictpr/search/en). We did not use any date or language restrictions in the electronic search for trials. We last searched the electronic databases on 20 June 2018.

Selection criteria

We included randomized trials that compared one material to another for the treatment of congenital ptosis.

Data collection and analysis

Two review authors independently completed eligibility screening, data abstraction, 'Risk of bias' assessment, and grading of the evidence.

Main results

We identified three randomized trials that had compared four different materials, two materials in each trial. The studies included a total of 160 participants. The surgical procedures compared were polytetrafluoroethylene (Gore-Tex), Ethibond suture, Mersilene mesh, and autogenous fascia lata.

We judged all studies to be at unclear risk of bias due to incomplete reporting of methods and other methodological deficiencies.

Because the three included studies compared different types of implants, we were unable to combine data in a meta-analysis. The limited data preclude any conclusion regarding the optimal implant for frontalis sling surgery.

In terms of the primary outcome of functional success, this was defined as widening of the opening between eyelids, assessed either by grade or by millimeter measurement. Bajaj 2004 showed that 93% of the Gore-Tex group and 83% of the Ethibond group had a good or satisfactory outcome (as defined by investigators). Elsamkary 2016 reported that 78.1% of the autogenous fascia group and 61.8% of the Gore-Tex group had a very good or good outcome. Salour 2008 did not include this type of grading system; they showed that the lid fissure increased $4.0 \text{ mm} \pm 1.46 \text{ mm}$ in the Mersilene group and $3.13 \text{ mm} \pm 1.72 \text{ mm}$ in the fascia lata group.

In terms of adverse events, Bajaj 2004, which included 15 patients per group, showed no recurrence in the Gore-Tex group and 1 in the Ethibond group; no need for removal in the Gore-Tex group and 1 in the Ethibond group; and no infections in the Gore-Tex group and 1 in the Ethibond group. Elsamkary 2016, which included 55 patients per group, had 3 recurrences in the fascia group and 6 in the Gore-Tex group; no need for removal in either group; and 1 infection in the fascia group and 2 in the Gore-Tex group. Salour 2008, which included 10 patients per group, had no recurrence, removals, or infections in either the Mersilene or the fascia group.

Authors' conclusions

The three trials included in this review evaluated four materials for frontalis sling surgery. Assessment of these three studies does not allow us to identify the optimal material. Future randomized trials should be rigorously designed so as to identify the best treatment for this condition.

PLAIN LANGUAGE SUMMARY

Types of materials for frontalis sling surgery for congenital ptosis

What was the aim of this review?

In frontalis sling surgery, the eyelid is connected to the eyebrow under the skin using a variety of materials. This is typically done for congenital ptosis, where the muscle that should open the eye did not develop well. The aim of this Cochrane Review was to find out whether different types of materials used for frontalis sling surgery for congenital ptosis led to different outcomes. Most importantly, we wanted to investigate what materials have the highest success rates.

Key messages

We are unsure which type of material has the highest success rate. There were three included trials, that had examined four different materials. None of the trials examined the same materials as another trial, so the results had to be considered individually. The three trials were small, and because they all compared different materials, there is no way to decide which material is the most successful in treating congenital ptosis.

What did we study in this review?

Congenital ptosis, where one or both eyelids droop at birth, is often caused by poor development of the muscles used to lift the eyelids. Frontalis sling surgery is the most effective surgical treatment. Many materials have been used or are still used in this surgery. The purpose of this review was to look at the 'functional success' rates (defined as widening of the opening between eyelids) of the different materials used in frontalis sling surgery.

What were the main results of this review?

We included three randomized controlled trials which compared frontalis sling materials. Among the three trials, four included materials were evaluated: Gore-Tex, Ethibond suture, Mersilene mesh, and autogenous fascia lata. Two trials included both eyes from the same participant, while the other trial included people with ptosis in one or both eyes. Data from the three studies could not be combined because the materials were different. It remains unclear which type of frontalis sling material has the highest success rate.

How up to date is the review?

We searched for studies that have been published up to 20 June 2018.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Gore-Tex compared to Ethibond for congenital ptosis for frontalis sling surgery for congenital ptosis

Gore-Tex compared to Ethibond for frontalis sling surgery for congenital ptosis

Patient or population: frontalis sling surgery for congenital ptosis

Setting: 1 centre, India

Intervention: Gore-Tex

Comparison: Ethibond for congenital ptosis

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with Ethibond for congenital ptosis	Risk with Gore-Tex				
Functional success of the surgery	833 per 1000	933 per 1000 (775 to 1000)	RR 1.12 (0.93 to 1.35)	60 (1 RCT)	⊕⊕⊕⊕ LOW ^{1 2}	Functional success defined as "good" or "satisfactory" degree of ptosis correction achieved
Recurrence after surgery	33 per 1000	11 per 1000 (0 to 221)	RR 0.33 (0.01 to 6.64)	60 (1 RCT)	⊕⊕⊕⊕ LOW ^{1 2}	
Sling removal	67 per 1000	13 per 1000 (1 to 225)	RR 0.20 (0.01 to 3.37)	60 (1 RCT)	⊕⊕⊕⊕ LOW ^{1 2}	
Infection	67 per 1000	67 per 1000 (9 to 352)	RR 1.00 (0.14 to 5.28)	60 (1 RCT)	⊕⊕⊕⊕ LOW ^{1 2}	
Ocular and systemic complications	Two eyelids developed granulomas in each group. There were no patients in either group with extrusion of the sling material, entropion, or wound dehiscence.		-	60 (1 RCT)	⊕⊕⊕⊕ LOW ^{1 2}	
Economic outcomes - not measured	-	-	-	-	-	Economic outcomes were not studied
Quality of life - not measured	-	-	-	-	-	Quality of life measures were not studied

*The risk in the intervention group (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).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio;

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect

Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

¹ High risk of bias (blinding of outcome assessment)

² Imprecision (wide confidence interval around estimate; small sample size)

Summary of findings 2. Autogenous fascia compared to Gore-Tex for congenital ptosis for frontalis sling surgery for congenital ptosis

Autogenous fascia compared to Gore-Tex for frontalis sling surgery for congenital ptosis

Patient or population: frontalis sling surgery for congenital ptosis

Setting: 1 centre, Egypt

Intervention: autogenous fascia

Comparison: Gore-Tex for congenital ptosis

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with Gore-Tex for congenital ptosis	Risk with autogenous fascia				
Functional success	618 per 1000	488 per 1000 (383 to 631)	RR 0.79 (0.62 to 1.02)	110 (1 RCT)	⊕⊕⊕⊖ LOW ^{1 2}	Functional success defined as "very good" or "good" by the study investigator
Recurrence after surgery	109 per 1000	54 per 1000 (13 to 196)	RR 0.50 (0.12 to 1.80)	110 (1 RCT)	⊕⊕⊕⊖ LOW ^{1 2 3}	
Sling removal	Zero patients in either group required sling removal.		-	110 (1 RCT)	⊕⊕⊕⊖ LOW ^{1 2}	
Infection	36 per 1000	18 per 1000 (2 to 174)	RR 0.50 (0.04 to 4.78)	110 (1 RCT)	⊕⊕⊕⊖ LOW ^{1 2}	
Ocular and systemic complications	127 per 1000	55 per 1000 (14 to 191)	RR 0.43 (0.11 to 1.50)	110 (1 RCT)	⊕⊕⊕⊖	

