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[Intervention Review]

Adjustable versus non-adjustable sutures for strabismus

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ABSTRACT

Background

Strabismus, or squint, can be defined as a deviation from perfect ocular alignment and can be classified in many ways according to its aetiology and presentation. Treatment can be broadly divided into medical and surgical options, with a variety of surgical techniques being available, including the use of adjustable or non-adjustable sutures for the extraocular muscles. There exists an uncertainty as to which of these techniques produces a better surgical outcome, and an opinion that the adjustable suture technique may be of greater benefit in certain situations.

Objectives

To determine if either an adjustable suture or non-adjustable suture technique is associated with a more accurate long-term ocular alignment and to identify specific situations in which it would be of benefit to use a particular method.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (which contains the Cochrane Eyes and Vision Trials Register) (2017, Issue 5); Ovid MEDLINE; Ovid Embase; LILACS; the ISRCTN registry; ClinicalTrials.gov and the ICTRP. The date of the search was 13 June 2017. We contacted experts in the field for further information.

Selection criteria

We included only randomised controlled trials (RCTs) comparing adjustable to non-adjustable sutures for strabismus surgery.

Data collection and analysis

We used standard procedures recommended by Cochrane. Two review authors independently screened search results and extracted data. We graded the certainty of the evidence using the GRADE approach.

Main results

We identified one RCT comparing adjustable and non-adjustable sutures in primary horizontal strabismus surgeries in 60 children aged less than 12 years in Egypt. The study was not masked and we judged it at high risk of detection bias. Ocular alignment was defined as orthophoria or a horizontal tropia of 8 prism dioptres (PD) or less at near and far distances. At six months, there may be a small increased chance of ocular alignment with adjustable sutures compared with non-adjustable sutures clinically, however, the confidence intervals (CIs) were wide and were compatible with an increased chance of ocular alignment in the non-adjustable sutures group, so there was no statistical difference (risk ratio (RR) 1.18, 95% CI 0.91 to 1.53). We judged this to be low-certainty evidence, downgrading for imprecision and risk of bias. At six months, 730 per 1000 children in the non-adjustable sutures group had ocular alignment. The study authors reported that there were no complications during surgery. The trials did not assess patient satisfaction and resource use and costs.

Authors' conclusions

We could reach no reliable conclusions regarding which technique (adjustable or non-adjustable sutures) produced a more accurate long-term ocular alignment following strabismus surgery or in which specific situations one technique is of greater benefit than the other, given the low-certainty and chance with just the one study. More high-quality RCTs are needed to obtain clinically valid results and to clarify these issues. Such trials should ideally 1. recruit participants with any type of strabismus or specify the subgroup of participants to be studied, for example, thyroid, paralytic, non-paralytic, paediatric; 2. randomise all consenting participants to have either adjustable or non-adjustable surgery prospectively; 3. have at least six months of follow-up data; and 4. include reoperation rates as an outcome measure.

PLAIN LANGUAGE SUMMARY

Adjustable versus non-adjustable sutures for strabismus (squint) surgery

What is the aim of this review?

The aim of this Cochrane Review was to find out if adjustable sutures (stitches) are better than non-adjustable sutures for strabismus (squint) surgery. Cochrane researchers collected and analysed all relevant studies to answer this question and found one study.

Key messages

The review shows that there is an evidence gap on this topic. The Cochrane researchers found only one small study to answer this question and the results were uncertain.

What was studied in the review?

Strabismus occurs when the eye deviates (moves) from its normally perfect alignment. This is commonly known as a squint. Strabismus can be corrected by surgery on the muscles surrounding the eye. A variety of surgical techniques are available, including the use of adjustable or non-adjustable sutures. There is uncertainty as to which of these suture techniques results in a better alignment of the eye and whether there are any disadvantages to the techniques.

What are the main results of the review?

Cochrane researchers found one relevant study from Egypt. Sixty children under the age of 12 years took part in the study which compared adjustable with non-adjustable sutures and followed participants for six months.

