The effectiveness of laceback ligatures during initial orthodontic alignment: a systematic review and meta-analysis

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SUMMARY Lacebacks may be used to limit unwanted incisor proclination during initial orthodontic alignment; however, their use has not met with universal approval. This systematic review aims to appraise the evidence in relation to the effectiveness of lacebacks in controlling incisor position during initial alignment. Electronic database searches of published literature (MEDLINE via Ovid, Cochrane Central Register of Controlled Trials, LILACS, and IBECS) and unpublished literature were performed. Search terms used included randomized controlled trial, controlled clinical trial, random allocation, double blind method, orthodontics, and laceback. Data were extracted using custom forms. Risk of bias assessment was made using the Cochrane Collaboration risk of bias tool. The quality of the evidence was also assessed using GRADE. Mean differences in incisor inclination and antero-posterior changes in incisor and molar position during alignment were calculated. Two studies involving 97 participants were found to be at low risk of bias and were included in the quantitative synthesis. The random effects meta-analysis demonstrated that the use of lacebacks was associated with 0.5 mm greater posterior movement of the incisors during alignment; this finding was of limited clinical importance and statistically non-significant [95 per cent confidence interval (CI): −1.25, 0.25, *P* = 0.19]. Little difference (0.46 mm) was also found between laceback and non-laceback groups with regards to mesial molar movement (95 per cent CI: −0.33, 1.24, *P* = 0.26). According to the GRADE assessment, the overall quality of evidence relating to the use of lacebacks was high. There is no evidence to support the use of lacebacks for the control of the sagittal position of the incisors during initial orthodontic alignment.

Introduction

The initial phase of orthodontic treatment is directed at orthodontic alignment in the horizontal and vertical plane involving arch alignment and rotational control. This is typically accomplished with NiTi archwires, which afford sufficient flexibility to engage multiple displaced teeth, and exhibit shape memory (Kusy, 1997; Riley and Bearn, 2009; Wang *et al.*, 2010).

Generally, orthodontic extractions are advocated to facilitate stable relief of crowding by generating space limiting unwanted advancement of the anterior segments and arch dimensional change. The mesial angulation in-built in canine brackets predisposes to forward movement of the incisors during alleviation of crowding in the initial alignment phase (McLaughlin *et al.*, 2001). While the incisors may be recaptured later in treatment, particularly during space closure, reciprocal movement of this nature ('round tripping') is considered undesirable. In particular, round tripping is believed to predispose to root resorption, periodontal attachment loss, and prolonged treatment.

Lacebacks, typically formed from 0.09" to 0.1" stainless steel wire spanning the first molars to canines, have been devised as a mechanism to control the antero-posterior position of the incisors during the initial alignment phase by controlling the angulation of the canine teeth. They are believed to be particularly useful where the canines are upright or distally angulated at the outset, as in these cases, significant mesial crown movement is likely to be accompanied by advancement of the incisors. Lacebacks are placed in a passive configuration and are typically intermittently activated during occlusal contact. While many clinicians routinely use lacebacks to control incisor position during orthodontic alignment, they have not met with universal approval. Disadvantages of laceback use may include loss of anchorage posteriorly manifesting as mesial migration and tipping of first permanent molars, potential for plaque stagnation, and limited additional chairside time and complexity.

Although randomized controlled trials (RCTs) on the effectiveness of laceback ligatures have been conducted, no systematic literature review has yet been undertaken. Consequently, this review aimed to amalgamate the evidence concerning the effectiveness of laceback ligatures during the initial alignment phase of orthodontic treatment.

Materials and methods

The protocol for a systematic review on the effectiveness of laceback ligatures was registered on the National Institute of Health Research Database (www.crd.york.ac.uk/prospero, Protocol: CRD42012001910). The following selection criteria were applied for the review:

1. Study design: Randomized prospective clinical trials.
2. Participants: Patients with full-arch, fixed, bonded orthodontic appliance(s). Participants of any age group will be considered.
3. Interventions: Orthodontic treatment with fixed appliances to align the dental arches involving use of laceback ligatures during the initial alignment phase; the control group was to involve initial alignment without use of lacebacks.
4. Exclusion criteria: Studies involving split-mouth designs and sectional appliances were to be excluded.
5. Outcome measures: The primary outcome measures were the mean differences in incisor and molar position following orthodontic alignment and levelling.
6. Secondary outcome measures included plaque accumulation and periodontal effects and breakages of appliances.

