ORIGINAL ARTICLE

Effectiveness of early orthodontic treatment with the Twin-block appliance: A multicenter, randomized, controlled trial. Part 1: Dental and skeletal effects

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This study evaluated the effectiveness of early orthodontic treatment with the Twin-block appliance for the developing Class II Division 1 malocclusion. This multicenter trial was carried out in the United Kingdom. A total of 174 children, aged 8 to 10 years old, with Class II Division 1 malocclusion were randomly allocated to receive treatment with a Twin-block appliance or to an untreated, control group. Data were collected at the start of the study and 15 months later. Results showed that early treatment with Twin-block appliances resulted in reduction of overjet, correction of molar relationships, and reduction in severity of malocclusion. Most of this correction was due to dentoalveolar change, but some was due to favorable skeletal change. Early treatment with the Twin-block appliance is effective in reducing overjet and severity of malocclusion. The small change in the skeletal relationship might not be considered clinically significant. (Am J Orthod Dentofacial Orthop 2003;124:234-43)

This article describes a randomized, controlled trial that studied the effectiveness of early orthodontic treatment with the Twin-block appliance. One area that causes much controversy in orthodontic treatment is the role of dentofacial orthopedics or orthodontic growth modification in the treatment of Class II malocclusion. The controversy is further compounded by the issue of timing, specifically whether it is more effective to provide treatment in 2 separate phases. Phase I is treatment with a functional appliance, to correct the Class II skeletal discrepancy, when the child is 7 to 10 years old. This is followed by phase II treatment with fixed appliances when the

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permanent dentition is established. Alternatively, growth modification treatment may be delayed until the late transitional dentition, when it is provided in 1 course of treatment, with an initial functional appliance phase.

Recently, these different approaches have been investigated in the United States by 3 randomized trials of growth modification therapy.[1-3] These landmark studies have provided answers to some important questions. The findings were broadly similar and concluded that early treatment does provide correction of the incisal relationship. This was partly due to dentoalveolar change and some favorable skeletal change. Interestingly, the amount of skeletal change varied according to the appliances used. The study by Tulloch et al[1] concluded that the bionator produced some mandibular change, whereas, with the headgear, there was some maxillary restraint. Keeling et al[2] suggested that a headgear biteplane combination resulted in restraint of the maxilla and also forward positioning of the mandible. Finally, the study by Ghafari et al[3] suggested that headgear produces some maxillary restraint and the Fränkel, mandibular growth increase. These are not the only randomized, controlled trials in this field. The first was carried out in 1976 by Jacobsson, who randomly allocated 60 children to treatment with either an Andreason activator or headgear, or to observation.[4] He concluded that treatment reduced the children's overjets and that both appliances restricted maxillary development but did not have an effect on mandibular growth.

Although these studies have been well designed and have been carried out rigorously, the findings have not always been universally accepted. This is because they have been carried out in single dental schools, with 1 to 4 operators, and the patients have been recruited from screening exercises and have been offered incentives to cooperate with treatment. Consequently, these investigations evaluate the *efficacy* of the treatment.[5] This is defined as "the provision of care under ideal conditions" and is a common feature of randomized, controlled trials. As a result, although these studies must be considered milestones in orthodontic research, the results might not be relevant to the "real" world of orthodontic practice, in which care is delivered from private offices. This problem can be addressed by carrying out investigations that evaluate the *effectiveness* of treatment. This is defined as "the provision of care under conditions that are more relevant to the setting under which the proposed care is routinely provided." This was the aim of our investigation.

MATERIAL AND METHODS

This investigation had the null hypotheses that orthodontic treatment provided with the Twin-block appliance during the transitional dentition stage of development has no effect on (1) anteroposterior relationship of the maxilla to the mandible after treatment, (2) overjet, and (3) dental malocclusion as recorded by the peer assessment rating (PAR).

Fourteen hospital-based orthodontic specialists in the United Kingdom (UK) agreed to take part in the study. Each had undergone basic specialty training followed by 3 years of advanced training in the treatment of severe malocclusion. All operators were based in their own orthodontic departments in the National Health Service of the UK. In this system, the orthodontists receive a salary, and treatment is provided at no direct cost to the patient and family.

