SCIENTIFIC SECTION

The effectiveness of laceback ligatures: A randomized controlled clinical trial

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Objective: To evaluate the effects of laceback ligatures on the anteroposterior and vertical position of lower incisors and the mesial position of the lower first molars.

Design: Randomized controlled trial.

Settings: Patients under treatment in the Department of Orthodontics, Royal Bournemouth Hospital, Dorset, during a 6 month period from November 1999 to March 2000.

Subjects: Sixty-two adolescents (mean 13.7 years, range 11.2–16.8 years) with similar malocclusions, requiring extraction of all first premolars, were randomly assigned to experimental (laceback: 30; 12 male, 18 female) and control (non-laceback: 32; 14 male, 18 female) groups.

Interventions: Treatment using upper and lower fixed appliances following extraction of four premolars. One group had lacebacks placed, whilst the control group had no lacebacks.

Main outcome measures: The participants were examined clinically and radiographically, and lateral cephalograms with radio-opaque tooth markers and lower study casts records were taken when lower fixed appliances were placed (T1) and following sufficient leveling with a 0.018 inch stainless steel round wire (T2). Linear measurements were recorded following digitization of the lateral cephalograms and using a vernier caliper on the study casts. A Student t-test was used to examine differences between the two groups following assessment for normality.

Results: In both groups the lower incisors retroclined during T1–T2; (Mean $\pm$ SD: Experimental -0.53 ± 1.9 mm, Control -0.44 ± 1.29 mm). There was no statistical significance between the two groups ($p=0.84$). The lower incisors extruded in both groups; 0.47 ± 0.98 mm in the experimental group and 0.44 ± 0.87 mm in the control group. There was no statistical difference between the groups ($p=0.9$). The lower first molars showed 0.83 mm greater mesial movement in the experimental group, which was statistically significant ($p<0.05$). Labial segment crowding decreased in both groups (experimental -3 ± 1.6 mm, control -2.67 ± 2.28 mm), the difference between the groups being non-significant ($p=0.51$). Arch length decreased in both groups (experimental -2.08 ± 2.82 mm , control -2.9 ± 3.06 mm), but the difference between them was not significant ($p=0.28$).

Conclusions: In first premolar extraction cases, the lower labial segment does not procline during the leveling stage with the pre-adjusted edgewise appliance and the use of laceback ligatures conveys no difference in the antero-posterior or vertical position of the lower labial segment. Furthermore, the use of laceback ligatures creates a statistically and clinically significant increase in the loss of posterior anchorage.

Key words: Randomized controlled trial, lacebacks, pre-adjusted edgewise appliance, straightwire

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Introduction

Fixed appliances are a common component of contemporary orthodontic treatment. Engagement of the bracket with a full size rectangular arch wire should, providing correct bracket placement has occurred, provide enough torque and tip to the tooth to allow it to assume the correct inclination and angulation necessary to achieve an Andrews 6 keys occlusion.[1]

One of the major disadvantages of incorporating second order values into the pre-adjusted edgewise bracket system, was it created stress on anchorage in

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the initial stages of treatment. These effects were expressed in both the antero-posterior and vertical planes.[2]

McLaughlin and Bennett[3] argued that the tip incorporated into the incisor and canine brackets increased the tendency for the labial segments to tip forward, and that this was more pronounced in the upper arch where bracket tip was greater. They suggested that the canine having the greatest tip value produced the greatest forward movement and if not controlled would lead to incisor proclination that would have consequences on future stability.

First described by McLaughlin and Bennett,[3,4] laceback ligatures are constructed of either 0.009 or 0.010 inch soft stainless steel tied in a figure of 8 from the most distally incorporated molar to the canine bracket. They were utilized to control anchorage during leveling and aligning they are claimed to provide the following benefits:

- prevention of lower labial segment proclination;
- canine distalization without tipping;
- protection from masticatory forces for light aligning archwires across the extraction spaces.

Their use has become widely accepted in certain countries during the leveling and aligning phase with the pre-adjusted edgewise appliance. Steel ligatures undergo plastic deformation when stretched and as lacebacks are tied passively, considerable doubt must exist to their ability to actively distalize canines.

