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Extraction of primary (baby) teeth for unerupted palatally displaced permanent canine teeth in children (Review)

Parkin N, Furness S, Shah A, Thind B, Marshman Z, Glenroy G, Dyer F, Benson PE

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[Intervention Review]

Extraction of primary (baby) teeth for unerupted palatally displaced permanent canine teeth in children

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ABSTRACT

Background

The permanent canine tooth in the maxillary (upper) jaw sometimes does not erupt into the mouth correctly. In about 1% to 3% of the population these teeth will be diverted into the roof of the mouth (palatally). It has been suggested that if the primary canine is removed at the right time this palatal eruption might be avoided. This is an update of a Cochrane review first published in 2009.

Objectives

To evaluate the effect of extracting the primary maxillary canine on the eruption of the palatally ectopic maxillary permanent canine.

Search methods

We searched the following electronic databases: the Cochrane Oral Health Group's Trials Register (to 20 April 2012), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2012, Issue 1), MEDLINE via OVID (1946 to 20 April 2012) and EMBASE via OVID (1980 to 20 April 2012). There were no restrictions regarding language or date of publication.

Selection criteria

Trials were selected if they met the following criteria: a randomised or quasi-randomised controlled trial, involving the extraction of the deciduous maxillary canine and assessing eruption/non-eruption of the palatally displaced maxillary permanent canine.

Data collection and analysis

Data extraction was undertaken independently by two review authors. The primary outcome was the reported prevalence of eruption or non-eruption of the ectopic permanent canine into the mouth following observation or intervention. Results were to be expressed as risk ratios for dichotomous outcomes with 95% confidence intervals and mean differences for continuous outcomes. Heterogeneity was to be investigated, including both clinical and methodological factors. Authors of trials were contacted to request unpublished data.

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Main results

Reports of two randomised controlled trials previously excluded from an earlier version of the review due to "deficiencies in reporting, insufficient data" have now been included. These two trials included approximately 128 children, with more than 150 palatally displaced canine teeth, and both were conducted by the same research group. Data presented in the trial reports are either incomplete or inconsistent. Both trials are at high risk of bias. It must be emphasised that both trials have serious deficiencies in the way they were designed, conducted, and reported, and attempts to contact the authors to obtain detailed information and clarify inconsistencies have been unsuccessful. Allocation to treatment appears to be at the level of the individual, but outcomes of successful treatment relate to included teeth and data are not reported for each treatment group. Adverse effects are not reported. Neither trial provides any evidence to guide clinical decision making.

Authors' conclusions

There is currently no evidence of the effects of extraction of primary canine teeth in 10-13 year old children with one or two palatally displaced permanent canine teeth.

PLAIN LANGUAGE SUMMARY

Extraction of baby canine teeth for correcting poorly aligned adult canine teeth in children

Occasionally, permanent canine teeth (sometimes called eye teeth) do not erupt properly in the mouth. In around 3% of children, either one or both canines (left and right) remain buried under the gum in the roof of the mouth, out of alignment from the tooth's correct position (known as palatally displaced teeth).

If these permanent canine teeth remain displaced, they can cause problems such as damage to, or change the position of neighbouring teeth, and very occasionally lead to cyst formation or infection.

One possible treatment for this problem is to extract the primary (baby) canine in 10 to 13 year old children and hope that the buried canine corrects its alignment of its own accord (called spontaneous correction), by moving from a displaced position to the correct placement in the mouth.

This review looks at whether extracting palatally displaced canine teeth in children is successful in preventing further complications for patients. Only two of the studies found were considered suitable for inclusion, with a total of 125 participants. There were concerns about aspects of the design and reporting in both of the studies; therefore we have found no reliable evidence of the effects of extraction of the baby canine tooth or teeth. High quality clinical trials are required to guide decision making.

BACKGROUND

Description of the condition

The permanent canine tooth in the maxilla (upper jaw) sometimes does not erupt into the mouth correctly and is described as ectopic, displaced or impacted. This is a common occurrence, the reported prevalence rate of ectopic maxillary canines varies from 1% to 3% (Grover 1985; Kramer 1970). Ectopic canines can be displaced in a palatal direction (in the roof of the mouth) or buccally. Buccal canine displacements are usually due to inadequate space and in most cases, the tooth eventually erupts into the mouth autonomously. For this reason a reliable ratio of buccal to palatal impactions is hard to establish (Jacoby 1983). It has been thought that the majority of ectopic canines (85%) are displaced into the roof of the mouth, however, a more recent computerised tomography (CT) study suggests that only 50% are palatally displaced and the remainder are either buccal or in the line of the arch (Ericson 2000). Since palatal displacement is a positional anomaly that generally occurs despite adequate space and buccal displacement is associated with insufficient space, it is highly unlikely that buccal and palatal impactions share the same aetiology. The aetiology of palatally impacted canines is thought to be multifactorial with a strong genetic component (Peck 1994). Retained primary canines (Thilander 1968), mal-shaped or missing lateral incisors

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(Brin 1986), crowded or delayed eruptive pathways, other local conditions (Moss 1972; Thilander 1968), have been considered to be important factors. Occurrence with other dental anomalies such as hypodontia, enamel hypoplasia and microdontia along with familial occurrence (Zilberman 1990), and racial variation are highly suggestive of a genetic aetiology.

Ectopic canines can lead to unwanted movement of neighbouring teeth, dental crowding and root resorption of adjacent teeth. Root resorption is a common sequelae; in the CT study by Ericson 2000, root resorption was found in 38% of lateral incisor teeth and 9% of central incisor teeth. On rare occasions, ectopic canines can lead to cyst formation, infection, referred pain and combinations of the above (Shafer 1963).

