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Flossing for the management of periodontal diseases and dental caries in adults (Review)

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Flossing for the management of periodontal diseases and dental caries in adults.
Cochrane Database of Systematic Reviews 2011, Issue 12. Art. No.: CD008829.
DOI: 10.1002/14651858.CD008829.pub2.

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[Intervention Review]

Flossing for the management of periodontal diseases and dental caries in adults

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Editorial group: Cochrane Oral Health Group.
Publication status and date: Edited (no change to conclusions), published in Issue 4, 2012.
Review content assessed as up-to-date: 28 October 2011.

Citation: Sambunjak D, Nickerson JW, Poklepovic T, Johnson TM, Imai P, Tugwell P, Worthington HV. Flossing for the management of periodontal diseases and dental caries in adults. *Cochrane Database of Systematic Reviews* 2011, Issue 12. Art. No.: CD008829. DOI: 10.1002/14651858.CD008829.pub2.

ABSTRACT

Background

Good oral hygiene is thought to be important for oral health. This review is to determine the effectiveness of flossing in addition to toothbrushing for preventing gum disease and dental caries in adults.

Objectives

To assess the effects of flossing in addition to toothbrushing, as compared with toothbrushing alone, in the management of periodontal diseases and dental caries in adults.

Search methods

We searched the following electronic databases: the Cochrane Oral Health Group Trials Register (to 17 October 2011), the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2011, Issue 4), MEDLINE via OVID (1950 to 17 October 2011), EMBASE via OVID (1980 to 17 October 2011), CINAHL via EBSCO (1980 to 17 October 2011), LILACS via BIREME (1982 to 17 October 2011), ZETOC Conference Proceedings (1980 to 17 October 2011), Web of Science Conference Proceedings (1990 to 17 October 2011), Clinicaltrials.gov (to 17 October 2011) and the metaRegister of Controlled Clinical Trials (to 17 October 2011). We imposed no restrictions regarding language or date of publication. We contacted manufacturers of dental floss to identify trials.

Selection criteria

We included randomised controlled trials conducted comparing toothbrushing and flossing with only toothbrushing, in adults.

Data collection and analysis

Two review authors independently assessed risk of bias for the included studies and extracted data. We contacted trial authors for further details where these were unclear. The effect measure for each meta-analysis was the standardised mean difference (SMD) with 95% confidence intervals (CI) using random-effects models. We examined potential sources of heterogeneity, along with sensitivity analyses omitting trials at high risk of bias.

Main results

Twelve trials were included in this review, with a total of 582 participants in flossing plus toothbrushing (intervention) groups and 501 participants in toothbrushing (control) groups. All included trials reported the outcomes of plaque and gingivitis. Seven of the included trials were assessed as at unclear risk of bias and five were at high risk of bias.

Flossing plus toothbrushing showed a statistically significant benefit compared to toothbrushing in reducing gingivitis at the three time points studied, the SMD being -0.36 (95% CI -0.66 to -0.05) at 1 month, SMD -0.41 (95% CI -0.68 to -0.14) at 3 months and SMD -0.72 (95% CI -1.09 to -0.35) at 6 months. The 1-month estimate translates to a 0.13 point reduction on a 0 to 3 point scale for Loe-Silness gingivitis index, and the 3 and 6 month results translate to 0.20 and 0.09 reductions on the same scale.

Overall there is weak, very unreliable evidence which suggests that flossing plus toothbrushing may be associated with a small reduction in plaque at 1 or 3 months.

None of the included trials reported data for the outcomes of caries, calculus, clinical attachment loss, or quality of life. There was some inconsistent reporting of adverse effects.

Authors' conclusions

There is some evidence from twelve studies that flossing in addition to toothbrushing reduces gingivitis compared to toothbrushing alone. There is weak, very unreliable evidence from 10 studies that flossing plus toothbrushing may be associated with a small reduction in plaque at 1 and 3 months. No studies reported the effectiveness of flossing plus toothbrushing for preventing dental caries.

PLAIN LANGUAGE SUMMARY

Flossing to reduce gum disease and tooth decay

It is assumed that removing plaque (a layer of bacteria in an organic matrix which forms on the teeth) will help prevent gum disease (gingivitis) and tooth decay (dental caries). Gum disease, which appears as red, bleeding gums, may eventually contribute to tooth loss. Untreated tooth decay may also result in tooth loss. Toothbrushing removes some plaque, but cannot reach in-between the teeth, where gum disease and tooth decay are common. This review looks at the added benefit of dental flossing, in people who brush their teeth regularly, for preventing gum disease and tooth decay.

Twelve trials were included in this review which reported data on two outcomes (dental plaque and gum disease). Trials were of poor quality and conclusions must be viewed as unreliable. The review showed that people who brush and floss regularly have less gum bleeding compared to toothbrushing alone. There was weak, very unreliable evidence of a possible small reduction in plaque. There was no information on other measurements such as tooth decay because the trials were not long enough and detecting early stage decay between teeth is difficult.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Flossing plus toothbrushing for periodontal disease and dental caries

Patient or population:
Settings: everyday self-care
Intervention: flossing plus toothbrushing

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Flossing plus toothbrushing				
Gingivitis Scale from: 0 to 3 Follow-up: mean 1 month	The mean gingivitis in the control groups was **0.67 points**	The mean gingivitis in the intervention groups was **0.13 lower** (0.02 to 0.23 lower)[1]		489 (7 studies)	⊕○○○ **very low**[2,3,4,5]	The estimate is for the 1-month time point. Results are consistent in other observed time points (3- and 6-month)
Interproximal caries			Not estimable	0 (0)	See comment	No included study assessed caries as an outcome
Harms and adverse effects			Not estimable	(5 studies)	See comment	Adverse effects were assessed in five studies, but they used different outcome measures, so meta-analysis was not appropriate
Plaque Scale from: 0 to 5 Follow-up: mean 29 days	The mean plaque in the control groups was **2.97 points**	The mean plaque in the intervention groups was **0.19 lower** (0.42 lower to -0.05		416 (5 studies)	⊕○○○ **very low**[2,5,7,8]	The estimate is for the 1-month time point. Results consistent with 6-month outcome. 3-

	lower)[6]				month outcome was statistically significant
Calculus		Not estimable	0 (0)	See comment	No included study assessed calculus as an outcome
Clinical attachment loss		Not estimable	0 (0)	See comment	No included study assessed calculus as an outcome
Quality of life		Not estimable	0 (0)	See comment	No included study assessed quality of life as an outcome

*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] Re-expressed from SMD into the Loe-Sillness Gingival Index score. Result should be interpreted with caution since back-translation of the effect size is based on the results of only one study (Hague 2007). The estimate is for the 1-month time point, results show similar effect for 3 months and larger effect for 6 months with SMDs of -0.36 (1 month), -0.41 (3 months) and -0.72 (6 months).
[2] Sensitivity analysis excluding a high risk of bias study (Vogel 1975) did not show a significant change in results.
[3] I^2 = 60%
[4] Only one study had more than 40 subjects in a study arm and one study had less than 10 subjects per study arm.
[5] Most of the included studies were small, industry-sponsored studies. A few had inadequately reported outcomes.
[6] Re-expressed from the SMD into the Turesky-modification of the Quigley-Hein Plaque Index score. Result should be interpreted with caution since back-translation of the effect size is based on the results of only one study (Jared 2005).
[7] I^2 = 51%
[8] Only one study had more than 40 subjects in a study arm.

BACKGROUND

Periodontal disease and dental caries are found in high, middle and low income countries. Although periodontal disease and dental caries incidence differs, based on regional, social and genetic factors, the prevention of these diseases has a significant healthcare and economic benefit, to both society as a whole and individual patients.

Periodontal diseases

Periodontal diseases are multifactorial oral conditions (Llorente 2006; Timmerman 2006), consisting of a diverse family of pathological conditions affecting the periodontium (a collective term that comprises gingival tissue, periodontal ligament, cementum and alveolar bone), that commonly occur in the population (Mariotti 1999).

Periodontal diseases were for the first time, in 1999 (Armitage 1999), separately classified into gingival diseases and periodontal diseases. Gingival diseases were sub classified as dental plaque induced and non-plaque induced.

The prevalence of periodontal disease is difficult to establish across studies, because of non-standardised criteria, different study population characteristics, different clinical measurements, and the use of partial versus full mouth examinations (Cobb 2009; Savage 2009). The differing definitions and clinical measurements used are of particular concern (Cobb 2009; Savage 2009). A recent study (Li 2010) found that 94% of American adults had gingivitis. Gingivitis does not directly progress into chronic periodontitis, although this was thought to be the case until the 1980s. Löe (Löe 1986) studied a population of male Sri Lankan tea workers, who had not had exposure to routine dental treatment, and found that 8% had rapid progression of periodontal disease, 81% had some disease and 11% no disease. This study has since been replicated in other populations and approximately 10% of any population is considered susceptible to rapidly progressive periodontal disease, ultimately leading to tooth loss. Chronic periodontal disease characterises the group of destructive periodontal diseases, generally slowly progressive but with episodes of rapid progression (Jeffcoat 1991).

Gingivitis has been shown to be a risk factor in the clinical course of chronic periodontitis (Schatzle 2004). This 26-year longitudinal study, found that teeth with inflamed gingivae were at much higher risk (46 times) of being lost compared to teeth that had inflammation-free gingivae.

Dental plaque is the primary aetiological factor for the exacerbation of periodontal diseases and caries formation (Dalwai 2006; Kuramitsu 2007; Marsh 2006; Periasamy 2009; Selwitz 2007). The effective removal of dental plaque is essential for the prevention of periodontal disease and dental caries. Calculus formation results from the mineralisation of plaque by saliva supersaturated with calcium phosphates (Grases 2009). However, an analysis of the 1998 UK Adult Dental Health Survey (Morris 2001) showed that 72% of subjects had visible plaque on at least one tooth, with little difference between the groups of respondents, stratified by age, gender and social class. This survey did not record specific information about methods of plaque removal used, only frequency of tooth cleaning. Although there are many types of periodontal diseases, they share common characteristics and thus, have similar professional and self-care treatment options. Generally, periodontal diseases are caused by, or severity is exacerbated by, the presence of periopathogens in an established oral biofilm, commonly known as dental plaque, within a susceptible host (Dalwai 2006; Kuramitsu 2007; Periasamy 2009). Initial therapy, which is the debridement of calculus and disruption of the oral biofilm by oral healthcare professionals, has been shown to be effective for reducing the clinical parameters of gingival bleeding and mean pocket depths by shifting the proportions of the species during recolonisation and by modifying the habitat (Haffajee 2006). Over 3 months there is a gradual shift back to pathogenesis if patients do not have meticulous, frequent removal of supragingival dental plaque. The recolonisation of periopathogens occurs when supragingival dental plaque is allowed to accumulate, triggering the inflammatory response, allowing bacteria to extend subgingivally, and establishing an environment that favours pathogen regrowth (Haffajee 2006). Dental plaque induced gingival disease and incipient, non-cavitated carious lesions are reversible (Mariotti 1999; Silverstone 1983). The progression in either disease may be attributed to a tip in the environmental equilibrium that favours disease conditions. For example, in periodontal disease, the key is to treat gingivitis when inflammation is only in the gingival tissues and has not affected other parts of the periodontal system (Mariotti 1999).

Dental caries

Dental caries is a multifactorial, bacteriologically mediated, chronic disease (Addy 1986; Richardson 1977; Rickard 2004). According to the World Oral Health Report 2003 (Petersen 2003), dental caries affects 60% to 90% of school children and the vast majority of adults, making it one of the most common diseases in the world's population (WHO 1990). Although the prevalence and severity of dental caries in most industrialised countries has substantially decreased in the past two decades (Marthaler 1996), this preventable disease continues to be a common public health problem for other parts of the world (Burt 1998).

Patients with carious teeth may experience pain and discomfort (Milsom 2002; Shepherd 1999) and if left untreated, may lose their teeth. For example, in the United Kingdom, tooth decay accounts for almost half of all dental extractions performed (NHS CRD 1999). Missing teeth negatively impact aesthetics and function, as well as the patient's quality of life.

The formation of carious lesions occurs when a patient has a susceptible tooth surface (i.e. deep pits or fissures that collect and

protect the oral biofilm), cariogenic bacteria in sufficient numbers within the dental plaque, fermentable carbohydrates that frequently supply the bacteria with an energy supply, and a compromised host response such as reduced salivary flow which encourages the presence and growth of the oral biofilm (Murray 1989). Fermentation of sugars by cariogenic bacteria results in localised demineralisation of the tooth surface, which may ultimately result in cavity formation (Marsh 2006; Selwitz 2007). Early carious lesions may or may not progress to the dentine depending on the dynamic equilibrium between demineralisation and remineralisation (Marinho 2002a; Marinho 2002b; Marinho 2003).

Oral healthcare professionals should encourage fluoride therapy and meticulous plaque control to encourage enamel remineralisation of incipient, non-cavitated lesions and thus prevent the need for restorative therapy (Burke 2003). If the equilibrium is allowed to favour demineralisation, carious lesions will form (Berglund 1990; Casey 1988).

Prevention of dental caries and periodontal disease is generally regarded as a priority for oral healthcare professionals because it is more cost-effective than treating it (Brown 2002; Burt 1998). Mechanical disruption of the oral biofilm by toothbrushing is considered an important adjunct to professionally provided plaque removal services (Needleman 2005). Effective plaque control by toothbrushing is a key self-care strategy for oral health (Addy 1986; Richardson 1977). Patients routinely use toothbrushes to remove supragingival dental plaque, but toothbrushes are unable to penetrate the interdental area where periodontal disease is prevalent (Asadoorian 2006; Berchier 2008; Berglund 1990; Casey 1988). Interdental plaque is more prevalent (Lindhe 2003), forms more readily (Igarashi 1989), and is more acidogenic than plaque on the other tooth surfaces in the mouth. Therefore, interdental cleansing devices are often recommended as an adjunctive self-care therapy. There are many types of interdental cleaning devices available, but dental floss is most commonly recommended by oral healthcare professionals.

Dental floss

The concept of interdental cleaning with a filamentous material was first introduced by Levi Spear Parmly (Parmly 1819), as a tool, together with a dentifrice and toothbrush, as a measure for preventing dental disease. Unwaxed silk floss was first produced in 1882, by Codman & Shurtleff, but it was Johnson & Johnson (Johnson 2010) who made silk floss widely available from 1887, as a by-product of sterile silk leftover from the manufacture of sterile sutures.

Since dental floss is able to remove some interproximal plaque (Asadoorian 2006; Waerhaug 1981), it is assumed that frequent regular dental flossing will reduce interproximal caries (Hujoel 2006) and periodontal disease risks. Daily dental flossing in combination with toothbrushing for the prevention of caries and periodontal diseases is frequently recommended (Asadoorian 2006; Bagramian 2009; Brothwell 1998). However, patient compliance with daily dental flossing is low (Asadoorian 2006; Schuz 2009). Patients attribute their lack of dental flossing compliance to lack of motivation and difficulties using the floss (Asadoorian 2006). A study of a cohort of young people at ages 15, 18 and 26 (Broadbent 2006) found that at age 26, 78% of females compared to significantly fewer males ($P < 0.01$) believed that using dental floss was important. However, even those who do floss are often not using the proper flossing technique; for example they quickly pass the floss through the contact points and fail to sufficiently deplaque the interdental surfaces.

Why it is important to do this review

There are a plethora of interdental cleaning aids available for patients, but there are compliance issues associated with their regular use. It is important to determine the effectiveness of the regular use of dental floss, one of the most commonly recommended and advertised interdental cleaning aids. Besides being time consuming, use of dental floss, in addition to toothbrushing, represents an additional cost to consumers; therefore, it is important to review its benefits and cost-effectiveness.

This systematic review of the literature about dental floss is needed to provide oral health professionals and consumers with evidence so that they can make informed decisions about their oral health.

OBJECTIVES

To evaluate the effectiveness of flossing in addition to toothbrushing, as compared with toothbrushing alone, in the management of:

- periodontal diseases;
- dental caries.

Also to examine the potential modifying effects of baseline periodontal disease and flossing performed by a professional.

A further objective is to assess the safety of the flossing procedures, in terms of potential harms and adverse effects, balancing important benefits against important harms.

In this review we focused exclusively on dental floss, in addition to toothbrushing, which is used as a default in the randomised controlled trials comparing interdental self-care products. However, we recognise that other aids can be used in maintaining interdental oral hygiene and we will explore the effectiveness of these aids in other reviews (Poklepovic (in press)).

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (including split-mouth design and crossover trials), and cluster-randomised trials. We excluded studies where random allocation was not used or indicated. Crossover studies were included provided there was a minimum washout period of 2 weeks between treatment phases or data were available for the first treatment period. Studies were included irrespective of publication status and language.

