Adjustable versus non-adjustable sutures for strabismus (Review)

Haridas A, Sundaram V

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Adjustable versus non-adjustable sutures for strabismus (Review)

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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 also an opinion that the adjustable suture technique may be of greater benefit in certain situations.

Objectives

To examine whether adjustable or non-adjustable sutures are associated with a more accurate long-term ocular alignment following strabismus surgery and to identify any specific situations in which it would be of benefit to use a particular method.

Search methods

We searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (The Cochrane Library 2010, Issue 3), MEDLINE (January 1950 to September 2010), EMBASE (January 1980 to September 2010), Latin American and Caribbean Literature on Health Sciences (LILACS) (January 1982 to September 2010), the metaRegister of Controlled Trials (mRCT) (www.controlled-trials.com) and ClinicalTrials.gov (www.clinicaltrials.gov). There were no date or language restrictions in the electronic searches for trials. The electronic databases were last searched on 27 September 2010. We also contacted experts in the field for further information.

Selection criteria

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

Data collection and analysis

We did not find any studies that met the inclusion criteria for this review.

Main results

We did not find any studies that met the inclusion criteria for this review, therefore none were included for analysis. Results of non-randomised studies that compared these techniques are reported.
Authors’ conclusions

No reliable conclusions could be reached regarding which technique (adjustable or non-adjustable sutures) produces a more accurate long-term ocular alignment following strabismus surgery or in which specific situations one technique is of greater benefit than the other. High quality RCTs are needed to obtain clinically valid results and to clarify these issues. Such trials should ideally a) recruit participants with any type of strabismus or specify the subgroup of participants to be studied, for example, thyroid, paralytic, non-paralytic, paediatric; b) randomise all consenting participants to have either adjustable or non-adjustable surgery prospectively; c) have at least six months of follow-up data; and d) include re-operation rates as a primary outcome measure.

Plain Language Summary

Adjustable versus non-adjustable sutures for the eye muscles in strabismus surgery

Strabismus occurs when the eye deviates from its normally perfect alignment, and can be corrected with surgery. A variety of surgical techniques are available, including the use of adjustable or non-adjustable sutures for the muscles surrounding the eye. There is uncertainty as to which of these suture techniques results in a more accurate alignment of the eye, and whether there are specific situations in which it is of benefit to use a particular technique. This review could not find enough evidence to answer these questions and suggests that more research is needed. The review authors used existing evidence to propose that future randomised controlled trials should directly compare the adjustable to the non-adjustable suture technique, in co-operative patients with any type of strabismus. Trials should have a minimum of six months follow-up and should include important outcome measures such as re-operation rates, accuracy of ocular alignment, complications, economics and patient satisfaction. The information generated from well-designed studies could support a change in the conventional surgical management of strabismus and help to direct planning of surgical training.

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 extra-foveal 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 in order to develop binocular visual function and ensure visual acuity. There are, however, 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 (for example spectacles, prisms), pharmacological therapies (for example 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 or weakened by either shortening or lengthening them respectively. Other important variables in strabismus surgery include:

a. the eye muscle to be adjusted;
b. the amount of muscle adjustment;
c. the suture material; and
d. the 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 which 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 patient has recovered sufficiently from the general anaesthesia. This method is not usually performed in children under the age of 12 due to difficulties with co-operation. With non-adjustable sutures any adjustment is made whilst the patient is still under general anaesthesia and ocular adjustment is dependent solely on examination of the corneal light reflexes (after pre-operative 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 re-operation (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 re-operations, 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 also 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
The aims of this review were 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.
2. Economics of either method (for example length of stay in hospital, hours of surgeons’ time).
3. Patient satisfaction with either method: discomfort during adjustment - any validated measurement scale that aims to measure patient satisfaction with a procedure was used.

Search methods for identification of studies

Electronic searches
We searched the Cochrane Central Register of Controlled Trials (CENTRAL) 2010, Issue 3, part of The Cochrane Library. www.thecochranelibrary.com (accessed 27 September 2010), MEDLINE (January 1950 to September 2010), EMBASE (January 1980 to September 2010), Latin American and Caribbean Literature on Health Sciences (LILACS) (January 1982 to September 2010), the metaRegister of Controlled Trials (mRCT) (www.controlled-trials.com) and ClinicalTrials.gov (www.clinicaltrials.gov). There were no date or language restrictions in the electronic searches for trials. The electronic databases were last searched on 27 September 2010.

See: Appendices for details of search strategies for CENTRAL (Appendix 1), MEDLINE (Appendix 2), EMBASE (Appendix 3), LILACS (Appendix 4), mRCT (Appendix 5) and ClinicalTrials.gov (Appendix 6).

Searching other resources
We did not handsearch journals or conference proceedings specifically for this review.