Clinically, there may be a small increased chance of a successful outcome with adjustable sutures, but the results showed no statistical difference. The Cochrane researchers judged this to be low-certainty evidence.

How up-to-date is this review?

Cochrane researchers searched for studies that had been published up to 13 June 2017.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Adjustable compared with non-adjustable sutures for strabismus

Adjustable compared with non-adjustable sutures for strabismus

Patient or population: people with strabismus

Settings: eye hospital

Intervention: adjustable sutures

Comparison: non-adjustable sutures

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Non-adjustable sutures	Adjustable sutures				
Ocular alignment at 6 months (orthophoria less than 8 prism dioptres)	730 per 1000	861 per 1000 (664 to 1000)	RR 1.18 (0.91 to 1.53)	60 (1)	⊕⊕⊕⊕ Low¹	-
Number and type of postoperative complications/adverse effects	Reported no complications.					
Resource use and costs	Not reported.					
Participant satisfaction	Not reported.					

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) 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.

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 effect, but there is a possibility that it is substantially different.

Low-certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.

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.

¹Downgraded one level for risk of bias and one level imprecision.

BACKGROUND

Description of the condition

Strabismus, or squint, can be defined as a deviation from perfect ocular alignment. Normally, under binocular viewing conditions, the image of an object of regard falls simultaneously on the fovea of each eye. In strabismus misalignment may be in any direction, with the image falling on an extrafoveal area in the deviating eye.

The classification of strabismus is potentially exhaustive. Examples include manifest versus latent strabismus depending on the conditions under which the strabismus is present (latent strabismus is present only after binocular vision has been interrupted), and paralytic versus non-paralytic (with the former occurring as a result of damage to extraocular muscles or the nerves supplying them). There are also numerous ways of identifying the type and severity of strabismus. Methods to help identify the type of strabismus include the cover/uncover test and alternate cover tests, with prism testing giving a more objective measure of the degree of deviation.

Strabismus is present in approximately 4% of children (Vaughan 1998), and ideally treatment should be started as soon as the diagnosis is made to develop binocular visual function and ensure visual acuity. However, there are cases that for various reasons are not treated in childhood or develop in adulthood (especially paralytic types).

Description of the intervention

Current methods of treating strabismus can be separated into non-surgical and surgical options. Non-surgical options include the use of optical devices (e.g. spectacles, prisms), pharmacological therapies (e.g. miotic agents and botulinum toxin) and occlusion (patch) therapy.

Surgical procedures for strabismus are usually performed with the intention of restoring binocular single vision or improving cosmetic appearance. Various surgical techniques are available for correcting strabismus, with perhaps the simplest procedures being resection and recession of the eye muscles. Here, the eye muscles are strengthened by shortening them or weakened by lengthening them. Other important variables in strabismus surgery include the:

1. eye muscle to be adjusted;
2. amount of muscle adjustment;
3. suture material; and
4. suture technique.

For suture technique, the choice lies between adjustable and non-adjustable sutures. When using adjustable sutures, the eye muscle is reattached to the sclera with a knot that can then be adjusted so that the eye position can be altered as indicated by cover testing. This adjustment is usually carried out under topical anaesthesia after the person has recovered sufficiently from the general anaesthesia. This method is not usually performed in children under the age of 12 years due to difficulties with co-operation. With non-adjustable sutures, any adjustment is made while the person is still under general anaesthesia and ocular adjustment is dependent solely on examination of the corneal light reflexes (after preoperative calculations).

How the intervention might work

The primary purpose of using adjustable sutures is to obtain a more accurate ocular alignment therefore decreasing the need for reoperation (which would be needed if an error in correction occurred using non-adjustable sutures). Another difficulty with using non-adjustable sutures is that the resting position of the eyes is affected by general anaesthesia (Apt 1977).

