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Interventions for treating oro-antral communications and fistulae due to dental procedures (Review)

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[Intervention Review]

Interventions for treating oro-antral communications and fistulae due to dental procedures

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ABSTRACT

Background

An oro-antral communication is an unnatural opening between the oral cavity and maxillary sinus. When it fails to close spontaneously, it remains patent and is epithelialized to develop into an oro-antral fistula. Various surgical and non-surgical techniques have been used for treating the condition. Surgical procedures include flaps, grafts and other techniques like re-implantation of third molars. Non-surgical techniques include allogenic materials and xenografts.

Objectives

To assess the effectiveness and safety of various interventions for the treatment of oro-antral communications and fistulae due to dental procedures.

Search methods

We searched the Cochrane Oral Health Group's Trials Register (whole database, to 3 July 2015), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, 2015, Issue 6), MEDLINE via OVID (1946 to 3 July 2015), EMBASE via OVID (1980 to 3 July 2015), US National Institutes of Health Trials Registry (http://clinicaltrials.gov) (whole database, to 3 July 2015) and the World Health Organization (WHO) International Clinical Trials Registry Platform (http://www.who.int/ictrp/en/) (whole database, to 3 July 2015). We also searched the reference lists of included and excluded trials for any randomised controlled trials (RCTs).

Selection criteria

We included RCTs evaluating any intervention for treating oro-antral communications or oro-antral fistulae due to dental procedures. We excluded quasi-RCTs and cross-over trials. We excluded studies on participants who had oro-antral communications, fistulae or both related to Caldwell-Luc procedure or surgical excision of tumours.

Data collection and analysis

Two review authors independently selected trials. Two review authors assessed trial risk of bias and extracted data independently. We estimated risk ratios (RR) for dichotomous data, with 95% confidence intervals (CI). We assessed the overall quality of the evidence using the GRADE approach.

Main results

We included only one study in this review, which compared two surgical interventions: pedicled buccal fat pad flap and buccal flap for the treatment of oro-antral communications. The study involved 20 participants. The risk of bias was unclear. The relevant outcome reported in this trial was successful (complete) closure of oro-antral communication.

The quality of the evidence for the primary outcome was very low. The study did not find evidence of a difference between interventions for the successful (complete) closure of an oro-antral communication (RR 1.00, 95% Cl 0.83 to 1.20) one month after the surgery. All oro-antral communications in both groups were successfully closed so there were no adverse effects due to treatment failure.

We did not find trials evaluating any other intervention for treating oro-antral communications or fistulae due to dental procedures.

Authors' conclusions

We found very low quality evidence from a single small study that compared pedicled buccal fat pad and buccal flap. The evidence was insufficient to judge whether there is a difference in the effectiveness of these interventions as all oro-antral communications in the study were successfully closed by one month after surgery. Large, well-conducted RCTs investigating different interventions for the treatment of oro-antral communications and fistulae caused by dental procedures are needed to inform clinical practice.

PLAIN LANGUAGE SUMMARY

Treatment of communications between the oral cavity and the maxillary sinus due to dental procedures

Review question

What evidence is available for the safe and effective treatment of openings between the mouth and main sinus caused by dental procedures?

Background

The floor of the main sinus near the nose is thin and lies directly above the roots of the teeth at the back of the mouth. Sometimes following infection or dental treatment, this structure becomes damaged and openings or channels between the mouth and the sinus are formed. These are known as oro-antral communications (OAC). If the OAC is left open (then described as an oro-antral fistula (OAF), it may become permanent, leading to long-lasting sinus infections. This condition can be treated surgically by using flaps, grafts and other techniques; or non-surgically using a variety of methods and materials. There is little evidence for the most effective and safe treatments for closing OACs and OAFs and clinicians who treat these conditions have identified an urgent need for this.

Study characteristics

We searched various databases until 3 July 2015. Only one study, which was conducted in Iran, is included in our review. The study ran for two years and involved 20 people with OAC aged between 25 and 56 years. Participants were divided into two groups and two surgical treatments were compared for treating oro-antral communications; one group was treated with pedicled buccal fat pad flap (PBFPF) and the other with buccal flap (BF).

Key results and quality of evidence

The study did not find evidence of a difference between PBFPF and BF in terms of successful (complete) closure of OAC. Both interventions resulted in successful closure by one month after surgery. The study did not therefore report any adverse effects of treatment failure. It may not be possible to generalise these findings because the quality of the evidence was very low, due to unclear risk of bias and the small numbers studied in the single included trial.

Conclusion

The evidence currently available is insufficient to draw reliable conclusions regarding the effects of interventions used to treat OAC or fistulae due to dental procedures. More well-designed and well-reported trials evaluating different interventions are needed to provide reliable evidence to inform clinical decisions.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Pedicled buccal fat pad flap compared to buccal flap for treatment of oro-antral communications and fistulae due to dental procedures

Patient or population: people with oro-antral communication/fistulae
Settings: hospital
Intervention: pedicled buccal fat pad flap
Comparison: buccal flap

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Buccal flap	Pedicled buccal fat pad flap				
Successful (complete) closure of oro-antral communication			**RR 1.00** (0.83 to 1.20)	20 (1 study[1])	⊕◯◯◯ **very low**[2,3]	Both groups showed 100% improvement in the closure of OAC after one month. Hence RR is one and the risk difference (absolute effect) is zero
Adverse effects of treatment failure (such as graft necrosis and rejection or chronic sinusitis)						None reported as there were no treatment failures.

*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 quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Nezafati 2012

[2] Results are imprecise as the single included study has relatively few participants and few events and thus have wide confidence intervals around the estimate of the effect. Hence downgraded by two levels for imprecision.

[3] Downgraded by one level for risk of bias due to unclear allocation concealment, selective reporting and other bias.

BACKGROUND

Description of the condition

Oro-antral communications (OAC) are pathological conditions characterised by the existence of an unnatural opening ('communication') between the oral cavity and maxillary sinus due to loss of soft and hard tissues that normally separate these compartments. The term 'oro-antral communications' has been used synonymously with the terms 'oro-antral perforation', 'antro-oral communication', 'oro-antral fistula', 'oro-sinusal communication' (Visscher 2010), and 'antro-alveolar fistula' (Eneroth 1961). Although the above-mentioned terms are often used synonymously, there is a difference between an oro-antral communication and an oro-antral fistula: only when the communication becomes epithelialized and remains patent is it referred to as oro-antral fistula (OAF) (Batra 2010; Sandhya 2013). OAC is most commonly encountered during maxillary posterior teeth extraction due to the anatomical proximity between root apices and the maxillary antrum (Logan 2003; Nezafati 2012). Its frequency ranges between 0.31% and 4.7% following the extraction of upper teeth (Gacic 2009). It can also occur as a result of iatrogenic complications while performing dental procedures such as surgical removal of cysts (Abuabara 2006; Borgonovo 2012; Dym 2012). It can also be caused as a complication due to infection of the antral filling used to stabilise zygomatic complex fracture (Goodger 2004). Various pathological lesions of the maxillary sinus, periodontal infections and trauma can also result in the formation of an OAC (Franco-Carro 2011).