Types of participants

The review included dentate participants 16 years of age and older, regardless of race, gender, socioeconomic status, geographical location, background exposure to fluorides, initial dental health status, setting or time of the intervention. Studies were excluded if the majority of participants had any orthodontic appliances. Studies were also excluded if their participants were selected on the basis of special (general or oral) health conditions, or if the majority of participants had severe periodontal disease.

Types of interventions

The review included all studies that compared a combination of toothbrushing and any flossing procedure with toothbrushing alone or toothbrushing plus a negative control. Interventions could be self- or professionally-performed, supervised or non-supervised. Primary comparison was self-performed unsupervised flossing plus toothbrushing versus toothbrushing alone. Studies had to have a minimum duration of 4 weeks.

Studies exploring other comparison interventions (such as mouth rinsing) were included if they contained study arms with interventions of interest to this review (i.e. flossing plus toothbrushing). However, we did include studies which included an inactive mouthrinse in the toothbrushing group. We thought this additional intervention (acting as a 'placebo') may reduce performance bias in these trials.

Studies where the intervention group alone or both the intervention and control groups received any additional active agent(s) as part of the study (e.g. chlorhexidine mouthwash, additional fluoride-based procedures, oral hygiene procedures, sealants, xylitol chewing gum) in addition to flossing and toothbrushing were excluded. Studies using floss impregnated with active agents such as chlorhexidine or fluoride were included. Studies that included participants receiving additional measures as part of their routine oral care such as oral hygiene advice, supervised brushing, fissure sealants etc, were included.

Types of outcome measures

Major outcomes:

We considered the following seven outcomes to be most relevant and important to clinicians and patients.

1. Periodontal disease, assessed by gingivitis indices (both inflammatory and bleeding).
2. Interproximal caries, assessed by (a) progression of caries into enamel or dentine, and (b) change in decayed, missing and filled tooth surfaces (D(M)FS) index. Studies had to contain explicit criteria for diagnosing dental caries. As caries increment could be reported differently in different trials, we used a set of a priori rules to choose the primary outcome data for analysis from each study (Marinho 2003).
3. Harms and adverse effects.
4. Plaque indices.
5. Calculus indices.
6. Clinical attachment loss.
7. Quality of life.

Minor outcomes:

1. Economic and resource cost of flossing.
2. Bad breath (halitosis).

Search methods for identification of studies

We used a comprehensive search to identify all relevant studies irrespective of language or date of publication.

Electronic searches

We searched the following electronic databases:

- The Cochrane Oral Health Group Trials Register (to 17 October 2011) (see Appendix 2)
- The Cochrane Central Register of Controlled Clinical Trials (CENTRAL) (*The Cochrane Library*, 2011, Issue 4) (see Appendix 3)
- MEDLINE via OVID (1950 to 17 October 2011) (see Appendix 1)
- EMBASE via OVID (1980 to 17 October 2011) (see Appendix 4)
- LILACs via BIREME (1982 to 17 October 2011) (see Appendix 5)
- CINAHL via EBSCO (1980 to 17 October 2011) (Appendix 6)

We combined the MEDLINE subject search with the Cochrane Highly Sensitive Search Strategy for identifying reports of randomised controlled trials (as published in Box 6.4.c in the *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 [updated March 2011] (Higgins 2011)). We linked the searches of

EMBASE and CINAHL to the Cochrane Oral Health Group filters for identifying randomised controlled trials, and we linked the search of LILACS to the Brazilian Cochrane Center filter.
For the identification of studies included or considered for this review, we developed detailed search strategies for each database. We based these on the search strategy developed for MEDLINE (see Appendix 1) but revised them appropriately for each database to take account of differences in controlled vocabulary and syntax rules. We used a combination of controlled vocabulary and free text terms for the subject search.

Searching other resources

We searched conference proceedings and abstracts using the following resources:

- ZETOC (1980 to 17 October 2011) (see Appendix 7)
- Web of Science Conference Proceedings (1990 to 17 October 2011) (see Appendix 8)

We searched the references of all the included studies, other reviews, guidelines and related articles, using both 'forward' (through citation databases such as Web of Science) and 'backward' (examining reference lists) citation searching.
Ongoing studies were searched in the following trial registries:

- ClinicalTrials.Gov (www.clinicaltrials.gov) (searched to 17 October 2011) (see Appendix 9)
- Meta Register of Controlled Trials (*m*RCT) (www.controlled-trials.com) (searched to 17 October 2011) (see Appendix 10)

We contacted manufacturers of flossing products and asked for their knowledge of any unpublished or ongoing clinical trials.

Data collection and analysis

Selection of studies

Two review authors independently screened the titles and abstracts of papers for eligibility. If the relevance of a report was unclear, the full text was assessed, and all disagreements were resolved by discussion. In cases of doubt a third review author was consulted about eligibility for inclusion or data extraction, as well as with regard to data analysis.

Data extraction and management

Two review authors independently extracted data from the eligible studies. Two sets of extracted data were compared against each other by a third review author and any disagreements were identified and resolved by consensus. The review authors were not blinded to the authors, interventions or results obtained in the included studies.

The following data were extracted and entered in a customised collection form.
(1) Study design, including details of how the study differed from standard parallel group design (e.g. split-mouth or crossover); date and duration of study; setting of the study.
(2) Participants:

- Number of participants randomised to intervention or control.
- Inclusion and exclusion criteria.
- Demographic characteristics of participants: age, sex, country of origin, ethnicity, gender, socioeconomic status, comorbidity, caries and periodontal disease risk status.

Demographic characteristics were recorded for the study as a whole, and for each intervention group, when available.

(3) Intervention:
Details of the experimental and comparison interventions were collected, such as:

- Type of floss (automated or manual, waxed or non-waxed, with or without fluoride), type of toothbrush (powered or manual), type of toothpaste (with or without fluoride).
- Frequency of flossing, duration of the intervention period and of the individual flossing procedure.
- Were the participants trained/instructed how to floss and/or toothbrush, and by whom?
- Control group intervention - toothbrushing alone or toothbrushing plus placebo.
- Length of follow-up, loss to follow-up.
- Assessment of compliance.
- Level of fluoride in water.

(4) Outcomes:

- Detailed description of the outcomes of interest (both beneficial and adverse), including the definition and timing of measurement.
- Methods of assessment.

Furthermore, a list of other outcomes found in the included studies was made.
Results were extracted for prespecified outcomes of interest.
Other data that were extracted included:

- ethical approval;
- sample size calculation (yes-no);
- funding sources.

The data extraction form was designed for this review and piloted before use. Basic coding instructions accompanied the data extraction form. In cases of studies reporting both preliminary and final results, only the final report (including full number of participants) was included.

Assessment of risk of bias in included studies

Assessment of risk of bias was done by using The Cochrane Collaboration's risk of bias tool as described in Chapter 8 of the *Cochrane*

Handbook for Systematic Reviews of Interventions (Higgins 2011). The tool addresses the following domains: sequence generation, allocation sequence concealment, blinding, incomplete outcome data, selective outcome reporting and other issues. Since blinding of the study participants for the interventions of interest was not realistic, the primary consideration was given to the blinding of the outcome assessors.

For crossover designs, assessment of risk of bias included additional considerations, such as the suitability of the design and the risk of carry-over or spill-over effects.

Each piece of information extracted for the risk of bias tool was recorded together with the precise source of this information. The review authors were not blinded to the names of the authors, institutions, journal or results of a study. The assessment of risk of bias was done independently by two review authors. Any cases of disagreement were resolved by consensus, with assistance of a third review author.

Risk of bias was tabulated for each included study (*see* Characteristics of included studies), along with a judgement of low, high or unclear risk of bias for each domain. A risk of bias graph and summary are presented in Figure 1 and Figure 2 respectively.

Figure 1. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

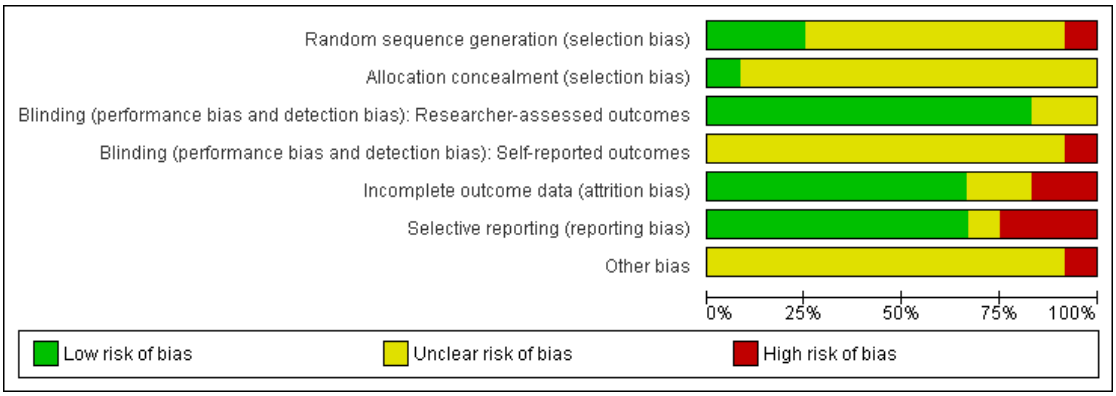
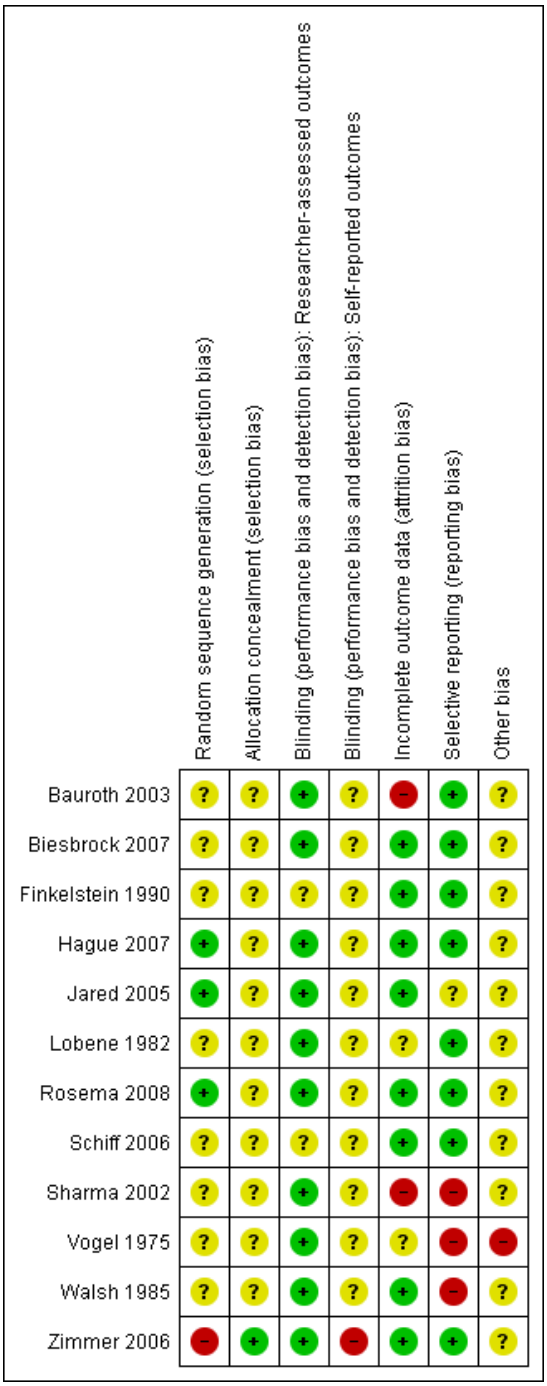


Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Measures of treatment effect

For periodontal disease outcomes, we expected the measures of treatment effect to be mostly continuous. In such cases, mean difference (or difference in means) was the statistic used. Both calculus and attachment loss can be continuous measures, but the incidence is often so low that it can be dichotomised on a patient basis and considered a binary measure. Therefore, risk ratios rather than odds ratios were planned to be used for calculus and attachment loss.

For caries outcomes, the prevented fraction (PF) was planned to be calculated where appropriate. The PF is expressed as the mean increment in the control group minus the mean increment in the intervention group divided by the mean increment in the control group (i.e. the caries increment in the treatment group expressed as a percentage of the control group).

For completeness, raw values (mean, standard deviation (SD), n) were presented for the periodontal indices. We planned that data from crossover trials included standard errors using the generic inverse variance outcome type in Review Manager (RevMan) (RevMan 2011).

Unit of analysis issues

The unit of analysis was individual patients or groups of measuring sites within individual patients (e.g. interproximal sites: proportion of sites that have bleeding averaged over the number of patients).

Dealing with missing data

As described in Table 16.1.a in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), there are several types of missing data in a systematic review or meta-analysis. The problem of missing studies and outcomes are addressed in the 'Assessment of reporting biases' part of this review. A common problem is missing summary data, such as standard deviations for continuous outcomes, or separate sample sizes for each intervention group. Missing summary data was not a reason to exclude a study from the review and methods outlined in section 16.1.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) were used for imputing missing standard deviations. In the analysis we made the assumption that the data were missing at random, so we included only the available data. Potential impact of missing data on the findings of the review is addressed in the 'Discussion' section of the review.

Assessment of heterogeneity

Prior to meta-analysis, studies were first assessed for clinical homogeneity with respect to type of therapy, control group and the outcomes. Clinically heterogeneous studies were not combined in a meta-analysis, but described descriptively. For studies judged as clinically homogeneous, statistical heterogeneity was tested by Q test (Chi^2) and I^2. We interpreted a Chi^2 test resulting in a P value < 0.10 as indicating statistically significant heterogeneity. In order to assess and quantify the possible magnitude of inconsistency (i.e. heterogeneity) across studies, we used the I^2 statistic with a rough guide for interpretation as follows: 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.

Assessment of reporting biases

Possible reporting biases were assessed on two levels: within-study and between-study.

Within-study selective outcome reporting was examined as a part of the overall risk of bias assessment (*see* Assessment of risk of bias in included studies). Attempts were made to find protocols of included studies and compare the outcomes stated in the protocols with those reported in the publications. If protocols were not found, outcomes listed in the methods sections on a publication were compared against those whose results are reported. Where some indications of reporting bias were found, study authors were contacted for clarification.

If there were at least 10 studies included in a meta-analysis in the review, a funnel plot of effect estimates against their standard errors was planned to be created to assess a possible between-study reporting bias. If an asymmetry of the funnel plot was found by inspection and confirmed by statistical tests, possible explanations were planned to be considered and taken into account in the interpretation of the overall estimate of treatment effects.

Data synthesis

Meta-analysis included only the studies reporting the same outcomes. Since there are a number of different indices measuring what we consider the same basic concept (e.g. gingivitis), we used the standardised mean difference (SMD), along with the appropriate 95% confidence intervals (CI), to combine the results on different indices in meta-analysis. It was expected that there would be considerable heterogeneity amongst the included studies, so we planned that a random-effects model would be used as a primary method of meta-analysis, provided there were more than three studies eligible for meta-analysis.

Subgroup analysis and investigation of heterogeneity

The following subgroup analyses were planned.

- Powered versus manual flossing.
- Trained (instructed) versus untrained (uninstructed) flossing.
- Powered versus manual toothbrushing.
- Dental floss versus dental tape.

It was planned that if there were sufficient studies, a subgroup analysis for powered verus manual flossing for the outcomes of plaque and gingivitis at 1-month end point would be undertaken.

Sensitivity analysis

Primary meta-analyses included all studies irrespective of their risk of bias. Sensitivity analysis was planned to assess how the results of meta-analysis were affected if studies at high risk of bias were excluded from the analysis. A sensitivity analysis was also planned to take into account the sources of funding of the included studies.