Robinson[5] in a prospective study found a 2.47 mm difference in the lower incisor antero-posterior position between cases treated with or without lacebacks. However, this study has never been published and there are concerns regarding the scope of this trial within CONSORT guidelines.

In the laceback group there was a mean 1.0 mm distal movement of the incisors and a mean 1.76 mm mesial movement of the first molars. In contrast the non-laceback group demonstrated a mean 1.47 mm proclination of the incisors compared with a mean 1.53 mm forward movement of the molars ($p<0.01$). This was a well-constructed study but some problems with the methodology were present that may have influenced the results (S. N. Robinson, personal communication).

Usmani *et al.*[6] published the first randomized clinical controlled trial on the effectiveness of lacebacks. They also examined the effect of pretreatment distal angulations of the canine on the effectiveness of lacebacks. They found a mean retroclination of the upper incisors in the laceback group of 0.5 mm with a mean proclination in the non-laceback group of 0.36 mm, which was statistically significant. No statistical difference for the mean mesial molar migration between the groups was found. If the canine was more distally inclined at the start of treatment then incisors were more likely to procline during treatment regardless of whether lacebacks were used or not. The groups were relatively small. However, within this study it was reported that the statistical power was such to identify a 3 mm difference (± 2 mm). The final stage study model was taken prior to placement of a 0.019×0.025 inch stainless-steel arch wire. This meant that full alignment of the upper labial segment had taken place at this stage. Space creation would have been required for the full alignment of the labial segment and this could only be achieved in one of three ways:

1. the canines distalized into the extraction spaces creating space with no influence on incisor proclination;
2. the incisors proclined to create space for their alignment;
3. space was actively created using traction to the canine or active push-coil, within the labial segment to provide space for full incisor alignment.

Both (2) and (3) would influence incisor proclination or retroclination and therefore the level of crowding within the upper labial segment could have affected the degree to which it occurred.

The aims of this study were:

- to evaluate the antero-posterior changes in lower labial segment position that occur during leveling and aligning with the pre-adjusted edgewise appliance;
- to evaluate the changes in antero-posterior position of the lower labial segment as a consequence of lacebacks used during leveling and aligning with the pre-adjusted edgewise appliance;
- to assess any changes in the vertical position of the lower labial under the influence of laceback ligatures;
- to assess the influence of lacebacks on the lower first molar.

As a consequence we tested the following hypotheses:

- there are no changes in the lower labial segment during leveling and aligning with the pre-adjusted edgewise appliance;
- lacebacks do not change the antero-posterior position of the lower labial segment during leveling and aligning with the pre-adjusted edgewise appliance;
- lacebacks do not affect the vertical position of the lower labial during leveling and aligning;
- there is no affect on the position of the lower first molar as a consequence of lacebacks.

Materials and method

Sixty-two participants were enrolled on the study, 30 (12 male, 18 female) in the laceback group and 32 (14 male, 18 female) non-laceback controls. These study group sizes were determined as those necessary to detect a similar level of difference to previous studies.[6] This gave the study a statistical power of 0.988 to detect a 2 mm difference in lower incisor positions at the significance level of $p=0.05$. Each patient was randomly assigned to one of the groups by the toss of a coin. The majority of participants had either a Class I or a mild Class II division 1 incisor relationships with crowding (Class I, 29; Class II division 1, 29; Class II division 2, 2; Class III, 2 with a uniform distribution between experimental and control groups).

Ethical approval for the study was sought from the East Dorset Local Research Ethics Committee and was granted on the 25th May 2001(LREC NO 29/01/E). The participants and parents (as appropriate) were invited to take part in the study after their recall from the treatment waiting list in preparation for active orthodontic therapy. After discussion only those willing to provide fully informed consent were accepted for the study.

The recruitment of the participants and subsequent numbers reflected a reasonable degree of loss to follow up (Figure 1).