Signs and symptoms

Symptoms have been classified based on whether the OAC is acute or chronic (OAF) (Malik 2008).
Symptoms of acute OAC:

- epistaxis;
- escape of fluid from mouth to nose;
- excruciating pain in and around the region of affected sinus;
- escape of air from mouth to nose on sucking, inhaling or puffing the cheeks;
- enhanced column of air causing alteration in vocal resonance and subsequently change in the voice.

Symptoms of chronic OAF:

- negligible pain as the fistula becomes established and allows the free escape of fluids;
- development of an antral polyp seen as a bluish red lump extruding through the fistula;
- postnasal drip accompanied by unpleasant taste, nocturnal cough, hoarseness of voice, ear ache or catarrhal deafness;
- persistent mucopurulent, foul, unilateral nasal discharge from the affected nostril especially when head is lowered.

Complications

Chronic communication between oral cavity and maxillary sinus can act as a pathway for further bacterial and fungal penetration (Borgonovo 2012). Sinusitis has been reported to occur in 60% of cases on the fourth day after sinus exposure (Watzak 2005). Long-standing OAF can cause a general systemic toxaemic condition leading to fever, malaise, morning anorexia, frontal and parietal headache, anosmia and cacosmia (Malik 2008).

Description of the intervention

Clinical decision-making about how to treat an OAC/OAF depends on multiple factors that include the size of the communication, time of diagnosis and presence of infection. Furthermore, the selection of treatment strategy is influenced by the amount and condition of tissue available for repair and the possible placement of dental implants in the future (Visscher 2010; Dym 2012). Communications of 1 to 2 mm diameter heal spontaneously by the formation of blood clot in the absence of any infection (Liversedge 2002). Interventions for closure of the OACs can be broadly categorised into surgical, non-surgical and pharmacological interventions.

Surgical interventions

Surgical interventions have been further divided into flaps, grafts and other techniques (Zide 1992; Kitagawa 2003; Visscher 2010; Borja 2011; Visscher 2011).

- **Soft tissue flaps:** some of the traditional methods include buccal advancement flaps, palatal rotational flaps, palatal transposition flaps and tongue flaps. Other techniques include local flaps such as a combination of buccal and palatal flap, pedicled buccal fat pad flap, Bichat's fat pad graft.
- **Grafts:** autogenous grafts from chin, retromolar area, zygoma, iliac crest, interseptal and inter-radicular areas and cryoplatelet gel have been advocated to close OAC. Xenografts (with flap closure) such as lyophilised porcine dermis, porcine collagen membrane, bovine bone and guided tissue regeneration (GTR) using bovine barrier membranes have also been used. Allogenous grafts such as lyophilised fibrin glue and GTR using allogenous barrier membranes have been reported for treating OAC.
- **Other techniques:** re-implantation of third molar, gingival suturing, metal plates, foils and polymethylmethacrylate plates by approximation of buccal and palatal flap, hydroxylapatite blocks and haemostatic gauze have been tried.

Non-surgical interventions

Non-surgical interventions (Grzesiak-Janas 2001; Thoma 2006; Gacic 2009; Visscher 2010; Buric 2012).

- **Allogenous materials** (without flap closure) such as fibrin glue, dura; synthetic bone graft materials such as polylactic acid/glycolic acid (PLGA)-coated porous beta tri-calcium phosphate, prolamine occlusion gel and synthetic absorbable implant are some of the non-surgical interventions used to manage OAC.
- **Xenografts** (without flap closure) such as porcine dermis and collagen.
- **Other methods** such as acrylic splints, laser light, root analogues and N-butyl cyanoacrylate gel have also been tried.

Pharmacological interventions

Used as an adjuvant to surgical and non-surgical interventions. The most commonly used drugs include antibiotics and nasal decongestants.

- **Antibiotics:** a combination of antibiotics such as amoxicillin and clavulanate potassium 875 mg, clindamycin 300 mg 4 times daily, or moxifloxacin 400 mg) have been used in treatment of OAC. (Dym 2012).
- **Nasal decongestants:** can be used as adjuvants to healing of OAC/OAFs if the patient has any sinus infection (Dym 2012).

How the intervention might work

Surgical interventions are mostly based on mobilising the tissue and advancing the resultant flap into the defect (Batra 2010). A small OAC can be closed immediately by suturing the gingiva with a figure-of-eight suture but when this does not provide adequate closure, a soft tissue flap is indicated (Visscher 2010; Dym 2012). In case of fully developed fistulae, the epithelium lining must be removed in order to facilitate healing (Moore 1991). A buccal advancement flap can be used along with mattress sutures in small OACs, when the alveolar ridge is very resorbed and the location of the fistula is more mesial. This flap is a broad-based trapezoid mucoperiosteal flap. Its broad base assures adequate blood supply and thus has a high success rate (93%) (Visscher 2010). The disadvantage of this method is that there is significant lowering of the vestibule and cheek oedema and post-operative pain. The palatal rotational flaps can be used in OAC larger than 1 cm in diameter. This flap can be easily mobilised over the defect and is firmer and resistant to infection and trauma. This technique has an advantage of good blood supply from palatine artery, rotation without tension and preservation of buccal vestibule. However, the disadvantages include denudation of the bone on the palate, pain and later roughening and deepening of the area as a result of secondary epithelialization. Also a kink is formed where the flap is rotated. To overcome this complication, a cut-back is given which may reduce the visualisation of the flap. A modified palatal flap has been proposed that involves only the mucous membrane, leaving the submucosa and periosteum intact to reduce the complication of a palatal rotational flap (Kale 2010). Grafts are recommended for the closure of chronic OAF when soft tissue flap closure fails or when augmentation of the alveolar ridge in conjunction with closure is desired (Waldrop 1993). The use of autogenous, allogenous or xenografts helps to correct the residual bone defects during closure of OACs (Scala 2007). Foils (Steiner 2008) and plates form a mechanical barrier encouraging growth of healthy tissue for the closure of OAC. Cryoplatelet gel and GTR accelerate tissue healing and also promote bone reconstruction by release of osteoinductive growth factors in cases of large OAC (Waldrop 1993).
Non-surgical interventions promote closure of OAC without the need for a soft tissue flap (Grzesiak-Janas 2001; Buric 2013). These interventions involve minimum tissue handling, hence reducing post-surgical trauma during healing (Choi 2006; Buric 2012; Buric 2013). Glues, adhesives and sealants have the structural ability to enhance the coagulation process and to create a mechanical barrier at the site of tissue breakdown that aids the closure of OAC (Buric 2013). Synthetic absorbable implants are press fitted directly into the defect to obtain the direct closure of the OAC (Buric 2012). Acrylic splints act as mechanical barriers in people who are immunocompromised to facilitate healing of OAC. Splints may also be appropriate in cases of large defects that do not respond to other treatment modalities. Prolamine occlusion gel is directly injected into the perforation, which hardens to form a barrier (Visscher 2010). Biostimulation with laser light has also been used for closure of OAC (Grzesiak-Janas 2001).
Antibiotics are needed to control infections of the sinus thereby helping with better healing of the oro-antral communication (Von Wowern 1982). Nasal decongestants or nasal sprays (steroidal and non-steroidal) or a combination of these should be used preoperatively to reduce the inflammation of the sinus mucosa thereby aiding a tension-free closure of soft tissue flap over intact bone (Kamadjaja 2008; Borgonovo 2012).