RESULTS

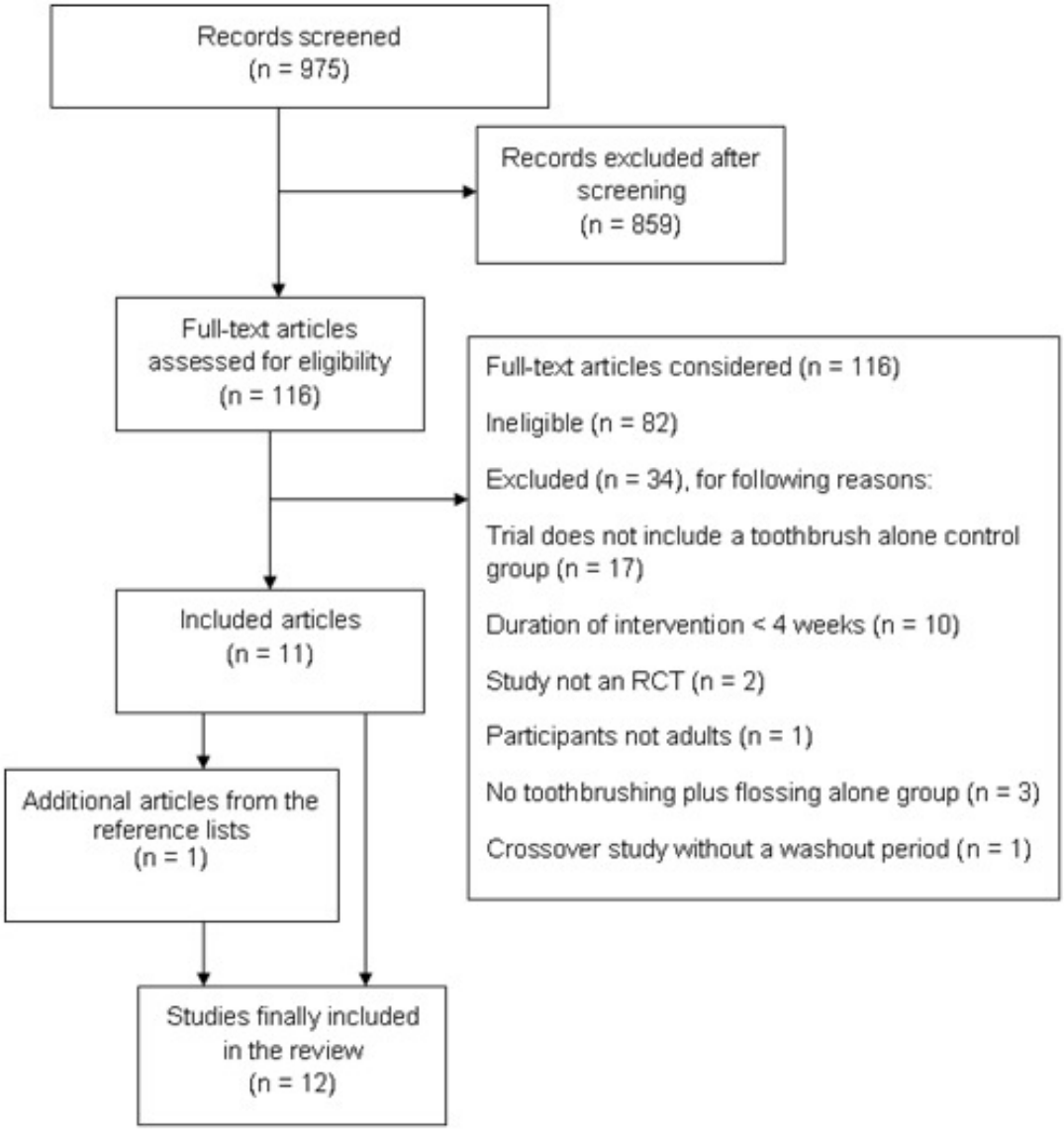
Description of studies

See Characteristics of included studies and Characteristics of excluded studies.

Results of the search

Figure 3 shows the study selection flow chart with the search strategy yielding 975 unique records, consisting of titles with or without abstracts. Of these, 859 were judged irrelevant for this review by two review authors independently. If even one of the two authors could not confidently exclude a record based on its title and abstract, the full text was obtained. One of the authors who screened the titles and abstracts used a "safety net" approach, therefore the number of the articles that were scrutinised in full text (116) was relatively large. Full texts were assessed by three review authors independently, and 82 articles were found ineligible for inclusion. The 'Characteristics of excluded studies' table contains the 34 studies that both review authors who screened the records could not confidently exclude based on their titles and abstracts.

Figure 3. Study selection flow diagram



The final number of studies included in this review was 12 (Figure 3), which included a trial identified from the reference lists (Walsh 1985). Among the articles judged eligible for inclusion, two were reporting the same study (Hague 2007).

Included studies

Design

Eleven studies had a parallel design, and one had a crossover design (Hague 2007). The crossover study had a 2-week washout period. All trials had more than two study arms: six studies had three arms, three studies had four arms, two studies had five arms, and one study had six arms.

Sample sizes

A total of 582 participants provided data for the review in the flossing plus toothbrushing arms and 292 participants in the tooth-

brushing alone control groups and 209 participants in the toothbrushing plus placebo control groups. The median number of participants enrolled in studies was 138 (range 24 to 218). No study reported a sample size calculation.

Setting

The majority of trials (10) were conducted in United States of America, one was conducted in Germany (Zimmer 2006), and one in the Netherlands (Rosema 2008).

Participants

The participants in 10 studies were selected only if they had signs of existing gingival inflammation (Bauroth 2003; Biesbrock 2007; Finkelstein 1990; Jared 2005; Lobene 1982; Rosema 2008; Schiff 2006; Sharma 2002; Walsh 1985; Zimmer 2006); the details are given below.

- Participants had to have at least 15 Löe and Silness bleeding sites at screening (Biesbrock 2007).
- Participants were to have at least 10 interdental bleeding sites using the Eastman Interdental Bleeding Index (EIBI) (Finkelstein 1990).
- Participants had to have at least one test site, defined as an interproximal space that exhibited bleeding from the facial and lingual sides (Jared 2005).
- Participants were required to show an average gingival inflammation of between 0.8 and 1.5 using the Löe and Silness Gingival Index (Lobene 1982).
- Participants were selected if they had no periodontal pockets > 5 mm but had a > 40% level of gingival bleeding (Rosema 2008).
- Participants had to have an initial Löe-Silness Gingival Index of ≥ 1.00 and an initial Quigley-Hein Plaque Index (Turesky modification) of ≥ 1.5 (Schiff 2006).
- Participants had to have an initial Löe-Silness Gingival Index of ≥ 1.75 and an initial Quigley-Hein Plaque Index (Turesky modification) of ≥ 1.95 (Bauroth 2003; Sharma 2002).
- Participants at the beginning of the study had generalised interproximal gingival inflammation and bleeding on probing (Walsh 1985).
- Participants were to have a papillary bleeding index of ≥ 0.5 per tooth and a modified proximal plaque index of ≥ 1.5 per tooth (Zimmer 2006).

Participants in (Hague 2007) were excluded if they had periodontitis although the severity of periodontitis was not described. The participants in (Vogel 1975) had a high level of gingival health, after 10 days of supervised tooth cleaning, (which was day zero of the study) determined by sampling intracrevicular exudate and Löe's Gingival Index.

The crossover study included in the review had two 1-month intervention periods with a 2-week washout period (Hague 2007). The median end point of the remaining studies was 2 months (range 1 to 9). Attrition was not addressed in four studies (Finkelstein 1990; Lobene 1982; Vogel 1975; Walsh 1985).

No study reported the socioeconomic status of participants.

Interventions

The data were extracted for toothbrushing plus flossing, toothbrushing alone and toothbrushing plus 'placebo' arms. In two trials the control arm was toothbrushing plus the use of an inactive mouthrinse (placebo) (Bauroth 2003; Sharma 2002). One study (Hague 2007) had both manual and automated flossing arms, and we used both arms in the meta-analyses. Another trial (Biesbrock 2007) also used a powered flossing device. One study (Lobene 1982) had waxed, unwaxed, and minted flossing arms and we combined the data from the three flossing arms for meta-analyses using methods outlined in Chapter 7 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). In one trial (Biesbrock 2007) the toothbrushing was done with a powered toothbrush and in all other studies toothbrushing was manual.

The frequency of flossing was once daily in the majority of studies, twice daily in a single study (Biesbrock 2007), and not reported in two studies (Finkelstein 1990; Rosema 2008). Participants were instructed how to floss in all studies except one (Finkelstein 1990), where no such instruction was reported.

Compliance was assessed in 6 out of 12 studies (Hague 2007; Jared 2005; Lobene 1982; Rosema 2008; Vogel 1975; Zimmer 2006).

Outcomes

The minimum duration of the intervention was 4 weeks. Based on what was found in the included studies and to allow comparison with the Cochrane review on toothbrushing (Deacon 2010), the decision was made to include the 1-month, 3-month and 6-month (or nearest) time points in the analyses. From a clinical viewpoint, one can usually see some tissue healing within 4 weeks (or 1 month) in patients with gingivitis and consequent reductions in the clinical indices used in the outcomes (bleeding, gingival, plaque). The 3-month mark is important because microbiologically, the periopathogens return in sufficient numbers to cause disease. Hence, patients with periodontal disease are recommended to be on 3-month periodontal maintenance recall visits (Haffajee 1997; Haffajee 2006).

The indices reported for each trial (and those included indicated by an asterisk) are shown below.

Study	Gingivitis Index (scale)	Plaque Index (scale)
Bauroth 2003	Löe-Silness Gingival Index {Lobene modification} (0-4)* Bleeding on Probing Index (0-1)	Quigley & Hein Plaque Index {Turesky modification) (0-5)
Biesbrock 2007	Löe-Silness Gingival Index (0-3)*	Navy Plaque Index {Rustogi modification} (0-1)
Finkelstein 1990	Löe-Silness Gingival Inflammation Index {modified to include visual assessment only} (0-3)* Eastman Interdental Bleeding Index (0-1)	Global Plaque Index (0-100%)
Hague 2007	Löe-Silness Gingival Index (0-3)	Quigley & Hein Plaque Index {Turesky modification) (0-5)
Jared 2005	Löe-Silness Gingival Index {Lobene modification} (0-4)* Bleeding on Probing {Van der Weijden method} (0-1)	Quigley & Hein Plaque Index {Turesky modification) (0-5)
Lobene 1982	Löe-Silness Gingival Index (0-3)	Quigley & Hein Plaque Index (0-5)
Rosema 2008	Bleeding on Marginal Probing (0-2)	Quigley & Hein Plaque Index {Paraskevas modification) (0-5)
Schiff 2006	Löe-Silness Gingival Index (0-3)	Quigley & Hein Plaque Index {Turesky modification) (0-5)
Sharma 2002	Löe-Silness Gingival Index {Lobene modification} (0-4)* Bleeding on Probing Index (0-1)	Quigley & Hein Plaque Index {Turesky modification) (0-5)
Vogel 1975	Löe-Silness Gingival Index (0-3)	Podshadley's Plaque Index (0-5)
Walsh 1985	Bleeding on Probing Index (0-1)	Silness-Löe Plaque Index {scored positive for plaque if 2 or 3} (0-1)
Zimmer 2006	Papillary Bleeding Index (1-4)	Quigley & Hein Plaque Index (0-5)* Modified Proximal Plaque Index

Excluded studies

Thirty-five studies were excluded and the reasons for exclusion were the following: no toothbrush only group (19), intervention less than 4 weeks (9), the study was not a randomised controlled trial (2), flossing not an intervention (2), participants were not adults (1), article was a preliminary report (1), and crossover trial which did not have a washout period (1).

Risk of bias in included studies

Allocation

Randomisation was mentioned in all included studies. In one study (Lobene 1982) randomisation was mentioned in an earlier conference abstract, but not in the included article. The generation of allocation sequence was clearly described in three studies (Hague 2007; Jared 2005; Rosema 2008). Randomisation was mentioned, but the method of sequence generation was not properly described in eight articles, and in one study the procedure was described, but the method of stratification by gender and papillary bleeding index into four groups may have resulted in selection bias (Zimmer 2006).

Allocation sequence was adequately concealed in one study (Zimmer 2006), and all other studies did not report any attempt to conceal the allocation sequence.

Blinding

Blinding of the examiner for researcher-assessed outcomes was clearly reported in the majority (10) of studies. One study did not mention blinding of the examiner at all (Finkelstein 1990), and the blinding procedure in one study (Schiff 2006) was unclear. Adverse effects were partially or completely assessed through participants' self-reports in three studies that were not participant-blinded (Jared 2005; Schiff 2006; Zimmer 2006), so they may involve a high risk of bias. In one of them (Schiff 2006) no adverse effects were reported by any of participants, so lack of blinding may have not influenced this outcome. In one of the three studies that assessed adverse effects, participants were instructed to use a journal, but no related results were reported in the article (Jared 2005).

Incomplete outcome data

The majority of studies (eight) were judged to have a low risk of bias in relation to incomplete outcome data. In these studies, attrition rates were either clearly reported or identifiable from the data. One study (Lobene 1982) provided only the number of subjects who completed the study, but not the number of those who were randomised. Loss to follow-up was also not clear in the study by Vogel et al (Vogel 1975). In two studies (Bauroth 2003; Sharma 2002) patients were excluded from the analysis if they did not comply with the interventions, and it is unclear how many were excluded for this reason.

Selective reporting

Eight studies were judged to have a low risk of selective outcome reporting. This risk was unclear in Jared 2005, where data on possible adverse effects were not reported, although the participants were asked to keep logs. Three studies were judged to have a high risk of selective outcome reporting. In one of them (Vogel 1975) interproximal plaque was scored as either absent or present, with corresponding scores of 0 or 1, but the results were not presented. Furthermore, no standard deviations were provided for any of the results in this study. In Sharma 2002 means and standard deviations for the bleeding outcomes were not reported. In Walsh 1985 an ordinal scale was used to score the plaque, but the measurements were then transformed into binary data (positive or negative), and finally reported as percentage of interproximal surfaces scored positive.

Other potential sources of bias

Risk of other potential sources of bias was judged unclear in 10 studies, and high in one study (Vogel 1975). Seven studies were industry-sponsored (Biesbrock 2007; Finkelstein 1990; Hague 2007; Jared 2005; Rosema 2008; Schiff 2006; Zimmer 2006), and the other five did not disclose the sources of financial support. Three of these were older studies, conducted in the 1970s and 1980s (Lobene 1982; Vogel 1975; Walsh 1985), before the awareness of conflict of interest issues became more widespread (Ancker 2007). The other two studies that did not disclose the source of information were both conducted by authors whose affiliations reveal possible or real association with the industry who produced the investigated products (Bauroth 2003; Sharma 2002)

In four studies (Bauroth 2003; Lobene 1982; Jared 2005; Sharma 2002), compliance was assessed, but not reported, and in one study (Vogel 1975) compliance was found to be suboptimal at the 2-week time point. In four studies compliance was not assessed (Jared 2005; Rosema 2008; Schiff 2006; Walsh 1985). It was unclear if it was assessed in the remaining studies.

Overall risk of bias

Overall, poor quality of reporting in many of the included studies resulted in considerable uncertainties in the risk of bias assessment. For example, no included study clearly demonstrated both adequate sequence generation and concealment of the sequence allocation (Figure 1; Figure 2). In a summary of risk of bias for each study across domains, five studies were considered to be high risk of bias (Bauroth 2003; Sharma 2002; Vogel 1975; Walsh 1985; Zimmer 2006) the remaining seven at unclear risk of bias.

An overall assessment of risk of bias for each outcome across studies was used for making judgements about the quality of evidence in Summary of findings for the main comparison. In this assessment, the key study-level domains were sequence generation and concealment of the sequence allocation (related to selection bias), and completeness of outcome data (related to attrition bias). The key outcome-level domains were blinding and selective reporting. Since blinding of participants was obviously not possible, attention was given to blinding of assessors, whereby some outcomes - such as gingivitis and plaque levels - were necessarily researcher-assessed, which allowed blinding. Other outcomes - such as harms and adverse effects - were assessed primarily by participants, without the possibility of blinding. Compliance was another important performance-related source of bias taken into consideration. For researcher-assessed outcomes (gingivitis and plaque), most of the studies reported adequate blinding and a small loss to follow-up. Risk of selective reporting was also low, especially for the 1-month time point, because the study at high risk of selective reporting bias (Walsh 1985) did not report 1-month outcome data. Selection bias for these outcomes was judged to be unclear, as most of the included studies did not adequately describe either the sequence generation or its concealment. There was some concern related to inadequate compliance and influence of confounders as other possible sources of bias.

For participants-assessed outcomes (harms and adverse effects) the major risk of bias was related to the lack of blinding and the selection bias due to inadequate sequence generation or allocation concealment or both.

Effects of interventions

See: **Summary of findings for the main comparison** Flossing plus toothbrushing for periodontal disease and dental caries

Comparison: Flossing plus toothbrushing versus toothbrushing alone (control)

The only included crossover study (Hague 2007) had the manual and automated flossing groups that did form a crossover trial, but subjects in the control group just carried on for both study periods with no crossover, so we decided to use only the data for the first period and treat the study as parallel-design. The data from both manual and automated flossing groups compared to control were used in the meta-analyses (adjusting the number in the control group to avoid double counting the patients) and were collected after a 30-day trial period, with 24-hour abstinence of any oral hygiene before the study visit and measurement (Hague 2007). The main analysis includes two studies (Bauroth 2003; Sharma 2002) where the control group rinsed with a negative 'placebo' rinse.