We based our sample size calculation for the number of patients necessary to achieve an 80% power with an α of .05 on a clinically meaningful difference in PAR index scores of 15% between the study groups.[6] The calculation showed that we needed to recruit 80 patients for each study group to allow for an estimated noncompletion rate of 15%.

We used inclusion criteria of a minimum 7-mm overjet (measured clinically), the absence of a craniofacial syndrome, and the willingness of the patient and parent to take part in the study. We followed the guidelines of the Declaration of Helsinki.[7]

When patients who satisfied the inclusion criteria attended a study clinic, they were invited to participate in the investigation. If the child and the parent consented, the orthodontist provided details of the patient to the study center at Manchester University by telephone. After initial recording of patient data, each patient was randomized to receive treatment with a Twin-block appliance or to have treatment delayed for at least 15 months. The randomization was made at the start of the study with preprepared random number tables with a block stratification on center and sex.

A modification of the Twin-block appliance, originally developed by Clark,[8] was used in this study. This appliance consisted of maxillary and mandibular removable appliances retained with 0.7-mm Adams clasps on the first permanent molars and 0.9-mm ball clasps placed in the mandibular incisor interproximal areas. A passive maxillary labial bow was also used to aid anterior retention and retrocline the maxillary incisors if they were proclined. The jaw registration was taken with approximately 7 to 8 mm protrusion and the blocks 7 mm apart in the buccal segments. The steep inclined planes interlocked at about 70° to the occlusal plane. When necessary, compensatory lateral expansion of the maxillary arch was achieved with a maxillary expansion screw that was turned once a week. Reactivation of the blocks was carried out when necessary. All patients were instructed to wear the appliance for 24 hours per day (except for contact sports and swimming). They were asked to wear the appliance while eating.

When the patient's overjet had been fully reduced, he or she continued to wear the appliance as a retainer at night only or was fitted with a retainer with a steep inclined biteplane, depending on the operator's preference.

A patient was classified as noncompliant for the treatment group if there was not at least a 10% reduction in overjet after 6 months, if the appliance was repeatedly damaged so that further treatment was not practical, or if he or she refused to wear the appliance. Final data were collected for these patients.

Data were collected on the patients and the control group when they entered the study (data collection 1) and 15 months later (data collection 2). The following were collected by each orthodontist and sent to the coordinating center:

- Study models of the teeth
- Cephalometric radiographs
- Patient's postal code (used to obtain data on the patient's level of social deprivation, according to the Carstairs index, a composite index of deprivation derived from UK national census data[9])

Cephalograms were corrected for magnification and analyzed with the Pancherz analysis.[10] The study casts were scored with the PAR and UK weightings.[6] The cephalograms and the study casts were scored with the examiner blinded to treatment group. The examiner rescored a sample of 30 sets of study casts and 20 cephalograms. Error was evaluated with the intraclass correlation coefficient (ICC). This showed that the ICC was 0.92 for the PAR index. The ICC for cephalometric landmark identification and digitizing ranged from 0.89 for position of the mandibular base (Pg/OLp) to 0.97 for position of maxillary central incisor (Is/OLp) and position of mandibular central incisor (Ii/OLp). The root mean square (SD of the error) ranged from 0.51 mm for position of the maxillary base (A/OLp) to 0.81 for Pg/OLp. These were acceptable levels of error.

The stages of maturation of the cervical spine were then recorded according to the method described by Hassel and Farman.[11] Thirty sets of radiographs were reanalyzed, and error was evaluated with the κ statistic, giving a κ value of 0.94; this was acceptable.

All other data were entered onto computer databases by research assistants who were also blinded to treatment group.

Data analysis

We decided that the data analysis should be restricted to a few variables to reduce the chance of false positives and other spurious findings resulting from multiple comparisons across many related cephalometric variables. As a result, the data analysis was restricted to descriptive and regression analyses on (1) final anteroposterior skeletal discrepancy, as calculated by the Pancherz analysis (defined as A/OLp − Pg/OLp), (2) final overjet, derived from the Pancherz analysis, and (3) final PAR.