LOW^{1 2}

Economic outcomes - not measured	-	-	-	-	Economic outcomes were not studied
Quality of life - not measured	-	-	-	-	Quality of life measures were not studied

***The risk in the intervention group** (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).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio;

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Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

¹ High risk of bias (blinding of outcome assessment)

² Imprecision (wide confidence interval around estimate; small sample size)

Summary of findings 3. Mersilene mesh compared to autogenous fascia for congenital ptosis for frontalis sling surgery for congenital ptosis

Mersilene mesh compared to autogenous fascia for frontalis sling surgery for congenital ptosis

Patient or population: frontalis sling surgery for congenital ptosis

Setting: 1 centre, Iran

Intervention: Mersilene mesh

Comparison: autogenous fascia for congenital ptosis

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with autogenous fascia for congenital ptosis	Risk with Mersilene mesh				
Functional success of surgery - not reported	-	-	-	-	-	Salour 2008 noted that lid fissure increased 4.0 mm ± 1.46 mm in the Mersilene group and 3.13 mm ± 1.72 mm in the fascia lata group. Changes in lid fissure in both groups were statistically significant (P = 0.00) but the difference between the two groups was

						not significant (P = 0.14). MRD1 increased 3 mm ± 1.46 mm in the Mersilene group and 2.87 mm ± 1.36 mm in the fascia lata group. (P = 0.027). There were 16 eyelids in the Mersilene group and 15 in the autogenous fascia group.
Recurrence after surgery follow up: range 6 months to 29 months	0 per 1000	0 per 1000 (0 to 0)	not estimable	31 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{1 2}	There was no recurrence after surgery reported in either group
Sling removal - not reported	-	-	-	-	-	There were no reported instances of sling removal required
Infection - not reported	-	-	-	-	-	There were no reported infections in either group
Ocular and systemic complications follow up: range 6 months to 29 months	In the Mersilene group, two eyes experienced extrusion of the sling material. Two eyes in the autogenous fascia group had entropion. Three eyes in the Mersilene group and seven eyes in the autogenous fascia group developed corneal epithelial defects. Two patients in the Mersilene group and 10 in the autogenous fascia group required blepharoplasty, which is worth noting but was not included in the analysis.		-	31 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{1 2}	
Economic outcomes - not reported	-	-	-	-	-	Economic outcomes were not reported
Quality of life - not reported	-	-	-	-	-	Quality of life measures were not reported

***The risk in the intervention group** (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).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio;

GRADE Working Group grades of evidence

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Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect

Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

- ¹ Severe risk-of-bias concerns (blinding of outcome assessment and incomplete outcome data)
- ² Imprecision (wide confidence interval around estimate; small sample size)

BACKGROUND

Description of the condition

Congenital ptosis is a drooping of one or both eyelids at birth, often due to poor development of the levator palpebrae superioris muscle responsible for lifting the eyelids (Takahashi 2010). Simple congenital ptosis occurs in 5.9 per 100,000 people (Griepentrog 2011). Syndromes associated with congenital ptosis include congenital cranial dysinnervation disorders, blepharophimosis ptosis epicanthus inversus syndrome, congenital fibrosis of the extraocular muscles, Marcus Gunn jaw-winking syndrome, and Horner's syndrome (SooHoo 2014).

In congenital ptosis, fibrous and adipose tissues are often present in place of the normal levator muscle tissue, hindering the contraction of the muscle (Yoon 2009). Moderate or severe instances can result in the eyelid obscuring part or all of the pupil, leading to complications including amblyopia, astigmatism, and ocular torticollis (Lin 2008). Consequently, correction of congenital ptosis usually necessitates surgical intervention in early childhood when vision or visual development is compromised (Takahashi 2010). When visual development is not compromised, surgery is not urgent and may be better delayed to avoid the risks of general anaesthesia in young children.

Description of the intervention

The most effective surgical treatment for moderate to severe congenital ptosis is frontalis sling (also known as frontalis suspension) surgery, as first described by Crawford 1956. This technique is indicated in children with poor levator function (Crawford 1971). It involves coupling the tarsal plate to the frontalis muscle, allowing the patient to raise the eyelid by lifting the brow, rather than relying on the dysfunctional levator palpebrae superioris (Philandrianos 2010). Many different materials have been used to form this attachment, including fascia lata (both autologous and preserved), silicone rods, temporalis fascia, sclera, nonabsorbable sutures, suture-reinforced sclera, frontalis muscle, Gore-Tex strips (polytetrafluoroethylene synthetic material), polyester mesh, and Supramid (polyfilament, cable-type 3-0 suture).

General anaesthesia is used for children undergoing the procedure. Incisions are made in the eyelid and the upper portion of the brow, and material is passed through the eyelid in the suborbicularis fascial plane and anchored to the incisions in the brow. The frontalis muscle, which typically serves to raise the brow, can subsequently be used to lift the eyelid as well (Woo 2014).

Frontalis sling surgery may exhibit decreased effectiveness in the long term, with the eyelid gradually reassuming its former position. Further surgery may be needed in these cases to improve the position of the eyelid. Complications of the surgery besides recurrence of ptosis may include exposure keratopathy, irregular lid contour, and granuloma formation (Mokhtarzadeh 2015), as well as sling extrusion and implant infection.

How the intervention might work

The short- and long-term efficacy of the surgery, as well as the rate of complications, have been shown to vary based on the material used to form the connection between the eyelid and the brow (Mehta 2004; Mokhtarzadeh 2015). Various features of the materials

have been posited to influence these outcomes, such as surface roughness (Choi 2011) and tensile strength (Mehta 2004).

Why it is important to do this review

Children undergo frontalis sling surgery to help their vision to develop normally in the affected eye. When the ptosis recurs, they are at risk for amblyopia and induced astigmatism. Using the best material may help avoid recurrence. Reducing the likelihood of recurrent ptosis also avoids the risks and discomforts of additional surgery. Furthermore, the effectiveness and reliability of the surgery may have cosmetic implications for the patient.

We undertook a systematic review regarding the functional and cosmetic effectiveness of the various materials currently used for frontalis sling surgery to identify the most desirable material and to establish preferred alternatives for instances in which that material is contraindicated, not available, or not cost effective.

OBJECTIVES

To evaluate the comparative effectiveness and safety of various materials used in frontalis sling surgery for congenital ptosis.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomized controlled trials (RCTs) which compared types of frontalis slings used to treat congenital ptosis. We included reports published in any language.

Types of participants

We included trials in which participants underwent frontalis sling surgery for congenital ptosis. We did not apply any restrictions regarding location or demographic factors. We included all age groups.