Data collection and analysis

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

Updates to the review
No studies were found which met the inclusion criteria for the review. If studies are found in the future we will use the following methods.

Data extraction and management
We will extract the following information from each study and enter in to the ‘Characteristics of included studies’ table:
1. Methods: methods of allocation, losses to follow up, unusual study design.
2. Participants: age, co-operation, type and severity of strabismus, presence of co-existing 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 patient discomfort during procedure.

In addition we will extract the following data from each study:
1. Ocular alignment: difference between intended and actual alignment at six months. The mean and standard deviation will be extracted. If the data are not normally distributed, we will record the number of patients who have actual alignment within < 5, 5 to 10 or > 10 dioptres from the intended alignment.
2. Occurrence of postoperative complications: the proportion of patients who suffer specific complications in each suture technique group will be extracted.
3. Economics of both methods: details about length of hospital admission and hours of surgeons’ time will be extracted.
4. Patient satisfaction: details about discomfort during procedure will be extracted, using a validated scale.

Assessment of risk of bias in included studies
Two authors will independently assess each study using the following parameters: sequence generation, allocation sequence concealment, incomplete outcome data and selective outcome reporting. We will not assess masking (blinding) as this will not be possible to achieve. We will judge trials on each parameter and assess them as ‘high’, ‘low’ or ‘unclear’ for levels of bias. We will contact study authors for further information on any parameter graded as ‘unclear’. We will present a comparative ‘Risk of Bias’ summary and graph across all trials. We will include trials that are graded ‘high’ risk on any of the above parameters. We will assess the effects of including such trials using a sensitivity analysis. We will resolve discrepancies by discussion.

Assessment of heterogeneity
We will check for heterogeneity amongst studies to consider whether a meta-analysis is 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 is detected, we will report the outcomes presented for any trial.
Assessment of reporting biases
If a sufficient number of trials are included in the review, we will use a funnel plot to assess for publication bias.

Data synthesis
We will summarise data from studies collecting similar continuous outcome measures with similar follow up times using the weighted mean difference (as long as the data are normally distributed). For any dichotomous data we will present the risk ratio. We will use the fixed-effect model if there are less than three trials and no heterogeneity has been detected. If there are more than three trials and no heterogeneity, then the random-effects model will be used.

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

RESULTS

Description of studies
See: Characteristics of excluded studies.

Results of the search
The electronic searches identified 211 reports of studies on strabismus surgery. The full-text copies were obtained 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.

Included studies
We did not identify any RCTs that met our inclusion criteria.

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 (Tripathi 2003). However, this study was excluded as the participants were not randomised. 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 patients, 16 out of the 17 complex patients (with paralysis or previous strabismus surgery) were in the adjustable surgery group. Also, the younger patients who generally do not tolerate adjustment, fell into the conventional (fixed suture) group. This distribution of patients between groups seems unlikely if there was true randomisation. For this reason we have excluded this trial from the review but will re-assess 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
No trials met the inclusion criteria and therefore no assessment of quality was undertaken.

Effects of interventions
No trials met the inclusion criteria for this review and therefore no meta-analysis was performed.

DISCUSSION
As this review has not identified any RCTs that directly compare non-adjustable and adjustable sutures for strabismus surgery, we will now discuss non-randomised controlled data. The few studies that did directly compare the two techniques were retrospective and generally limited by small participant numbers.

One large, prospective, controlled clinical trial almost met the inclusion criteria for this review (Tripathi 2003). This study looked at 443 participants (adolescents and adults with any type and amount of strabismus) who had surgery with either adjustable sutures (n = 141) or with non-adjustable sutures (n = 302). They studied three outcome measures (re-operation rates, patient satisfaction with regard to final cosmetic appearance or relief of diplopia, and percentage change in angle of deviation). This study demonstrated a better result in the group who had adjustable sutures on all three outcome measures (re-operation rates were 8.51% in the adjustable group compared to 27.15% in the non-adjustable group). In addition the trial authors reported that neither age, sex, number of previous surgeries, previous treatments such as botulinum toxin, type or amount of deviation, had any influence on the final outcome in their participants. They suggested that adjustable sutures need not necessarily be reserved for the more unpredictable or complex cases of strabismus (that is situations in which the use of adjustable sutures is commonly thought to be advantageous). However, as mentioned previously, participants were not randomised and method of allocation to treatment was unclear (in particular...
the reasons for the majority of patients 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 patient groups was not available; for example, whether or not patients with thyroid ophthalmopathy were present in either group. All re-operations in the adjustable suture group were for undercorrections, however, it was unclear whether any of these patients originally underwent inferior rectus recessions. This is relevant as we know from the literature that this adjustable suture subgroup of patients 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 both techniques to be equally as effective (Altintas 2006; Bishop 2004, Kono 2000; Kraus 1993, Mohan 1998; Park 2009; Yanovitch 2009).