With regard to palatally displaced canines, their management is complex. To avoid complicated treatment with surgery and fixed braces, one might consider leaving palatal canines in situ. This is a reasonable option if the primary canine has a good sized crown and root. However, even in these favourable circumstances, the primary canine may be lost and the timing of this loss is unpredictable. Loss may occur early on in teenage years or as late as the 6th and 7th decade of life. The outcome is often an unsightly gap and filling this gap with either a denture, dental bridge or implant may be necessary. It is therefore generally recommended to align palatally displaced canines if the displacement is not too severe and the patient is suitable for treatment with fixed braces. If alignment is carried out, this will involve a surgical procedure (often under general anaesthetic) to uncover the buried tooth followed by over 2 years of fixed brace treatment to move the canine into the correct position (Iramaneerat 1998). This comprehensive management requires significant commitment from the patient and cost to the healthcare provider.

Description of the intervention

One suggested intervention to prevent ectopic eruption of the permanent canine is to extract the primary canine in individuals aged 10 to 13 years, provided that normal space conditions are present. The main evidence offered in support of this practice has arisen from a study by Ericson and Kurol (Ericson 1988). This prospective case series, with no control group, followed a consecutive group of children aged 10-13 years, receiving the intervention (i.e. extraction of the primary canine). Royal College Guidelines were first published by Burden et al in 1997 (Burden 1997), supporting this practice of extraction of the primary canine based on the evidence provided by this uncontrolled study. These clinical guidelines have been recently updated (Husain 2010).

How the intervention might work

Extraction of the primary canine might lead to a change in the path of development of the palatally displaced canine and ultimately eruption into the dental arch. Success following this intervention means the avoidance of a costly procedure involving surgery and fixed braces.

Why it is important to do this review

Children who have primary canines extracted to treat displaced permanent canines will require local anaesthesia. Since this is often their first experience of having something done at the dentist, it is important that this invasive intervention is fully justified. This is an update of a Cochrane review first published in 2009 (Parkin 2009).

OBJECTIVES

The primary objective of this review was to assess the effect of extracting a maxillary primary canine on the eruption of a palatally displaced canine.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) or quasi-RCTs with at least a 6-month follow-up period after the intervention. These were restricted to parallel group studies, because neither cross-over studies nor split-mouth studies are considered appropriate designs to assess this intervention.

Types of participants

Participants in included studies were children with palatally displaced maxillary canines, where at least 80% of the participants were 10 to 13 years of age. Trials where participants had craniofacial syndromes or anomalies were excluded.

Types of interventions

Extraction of the primary maxillary canine, compared to either no treatment, delayed treatment or an alternative treatment such as extraction plus the use of headgear.

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Types of outcome measures

Primary outcomes

The primary outcome was the reported prevalence of eruption or non-eruption of the permanent canine into the mouth.

Secondary outcomes

(1) The reported improvement in the vertical position or angulation of the ectopic canine, as measured from radiographs.
(2) The reported incidence or prevalence of root resorption of the impacted canine and/or incisors and cyst formation.
(3) Any reported evaluation of patient satisfaction and pain experience during extraction of the primary canine.

Search methods for identification of studies

Electronic searches

For the identification of studies included or considered for this review, we developed detailed search strategies for each database searched. These were based on the search strategy developed for MEDLINE (OVID) but revised appropriately for each database. We searched the following electronic databases:

- The Cochrane Oral Health Group's Trials Register (to 20 April 2012) (Appendix 1)
- The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2012, Issue 1) (Appendix 2)
- MEDLINE via OVID (1946 to 20 April 2012) (Appendix 3)
- EMBASE via OVID (1980 to 20 April 2012) (Appendix 4).

Searching other resources

A programme of handsearching is being carried out by The Cochrane Collaboration (*see* the Cochrane Masterlist of journals being searched for information). The results of this handsearching were incorporated into the review with the search of the Cochrane Oral Health Group's Trials Register.
The references of relevant publications and included studies were checked for further studies. Letters and emails were sent to corresponding authors of relevant studies to identify unpublished trials or data and for clarification. The clinical trials website (clinicaltrials.gov) was searched (April 2012) to identify any ongoing trials.

Data collection and analysis

Selection of studies

Two review authors independently and in duplicate examined the title, keywords and abstract of reports identified from electronic searching for evidence of three criteria.
(1) It was a randomised or quasi-randomised clinical trial.
(2) It involved the extraction of the primary maxillary canine.
If the report fulfilled these three criteria or if one or both review authors were not able to assess this from the title, keywords or abstract then the full article was obtained. Disagreements between review authors were resolved by discussion. If agreement could not be reached, a third review author was asked to arbitrate.

Data extraction and management

Two review authors carried out data extraction independently and authors of articles were contacted for any missing data where possible. The following data were to be collected.
(1) Number and age of subjects pre-treatment.
(2) Mean duration of follow-up.
(3) Eruption of displaced palatal canines.
(4) Improvement in position of displaced palatal canine.
(5) Method of canine extraction (local anaesthesia (LA), intravenous (I/V) sedation or general anaesthesia (GA)).
(6) Root resorption of the impacted canine or the adjacent incisors and cyst formation.
(7) Patient satisfaction (yes, no, or not reported) and pain experience during or after extraction of the primary tooth.
In addition, the following methodological criteria were examined.
(1) Sample size calculation reported.
(2) Comparability of groups at the start in terms of age, gender, position of canine, crowding/spacing of teeth and malocclusions. In addition, variation in the observation period after the intervention was another factor in producing heterogeneity.
(3) Clear inclusion/exclusion criteria.
(4) Validity and reproducibility of the method of assessment.

Assessment of risk of bias in included studies

For the studies included in this review assessment of risk of bias was conducted independently and in duplicate by two review authors using the Cochrane Collaboration's risk of bias assessment tool (Higgins 2011). We assessed six domains for each included study: random sequence generation, allocation concealment, blinding (of patient, and outcome assessor), completeness of outcome data, risk of selective outcome reporting and risk of other potential sources of bias.
For this systematic review we assessed risk of bias according to the following.