Gingivitis

Gingivitis as an outcome was assessed in all 12 included studies, by use of gingivitis indices (Biesbrock 2007; Hague 2007; Lobene 1982; Schiff 2006; Vogel 1975), bleeding indices (Rosema 2008; Walsh 1985; Zimmer 2006), or both (Bauroth 2003; Finkelstein 1990; Jared 2005; Sharma 2002), and gingivitis data from all included trials were used in meta-analysis for at least one time point.

- Five studies used the Loe-Silness Gingival Index (Löe 1963; Löe 1965; Löe 1967), with two of them reporting both total and interproximal scores (Schiff 2006; Vogel 1975), two reporting only total scores (Biesbrock 2007; Lobene 1982), and one reporting only interproximal scores (Hague 2007). When both total and interproximal scores were available, total scores were used for the meta-analyses.
- Three studies used Lobene modification of the gingival indices (Lobene 1986), two reporting both whole mouth and interproximal scores (Bauroth 2003; Sharma 2002), and the other only interproximal scores (Jared 2005).
- Finkelstein 1990 used the Loe-Silness Gingival Inflammation Index (Löe 1963) modified to include visual assessment only.

The following bleeding indices were used in the included studies:

- Papillary bleeding index (Saxer 1975) in Zimmer 2006.
- Bleeding on marginal probing index (Lie 1998) in Bauroth 2003; Rosema 2008; Sharma 2002.
- Modified bleeding on marginal probing method (van der Weijden 1994) in Jared 2005.
- Eastman Interdental Bleeding Index (Caton 1985) in Finkelstein 1990.
- In Walsh 1985 gingival sites were scored positive for bleeding if they bled after gentle probing with a periodontal probe.

For the studies that used both gingivitis and bleeding indices, only gingivitis scores were used in meta-analyses. Two studies that used Loe-Silness Gingival Index reported mean values without standard deviations (Finkelstein 1990; Vogel 1975) their results were nevertheless included in meta-analyses, with standard deviations calculated as the median value from other studies with that index. Sensitivity analyses were conducted to explore how the inclusion of these two studies affect the estimates.

Gingivitis at 1 month

(*See* Analysis 1.1)

Seven studies (five assessed as unclear and two as at high risk of bias) were included in the meta-analysis for gingivitis at the 1-month time point (Biesbrock 2007; Finkelstein 1990; Hague 2007; Jared 2005; Lobene 1982; Vogel 1975; Zimmer 2006) and the standardised mean difference (SMD) was -0.36 (95% confidence interval (CI) -0.66 to -0.05) with a statistically significant benefit associated with flossing plus toothbrushing (P = 0.02). There was

moderate heterogeneity between the studies, with Chi^2 17.54 (df = 7); P = 0.01; I^2 = 60%. The effect estimate remained similar when a meta-analysis was conducted without the two studies which did not report standard deviations (Finkelstein 1990; Vogel 1975), pooled SMD -0.44 (95% CI -0.78 to -0.09) (analysis not shown). It was planned that if there were sufficient studies, a subgroup analysis for powered versus manual flossing for the outcomes of plaque and gingivitis at 1-month end point would be undertaken. The results for gingivitis at 1 month are presented for the two subgroups: manual (six trials) and automated flossing (two trials). There was no apparent difference between the two subgroups (Analysis 1.1 (P = 0.48))

Gingivitis at 3 months

(*See* Analysis 2.1)

Six studies (three assessed as unclear and three as at high risk of bias) assessed gingivitis at 3-month time point (Bauroth 2003; Finkelstein 1990; Rosema 2008; Schiff 2006; Sharma 2002; Walsh 1985) and the SMD was -0.41 (95% CI -0.68 to -0.14) in favour of flossing (P = 0.003). There was substantial heterogeneity (I^2 = 60%; P = 0.03) caused by an outlying trial (Walsh 1985). This small trial evaluated gingivitis only by bleeding on probing. Omitting Walsh 1985 led to a lower SMD -0.33 (95% CI -0.49 to -0.18) which was still statistically significant (P = 0.0001) with no evidence of heterogeneity (I^2 = 0%; P = 0.75).

Gingivitis at 6 months

(*See* Analysis 3.1)

For the 6-month time point, four studies (three assessed as unclear and one as at high risk of bias) were included in the meta-analysis (Bauroth 2003; Rosema 2008; Schiff 2006; Sharma 2002) and the SMD was -0.72 (95% CI -1.09 to -0.35), once again indicating a significant benefit in flossing (P < 0.0001). There was substantial heterogeneity (I^2 = 76%; P = 0.006).

Heterogeneity was investigated for gingivitis at 1 and 6 months. This was not explained by different types of flossing (automated versus manual), or by risk of bias. Only one study did not report training the subjects into how to use floss (Biesbrock 2007) and the same study was the only study where the participants used a powered toothbrush. Omitting this study did not account for the heterogeneity.

Overall there is some evidence that flossing reduces gingivitis at 1, 3 and 6 months.

Plaque

Plaque as an outcome was assessed in 12 included studies, but only 10 studies reported data in a form that could be used in meta-analysis.

- Five trials (Bauroth 2003; Hague 2007; Jared 2005; Schiff 2006; Sharma 2002) used the Turesky modification of Quigley-Hein Plaque Index (Quigley 1962; Turesky 1970). Of these studies, three assessed both whole mouth and interproximal scores (Bauroth 2003; Schiff 2006; Sharma 2002), one assessed whole mouth scores only (Hague 2007), and one assessed interproximal scores only (Jared 2005). We used whole mouth scores in meta-analyses, if available.
- One study used the Quigley-Hein Plaque Index modified by Paraskevas et al (Paraskevas 2007) to assess whole mouth plaque scores (Rosema 2008).
- The original Quigley-Hein Plaque Index (Quigley 1962) was used in two studies (Lobene 1982; Zimmer 2006).
- One study (Zimmer 2006) reported both the Quigley-Hein Plaque Index, and the Modified Proximal Plaque Index. For this study, we used data reported for the Quigley-Hein Plaque Index for the meta-analyses.
- The Rustogi modification of the Navy Plaque Index (Rustogi 1992) was used in one study (Biesbrock 2007).
- One study (Walsh 1985) reported the percentage of interproximal surfaces scored positive for plaque, defined as a score of 2 or 3 on the Loe-Silness Plaque Index (Silness 1964).

One study (Finkelstein 1990) used the Global Plaque Index (Finkelstein 1984), but reported only percent change from baseline, which was 39% in flossing group and 36% in toothbrush-only group (no significant difference) at 6-weeks time point, and 55% in flossing group and 52% in toothbrush-only group (no significant difference) at 12-weeks time point. As no other included study used the Global Plaque Index, standard deviations could not be estimated, so the results of this study could not be used in the meta-analysis.

Another study (Vogel 1975) used the Podchadley total plaque index (Podshadley 1968), without providing standard deviations. Total plaque score at 1-month time point was 0.98 in flossing group and 0.80 in toothbrush-only group, with no significant difference reported between the groups. As Podchadley's total plaque index was not used in any other included study, standard deviations could not be estimated and these results could not be used in the meta-analysis.

Plaque at 1 month

(*See* Analysis 1.2)

Five studies (four assessed as unclear and one as at high risk of bias) assessed plaque at 1 month and the pooled estimate showed weak unreliable evidence of a possible small benefit for flossing plus toothbrushing (SMD -0.23 (95% CI -0.52 to 0.06; P = 0.12) with moderate heterogeneity (I^2 = 51%; P = 0.07)).

Plaque at 3 months

(*See* Analysis 2.2)

Five studies (two assessed as unclear and three as at high risk of bias) assessed the plaque outcome at 3-month time point with

SMD -0.20 (95% CI -0.36 to -0.04; P = 0.01), with no evidence of heterogeneity (I^2 = 0%; P = 0.78). There is weak, very unreliable evidence of a possible small benefit for flossing plus toothbrushing.

Plaque at 6 months

(*See* Analysis 3.2)

Three studies (one assessed as unclear and two as at high risk of bias) assessed the plaque outcome at 6-months time point with SMD -0.06 (95% CI -0.23 to 0.12; P = 0.53) with little heterogeneity (I^2 = 30%; P = 0.24). There is weak, very unreliable evidence and we are unable to claim or refute a benefit for flossing plus toothbrushing.

Overall these 10 studies provide weak, very unreliable evidence which suggests that flossing plus toothbrushing may be associated with a small reduction in plaque at 1 and 3 months.

Sensitivity Analysis

Sensitivity analysis conducted omitting Bauroth 2003 and Sharma 2002 (inclusion of control rinse) at 3 and 6 months led to similar effect sizes to gingivitis at 1 month (SMD at 3 months -0.53 (95% CI -1.08 to 0.02) and SMD at 6 months -0.58 (95% CI -0.91 to -0.25)). Sensitivity analysis for plaque omitting Bauroth 2003 and Sharma 2002 did not change the results for plaque.

Sensitivity analyses excluding high risk of bias studies also led to similar effect sizes for gingivitis SMD -0.37 (95% CI -0.76 to 0.02), -0.25 (95% CI -0.52 to 0.02) and -0.58 (95% CI -0.91 to -0.25) at 1, 3 and 6 months respectively.

Excluding the seven industry-sponsored studies from the analysis did not significantly change the effect estimates for both gingivitis and plaque outcome, in all observed time points (analyses not shown).

Converting SMDs back to original indices

As the results of both gingivitis and plaque meta-analyses were calculated as SMDs, which are unit-less and difficult to interpret, we re-expressed them in Summary of findings for the main comparison by calculating SMDs back into selected original scales and presented them on the scale used in these studies. For this purpose, we selected studies that used the most common indices, Loe-Silness Gingival Index and Turesky modification of the Quigley-Hein Plaque Index, and were assessed as at unclear risk of bias. Hague 2007 was selected for the gingivitis outcome at 1 month, and Schiff 2006 for 3- and 6-month data. The study Jared 2005 was used for the plaque outcome at 1 month, Schiff 2006 for both the 3- and 6-month data. We calculated mean difference by multiplying the standard deviation of the control group (end of study mean) by the pooled SMD. The table below shows this for gingivitis indices at each time point, and the differences are expressed as percentage reductions of the control group mean.

Gingivitis index	Study	Time	Reduction in mean scores (95% CI)	Control mean	Reduction as % of control mean
Loe-Silness	Hague 2007 (manual flossing)	1 month	0.13 (0.02 to 0.23)	0.67	19
Loe-Silness	Schiff 2006	3 months	0.20 (0.07 to 0.33)	0.77	30
Loe-Silness	Schiff 2006	6 months	0.09 (0.07 to 0.11)	1.06	8

The same calculations for the plaque index illustrate how small the effect measures were.

Plaque index	Study	Time	Difference in mean scores	Control mean	Difference as % of control mean
Quigley-Hein	Jared 2005	1 month	0.19 (-0.05 to 0.42)	2.97	6
Quigley-Hein	Schiff 2006	3 months	0.09 (0.02 to 0.16)	1.57	6
Quigley-Hein	Schiff 2006	6 months	0.01 (-0.03 to 0.05)	1.49	< 1

Adverse effects

Adverse effects were reported in four studies (Hague 2007; Rosema 2008; Schiff 2006; Zimmer 2006), but each trial used different ways of recording these, so a meta-analysis was not appropriate. The results here are presented descriptively.

Schiff et al (Schiff 2006) reported that no adverse effects on the oral hard or soft tissues were observed by the examiner or reported by the participants when questioned.

Zimmer et al (Zimmer 2006) registered the following adverse effects at the final examination: discomfort in taste, discomfort in sensibility, gingival damage, gingival bleeding, mouth burning, and white plaque on the tongue immediately after the assigned intervention. In the toothbrush plus flossing arm, the only adverse effect reported was gingival damage in 3 of 39 subjects at 1-month time point and in one of 39 subjects at 2-month time point. In the toothbrush-only arm, one in 39 subjects at 1-month time point reported discomfort in taste and bleeding of gingiva, respectively, and no side effects were reported at 2-month time point.

Hague et al (Hague 2007) performed oral examinations at the start of each study visit and found soft tissue trauma from improper use of the automated flossing device in two subjects, both at 2-week time point.

Rosema et al (Rosema 2008) used two indices to assess possible adverse effects: Gründemann Modification of the Staining Index (GMSI) (Gründemann 2000), with staining assessed according to the intensity stain index of Lobene (Lobene 1968), and gingival abrasion score (GAS) (Van der Weijden 2004; Versteeg 2005).

- Mean (SD) GMSI score for manual toothbrushing-only group was 5.74 (7.43) at 10-weeks, 5.17 (7.06) at 6-months, and 7.51 (6.84) at 9-months time point.
- For the manual toothbrushing plus flossing group, mean (SD) GMSI score was 3.95 (4.72) at 10-weeks, 3.73 (4.35) at 6-months, and 6.17 (4.80) at 9-months time point.
- Mean (SD) GAS score for manual toothbrushing-only group was 4.61 (5.48) at 10-weeks, 4.21 (3.38) at 6-months, and 7.82 (6.90) at 9-months time point.
- For the manual toothbrushing plus flossing group, mean (SD) GAS score was 4.31 (3.45) at 10-weeks, 4.26 (3.39) at 6-months, and 6.03 (3.98) at 9-months time point. Throughout the study, the differences between groups did not reach statistical significance set at $P < 0.05$ for any of the comparisons related to adverse effects (Rosema 2008).

In one study (Jared 2005), participants were requested to keep a log with details of any symptoms experienced during the trial period, but no data on adverse effects were reported in the trial.

DISCUSSION

Summary of main results

This review found evidence of the effect of flossing plus toothbrushing for the outcomes of gingivitis and plaque relating to periodontal diseases.

There was a statistically significant benefit associated with flossing plus toothbrushing compared to toothbrushing alone in reducing gingivitis:

- at 1 month (standardised mean difference (SMD) -0.36, 95% confidence interval (CI) -0.66 to -0.05);
- at 3 months (SMD -0.41, 95% CI -0.68 to -0.14);
- at 6 months (SMD -0.72, 95% CI -1.09 to -0.35).

The SMDs for gingivitis indicated a larger effect over time with SMDs -0.36, -0.41, -0.72 at 1, 3 and 6 months respectively. As a rule of thumb SMDs are sometimes interpreted as 0.2 being a small effect, 0.5 a moderate effect and 0.8 a large effect (Higgins 2011 Chapter 12) and so there is evidence of a moderate effect at 6 months. If the absolute effects are expressed as a percentage of the control group means then the large SMD for gingivitis (using bleeding index) at 6 months approximates to a reduction in gingivitis of 8%.

Overall there was insufficient evidence to claim or refute a benefit for flossing in reducing plaque at 1, 3 or 6 months.

No studies were identified that reported dental caries as an outcome although the presence of plaque biofilm is implicit in the development of caries. Therefore it is not possible to state the effectiveness or not, of flossing in combination with toothbrushing for managing dental caries. The studies also did not report calculus, clinical attachment loss or quality of life.

Harms and adverse events were reported in five studies. The important harm identified was that flossing has the potential to cause soft tissue trauma to gingival tissues and this was identified for groups that used both manual and automated flossing devices. It is likely that this undesirable effect is self-limiting, as soft tissue trauma encountered whilst flossing normally evokes a nociceptive response and flossing action is modified. The desirable benefits of flossing in reducing gingivitis, appear to be greater than the undesirable harms.

The 'Summary of findings' table (Summary of findings for the main comparison) shows the seven main outcomes and the quality of evidence associated with them, using the GRADE approach (Atkins 2004).

Overall completeness and applicability of evidence

The objectives of this review were to assess the effects of flossing in addition to toothbrushing, compared with toothbrushing alone, in the management of periodontal diseases and dental caries in adults. Adults were described as participants aged 16 years and over, as a decision was made to exclude studies in mixed primary and secondary dentitions and to exclude potential variability asso-

ciated with younger participants who might have found flossing technically difficult to carry out by themselves.

Study participants were aged between 18 and 70 and, overall, more females than males took part in the studies. The overall percentages were 37% male and 63% female, although four studies did not give any information about gender proportions. Gingivitis is more prevalent in males and a recent study by Furata 2010 has sought to explain the epidemiological differences in gingivitis between males and females. This study found that females had greater knowledge of, and took a more positive approach to, oral health compared to their male counterparts. It is possible that the greater number of female participants in the studies included in this review may have influenced the gingivitis outcomes, and it is unclear whether these results are equally applicable to men and women in the general population.

As previously stated, no trials reported the outcomes of calculus, clinical attachment loss or quality of life measures. Although they were not primary outcomes in this review we think that both halitosis and the economic cost of flossing may be important to measure in future trials.