The advantages of an adjustable technique are thought to be most apparent when the results of conventional surgery are unpredictable. Specific situations include reoperations, large-angle squints, thyroid eye disease, blow-out fractures, diplopia following retinal detachment surgery and paralytic squints (Morris 1992). This may be due to extra scarring, tethering or contracture of extraocular muscles in these cases. Combined horizontal and vertical muscle procedures are also thought to benefit from the adjustable suture technique. A possible drawback of the adjustable suture method is that there is evidence for a poor correlation between the results of realignment at one day and at one month (van Noorden 1980). This is possibly due to alterations in the motor drive to the muscles following realignment.

Why it is important to do this review

There is uncertainty as to whether the use of an adjustable or non-adjustable suture technique produces a more accurate long-term ocular alignment and in which specific situation(s) one of the methods may be of greater benefit. A systematic review is needed to assess and clarify these issues.

OBJECTIVES

To determine if either an adjustable suture or non-adjustable suture technique is associated with a more accurate long-term ocular alignment and to identify specific situations in which it would be of benefit to use a particular method.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials (RCTs).

Types of participants

We included trials in participants of any age. Their ability to co-operate with postoperative adjustment was reported. Participants with any type and severity of strabismus, and with simultaneous ocular disease were included.

Types of interventions

We included trials in which the use of adjustable sutures was compared to non-adjustable sutures. We included adjustments at any time following surgery and any adjustable suture technique was accepted.

Types of outcome measures

Primary outcomes

1. Ocular alignment at six months. Accuracy was defined as the difference in ocular position at six months compared to the intended postoperative alignment. Any method of measuring

ocular alignment was accepted. The units of deviation were measured in prism dioptres (PD).

Secondary outcomes

1. Number and type of postoperative complications/adverse effects with either method such as:
 - a. diplopia;
 - b. haemorrhage;
 - c. scleral perforation;
 - d. anterior segment ischaemia;
 - e. lost muscles;
 - f. subconjunctival cysts;
 - g. stitch reactions,
2. Resource use and costs (e.g. length of stay in hospital, hours of surgeons' time).
3. Participant satisfaction: discomfort during adjustment using any validated measurement scale that aimed to measure participant satisfaction with a procedure.

Search methods for identification of studies

Electronic searches

The Cochrane Eyes and Vision Information Specialist conducted systematic searches in the following databases for randomised controlled trials and controlled clinical trials. There were no language or publication year restrictions. The date of the search was 13 June 2017.

1. Cochrane Central Register of Controlled Trials (CENTRAL; 2017, Issue 5) (which contains the Cochrane Eyes and Vision Trials Register) in the Cochrane Library (searched 13 June 2017) ([Appendix 1](#));
2. MEDLINE Ovid (1946 to 13 June 2017) ([Appendix 2](#));
3. Embase Ovid (1980 to 13 June 2017) ([Appendix 3](#));
4. LILACS (Latin American and Caribbean Health Science Information database (1982 to 13 June 2017) ([Appendix 4](#));
5. ISRCTN registry (www.isrctn.com/editAdvancedSearch; searched 13 June 2017) ([Appendix 5](#));
6. US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov; searched 13 June 2017) ([Appendix 6](#));
7. World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictip; searched 13 June 2017) ([Appendix 7](#)).

Searching other resources

We did not handsearch journals or conference proceedings specifically for this review. We searched the reference list of the included study to identify any other potentially relevant studies.

Data collection and analysis

Selection of studies

Two review authors independently screened the titles and abstracts obtained by the electronic searches and obtained full-text copies of definitely or potentially relevant studies. Where a trial was not fully reported, we contacted the authors to obtain as much data as possible.

Data extraction and management

We extracted the following information from each study using a data extraction form and entered the data into the [Characteristics of included studies](#) table of the review using Review Manager 5 ([RevMan 2014](#)).

1. Methods: methods of allocation, losses to follow-up, unusual study design.
2. Participants: age, co-operation, type and severity of strabismus, presence of coexisting ocular disease.
3. Interventions: adjustable or non-adjustable sutures used, length to follow-up.
4. Outcomes: difference between intended and actual ocular alignment at six months, occurrence of postoperative complications, economics of both methods and participant discomfort during procedure.

In addition, we extracted the following data from each study.