Search strategy for identification of studies

The following electronic databases were searched: MEDLINE via Ovid (1966 to January 2012, Appendix) and the Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library Issue 4, 2011). Language restrictions were not applied. Non-English language engines including LILACS and IBECS were also searched. Unpublished literature was searched electronically using the National Research Register (www.controlled-trials.com). In addition, Pro-Quest Dissertation Abstracts and Thesis database was searched (http://proquest.umi.com/pqdweb?RQT=302&cfc=1) using 'orthodontic*' and 'laceback*'. Conference proceedings and abstracts were also accessed where possible. Authors were to be contacted to identify unpublished or ongoing clinical trials and to clarify data as required. Reference lists of the included studies were also to be screened for relevant research.

Data collection and analysis

Selection of studies.   Assessment of research for inclusion in the review, assessment of risk of bias, and extraction of data were performed independently and in duplicate by two investigators (PSF and AJ) who were not blinded to identity of the authors, their institution, or the results of the research. The full report of publications considered by either author to meet the inclusion criteria was obtained and assessed independently. Disagreements were resolved by discussion and consultation with a third author (NP).

Assessment of risk of bias in included studies.   Seven domains were considered separately to grade the risk of bias inherent in individual studies. Specific criteria included random sequence generation, allocation concealment, blinding participants and personnel, blinding of assessors, incomplete outcome data, selective reporting of outcomes, and other potential sources of bias. An overall assessment of risk of bias (high, unclear, low) was made for each included trial using the Cochrane Collaboration risk of bias tool as follows:

1. Low risk of bias—low risk for all key domains,
2. Unclear risk of bias—unclear risk of bias for one or more key domains, and
3. High risk of bias—high risk of bias for one or more key domains.

Data extraction and synthesis

A data extraction form was developed after piloting to record information on study design, observation period, participants, interventions, outcomes, and outcome data of interest including initial incisor inclination and position, initial molar position, and changes in incisor inclination and position, and molar position. Assessment of extracted data was done independently with disagreement discussed with the third author.

Clinical heterogeneity of included studies was gauged by assessing the treatment protocol particularly participants and setting, materials used, timing of data collection, and measurement techniques. Statistical heterogeneity was assessed by inspecting a graphical display of the estimated treatment effects from the trials in conjunction with 95 per cent confidence intervals (CIs). The chi-square test was used to assess heterogeneity; a P value below 0.1 would be considered indicative of significant heterogeneity (Higgins *et al.*, 2003). I^2 tests for homogeneity was also to be undertaken to quantify the extent of heterogeneity prior to each meta-analysis.

Mean differences with 95 per cent CIs were to be used for continuous data including differences in incisor inclination and position and molar position. A weighted mean pooled treatment effect would be calculated with 95 per cent CIs for the continuous outcomes of interest using a random-effects model; a random-effects model was considered more appropriate in view of the variation in population and settings. If more than 10 studies were to be included in meta-analysis, standard funnel plots and contoured enhanced funnel plots (Sterne *et al.*, 2011) would be used to examine publication bias.

Sensitivity analysis

Sensitivity analysis would be undertaken to account for studies at higher risk of bias, publication bias, and other potential sources of heterogeneity including dominant effects of individual studies and methodological differences. If quantitative data synthesis were applicable, meta-analyses and

sensitivity analyses would be undertaken in STATA version 12.1™ (STATA Corporation, College Station, TX, USA).

Quality of evidence

The quality of evidence was to be assessed using GRADE and a summary of findings table produced (Balshem *et al.*, 2011; Guyatt *et al.*, 2011a,b,c,d,e,f,g). The GRADE system is used to assess the overall body of evidence. GRADE assumes high level of evidence from RCTs but may downgrade the level of evidence based on the following domains: 1. study limitations (risk of bias), 2. inconsistency of results, 3. indirectness of evidence, 4. imprecision of results, and 5. publication bias. According to GRADE, the quality of evidence may be classified as follows—high: further research is very unlikely to change our confidence in the estimate of effect; moderate: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate; low: 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; and very low: any estimate of effect is very uncertain.

Results

Description of studies

Four studies were felt to be appropriate for inclusion in the review initially (Figure 1). Of these, one study was subsequently omitted from the qualitative synthesis in view
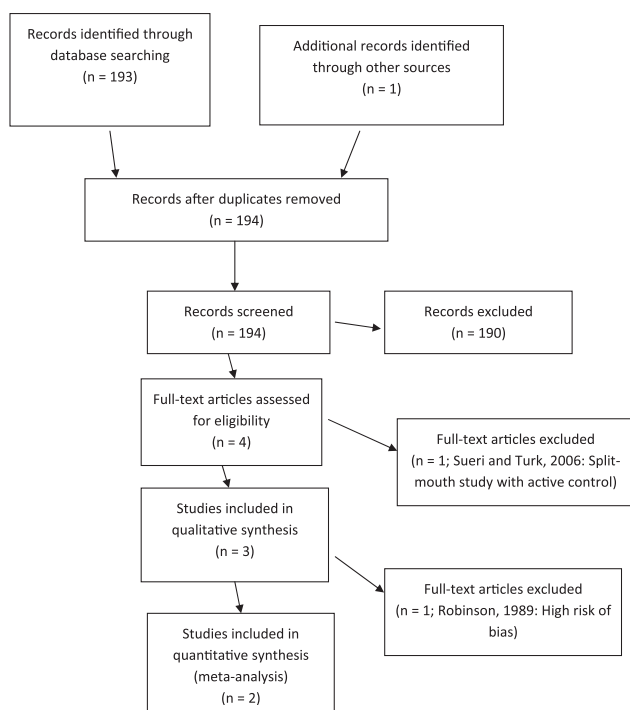