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- Random sequence generation: use of a random number table, use of a computerised system, central randomisation by statistical co-ordinating centre, randomisation by an independent service using minimisation technique, permuted block allocation or Zelan technique was assessed as low risk of bias. If the paper merely states randomised or randomly allocated with no further information this domain was assessed as being unclear.
- Allocation concealment: centralised allocation including access by telephone call or fax, or pharmacy-controlled randomisation, sequentially numbered, sealed, opaque envelopes was assessed as low risk of bias. If allocation concealment is not mentioned this was assessed as unclear.
- Blinding: it is not possible to blind patients and their carers to the allocated intervention. However it is possible to blind outcome assessors. One possible way of blinding the assessor was to block out the primary canine space on the radiograph in both groups, post-treatment or alternatively where the assessor had no knowledge about the study. If blinding is not mentioned we assumed that no blinding occurred and assessed the study at high risk of bias.
- Outcome data: outcome data were considered complete if all patients randomised were included in the analysis of the outcome(s). Trials where less than 10% of those randomised were excluded from the analysis, where reasons for exclusions were described for each group, and where both numbers and reasons were similar in each group, was assessed as being at low risk of bias due to incomplete outcome assessment. Where post-randomisation exclusions were greater than 10%, or reasons were not given for exclusions from each group, or where rates and reasons were different for each group, the risk of bias due to (in)complete outcome data was assessed as unclear or high based on our judgement of the effect of missing information relative to the treatment effects.
- Selective outcome reporting: a trial was assessed as being at low risk of bias due to selective outcome reporting if the outcomes described in the methods section, were systematically reported in the results section. Where reported outcomes did not include all those outcomes specified, or where additional analyses were reported, this domain was assessed as unclear. Where important outcomes were not reported, or where data were incompletely reported (e.g. no data reported by treatment group, or no estimates of variance) risk of bias due to selective outcome reporting was assessed as high.
- Other bias: imbalance in potentially important prognostic factors between the treatment groups at baseline, or the use of a co-intervention in only one group are examples of potential sources of bias noted.

After taking into account the additional information provided by the authors of the trials, studies were grouped into the following categories.

1. Low risk of bias in all domains (plausible bias unlikely to seriously alter the results).
2. Unclear risk of bias if one or more of the domains are assessed as unclear.
3. High risk of bias (plausible bias that weakens confidence in the results) if one or more domains are assessed at high risk of bias.

A summary of risk of bias was presented in Figure 1.

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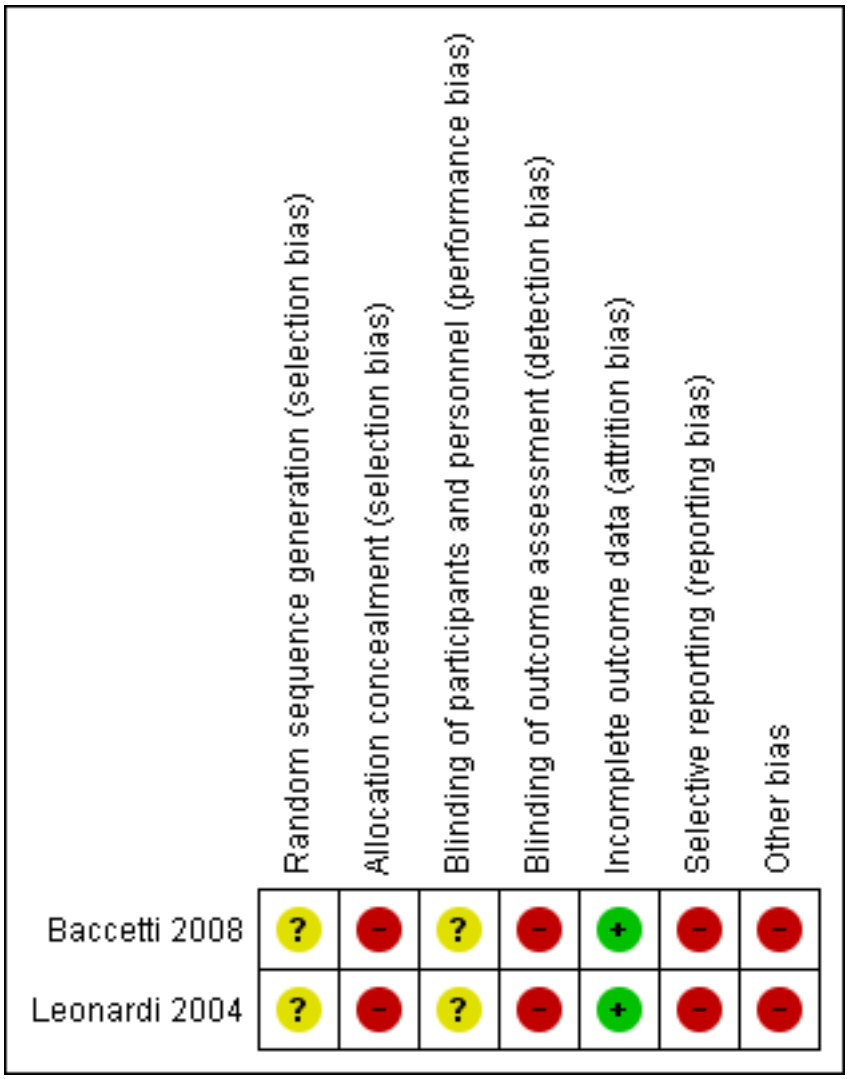
Figure 1. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Measures of treatment effect

We planned to assess outcomes at more than one period of follow-up. All such assessments were recorded and decisions on which time of outcome assessment to use from each study (presenting results at more than one follow-up time) were based on the most commonly reported timing of assessment among all included studies.

