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SCIENTIFIC SECTION

A randomized clinical trial to compare the effectiveness of canine lacebacks with reference to canine tip

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Abstract

Aim: To assess the effectiveness of canine lacebacks on the proclination of the upper incisors with reference to pre-treatment canine tip.

Study design: Randomized clinical trial.

Sample: Patients receiving upper and lower fixed appliances attending the orthodontic departments of five orthodontic treatment providers. Sixteen patients received canine lacebacks as part of their treatment and 19 patients did not have canine lacebacks.

Method: Patients were randomly allocated to receive canine lacebacks or not receive canine lacebacks. Upper study models were collected at the initial archwire placement and then when the working 0.019×0.025-inch stainless steel archwire was placed. The start canine angulation, change in upper incisor proclination/overjet, and any mesial movement of the upper first permanent molars during levelling and aligning was measured with a reflex metrograph.

Statistics: The effect of the use of canine lacebacks on upper incisor proclination and mesial molar movement was assessed using Student t-tests. Regression analysis was used to evaluate any effect of the initial angulation of the canine.

Results: A mean incisor retroclination of 0.5 mm was observed in the canine lacebacks compared with a mean proclination of 0.36 mm when canine lacebacks were not used ($P = 0.025$). There was no statistically significant difference between groups for mesial movement of upper first molars ($P = 0.99$). If the canine was more distally inclined at the start of treatment, the incisors was more likely to procline, regardless of whether or not canine lacebacks were used ($P = 0.027$).

Conclusions: The effect of canine lacebacks on preventing upper incisor proclination at the start of treatment is in the order of 1 mm and their effect on mesial molar movement is insignificant. Canines lacebacks have similar effects that are independent of pre-treatment canine angulation.

Index words:
Canine lacebacks, upper incisor proclination, overjet, canine tip, randomized clinical trial.

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Introduction

The purpose of this study was to compare the effectiveness of canine lacebacks on upper incisor proclination, taking into account the tip of the upper canine at the start of treatment.

One problem that is encountered clinically, when using edgewise appliances is that the incisor may procline during the levelling and aligning phase. Clinical experience suggests that this is associated with the mesial crown tip that is built into the canine bracket, which is exacerbated by any pre-treatment tip of the canine.[1]

One method of minimizing this problem is the use of a steel ligature between the canine and the first molar, this is called a laceback. In theory, the laceback will hold the canine crown back and, as a result, the canine root should tip distally as the tip in the bracket is expressed. Despite being a commonly used procedure, a search of the published literature reveals that this has never been examined using a prospective randomized clinical trial.

Therefore, we aimed to investigate the following questions:

1. What are the effects of canine lacebacks on upper incisor proclination?
2. Are canine lacebacks effective for all patients or just when the canine tooth is distally tipped?

As a result we tested the following null hypothesis.

1. Canine lacebacks do not have an effect on upper incisor proclination.
2. The effects of canine lacebacks are not influenced by pre-treatment canine angulation.

Sample

The sample size for each group of patients was calculated as $n = 11$ based on an alpha significance level of 0.05 and a beta of 0.1. This gave a 90 per cent power to detect a difference of 3 mm ($\pm$2 mm) of change in overjet during levelling, and aligning between the canine lacebacks groups and control.

The sample of patients was obtained from patients attending for orthodontic treatment at five orthodontic treatment providers. The following inclusion criteria were applied:

- Age 10–16 years at start of treatment.
- Premolar extraction cases only
- Upper and lower pre-adjusted edgewise appliance (Roth prescription 022 slot)
- Upper and lower permanent canines present and erupted
- Patient and parent written consent.

Ethical approval

The project was approved by the relevant ethical committees and all patients were treated according to the Declaration of Helsinki.[2]

Random allocation method

Randomization was carried out 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. The treatment allocation was then concealed in envelopes labelled with the study identification number.

When the patient was consented to enter the study and registered, a telephone call was made to research assistant, who then revealed whether the patient (the unit of randomization) would or would not receive canine lacebacks. During the trial, the operator could not be blind to whether canine lacebacks were used. However, the examiner carrying out the model outcome measurements did not know whether canine lacebacks were used or not.

Interventions and their timing

The planned interventions were placement of canine lacebacks in the test group and no canine lacebacks in the control group. All patients were therefore treated identically, apart from the named interventions according to the following protocol:

- 0.009-inch ligature wire was used for all canine lacebacks, placed from the hook on the first permanent molar band to the permanent canine bracket in a figure of eight in each quadrant.
- Archwire sequence 016-inch NiTi, 0.018 × 0.025-inch NiTi, 0.019 × 0.025-inch stainless steel.
- Canine lacebacks were adjusted as necessary at each appointment, so that there was enough tension in the ligature wire but the laceback was passive. The canine laceback was replaced if broken.

Outcome measures

The outcome measures to be assessed in the trial were change in proclination of the upper incisors and any mesial movement (loss of anchorage) of the upper first permanent molars.

Patient records

An upper study model was collected at the initial archwire placement and again when the 0.019 × 0.025-inch stainless steel archwire was placed.