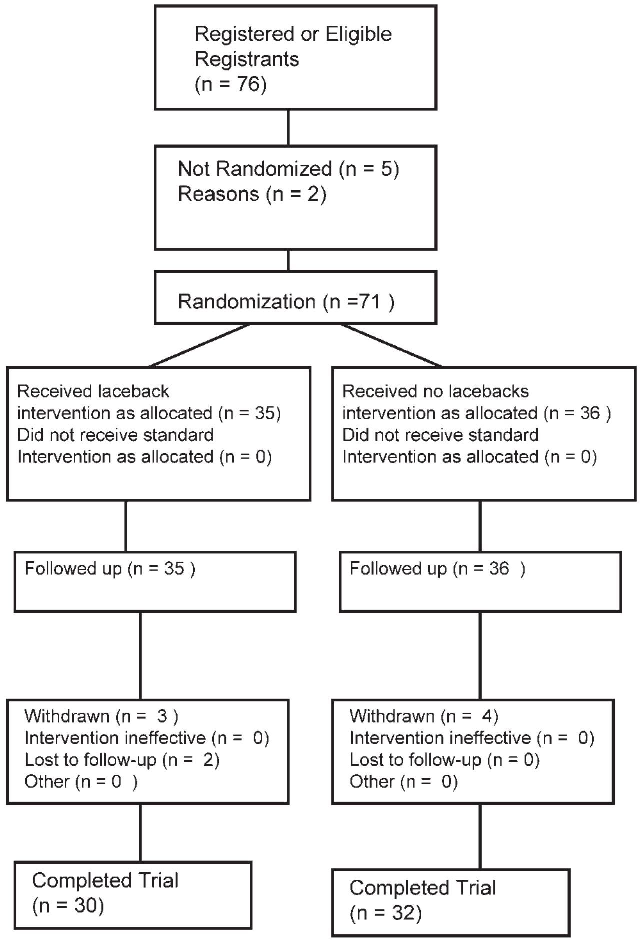

Figure 1 Profile of a randomized clinical trial to evaluate the effect of lacebacks on the position of the lower incisors during initial aligning

Patient selection

The inclusion criteria for patient entry into the study were as follows:

- a malocclusion requiring the extraction of all first premolars;
- no previous orthodontic treatment;
- lateral cephalometric radiographs to have been taken of the patient within the previous 12 months at the start of treatment.

Treatment protocol

The treatment procedure was as follows:

1. All participants were treated by the same operator (SP).
2. All first premolars were extracted approximately 1–2 weeks prior to the fitting of appliances.
3. Upper and lower fixed appliances using 3 M Unitek Dyna Lock pre-adjusted edgewise brackets from the non-extraction series (Andrews values for tip and torque using a 0.022 inch slot).
4. The plan of treatment for the study was to follow each patient to the point at which leveling and aligning of the buccal segments had been achieved with a 0.018 inch stainless steel arch wire; it was agreed that this should be following six weeks with the 0.018 inch stainless steel arch wire *in situ*.

All teeth from first molar to first molar had attachments placed. Severe vertical or rotational discrepancies between adjacent teeth were partially ligated at the first visit. Extremely crowded and displaced teeth in the labial segment were passively tied to the arch wire and were not engaged until sufficient space was available. Each patient went through the same arch wire sequence of 0.014 inch NiTi, 0.018 inch NiTi and 0.018 inch stainless steel. Participants were seen routinely at 6-week intervals.

5. The arch wire was cut distal to the first molar tube and no cinching of the arch wire took place.

6. No bite planes, lingual arches, inter maxillary elastics or headgear direct to the lower arch was used during the study period.
7. Laceback ligatures were passively tied from the first molar tube to the canine bracket on both sides in the experimental group and tightened to take up any apparent reduction in tension in the laceback at routine visits.
8. Records of each case included standardized lateral cephalometric radiographs. Study models were taken immediately after the placement of fixed appliances (T1) and again following leveling of the canine with a 0.018 inch stainless-steel arch wire (T2). The Ethics committee accepted the second radiograph as part of both validation of clinical techniques and to support information to determine how to close the extraction space; either by maintaining the position of the labial segments and allowing the buccal segments to move mesially or by retraction of the labial segment. Due to the time the participants were on the waiting list, T2 radiographs were all taken a minimum of 14 months from T1 radiographs.

Group characteristics

Patients in the two groups were matched for age at T1 (Experimental mean age 13.6 ± 1.5 years; control mean age 13.8 ± 1.5 years), had similar lengths of treatment T2–T1 (Experimental group 7.1 ± 2.5 months; control group 7.1 ± 2.3 months) and had similar sex distributions.