The primary outcome was assessed using dichotomous data (i.e. 'yes' if the permanent canine erupted and 'no' if the canine did not erupt) and the results would have been expressed as risk ratios (RR) and 95% confidence intervals (CI). Secondary outcomes such as improvement in the path of eruption of the canine, root resorption of neighbouring teeth and satisfaction or pain of treatment would most likely be continuous and would have been assessed using the mean difference and 95% confidence intervals between the intervention and control groups (or two intervention groups).

Unit of analysis issues

It was planned that the unit of analysis would be children; however, where the included studies reported data per tooth rather than per

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child it was planned that we would treat the data as if it were per child, and make a statement that the confidence intervals around the estimates should in fact be wider than those thus calculated.

Dealing with missing data

Where data were missing from the trial reports we contacted authors requesting additional data or clarification of inconsistencies. Variance imputation methods would have been used to estimate appropriate variance estimates, where the appropriate standard deviation of the differences was not included in study reports (Follmann 1992). We planned to conduct intention-to-treat analyses.

Assessment of heterogeneity

We planned to assess clinical heterogeneity by examining the types of participants, interventions and outcomes in each study. Statistical heterogeneity would have been assessed by inspection of a graphical display of the estimated treatment effects from trials, along with Cochran's test for heterogeneity, and quantified by the I^2 statistic. Heterogeneity would have been considered statistically significant if the P value was < 0.1. A rough guide to the interpretation of I^2 is: 0% to 40% might not be important, 30% to 60% may represent moderate heterogeneity, 50% to 90% may represent substantial heterogeneity, 75% to 100% considerable heterogeneity (Higgins 2011).

Assessment of reporting biases

Reporting biases arise when the reporting of research findings is influenced by the nature and direction of the findings of the research. We attempted to minimise potential reporting biases including publication bias, multiple (duplicate) publication bias and language bias in this review, by conducting a sensitive search of multiple sources with no restriction on language. We also searched for ongoing trials.

If there had been more than 10 studies in one outcome we would have constructed a funnel plot and investigated any asymmetry detected.

Data synthesis

Meta-analyses were planned if there were studies of similar comparisons reporting the same outcomes. Risk ratios would have been combined for dichotomous data using fixed-effect models (unless there were more than three studies in the meta-analysis, when random-effects models would have been used).

If there were insufficient studies included or if included studies were not able to be pooled, results were presented narratively.

Subgroup analysis and investigation of heterogeneity

We planned to investigate clinical heterogeneity by examining the types of participants, interventions and outcomes in each study. Additional potential sources of heterogeneity would have been investigated as determined from the study reports, although these would have been clearly identified as 'post hoc' analyses and the results treated with caution. No *a priori* subgroup analyses were planned.

Sensitivity analysis

A sensitivity analysis was planned to be conducted for studies with low risk of bias.

Presentation of main results

A summary of findings table was planned to be developed for the primary outcomes of this review using GRADEPro software. The quality of the body of evidence would have been assessed with reference to the overall risk of bias of the included studies, the directness of the evidence, the inconsistency of the results, the precision of the estimates, the risk of publication bias, the magnitude of the effect and whether or not there is evidence of a dose response. The quality of the body of evidence for each of the primary outcomes would have been categorised as high, moderate, low or very low.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

Results of the search

The original search identified 324 publications of which 293 were excluded after preliminary screening of the titles and abstracts by two review authors. Full articles were obtained for the remaining 31, 19 of which were written in languages other than English and required translation prior to assessment. These were assessed by two review authors independently. Seven studies were excluded and the reasons recorded in the Characteristics of excluded studies table. The remaining studies were rejected as it was clear that they did not meet the inclusion criteria. Although no studies were included in the review, two of the excluded studies were evaluated in detail in the previous version of this review.

An updated search was conducted in April 2012 and a further 125 references were identified, which were screened independently by two review authors. Full text copies were obtained of seven

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references to six studies, and it was decided to include two studies (three trial reports) in this updated review. These studies were two of those previously excluded (Baccetti 2008; Leonardi 2004). No ongoing trials were identified.

Included studies

Two randomised controlled trials (RCTs) were identified (Baccetti 2008; Leonardi 2004), which had previously been excluded from this review because of "deficiencies in reporting; insufficient data". After much discussion it was decided that these two studies should be included in this update of the review because based on the published reports, they appear to meet the inclusion criteria for this review and therefore we appraise their design, conduct and reporting together with unpublished information available to the review authors. Current guidance from the *Cochrane Handbook for Systematic Reviews of Interventions* is that outcomes are not part of the criteria for including studies, except in reviews which explicitly restrict eligibility to specific outcomes (Higgins 2011 section 5.1.2).

Sadly Dr Baccetti, who was a researcher in both studies, died in an accident in November 2011. There are flaws and/or errors in both these studies, and communications from the co-authors of the studies have indicated that information concerning the design and conduct of the studies and the outcome data are no longer available.

Characteristics of the trial design and setting

Both of the included trials were conducted in Florence, Italy, by the same group of researchers at the University of Florence, Department of Orthodontics.

Both studies are described as prospective randomised controlled trials in which children with one or two palatally displaced canines are "assigned randomly" to either extraction of primary canines alone, extraction followed by orthodontic headgear or a no treatment control group. For this review the extraction only and untreated control groups are the comparison of interest. Both the numbers of children and the numbers of palatally displaced canine teeth are different in each group (Additional Table 1).

Characteristics of the participants

Leonardi 2004 states that there were 50 participants randomised, that the 'dental age' of the participants was between 8 and 13 years "according to the method of Becker and Chaushu", but the information on the mean chronological age of the children in each group at baseline was only presented for those who completed the study and were evaluated. It was reported that seven children did not complete the trial, suggesting that perhaps 53 children were originally included. We were unable to confirm the number of participants, or the number of palatally displaced canine teeth included in the study at baseline. Of the 46 children who did complete, there was a total of 62 palatally displaced canines (PDCs). Thirty children had a unilateral PDC and 16 children had bilateral PDC. In those who completed the trial the distribution of children and teeth between the three treatment groups was as follows.