Only one study reported follow-up data longer than 6 months (Rosema 2008), and had data at 9 months. There is a paucity of studies of long duration. Gingivitis and plaque indices can be seen as surrogate outcome measures, in that they are related to the important outcomes of caries and tooth loss, that would require trials with much longer intervention and follow-up periods. There is also the possible issue of long-term compliance with daily flossing required to reduce caries over the long term. Also the participants in all included studies generally had low levels of gingivitis at study entry, below the levels of gingivitis or chronic periodontitis associated with clinical attachment loss. It is important that future trials assess the effectiveness of flossing in patients with high levels of gingivitis or chronic periodontitis with clinical attachment loss.

Quality of the evidence

The review achieved its objective of assessing the management of periodontal diseases using the outcomes of gingivitis and plaque indices. No information was obtained on calculus, although calculus formation is due to the mineralisation of plaque by saliva supersaturated with calcium phosphates (Grases 2009). No studies were found that considered the other main objective, the management of dental caries. This may be due to the length of study required and the difficulties in detecting early interdental carious lesions (Ismail 2004).

Two trials included a 'placebo' (a negative control mouthrinse plus toothbrushing as a control arm). We decided to include these trials as we think it is possible that use of a placebo in this way may help to reduce performance bias. However, it is also possible that the use of a control mouthrinse may flush away residual fluoride from the dentifrice.

Twelve studies were identified that fitted the inclusion criteria, with a total of 1083 randomised participants who completed the studies. In all of these studies there were more than two arms, and there was a total of 582 participants in flossing plus toothbrushing (intervention) groups and 501 participants in toothbrushing (control) groups. The 'Description of studies' section describes in detail the methodological limitations found amongst the included studies.

The included studies show reliability in terms of their overall consistency of findings, although the risk of bias assessments should also be taken into account. The presence or absence of bias was unclear in the trial reports for many domains. Overall, there was consistency in the outcomes measured for both gingivitis and plaque indices. Also, there was a lack of reporting of sample size calculations. The outcomes measured had good content validity. The quality of the evidence, using the GRADE Working Group grades of evidence, as presented in the 'Summary of findings' table (Summary of findings for the main comparison), can be seen to be very low, which means that the estimates are very uncertain.

Potential biases in the review process

The search strategy used to find relevant studies was not limited to English and would have identified studies in other languages, avoiding language bias. However, although studies not in English were identified during the search process, none fitted the inclusion criteria and all the studies included in the review were in English. Grey literature bias and studies published in non-indexed journals, particularly in developing countries (Zielinski 1995) may result in not all relevant studies being identified. As well as searching, using the strategies to be found in Appendices 1 to 10, manufacturers of dental floss were contacted to try to identify any unpublished or ongoing studies but none were found. It is not possible to quantify the effect that publication bias may have had in this review.

Agreements and disagreements with other studies or reviews

A published systematic review (Berchier 2008) concluded that using dental floss in conjunction with toothbrushing provided no additional benefit compared to toothbrushing alone. However, of the ten studies that met the inclusion criteria for the review, three studies found a significant benefit for plaque removal over toothbrushing alone and one study showed a significant effect when using the bleeding index as an outcome. No significant benefit was found for plaque removal when using floss in addition to toothbrushing. Berchier 2008 included seven studies that were common to our review. When undertaking the meta-analysis for gingivitis, our review used data from all twelve included studies, whereas Berchier 2008 used four from their eleven studies, and only two of those four studies were included in our review. Similarly, when

undertaking the meta-analysis for plaque, our review used data from nine included studies, whereas Berchier 2008 used three, and those three studies were included in our review. The conclusions from Berchier 2008 contrast to our review, where we have found that flossing in addition to toothbrushing was associated with a significant benefit in reducing gingivitis at all the time points that the studies reported (1, 3 and 6 months).

A systematic review (Hoenderdos 2008) that assessed the efficacy of wood sticks, used for interdental cleaning, on plaque levels and gingival inflammation, found that wood sticks had no visible effect on interdental plaque and did not reduce the gingival index. However, wood sticks were effective in reducing interdental gingival inflammation when tendency to bleeding was investigated. Our review also found that there was insufficient evidence to claim or refute a benefit for flossing in reducing plaque, but our review has found that flossing is beneficial in reducing gingivitis.

Our review has not found any studies that considered caries as an outcome. However, a published systematic review (Hujoel 2006) found six studies with participants aged from 4 to 13 where flossing was performed by dental health professionals on school days for 1.7 years, mainly on primary teeth. This flossing intervention resulted in a 40% risk reduction in interproximal caries in children with low fluoride exposure. However, no flossing trials in adults or under unsupervised conditions were identified by these reviewers.

AUTHORS' CONCLUSIONS

Implications for practice

In assessing the evidence for a reduction in gingivitis due to flossing plus toothbrushing, the quality of the evidence must also be taken into account. This review has used the GRADE system, which has assessed the quality of the evidence as very low. However, despite the uncertain or low quality of most of the studies, and given the importance of avoiding plaque deposition, plus the absence of any major disadvantages, these results support the use of regular flossing with toothbrushing. However, there is no evidence to support or refute that flossing reduces plaque, and plaque is important in the development of periodontal diseases and dental caries in adults. It is not possible to state whether flossing may be beneficial in reducing the risk of dental caries as no studies were found that investigated caries as an outcome.

Although there is not a direct progression from gingivitis to periodontitis, the work from the University of Berne (Schatzle 2004) has identified gingivitis as a risk factor in the development of chronic periodontitis. We conclude that flossing is an effective adjunct to toothbrushing, as the important benefits outweigh any potential harms.

Implications for research

Additional well designed and conducted randomised controlled trials are needed, running for longer periods, as only four studies ran for more than 3 months and longer studies would mitigate against any possible "trial effect". Ideally, trials would run for 12 months or longer, which would also be important in any study that considered dental caries as an outcome, since it takes longer for caries to develop to a stage that can be detected by any of the methods currently available. Also, the inclusion of more male participants would address the question of gender bias in the current research for flossing. Further studies that assess both whole mouth and interproximal plaque scores are needed, since it is likely that the principal effect of flossing, related to plaque, is interproximal.

Studies with participants having higher levels of gingival disease, or chronic periodontitis with clinical attachment loss (which would have been excluded from this review), would yield important information about the effectiveness of flossing in patients with disease that needs treatment.

ACKNOWLEDGEMENTS

The authors would like to acknowledge the support of the Cochrane Oral Health Group and in particular Jan Clarkson for her help in addressing the referees comments. We would also like to thank the referees for their helpful constructive comments: Sue Furness, Ian Needleman, Aubrey Sheiham, Dagmar E Slot and Edward CM Lo.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Bauroth 2003

Methods	Design: RCT, parallel, 3 arms Measurements: At baseline, 3 months and 6 months Attrition: 38 non-evaluable at 3 months and 48 at 6 months. Deemed non-evaluable for protocol infractions, failing to comply with produce usage instructions or initiating systemic drug therapy. Not given by group
Participants	Randomised: n = 362 Completed: n = 314 Age: Range 18 to 65 Males/females: 37/63 (%) Oral health status: Not reported (NR) Location: USA
Interventions	Baseline cleaning: Dental prophylaxis administered after the assessment of eligibility Control group (n = 110): Brushing with soft textured toothbrush (Oral B 35) plus twice daily rinsing with a 5% hydro-alcohol negative control rinse Intervention (n = 108): Brushing with soft textured toothbrush (Oral B 35) plus once-daily use of floss (Reach waxed dental floss (Johnson & Johnson) Other intervention (not included in the review): Brushing with soft textured toothbrush (Oral B 35) plus twice daily rinsing with an essential oil mouth rinse Training: Subjects in the flossing group received flossing instruction from a dental hygienist and were required to demonstrate their ability to floss Compliance assessment: NR
Outcomes	Periodontal disease - gingivitis: Whole mouth Modified Gingival Index (Lobene) (MGI) , Bleeding Index (BI), Turesky modification of Quigley-Hein Plaque Index
Source of funding	Unclear but authors had affiliations with pharmaceutical industry (Pfizer)
Notes	Unclear if examiners blinded. Had to estimate n per group at 6 months by dividing total n by 3. Used whole mouth MGI This study used the same protocol design as Sharma 2002

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"We assigned each enrolled subject to one of three groups according to a randomization schedule."
Allocation concealment (selection bias)	Unclear risk	Not reported

Bauroth 2003 (*Continued*)

Blinding (performance bias and detection bias) Researcher-assessed outcomes	Low risk	The study was observer-blind. Subjects refrained from use of their test products for at least 4 hours prior to the examinations to eliminate potential bias resulting from residual product odour
Blinding (performance bias and detection bias) Self-reported outcomes	Unclear risk	Unclear
Incomplete outcome data (attrition bias) All outcomes	High risk	"Subjects deemed non-evaluable for protocol infractions, failing to comply with produce usage instructions or initiating systemic drug therapy." Exact number of subjects lost to follow-up in each of the groups cannot be ascertained from the report. The numbers are not given by group, and as compliance formed part of this decision to omit subjects it was felt to be at high risk of bias
Selective reporting (reporting bias)	Low risk	No protocol available. All outcomes stated in the 'Methods' section were addressed in the 'Results'
Other bias	Unclear risk	Some unreported conflicts of interest for authors

Biesbrock 2007

Methods	Design: RCT, parallel, 6 arms Measurements: At baseline, 4 weeks, and 8 weeks Attrition: No subject discontinued treatment due to product-related adverse events, details not reported
Participants	Randomised: n = 179 Completed: n = 174 Age: Range 18 to 69 Males/females: 31/69 (%) Oral health status: NR Location: USA
Interventions	Baseline cleaning: Dental prophylaxis administered after the assessment of eligibility Control group (n = 29): Oscillating/rotating power toothbrush (Oral-B Professional Care, Procter & Gamble Co) Intervention (n = 28): Power toothbrush + power flosser (Oral-B Hummingbird, Procter & Gamble Co) used twice a day Other interventions (not included in the review): 1) (n = 30) manual toothbrush Colgate

	Wave; 2) (n = 29) manual toothbrush Colgate Wave + essential oil rinse; 3) (n = 30) manual toothbrush Oral-B CrossAction; 4) (n = 28) manual toothbrush Oral-B Cross-Action + cetylpyridinium chloride rinse Training: Subjects received written (test kit) and verbal (supervised) instructions on product usage. Product usage was supervised at the baseline and week 4 visits Compliance assessment: NR	
Outcomes	Periodontal disease - gingivitis: Loe-Silness Gingival Index Plaque and calculus: Navy Plaque Index (Rustogi Modification)	
Source of funding	Industry (Procter & Gamble Co)	
Notes	Examiners were blinded	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"Eligible subjects were stratified based on gender and the number of baseline bleeding sites... and randomly assigned to one of six test regimens."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias) Researcher-assessed outcomes	Low risk	"All test products were distributed in blinded kit boxes, instructions were provided remotely from examination, and all clinical assessments were conducted by examiners who were blinded as to treatment assignment."
Blinding (performance bias and detection bias) Self-reported outcomes	Unclear risk	Unclear
Incomplete outcome data (attrition bias) All outcomes	Low risk	Exact number of subjects lost to follow-up in each of the groups cannot be ascertained from the report, but the probable number is 1 to 2 persons per group. Attrition seems low and balanced between groups, therefore unlikely to affect the results
Selective reporting (reporting bias)	Low risk	No protocol available. All outcomes stated in the 'Methods' section were addressed in the 'Results'

Biesbrock 2007 (*Continued*)

Other bias	Unclear risk	Study funded by the company who produces automated flossing device

Finkelstein 1990

Methods	Design: RCT, parallel, 5 arms Measurements: At baseline, 6 weeks and 12 weeks Attrition: NR
Participants	Randomised: n = 161 Completed: n = 158 Age: NR Males/females: NR Oral health status: Gingival inflammation Location: USA
Interventions	Baseline cleaning: None Control (n = 32): Toothbrush Intervention (n = 30): Toothbrush + waxed dental floss (Johnson & Johnson) Other interventions: 1) (n = 31) toothbrush (TB) + wooden interdental cleaner, 2) (n = 32) TB + essential oil mouthrinse, 3) (n = 33) TB + cetylpyridinium chloride mouthrinse Training: NR Compliance assessment: NR
Outcomes	Periodontal disease - gingivitis: Loe-Silness Gingival Inflammation Index (VGI) modified to include visual assessment only Periodontal disease - bleeding: Eastman Interdental Bleeding Index Plaque and calculus: Global Plaque Index
Source of funding	Industry (Johnson & Johnson Dental Care Co)
Notes	Blinding not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"Subjects were randomly assigned to one of the five test groups…"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias) Researcher-assessed outcomes	Unclear risk	Not reported

Finkelstein 1990 (*Continued*)

Blinding (performance bias and detection bias) Self-reported outcomes	Unclear risk	Unclear
Incomplete outcome data (attrition bias) All outcomes	Low risk	Exact number of subjects lost to follow-up in each of the groups cannot be ascertained from the report. The total number of subjects lost to follow-up was 3 out of 161, so attrition seems low and therefore unlikely to affect the results
Selective reporting (reporting bias)	Low risk	No protocol available. All primary outcomes in the 'Methods' section were address in the 'Results'
Other bias	Unclear risk	Compliance was not assessed, breakdown by gender not reported

Hague 2007

Methods	Design: RCT, 2-treatment period, crossover, 3 arms Measurements: At baseline, on days 15 and 30 Attrition: 13 subjects withdrew from the study because of scheduling conflicts or refusal to use the products assigned. Out of these, 4 were from the control group, 3 from the manual group and 6 from the automated flossing group. The analyses included only data from those who completed the trial
Participants	Randomised: n = 115 Completed: n = 102 Age: mean ± SD = 23.3 ± 5.2 y Males/females: 34/68 Oral health status: Moderate plaque formation after refraining from oral hygiene for 24 hours; minimal gingivitis at the baseline Location: USA
Interventions	Baseline cleaning: None Control (n after 1st treatment period = 35): Toothbrush (Oral-B Indicator, soft compact 35, Procter & Gamble Co), twice a day Interventions: 1) (n after 1st treatment period = 32) toothbrush + battery-operated automated flossing device (Ultra Flosser, William Getgey Co) once a day; 2) (n after 1st treatment period = 35) toothbrush + manual flossing (Glide Floss Comfort Plus, Procter & Gamble Co) once a day Other interventions: None Training: Each subject received toothbrushing instruction and instructions in the use of manual floss and the automated flosser. A dental health educator provided oral hygiene instruction using a typodont and written/visual instructions After the instructions, each subject showed the appropriate techniques intraorally Compliance assessment: Self-assessment, measurements of returned supplies

Hague 2007 (*Continued*)

Outcomes	Periodontal disease - gingivitis: Loe-Silness Gingival Index Plaque and calculus: Quigley-Hein Plaque Index (Turesky modification) Adverse effects	
Source of funding	Industry (William Getgey Co)	
Notes	Third molars were not graded for plaque or gingivitis. The examiner was blind to the subjects' group assignments. We used data from the first period only for both manual and automated flossing groups compared with non flossing control group	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"At the initial baseline visit, subjects were randomly assigned to a control, manual, or automated floss group using computer-generated-randomized sequencing to ensure a balanced design."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias) Researcher-assessed outcomes	Low risk	"The researcher examiner was blind to the subjects' group assignments."
Blinding (performance bias and detection bias) Self-reported outcomes	Unclear risk	Nor reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Withdrawals from the study properly reported (manual flossing group = 3; automated flossing group = 6; toothbrushing alone = 4), unlikely to affect the results
Selective reporting (reporting bias)	Low risk	No protocol available. All outcomes stated in the 'Methods' section were addressed in the 'Results'
Other bias	Unclear risk	Study funded by the company who produces automated flossing device

Jared 2005

Methods	Design: RCT, parallel, 5 arms Measurements: At baseline, 2 weeks and 4 weeks Attrition: Of the 10 subjects who did not complete the study, 9 withdrew prior to baseline, and one was dismissed due to health issues. None of the withdrawals were product-related
Participants	Randomised: n = 162 Completed: n = 152 Age: NR Males/females: 60/92 Oral health status: NR Location: USA
Interventions	Baseline cleaning: Before clinical data were collected, participants were asked to brush their teeth. After the baseline data collection, dental plaque was removed from all teeth using a rubber cup and fine grit prophy paste Control (n = 32): Toothbrush (GUM #409, Sunstar Inc), twice a day Intervention (n = 29): Toothbrush + floss (GUM Easy-through Floss Sunstar Inc) once a day Other interventions: 1) (n = 31) toothbrush + Interdental brush (IDB) + investigational (CPC) gel; 2) (n = 30) toothbrush + IDB + placebo gel; 3) (n = 30) toothbrush + IDB Training: Subjects received verbal and written oral hygiene instructions, as well as appropriate demonstrations of the mechanical cleaning procedures Compliance assessment: self-reported but not reported
Outcomes	Periodontal disease - gingivitis: Lobene modification of the Gingival Index Periodontal disease - bleeding: Bleeding on Marginal Probing (Van der Weijden modification) Plaque and calculus: Quigley-Hein Plaque Index (Turesky modification)
Source of funding	Industry (Sunstar Inc, Japan)
Notes	Examiners were blinded