Landmark identification

To improve the accuracy and validity of the study it was decided that the lower right first molar (46) would be used to study the mesial molar movement and the lower right central incisor (41) would be used to study the anteroposterior movement of the lower labial segment. To evaluate a method to identify the teeth, the mandibular arch of a dried skull was bonded with a pre-adjusted edgewise appliance. A method utilizing identification markers constructed of 0.021×0.025 inch stainless-steel wire was the most successful when analysing the lateral skull radiographs. The markers were placed into the tube of 46 and the bracket of 41, and were tied with elastic ligatures.

Patient positioning

The mid-sagittal plane to cephalometric film distance was standardized for all the lateral cephalometric radiographs, producing a magnification factor of 11%. Most of lateral cephalometric radiographs were taken by one operator (RI), but if he was not available the radiographer would take the exposures under the supervision of one of the consultants (SP). The patient was positioned standing in the machine in the natural head position.

Digitization of lateral cephalometric radiographs

Lateral cephalometric radiographs were scanned using a flat bed transparent scanner and the images stored on an Apple Macintosh computer. The images were then digitized on screen using the Quickceph digitization program incorporating additional software to analyse the specific points relevant to the study. Panesar[7] identified on-screen digitization as the most accurate method of cephalometric tracing. Four specific points were identified for measuring antero-posterior changes in the incisor and first molar positions (Figure 2):

- I—the incisor tip of the lower right central incisor.
- IM—the point where the radio-opaque marker left the occlusal aspect of the lower right central incisor bracket.
- M6—the mesio-buccal cusp of the lower right first molar.
- MM—the most inferior point of the radio-opaque marker placed in the bonded tube on the lower right first molar.

Two methods of measuring anteroposterior linear changes in lower incisor and lower first molar positions were evaluated for accuracy.

1. 7° to SN (Figure 2) was used as a horizontal reference line and a y-axis dropped perpendicular to this through Sella.[8,9] Linear measurements to the 4 cephalometric points were recorded perpendicular to this y-axis to assess antero-posterior changes.
2. Fiducial points (F1, F2, Figure 2) were marked on the T1 radiograph below the lower border of the mandible. These points were transferred to the T2 radiograph following superimposition on Björk structures.[10] Connecting these two fiducial points created an x-axis and a y-axis was raised perpendicular to this through the most posterior fiducial point. Linear measurements to the 4 cephalometric points were recorded perpendicular to this y-axis to assess antero-posterior changes. Linear measurements perpendicular to the x-axis to points I and IM were recorded to assess vertical changes in the incisor positions.

The two methods were analysed to find the method and cephalometric landmarks that carried the lowest method

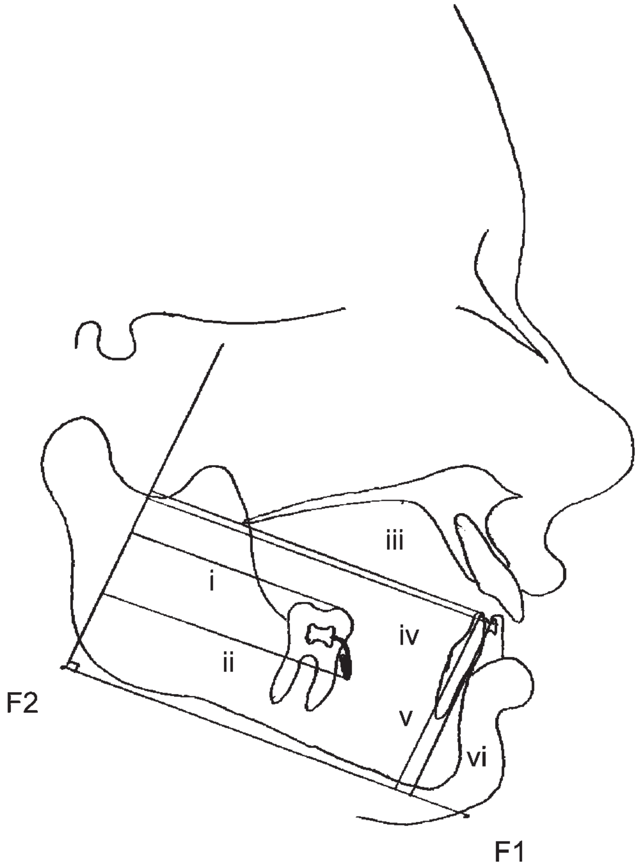

Figure 2 Linear cephalometric measurements using *y*-axis constructed fiducial points. Linear measurements: i. M6-*y*-axis; ii. MM-*y*-axis; iii. I-*y*-axis; iv. IM-*y*-axis; v. I-*x*-axis; vi. IM-*x*-axis