- Extraction only: 11 children (3 bilateral PDCs).
- Extraction plus headgear: 21 children (11 bilateral PDCs).
- Untreated control: 14 children (2 bilateral PDCs).

We sought an explanation for the differences between the groups in the numbers of children included and the proportions of unilateral and bilateral PDCs. No specific information was available.

In the other study (Baccetti 2008), authors reported 75 enrolled participants had a mean age of 11.7 years at study entry, but the age range of participants was not reported. The study design was similar to Leonardi 2004: children were randomised into three treatment groups, five children left the study and 69 completed. Once again there is a discrepancy between the numbers enrolled and evaluated, which is not explained by the withdrawals. The distribution of children and PDCs was.

- Extraction only: 23 children (25 PDCs, 2 bilateral).
- Extraction plus headgear: 24 children (35 PDCs, 11 bilateral).
- Untreated control: 22 children (26 PDCs, 2 bilateral).

For this study an explanation for the differences between the groups in the numbers of children included and the proportions of unilateral and bilateral PDCs was requested. Again no specific information was available.

Characteristics of the interventions

Participants with one or two palatally displaced canines were included in the study by Leonardi 2004, and teeth were randomly allocated to one of three intervention groups.

1. Extraction of the primary maxillary canine.
2. Extraction of the primary maxillary canine plus the use of a cervical pull headgear.
3. An untreated control group - no extraction and no headgear.

In the Baccetti 2008 trial, there were the same three treatment groups.

1. Extraction of the primary maxillary canine.
2. Extraction of the primary maxillary canine plus the use of a cervical pull headgear.
3. An untreated control group - no extraction and no headgear.

Characteristics of the outcomes

Neither trial reported raw outcome data for each treatment group. Baccetti 2008 reported percentages for each group. The data that were presented were incomplete and sometimes contradictory. The authors of both trials were contacted in an attempt to clarify certain

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ambiguities and inconsistencies in the reporting of these trials, and one of the review authors spoke with Dr Baccetti. However, no additional information has been made available to the review authors. We have decided to present the published information (Additional Table 1) together with a narrative.

Excluded studies

Seven studies have been excluded from this review (Characteristics of excluded studies). Two studies were excluded because the participants did not meet the age criteria (Bonetti 2010; Bonetti 2011), two were case series (Ericson 1988; Power 1993), one was not randomised (Sigler 2011) and in Baccetti 2009 extraction was not part of the intervention. Baccetti 2011 which was described as a randomised study was excluded because it describes a long period of recruitment (1991-2009) and we were unable to determine whether the participants in this study were different people from those included in the two other studies from this research group (Baccetti 2008; Leonardi 2004).

Risk of bias in included studies

Allocation

Random sequence generation

Neither of the two studies in this review (Baccetti 2008; Leonardi 2004) provided information about the method used to generate the randomisation sequence. In both studies the groups were very imbalanced at baseline; there were many more children with bilateral PDCs in the extraction plus headgear group compared to the other groups, which suggests that allocation may not have been truly random.

Allocation concealment

Neither study mentioned the method of allocation concealment. Both studies are at high risk of selection bias.

Blinding

It was not possible to blind the study participants to the allocated intervention in the two included trials. Outcome assessor blinding would have been possible and would have been a means of reducing detection bias, but outcome assessor blinding was not described in either of the trial reports. Both trials are therefore assessed as being at high risk of performance and detection bias.

Incomplete outcome data

In Leonardi 2004, it was stated that 50 participants were recruited to the trial and seven participants did not complete the trial. However, the paper then states that the remaining 46 participants with 62 palatally displaced canines were distributed 11 in extraction only group, 21 in extraction plus headgear, and 14 in untreated control group at T“ (18 months after enrolment). Attempts to clarify this information were unsuccessful.

In Baccetti 2008, five of the 75 children enrolled in the study (8%) did not complete the trial because the families moved away. The paper states that 70 participants with 86 palatally displaced canines completed the trial, but then describes only 69 children, allocated to extraction (23 participants), extraction plus headgear (24 participants) and control (22 participants). Attempts to contact the authors and clarify this information were unsuccessful.

Both studies provided conflicting information about the numbers of participants but were judged to be at low risk of attrition bias because the number of participants lost was small (less than 10%) and the reasons given were judged to be unlikely to be related to the allocated treatment.

Selective reporting

Both studies reported the outcomes that were described in the methods of the report as percentages, but neither presented the number of successful treatments, or the radiographic measurements for each treatment group. Only the between group comparison test was presented, and requests for additional information from the authors have not received any response. Both trials are assessed as being at high risk of reporting bias.

Other potential sources of bias

In both the included studies some of the participants had bilateral displaced canines and some unilateral. In both trials the proportion of bilateral displaced canines was quite different in each of the treatment groups. There is no mention of whether the analyses that were done were adjusted according to the paired nature of some of the data in each group. According to the trial reports the unit of randomisation in both trials appears to have been individual children, but it is unclear whether the unit of analysis was children or teeth. Attempts to clarify this with the authors were unsuccessful. Both trials were judged to be at high risk of bias for this domain.

Overall risk of bias

Both of these studies are at high overall risk of bias (Figure 1).

Effects of interventions

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Both Baccetti 2008 and Leonardi 2004 reported outcomes that would be relevant for this review, but unfortunately the data in the publications were inconsistent, not reported for each treatment group and not presented in a form that could be included in a meta-analysis. Although the extraction only and control groups are relevant to this review, the study reports do not make this explicit comparison, but refer to these groups in relation to the extraction plus headgear intervention. What follows is a narrative summary of the results reported.

Successful eruption of the palatally displaced permanent canine, defined as "the full eruption of the tooth, thus permitting bracket positioning for final arch alignment when needed" after 4 years, and time to eruption of this canine were reported by Baccetti 2008 and Leonardi 2004. Baccetti 2008 also reported change in the sagittal position of the upper first molars.