Figure 1 PRISMA diagram of article retrieval.

of the general design as it involved a split-mouth analysis (Sueri and Turk, 2006). Therefore, in that study, measurement of changes in incisor position was not attributable to the effect of lacebacks in isolation. In addition, the non-laceback side involved use of active mechanics (NiTi closing springs).

The other three papers were all prospective clinical trials; however, one of these (Robinson, 1989) was non-randomized (Table 1) and was eventually excluded. All three studies were carried out in the United Kingdom. Sample sizes varied from 35 to 62 participants with sample size calculations performed in two of the studies. Measurements were undertaken in the mandibular arch in two studies and in the maxillary arch in the remaining trial. None of the selected studies considered the secondary outcome measures of this review namely plaque accumulation, periodontal effects, and appliance breakages.

Risk of bias of included studies

One of the studies did not involve random allocation; this study, therefore, also lacked allocation concealment (Robinson, 1989, Table 2). Consequently, this study was deemed to be at high risk of bias and could not be included in quantitative synthesis. In respect of the other two studies, all seven domains were initially considered to be at low risk of bias in one study (Usmani *et al.*, 2002) with randomization performed with an unweighted dice and allocation concealed using opaque, sealed envelopes. The other study involved randomization using coin toss; allocation concealment was clarified by the authors following electronic communication (Irvine *et al.*, 2004). The use of simple randomization in both included studies, considering the small sample size, risked numeric imbalances between treatment groups. Nevertheless, baseline imbalances were minimal; risk of bias for random number generation was therefore considered to be low. Similarly, blinding of assessors was not mentioned in one study (Irvine *et al.*, 2004), but was later confirmed by the authors for both radiographic and study model assessment. Blinding of participants and personnel was not feasible in either trial. However, it was felt that the outcomes were unlikely to have been biased by lack of operator or participant blinding. Therefore, overall two studies were considered to be at low risk of bias and were deemed appropriate for quantitative synthesis.

Effects of interventions (laceback versus non-laceback)

Linear changes in molar and incisor position were reported in all three studies (Tables 3 and 4, Figures 2 and 3). The incisors were found to move posteriorly in the laceback group in each study (0.5–1.04 mm). Similarly, retraction of the incisors was also found in the study by Irvine *et al.* (2004) in the participants treated without lacebacks, although the amount of posterior movement was minimal (0.44 ± 1.29 mm). However, without use of lacebacks, anchorage loss manifest as advancement of the incisors was

Table 1 Summary of included and excluded research.

Study	Methods	Observation period	Participants	Interventions	Outcomes
Robinson (1989)	CCT	Until rectangular archwire placed: LB group, 8 ± 2.4 months; non-LB, 8.8 ± 2.2 months	57 participants: mean age for LB group, 14.5 ± 2.3 years; for non-LB, 15.0 ± 4.7 years	29 LB, 28 non-LB on light multi-strand SSW with a progressive increase in round SSW until 0.018" SSW could be engaged in buccal segments	Antero-posterior and vertical changes in position of lower incisors; Mesial movement of lower first permanent molars; Change in lower canine angulation
Usmani et al. (2002)	Parallel-group RCT	Until placement of 0.019 × 0.025" SSW	35 participants: mean age, 13.7 ± 1.8 years overall	16 LB, 19 non-LB on 0.016" NiTi and 0.018 × 0.025" NiTi	Change in position of upper incisors; Mesial movement (loss of anchorage) of the upper first permanent molars
Irvine et al. (2004)	Parallel-group RCT	Experimental group 7.1 ± 2.5 months; control group 7.1 ± 2.3 months	62 participants: mean age for LB group, 13.6 ± 1.5 years; for non-LB, 13.8 ± 1.5 years	30 LB, 32 non-LB on 0.014" NiTi, 0.018" NiTi, and 0.018" SSW (6 weeks)	Antero-posterior and vertical changes in lower incisor position. Mesial movement of lower molar
Sueri and Turk (2006)	Split-mouth RCT	Until anterior crowding resolved in one quadrant	15 participants: 12 females, 3 males	15 participants with unilateral laceback and superelastic NiTi coilspring on contralateral side on 0.012", 0.014", and 0.016" NiTi wires	Inclination change and antero-posterior change in maxillary incisors, canines, and first permanent molars; Vertical change in maxillary canine and first molar relative to maxillary plane

RCT, randomized controlled trial; LB, laceback; CCT, controlled clinical trial; SSW, stainless steel wire.

reported in the other trials (Robinson, 1989; Usmani *et al.*, 2002). Similarly, laceback use was associated with greater mesial displacement of the molars during arch alignment in two studies (Robinson, 1989; Irvine *et al.*, 2004).