Types of interventions

We included trials in which materials used in the frontalis sling surgery were compared in regard to their effectiveness in maintaining eyelid lift. Specific materials of interest included autologous fascia lata, preserved (banked) fascia lata, and silicone rods. We did not include trials in which only one material was studied, with no comparison involved. We did not exclude trials that used other background therapy or cointerventions, such as treatment of amblyopia, as long as the main comparison was of materials used in the frontalis sling surgery.

Types of outcome measures

Primary outcomes

The primary outcome for this review was functional success of the surgery, defined as improvement of the eyelid position above the pupillary margin. Functional success may be measured differently in different trials. Examples we have found are categorization as 'good', 'fair', or 'poor' results; measurements in millimetres above the visual axis; measurements of margin-to-reflex distance; and comparison to the other (normal) side in millimetres.

The primary timing of assessment was at one-year follow-up; we also considered different follow-up times as reported by included trials.

Secondary outcomes

The secondary outcomes included:

- the proportion of participants with recurrence after surgery at one-year follow-up;
- the proportion of participants with sling removal at one-year follow-up; and
- the proportion of participants with infection at one-year follow-up.

Adverse outcomes

We tabulated any ocular and systemic complications related to the surgery as reported in the included studies. Our specific adverse events of interest included granuloma formation, extrusion of sling material, entropion, and wound dehiscence.

Economic data

Economic data were not reported in any of the included studies. In future updates, we will include any relevant economic data regarding costs of treatment.

Quality of life data

The included studies did not report quality of life outcomes. In future updates, we will include quality of life data, measured with questionnaires, when available.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (which contains the Cochrane Eyes and Vision Trials Register) (June 2018), Ovid MEDLINE, Ovid MEDLINE E-pub Ahead of Print, Ovid Medline In-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily (January 1946 to 20 June 2018), Embase (January 1947 to 20 June 2018), PubMed (1948 to 20 June 2018), Latin American and Caribbean Health Sciences Literature Database (LILACS) (1982 to 20 June 2018), ClinicalTrials.gov (www.clinicaltrials.gov) and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictip/search/en). We did not use any date or language restrictions in the electronic search for trials. We last searched the electronic databases on 20 June 2018.

See Appendices for details of search strategies for CENTRAL (Appendix 1), MEDLINE (Appendix 2), Embase (Appendix 3), PubMed (Appendix 4), LILACS (Appendix 5), ClinicalTrials.gov (Appendix 6), and the ICTRP (Appendix 7).

Searching other resources

We searched the reference lists of trials included in the review for additional trials. We also used the Science Citation Index to find trials that cited the included trials.

Data collection and analysis

Selection of studies

Two authors independently reviewed the titles and abstracts identified by the electronic and manual searches to identify potential citations for inclusion. We placed the abstracts in three categories: include, uncertain, exclude. We acquired full-text reports of all records in the first two categories. Two authors independently reviewed the reports to determine eligibility for inclusion, again placing them into three categories: include, exclude, or awaiting assessment. We documented all excluded studies and reported the reason for exclusion in a table. We assessed articles in the 'include' category for risk of bias. We classified no report as 'awaiting assessment', thus we did not need to contact study authors by email to obtain information to allow us to include or exclude the study from review. We had planned, if they did not respond within two weeks, to contact them a second time and allow four weeks for a response. We resolved all discrepancies by discussion with a third author. Names of authors, institutions, and journals were not masked during the review.

Data extraction and management

Two review authors extracted data on study characteristics, including study design, participant characteristics, interventions and outcomes assessed (Appendix 8). We resolved discrepancies by discussion. We did not contact authors of trials for additional data and evaluated the study based on the published data only. One author entered the data into Review Manager 5 (RevMan 5) (Review Manager 2014); a second author verified for discrepancies.

Assessment of risk of bias in included studies

To assess the risk of bias in included studies, we used the guidelines provided in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017). We considered:

1. sequence generation;
2. allocation concealment before randomization;
3. masking (blinding) of participants and personnel;
4. masking (blinding) of outcome assessors;
5. incomplete outcome data;
6. selective outcome reporting; and
7. other sources of bias.

Two review authors independently conducted the assessments using the 'Risk of bias' tool. Levels of biases were designated 'high', 'low' or 'unclear'. We resolved disagreements by discussion.

Measures of treatment effect

We reported the outcomes both as dichotomous and continuous outcomes.

We calculated risk ratios (RRs) using confidence intervals (CIs) of 95% for dichotomous outcomes, which included the proportion of participants with functional success ('good' or 'fair' surgical results), the proportion of participants with recurrence after surgery, the proportion of participants with sling removal, the proportion of participants with infection, and the proportion with complications.

We calculated mean differences (MDs) using CIs of 95% for continuous outcomes, such as functional success measured as margin-to-reflex distance in millimetres.

Unit of analysis issues

The unit of analysis was the individual, including one eye from each participant. We documented trials where both eyes were treated as units for analysis. In trials where both eyes were treated, we analyzed eyes independently.

Dealing with missing data

We planned to contact study authors by email to obtain missing or unclear data. We planned to allow two weeks to respond to our first attempt to contact them before attempting to contact them a second time. We did not impute data for the purpose of this review but considered imputed data when they were included in the studies using appropriate methods, such as multiple imputation. We documented studies using inappropriate methods of imputation, such as last observation carried forward.

Assessment of heterogeneity

We examined the clinical, methodological and statistical heterogeneity among included studies. We examined clinical heterogeneity by evaluating differences in study participants, interventions and outcomes. Methodological heterogeneity implies differences in study design and analysis. To assess statistical heterogeneity between trials and consistency across studies we planned to examine the forest plot of trial results and the I^2 value. If the I^2 value exceeded 60%, we planned to interpret that as evidence of substantial statistical heterogeneity.

Assessment of reporting biases

We analyzed possible reporting biases according to the tool outlined in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017). We assessed for selective outcome reporting at the trial level as part of the 'Risk of bias' assessment. As fewer than 10 studies were included in the review, we did not analyze funnel plots to judge the possibility of small-study effects.

Data synthesis

We planned to use a random-effects model if there were more than three trials that contributed to a meta-analysis, and a fixed-effect model if there were fewer than three trials that contributed to a meta-analysis. We planned to write a narrative summary of findings from included studies if there was evidence of significant heterogeneity.

Subgroup analysis and investigation of heterogeneity

We did not perform a subgroup analysis for this review.

Sensitivity analysis

We did not perform any sensitivity analysis for this review. We determined and reported the effect of incorporating studies for which we judged the risk of bias to be 'high' for any of the domains assessed.

Summary of findings

We used the GRADE Working Group approach to assess the overall certainty of the evidence for each outcome estimate as 'very low', 'low', 'moderate', or 'high' (GRADEpro 2015). We assessed the five major domains of risk of bias, imprecision, inconsistency, publication bias, and indirectness. Two review authors independently graded the evidence and resolved discrepancies by discussion. We summarized the GRADE assessments for the following outcomes in the 'Summary of findings' table.