Measurement method

Measurements were recorded using a reflex metrograph.[3] This is a three-dimensional plotter. The principle of the reflex metrograph is that a tiny moveable light is adjusted to coincide with a point on the model, and a computer programme calculates distances, angles, and angles between planes. The measurements that were recorded were:

1. A lateral point on a right and left palatal rugae, which were joined to construct a rugae line going across the arch.
2. The upper incisor proclination was measured as the distance perpendicular from the rugae line to the most prominent incisal edge (Figure 1).
3. The right and left molar position was measured as the distance perpendicular from the rugae line to the buccal grooves of the first molars.
4. The start canine tip was assessed by measuring the angle between a line of best fit of the right and left upper occlusal plane, and the long axis of the right and left canine, respectively.

Registered or eligible patients $n = 42$

Not randomized $n = 0$

Randomization $n = 42$

Lacebacks	***No lacebacks***
Received standard Intervention $n = \mathbf{19}$	Received standard Intervention $n = \mathbf{23}$
Followed up $n = 16$	Followed up $n = 19$
Withdrawn $n = \mathbf{3}$ Intervention ineffective $n = 0$ Lost to follow-up $n = 3$ Other $n = 0$	Withdrawn $n = \mathbf{4}$ Intervention ineffective $n = 0$ Lost to follow-up $n = 4$ Other $n = 0$
Completed trial $n = 16$	Completed trial $n = 19$

Fig. 1 Profile of a randomized clinical trial to evaluate the effect of canine lacebacks on upper incisor proclination / overjet change during initial levelling and aligning.

In order to calculate the change in the recorded points, it was necessary to superimpose the two sets of metrograph reading on each other. We did this by recording the lateral aspects of the palatal rugae and using these as fiducial points. We chose the palatal rugae because it has been shown that these positions are stable.[4,5] This method has been used in a previous investigation of aligning archwires.[6]

Method error

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.

Random error may have occurred or error in locating the measurement landmarks. This was addressed by taking each measurement three times and calculating an average. The error associated with the alginate impression technique and model preparation has been shown to have a 97 per cent coefficient of reliability.[6]

Examiner calibration and reliability

The examiner was calibrated for the reflex metrograph using four metal calibration cubes of different sizes. The exact measurements of the cubes were determined by the engineering department, University of Manchester, who constructed them. Reliability of the measurements was assessed by re-measuring all the study models at least 1 week later.

Statistics

The following data were analysed with the Student *t*-test.

- Examiner calibration
- Assessment of pre-treatment equivalence.
- Comparison of the change in upper incisor proclination and mesial movement of upper first permanent molars between the canine lacebacks group and control group.
- Comparison of patients who completed the study and drop-outs.

Intra-class correlation coefficients were used to assess intra-examiner reliability.

Multiple linear regression analysis was used to assess the effect of canine lacebacks and canine tip (and any interaction between these independent variables) on the change in overjet (dependent variable).

Results

Examiner calibration and reliability

Table 1 contains data on examiner calibration for the calibration blocks and Table 2 shows reliability for the repeated measurements of the study casts. This reveals that adequate levels of calibration and reliability were achieved.

Trial profile and summary statistics

The trial profile for the registered patients is shown in Figure 1. This shows that of the 42 patients initially registered in the trial, seven patients were lost to follow-up and were therefore not included in the main data analysis. This gave a final sample of 35 children.

The mean patient age at the start of the trial was 13.7 years (SD = 1.8) and the sample consisted of 13 boys and 22 girls. The malocclusion types consisted of incisor Class I (n = 15), Class II division 1 (n = 14), Class II division 2 (n = 4) and Class III (n = 2). The mean change in upper incisor proclination was an increase of 0.36 mm (SD = 1.1 mm) when canine lacebacks were not used and a decrease of 0.50 mm (SD = 1.1 mm) when canine lacebacks were used.

Table 3 shows data on changes incisor proclination and mean mesial movement of upper first molars. Data analysis revealed that the use of lacebacks resulted in a statistically significant reduction in incisor proclination (P = 0.025), but had no statistically significant effect on mesial molar movement (P = 0.99).

The results of the multiple linear regression analysis that was used to assess the effect of canine lacebacks and start canine tip on changes in incisor proclination during treatment are included in Table 4. This confirmed the effect of canine lacebacks in preventing some upper incisor proclination (P = 0.019). In addition, this analysis revealed that if the canine was more distally angulated at the start of treatment, the upper incisors were more likely to procline. Importantly, as there was no interaction between lacebacks and canine tip, we could conclude that the increase in incisor proclination occurred regardless of whether canine lacebacks were used.