Given that the study by Robinson (1989) was omitted, a total of 97 participants were included in the quantitative analysis of the 2 remaining studies (Usmani *et al.*, 2002; Irvine *et al.*, 2004). Following statistical amalgamation of these studies, use of lacebacks was associated with 0.5 mm greater posterior movement of the incisors during alignment. This difference, which is of limited clinical importance, was also not found to be of statistical significance (95 per cent CI: −1.25, 0.25, $P = 0.19$). Similarly, little difference was observed between laceback (LB) and non-LB groups with respect to anchorage loss with 0.45 mm more mesial molar movement in the LB group (95 per cent CI: −0.33, 1.24, $P = 0.26$).

Statistical heterogeneity, publication bias, and quality of evidence (GRADE)

Despite the low number of studies contributing to the meta-analysis, test for homogeneity suggested that conduct of the quantitative synthesis was appropriate. The I^2 values were 48.5 and 50.5 per cent for incisor and molar changes,

respectively. Chi-square for heterogeneity also indicated that meta-analysis was reasonable for both outcomes ($P = 0.16$). Given that only studies with a low risk of bias were included in the statistical analysis, sensitivity analysis to account for varying levels of bias was unnecessary. The assessment of the quality of the collected evidence on the use of lacebacks during alignment indicated that the evidence was of high quality (Table 4) suggesting that further research is unlikely to have an important impact on confidence in effect estimates.

Discussion

On the basis of this review and meta-analysis, there is little evidence to support the use of lacebacks during orthodontic alignment. In particular, use of lacebacks had an insignificant effect on the antero-posterior position of the incisors during orthodontic alignment. Similarly, there was a minor difference in molar anchorage loss with use of laceback ligatures, which is of little clinical relevance. In addition, while slightly more incisor retraction occurred during alignment in conjunction with lacebacks (0.5 mm), this was counterbalanced by an analogous amount of anchorage loss manifesting as mesial migration of first molars (0.45 mm).

Table 2 Risk of bias of studies included in qualitative synthesis.

Robinson (1989)	Risk of bias	Explanation
Random number generation	High	'Divided into two groups', 'a prospective study but it was not possible to randomly allocate patients to either group because of operator preferences'. Non-random.
Allocation concealment	High	Non-random. Hence, not done.
Blinding participants and personnel	Low	Not feasible. Blinding not feasible, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding.
Blinding assessor	Low	'The records were measured in random order. The model study was carried out "blind," . . . the operator was unaware of the group to which each model belonged'.
Free of incomplete data	Low	No dropouts reported.
Selective outcome reporting	Low	The study protocol is not available but it is clear that the published reports include all of the study's pre-specified outcomes and all expected outcomes that are of interest in the review.
Other	Low	The study appears to be free of other sources of bias.
Usmani *et al.* (2002)	Risk of bias	Explanation
Random number generation	Low	'By throwing an unweighted dice. A restricted randomization method was used in blocks of 12 to ensure that equal numbers of patients were allocated to each of the two groups'.
Allocation concealment	Low	'In envelopes labelled with the study identification number'.
Blinding participants and personnel	Low	Not feasible. Blinding not feasible, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding.
Blinding assessor	Low	'Observer bias was reduced by ensuring that the examiner was blind to whether the patient had received canine lacebacks or not. All models were measured in a random order so that the same patient's start and completion of trial models were not measured consecutively'.
Free of incomplete data	Low	Per protocol analysis: 17% dropout rate. Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
Selective outcome reporting	Low	The study protocol is not available but it is clear that the published reports include all of the study's pre-specified outcomes and all expected outcomes that are of interest in the review.
Other	Low	The study appears to be free of other sources of bias.
Irvine *et al.* (2004)	Risk of bias	Explanation
Random number generation	Low	Each patient was randomly assigned to one of the groups by the toss of a coin.
Allocation concealment	Low	Initially graded as unclear as not mentioned in manuscript. Correspondence with author confirmed use of opaque sealed envelopes.
Blinding participants and personnel	Low	Blinding not feasible, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding.
Blinding assessor	Low	Initially graded as unclear as not mentioned in manuscript. Correspondence with author confirmed that lacebacks were not apparent on either radiographs or models.
Free of incomplete data	Low	Per protocol analysis: 12.7% dropout rate. Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
Selective outcome reporting	Low	The study protocol is not available but it is clear that the published reports include all of the study's pre-specified outcomes and all expected outcomes that are of interest in the review.
Other	Low	The study appears to be free of other sources of bias.