1. Functional success of the surgery, defined as improvement of the eyelid position above the pupillary margin. Functional success may be measured differently in different trials. Examples we have found are categorized as 'good', 'fair', or 'poor' results; measurements in millimetres above the visual axis; measurements of margin-to-reflex distance; and comparison to the other (normal) side in millimetres.
2. The proportion of participants with recurrence after surgery.
3. The proportion of participants with sling removal.
4. The proportion of participants with infection.
5. The number of ocular and systemic complications.
6. Economic data regarding costs of treatment.
7. Quality of life data, measured with questionnaires, when available.

RESULTS

Description of studies

Results of the search

We conducted an electronic literature search on 20 June 2018 and identified a total of 3268 records (Figure 1). We excluded 3242 records based on titles and abstracts, and requested full-text reports for a total of 26 records. We included three studies and excluded 23 studies from this search. There were no ongoing studies identified.

Figure 1. Study flow diagram.

Included studies

We included three trials and summarized them below. Additional details can be found in the [Characteristics of included studies](#) table.

The three trials studied the use of frontalis slings for ptosis repair in a total of 160 participants. All three trials limited their participant population to include only participants with congenital ptosis; two studies included only bilateral ptosis ([Bajaj 2004](#) and [Elsamkary](#)

[2016](#)); and one included both bilateral and unilateral ptosis ([Salour 2008](#)). Two studies described that patients had levator function less than 5 mm ([Bajaj 2004](#)) or 4 mm ([Salour 2008](#)), but this was not described in the final paper ([Elsamkary 2016](#)). All of these three studies included adults and children, with an age range of 3 years to 42 years. One study each was conducted in India, Egypt, and Iran. All trials were parallel-group RCTs that compared two types of frontalis sling materials with each other; however, the two types of materials

compared were different for each trial. The outcomes and follow-up times also differed across trials.

[Bajaj 2004](#) randomized 30 participants with moderate to severe bilateral, congenital, simple ptosis, with levator action less than 5 mm, to polytetrafluoroethylene (PTFE, Gore-Tex CV-4) suture or polybutylate-coated braided polyester (Ethibond 4-0) suture. Both groups were regarded as comparable for age and amount of pre-operative ptosis. The trial authors compared these groups to each other for the degree of ptosis present postoperatively, which was graded as good (residual ptosis less than or equal to 1 mm), satisfactory (residual ptosis 1 mm to 2 mm), or unsatisfactory (residual ptosis more than 2 mm). The minimum follow-up was one year and the mean follow-up achieved was 16 months $\pm$ 3.24 months.

[Elsamkary 2016](#) randomized 110 participants with bilateral congenital ptosis to autogenous fascia lata or Gore-Tex. Both groups were regarded as comparable in terms of age and sex. The trial authors compared the groups to each other for the upper eyelid margin position below the superior limbus, indicating whether the position was very good (less than 3 mm), good (3 mm to 5 mm), or poor (more than 5 mm). The trial achieved follow-up to two years.

[Salour 2008](#) randomized 20 participants with congenital unilateral or bilateral ptosis to Mersilene mesh or autogenous fascia lata. The groups were comparable for age, but it is not clear whether the proportion of unilateral versus bilateral cases was the same within the two groups. The trial authors compared the groups to each other for change in lid fissure width and change in MRD1. The trial achieved minimum follow-up of 6 months.

Excluded studies

We excluded 22 studies after examining the full text. For the 23rd paper ([Ahmed 2009](#)), we exhausted all methods to obtain the full text and ultimately excluded it based on the abstract, which did not indicate a randomized study.

The reasons for exclusion were as follows: 20 studies were excluded because they were not randomized controlled trials and three studies examined interventions or comparators which did not meet our eligibility criteria. Please see the “[Characteristics of excluded studies](#)” table.

Risk of bias in included studies

We assessed all included studies for multiple types of bias. See [Figure 2](#) and [Figure 3](#) for an overview.

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bajaj 2004	?	?	+	-	+	?	+
Elsamkary 2016	?	?	+	-	+	?	+
Salour 2008	?	?	+	-	?	?	+

Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Random sequence generation (selection bias)

Method of sequence generation was unclear in all trials. All trial authors stated that randomization had occurred but did not state the method by which participants were randomized.

Allocation

No trial reported how the allocation was concealed before assignment. Thus, we assessed selection bias as unclear in all trials.

Blinding

The participants and investigators were not masked to treatment assignment in any of the trials. Lack of blinding was unlikely to be a source of bias for participants, but may be of high risk for investigators. We assessed performance and detection bias as high risk in all trials.

Incomplete outcome data

The trial authors accounted for all participants throughout two trials and with outcome data reported ([Bajaj 2004](#); [Elsamkary 2016](#)); for these reasons, we assessed the two trials to be at low risk and [Salour 2008](#) to be at unclear risk of attrition bias.

Selective reporting

Risk of bias for selective reporting was unclear for all three trials; we were unable to locate trial protocols.

Other potential sources of bias

There were no other apparent sources of bias in the three included studies.

Effects of interventions

See: [Summary of findings for the main comparison](#) Gore-Tex compared to Ethibond for congenital ptosis for frontalis sling surgery for congenital ptosis; [Summary of findings 2](#) Autogenous fascia compared to Gore-Tex for congenital ptosis for frontalis sling surgery for congenital ptosis; [Summary of findings 3](#) Mersilene

[mesh compared to autogenous fascia for congenital ptosis for frontalis sling surgery for congenital ptosis](#)

The details of each study are listed below. In brief, [Bajaj 2004](#) had a total of 93% of their Gore-Tex group and 83% of their Ethibond group with good or satisfactory results. [Elsamkary 2016](#) had approximately 78% of their autogenous fascia group and 62% of their Gore-Tex group with very good or good results. [Salour 2008](#) used a different method of reporting their results. They showed an increase in the lid fissure of approximately 4 mm in their Mersilene group and 3 mm in their autogenous fascia group ([Salour 2008](#)).

1. Gore-Tex versus Ethibond (Bajaj 2004)

1.1 Functional success of the surgery

[Bajaj 2004](#) measured the degree of ptosis correction at last follow-up, which was a mean of 16.0 months $\pm$ 3.24 months. In the Gore-Tex group (15 patients, 30 eyelids), 40% had a good outcome, 53% had a satisfactory outcome, and 7% had an unsatisfactory outcome. In the Ethibond group (15 patients, 30 eyelids), 20% had a good outcome, 63% had a satisfactory outcome, and 17% had an unsatisfactory outcome. This trial also included postoperative parameter measurements, but the follow-up time was unclear. Using GRADE to assess the certainty of evidence for this outcome, we downgraded for risk of bias and imprecision and assessed the level of evidence for this outcome as low.

1.2 Recurrence after surgery

The Gore-Tex group had no participants with recurrence after surgery. In the Ethibond group, one participant had slippage of the knot on one side with recurrence of ptosis in that eyelid. Using the GRADE method, we assessed the certainty of evidence for this outcome again as low, due to risk of bias and imprecision.

1.3. Sling removal

The Gore-Tex group had no participant who required removal of the sling. In the Ethibond group, one participant had bilateral suture abscesses requiring removal of the sling from both sides. We

assessed the certainty of this outcome as low, again downgrading for risk of bias and imprecision.