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Block randomization was used, and was based on baseline dental plaque scores to assure greater baseline comparability among treatment groups for plaque levels and, presumably, gingivitis and bleeding scores. While block randomization can introduce bias, the groups were stratified based on plaque scores, likely reducing bias."
Allocation concealment (selection bias)	Unclear risk	Not reported

Jared 2005 (*Continued*)

Blinding (performance bias and detection bias) Researcher-assessed outcomes	Low risk	"This study was designed as a single-blind trial."
Blinding (performance bias and detection bias) Self-reported outcomes	Unclear risk	Adverse effects were self-reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition reported and explained: "Of the 10 subjects who did not complete the study, nine withdrew prior to baseline, and one was dismissed due to health issues. None of the withdrawals were product-related." Attrition was judged as unlikely to affect the results
Selective reporting (reporting bias)	Unclear risk	Previously published abstract available. All primary outcomes in the 'Methods' section were address in the 'Results'. However, data on possible adverse effects were not reported, although the participants were asked to keep logs
Other bias	Unclear risk	Compliance was not reported, although participants were asked to keep a log of their dental cleaning habits

Lobene 1982

Methods	Design: RCT, parallel, 4 arms Measurements: At baseline, 2 weeks, 4 weeks, and 8 weeks Attrition: NR
Participants	Randomised: NR Completed: n = 115 Age: Range 20 to 50 Males/females: NR Oral health status: Average gingival inflammation between 0.8 and 1.5 using the Loe-Silness Gingival Index Location: USA
Interventions	Baseline cleaning: Complete oral prophylaxis which reduced plaque to zero Control (n = 33): Toothbrushing Interventions: 1) (n = 31) toothbrushing + waxed floss 2) (n = 25) toothbrushing + unwaxed floss 3) (n = 29) toothbrushing + mint-flavored floss (all floss Johnson & Johnson) Other interventions: None

Lobene 1982 (*Continued*)

	Training: Subjects using dental floss viewed a video tape on the proper flossing technique, which was followed by personal supervised instruction for those subjects who experienced difficulty in flossing. They were also given written instructions and an illustrated brochure on the proper method of flossing Compliance: Self-reported, researcher-assessed
Outcomes	Periodontal disease - gingivitis: Loe-Silness Gingival Index Plaque and calculus: Quigley-Hein Index
Source of funding	NR
Notes	The examiner was blinded to the subject's treatment group

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomisation mentioned only in an earlier conference abstract
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias) Researcher-assessed outcomes	Low risk	"Examinations were conducted so that the examiner was blind to the subject's treatment group."
Blinding (performance bias and detection bias) Self-reported outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not clear how many subjects were randomised, attrition not addressed
Selective reporting (reporting bias)	Low risk	Previously published abstract available. All primary outcomes reported in the 'Abstract', and in the 'Methods' section of the article, were addressed in the 'Results'
Other bias	Unclear risk	Compliance assessed, but not reported. Financial support not declared

Rosema 2008

Methods	Design: RCT, parallel, 3 arms Measurements: At baseline, 10 weeks, 6 months, and 9 months Attrition: Two subjects (one in the MBF group and one in the PB group) failed to attend the baseline visit because of scheduling conflicts. Two subjects were lost at 9-month visit; one subject (MB group) was hospitalised due to a leg injury, and one had moved to a different part of the country
Participants	Randomised: n = 118 Completed: n = 114 Age: Years (± SD): manual toothbrush group: 21.6 ± 2.54; flossing group: 22.2 ± 3.25; powered toothbrush group: 22.4 ± 2.93 Males/females: Manual toothbrush group: 6/32; flossing group: 7/32; powered toothbrush group: 9/28 Oral health status: Excellent oral health condition Location: The Netherlands
Interventions	Baseline cleaning: 3-week pre-experimental toothbrushing using the Bass technique twice daily for 2 minutes plus rinsing with hydrogen peroxide solution and chlorhexidine 0.2% mouthwash. Professional dental scale and polish at the baseline Control (n = 38): Manual toothbrushing (ADA Soft reference toothbrush) Intervention (n = 39): Manual toothbrushing + flossing (Oral-B Satin waxed floss, Procter & Gamble) Other interventions (n = 37): Powered toothbrushing (Oral-B Triumph Professional Care 9000, Procter & Gamble) Training: Thorough professional instruction in the use of a manual toothbrush and floss. The assigned brushing and flossing technique was reinforced at 6 and 10 weeks Compliance assessment: Self-reported, researcher-assessed duration of oral hygiene procedure
Outcomes	Periodontal disease - bleeding: Bleeding on marginal probing (BOMP) index Plaque and calculus: Qugley and Hein Plaque Index (Paraskevas et al. modification) Adverse effects: Gingival abrasion scores, Gruendemann Modification of the Staining Index
Source of funding	Industry (Procter & Gamble Co)
Notes	Examiners were blinded to treatment randomisation

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomisation was performed using true random numbers that are generated by sampling and processing a source of entropy outside the computer
Allocation concealment (selection bias)	Unclear risk	Not reported

Rosema 2008 (*Continued*)

Blinding (performance bias and detection bias) Researcher-assessed outcomes	Low risk	"The examiners were masked to treatment randomization, and records of earlier examinations were not available at the time of reexaminations."
Blinding (performance bias and detection bias) Self-reported outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Exact number of subjects lost to follow-up in each of the groups cannot be ascertained from the report. However, the total number of subjects lost to follow-up is low, so attrition is unlikely to affect the results
Selective reporting (reporting bias)	Low risk	No protocol available. All primary outcomes in the 'Methods' section were address in the 'Results'
Other bias	Unclear risk	Compliance was not assessed during the experimental period. Baseline values between groups seem imbalanced

Schiff 2006

Methods	Design: RCT, parallel, 3 arms Measurements: At baseline, 3 and 6 months Attrition: Those subjects who did not complete the 6-month examinations dropped out for reasons unrelated to the use of the treatments
Participants	Randomised: n = 120 Completed: n = 114 Age: Flossing (range) = 28.3 (22 to 46); control (range) = 25.9 (18 to 43) Males/females: Flossing 20/17; control 26/11 Oral health status: NR Location: USA
Interventions	Baseline cleaning: Complete oral prophylaxis, verified for thoroughness by the use of a red disclosing solution Control (n = 37): Soft-bristled adult toothbrush (Colgate Plus), brushing for one minute twice daily Intervention (n = 37): Toothbrush + flossing (Colgate Dental Floss), once a day Other interventions (n = 40): Toothbrushing + floss + a different dentifrice Training: All subjects were instructed to use only the dentifrice and floss provided, and to refrain from using any other oral hygiene products for the entire 6 months of the study Compliance assessment: NR

Schiff 2006 (*Continued*)

Outcomes	Periodontal disease - gingivitis: Loe-Silness Gingival Index Plaque and calculus: Quigley-Hein Plaque Index (Turesky modification) Adverse effects
Source of funding	Industry (Colgate-Palmolive Co)
Notes	Third molars and those teeth with cervical restorations or prosthetic crowns were excluded from the scoring procedure. Examiners were blinded

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"Qualifying subjects were stratified into three balanced groups according to their baseline supragingival plaque scores. These groups were then randomly assigned to one of the three treatment regimens."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias) Researcher-assessed outcomes	Unclear risk	Study states that it is a "stratified, examiner-blind, clinical study…" and that all products were packaged in their original tubes, but over-wrapped with a white label to ensure that neither the subject nor the examiner would be aware of the identity of the product". It is questionable how useful a white label was in concealing the identity of the product
Blinding (performance bias and detection bias) Self-reported outcomes	Unclear risk	Adverse effects of the oral hard or soft tissues of the oral cavity were partially assessed by self-reporting. However, no adverse effects were reported, so lack of blinding may have not influenced this outcome
Incomplete outcome data (attrition bias) All outcomes	Low risk	Not clear what was the exact attrition rate in each of the study arms; however the attrition rate was small and unlikely to affect the results
Selective reporting (reporting bias)	Low risk	No protocol available. All outcomes stated in the 'Methods' section were addressed in the 'Results'
Other bias	Unclear risk	Compliance was not assessed

Sharma 2002

Methods	Design: RCT, parallel, 3 arms Measurements: At baseline, 3 months and 6 months Attrition: Subjects were deemed non-evaluable if they did not return for post-baseline examinations, they failed to comply with usage instructions, or they were taking concomitant medications during the time of the 3- or 6-month examination which could influence results
Participants	Randomised: n = 318 Completed: n = 301 Age: Mean (SD), range: flossing 35.5 (9.61), 18 to 59; control 35.0 (9.58), 18 to 56 Males/females: Flossing 36/66; control 31/70 Oral health status: NR Location: USA
Interventions	Baseline cleaning: Complete dental prophylaxis to remove plaque, stain, and calculus Control (n = 101): Toothbrushing (Oral-B 35, Gillette) plus 5% hydroalcohol negative control rinse Intervention (n = 102): Toothbrushing + flossing (Reach Waxed Dental Floss, Johnson & Johnson) Other interventions (n = 98): Toothbrushing + essential oil mouthrinse Training: First rinse or use of floss performed with instruction and supervision. Subjects in the floss group received flossing instruction from a dental hygienist and were required to demonstrate their ability to floss all regions of the mouth. The subjects were also provided written flossing instructions Compliance assessment: Self-reported, measurements of returned supplies
Outcomes	Periodontal disease - gingivitis: Lobene modification of the gingival index Periodontal disease - bleeding: Ainamo & Bay Gingival Bleeding Index Plaque and calculus: Quigley-Hein Plaque Index (Turesky modification)
Source of funding	Not reported
Notes	Third molars and teeth that were either orthodontically banded or served as abutment teeth were not included in the tooth count. Examiners were blinded This study protocol design was used in Bauroth 2003

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"Each subject was assigned to one of three groups according to a randomization schedule."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias) Researcher-assessed outcomes	Low risk	The study was observer-blind. Subjects refrained from use of their test products for at least 4 hours prior to the examinations

Sharma 2002 (*Continued*)

		to eliminate potential bias resulting from residual product odour
Blinding (performance bias and detection bias) Self-reported outcomes	Unclear risk	Unclear
Incomplete outcome data (attrition bias) All outcomes	High risk	Not clear what was the exact attrition rate in each of the study arms. However, the loss to follow-up was relatively low (18 of 319) and the demographic characteristics of the randomised subjects were similar to those of the evaluable subjects. The risk of bias related to attrition was judged to be high as subjects could be excluded from analysis if they did not comply with usage instructions
Selective reporting (reporting bias)	High risk	Means and standard deviations for the bleeding outcome were not reported
Other bias	Unclear risk	Financial support not declared, potential conflict of interest for authors

Vogel 1975

Methods	Design: RCT, parallel, 4 arms Measurements: At baseline, on days 9, 15, 33 Attrition: NR
Participants	Randomised: n = 24 Completed: NR Age: NR Males/females: NR Oral health status: High level of interproximal gingival health Location: USA
Interventions	Baseline cleaning: Thorough scaling and prophylaxis; each participant was instructed to use unwaxed floss, rubber tip stimulator and the modified Bass intrasulcular brushing technique once a day during 9 days. The 10th day was designated day zero of the study Control (n = 6): Modified Bass intrasulcular brushing technique using a soft nylon multi-tufted rounded bristle brush Intervention (n = 6): Toothbrushing + unwaxed floss once a day Other interventions: 1) (n = 6) toothbrush and rubber tip stimulator; 2) (n = 6) toothbrush, floss and rubber tip stimulator Training: All participants were given standardised instructions on the use of all devices every third day during the 9-day baseline cleaning period. Additionally, individual home care techniques were reinforced on assessment days during the trial Compliance assessment: Self-reported

Vogel 1975 (*Continued*)

Outcomes	Periodontal disease - gingivitis: Intracrevicular exudate, Loe's Gingival Index Plaque and calculus: Podchladley's total plaque index
Source of funding	Not reported
Notes	Participants were dental students

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"Subjects were randomly divided…"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias) Researcher-assessed outcomes	Low risk	"Gingival exudate was measured by an examiner who was unaware of the groupings or the results of the clinical scorings. All subjects were evaluated by an investigator calibrated in the use of the scoring criteria and having no knowledge of the groupings. "
Blinding (performance bias and detection bias) Self-reported outcomes	Unclear risk	Unclear
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not clear if there was any loss to follow-up
Selective reporting (reporting bias)	High risk	Protocol not available. Interproximal plaque was scored as binary outcome (absent or present), but reported as mean; standard deviations not reported
Other bias	High risk	Compliance in the flossing group after 15 days was sub optimal

Walsh 1985

Methods	Design: RCT, parallel, 3 arms Measurements: At baseline, 3 months before and after baseline
Participants	Randomised: n = 36 Completed: n = 36 Age: Mean = 36, range 30 to 70 Males/females: NR

Walsh 1985 (*Continued*)

	Oral health status: Generalised interproximal gingival inflammation and bleeding on probing Location: USA
Interventions	Baseline cleaning: All subjects received an oral prophylaxis at the baseline. A 3-month pre-experimental period of oral hygiene by use of toothbrush only, without the use of interproximal cleaning devices Control (n = 12): Soft toothbrush, once a day Intervention (n = 12): Soft toothbrush + unwaxed floss, once a day Other interventions (n = 12): Toothbrush + round toothpick Training: At the baseline, instruction was given on the bacterial nature of plaque and its effect on periodontal tissues, and intraoral instruction on sulcular toothbrushing. All home care instructional sessions included a demonstration of the assigned plaque control procedure in the patient's own mouth followed by guided intraoral practice by the patients until they were able to perform the procedure correctly. Also, written and illustrated handout was given Compliance assessment: NR
Outcomes	Periodontal disease - bleeding: Percentage of interproximal surfaces scored positive for bleeding Plaque and calculus: Percentage of interproximal surfaces scored positive for plaque
Source of funding	Not reported
Notes	Examinations performed by a single blinded examiner

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"Subjects were randomly divided into three groups of 12 subjects each, matched by age and percentage of sites bleeding on probing."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias) Researcher-assessed outcomes	Low risk	"One investigator, functioning on a blind basis and having no access to previously recorded scores, performed all clinical examinations."
Blinding (performance bias and detection bias) Self-reported outcomes	Unclear risk	Unclear
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition not explicitly addressed, however it appears that all subjects randomised also completed the study

Walsh 1985 (*Continued*)

Selective reporting (reporting bias)	High risk	Surfaces were scored positive for plaque if they demonstrated visible plaque with a score of 2 or 3 by the Loe-Silness and positive for bleeding after probing. These scores are not recorded, but are interpreted into binary outcomes
Other bias	Unclear risk	Compliance was not assessed during the experimental period

Zimmer 2006

Methods	Design: RCT, parallel, 4 arms Measurements: At baseline, weeks 4 and 8 Attrition: 0
Participants	Randomised: n = 156 Completed: n = 156 Age: 31.7 years (range: 20.0 to 64.4 years) Males/females: 78/78 Oral health status: Suboptimal oral hygiene Location: Germany
Interventions	Baseline cleaning: Calculus removal in the lower front teeth Control (n = 39): Toothbrushing (Dr Best flex plus medium, GlaxoSmithKline), in usual manner Intervention (n = 39): Toothbrushing + flossing (Odol med 3 dental floss, GlaxoSmithKline), once a day Other interventions: 1) (n = 39) toothbrushing and mouth rinsing (0.06% chlorhexidine and 0.025% fluoride as sodium fluoride); 2) (n = 39) toothbrushing and mouth rinsing (0.1% cetylpyridiniumchloride and 0.025% F as NaF) Training: Short (2-min) instruction on flossing, no instruction on toothbrushing Compliance assessment: Self-reported
Outcomes	Periodontal disease - bleeding: Papillary Bleeding Index - PBI Plaque and calculus: modified proximal plaque index - MPPI, Quiegley-Hein Plaque Index - QHI Adverse effects
Source of funding	Industry (GlaxoSmithKline)
Notes	Third molars excluded from the analysis. All examinations performed by a single blinded examiner