Table 3 Outcome data from both included and excluded studies.

Study	Intervention	Antero-posterior change of incisors (mm, positive value represents forward movement)		Mesial molar movement (mm, positive value represents forward movement)		Vertical change in incisor position (mm, positive value represents extrusion)	
		LB	Non-LB	LB	Non-LB	LB	Non-LB
Robinson (1989)	LB (29), non-LB (28)	−1.04 mm(±1.19)	1.47 mm (±1.79)	1.76 mm (±2.36)	1.53 mm (±1.03)	0.85 mm (±0.65)	1.03 mm (±1.19)
Usmani *et al.* (2002)	0.009" LB (16), non-LB (19)	−0.50 mm(±1.06)	0.36 mm (±1.09)	Right: 0.40 (1.66) and left: 0.58 (2.10)	Right: 0.15 (0.63) and left: 0.84 (2.66)		
Irvine *et al.* (2004)	LB (30), non LB (32)	−0.53 mm (±1.9, 95% CI: −4.33, 3.27)	−0.44 (±1.29, −95% CI: −3.02, 2.44)	0.75 (±1.08 mm, 95% CI: −1.41, 2.91)	−0.08 (±1.55 mm, 95% CI: −3.18, 3.02)	0.47 (±0.98 mm, 95% CI: −1.49, 2.43)	0.44 (±0.8 mm, 95% CI: −1.3, 2.18)
Sueri and Turk (2006)	Split-mouth: 0.01" LB (15), non-LB* (15)	−1.27 mm (±1.33)		0.7 (0.86)	1.93 (1.13)		

CI, confidence interval; LB, laceback.
*NiTi closed coil spring.

Table 4   GRADE assessment of the use of lacebacks versus control on antero-posterior changes of incisors and molars.

Effect of lacebacks on antero-posterior incisor movement and molar drift

Patient or population: patients with orthodontic crowding

Settings—Intervention: lacebacks; Comparison: no lacebacks

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	No lacebacks	Lacebacks				
Antero–posterior change of incisor position		The mean antero–posterior advancement of incisor position in the intervention groups was 0.50 mm less (1.25 less to 0.25 more)		97 (2 studies)	⊕⊕⊕⊕ High	
Mesial molar drift		The mean mesial molar drift in the intervention groups was 0.46 more (0.33 less to 1.24 more)		97 (2 studies)	⊕⊕⊕⊕ High	

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; and very low quality: we are very uncertain about the estimate.
*The basis for the 'assumed risk' (e.g. the median control group risk across studies) is provided in the above footnote. The 'corresponding risk' [and its 95% confidence interval (CI)] is based on the assumed risk in the comparison group and the 'relative effect' of the intervention (and its 95% CI).
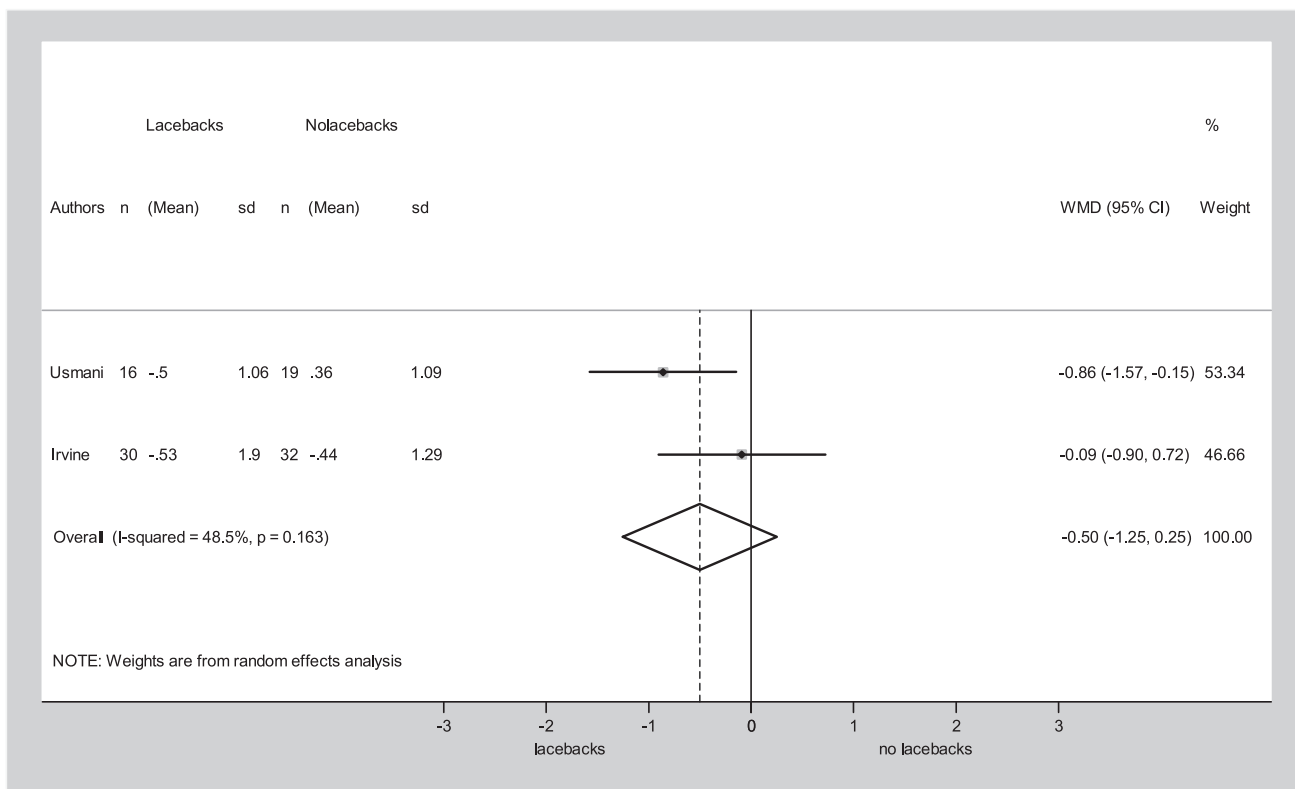