1.4 Infection

The Gore-Tex group had no infections. In the Ethibond group, one participant had bilateral suture abscesses, as mentioned above. We assessed the certainty of this outcome as low, downgrading for risk of bias and imprecision.

1.5 Adverse events

Two eyelids in each group developed granulomas. There was no participant in either group with extrusion of the sling material, entropion, or wound dehiscence. Recurrence, sling removal, and infection are described above. We assessed the certainty of this outcome as low, using GRADE, downgrading for risk of bias and imprecision.

1.6 Economic outcomes

Economic outcomes were not reported.

1.7 Quality of life

Quality of life measures were not reported.

2. Autogenous fascia versus Gore-Tex (Elsamkary 2016)

2.1 Functional success of the surgery

[Elsamkary 2016](#) measured the functional outcome after two years. In the autogenous fascia lata group, the outcomes were very good in 54%, good in 24%, poor in 9%, and failure in 13%. In the Gore-Tex group, the outcomes were very good in 44%, good in 18%, poor in 9%, and failure in 29%. The failure rate was calculated to be statistically significantly different ($P = 0.035$), but the other categories were not different (very good $P = 0.25$, good $P = 0.48$, poor $P = 1$). We assessed this outcome to have low certainty of evidence, downgraded for risk of bias and imprecision.

2.2 Recurrence after surgery

In the autogenous fascia group, three participants had recurrence after surgery. In the Gore-Tex group, six patients had recurrence. This outcome had low certainty of evidence due to risk of bias and imprecision.

2.3 Sling removal

No participants in either group required sling removal. Again, we assessed the certainty of this outcome as low, downgraded for risk of bias and imprecision.

2.4 Infection

In the autogenous fascia group, one participant developed an infection. In the Gore-Tex group, two participants developed infections. Using the GRADE approach, as with the above outcomes, we assessed the certainty of evidence as low due to risk of bias and imprecision.

2.5 Adverse events

One participant in the autogenous fascia group and two in the Gore-Tex group developed ectropion. Two participants in the autogenous fascia group and five in the Gore-Tex group had lagophthalmos. Recurrence, sling removal, and infection are

detailed above. The certainty of evidence for this outcome was assessed as low for the same reasons given above.

2.6 Economic outcomes

Economic outcomes were not reported.

2.7 Quality of life

Quality of life measures were not reported.

3. Mersilene mesh versus autogenous fascia (Salour 2008)

3.1 Functional success of the surgery

[Salour 2008](#) graded functional success in a different way. They did not report a grade of good, satisfactory, or poor results but instead reported data on the change in the lid fissure and margin-to-reflex distance (MRD), though did not specify a time point for any reported outcomes in the results. Lid fissure increased $4.0 \text{ mm} \pm 1.46 \text{ mm}$ in the Mersilene group and $3.13 \text{ mm} \pm 1.72 \text{ mm}$ in the fascia lata group. Changes in lid fissure in both groups were statistically significant ($P = 0.00$) but the difference between the two groups was not significant ($P = 0.14$). MRD1 increased $3 \text{ mm} \pm 1.46 \text{ mm}$ in the Mersilene group and $2.87 \text{ mm} \pm 1.36 \text{ mm}$ in the fascia lata group. ($P = 0.027$). There were 16 eyelids in the Mersilene group and 15 in the autogenous fascia group. We assessed the quality of evidence as very low due to severe risk-of-bias concerns and imprecision.

3.2 Recurrence after surgery

There was no recurrence after surgery reported in either group. Using the GRADE approach, we assessed the certainty of this evidence as very low due to risk-of-bias concerns and imprecision.

3.3 Sling removal

There was no reported instance of sling removal, and the authors did not specifically comment on this.

3.4 Infection

There was no reported infection in either group, and the authors did not specifically comment on this.

3.5 Adverse events

In the Mersilene group, two eyes experienced extrusion of the sling material. Two eyes in the autogenous fascia group had entropion. Three eyes in the Mersilene group and seven eyes in the autogenous fascia group developed corneal epithelial defects. Two participants in the Mersilene group and 10 in the autogenous fascia group required blepharoplasty, which was not included in the analysis but is worth noting. Using the GRADE method we assessed the quality of evidence to be very low, due to risk-of-bias concerns and imprecision.

3.6 Economic outcomes

Economic outcomes were not reported.

3.7 Quality of life

Quality of life measures were not reported.

DISCUSSION

Severe congenital ptosis with poor levator function is typically treated with frontalis sling surgery. There are a number of different

implants that can be used for this procedure. However, data comparing these implants are few. We found three randomized trials that had compared types of implants from our search of multiple publication databases and registers of clinical trials. The three trials reviewed a total of four types of implants.

Summary of main results

We found three RCTs (311 eyelids of 160 participants) comparing two types of frontalis sling materials used in surgery for congenital ptosis. Because the three included studies each compared different types of implants, we were unable to combine outcome data into a meta-analysis. The limited data preclude any conclusion regarding the optimal implant for frontalis sling surgery.

In terms of the primary outcome of functional success, [Bajaj 2004](#) showed that 93% of the Gore-Tex group and 83% of the Ethibond group had a good or satisfactory outcome. [Elsamkary 2016](#) reported that 78% of the autogenous fascia group and 62% of the Gore-Tex group had a very good or good outcome. [Salour 2008](#) did not include this type of grading system; the results of this study showed an increase of lid fissure by $4.0 \text{ mm} \pm 1.46 \text{ mm}$ in the Mersilene group and $3.13 \text{ mm} \pm 1.72 \text{ mm}$ in the fascia lata group.

In terms of the secondary outcomes of number of participants with recurrence, sling removal, and infection, these were reported in all studies. [Salour 2008](#) did not mention sling removal, possibly because no participants required removal. Adverse events were reported in all included studies. Economic outcomes and quality of life measures were not reported in any of the included studies.

Overall completeness and applicability of evidence

All of the included studies in this review had limitations that affect applicability.

The timing of reported results in [Bajaj 2004](#) was inconsistent, with the final functional determination being made at "final follow up" rather than at a defined end-point.

The [Elsamkary 2016](#) study had the largest number of participants and the most well-defined outcome reporting. However, the difference between a "poor result" and "recurrence" was not described.

[Salour 2008](#) was the only study to include both bilateral and unilateral cases. This design may have introduced significant variability in the effect of surgery, especially as the authors did not indicate how many unilateral and bilateral cases were included in each group. The authors did not report outcomes at defined intervals, and in fact do not even describe the timing at which their measurements occurred.

There was no discussion in any of the reports from included studies of participants lost to follow-up or excluded after the study began.

Quality of the evidence

We graded the overall quality of the evidence as low to very low in the included studies ([Summary of findings for the main comparison](#); [Summary of findings 2](#); [Summary of findings 3](#)). None of the studies described methods of randomization; none of the studies attempted to blind the participants or the graders.