Why it is important to do this review

The Cochrane Oral Health Group undertook an extensive prioritisation exercise in 2014 to identify a core portfolio of titles that were the most clinically important ones to maintain on *The Cochrane Library* (Worthington 2015); this review was identified as a priority title by an oral and maxillofacial surgery expert panel (Cochrane OHG priority review portfolio).
There are many techniques suggested for the treatment of OAC/OAF encountered during dental procedures. So far there has been no systematic review to summarise the effects of various interventions available to treat OAC/OAF and provide evidence to guide dental practice. Considering the different complex interventions available to treat OAC/OAF in dental patients, it is important to identify the best intervention strategies to help clinicians to treat people with OAC/OAF efficiently and improve patient comfort. A systematic review will impact the implementation of different approaches and trigger the development of new interventions on the basis of current best evidence. A systematic review on this topic

is needed since interventions of questionable effectiveness and unclear consequences might be in use.

OBJECTIVES

To assess the effectiveness and safety of various interventions for the treatment of oro-antral communications and fistulae caused by dental procedures.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials (RCTs) evaluating any intervention for treating oro-antral communications and oro-antral fistulae due to dental procedures. We excluded quasi-RCTs and cross-over trials.

Types of participants

Inclusion criteria

People of any age with oro-antral communications and fistulae caused by dental procedures.

Exclusion criteria

People with oro-antral communications or fistulae created due to Caldwell-Luc procedure (fenestration of the anterior wall of the maxillary sinus and the surgical drainage of this sinus into the nose via an antrostomy) or surgical excision of tumours.

Types of interventions

Any surgical or non-surgical technique or material used for the management of oro-antral communications or oro-antral fistulae due to dental procedures. We intended to make the following comparisons:

- surgical technique A versus B;
- non-surgical technique A versus B;
- surgical technique versus non-surgical technique;
- surgical technique versus no treatment;
- non-surgical technique versus no treatment.

Types of outcome measures

Primary outcomes

- Complete closure of OACs, OAFs, or both, as assessed clinically and with participant-reported outcomes, by absence of associated signs and symptoms such as nasal regurgitation, pain, inflammation, etc.

Secondary outcomes

- Adverse effects, such as graft necrosis and rejection, chronic sinusitis due to failure of OACs, OAFs, or both.
- Time required for healing.

Search methods for identification of studies

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. The search strategy used a combination of controlled vocabulary and free text terms and was linked with the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials (RCTs) in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 (updated March 2011) (Higgins 2011). Details of the MEDLINE search are provided in Appendix 3.

Electronic searches

We searched the following databases:

- the Cochrane Oral Health Group Trials Register (whole database, to 3 July 2015) (see Appendix 1);
- the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, 2015, Issue 6) (see Appendix 2);
- MEDLINE via OVID (1946 to 3 July 2015) (see Appendix 3);
- EMBASE via OVID (1980 to 3 July 2015) (see Appendix 4).

We did not apply any language or date restrictions to the electronic searches.

Searching other resources

We searched for ongoing studies in the following trials registries:

- US National Institutes of Health Trials Registry (http://clinicaltrials.gov) (whole database, to 3 July 2015) (see Appendix 5);

- The WHO Clinical Trials Registry Platform (http://apps.who.int/trialsearch/default.aspx) (whole database, to 3 July 2015) (see Appendix 6).

We searched the reference lists of included and excluded trials for any RCTs.

Data collection and analysis

Selection of studies

Two review authors (HA, RJM) independently screened the titles and abstracts from the electronic searches to identify potentially eligible studies that required further evaluation to determine whether they met the inclusion criteria for this review. We obtained full-text copies of all eligible and potentially eligible studies. Two review authors (SK, SN) evaluated these to identify the studies that actually met all the inclusion criteria. From this group, we intended to record the studies that did not meet the inclusion criteria in the 'Characteristics of excluded studies' table, noting the reasons for exclusion. However we had no studies in this category. We resolved disagreements by discussion. When resolution was not possible, we consulted an arbiter (KNS). We assessed articles in languages other than English by their abstracts, where possible, and if they appeared to be potentially eligible, we intended to translate the full text of the article. However, we did not need to do any translations.

Data extraction and management

Two review authors (SK, SN) independently extracted the data. The review authors were not blinded to the authors of the included study. We resolved disagreements by discussion and when necessary, we consulted a third review author (EP) in order to reach consensus. We extracted data using a customised data extraction form, which was first pilot tested using a sample of the included study. All the items in the data extraction form were designed following guidance from the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We entered study details in Review Manager 5 (RevMan 2014).

We recorded the following details:

- publication details such as year of publication, language;
- demographic details of the report;
- inclusion and exclusion criteria;
- type of trial, sample size, method of randomisation, allocation concealment, blinding, method of assessing the outcomes and drop-outs;
- type of intervention;
- details of the outcomes reported;
- duration of follow-up;
- results of the intervention;
- funding details.

We emailed to the author of the included study where clarification of details or any additional data were required.

Assessment of risk of bias in included studies

We independently assessed the risk of bias in the included trial for seven domains: sequence generation; allocation concealment; performance bias; detection bias; incomplete outcome data; selective outcome reporting; and other biases. For each of these components, we assigned a judgment regarding the risk of bias as either 'high', 'low' or 'unclear', based on guidance in the *Cochrane Handbook for Systematic Reviews of Interventions (*Higgins 2011). We contacted the trial authors if details were missing in the publication or were unclear. We resolved disagreements through consensus. We recorded our judgements and justifications in 'Risk of bias' tables for each included study and generated a 'Risk of bias' summary figure. We used these judgements while grading the overall quality of evidence for outcomes in the 'Summary of findings' table.