error. Twenty participants records were chosen at random and digitization of the cephalometric points were performed for each method. These measurements were repeated exactly 4 weeks later and the difference between the two sets of measurements was analysed using a paired *t*-test following an analysis of normality to validate the use of the Student *t*-test (Sigma Stat Version 2.01, California). This demonstrated that the fiducial point method using landmarks I and MM provided the greatest accuracy, and this was used in the study.

Study model analysis

Lower arch alginate impressions were taken when lower fixed appliances were placed (T1) and following 6–8 weeks leveling with a 0.018 inch stainless-steel round wire (T2). Impressions were immediately taken to the laboratory and, following a 20-minute immersion in a cold sterilizing fluid, the impressions were poured using a plaster/stone mix.

An estimate of crowding or spacing within the lower labial segment was produced by comparison between the estimation of the amount of space available for the alignment of teeth and the combined mesio-distal widths of the teeth.[8] The measurements were made using Vernier calipers with gradations allowing for readings to an accuracy of 0.1 mm.

In addition to the above measurements, the change in arch length between the two groups was also studied. Using the same procedure as above the arch length was measured as the sum of a straight line between the marginal ridge of the lower first molar and the mesio-incisal edge of the most prominent central incisor on both sides of the arch.

Twenty sets of study models were randomly selected and measured twice after a 4-week interval to determine the method error of measurements. This was analysed using a paired *t*-test, again following confirmation of normality and there was no statistically significant difference.

Statistical methods

The following tests (Sigma Stat Version 2.01, California) were used to analyse the experimental data:

- Student *t*-test;
- Mann–Whitney *U*-test: this was used when one or both variables were significantly skewed.

Before analysis with either test the data were analysed for normality using the Kolmogorov-Smirnov test (with Lilliefors correction; p was set as 0.05). Data that demonstrated a Gaussian distribution was analysed using parametric statistics (Student *t*-test), whilst non-parametric statistics (Mann–Whitney *U*) were used for skewed data.

Results

A summary of the results is presented as tables

The cephalometric and study model data before and after treatment (T1 andT2) are reported in Tables 1–4. The means and standard deviations for each variable are listed together with the differences between the two groups.

Table 5 shows the serial changes (T1–T2) for both groups.

Both groups were evenly matched at T1 and T2 and no statistically significant differences existed between them for any of the measurements undertaken. The lower incisor in both groups retroclined (experimental -0.53 ± 1.9 mm, control -0.44 ± 1.29 mm)

Table 1 Experimental and control groups: a comparison at T1 cephalometric and study model measurements

	Experimental Mean	95% CI	Control Mean	SD	Difference
y—I	60.57	51.47–69.67	61.05	50.79–71.31	−0.48 NS (p=0.69)
y—MM	43.07	31.91–54.23	43.51	33.85–53.17	−0.44 NS (p=0.74)
x—I	39.88	34.12–45.64	40.14	33.96–46.27	−0.26 NS (p=0.74)
Crowding	3.12	−0.1–6.34	3.04	−1.44–7.52	0.09 NS (p=0.86)
Arch length	58.25	46.69–66.81	58.45	51.77–65.13	−0.20 NS (p=0.84)

All measurements in mm. No statistically significant differences existed between the groups at T1.
Both groups were equally matched for crowding and arch length at T1.
NS, not statistically significant; *statistically significant $p<0.05$; **statistically significant $p<0.01$; ***statistically significant $p<0.001$.

Table 2 Experimental and control groups: a comparison at T2 cephalometric and study model measurements

	Experimental Mean	95% CI	Control Mean	95% CI	Difference
y–I	60.04	50.36–69.72	60.61	50.07–71.15	−0.57 NS (p=0.66)
y—MM	43.82	32.72–54.92	43.43	34.85–52.01	0.39 NS (p=0.76)
x—I	40.35	34.01–46.69	40.58	34.52–46.64	−0.23 NS (p=0.77)
Crowding	0.12	–2.66–2.9	0.37	−4.87–5.61	−0.25 NS (p=0.85)
Arch length	56.17	46.35–65.99	55.54	47.2–63.88	0.63 NS (p=0.59)

All measurements in mm.
No statistically significant differences existed between the groups at T2.
Both groups were equally matched in crowding and arch length at T2.