Additionally, [Bajaj 2004](#) and [Salour 2008](#) had poor reporting of the time interval at which their results were measured. Both studies had small sample sizes (30 and 20 participants). [Salour 2008](#) possibly was confounded by the inclusion of participants with both unilateral and bilateral ptosis. Neither of these studies reported a sample size calculation or computation of post hoc power to detect or rule out differences between surgeries in outcome estimates.

Although [Elsamkary 2016](#) did have better reporting of their results, they also did not describe their methods of randomization. The authors stated "sample size has been calculated to compare failure and success rates", but they did not provide further details.

Potential biases in the review process

We did not identify any potential biases in the review process.

Agreements and disagreements with other studies or reviews

The existing literature on materials for frontalis sling surgery is mainly limited to reports of retrospective case series. These papers describe the use of one type of material or compare two materials without randomisation. For example, [Lee 2009](#) described 123 patients with congenital ptosis who received either silicone rod or preserved fascia lata for their sling. The cosmetic results were similar between their groups at six months, but the silicone rod group had better cosmetic results at one, two, and three years after surgery. The recurrence rates at three years were also better in the silicone rod group. Another group compared 70 eyelids of 49 patients who received nylon monofilament suture or Gore-Tex (or both; nine eyelids of seven patients underwent both procedures) ([Hayashi 2013](#)). The authors found more recurrence but fewer complications in the nylon group.

These retrospective studies are subject to bias due to lack of randomisation and masking. We did not identify any prior systematic review or meta-analysis of this topic.

AUTHORS' CONCLUSIONS

Implications for practice

Evaluation of these three studies does not allow us to definitively determine the optimal material to use in frontalis sling surgery.

Implications for research

This review shows the need for further high-quality research to determine the best material for frontalis sling surgery. Future studies should clearly indicate their randomization sequence, attempt to mask outcome assessors, and have clearly defined time points for the grading of their results. In order to make the results more uniform, future studies should use a millimetre measurement above the pupil for their analysis rather than qualitative measurements (e.g. at one year). Economic and quality of life measures should also be reported.

Additionally, assessment of social implications in patients who undergo this type of surgery is an important avenue for further research. Facial asymmetry or any sort of irregularity can lead to social stigma, especially in children. If one type of material produces a better cosmetic outcome, this may lead to better social acceptance.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Bajaj 2004

Methods	<p>Study design: parallel group randomized controlled trial</p> <p>Study centre(s): 1, India</p> <p>Number randomized: 30 participants</p> <p>Study follow-up: 1 year</p> <p>Exclusions and losses to follow-up: not reported</p>
Participants	<p>Age, mean (standard deviation): polytetrafluoroethylene suture group 13.27 (8.82) years; Ethibond group 10.73 (5.80) years. Overall range 4 to 20 years.</p> <p>Gender: 14 men, 16 women</p> <p>Inclusion criteria: bilateral, congenital, simple ptosis, moderate to severe, with levator action less than 5 mm</p> <p>Exclusion criteria: unilateral involvement, residual or complicated ptosis or with poor Bell's phenomenon</p>
Interventions	<p>Intervention #1 (n = 15 patients, 30 eyes): polytetrafluoroethylene suture (Gore-Tex CV-4) suture</p> <p>Intervention #2/control (n = 15 patients, 30 eyes): polybutylate-coated braided polyester (Ethibond 4-0) suture</p> <p>All patients had standard modified Crawford's double triangle method with interlocking at the center of the upper lid margin.</p>
Outcomes	<p>Primary outcome: degree of ptosis correction</p> <p>Secondary outcomes: palpebral aperture, residual ptosis, lagophthalmos</p> <p>Measurements taken at 1 day, 4 days, 1 week, 2 weeks, 1 month, 3 months, 6 months, 1 year.</p> <p>The degree of ptosis correction postoperatively was graded as good, satisfactory or unsatisfactory. Good results were those where residual ptosis was less than or equal to 1 mm; satisfactory, where the residual ptosis was 1 mm to 2 mm; and unsatisfactory where the residual ptosis was more than 2 mm.</p> <p>Unit of analysis: patient randomized but eyes analyzed as independent units.</p>
Notes	<p>Study dates: not listed</p> <p>Trial registration: not reported</p> <p>Funding source(s): not reported</p> <p>Declarations of interest: not reported</p>

Risk of bias

Types of materials for frontalis sling surgery for congenital ptosis (Review)

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Bajaj 2004 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described, but all participants had congenital ptosis so should not bias results
Allocation concealment (selection bias)	Unclear risk	Not described, but all participants had congenital ptosis so should not bias results
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Not described, but participants' knowledge of their group should not bias results
Blinding of outcome assessment (detection bias) All outcomes	High risk	Assessors were not blinded to the groups. This could bias the results
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcome data were complete
Selective reporting (reporting bias)	Unclear risk	Outcomes reported match outcomes listed in methods
Other bias	Low risk	No concerns

Elsamkary 2016

Methods	<p>Study design: parallel group randomized controlled trial</p> <p>Study centre(s): 1, Egypt</p> <p>Number randomized: 110 participants</p> <p>Study follow-up: 2 years</p> <p>Exclusions and losses to follow-up: 0 participants who were randomized were excluded from the analyses; 0 were lost to follow-up</p>
Participants	<p>Age, mean: 6.1 years (range 3 to 13 years)</p> <p>Gender: 59 men, 51 women</p> <p>Inclusion criteria: bilateral congenital ptosis</p> <p>Exclusion criteria: jaw-winking phenomenon, abnormal ocular motility, absent Bell's phenomenon</p>
Interventions	<p>Intervention #1 (n = 55): autogenous fascia lata</p> <p>Intervention #2/control (n = 55): Gore-Tex</p> <p>All subjects had Crawford double rhomboid technique with non-absorbable 5-0 polyester silicone-coated suture to tie sling to deeper tissue</p>
Outcomes	<p>Primary outcome: (as defined in the study report) functional outcome, assessed by measuring the upper eyelid margin position below the superior limbus (very good, less than 3 mm; good, 3 mm to 5 mm; poor, over 5 mm)</p>

Elsamkary 2016 (Continued)

Secondary outcomes: aesthetic outcomes assessed in terms of uniform eyelid contour, eyelid height symmetry between both eyes, formed eyelid crease as in normal anatomical measures

Measurements taken at 2 years

Unit of analysis: participant (both eyes analyzed together)

Notes	<p>Study dates: 2010 to 2013</p> <p>Trial registration: not reported</p> <p>Funding source(s): not listed</p> <p>Declarations of interest: none</p>
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Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described, but all participants had congenital ptosis so should not bias results
Allocation concealment (selection bias)	Unclear risk	Not described, but all participants had congenital ptosis so should not bias results
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Not described, but participants' knowledge of their group should not bias results
Blinding of outcome assessment (detection bias) All outcomes	High risk	Assessors were not blinded to the groups. This could bias the results
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcome data were complete
Selective reporting (reporting bias)	Unclear risk	Outcomes reported match outcomes listed in methods
Other bias	Low risk	No concerns