We summarised the risk of bias according to Higgins 2011, as follows:

Risk of bias	Interpretation	In outcome	In included studies
Low risk of bias	Plausible bias unlikely to seriously alter the results	Low risk of bias for all key domains	Most information is from studies at low risk of bias
Unclear risk of bias	Plausible bias that raises some doubt about the results	Unclear risk of bias for ≥ 1 key domains	Most information is from studies at low or unclear risk of bias
High risk of bias	Plausible bias that seriously weakens confidence in the results	High risk of bias for ≥ 1 key domains	The proportion of information from studies at high risk of bias is sufficient to affect the interpretation of results

Measures of treatment effect

Data for complete closure of OAC was dichotomous. We expressed this effect estimate as a risk ratio (RR) together with 95% confidence intervals (CI). If continuous data had been present, we would have expressed it as mean and standard deviation.

We planned to use standardised mean difference (SMD) if studies used different scales to measure the same outcome. If data expressed were in ordinal scales, we planned to explore the possibility of converting them to dichotomous outcomes. If outcomes were reported both at baseline and at follow-up or at trial endpoints, we intended to extract both the mean change from baseline and the standard deviation of this mean for each treatment group, as well as the same for endpoint data. We had planned to prefer end scores. However, as there was only one included study we did not encounter any of the above.

Unit of analysis issues

We did not find any cluster-randomised trials or split-mouth designs for this condition. In case of a trial with multiple treatment arms, we planned to combine groups to create a single pair-wise comparison as recommended in Higgins 2011. However, we did not find any trial with multiple treatment groups.

If the search found trials with repeated observations on participants, we would have followed the method as described in Section 9.3.4 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). In case of multiple treatment attempts per participant, we planned to use the number of participants randomised to calculate the CIs (Higgins 2011). In trials where adverse effects were described as counts, we intended to follow the method described in Section 9.2.5 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). However we did not encounter these situations in our included study.

Dealing with missing data

We tried to contact study authors to obtain missing data. If missing statistics had been present, we would have imputed data by using the formulas as described in section 7.7.3.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). As the included study had drop-outs, we used what the paper reported and dealt with it in the 'Risk of bias' assessment.

Assessment of heterogeneity

We intended to assess heterogeneity between the trials by examining the forest plot to check for overlapping CIs, using the Chi² test for heterogeneity with a 10% level of significance to detect inconsistency in study results that were not due to random error (chance), and the I^2 statistic to denote the percentage of inconsistency in results due to inter-trial variability that exceeded chance. In general, we interpret an I^2 value of 50% or greater to denote significant heterogeneity (Higgins 2003). We acknowledge that this cut-off is arbitrary. Therefore, we intended to interpret I^2 values between 0% to 40% as possibly insignificant, 30% to 60% as possibly significant, 50% to 90% as possibly substantial and 75% to 100% as substantial; depending on whether the inconsistency in results was due to differences in the direction of effects estimates between trials rather than due to differences in the magnitude of effect estimates favouring an intervention; and the strength of the evidence for heterogeneity from the P value for the Chi² test for heterogeneity (Deeks 2011). However, we did not need to assess for heterogeneity in the present review.

Assessment of reporting biases

As there is only one study included in the review, we did not assess the possible presence of reporting bias by testing for asymmetry in a funnel plot. If there had been a sufficient number of trials (more than 10), we would have done statistical analysis using the methods described by Egger 1997.

Data synthesis

We analysed the data using Review Manager 5 software (RevMan 2014). If the data available from the studies had similar comparisons and outcomes, we planned to undertake meta-analysis. We planned to use a random-effects model because in this approach, the CIs for the mean intervention effect will be wider than those obtained using a fixed-effect approach, leading to a more conservative interpretation. We planned to use all change scores or end scores when available, and combine change and end scores where necessary using the criteria in Section 9.4.5.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We planned to report the results from studies not suitable for inclusion in a meta-analysis in additional tables. However, none of them were done as there was only one included study in the review.

Subgroup analysis and investigation of heterogeneity

We did not conduct any subgroup analysis as there was only one included trial. In future updates, we may consider the following:

- size of the defect;
- immune status of the participant;
- end score versus change score.

Sensitivity analysis

As there was only one included study, we did not undertake sensitivity analysis.

Summary of findings

We used the GRADE approach to interpret findings (Schünemann 2011). We used GRADE Profiler software (GRADE 2004); and

imported data from Review Manager 5 (RevMan 2014) to create 'Summary of findings' tables for each comparison included in the review. These tables provided information concerning the overall quality of the evidence from the trials, the magnitude of effect of the interventions examined and the sum of available data on the primary and secondary outcomes. The GRADE approach considers 'quality' to be a judgement of the extent to which we can be confident that the estimates of effect are correct (Schünemann 2011). A body of evidence from RCTs is initially graded as high and downgraded by one or two levels on each of five domains after full consideration of: risk of bias, directness (or applicability) of the evidence, consistency of results, precision of results and possibility of publication bias. A quality level of 'high' reflects confidence that the true effect lies close to that of the estimate of the effect for an outcome. A judgement of 'moderate' quality indicates that the true effect is likely to be close to the estimate of the effect, but acknowledges the possibility that it could be substantially different. 'Low' and 'very low' quality evidence limit our confidence in the effect estimate (Balshem 2011).