Figure 2   Forest plot of the effect of laceback use versus control on the change in antero-posterior position of the incisors.

Mesial molar drift

Authors	Lacebacks n (Mean) sd	Nolacebacks n (Mean) sd	WMD (95% CI)	% Weight
Usmani	16 .49 1.34	19 .5 1.37	-0.01 (-0.91, 0.89)	42.60
Irvine	30 .75 1.08	32 -.05 1.55	0.80 (0.14, 1.46)	57.40
Overall (I-squared = 50.5%, p = 0.155)			0.45 (-0.33, 1.24)	100.00

NOTE: Weights are from random effects analysis

lacebacks — no lacebacks
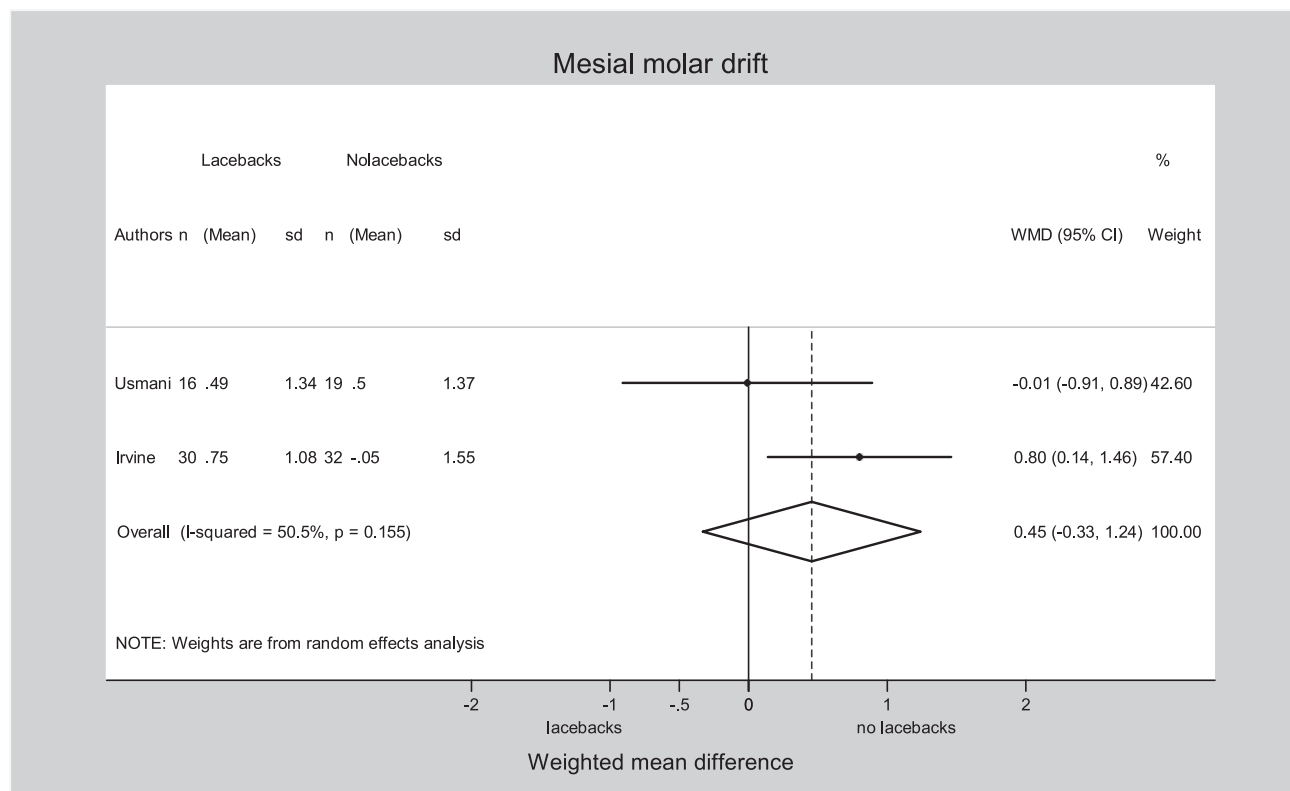
Weighted mean difference