Salour 2008

Methods	<p>Study design: parallel-group randomized controlled trial</p> <p>Study centre(s): 1, Iran</p> <p>Number randomized: 20 participants</p> <p>Study follow-up: Group A = 14.2 months, Group B = 15.1 months</p> <p>Exclusions and losses to follow-up: not listed</p>
Participants	<p>Age, mean (standard deviation): mean — Group A = 15.7 (12.6) years (range 3 to 42), Group B = 14.1 (8.6) years (range 4 to 26), overall average not listed</p> <p>Gender: noted as "comparable"</p>

Types of materials for frontalis sling surgery for congenital ptosis (Review)

Salour 2008 (Continued)

Inclusion criteria: very weak levator function (< 4 mm), minimum 4 years old for adequate autogenous fascia

Exclusion criteria: weak Bell's phenomenon (< 50% of normal), positive phenylephrine test, jaw-winking phenomenon, blepharophimosis syndrome, systemic or myopathic disorders with secondary ptosis such as myasthenia gravis, myotonic dystrophy, CPEO. Graves' disease, any history of intra- or extraocular and eyelid surgery, and any history of sharp or blunt trauma to eyelids, eyelid tumors, and scars

Interventions	<p>Intervention #1 (n = 10 patients, 16 eyelids): Mersilene</p> <p>Intervention #2/control (n = 10 patients, 15 eyelids): autogenous fascia lata</p> <p>All patients had Crawford bitriangular method. All had Frost suture post-operatively for 24 hours until epithelial healing. All received oral cephalexin for 5 days.</p>
Outcomes	<p>Primary outcome: MRD1 and eyelid fissure height</p> <p>Secondary outcomes: not listed</p> <p>Measurements taken at 14.2 months on average (Mersilene) and 15.1 months on average (autogenous fascia lata)</p> <p>Unit of analysis: patient randomized, eyelid analyzed as independent unit</p>
Notes	<p>Study dates: July 2003 to Dec 2004</p> <p>Trial registration: not reported</p> <p>Funding source(s): none</p> <p>Declarations of interest: none listed</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described, but all participants had congenital ptosis so should not bias results
Allocation concealment (selection bias)	Unclear risk	Not described, but all participants had congenital ptosis so should not bias results
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Not described, but participants' knowledge of their group should not bias results
Blinding of outcome assessment (detection bias) All outcomes	High risk	Assessors were not blinded to the groups. This could bias the results
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	There were no mention of incomplete data
Selective reporting (reporting bias)	Unclear risk	Outcomes reported match outcomes listed in methods
Other bias	Low risk	No concerns

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Ahmadi 2002	Not RCT
Ahmed 2009	Not RCT
Ali 2011	Not RCT
Arnaud 1989	Not RCT
Bagheri 2007	Intervention does not meet eligibility criteria
Bagheri 2008	Not RCT
Bastrikov 1986	Not RCT
Beard 1966	Not RCT
El-Toukhy 2001	Not RCT
Federmann 1986	Not RCT
Ferreira 1995	Not RCT
Freitas 2009	Not RCT
Gómez Cabrera 2014	Not RCT
Hejsek 2014	Not RCT
Junceda-Moreno 2005	Not RCT
Liu 2011	Comparator does not meet eligibility criteria
Mir 1995	Not RCT
Müllner 2002	Not RCT
NCT00753831	Not RCT
NCT03149367	Intervention does not meet eligibility criteria
Pitanguy 1963	Not RCT
Velasco e Cruz 1989	Not RCT
VásquezMarín 1994	Not RCT

DATA AND ANALYSES

Comparison 1. Gore-Tex versus Ethibond for congenital ptosis

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Recurrence after surgery	1	60	Odds Ratio (M-H, Fixed, 95% CI)	0.32 [0.01, 8.24]
2 Sling removal	1	60	Odds Ratio (M-H, Fixed, 95% CI)	0.19 [0.01, 4.06]
3 Infection	1	60	Odds Ratio (M-H, Fixed, 95% CI)	1.0 [0.13, 7.60]

Analysis 1.1. Comparison 1 Gore-Tex versus Ethibond for congenital ptosis, Outcome 1 Recurrence after surgery.

Analysis 1.2. Comparison 1 Gore-Tex versus Ethibond for congenital ptosis, Outcome 2 Sling removal.

Analysis 1.3. Comparison 1 Gore-Tex versus Ethibond for congenital ptosis, Outcome 3 Infection.

Comparison 2. Autogenous fascia versus Gore-Tex for congenital ptosis

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Recurrence after surgery	1	110	Odds Ratio (M-H, Fixed, 95% CI)	0.47 [0.11, 1.99]
2 Infection	1	110	Odds Ratio (M-H, Fixed, 95% CI)	0.49 [0.04, 5.58]
3 Adverse events	1	110	Odds Ratio (M-H, Fixed, 95% CI)	0.40 [0.10, 1.62]

Analysis 2.1. Comparison 2 Autogenous fascia versus Gore-Tex for congenital ptosis, Outcome 1 Recurrence after surgery.

Analysis 2.2. Comparison 2 Autogenous fascia versus Gore-Tex for congenital ptosis, Outcome 2 Infection.

Analysis 2.3. Comparison 2 Autogenous fascia versus Gore-Tex for congenital ptosis, Outcome 3 Adverse events.

Comparison 3. Mersilene mesh versus autogenous fascia for congenital ptosis

Outcome or subgroup title	No. of studies	No. of partici-pants	Statistical method	Effect size
1 Functional success of surgery	1	31	Mean Difference (IV, Fixed, 95% CI)	0.87 [-0.26, 2.00]
2 Adverse events	1	31	Odds Ratio (M-H, Fixed, 95% CI)	0.30 [0.07, 1.33]

Analysis 3.1. Comparison 3 Mersilene mesh versus autogenous fascia for congenital ptosis, Outcome 1 Functional success of surgery.

Analysis 3.2. Comparison 3 Mersilene mesh versus autogenous fascia for congenital ptosis, Outcome 2 Adverse events.

APPENDICES

Appendix 1. CENTRAL search strategy

#1 MeSH descriptor: [Blepharoptosis] explode all trees
 #2 (Blepharoptos* or ptosis or ptoses or ptotic)
 #3 ((droop* or sag* or bag*) and (eye* or lid* or palpebra*))
 #4 #1 or #2 or #3
 #5 MeSH descriptor: [Surgical Procedures, Operative] explode all trees
 #6 (Blepharoplast* or Frontalis or sling* or suspension*)
 #7 (surger* or surgi* or reconstruct* or correction*)
 #8 #5 or #6 or #7
 #9 #4 and #8

Appendix 2. MEDLINE Ovid search strategy

1. Randomized Controlled Trial.pt.
 2. Controlled Clinical Trial.pt.
 3. (randomized or randomised).ab,ti.
 4. placebo.ab,ti.
 5. drug therapy.fs.
 6. randomly.ab,ti.
 7. trial.ab,ti.
 8. groups.ab,ti.
 9. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
 10. exp animals/ not humans.sh.
 11. 9 not 10
 12. exp Blepharoptosis/
 13. (Blepharoptos* or ptosis or ptoses or ptotic).tw.
 14. ((droop* or sag* or bag*) and (eye* or lid* or palpebra*)).tw.
 15. 12 or 13 or 14
 16. exp Surgical Procedures, Operative/
 17. (Blepharoplast* or Frontalis or sling* or suspension*).tw.
 18. surgery.fs.
 19. (surger* or surgi* or reconstruct* or correction*).tw.
 20. 16 or 17 or 18 or 19
 21. 15 and 20
 22. 11 and 21