RESULTS

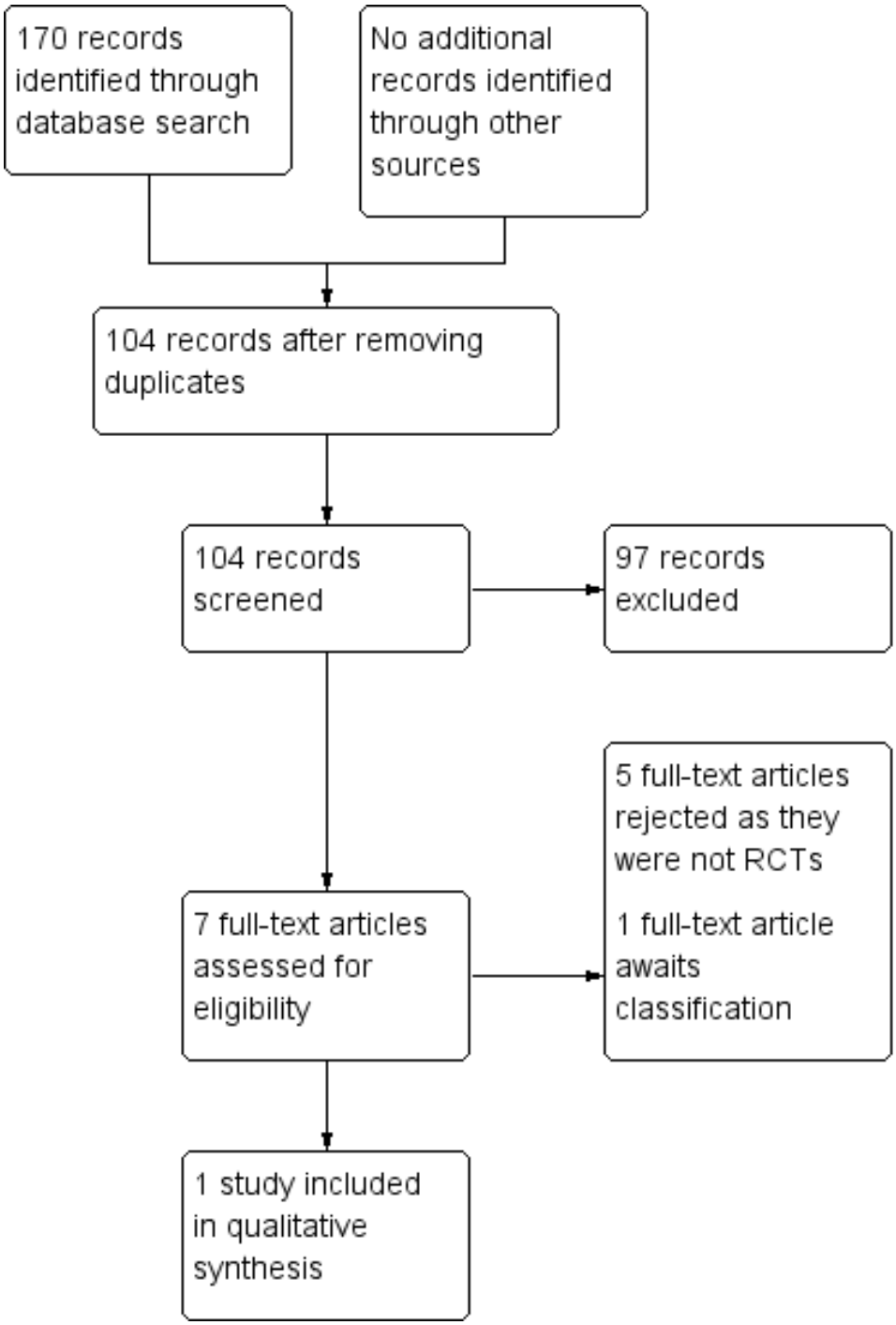
Description of studies

See Characteristics of included studies and Characteristics of studies awaiting classification table.

Results of the search

The electronic search strategies identified 170 records from English and other language databases. We had 104 records after deduplication. Among the 104 records, we discarded 97 after screening the abstracts as they were not relevant; and requested full-text copies of seven studies. From the seven studies, five were rejected as they were not RCTs. The remaining two studies were assessed for eligibility. Only one RCT met the inclusion criteria of this review. One study awaits further classification. See Figure 1 for details of the selection process and Table 1 for summary of the search process.

Figure 1. Study flow diagram



Included studies

Trial design

Nezafati 2012, the included trial, was conducted in Iran. It was a single centre trial with parallel group design. The trial was funded by Tabriz University of Medical Sciences, Iran.

Participants

The trial included a total of 22 adults aged 25 to 56 years, and did not state how many participants were male and how many were female. Consenting patients who had established oro-antral communications which were closed at the time of surgery were recruited in the trial. Two of the 22 participants did not report for follow-up and were excluded from the study.

Interventions

The trial compared pedicled buccal fat pad flap with buccal flap. The trial duration was two years.

Outcomes

The reported relevant outcome was successful (complete) closure of oro-antral communication (measured at one month). The authors reported that both the groups achieved successful closure of OAC. We presented this outcome as dichotomous data in our analysis.

Excluded studies

There are no excluded studies in our review.

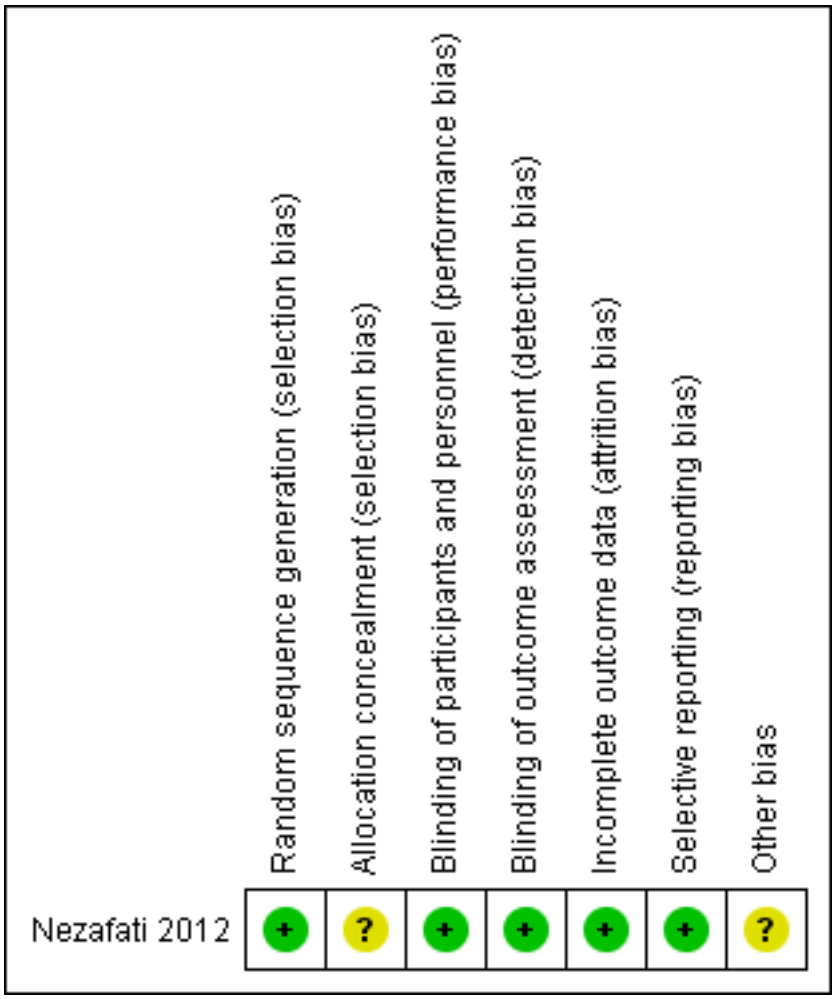
Studies awaiting classification

One study currently awaits classification (Gacic 2009). The trial compared resorbable PLGA-coated beta-TCP root analogues, haemostatic gauze and buccal flaps. We are unclear whether the study is a randomised controlled trial or not as the authors did not explain the randomisation method. We are awaiting additional information and clarification from the authors. See Characteristics of studies awaiting classification.