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Random sequence generation (selection bias)	High risk	"By using the stratification by gender and PBI… the 156 participants were randomly assigned to four groups with 39 subjects in each group… In a box containing 156 envelopes in four strata… each participant had to draw one envelope containing the number of the attributed product."
Allocation concealment (selection bias)	Low risk	"The assignment of subjects to groups was performed by a person not involved in the experimentation."
Blinding (performance bias and detection bias) Researcher-assessed outcomes	Low risk	"The study was conducted by a blinded operator… Clinically visible side effects (staining of teeth and tongue) might have influenced examiner blinding, so an additional statistical analysis was performed on a subgroup of subjects without visible side effects to account for that. The results of this analysis indicate that clinically visible side effects did not affect examiner accuracy."
Blinding (performance bias and detection bias) Self-reported outcomes	High risk	Side effects were reported by individuals who were not blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up
Selective reporting (reporting bias)	Low risk	No protocol available. All outcomes stated in the 'Methods' section were addressed in the 'Results'
Other bias	Unclear risk	Study funded by the company who produces both mouth rinsing and flossing tools

NR = not reported; RCT = randomised controlled trial

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

Study	Reason for exclusion
Barnes 2005	Intervention: study does not include toothbrush only group
Bellamy 2004	Intervention: intervention period less than 4 weeks
Bergenholtz 1974	Intervention: intervention period less than 4 weeks
Bergenholtz 1980	Intervention: study does not include toothbrush only group; intervention period less than 4 weeks
Bergenholtz 1984	Intervention: study does not include toothbrush only group
Biesbrock 2006	Participants: age range 12 to 20 (mean age 15.9)
Caton 1993	Intervention: flossing not included as an intervention
Cercek 1983	Design: not a randomised controlled trial
Christou 1998	Intervention: study does not include toothbrush only group
Faveri 2006	Intervention: intervention period less than 4 weeks
Gjermo 1970	Intervention: intervention period less than 4 weeks
Graves 1989	Intervention: intervention period less than 4 weeks
Hill 1973	Design: no mention of randomisation
Isaacs 1999	Intervention: study does not include toothbrush only group
Jackson 2006	Intervention: study does not include toothbrush only group
Kazmierczak 1994	Intervention: study does not include toothbrush only group
Kiger 1991	Intervention: crossover study without a washout period
Kocher 2000	Intervention: study does not include toothbrushing plus flossing alone group
Lamberts 1982	Intervention: study does not include toothbrush only group
Newbrun 1980	Intervention: study does not include toothbrush only group
Noorlin 2007	Intervention: study does not include toothbrush only group
Ong 1990	Intervention: study does not include toothbrush only group

(*Continued*)

Pucher 1995	Intervention: study does not include toothbrush only group
Schmage 1999	Intervention: study does not include toothbrush only group
Schmid 1976	Intervention: intervention period less than 4 weeks
Sjogren 2004	Intervention: intervention period less than 4 weeks
Smith 1988	Intervention: study does not include toothbrush only group
Spolsky 1993	Intervention: study does not include toothbrush only group
Van Swol 1977	Intervention: intervention period less than 4 weeks
Vilani 1998	Intervention: study does not include toothbrush plus flossing group
Wolffe 1976	Intervention: intervention period less than 4 weeks
Wong 1985	Intervention: study does not include toothbrush only group
Yankell 2002	Intervention: study does not include toothbrush only group
Yost 2006	Intervention: study does not include toothbrush only group

DATA AND ANALYSES

Comparison 1. Toothbrushing plus flossing vs toothbrushing alone at 1 month

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Gingival Index (lower better)	7	489	Std. Mean Difference (IV, Random, 95% CI)	-0.36 [-0.66, -0.05]
1.1 Manual flossing	6	383	Std. Mean Difference (IV, Random, 95% CI)	-0.42 [-0.78, -0.07]
1.2 Automated flossing	2	106	Std. Mean Difference (IV, Random, 95% CI)	-0.16 [-0.80, 0.47]
2 Plaque (lower better)	5	416	Std. Mean Difference (IV, Random, 95% CI)	-0.23 [-0.52, 0.06]
2.1 Manual flossing	4	310	Std. Mean Difference (IV, Random, 95% CI)	-0.28 [-0.70, 0.14]
2.2 Automated flossing	2	106	Std. Mean Difference (IV, Random, 95% CI)	-0.12 [-0.51, 0.27]

Comparison 2. Toothbrushing plus flossing vs toothbrushing alone at 3 months

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Gingival index (0-3 scale, lower better)	6	656	Std. Mean Difference (IV, Random, 95% CI)	-0.41 [-0.68, -0.14]
2 Plaque (0-5 scale, lower better)	5	594	Std. Mean Difference (IV, Random, 95% CI)	-0.20 [-0.36, -0.04]

Comparison 3. Toothbrushing plus flossing vs toothbrushing alone at 6 months

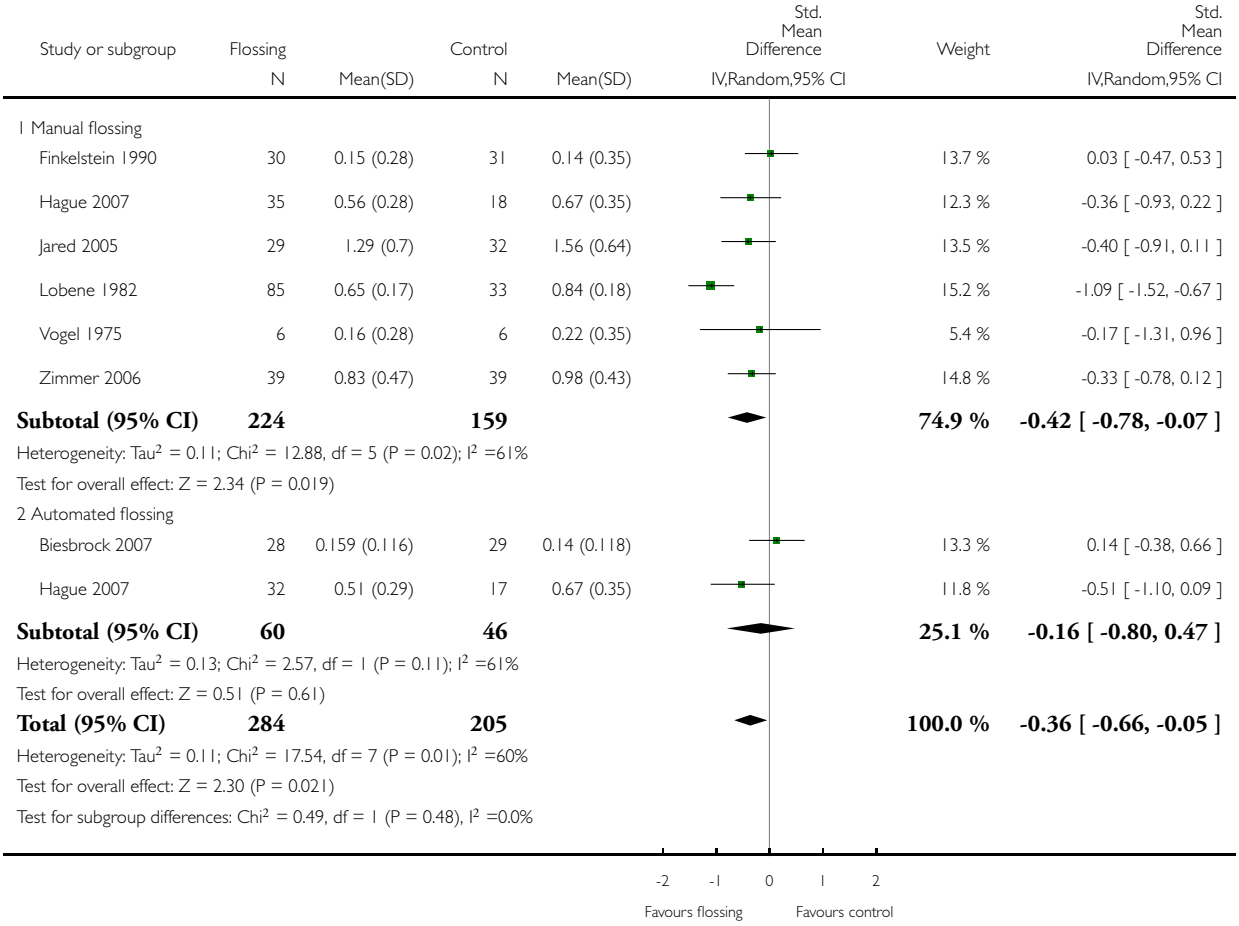
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Gingival index (0-3 scale, lower better)	4	564	Std. Mean Difference (IV, Random, 95% CI)	-0.72 [-1.09, -0.35]
2 Plaque (0-5 scale, lower better)	3	487	Std. Mean Difference (IV, Fixed, 95% CI)	-0.06 [-0.23, 0.12]

Analysis 1.1. Comparison 1 Toothbrushing plus flossing vs toothbrushing alone at 1 month, Outcome 1 Gingival Index (lower better).

Review: Flossing for the management of periodontal diseases and dental caries in adults

Comparison: 1 Toothbrushing plus flossing vs toothbrushing alone at 1 month

Outcome: 1 Gingival Index (lower better)

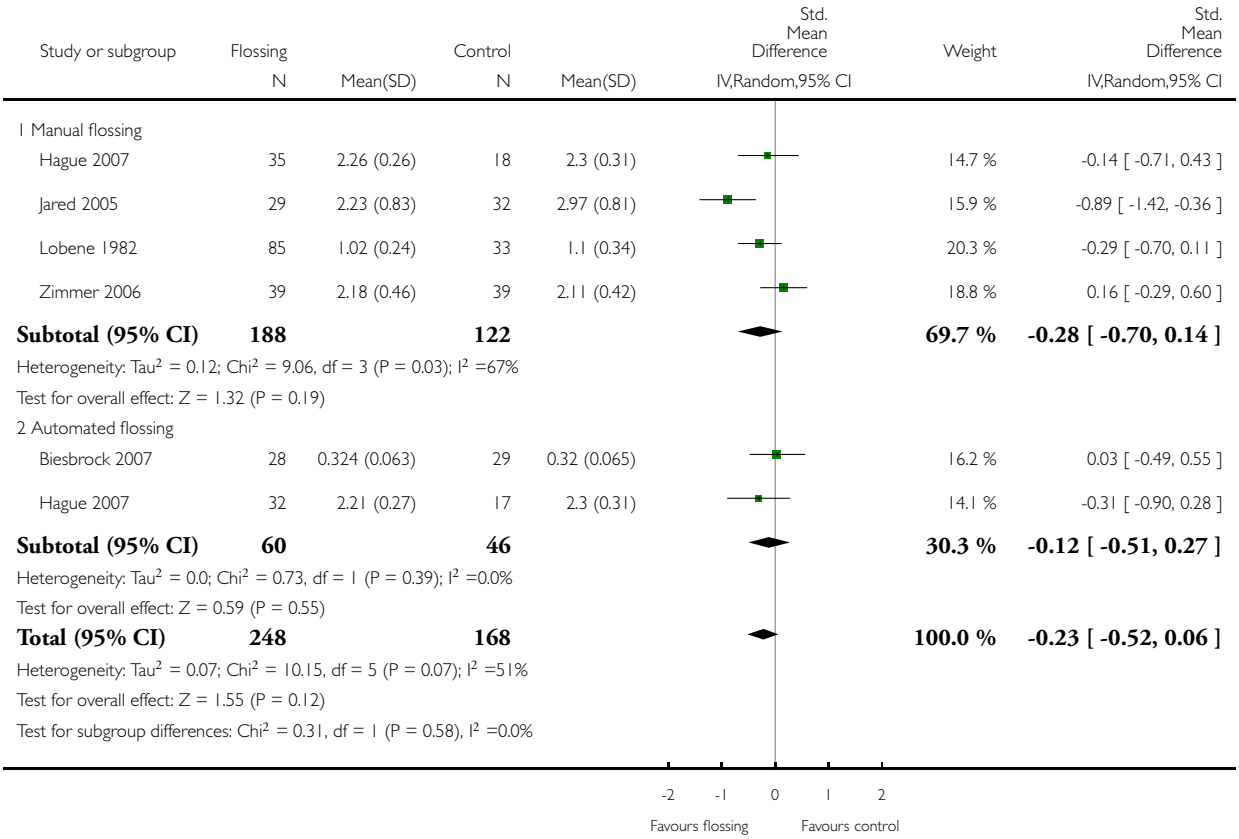


Analysis 1.2. Comparison 1 Toothbrushing plus flossing vs toothbrushing alone at 1 month, Outcome 2 Plaque (lower better).

Review: Flossing for the management of periodontal diseases and dental caries in adults

Comparison: 1 Toothbrushing plus flossing vs toothbrushing alone at 1 month

Outcome: 2 Plaque (lower better)



Analysis 2.1. Comparison 2 Toothbrushing plus flossing vs toothbrushing alone at 3 months, Outcome 1 Gingival index (0-3 scale, lower better).

Review: Flossing for the management of periodontal diseases and dental caries in adults

Comparison: 2 Toothbrushing plus flossing vs toothbrushing alone at 3 months

Outcome: 1 Gingival index (0-3 scale, lower better)

Study or subgroup	Flossing N	Mean(SD)	Toothbrushing alone N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
Bauroth 2003	108	1.92 (0.18)	108	1.98 (0.23)		23.4 %	-0.29 [-0.56, -0.02]
Finkelstein 1990	30	0.13 (0.2)	32	0.15 (0.185)		15.0 %	-0.10 [-0.60, 0.40]
Rosema 2008	39	0.38 (0.22)	38	0.47 (0.3)		16.6 %	-0.34 [-0.79, 0.11]
Schiff 2006	37	0.63 (0.51)	37	0.77 (0.48)		16.3 %	-0.28 [-0.74, 0.18]
Sharma 2002	102	1.93 (0.147)	101	2.01 (0.188)		23.0 %	-0.47 [-0.75, -0.19]
Walsh 1985	12	0.64 (0.14)	12	0.9 (0.1)		5.7 %	-2.06 [-3.09, -1.04]
Total (95% CI)	**328**		**328**			**100.0 %**	**-0.41 [-0.68, -0.14]**

Heterogeneity: $Tau^2 = 0.06$; $Chi^2 = 12.65$, df = 5 (P = 0.03); $I^2 = 60\%$

Test for overall effect: Z = 2.96 (P = 0.0030)

Test for subgroup differences: Not applicable

Analysis 2.2. Comparison 2 Toothbrushing plus flossing vs toothbrushing alone at 3 months, Outcome 2 Plaque (0-5 scale, lower better).

Review: Flossing for the management of periodontal diseases and dental caries in adults

Comparison: 2 Toothbrushing plus flossing vs toothbrushing alone at 3 months

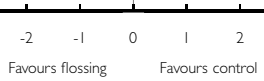
Outcome: 2 Plaque (0-5 scale, lower better)

Study or subgroup	Flossing N	Mean(SD)	Toothbrushing alone N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
Bauroth 2003	108	2.31 (0.48)	108	2.42 (0.43)		36.3 %	-0.24 [-0.51, 0.03]
Rosema 2008	39	1.61 (0.42)	38	1.61 (0.52)		13.1 %	0.0 [-0.45, 0.45]
Schiff 2006	37	1.52 (0.34)	37	1.57 (0.43)		12.5 %	-0.13 [-0.58, 0.33]
Sharma 2002	102	2.32 (0.37)	101	2.4 (0.363)		34.2 %	-0.22 [-0.49, 0.06]
Walsh 1985	12	0.88 (0.08)	12	0.93 (0.09)		3.9 %	-0.57 [-1.39, 0.25]
Total (95% CI)	**298**		**296**			**100.0 %**	**-0.20 [-0.36, -0.04]**

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 1.74$, df = 4 (P = 0.78); $I^2 = 0.0\%$

Test for overall effect: Z = 2.43 (P = 0.015)

Test for subgroup differences: Not applicable



Analysis 3.1. Comparison 3 Toothbrushing plus flossing vs toothbrushing alone at 6 months, Outcome 1 Gingival index (0-3 scale, lower better).

Review: Flossing for the management of periodontal diseases and dental caries in adults

Comparison: 3 Toothbrushing plus flossing vs toothbrushing alone at 6 months

Outcome: 1 Gingival index (0-3 scale, lower better)

Study or subgroup	Flossing N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
Bauroth 2003	105	1.91 (0.21)	105	2.02 (0.23)		28.4 %	-0.50 [-0.77, -0.22]
Rosema 2008	39	0.4 (0.19)	38	0.59 (0.31)		22.0 %	-0.73 [-1.20, -0.27]
Schiff 2006	37	1.01 (0.11)	37	1.06 (0.12)		22.0 %	-0.43 [-0.89, 0.03]
Sharma 2002	102	1.74 (0.217)	101	1.95 (0.131)		27.6 %	-1.17 [-1.46, -0.87]
Total (95% CI)	**283**		**281**			**100.0 %**	**-0.72 [-1.09, -0.35]**

Heterogeneity: $Tau^2 = 0.11$; $Chi^2 = 12.57$, df = 3 (P = 0.01); $I^2 = 76\%$

Test for overall effect: Z = 3.82 (P = 0.00013)

Test for subgroup differences: Not applicable

Analysis 3.2. Comparison 3 Toothbrushing plus flossing vs toothbrushing alone at 6 months, Outcome 2 Plaque (0-5 scale, lower better).