1. Ocular alignment: difference between intended and actual alignment at six months. We extracted the mean and standard deviation. If the data were not normally distributed, we recorded the number of participants who had actual alignment within less than 5 dioptres, 5 dioptres to 10 dioptres, or more than 10 dioptres from the intended alignment.
2. Occurrence of postoperative complications: the proportion of participants who experienced specific complications in each suture technique group.
3. Economics of both methods: details about length of hospital admission and hours of surgeons' time.
4. Participant satisfaction: details about discomfort during procedure, using a validated scale.

Assessment of risk of bias in included studies

Two review authors independently assessed the risk of bias of the included trial according to Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* using the following parameters ([Higgins 2011](#)): sequence generation, allocation sequence concealment, incomplete outcome data and selective outcome reporting. We judged each parameter and assessed included studies as 'high,' 'low' or 'unclear' for levels of bias. We contacted study authors for further information on any parameter graded as 'unclear.' We resolved discrepancies by discussion.

Measures of treatment effect

For dichotomous outcomes, we used the risk ratio (RR) and 95% confidence interval (CI). For continuous measures, for example, patient satisfaction, we planned to use the mean difference and 95% CI.

Unit of analysis issues

We used the data as reported by the included study which assessed surgery on 115 eyes of 60 children. The only relevant review outcome available from that study was for the person (orthophoria) so a unit of analysis issue did not apply.

Dealing with missing data

We used data as reported by the included study. All children included were followed up.

Assessment of heterogeneity

We planned to check for heterogeneity among studies to consider whether a meta-analysis was appropriate by examining the:

1. characteristics of the study;
2. forest plot of results of the study;
3. results of the Chi² test for heterogeneity.

If heterogeneity had been detected, we planned to report the outcomes presented for any trial.

Assessment of reporting biases

If we had included a sufficient number of trials in the review, we planned to use a funnel plot to assess for publication bias.

Data synthesis

For dichotomous data, we presented the RR and 95% CI. We used the fixed-effect model if there were fewer than three trials and no detected heterogeneity. If there had been more than three trials and no heterogeneity, we planned to use the random-effects model. We planned to summarise data from studies collecting similar continuous outcome measures with similar follow-up times using the mean difference (as long as the data were normally distributed).

Sensitivity analysis

We planned to conduct sensitivity analysis to assess the effects of including trials with a 'high' risk of bias on any parameter and we use appropriate caution when interpreting data from such trials.

'Summary of findings' table

For the 2018 update, in line with updated Cochrane methods, we prepared a 'Summary of findings' table and assessed the certainty

of the evidence using the GRADE approach ([GRADEpro GDT 2015](#)). One review author (SH) did the GRADE assessment with advice from the Cochrane Eyes and Vision Editorial Base and discussed this with the other review authors. The GRADE assessment considered the precision and directness of the effect estimate, and the risk of bias of the included study.

RESULTS

Description of studies

Results of the search

The electronic searches ran in July 2004 identified 211 reports of studies on strabismus surgery. We obtained full-text copies for 11 reports and after further assessment all were excluded.

Updated searches

The electronic searches were updated in September 2010 and 62 new reports of studies were identified. We obtained the full-text copies for two reports but neither met the inclusion criteria.

An update search in January 2013 identified a further 43 references. The Trials Search Co-ordinator removed 10 duplicates, scanned 33 references and removed 10 records that were not relevant to the scope of the review. We screened the remaining 23 references but found no trials that met the inclusion criteria for the review.

Update searches run in June 2017 yielded a further 93 records ([Figure 1](#)). After removing 25 duplicates, the Cochrane Information Specialist screened the remaining 68 records and removed 61 references that were not relevant to the review. We screened the remaining seven references and obtained one full-text report for further assessment. This study met the inclusion criteria and was added to the review ([Kamal 2016](#)). See [Characteristics of included studies](#) for details.

Figure 1. Study flow diagram.

Included studies

For the 2017 update, we identified one RCT for inclusion that compared adjustable and non-adjustable sutures in primary horizontal strabismus surgeries in children ([Kamal 2016](#)).