Risk of bias in included studies

See Figure 2.

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



Allocation

Sequence generation was judged as low risk as the trial authors used Rand List 1.2 software to generate the randomisation sequence; however, the trial authors did not describe the method of allocation concealment and hence was judged as unclear risk of selection bias.

Blinding

The study was at low risk of performance and detection bias since the participants and the dentist who gathered the data were not aware of the type of surgery.

Incomplete outcome data

The study was at low risk of bias as there are only two drop-outs, one from each group.

Selective reporting

Although a study protocol was not available to compare the outcomes as the trial was not registered in the Iranian Clinical Trial Registry, we judged the study as being at low risk of reporting bias as the expected outcomes were appropriately reported.

Other potential sources of bias

The study was at unclear risk of bias due to the following aspects:

1. Some of the participants whose surgery was not in the first two days of the trial had an additional sinus lavage with saline to reduce the chances of contamination.
2. The length of time participants had OAC is not mentioned.
3. A table of baseline characteristics is not provided.

Overall risk of bias

The overall risk of bias is judged unclear.

Effects of interventions

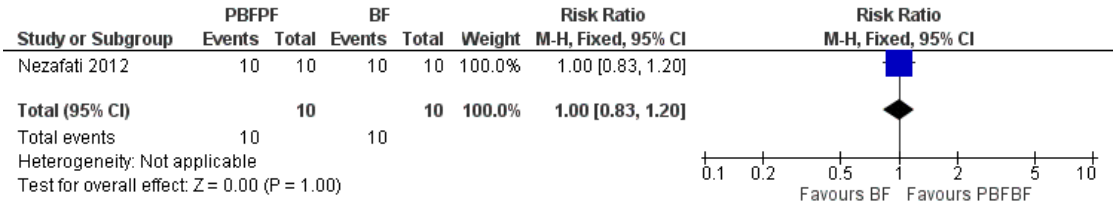
See: **Summary of findings for the main comparison** Pedicled buccal fat pad flap compared to buccal flap for treatment of oro-antral communications and fistulae due to dental procedures

Pedicled buccal fat pad flap (PBFPF) versus buccal flap (BF)

1.1 Successful (complete) closure of the oro-antral communication

There was no difference between BF and PBFPF for the complete closure of oro-antral communication (RR 1.00, 95% CI 0.83 to 1.20; one RCT, 20 participants; Analysis 1.1; Figure 3).

Figure 3. Forest plot of comparison: 1 PBFPF versus BF, outcome: 1.1 Successful (complete) closure of the oro-antral communication



Secondary outcomes

The study did not report any adverse effects or the time required for healing.

Subgroup and sensitivity analyses

We did not conduct subgroup analysis and sensitivity analysis as there was only a single included trial in this review.

DISCUSSION

Summary of main results

The main objective of the review was to assess effectiveness and safety of various interventions for the treatment of oro-antral communications and fistulae due to dental procedures. We found only one study, which compared pedicled buccal fat pad flap (PBFPF) with buccal flap (BF) (Nezafati 2012). The trial provided the data for the primary outcome of successful (complete) closure of oral-antral communication (OAC).

The authors did not report any adverse events. We assessed the body of evidence using GRADE 2004, which incorporates risk of bias, the directness of the evidence, the consistency of the results, the precision of the estimates and the possibility of publication bias. The quality of the evidence is very low.

The main results of this review are as follows.

- The single trial included was judged as unclear for risk of bias.
- PBFPF compared to BF showed no difference in the closure of OAC (very low quality of evidence) (Summary of findings for the main comparison).

Overall completeness and applicability of evidence

Completeness

In spite of our comprehensive search of multiple databases, we found only one trial assessing the effectiveness of PBFPF compared to BF for treating OAC due to dental procedures with a total sample size of 20. Data from this trial was insufficient to provide precise results, as it had insufficient sample size for relevant comparisons and was judged unclear for risk of bias. The trial did not report any definite adverse events with interventions.

We found one trial evaluating resorbable PLGA-coated β-TCP root analogues, haemostatic gauze and buccal flaps for the closure of the OAC, and if it is included in future updates of this review,

it may provide additional evidence on effects of interventions for treating OAC due to dental procedures.

We are not aware of any ongoing trials assessing any of the interventions proposed or commonly used for treating OAC and oral-antral fistula (OAF). We did not find any trials assessing the effectiveness of interventions on children. The evidence base is thus incomplete and insufficient to draw robust conclusions about the most effective intervention for treating OAC due to dental procedures.

Applicability

The results obtained from this Cochrane review are insufficient to determine the relative efficacy of PBFPF and BF for treatment of oro-antral communications or fistulae. The study awaiting classification has compared two non-surgical techniques (PLGA-coated β-TCP and haemostatic gauze) with a surgical technique (buccal flap). Even if the efficacy of these interventions is confirmed in future trials, it is uncertain whether these techniques can be universally applied to different cases of OAC/OAF with varying defect sizes. More RCTs involving surgical and non-surgical interventions with emphasis on the size and type of defect need to be done in order to draw definitive conclusions on the applicability of the interventions.

Quality of the evidence

We have included one parallel-arm RCT comparing PBFPF with BF in 20 adult participants after two dropouts. The quality of evidence was assessed for the primary outcome, namely successful (complete) closure of oro-antral communication. We downgraded the quality of evidence by one level for unclear risk of bias and by two levels for imprecision. Overall, the evidence is very low quality. The results do not allow us to draw any firm conclusions regarding whether one of these interventions is more effective than the other.

Potential biases in the review process

We have taken steps to minimise the bias in every step of the review. All the mentioned databases, conference proceedings and trial registries have been searched to include all the relevant reports. We tried to contact the authors for missing data through emails. If the reports were very old, we tried to get the contact details of the authors through peer contacts, Google search and university/hospital web sites where they were previously affiliated. We tried our best to follow the methodology stated in the protocol. We used standard methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), and also ensured compliance with the Cochrane standards for the conduct of new reviews of interventions (MECIR 2011). In spite of our comprehensive search strategies, we cannot rule out publication bias occurring due to non-identification of unpublished trials.

Agreements and disagreements with other studies or reviews

We found one systematic review and meta-analysis on the frequency and treatment of oro-antral communications (Borja 2011). The purpose of the review was to determine the optimum surgical treatment for OAC and to understand the postoperative complications associated with the procedure. The literature search was carried out for the period between 1983 and 2008. Fifteen non-RCTs were included in this systematic review. The review author concluded that Bichat's fat pad grafts showed excellent results for closure of OAC and low rate of failure and good patient satisfaction postoperatively.