Review: Flossing for the management of periodontal diseases and dental caries in adults

Comparison: 3 Toothbrushing plus flossing vs toothbrushing alone at 6 months

Outcome: 2 Plaque (0-5 scale, lower better)

Study or subgroup	Flossing N	Mean(SD)	Control N	Mean(SD)	Std. Mean Difference IV,Fixed,95% CI	Weight	Std. Mean Difference IV,Fixed,95% CI
Bauroth 2003	105	2.46 (0.55)	105	2.57 (0.48)		43.0 %	-0.21 [-0.48, 0.06]
Schiff 2006	37	1.47 (0.19)	37	1.49 (0.21)		15.2 %	-0.10 [-0.55, 0.36]
Sharma 2002	102	2.52 (0.297)	101	2.48 (0.369)		41.8 %	0.12 [-0.16, 0.39]
Total (95% CI)	**244**		**243**			**100.0 %**	**-0.06 [-0.23, 0.12]**

Heterogeneity: Chi^2 = 2.86, df = 2 (P = 0.24); I^2 =30%

Test for overall effect: Z = 0.62 (P = 0.53)

Test for subgroup differences: Not applicable

APPENDICES

Appendix 1. MEDLINE (OVID) Search Strategy

1. exp Dental Devices, Home Care/
2. floss$.mp.
3. "dental tape$".mp.
4. ((interdental adj3 clean$) or (inter-dental adj3 clean$)).mp.
5. ((interproximal adj3 clean$) or (inter-proximal adj3 clean$)).mp.
6. or/1-5
7. exp TOOTH DEMINERALIZATION/
8. (caries or carious).mp.
9. (teeth adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
10. (tooth adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
11. (dental adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
12. (enamel adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
13. (dentin$ adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
14. (root$ adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or demineral$ or remineral$)).mp.
15. Dental plaque/
16. ((teeth or tooth or dental or enamel or dentin) and plaque).mp.
17. exp DENTAL HEALTH SURVEYS/

18. ("DMF Index" or "Dental Plaque Index" or "Periodontal Index" or "Papillary Bleeding Index").mp.
19. exp Periodontal Diseases/
20. periodont$.mp.
21. (gingiva$ adj3 pocket$).mp.
22. (periodontal adj3 pocket$).mp.
23. ((blood or bleed$) adj4 prob$).mp.
24. (gingival$ and (blood$ or bleed$ or inflamm$)).mp.
25. or/7-24
26. 6 and 25

We linked the above subject search 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] (Higgins 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 2. Cochrane Oral Health Group Trials Register Search Strategy

((floss* or "dental tape*" or interdental or inter-dental or interproximal or inter-proximal) AND (caries or cavit* or decay* or carious or lesion* or demineral* or remineral* or periodont* or plaque))

Appendix 3. Cochrane Cental Register of Controlled Trials (CENTRAL) Search Strategy

#1 MeSH descriptor Dental Devices, Home Care explode all trees
#2 floss*
#3 "dental tape*"
#4 ((interdental near/3 clean*) or (inter-dental near/3 clean*))
#5 ((interproximal near/3 clean*) or (inter-proximal near/3 clean*))
#6 (#1 OR #2 OR #3 OR #4 OR #5)
#7 MeSH descriptor Tooth Demineralization explode all trees
#8 (caries or carious)
#9 ((teeth near/5 cavit*) or (teeth near/5 caries) or (teeth near/5 carious) or (teeth near/5 decay*) or (teeth near/5 lesion*) or (teeth near/5 demineral*) or (teeth near/5 remineral*))
#10 ((tooth near/5 cavit*) or (tooth near/5 caries) or (tooth near/5 carious) or (tooth near/5 decay*) or (tooth near/5 lesion*) or (tooth near/5 demineral*) or (tooth near/5 remineral*))
#11 ((dental near/5 cavit*) or (dental near/5 caries) or (dental near/5 carious) or (dental near/5 decay*) or (dental near/5 lesion*) or (dental near/5 demineral*) or (dental near/5 remineral*))
#12 ((enamel near/5 cavit*) or (enamel near/5 caries) or (enamel near/5 carious) or (enamel near/5 decay*) or (enamel near/5 lesion*) or (enamel near/5 demineral*) or (enamel near/5 remineral*))
#13 ((dentin* near/5 cavit*) or (dentin* near/5 caries) or (dentin* near/5 carious) or (dentin* near/5 decay*) or (dentin* near/5 lesion*) or (dentin* near/5 demineral*) or (dentin* near/5 remineral*))
#14 ((root* near/5 cavit*) or (root* near/5 caries) or (root* near/5 carious) or (root* near/5 decay*) or (root* near/5 lesion*) or (root* near/5 demineral*) or (root* near/5 remineral*))
#15 MeSH descriptor Dental Plaque, this term only

#16 ((teeth or tooth or dental or enamal or dentin) and plaque)
#17 MeSH descriptor Dental Health Surveys explode all trees
#18 ("DMF Index" or "Dental Plaque Index" or "Periodontal Index" or "Papillary Bleeding Index")
#19 MeSH descriptor Periodontal Diseases explode all trees
#20 periodont*
#21 (gingiva* near/3 pocket*)
#22 (periodontal near/3 pocket*)
#23 ((blood near/4 prob*) or (bleed* near/4 prob*))
#24 ((gingiva* and blood*) or (gingiva* and bleed*) or (gingiva* and inflamm*))
#25 (#7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24)
#26 (#6 AND #25)

Appendix 4. EMBASE (OVID) Search Strategy

1. exp Dental Devices, Home Care/
2. floss$.mp.
3. "dental tape$".mp.
4. ((interdental adj3 clean$) or (inter-dental adj3 clean$)).mp.
5. ((interproximal adj3 clean$) or (inter-proximal adj3 clean$)).mp.
6. or/1-5
7. exp TOOTH DEMINERALIZATION/
8. (caries or carious).mp.
9. (teeth adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp.
10. (tooth adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp.
11. (dental adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp.
12. (enamel adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp.
13. (dentin$ adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp.
14. (root$ adj5 (cavit$ or caries$ or carious or decay$ or lesion$ or deminerali$ or reminerali$)).mp.
15. Dental plaque/
16. ((teeth or tooth or dental or enamel or dentin) and plaque).mp.
17. exp DENTAL HEALTH SURVEYS/
18. ("DMF Index" or "Dental Plaque Index" or "Periodontal Index" or "Papillary Bleeding Index").mp.
19. exp Periodontal Diseases/
20. periodont$.mp.
21. (gingiva$ adj3 pocket$).mp.
22. (periodontal adj3 pocket$).mp.
23. ((blood or bleed$) adj4 prob$).mp.
24. (gingival$ and (blood$ or bleed$ or inflamm$)).mp.
25. or/7-24
26. 6 and 25

We linked the above subject search 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. ANIMAL/ or NONHUMAN/ or ANIMAL EXPERIMENT/
16. HUMAN/
17. 16 and 15
18. 15 not 17
19. 14 not 18

Appendix 5. LILACs (BIREME) Search Strategy

(Mh dental devices, home care OR floss$ or "dental tape$" or interdental or inter-dental or interproximal or inter-proximal) [Words] and (Mh tooth demineralization or caries or carious or "tooth decay$" or deminerali$ or remineral$ or plaque or Mh Dental Plaque or Mh Dental Health Surveys or "DMF Index" or "Dental Plaque Index" or "Periodontal Index" or "Papillary Bleeding Index" or Mh Periodontal Diseases or periodont$ or "bleeding on probing" or (gingiva$ and bleed$) or (gingiva$ and blood) or (gingiva$ and inflamm$)) [Words]
We linked the above subject search to the Brazilian Cochrane Center filter for identifying RCTs in LILACS via BIREME:
Pt randomized controlled trial OR Pt controlled clinical trial OR Mh randomized controlled trials OR Mh random allocation OR Mh double-blind method OR Mh single-blind method) AND NOT (Ct animal AND NOT (Ct human and Ct animal)) OR (Pt clinical trial OR Ex E05.318.760.535$ OR (Tw clin$ AND (Tw trial$ OR Tw ensa$ OR Tw estud$ OR Tw experim$ OR Tw investiga$)) OR ((Tw singl$ OR Tw simple$ OR Tw doubl$ OR Tw doble$ OR Tw duplo$ OR Tw trebl$ OR Tw trip$) AND (Tw blind$ OR Tw cego$ OR Tw ciego$ OR Tw mask$ OR Tw mascar$)) OR Mh placebos OR Tw placebo$ OR (Tw random$ OR Tw randon$ OR Tw casual$ OR Tw acaso$ OR Tw azar OR Tw aleator$) OR Mh research design) AND NOT (Ct animal AND NOT (Ct human and Ct animal)) OR (Ct comparative study OR Ex E05.337$ OR Mh follow-up studies OR Mh prospective studies OR Tw control$ OR Tw prospectiv$ OR Tw volunt$ OR Tw volunteer$) AND NOT (Ct animal AND NOT (Ct human and Ct animal)))and not (Ct ANIMAL AND NOT (Ct HUMAN and Ct ANIMAL)))

Appendix 6. CINAHL (EBSCO) Search Strategy

S1 MH "Dental Devices, home care+"
S2 floss*
S3 "dental tape*"
S4 interdental n3 clean* or inter-dental n3 clean*
S5 interproximal n3 clean* or inter-proximal n3 clean*
S6 S1 or S2 or S3 or S4 or S5
S7 MH "Tooth demineralization+"
S8 caries or carious
S9 teeth n5 cavit* or teeth n5 caries or teeth n5 carious or teeth n5 decay* or teeth n5 lesion* or teeth n5 deminerali* or teeth n5 remineral*
S10 tooth n5 cavit* or tooth n5 caries or tooth n5 carious or tooth n5 decay* or tooth n5 lesion* or tooth n5 deminerali* or tooth n5 remineral*
S11 dental n5 cavit* or dental n5 caries or dental n5 carious or dental n5 decay* or dental n5 lesion* or dental n5 deminerali* or dental n5 remineral*
S12 enamel n5 cavit* or enamel n5 caries or enamel n5 carious or enamel n5 decay* or enamel n5 lesion* or enamel n5 deminerali* or enamel n5 remineral*
S13 dentin* n5 cavit* or dentin* n5 caries or dentin* n5 carious or dentin* n5 decay* or dentin* n5 lesion* or dentin* n5 deminerali* or dentin* n5 remineral*
S14 root* n5 cavit* or root* n5 caries or root* n5 carious or root* n5 decay* or root* n5 lesion* or root* n5 deminerali* or root* n5 remineral*
S15 MH "Dental plaque"
S16 ((teeth or tooth or dental or enamel or dentin) and plaque)

S17 ("DMF Index" or "Dental Plaque Index" or "Periodontal Index" or "Papillary Bleeding Index")
S18 MH "Periodontal Diseases+"
S19 periodont*
S20 gingiva* N3 pocket*
S21 periodontal N3 pocket*
S22 (blood N4 prob*) or (bleed* N4 prob*)
S23 (gingiva* and blood*) or (gingiva* and bleed*) or (gingiva* and inflamm*)
S24 S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23
S25 S6 and S24

We linked the above subject search to the Cochrane Oral Health Group filter for identifying RCTs in CINAHL via EBSCO:

S1 MH Random Assignment or MH Single-blind Studies or MH Double-blind Studies or MH Triple-blind Studies or MH Crossover design or MH Factorial Design
S2 TI ("multicentre study" or "multicenter study" or "multi-centre study" or "multi-center study") or AB ("multicentre study" or "multicenter study" or "multi-centre study" or "multi-center study") or SU ("multicentre study" or "multicenter study" or "multi-centre study" or "multi-center study")
S3 TI random* or AB random*
S4 AB "latin square" or TI "latin square"
S5 TI (crossover or cross-over) or AB (crossover or cross-over) or SU (crossover or cross-over)
S6 MH Placebos
S7 AB (singl* or doubl* or trebl* or tripl*) or TI (singl* or doubl* or trebl* or tripl*)
S8 TI blind* or AB mask* or AB blind* or TI mask*
S9 S7 and S8
S10 TI Placebo* or AB Placebo* or SU Placebo*
S11 MH Clinical Trials
S12 TI (Clinical AND Trial) or AB (Clinical AND Trial) or SU (Clinical AND Trial)
S13 S1 or S2 or S3 or S4 or S5 or S6 or S9 or S10 or S11 or S12

Appendix 7. ZETOC Search Strategy

Keyword search limited to conference proceedings only:
dent* and floss*
teeth* and floss*
gingiva* and floss*
caries and floss*
"tooth decay" and floss*
periodont* and floss*

Appendix 8. Web of Science Search Strategy

Search limited to conference proceedings only:
1 TS=(floss*)
2 TS="dental tape"
3 TS="interdental clean*" or TS="inter-dental clean*" or TS="interproximal clean*" or TS="inter-proximal clean*"
4 #3 OR #2 OR #1
5 TS=(cavit* or carious or caries or decay* or deminerali* or reminerali*)
6 TS=plaque
7 TS=("DMF Index" or "Dental Plaque Index" or "Periodontal Index" or "Papillary Bleeding Index")
8 TS=periodont*
9 TS=(gingiva* and (bleed* or blood or inflamm*))
10 TS=(gingiva* and pocket*)
11 TS=(periodont* and pocket)
12 TS=((blood or bleed*) and prob*)

13 #12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5
14 #13 AND #4

Appendix 9. ClinicalTrials.gov Search Strategy

We performed a keyword search of ClinicalTrials.gov to identify ongoing trials:
floss or flossing

Appendix 10. Meta Register of Controlled Clinical Trials Search Strategy

We performed a keyword search of the Meta Register of Controlled Clinical Trials to identify ongoing trials:
floss or flossing

WHAT'S NEW

Last assessed as up-to-date: 28 October 2011.

Date	Event	Description
1 March 2012	Amended	Minor changes to 'Summary of findings' table: changing 'manual flossing' to 'flossing' in heading, number of participants from 491 to 489 and changing figure in footnote

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- Conceiving, designing and co-ordinating the review: Dario Sambunjak (DS), Tina Poklepovic (TP), Peter Tugwell (PT), Jason Nickerson (JN)
- Designing search strategies and undertaking searches: DS, JN, Pauline Imai (PI), Trevor Johnson (TJ)
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- Appraising quality of papers: PI, DS, HW, JN, TJ
- Extracting data from papers: DS, JN, HW, TP
- Writing to authors of papers for additional information: DS, JN, TJ
- Data management for the review and entering data into RevMan: DS, JN, HW
- Analysis and interpretation of data: HW, DS, JN, TJ, PT
- Providing a clinical perspective: TP, PI, TJ
- Writing the review: DS, JN, TJ, HW
- Providing general advice on the review: HW, PT
- Performing previous work that was the foundation of the current review: HW

DECLARATIONS OF INTEREST

This review will be used by some of the authors as part of other research projects. None of the authors has any other interests related to this review.

SOURCES OF SUPPORT

Internal sources

- MAHSC, UK.

The Cochrane Oral Health Group is supported by the Manchester Academic Health Sciences Centre (MAHSC) and the NIHR Manchester Biomedical Research Centre

- Croatian Ministry of Science, Education and Sports, Croatia.

Dario Sambunjak is financially supported by the Croatian Ministry of Science, Education and Sports (grant No. 216-1080314-0245 to Matko Marusic)

- University of Ottawa, Canada.

External sources

- British Orthodontic Society (BOS), UK.

The BOS have provided funding for the Cochrane Oral Health Group Global Alliance (see www.ohg.cochrane.org)

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

It was decided that studies with a crossover trial design were suitable for inclusion in this review provided that each treatment phase lasted for a minimum of 4 weeks, there was a minimum of 2-weeks washout between treatment phases or data was available from the first treatment phase and could be treated as a parallel group trial.

It was decided to include studies where the toothbrushing control group also used a 'placebo' inactive mouthrinse. We considered that use of a 'placebo' mouthrinse may possibly reduce performance bias.

It was decided that studies which included a majority of participants undergoing orthodontic treatment should be excluded. In studies where some participants were undergoing any type of orthodontic treatment, data from banded teeth were not used in this review.

INDEX TERMS

Medical Subject Headings (MeSH)

*Dental Devices, Home Care; Dental Caries [*prevention & control]; Dental Plaque [prevention & control]; Gingivitis [prevention & control]; Periodontal Diseases [*prevention & control]; Randomized Controlled Trials as Topic; Toothbrushing [*methods]

MeSH check words

Adult; Humans