Excluded studies

We excluded 13 reports after reviewing the full-text copies. One study was a prospective controlled trial comparing adjustable to non-adjustable sutures for strabismus surgery, but the participants were not randomised ([Tripathi 2003](#)). One study was reported by the authors as being a randomised trial ([Altintas 2006](#)). However, on further inspection there were no details of any clear method of randomisation and we were unable to contact the authors

for clarification. In this study of 88 participants, 16/17 complex participants (with paralysis or previous strabismus surgery) were in the adjustable surgery group. Also, the younger participants who generally do not tolerate adjustment, fell into the conventional (fixed suture) group. This distribution of participants between groups seems unlikely if there was true randomisation. For this reason, we excluded this trial from the review but will reassess if further information regarding randomisation becomes available. One report was not a trial ([Apt 2002](#)). The remaining studies were all retrospective. See the [Characteristics of excluded studies](#) table for more information.

Risk of bias in included studies

We assessed the risk of bias in the included study (Kamal 2016). See: [Figure 2](#).

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

Allocation

There was a relatively low risk of selection bias given the authors clearly described randomly allocating participants using a random number generator. However, allocation concealment was not clearly described.

Blinding

Masking (blinding) was not mentioned within the study and may have been problematic given the nature of the interventions. The extent to which this would affect performance bias was unclear, but we judged that it might well have had an impact on detection bias.

Incomplete outcome data

There was a low risk of attrition bias as no participants dropped out.

Selective reporting

It was difficult to assess reporting bias as we did not have access to a study protocol and the trial was not registered.

Effects of interventions

See: [Summary of findings for the main comparison Adjustable compared with non-adjustable sutures for strabismus](#)

Primary outcome

Ocular alignment at six months

The study authors defined a successful motor outcome as orthophoria or a horizontal tropia of 8 PD or less at both near and far distances at six months.

The study reported that 26/30 (87%) participants had a successful motor outcome compared with 22/30 (73%) participants in the adjustable sutures group (RR 1.18, 95% CI 0.91 to 1.53; [Analysis 1.1; Figure 3](#)). We judged this to be low-certainty evidence downgrading for risk of bias and imprecision ([Summary of findings for the main comparison](#)).

Figure 3. Forest plot of comparison: 1 Adjusted versus non-adjustable sutures, outcome: 1.1 Successful alignment at 6 months (orthophoria less than 8 prism dioptres).

Secondary outcomes

Number and type of postoperative complications/adverse effects

The included study did not report any postoperative complications or adverse effects; however, there were no complications recorded during adjustment.

Resource use and costs

The included study did not report resource use and costs.

Participant satisfaction

The included study did not report participant satisfaction.

DISCUSSION

Summary of main results

We identified one RCT comparing adjustable and non-adjustable sutures in primary horizontal strabismus surgeries in children aged less than 12 years in Egypt. The study was not masked and we judged it at high risk of detection bias. Ocular alignment was defined as orthophoria or a horizontal tropia of 8 PD or less at near and far distances. At six months, there may be a small increased chance of ocular alignment with adjustable sutures compared with non-adjustable sutures clinically however, the CIs were wide and were compatible with an increased chance of ocular alignment in the non-adjustable sutures group, so there was no statistical difference (RR 1.18, 95% CI 0.91 to 1.53). We judged this low-certainty evidence, downgrading for imprecision and risk of bias. At six months, 730 per 1000 children in the non-adjustable sutures group had ocular alignment in this study. The study did not report adverse effects and participant satisfaction.

Overall completeness and applicability of evidence

Overall, the review was not complete as there was only one small study (60 children) in Egypt. However, the review is applicable clinically given the study population was as expected in practice and the procedures used were clinically relevant, despite not reaching a statistically significant result between adjustable and non-adjustable sutures.

Certainty of the evidence

Despite the study being an RCT, we assessed the certainty as low. The reasons for this were because the study was at risk of bias given masking was not performed, and, as the study was small, the effect estimate was imprecise.

Potential biases in the review process

We attempted to minimise errors and biases in the review processes by performing duplicate screening and data extraction.