The inclusion criteria for Borja 2011 and our review vary considerably and hence the results are not comparable.

AUTHORS' CONCLUSIONS

Implications for practice

There is very low quality evidence to inform clinicians and patients how best to treat oro-antral communications. There was no RCT evidence available for treating oro-antral fistulae. We found a single small study that compared surgical techniques PBFPF and BF and did not show evidence of a difference in effectiveness for treating OAC caused by dental procedures. All oro-antral communications were closed by one month after surgery so it was not possible to assess adverse effects from treatment failure. We did not find any evidence on any other interventions for treating this condition.

Implications for research

Further research should be done in interventions for treating oro-antral communications and fistulae due to dental procedures by conducting well-planned RCTs with more clarity and uniformity in the variables. In designing such clinical trials, the following should be considered.

Evidence: Trials should evaluate all the outcomes mentioned in this review. Future research on adverse effects of different interventions should include longer follow-up. Furthermore, reports on clinical trials would be improved by following CONSORT group guidelines.

Population: Inclusion criteria for clinical trials should be well defined. The trials should include different sizes of OAC/OAF. Outcome measures should be clearly defined for different age groups.

Intervention: More interventional studies should be conducted on both surgical and non-surgical interventions.

Comparison: Comparisons between two different interventions (surgical versus non-surgical or non-surgical versus non-surgical) can be considered in future trials.

Outcome: Along with complete closure of OAC and OAF, patient-reported outcomes in terms of satisfaction and quality of life should be evaluated in the trials.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Nezafati 2012

Methods	Trial design: double-blinded randomised clinical trial Trial location: Tabriz University of Medical Sciences Number of centres: one Recruitment period (duration): two years (2006 to 2008) Funding source: Tabriz University of Medical Sciences
Participants	Participants with chief complaint of oro-antral communication Total number: 20 participants aged 25 to 56 years (actual enrolment was 22 but 2 participants, one from each group, did not attend for follow-up and they were excluded) Inclusion criteria • Oro-antral communication Exclusion criteria • Systemic disease affecting healing • Smoking, drug and alcohol abuse • History of sinus disease • History of sinus surgery • Intra-antral foreign body • People with need for Caldwell-Luc Procedure Number randomised: 22 Number evaluated: 20 (2 dropouts - one from each group)
Interventions	Total number of intervention groups: two Group 1: buccal flap Group 2: pedicled buccal fat pad flap Duration of treatment: from first incision to the last suture measured with a chronometer Group 1: buccal flap - 23.61 ± 7.02 minutes Group 2: pedicled buccal fat pad flap - 26.01 ± 10.49 minutes
Outcomes	Relevant outcome reported and used in our review: • Successful (complete) closure of oro-antral communication (OAC) Other outcomes reported in the trial: • Mean pain score • Proportion of postoperative swelling • Reduction in maximum mouth opening (MMO)
Notes	Sample size calculation: not reported Adverse effects: none reported Health-related quality of life: not reported Key conclusions of the study authors: both methods were equally successful for the closure of OAC as tested by negative nose blowing one month later indicating closure PBFPF group had a higher mean pain score, more pronounced swelling, and reduced mouth opening at 2 and 7 days after surgery compared to control group. Maximum mouth opening was no different between groups at 1 month Correspondence required: yes, author was contacted via email on 8/07/2015 and 25/07/

	2015 with the following queries, however there was no response • Number randomised • Method of allocation concealment • Baseline characteristics

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote from article: "After completing the consent form, the patients were randomly divided into two groups using Rand List 1. 2 software"
Allocation concealment (selection bias)	Unclear risk	Not mentioned in the trial. Authors contacted regarding the same (8/07/2015 and 25/07/2015). No response has been received to date
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote from article: "The patients and the dentist who gathered the data were not aware of the type of surgery"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote from article: "The patients and the dentist who gathered the data were not aware of the type of surgery"
Incomplete outcome data (attrition bias) All outcomes	Low risk	The study was at low risk as there were only two drop-outs, one from each group
Selective reporting (reporting bias)	Low risk	Study trial not registered in Iranian National Trial Registry (we searched Iranian Clinical Trial Registry on 15 April 2016) so study protocol was not available to compare the outcomes; however, expected outcomes seemed to be reported appropriately
Other bias	Unclear risk	1. Some of the participants whose surgery was not in the first two days of the trial had an additional sinus lavage with saline to reduce the chances of contamination. 2. The length of time participants had OAC is not mentioned. 3. A table of baseline characteristics is not provided.

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

Gacic 2009

Methods	Trial design (including number of arms): not clear Location and setting: University of Belgrade Number of centres: one Recruitment period (duration): not available Funding source: PLGA-coated β-TCP and instruments for making root analogue provided by Degradable Solutions Schlieren, Switzerland
Participants	Total number: 30 Inclusion criteria • Oro-antral communication following extraction of tooth Exclusion criteria • Smokers • Pregnant or lactating women • Patient under medication Number randomised: not available Method of randomisation: not available Method of allocation concealment: not available Method of blinding: not available Number evaluated: not available
Interventions	Total number of intervention groups: three • Group 1: PLGA-coated β-TCP • Group 2: haemostatic gauze • Group 3: buccal flap Duration of treatment: not available
Outcomes	• Closure OAC • Vestibular depth • Pain intensity • Swelling • Histologic analysis of the surgical site after implant placement: to check for necrosis/inflammation
Notes	Sample size calculation: not mentioned Adverse effects: not available Health-related quality of life: not available Key conclusions of the study authors: closure of OAC with PLGA-coated β-TCP or haemostatic guaze are reliable and minimally invasive methods. They showed minimal atrophy of alveolar bone, swelling and pain compared to buccal flap technique Correspondence required: yes, author was contacted via email on 8/07/2015 with the following queries, however there was no response: • Trial design • Number randomised • Method of randomisation • Method of allocation concealment • Method of blinding • Number evaluated

DATA AND ANALYSES

Comparison 1. PBFPF versus BF

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Successful (complete) closure of the oro-antral communication	1	20	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.83, 1.20]

Analysis 1.1. Comparison 1 PBFPF versus BF, Outcome 1 Successful (complete) closure of the oro-antral communication.