In the Leonardi 2004 trial, the children that were randomised into the extraction only group, had a prevalence of successful eruption of the permanent canine tooth of 50% "which was not significantly greater than the success rate in untreated controls". The prevalence of successful eruption of the permanent canine was 80% in the children where a primary canine tooth was extracted and then cervical pull headgear was used, and this proportion was significantly higher compared to the untreated control group (Chi ^{2} 14.9; P < 0.01) and the extraction only group (Chi^2 4.69; P < 0.05), but no data on the success rates in each of these groups are presented in this paper (Additional Table 1).

The paper reports that there was "no significant difference between the two interceptive approaches in the time required for canine eruption".

In the second study by this group (Baccetti 2008) 75 children were enrolled, five were lost to follow-up and 69 children (with 86 PDCs) completed treatment. The children in the extraction only group had a statistically significantly higher prevalence of successful eruption of permanent canines compared to the control group (Chi^2 8.7; P < 0.01), but the prevalence of successful eruption of the permanent canine was significantly greater in the group who had both extraction plus cervical headgear compared to both the extraction only (Chi^2 5.2; P = 0.01) and the control group (Chi^2 23.5; P < 0.001). The average amount of sagittal displacement of the upper first molars was 0.24 mm in the extraction plus headgear group, 2.65 mm in the extraction only group and 2.32 mm in the control group. No estimates of variance in each group were provided.

Neither trial reported the outcome of pain, or patient satisfaction. Other outcomes reported in the publications were changes in the position of the displaced canine as measured from radiographs. These included changes in the inclination of the canine to the midline, the distance of the permanent canine cusp tip to the occlusal line and the medial position of the canine tooth crown assessing relative to five defined sectors. Data are presented as medians, because the authors state that the distribution was not normal and although the range of measurements (i.e. minimum and maximum values) are included in the tables, the interquartile ranges are not. Unfortunately, these data are also unusable without further information from the trial authors.

Both trials included participants with both unilateral and bilateral ectopic canines. It is unclear from the trial reports whether the authors took this lack of independence of bilaterally impacted teeth into account in the statistical analysis.

DISCUSSION

Summary of main results

We have decided to include two randomised controlled trials in this update of the review. There are inconsistencies in the data and concerns about the actual design and conduct of both studies. Both are at high risk of bias in several domains. Neither trial provides evidence of the positive effects of extraction of the primary canine as an interceptive intervention for the management of palatally displaced maxillary permanent canines.

Overall completeness and applicability of evidence

Although two trials have been identified for inclusion in this review, both have serious deficiencies in the way they were designed, conducted, and reported. Both are at high risk of bias. Neither trial provides any reliable evidence to guide clinical decision making.

Quality of the evidence

Neither trial report contains data suitable for inclusion in meta-analysis and both trials are assessed at high risk of bias. Both trials are conducted by the same group of researchers and both include children with either unilateral palatal canine displacement or bilateral palatal canine displacement. There is no indication that the paired nature of some of the data has been taken into account in the analysis, and the distribution of unilateral and bilateral palatal canine displacements is different in each of the groups and appears to be associated with the interventions.

We cannot confirm whether the children included in these studies meet our inclusion criteria of 80% of participants being aged 10-13 years, and we have been unable to obtain this information from the trialists. This inclusion criterion was chosen for the review because there is evidence that x-rays taken in children aged less than 10 years offer little benefit in terms of knowledge gained about position of the unerupted canine (Husain 2004).

In one trial (Leonardi 2004) it was not clear if the treatment and control groups were similar at the start of the trial. The trial authors

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reported that there were no differences, but Table 1 in the article suggests otherwise. There was a large difference in the Alpha angle between the groups. In addition, there was a high proportion of females in groups 2 and 3. The duration of the observation was not clear. At one point it was reported to be 18 months at T2 and at another place it was reported to be 48 months. The authors reported that the rate of successful eruption was 50% in group 1 (extraction of the primary canine only) and it was not significantly different from the rate for spontaneous eruption in the untreated control group (group 3). This suggests that in group 3 the successful eruption was close to 50%; however, at another place the paper reported that one in four of the palatally displaced canines achieved spontaneous eruption in the absence of any interceptive intervention, which suggests a 25% success rate in the control group. Also there is a discrepancy in the figures with regard to the number of participants enrolled. It is stated that 50 participants were enrolled in the study, seven participants 'dropped out' of the trial and 46 participants were included in the analysis. This leaves a discrepancy of three participants, leading the reader to presume that 53 participants were actually enrolled. More importantly, no sample size calculation was carried out and it is unclear whether the study had the power to detect a true difference.

In the second trial (Baccetti 2008) an adequate sample size (power > 0.85) is reported and there appears to be pre-treatment equivalence. The inclusion criteria and the duration of observation are clearly stated; however, it is not clear if researchers assessing the outcome were masked with regard to group allocation. There is incomplete reporting of outcome data (no estimates of variance).

Potential biases in the review process

We conducted a broad search of a range of databases and imposed no restriction in terms of language or publication status. We sought additional information from the authors of the two studies that are included but this information was not available.

Agreements and disagreements with other studies or reviews

Subsequent to this review, Naoumova and colleagues (Naoumova 2011) conducted a systematic review looking at the interceptive treatment of palatally displaced maxillary canines. They identified the same two trials and in agreement with our updated review, noted that statistical methods to take into account the "clustering of patients with bilateral PDCs" was not reported, and that none of the outcome assessments were conducted blinded to treatment. Naoumova 2011 also concluded that there was no reliable scientific evidence to support interceptive treatment in the prevention of impaction of palatally displaced canines.

AUTHORS' CONCLUSIONS

Implications for practice

There is currently no reliable evidence from the two included studies of the effect of extraction of primary maxillary canine to facilitate the eruption of the palatally ectopic maxillary permanent canine. Both studies have deficiencies in design, conduct, analysis and reporting and are at high risk of bias. Therefore, in the absence of evidence of effectiveness, the routine practice of subjecting children between the ages of 10 and 13 years of age to extraction of primary canines should be questioned.