Figure 3 Forest plot of the effect of laceback use versus control on the change in antero-posterior position of the molars.

Consequently, it may be assumed that lacebacks represent an unnecessary complexity with negligible therapeutic benefit.

As relatively few parallel-group randomized controlled trials investigating the use of lacebacks were noted, the strength of the evidence contributing to this conclusion was evaluated. The combined sample available for meta-analysis comprised just 97 participants; downgrading the GRADE score for the quality of evidence to moderate was therefore considered. However, it was decided not to downgrade the quality of evidence score as the CI around the effect of the intervention was narrow and neither the upper nor the lower bounds reached levels of clinical importance. Furthermore, sample calculations using the GRADE optimal information criterion considering a 1.5-mm (standard deviation = 1.5 mm) difference in incisor position as clinically important indicated that a sufficient number of patients were included in the meta-analysis to obviate a downgrade (Guyatt *et al.*, 2011e). One controlled clinical trial was identified which demonstrated beneficial effects of the use of lacebacks with a clinically significant difference (2.5 mm) in the sagittal position of the lower incisors following initial alignment (Robinson, 1989). However, in that study, the decision to use lacebacks was based on operator discretion introducing the possibility of selection bias during treatment allocation. There was also a disparity between the groups in respect of extraction patterns with both first and premolar extraction

cases considered; slightly more first premolars were removed in the laceback group. Consequently, this study was omitted from the quantitative analysis.

A random-effects model was used in the present meta-analysis. This type of model assumes that true treatment effects differ between settings; the calculated estimate and CIs therefore indicate the average treatment effect and the range in which the true average effect lies. However, under the random-effects model, as in different settings the true effect is allowed to vary, the reported CI of the average effect may be misleading. The prediction interval incorporating uncertainty in the location and spread of the random-effects distribution is therefore more appropriate. Practically, the prediction interval may indicate treatment effect in future studies; however, in the current random-effects meta-analysis, prediction intervals could not be estimated as a minimum of three studies are required to infer this (Higgins *et al.*, 2009). Consequently, further studies dealing with the primary outcome may be helpful.

There was no information obtained in relation to any of the secondary outcomes. However, it would be reasonable to suggest that initial placement of lacebacks and intermittent activation at follow-up visits is likely to result in a limited increase in chairside time. Lacebacks may also hamper oral hygiene measures. However, there are no published studies relating to these outcomes. With respect to breakages,

introduction of lacebacks adds a further component, which in itself is prone to breakage, detachment, or loosening. Notwithstanding this lacebacks are used by some clinicians to augment the archwire in extraction sites limiting the risk of fracture, and displacement of the base wire. Similarly, there was no evidence to support or question this practice.

Both studies considered appropriate for inclusion in the meta-analysis were deemed to be at low risk of bias, with all seven domains explained clearly (Usmani *et al.*, 2002). Evidence of allocation concealment was not explicit in the manuscript in one of these (Irvine *et al.*, 2004). Failure to conceal allocation is typically associated with inflated intervention effect estimates (Schulz *et al.*, 1995; Moher *et al.*, 1998); this was unlikely in this trial as the effectiveness of lacebacks was found to be lower than in the study involving clear allocation concealment (Usmani *et al.*, 2002). This finding is supported by meta-epidemiological studies, suggesting that biased estimates are more likely to be introduced in studies having subjective measures of outcome; with objective measures such as change in tooth position, biased results were less likely to occur (Wood *et al.*, 2008). The search strategy used in this review was comprehensive with multiple databases accessed in keeping with guidance on the assessment of multiple systematic reviews (Shea *et al.*, 2007). In addition, non-English language searches and grey literature searches were undertaken to identify all relevant published and ongoing research. The existence of further unpublished studies can only be speculated upon; it may be assumed that any unpublished studies are those that have failed to demonstrate significant effects (Rosenthal, 1979). No published protocols of previously registered or ongoing studies relating to lacebacks were found, however. Consequently, it is likely that the trials identified in this review are representative of research and clinical practice generally. It is therefore reasonable to assume that the results of this systematic review are likely to be applicable to other settings involving adolescent patients.