Agreements and disagreements with other studies or reviews

There were very few studies that directly compared the two techniques. These were retrospective non-randomised trials, generally limited by small participant numbers.

We found one large, prospective, controlled clinical trial with non-random allocation (Tripathi 2003). The study reported 443 operations on adolescents and adults with any type and amount of strabismus who had surgery with either adjustable sutures (141 participants) or non-adjustable sutures (302 participants). The authors studied three outcome measures (reoperation rates, participant satisfaction with regard to final cosmetic appearance or relief of diplopia, and percentage change in angle of deviation). The study demonstrated a better result in the group who had adjustable sutures on all three outcome measures (reoperation rates were 8.51% in the adjustable group compared to 27.15% in the non-adjustable group). In addition, the trial authors reported that age, sex, number of previous surgeries, previous treatments such as botulinum toxin, type or amount of deviation, had no influence on the final outcome in their participants. The authors suggested that adjustable sutures need not be reserved for the more unpredictable or complex cases of strabismus (i.e. situations in which the use of adjustable sutures is commonly thought to be advantageous). However, participants were not randomised and the method of allocation to treatment was unclear (in particular, the reasons for the majority of participants declining the adjustable suture technique were not given). Methods used (if any) to reduce detection bias, were also not reported. In addition, information regarding the profile of the two participant groups was not available; for example, whether people with thyroid ophthalmopathy were present in either group. All reoperations in the adjustable suture group were for undercorrections; however, it was unclear whether any of these participants originally underwent inferior rectus recessions. This is relevant as we know from the literature that this adjustable suture subgroup of participants tended to develop overcorrection following inferior rectus recession.

In terms of accuracy of long-term ocular alignment, we found studies supporting the benefit of the adjustable technique over the non-adjustable technique (Awadein 2008; Broniarczyk 2003; Tripathi 2003), with others suggesting the non-adjustable method was more advantageous (Correa 1998; Vazquez 1999), and some studies reporting the techniques to be equally effective (Altintas

2006; Bishop 2004; Kono 2000; Kraus 1993; Mohan 1998; Park 2009; Yanovitch 2009).

In terms of whether one technique was superior in specific situations, we found very few studies that directly compared the two techniques. Two articles looked at people with thyroid disease and vertical squints (Kono 2000; Kraus 1993), but neither of these studies individually showed a significant benefit of using a particular technique. Although when pooling their results with those of others, there was a significant improvement in outcome with adjustable sutures (Kraus 1993). The adjustable suture technique is commonly thought to be of benefit in producing more accurate alignment in unpredictable cases. However, the largest study identified in this review, Tripathi 2003, also argued that there is a role for adjustable sutures in more conventional cases. In contrast to this, one retrospective case-matched study of people with non-thyroid eye disease reported no significant differences in success rates between either technique, and concluded that there was insufficient evidence that people without thyroid eye disease benefited from the longer and potentially uncomfortable procedure of adjustable suture surgery (Bishop 2004). One large study looked at the use of the adjustable technique in children under 10 years of age with a variety of squints (Awadein 2008). The authors performed adjustments under topical anaesthesia or intravenous propofol and found the adjustable technique to be superior in terms of early (three months) postoperative alignment. This challenges the conventional view that adjustable suture surgery should be reserved for older people who are likely to be more co-operative.

Patient satisfaction (Tripathi 2003) and relief from diplopia (Broniarczyk 2003; Tripathi 2003) were outcome measures and there were better results with the adjustable technique. No trials formally studied economics of either method.

It is noteworthy that many reports used reoperation rates as an outcome measure and the review authors acknowledge this should subsequently be used as the primary outcome measure should further studies become available for inclusion in this review. This is particularly important as accurate ocular alignment does not necessarily correlate with the optimal result as far as the patient is concerned and, therefore, will not necessarily correlate with reoperation rates.

AUTHORS' CONCLUSIONS

Implications for practice

There was only one randomised controlled trial comparing adjustable and non-adjustable sutures. This study showed a small increased chance of improvement with adjustable sutures, but the evidence was low certainty due to risk of bias (study was not masked) and imprecision (confidence intervals included no effect).