Pre-treatment equivalence of patients in lacebacks and no lacebacks groups

Pre-treatment equivalence of the patient groups was assessed by comparing the mean start canine angulation between patients either receiving or not receiving canine lacebacks (Table 5). There was no difference between the groups (P = 0.94). The crowding in the upper labial

Table 1 Examiner calibration for the use of the reflex metrograph (combined height, width, and length measurements)

	n	Mean (mm)	SD (mm)	SE mean	P value
Examiner	12	27.37	25.65	7.40	0.09
Gold standard	12	27.51	25.79	7.46	

Table 2 Examiner reliability for the use of the reflex metrograph

Measurements (start)	Intra-class correlation coefficient	95% CI
Overjet	0.90	0.81–0.95
Left molar	0.86	0.72–0.93
Right molar	0.88	0.75–0.94
Left canine	0.76	0.57–0.87
Right canine	0.64	0.39–0.80

Table 3 t-tests to compare the change in overjet and mesial first molar movement during initial levelling and aligning, according to whether the patients received canine lacebacks

Measurement	With canine lacebacks	Without canine lacebacks	t value	Mean difference	P value
Mean change in upper incisor proclination (mm) (SD)	–0.50 (1.06)	+ 0.36 (1.09)	–2.34	–8.59	<0.05
Mean right and left mesial molar movement (mm) (SD)	Right: 0.40 (1.66) Left: 0.58 (2.10)	Right: 0.15 (1.63) Left: 0.84 (2.66)	0.009	4.05×10^{-3}	>0.05

'+' = increase and '–' = decrease in upper incisor proclination.

Table 4 Multiple stepwise linear regression analysis to assess the influence of lacebacks, and start canine angulation on change in overjet during the levelling and alignment phase of treatment.

Dependent variable	*B* value	SE	+ value	Independent variables	*P* value
Change in upper incisor proclination*	0.94	0.35	2.73	Use of lacebacks	<0.05
	-4.84×10^{-2}	0.021	–2.32	Increasing right canine tip	< 0.05
	-3.82×10^{-2}	0.018	–2.15	Increasing left canine tip	< 0.05

*A positive value signifies a reduction in overjet and a negative value an increase in overjet.
Note: there was no statistically significant interaction or effect of lacebacks and canine tip ($P > 0.05$).

Table 5 Test of pre-treatment equivalence for canine tip between the groups with canine lacebacks and no canine lacebacks

Start measurement	Lacebacks	No lacebacks	*t*-value	Mean difference	*P* value
Right canine tip (degrees) (SD)	82.6 (9.0)	80.8 (8.0)	–6.11	–1.76	> 0.05
Left canine tip (degrees) (SD)	79.8 (10.9)	79.8 (9.3)	0.004	0.10	> 0.05

The greater the angulation, the more distally the canine was tipped.

segment was also assessed by calculating the difference between the mesiodistal widths of upper incisors and canines and the space available in the upper labial segment. The available space was measured as the distance from the distal contact point on the canine to the mesial contact point of the central incisor on each side of the upper labial segment. The mean upper labial segment crowding was 2.9 mm (SD 3.9 mm) in the control group and 1.4 mm (SD 2.1 mm) in the canine lacebacks group. Since there was no statistically significant difference between the study groups ($P = 0.17$), pre-treatment equivalence was shown for start upper labial segment crowding.

Comparison of patients who remained in the trial and drop-outs

Pre-treatment canine angulation was compared between patients completing the trial and the seven drop-outs. We found that there were no statistically significant differences between the start canine angulations (right canine $P = 0.55$, left canine $P = 0.10$) between the two types of patient. We can therefore assume that the characteristics of the drop-outs were no different to the patients who completed the study.

Discussion

This was the first randomized clinical trial of the effects of canine lacebacks. As a result, there is no relevant literature to compare with the results of this study. Nevertheless, we can conclude that canine lacebacks have an effect and they cause some retroclination of upper incisors and prevent increase in overjet during the initial aligning phase of Edgewise fixed appliance treatment. However, it should be emphasized that this effect is small and may not be of clinical significance. Furthermore, if the canine was distally tipped, the overjet was still likely to increase *regardless* of the use of canine lacebacks.

We should consider if the findings of this study have implications for clinical practice. When an operator interprets the results of a clinical trial they need to consider if the benefits of an intervention outweigh the risks and costs of using that intervention. Certainly, placing canine lacebacks is an easy procedure that does not carry any risk to the patient, apart from occasional soft tissue trauma. However, the benefits do not appear to be worthwhile. As a result, we can suggest from our findings that upper canine lacebacks are not of benefit, as a routine procedure, even if the canines are distally angulated.

Deficiencies of this investigation

Ideally, we would have liked to measure the effects of lacebacks on the lower arch, in addition to the upper dentition. However, there are no points in the mandible that we can use as fiducial points. The only alternative would be to use cephalograms; however, this is unlikely to gain ethical committee approval, as the additional radiation exposure could not be justified.

The sample size calculation was based on an expected difference in overjet of 3 mm between the test and control groups. In the absence of published literature on which to base our calculation, a value of 3 mm was chosen to reflect what might be a clinically significant effect of canine lacebacks. Since the study detected a statistically significant effect of lacebacks around 1 mm, this suggests that the sample size had enough power to detect a difference of less than 3 mm between groups. However, as we previously suggested, a 1 mm effect on overjet may not be clinically significant.

Conclusions

The effect of canine lacebacks on preventing an increase in upper incisor proclination at the start of treatment is in the order of 1 mm and their effect on mesial molar movement is insignificant. Canines lacebacks are similarly effective for patients with mesially inclined, upright or distally angulated upper canines.

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