Review: Interventions for treating oro-antral communications and fistulae due to dental procedures

Comparison: 1 PBFPF versus BF

Outcome: 1 Successful (complete) closure of the oro-antral communication

Study or subgroup	PBFPF n/N	BF n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Nezafati 2012	10/10	10/10		100.0 %	1.00 [0.83, 1.20]
Total (95% CI)	**10**	**10**		**100.0 %**	**1.00 [0.83, 1.20]**
Total events: 10 (PBFPF), 10 (BF)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.0 (P = 1.0)					
Test for subgroup differences: Not applicable					

ADDITIONAL TABLES

Table 1. Summary of the search results

July 2015 Searches carried out by Anne Littlewood Trials Search Co-ordinator, Cochrane Oral Health Group			
Database	**Version/issue**	**Date of search**	**Records retrieved**
OHG Register	Whole database	03.07.15	22

Table 1. Summary of the search results (*Continued*)

CENTRAL via *The Cochrane Library*	To Issue 6, 2015	03.07.15	25
MEDLINE via OVID	1946-3 July 2015	03.07.15	92 (with filter)
EMBASE via OVID	1980-3 July 2015 (week 26)	03.07.15	31 (with filter)
ClinicalTrials.gov	Whole database	03.07.15	0
WHO International Clinical Trials Registry Platform	Whole database	03.07.15	0
Total retrieved from electronic searches: 170 Total left after de-duplication: 104 Total sent to authors for this search: 104			

APPENDICES

Appendix 1. Cochrane Oral Health Group Trials Register search strategy

1. (((oroantral* or oro-antral*) and (fistula* or communicat*))) AND (INREGISTER)
2. (((orosinusal or oro-sinusal) and (fistula* or communicat*))) AND (INREGISTER)
3. ((antral and perforation*)) AND (INREGISTER)
4. ("antro-alveolar fistula*") AND (INREGISTER)
5. ((antrooral or antro-oral)) AND (INREGISTER)
6. (((alveolo-sinusal or palatal-sinusal or vestibulo-sinusal) and fistula*)) AND (INREGISTER)
7. (("maxillary sinus" or "maxillary antrum")) AND (INREGISTER)
8. ((fistula* or perforat*)) AND (INREGISTER)
9. (#7 and #8) AND (INREGISTER)
10. (#1 or #2 or #3 or #4 or #5 or #6 or #9) AND (INREGISTER)

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

#1 [mh ^"oroantral fistula"]
#2 ((oroantral* or oro-antral*) and (fistula* or communicat*))
#3 ((orosinusal or oro-sinusal) and (fistula* or communicat*))
#4 (antral near/2 perforation*)
#5 (antro-alveolar next fistula*)
#6 (antrooral or antro-oral)
#7 ((alveolo-sinusal or palatal-sinusal or vestibulo-sinusal) next fistula*)
#8 [mh ^"Maxillary sinus"]
#9 ("maxillary sinus" or "maxillary antrum")

#10 #8 or #9
#11 (fistula* or perforat*)
#12 #10 and #11
#13 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #12

Appendix 3. MEDLINE (OVID) search strategy

1. Oroantral fistula/
2. ((oroantral$ or oro-antral$) and (fistula$ or communicat$)).mp.
3. ((orosinusal or oro-sinusal) and (fistula$ or communicat$)).mp.
4. (antral adj2 perforation$).mp.
5. (antro-alveolar adj fistula$).mp.
6. (antrooral or antro-oral).mp.
7. ((alveolo-sinusal or palatal-sinusal or vestibulo-sinusal) adj fistula$).mp.
8. Maxillary sinus/
9. ("maxillary sinus" or "maxillary antrum").mp.
10. 8 or 9
11. (fistula or perforat$).mp.
12. 10 and 11
13. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 12

The above subject search was linked to the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomized trials in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of *The Cochrane Handbook for Systematic Reviews of Interventions,* Version 5.1.0 [updated March 2011].

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
10. exp animals/ not humans.sh.
11. 9 not 10

Appendix 4. EMBASE (OVID) search strategy

1. Oroantral fistula/
2. ((oroantral$ or oro-antral$) and (fistula$ or communicat$)).mp.
3. ((orosinusal or oro-sinusal) and (fistula$ or communicat$)).mp.
4. (antral adj2 perforation$).mp.
5. (antro-alveolar adj fistula$).mp.
6. (antrooral or antro-oral).mp.
7. ((alveolo-sinusal or palatal-sinusal or vestibulo-sinusal) adj fistula$).mp.
8. Maxillary sinus/
9. ("maxillary sinus" or "maxillary antrum").mp.
10. 8 or 9
11. (fistula or perforat$).mp.
12. 10 and 11
13. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 12

The above subject search was linked to the Cochrane Oral Health Group filter for identifying RCTs in EMBASE via OVID:

1. random$.ti,ab.

2. factorial$.ti,ab.
3. (crossover$ or cross over$ or cross-over$).ti,ab.
4. placebo$.ti,ab.
5. (doubl$ adj blind$).ti,ab.
6. (singl$ adj blind$).ti,ab.
7. assign$.ti,ab.
8. allocat$.ti,ab.
9. volunteer$.ti,ab.
10. CROSSOVER PROCEDURE.sh.
11. DOUBLE-BLIND PROCEDURE.sh.
12. RANDOMIZED CONTROLLED TRIAL.sh.
13. SINGLE BLIND PROCEDURE.sh.
14. or/1-13
15. (exp animal/ or animal.hw. or nonhuman/) not (exp human/ or human cell/ or (human or humans).ti.)
16. 14 NOT 15

Appendix 5. The US National Institutes of Health Trials Registry (ClinicalTrials.gov) search strategy

oroantral communication
oroantral fistula

Appendix 6. WHO International Clinical Trials Registry Platform search strategy

oroantral

CONTRIBUTIONS OF AUTHORS

- Salian Kiran Kumar Krishanappa: drafting the protocol, selection of trials, data extraction and entering data into Review Manager 5, data analysis, drafting the final review and updating the review.
- Eachempati Prashanti, Kumbargere Nagraj Sumanth: arbiter, drafting the protocol, carrying out analysis, drafting final review and updating the review.
- Shetty Naresh: drafting the protocol, selection of trials, data extraction and entering data into RevMan and drafting the final review.
- Soe Moe: drafting the protocol, carrying out and interpreting analysis and drafting the final review.
- Himanshi Aggarwal: undertaking searches, selection of trials, drafting final review.
- Rebecca J Mathew: undertaking searches, selection of trials, carrying out and interpreting analysis and drafting final review.

DECLARATIONS OF INTEREST

Salian Kiran Kumar Krishanappa: none known

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

There are no differences between the protocol and review.

INDEX TERMS

Medical Subject Headings (MeSH)

Adipose Tissue [*transplantation]; Dental Care [*adverse effects]; Oroantral Fistula [etiology; *surgery]; Randomized Controlled Trials as Topic; Surgical Flaps [*transplantation]

MeSH check words

Adult; Humans; Middle Aged