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

Appendix 3. EMBASE.com search strategy

#1 'randomized controlled trial'/exp
 #2 'randomization'/exp
 #3 'double blind procedure'/exp
 #4 'single blind procedure'/exp
 #5 random*:ab,ti
 #6 #1 OR #2 OR #3 OR #4 OR #5
 #7 'animal'/exp OR 'animal experiment'/exp
 #8 'human'/exp
 #9 #7 AND #8
 #10 #7 NOT #9
 #11 #6 NOT #10
 #12 'clinical trial'/exp
 #13 (clin* NEAR/3 trial*):ab,ti
 #14 ((singl* OR doubl* OR trebl* OR tripl*) NEAR/3 (blind* OR mask*)):ab,ti
 #15 'placebo'/exp
 #16 placebo*:ab,ti
 #17 random*:ab,ti
 #18 'experimental design'/exp
 #19 'crossover procedure'/exp
 #20 'control group'/exp
 #21 'latin square design'/exp

Types of materials for frontalis sling surgery for congenital ptosis (Review)

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#22 #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21
#23 #22 NOT #10
#24 #23 NOT #11
#25 'comparative study'/exp
#26 'evaluation'/exp
#27 'prospective study'/exp
#28 control*:ab,ti OR prospectiv*:ab,ti OR volunteer*:ab,ti
#29 #25 OR #26 OR #27 OR #28
#30 #29 NOT #10
#31 #30 NOT (#11 OR #23)
#32 #11 OR #24 OR #31
#33 'ptosis'/exp
#34 blepharoptos*:ab,ti OR ptosis:ab,ti OR ptoses:ab,ti OR ptotic:ab,ti
#35 (droop*:ab,ti OR sag*:ab,ti OR bag*:ab,ti) AND (eye*:ab,ti OR lid*:ab,ti OR palpebra*:ab,ti)
#36 #33 OR #34 OR #35
#37 'eyelid reconstruction'/exp
#38 blepharoplast*:ab,ti OR frontalis:ab,ti OR sling*:ab,ti OR suspension*:ab,ti
#39 'surgery'/exp
#40 surgery:lnk
#41 surger*:ab,ti OR surgi*:ab,ti
#42 #37 OR #38 OR #39 OR #40 OR #41
#43 #36 AND #42
#44 #32 AND #43
```

Appendix 4. PubMed search strategy

1. ((randomized controlled trial[pt]) OR (controlled clinical trial[pt]) OR (randomised[tiab] OR randomized[tiab]) OR (placebo[tiab]) OR (drug therapy[sh]) OR (randomly[tiab]) OR (trial[tiab]) OR (groups[tiab])) NOT (animals[mh] NOT humans[mh])
2. (Blepharoptos*[tw] OR ptosis[tw] OR ptoses[tw] OR ptotic[tw]) NOT Medline[sb]
3. ((droop*[tw] OR sag*[tw] OR bag*[tw]) AND (eye*[tw] OR lid*[tw] OR palpebra*[tw])) NOT Medline[sb]
4. #2 OR #3
5. (Blepharoplast*[tw] OR Frontalis[tw] OR sling*[tw] OR suspension*[tw]) NOT Medline[sb]
6. (surger*[tw] OR surgi*[tw] OR reconstruct*[tw] OR correction*[tw]) NOT Medline[sb]
7. #5 OR #6
8. #4 AND #7
9. #1 AND #8

Appendix 5. LILACS search strategy

(Blepharoptos\$ or Blefaroptos\$ or MH:C11.338.204\$ or ptosis or ptoses or ptotic or ((droop\$ or sag\$ or bag\$) and (eye\$ or lid\$ or palpebral \$))) AND (MH:E04\$ or MH:VS3.003.001.006.002\$ or Blepharoplast\$ or Blefaroplast\$ or Frontalis or sling\$ or suspension\$ or surger\$ or Cirugía \$ orurgi\$ or reconstruct\$ or correction\$)

Appendix 6. ClinicalTrials.gov search strategy

blepharoptosis OR eyelid ptosis OR blepharoplasty

Appendix 7. WHO ICTRP search strategy

blepharoptosis OR eyelid ptosis OR blepharoplasty

Appendix 8. Data on study characteristics

Mandatory items		Optional items
Methods		
Study design	<ul style="list-style-type: none"> • Parallel group RCT <i>i.e. people randomized to treatment</i> • Within-person RCT <i>i.e. eyes randomized to treatment</i> • Cluster RCT <i>i.e. communities randomized to treatment</i> 	Exclusions after randomization Losses to follow up

(Continued)

	<ul style="list-style-type: none"> · Cross-over RCT · Other, specify 	Number randomized/analyzed
Eyes or	<ul style="list-style-type: none"> · One eye included in study, specify how eye selected 	How were missing data handled? e.g. available case analysis, imputation methods
Unit of randomization/ unit of analysis	<ul style="list-style-type: none"> · Two eyes included in study, both eyes received same treatment, briefly specify how analyzed (best/worst/average/both and adjusted for within person correlation/both and not adjusted for within person correlation) and specify if mixture one eye and two eye · Two eyes included in study, eyes received different treatments, specify if correct pair-matched analysis done 	Reported power calculation (Y/N), if yes, sample size and power Unusual study design/issues
Participants		
Country		Setting
Total number of participants	This information should be collected for total study population recruited into the study. If these data are only reported for the people who were followed up only, please indicate.	Ethnic group
Number (%) of men and women		Equivalence of baseline characteristics (Y/N)
Average age and age range		
Inclusion criteria		
Exclusion criteria		
Interventions		
Intervention (n=)	· Number of people randomized to this group	
Comparator (n=)	· Drug (or intervention) name	
See MECIR 65 and 70	<ul style="list-style-type: none"> · Dose · Frequency · Route of administration 	
Outcomes		
Primary and secondary outcomes as defined in study reports	List outcomes Adverse events reported (Y/N)	Planned/actual length of follow up
See MECIR R70	Length of follow up and intervals at which outcomes assessed	

CONTRIBUTIONS OF AUTHORS

- Conception and design of study: JBR, JJA, AB
- Drafting the review or commenting on it critically for intellectual content: JBR, JJA, AB
- Final approval of the document to be published: JBR, JJA, AB

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JBR: none known

JJA: none known

AB: none known

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The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS or the Department of Health.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Due to lack of data, we did not conduct any of the quantitative analyses as outlined in the protocol ([Andersen 2017](#)).

INDEX TERMS

Medical Subject Headings (MeSH)

Blepharoptosis [congenital] [*surgery]; Oculomotor Muscles [*surgery]; Randomized Controlled Trials as Topic; Treatment Outcome

MeSH check words

Child; Humans