Other studies that directly compare adjustable and non-adjustable suture techniques are available; however, these are non-randomised, few in number, mainly retrospective, and difficult to compare as a result of marked clinical heterogeneity.

Therefore, reliable conclusions cannot be drawn concerning which technique produces a better long-term ocular alignment or in which conditions one technique is more appropriate than the other.

Implications for research

High-quality randomised controlled clinical trials are certainly feasible in this area and this review has demonstrated a need for them in order to produce clinically valid results. In such a study, participants with any type of strabismus may be recruited and those participants agreeable to having either the adjustable or non-adjustable suture technique could then be randomised using acceptable methods to either technique. We suggest that trials should have a minimum of six months' follow-up and should include important outcome measures such as reoperation rates, accuracy of ocular alignment, complications, economics and participant satisfaction. The researchers measuring outcomes should be masked as to which type of suture technique was used. Masking of surgeons would not be possible and masking participants would be extremely difficult. It is clear from these results that well-planned clinical trials could greatly improve the evidence base in this area, potentially producing a change in the conventional surgical management of strabismus.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Kamal 2016

Methods	Randomised controlled trial.
Participants	Children aged < 12 years presenting with any type of primary horizontal strabismus and scheduled for surgery. Included children with vertical deviations, but only studied the horizontal component.
Interventions	<p>115 eyes of 60 children with any type of primary horizontal strabismus (sample calculation formula was not used) divided using a random number generator into adjustable suture group or non-adjustable suture group.</p> <p>Adjustable suture group: 57 eyes of 30 participants.</p> <p>Non-adjustable suture group: 58 eyes of 30 participants.</p> <p>Cases recruited between June 2012 and June 2014.</p>
Outcomes	<p>Ocular alignment assessed and successful motor outcome was defined as orthophoria or a horizontal tropia of ≤ 8 prism dioptres at near and far distances. Results reported ignoring within-person correlation of other eye.</p> <p>Follow-up: ≥ 6 months after surgery (initially at 1 week, 1 month, 3 months and 6 months).</p>
Notes	<p>"The authors declare no conflict of interests."</p> <p>Study approved by Cairo University and Beni Suef University Research Ethics Committee. Research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors. No trial registration number.</p> <p>We contacted the author for further data but received no reply.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	<p>Quote: "patients were randomly divided using a random number generator."</p> <p>Comment: most likely done as the report clearly described using random allocations in other areas in the paper.</p>
Allocation concealment (selection bias)	Unclear risk	<p>Quote: "randomly divided using a random number generator."</p> <p>Comment: no further comments regarding this made by the author.</p>

Kamal 2016 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Masking was not mentioned, though it may be near impossible given this involves a surgical procedure. Unclear impact this would have had on participants.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Masking was not mentioned, though it may be near impossible given this involves a surgical procedure. Outcomes assessors were not masked to treatment group.
Incomplete outcome data (attrition bias) All outcomes	Low risk	None of the participants dropped out.
Selective reporting (reporting bias)	Unclear risk	Difficult to assess as no trial number was available.

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

Study	Reason for exclusion
Altintas 2006	Non-randomised trial.
Apt 2002	Analysis, not a trial.
Awadein 2008	Retrospective study.
Bishop 2004	Non-randomised retrospective study.
Broniarczyk 2003	Non-randomised study.
Correa 1998	Non-randomised retrospective study.
Kono 2000	Non-randomised retrospective study.
Kraus 1993	Non-randomised retrospective study.
Mohan 1998	Non-randomised retrospective study.
Park 2009	Retrospective study.
Tripathi 2003	Prospective controlled clinical study of 443 participants; however, participants were not randomised to treatment.
Vazquez 1999	Non-randomised retrospective study.
Yanovitch 2009	Retrospective study.