Table 3 Experimental group: a comparison at T1 and T2 cephalometric and study model measurements

	T1 Mean	95% CI	T2 Mean	95% CI	Difference
y–I	60.57	51.47–69.67	60.04	50.36–69.72	–0.53 NS (p=0.67)
y—MM	43.07	31.91–54.23	43.82	32.72–54.92	0.75 NS (p=0.60)
x—I	39.88	34.12–45.64	40.35	34.01–46.69	0.47 NS (p=0.55)
Crowding	3.12	−0.1–6.34	0.12	−2.66–2.9	–3.00***
Arch length	58.25	46.69–66.81	56.17	46.35–65.99	–2.08 NS (p=0.08)

All measurements in mm.
The mean changes that occurred in lower incisor and lower first molar positions during leveling in the experimental group were not statistically significant.
The reduction of crowding in the experimental group during leveling was highly statistically significant. The reduction in arch length was not statistically significant.

Table 4 Control group: a comparison at T1 and T2 cephalometric and study model measurements

	T1 Mean	95% CI	T2 Mean	95% CI	Difference
y–I	61.05	50.79–71.31	60.61	50.07–71.15	−0.44 NS (p=0.74)
y—MM	43.51	33.85–53.17	43.43	34.85–52.01	−0.08 NS (p=0.95)
x—I	40.14	33.96–46.27	40.58	34.52–46.64	0.44 NS (p=0.56)
Crowding	3.04	−1.44–7.52	0.37	−4.87–5.61	−2.67 ***
Arch length	58.45	51.77–65.13	55.54	47.2–63.88	−2.9**

All measurements in mm.
The mean changes that occurred in lower incisor and lower first molar positions during leveling in the control group were not statistically significant.
The reduction of labial segment crowding and arch length in the control group during leveling was highly statistically significant.

Table 5 Experimental and control groups: serial changes T1–T2 cephalometric measurements

	Experimental Mean	95% CI	Control Mean	95% CI	Difference
y–I	−0.53	−4.33–3.27	–0.44	−3.02–2.14	−0.09 NS (*p*=0.84)
y—MM	0.75	−1.41–2.91	–0.08	−3.18–3.02	0.83*
x—I	0.47	−1.49–2.43	0.44	−1.3–2.18	0.03 NS (*p*=0.90)
Crowding	−3.00	−6.2–0.2	−2.67	−7.23–1.89	−0.33 NS (*p*=0.51)
Arch length	−2.08	−5.65–2.07	−2.90	−9.02–3.22	0.82 NS (*p*=0.28)

All measurements in mm.
The differential mesial molar movement between the two groups was statistically significant. No statistical significant difference existed between the two groups with respect to changes in incisor positions.
No statistical significance existed between the two groups with respect to decrease in crowding and arch length.

and extruded (experimental 0.47±0.98 mm, control 0.44±0.8 mm) during the observation period; no statistically significant difference was observed between the two groups. Crowding (experimental −3±1.6 mm, control −2.67±2.28 mm) and arch length (experimental −2.08±2.82 mm, control −2.9±3.06 mm) both decreased over the observation period and differences between the groups were again non-significant. There was a statistically significant difference with respect to the mesial movement of the lower first molar (experimental 0.75±1.08 mm, control −0.08±1.55 mm; p= 0.05). This 0.83 mm molar movement variation was felt to be of clinical significance in terms of anchorage control.

Discussion

Summary of results

In both groups the lower incisors retroclined during the time between T1 and T2 (experimental −0.53±1.9 mm, control −0.44±1.29 mm) and there was no statistical significance between the two groups (p=0.84). The lower incisors extruded in both groups; 0.47±0.98 mm in the experimental group and 0.44±0.87 mm in the control group. This difference showed no statistical difference between the groups (p=0.9). The lower first molars showed 0.83 mm greater mesial movement in the experimental group ($p<0.05$). Labial segment crowding decreased in both groups (Experimental −3±1.6 mm, control −2.67±2.28 mm; p=0.51). Arch length decreased in both groups (experimental −2.08±2.82 mm, control −2.9±3.06 mm; p=0.28).

