Letters to the Editor

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

Sir,

We read the systematic review with great interest regarding the effectiveness of canine laceback by Fleming *et al.* (2012). The authors aimed to critically appraise the current evidence to determine the effectiveness of canine laceback in controlling incisor proclination during the alignment stage. We would like to congratulate the authors for their efforts in this valuable systematic review. After carefully reading this article, we would like to share a few concerns with readers of *European Journal of Orthodontics*.

The authors included two studies (Usmani *et al.*, 2002; Irvine *et al.*, 2004) in the meta-analysis to determine the comparison between laceback and control regarding the changes (before and after treatment) in sagittal position of incisors (Figure 2). The two original studies had contradictory results: Usmani *et al.* (2002) revealed that laceback was effective in controlling incisor proclination [mean difference: -0.86; 95% confidence interval (CI): -1.57, -0.15], whereas Irvine *et al.* (2004) did not (mean difference: -0.09; 95% CI: -0.90, 0.72). However, the authors then performed a statistical pooling (mean difference: -0.50; 95% CI: -1.25, 0.25) and concluded that laceback was ineffective in controlling sagittal position of incisors. After carefully reading the two original studies, we found that several critical heterogeneities existed, which should have prevented the authors from the statistical pooling. Firstly and most importantly, Usmani *et al.* (2002) investigated incisor proclination on upper incisors, whereas Irvine *et al.* (2004) on lower incisors. Secondly, Usmani *et al.* (2002) employed reflex metrography, whereas Irvine *et al.* (2004) used lateral cephalometry for measurements. The two modalities differ significantly regarding their accuracy, with measurement error being 5 mm for lateral cephalometry (Gribel *et al.*, 2011) and 0.2 mm for reflex metrography (Speculand *et al.*, 1988). However, the authors performed meta-analysis without acknowledging these critical heterogeneities, which may be misleading and would bias the results. Thus, the conclusion that canine laceback is ineffective in controlling incisor proclination would be questioned.

Moreover, in a systematic review, results in meta-analysis rely largely on the validity of included studies, and an assessment of risk of bias is essential (Higgin and Altman, 2008). In this systematic review, the authors draw the conclusion with confidence that the risks of bias were low in included studies. Specifically, as displayed in Table 2, although both studies had a dropout rate of 12.7 and 17 per cent, the authors evaluated both articles to be low risk of bias for the item 'free of incomplete data' due to balanced number of missing data across groups in both studies. However, Cochrane collaboration's tools for assessing risk of bias state that even if the number of missing data was balanced across groups, bias could be introduced if reasons for missing outcome differed (Higgin and Altman, 2008). However, no evidence was mentioned regarding reasons for missing outcome in both studies. Thus, with such high dropout rate, this item would be assessed at most to be unclear risk of bias. Moreover, as reported previously, the baseline mesiodistal angulation of canine would influence incisor proclination (Usmani *et al.*, 2002) and confound the evaluation of laceback effectiveness. However, the initial canine tip was not assessed in Irvine *et al.* (2004), and we are unable to know whether this confounding factor was well balanced between groups in this study. Thus, for the item 'other apparent bias' in the evaluation of risk of bias, it should be evaluated to be 'unclear risk of bias' rather than 'low risk of bias' for this study. Considering these risks of bias, the results from the included studies may not be reliable, which would further decrease the credence of the results in this systematic review.

Therefore, with regards to inappropriate statistical pooling and unclear risks of bias in included studies, an alternative conclusion—whether canine laceback is effective in controlling incisor proclination cannot be determined based on current evidence—would be more appropriate.

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Reply

We would like to thank the authors for their interest in our review. We appreciate the comments which highlight some of the difficulties in conducting systematic reviews and meta-analyses.

The decision to conduct quantitative synthesis is often somewhat subjective and opaque. It is unrealistic to expect trials from different settings to be identical in all respects; therefore, discretion is invariably required to assess their similarity. In this instance, we felt laceback use in the upper and lower arches to be comparable as they are applied and act in an identical manner. Furthermore, while although different measurement techniques were used in the two studies, both recorded the same outcome: antero-posterior change in incisor position. In view of the overlap of the confidence intervals (CIs), low statistical heterogeneity, allied to what we regarded as low clinical heterogeneity, it was decided that synthesis was reasonable using a random effects model. Furthermore, although only one of the two studies found a significant effect, the direction of the effect in the studies was consistent. Moreover, the range of the confidence intervalsCIs did not include genuinely important clinical effects, particularly in view of the potential measurement errors the authors refer to.

Missing data is are often problematic in clinical trials; however, if the data is are MAR (missing at random), the likely consequence is dilution of the effect, rather than biased inferences (Carpenter and Kenward, 2008). Adjudication of risk of bias necessitates assumptions and inferences, with varying levels of agreement among assessors (Hartling et al., 2011). In both included studies, loss to follow-up was relatively balanced in both groups; reasons for failure to complete the study were also outlined in participant flow diagrams. Furthermore, even if, as the authors suggest, an unclear risk of bias judgment were given, according to Cochrane guidelines, meta-analysis would still be legitimate.

The authors had concerns that differences in baseline canine angulation between the respective groups may have resulted in biased estimates. While Although differences in baseline characteristics can confound the results of a trial, robust randomisation randomization procedures were implemented in both included studies. Consequently, baseline differences are less likely to be a problem, and would arise randomly. In fact, the paper by Usmani *et al.* (2002) reported the following mean canine angulation: 82.6 (9.0) 80.8 (8.0) [right side], 79.8 (10.9) 79.8 (9.3) [left side] for the laceback and the control group, respectively. Given the potential measurement error, such minor differences are likely to be insignificant.

Finally, our conclusions do indicate that: '"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"'. We consider the clinical effect to be of greater importance than statistical significance; our interpretation was made on that basis.

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