Conclusions

On the basis of the available evidence, the use of lacebacks has neither a clinically nor a statistically significant effect on the sagittal position of the incisors and molars during initial orthodontic alignment. There is no evidence concerning the use of lacebacks on chairside time or periodontal health. Further high-quality randomized controlled trials on the impact of lacebacks during orthodontic alignment would be welcome.

References

Balshem H *et al.* 2011 GRADE guidelines: 3. Rating the quality of evidence. Journal of Clinical Epidemiology 64: 401–406

Guyatt G *et al.* 2011a GRADE guidelines: 1. Introduction: GRADE evidence profiles and summary of findings tables. Journal of Clinical Epidemiology 64: 383–394

Guyatt G H *et al.* 2011b GRADE guidelines: 2. Framing the question and deciding on important outcomes. Journal of Clinical Epidemiology 64: 395–400

Guyatt G H *et al.* 2011c GRADE guidelines: 4. Rating the quality of evidence: study limitations (risk of bias). Journal of Clinical Epidemiology 64: 407–415

Guyatt G H *et al.* 2011d GRADE guidelines: 5. Rating the quality of evidence: publication bias. Journal of Clinical Epidemiology 64: 1277–1282

Guyatt G H *et al.* 2011e GRADE guidelines: 6. Rating the quality of evidence: imprecision. Journal of Clinical Epidemiology 64: 1283–1293

Guyatt G H *et al.* 2011f GRADE guidelines: 7. Rating the quality of evidence: inconsistency. Journal of Clinical Epidemiology 64: 1294–1302

Guyatt G H *et al.* 2011g GRADE guidelines: 8. Rating the quality of evidence: indirectness. Journal of Clinical Epidemiology 64: 1303–1310

Higgins J P, Thompson S G, Spiegelhalter D J 2009 A re-evaluation of random-effects meta-analysis. Journal of Royal Statistical Society 172: 137–159

Higgins J P, Thompson S G, Deeks J J, Altman D G 2003 Measuring inconsistency in meta-analyses. British Medical Journal 327: 557–560

Irvine R, Power S, McDonald F 2004 The effectiveness of laceback ligatures: a randomized controlled clinical trial. Journal of Orthodontics 31: 303–311

Kusy R P 1997 A review of contemporary archwires: their properties and characteristics. Angle Orthodontist 67: 197–207

McLaughlin R P, Bennett J C, Trevisi H 2001 Systematized orthodontic treatment mechanics, 2nd edn. Mosby International Ltd, Edinburgh

Moher D *et al.* 1998 Does quality of reports of randomised trials affect estimates of intervention efficacy reported in meta-analyses? Lancet 352: 609–613

Riley M, Bearn D R 2009 A systematic review of clinical trials of aligning archwires. Journal of Orthodontics 36: 42–51

Robinson S N 1989 An evaluation of the changes in lower incisor position during the initial stages of clinical treatment using a pre-adjusted edgewise appliance. MSc Thesis, University of London

Rosenthal R 1979 The file drawer problem and tolerance for null results. Psychological Bulletin 86: 638–641

Schulz K F, Chalmers I, Hayes R J, Altman D G 1995 Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. Journal of American Medical Association 273: 408–412

Shea B J *et al.* 2007 Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. BMC Medical Research Methodology 15: 1–7

Sterne J A C, Egger M, Moher D (eds) 2011 Chapter 10: addressing reporting biases. In: Higgins J P T, Green S (eds). Cochrane handbook for systematic reviews of intervention. Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. www.cochrane-handbook.org (11 January 2012, date last accessed)

Sueri M Y, Turk T 2006 Effectiveness of laceback ligatures on maxillary canine retraction. Angle Orthodontist 76: 1010–1014

Usmani T *et al.* 2002 A randomized clinical trial to compare the effectiveness of canine lacebacks with reference to canine tip. Journal of Orthodontics 29: 281–286

Wang Y *et al.* 2010 Initial arch wires for alignment of crooked teeth with fixed orthodontic braces. Cochrane Database of Systematic Reviews CD007859

Wood L *et al.* 2008 Empirical evidence of bias in treatment effect estimates in controlled trials with different interventions and outcomes: meta-epidemiological study. British Medical Journal 336: 601–605