Implications for research

Well designed and conducted, adequately powered randomised controlled trials are required to determine the effects of extraction of primary canines as a treatment for palatally displaced canines in children aged 10-13 years. Future clinical trials should follow the Consolidated Standards of Reporting Trials (CONSORT) Statement (Moher 2001). Attention should be given to ensuring important factors, such as concealed random allocation, blind assessment, sample size, correct statistical analysis (taking into account clustering in patients with bilateral ectopic canines) should be carefully considered when planning, conducting and reporting clinical trials of treatments for this condition.

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* *Indicates the major publication for the study*

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CHARACTERISTICS OF STUDIES

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

Baccetti 2008

Methods	Location: Florence, Italy. Number of centres: 1. Recruitment period: not stated. Funding source: not stated. Trial design: parallel group RCT.
Participants	Inclusion criteria: Caucasian, with either unilateral or bilateral PDCs, dental ages 8-13 years, skeletal age showing active phases of growth Exclusion criteria: previous orthodontic treatment, craniofacial syndromes, odontomas, cysts, cleft lip and/or palate, sequelae of traumatic injury to face, multiple and/or advanced caries. Crowding of upper arch, aplasia or severe hypoplasia of crown of upper lateral incisors Age: mean at entry 11.7 years. Number patients randomised: 75. Number evaluated: 70 or 69? (86 PDCs).
Interventions	**Comparison: extraction alone versus extraction plus headgear versus no treatment.** Group A (n = 23 children with 25 PDCs) EG: extraction of primary canine corresponding to PDC Group B (n = 24 children with 35 PDCs) EHG: extraction of primary canine corresponding to PDC plus use of cervical-pull headgear Group C (n = 22 children with 26 PDCs) CG: no treatment given All patients in the trial were observed for 18 months.
Outcomes	Full eruption of the permanent canine, change in sagittal position of upper first molars at 18 months (T2)
Notes	Sample size calculation: not reported. However, paper states that "The present investigation achieved an adequate power (greater than 0.85)". Conflicting information about the numbers of participants

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "All PDC subjects were assigned randomly". Method of sequence generation not described
Allocation concealment (selection bias)	High risk	Not mentioned.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible.

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Baccetti 2008 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	High risk	Not mentioned.
Incomplete outcome data (attrition bias) All outcomes	Low risk	75 children randomised (number of PDCs not stated) and 70 children completed the trial (but 69 children and 86 PDCs reported). Reasons for non-completion were that children moved away from treatment centre
Selective reporting (reporting bias)	High risk	Success (defined), and comparison in the changes of the sagittal position of upper first molars planned and reported (mesial inclination of the crown of the canine to the midline - α angle and distance of cusp tip of permanent canine from occlusal line - d); however, the published trial reported the Chi^2 test for the difference between groups, rather than the data for each treatment group
Other bias	High risk	The ratio of PDCs to participants was quite different in each of the allocated treatment groups at baseline (0.92, 0.69 and 0.85 in EG, EHG and CG respectively)

Leonardi 2004

Methods	Location: Florence, Italy. Number of centres: 2. Recruitment period: not stated. Funding source: not stated. Trial design: parallel group RCT.
Participants	Inclusion criteria: children of Caucasian ancestry, no previous orthodontic treatment, with unilateral or bilateral PDCs, dental age 8-13 years, skeletal age showing active phases of skeletal growth, absence of crowding of upper arch and absence of hypoplasia or aplasia of the crown of the upper lateral incisors Exclusion criteria: craniofacial syndromes, odontomas, cysts, cleft lip and/or palate, sequelae of traumatic injuries to the face or advanced or multiple caries Age group: 8-13 years. Number randomised: 50 or 53?. Number evaluated: 46 (62 PDCs).
Interventions	**Comparison: extraction alone versus extraction plus headgear versus no treatment.** Group A (n = 11) (14 PDCs) EG: extraction of the primary canine(s) corresponding to the PDC only

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Leonardi 2004 (*Continued*)

	Group B (n = 21) (32 PDCs) EHG: extraction of primary canine(s) corresponding to PDC followed by the use of cervical pull headgear, for 12-14 hours/day, to maintain the length of the upper arch for 6 months post-extraction Group C (n = 14) (16 PDCs) CG: no treatment between T1 and T2
Outcomes	Success defined as full eruption of PDC, within the 48-month clinical observation period, mesial inclination of the crown of the canine to the midline (α angle) and distance of cusp tip of permanent canine from occlusal line (d)
Notes	Sample size calculation: not stated. Conflicting information about number of participants

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "assigned randomly to one of the following groups". Method of sequence generation not described
Allocation concealment (selection bias)	High risk	Not mentioned.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not mentioned.
Incomplete outcome data (attrition bias) All outcomes	Low risk	7 children did not complete the trial (48 months) because they moved away or asked to be transferred to another clinician. 46 are included in outcomes at T2 (18 months after T1)
Selective reporting (reporting bias)	High risk	Success and cephalometric measures reported, but not by participant for each treatment group. No significant differences between groups reported, possibly due to lack of statistical power
Other bias	High risk	Ratio of bilateral to unilateral PDC very different in each group 3:8, 11:10, 2:12 for EG, EHG and CG respectively

PDCs = palatally displaced canines; RCT = randomised controlled trial.