Comparison with other studies

This demonstrates that in this study, rather than proclining during the leveling stage of treatment the lower incisors retroclined slightly. This result is in contrast with the observations of Meyer and Nelson[2] and McLaughlin and Bennett,[3] who suggested that the pre-adjusted edgewise appliance proclined the labial segments and compromised anchorage during the initial stages of treatment. What factors could possibly account for the discrepancy between these results and their clinical observations? The standard edgewise appliance uprights teeth 90° to the occlusal plane provided full engagement of the slot by the arch wire. According to Hussels and Nanda[11] these teeth would occupy less space than they would at Second Order angulations and, therefore, more space within the arch would be present when compared to pre-adjusted edgewise cases at the end of leveling and aligning. The use of flexible archwires would also encourage these dental changes.[12] This space deficiency was interpreted as loss of anchorage and attributed to the lower incisors becoming proclined and dragging the first molar anteriorly. This study suggests that, rather than 'burning' anchorage this loss of space within the arch was a reflection of teeth aligning around the arch wire as they achieved Andrews second key in the first stage of treatment.

Rather than proclining, the lower labial segment in the control group in this study showed a mean non-significant retroclination of 0.44 mm. The experimental group also showed a mean retroclination of the lower labial segment of 0.53 mm, this was also not statistically significant. The difference of 0.09 mm greater retroclination in the experimental group was not statistically significant (p=0.84). It can be concluded from this evidence that passive laceback ligatures have no influence on the antero-posterior position of the lower labial segment.

These results differ from the finding of Robinson[5] and Usmani *et al.*,[6] who found a 2.47 and 0.86 mm difference, respectively, between the two groups.

There was a major bias in the Robinson study[5] in the non-randomization of participants, who were allocated according to operator preference S. N. Robinson, personal communication). This would give the extraction choice, as a reflection of crowding, and the choice of T2 intervention time (following full labial segment alignment) greater influence on the results of the two groups.

The Usmani *et al.*[6] study was randomized and reported a smaller difference of 0.86 mm in the upper arch where canine tip is greater. This study also took T2 measurements following full labial segment alignment. This may have influenced the findings, as twice the crowding was present in the control group. This study also lacked insufficient power to record negative findings ($p=0.625$), with an increased size of study group the results may have differed.

Implications for clinical practice

With the results of this report and also supported by Usmani *et al.*[6] the validity of lacebacks as an adjunct for the straight wire technique has to be questioned. Further work is required to examine the levels of plaque accumulation with and without lacebacks as the possibility that the appliance is a plaque retention factor is clear.

Implications for research

There are several implications for further work, but the most logical concept is now to examine cases that are non-extraction with respect to the overall treatment plan.

Validity of the study groups

In order to draw conclusions the validity of both the control and experimental groups must be considered. Comparisons of the initial measurements (T1) demonstrated no statistically significant difference between the groups. Both groups were evenly matched for age and sex at the start of treatment. Malocclusions within the groups were evenly distributed.

Randomization of this prospective study ensured that all other variables were equally distributed between the two groups.

Reliability of the data

The error of the method for the cephalometric and study model measurements was very low and not statistically significant. The measurements recorded were therefore a true reflection of the treatment changes and not biased by random error.

Conclusions

In first premolar extraction cases, the lower labial segment does not procline during the leveling stage with the pre-adjusted edgewise appliance.

The use of laceback ligatures conveys no statistical or clinical difference in the anteroposterior or vertical position of the lower labial segment or in the relief of labial segment crowding.

The use of laceback ligatures creates a statistically and clinically significant increase in the loss of posterior anchorage, through mesial movement of the lower first molars.

Authors and contributors

Fraser McDonald was responsible for study design, logistic, administrative, and technical support and data interpretation; drafting, critical revision and final approval of the article. Robert Irvine was responsible for recruitment of participants and data collection, analysis, and drafting, critical revision and final approval of the article. Susan Power was also responsible for recruitment of participants and treatment, analysis, and drafting, critical revision and final approval of the article. Fraser McDonald is the guarantor.

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