In terms of whether one technique is superior in specific situations, we found very few studies that directly compared the two techniques. Two articles looked at patients 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, a significant improvement in outcome with adjustable sutures was found (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, a retrospective case-matched study of non-thyroid eye disease patients reported no significant differences in success rates between either technique, and concluded that there is insufficient evidence that patients without thyroid eye disease, benefit from the longer and potentially uncomfortable procedure of adjustable suture surgery (Bishop 2004). One large study recently 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 patients who are likely to be more co-operative.

Patient satisfaction (Tripathi 2003) and relief from diplopia (Broniarczyk 2003; Tripathi 2003) were reported as outcome measures and better results were demonstrated with the adjustable technique. No trials formally studied economics of either method. It is noteworthy that many reports use re-operation 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 re-operation rates.

**AUTHORS’ CONCLUSIONS**

**Implications for practice**

The available studies that directly compare adjustable and non-adjustable suture techniques are non-randomised, few in number, mainly retrospective, and difficult to compare as a result of marked clinical heterogeneity. Thus, 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 patients 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 re-operation rates, accuracy of ocular alignment, complications, economics and patient 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.

**ACKNOWLEDGEMENTS**

We are grateful to Katherine Henshaw, Anupa Shah and Sarah Hatt for their comments and help with this review. We would also like to thank John Lee, Catey Bunce and Roberta Scherer for peer reviewing this review and Liam Smeeth and Suzanne Brodney-Folse for their comments on the protocol for this review. We thank Iris Gordon for developing and executing the electronic searches for this review.
References to studies excluded from this review

Altintas 2006  {published data only}

Apt 2002  {published data only}
Apt L. Followups on the 25th anniversary of the postop’ adjustable suture (versus intraoperative adjustments based on the binocular alignment under general anesthesia) in eye muscle surgery for strabismus. *Binocular Vision & Strabismus Quarterly* 2002;17(2):80.

Awadein 2008  {published data only}

Bishop 2004  {published data only}

Broniarczyk 2003  {published data only}

Correa 1998  {published data only}

Kono 2000  {published data only}

Kraus 1993  {published data only}

Mohan 1998  {published data only}

Park 2009  {published data only}

Tripathi 2003  {published data only}

Vazquez 1999  {published data only}

Yanovitch 2009  {published data only}

Additional references

Apt 1977

Glanville 2006

Morris 1992

van Noorden 1980

Vaughan 1998

* Indicates the major publication for the study
### Characteristics of Excluded Studies

**Characteristics of excluded studies**  *(ordered by study ID)*

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</tr>
<tr>
<td>Park 2009</td>
<td>This was a retrospective study.</td>
</tr>
<tr>
<td>Tripathi 2003</td>
<td>This was a prospective controlled clinical study of 443 patients, however, patients were not randomised to treatment</td>
</tr>
<tr>
<td>Vazquez 1999</td>
<td>This was a non-randomised retrospective study.</td>
</tr>
<tr>
<td>Yanovitch 2009</td>
<td>This was a retrospective study.</td>
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DATA AND ANALYSES

This review has no analyses.

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 et al (Glanville 2006).
Appendix 3. EMBASE (OVID) search strategy

1 exp randomized controlled trial/
2 exp randomization/
3 exp double blind procedure/
4 exp single blind procedure/
5 random$.tw.
6 or/1-5
7 (animal or animal experiment).sh.
8 human.sh.
9 7 and 8
10 7 not 9
11 6 not 10
12 exp clinical trial/
13 (clin$ 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 propspectiv$ 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. metaRegister of Controlled Trials search strategy**

strabismus AND sutures

**Appendix 6. ClinicalTrials.gov search strategy**

(Strabismus OR Squint) AND Sutures

**WHAT’S NEW**

Last assessed as up-to-date: 26 September 2010.

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**HISTORY**


Review first published: Issue 1, 2005

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**CONTRIBUTIONS OF AUTHORS**

Conceiving the review: VS

Designing the review: VS, AH

Co-ordinating the review: AH

Data Collection for the review: AH, VS

Screening search results: AH, VS

Organising retrieval of papers: AH

Screening retrieved papers against inclusion criteria: AH, VS
Appraising quality of papers: AH, VS
Abstracting data from papers: 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: AH, VS
Entering data into RevMan: VS, AH
Analysis of data: AH, VS
Interpretation of data: AH, VS
Writing the review: VS, AH

DECLARATIONS OF INTEREST

None known.

NOTES

As of 2010, Issue 12, the co-author Anjana Haridas has now taken the lead on this review and the lead author of the original review Venki Sundaram has now become the co-author.

INDEX TERMS

Medical Subject Headings (MeSH)
*Suture Techniques; Strabismus [*surgery]

MeSH check words
Humans