DATA AND ANALYSES

Comparison 1. Adjusted versus non-adjustable sutures

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Successful alignment at 6 months (orthophoria less than 8 prism dioptres)	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

Analysis 1.1. Comparison 1 Adjusted versus non-adjustable sutures, Outcome 1 Successful alignment at 6 months (orthophoria less than 8 prism dioptres).

Study or subgroup	Adjustable n/N	Non-adjustable n/N	Risk Ratio M-H, Fixed, 95% CI					Risk Ratio M-H, Fixed, 95% CI	
Kamal 2016	26/30	22/30						1.18[0.91,1.53]	
			Favours non-adjustable	0.01	0.1	1	10	100	Favours adjustable

APPENDICES

Appendix 1. CENTRAL search strategy

#1 MeSH descriptor Strabismus
#2 strabism* OR squint*
#3 (#1 OR #2)
#4 MeSH descriptor Sutures
#5 suture*
#6 (#4 OR #5)
#7 (#3 AND #6)

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 or/1-7
9 exp animals/
10 exp humans/
11 9 not (9 and 10)
12 8 not 11
13 exp strabismus/
14 (strabism\$ or squint\$).tw.
15 or/13-14
16 exp sutures/
17 suture\$.tw.
18 or/16-17
19 15 and 18
20 12 and 19

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

Appendix 3. Embase Ovid search strategy

1 exp randomized controlled trial/

Adjustable versus non-adjustable sutures for strabismus (Review)

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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.
 9 7 and 8
 10 7 not 9
 11 6 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/
 21 exp 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 strabismus/
 34 (strabism\$ or squint\$).tw.
 35 or/33-34
 36 exp suture/
 37 suture\$.tw.
 38 or/36-37
 39 35 and 38
 40 32 and 39

Appendix 4. LILACS search strategy

strabism\$ or squint\$ and suture\$

Appendix 5. ISRCTN search strategy

strabismus AND sutures

Appendix 6. ClinicalTrials.gov search strategy

(Strabismus OR Squint) AND Sutures

Appendix 7. WHO ICTRP search strategy

Strabismus = Condition AND Sutures = Intervention

WHAT'S NEW

Date	Event	Description
13 June 2017	New search has been performed	Issue 3, 2018: Electronic searches were updated.

Date	Event	Description
13 June 2017	New citation required but conclusions have not changed	Issue 3, 2018: One new trial included (Kamal 2016).

HISTORY

Protocol first published: Issue 2, 2003

Review first published: Issue 1, 2005

Date	Event	Description
26 June 2013	New citation required but conclusions have not changed	Issue 7, 2013: No trials met the inclusion criteria.
26 June 2013	New search has been performed	Issue 7, 2013: Electronic searches were updated.
5 November 2010	New search has been performed	Issue 12, 2010: An updated search yielded no new trials for inclusion. One trial was excluded due to the uncertainty of randomisation.
20 August 2008	Amended	Converted to new review format.
12 September 2004	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Conceiving the review: VS.

Designing the review: VS, AH, SH.

Co-ordinating the review: AH.

Data Collection for the review: SH, AH, VS.

Screening search results: SH, AH, VS.

Organising retrieval of papers: SH, AH.

Screening retrieved papers against inclusion criteria: AH, VS.

Appraising quality of papers: SH, AH, VS.

Abstracting data from papers: SH, AH, VS.

Writing to authors of papers for additional information: AH.

Obtaining and screening data on unpublished studies: AH, VS.

Data management for the review: SH, AH, VS.

Entering data into Review Manager 5: VS, AH, SH.

Analysis of data: SH, AH, VS.

Interpretation of data: SH, AH, VS.

Writing the review: VS, AH, SH.

DECLARATIONS OF INTEREST

SH: none known.

AH: none known.

VS: none known.

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Internal sources

- No sources of support supplied

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Due to updates in Cochrane methods, the 2018 version includes a 'Summary of findings' table and GRADE assessment that was not considered at the protocol stage.

We added a third review author to the review team (Shoaib Hassan).

INDEX TERMS

Medical Subject Headings (MeSH)

*Suture Techniques; Strabismus [*surgery]; Treatment Outcome

MeSH check words

Child; Humans