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

Study	Reason for exclusion
Baccetti 2009	Extraction of primary canine not part of intervention.
Baccetti 2011	Study is described as RCT, but following communication between review authors and first author of this study, it has been decided to exclude this study. It has not been possible to confirm randomisation, and it seems unlikely that a method of sequence generation was used to assign treatments prospectively. Furthermore the recruitment period of 1991-2009 suggests that many of these participants may be included in another report (Baccetti 2008). The first author of the study is now deceased. The other authors were contacted and were not able to provide any information on study design
Bonetti 2010	Mean age of participants is only 10 years. Inclusion criteria for this review state that 80% of participants should be aged 10-13 years
Bonetti 2011	Mean age of participants is only 10 years. Inclusion criteria for this review state that 80% of participants should be aged 10-13 years
Ericson 1988	Prospective case series, no control group.
Power 1993	Prospective case series, no control group.
Sigler 2011	Random not mentioned and mean age of participants in this study is 10.5 years

RCT = randomised controlled trial.

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DATA AND ANALYSES

This review has no analyses.

ADDITIONAL TABLES

Table 1. Information reported in included studies

	Number children randomised	Number of children lost to follow-up	Number completing treatment								Treatment success		
			Children				Bilateral partially displaced canines (total PDC)				Treatment success		
			Extraction (EG)	Extraction plus headgear (EHG)	Control (CG)	Total	Extraction (EG)	Extraction plus headgear (EHG)	Control (CG)	Total	Extraction (EG)	Extraction plus headgear (EHG)	Control (CG)
Baccetti 2008	75	5	23	24	22	69	2 (25)	11 (35)	2 (26)	15 (86)	65.2%	87.5%	36%
											Difference between EG & CG (Chi^2 = 8.7, P < 0.01)	Difference between EHG & CG (Chi^2 = 23.5, P < 0.001) Difference between EHG & EG (Chi^2 = 5.2, P < 0.01)	

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Table 1. Information reported in included studies (*Continued*)

Leonardi 2004	50	7	11	21	14	46	3 (14)	11 (32)	2 (16)	62	50% Difference between EG & CG (Chi^2 = 2.01, P = 0.15)	80% Difference between EHG & CG (Chi^2 = 14.9, P < 0) Difference between EHG & EG (Chi^2 = 4.69, P < 0.05)	?

APPENDICES

Appendix 1. Cochrane Oral Health Group's Trials Register search strategy

((”tooth impact*“ OR ”tooth unerupt*“ OR impact* OR unerupt* OR ectopic* OR displace* OR ”palatal* erupt*“ OR ”tooth eruption ectopic*“) AND (cuspid* OR canine* OR eyetooth OR eyeteeth OR eye-tooth OR eye-teeth) AND (”tooth extraction*“ OR ((extract* OR remov*) AND (tooth OR teeth OR dental))))

Appendix 2. Cochrane Central Register of Controlled Trials (CENTRAL) search strategy

#1 TOOTH IMPACTED
#2 TOOTH UNERUPTED
#3 (impact* or unerupt* or ectopic* or displace* or (palatal* next erupt*))
#4 TOOTH ERUPTION ECTOPIC
#5 (#1 or #2 or #3 or #4)
#6 (cuspid* or canine* or eyetooth or eyeteeth or eye-tooth or eye-teeth)
#7 TOOTH EXTRACTION
#8 ((extract* or remov* or exodontia) and (tooth or (tooth next deciduous) or teeth or dental))
#9 (#7 or #8)
#10 (#5 and #6 and #9)

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Appendix 3. MEDLINE (OVID) search strategy

1. Tooth, Impacted/
2. Tooth, Unerupted/
3. (impact$ or unerupt$ or ectopic$ or displace$ or (palatal$ adj erupt$)).mp.
4. Tooth Eruption, Ectopic/
5. (cuspid$ or canine$ or eyetooth or eyeteeth or eye-tooth or eye-teeth).mp.
6. Tooth Extraction/
7. ((extract$ or remov$ or exodontia) and (tooth or tooth deciduous or teeth or dental)).mp.
8. or/1-4
9. or/6-7
10. 8 and 5 and 9

Appendix 4. EMBASE (OVID) search strategy

1. ((Tooth adj4 Impact$) or (teeth adj4 impact$)).mp. [mp=ti, ab, ot, rw, sh]
2. (Tooth adj4 unerupt$).mp.
3. (impact$ or unerupt$ or ectopic$ or displace$ or (palatal$ adj erupt$)).mp.
4. Tooth Eruption/
5. (cuspid$ or canine$ or eyetooth or eyeteeth or eye-tooth or eye-teeth).mp.
6. Tooth Extraction/
7. ((extract$ or remov$ or exodontia) and (tooth or tooth deciduous or teeth or dental)).mp. [mp=ti, ab, ot, rw, sh]
8. or/1-4
9. or/6-7
10. 8 and 5 and 9

WHAT'S NEW

Last assessed as up-to-date: 20 April 2012.

Date	Event	Description
10 October 2012	New citation required but conclusions have not changed	Methods updated. Two previously excluded studies now included, no change to the conclusions of the review. New co-author
10 October 2012	New search has been performed	Searches updated to 20 April 2012. No further included trials identified

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HISTORY

Protocol first published: Issue 1, 2004

Review first published: Issue 2, 2009

Date	Event	Description
16 December 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Nicola Parkin (NP) was responsible for co-ordinating all stages in the review process.

NP, Susan Furness (SF), and Philip Benson (PB) were responsible for the writing up of the review.

NP, SF, PB, Anwar Shah (AW), Bikram Thind (BT), Zoe Marshman (ZM), Gillian Glenroy (GG) and Fiona Dyer (FD) undertook screening of search results, data extraction and quality assessment.

DECLARATIONS OF INTEREST

None known.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Under Selection of studies it was decided to delete the requirement that the outcome of "Eruption/non-eruption of the palatally displaced permanent canine was assessed" as an inclusion criteria for this review, because it was acknowledged that this could potentially introduce outcome reporting bias.

INDEX TERMS

Medical Subject Headings (MeSH)

*Dentition, Primary; *Tooth Extraction; Cuspid [*surgery]; Tooth Eruption, Ectopic [*prevention & control]; Tooth, Unerupted [*prevention & control]

MeSH check words

Child; Humans

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