We carried out an intention-to-treat analysis so that the data from all patients, regardless of treatment outcome, were included in the analysis. This comprised an analysis of all patients who entered the trial and for whom baseline and final records were available. There were some missing PAR and index of orthodontic treatment need (IOTN) baseline data due to imperfect models. We imputed this data by using regression coefficients for models obtained with sex and overjet determined from the cephalograms.

The following variables were included at the start of the modeling process: baseline data on the dependent variable; treatment group; weighted PAR at start; age; Carstairs deprivation score; center and center × treatment group interaction term; sex and sex × treatment interaction term; and time from registration to first and second cephalograms.

The regressions were carried out with sums of squares type II.

In none of the regressions was center or center × treatment group significant. Where treatment group was significant, simpler models were found by removing nonsignificant variables. When variables were removed, the regression coefficients and adjusted R^2 were compared with the previous model to check stability of effect. All models were tested for homogeneity of variance and normality of residuals.

We did not carry out pretreatment univariate analysis of the variables that we measured, because this is not current recommended statistical practice.[12] We did, however, fit the pretreatment values into the regression analysis. The means and 95% confidence intervals (CIs) of these variables are shown in Tables I and II.

RESULTS

A total of 174 patients were enrolled into the project. Of these, 89 (41 girls, 48 boys) were allocated to the Twin-block and 85 (39 girls, 46 boys) to the control group. Enrollment started in March 1997 and

Table I. Pancherz analysis variables at start and end of study

	Twin-block (n = 73)				*Control (n = 74)*			
	Before		*After*		*Before*		*After*	
	Mean	*95% CI*	*Mean*	*95% CI*	*Mean*	*95% CI*	*Mean*	*95% CI*
Overjet (Is/OLp − Ii/OLp)	+10.33	+9.70 to +10.33	+3.70	+3.14 to +4.25	+10.41	+9.88 to +10.93	+10.71	+10.13 to +11.29
Molar relation (Ms/OLp − Mi/OLp)	+2.05	+1.54 to +2.55	−2.88	−3.67 to +2.09	+1.88	+1.53 to +2.23	+1.55	+1.17 to +1.93
Maxillary base (A point to OLp)	+70.05	+69.11 to +70.98	+70.62	+69.63 to +71.59	+71.08	+70.30 to +71.86	+72.53	+71.73 to +73.34
Mandibular base (Pg/OLp)	+69.95	+68.79 to +71.12	+73.47	+72.18 to +74.75	+71.18	+70.19 to +71.18	+73.70	+72.55 to +74.83
Skeletal Discrepancy (A/OLp − Pg/OLp)	−0.095	−0.80 to +0.61	+2.85	+2.11 to +3.59	+0.098	−0.58 to +0.78	+1.16	+0.32 to +2.00
Condylar head (Co/OLp)	+11.14	+10.61 to +11.67	+11.31	+10.67 to +11.95	+10.84	+10.26 to +11.42	+11.55	+10.91 to +12.19
Mandibular length (Pg/OLp + Co/OLp)	+58.81	+57.40 to +60.22	+62.16	+60.62 to +63.70	+60.34	+59.11 to +61.56	+62.14	+60.78 to +63.51
Maxillary incisor (Is/OLp − Ss/OLp)	+8.59	+8.13 to +9.05	+6.29	+5.81 to +6.78	+8.68	+8.30 to 9.07	+9.41	+8.98 to +9.83
Mandibular incisor (Ii/OLp − Pg/OLp)	−1.64	−2.27 to −1.02	−0.26	−0.96 to +0.45	−1.82	−2.54 to −1.10	−2.47	−3.33 to −1.60
Maxillary molar (Ms/OLp − Ss/OLp)	−22.71	−23.13 to −22.28	−23.48	−24.09 to −22.86	−23.31	−23.70 to −22.92	−22.89	−23.32 to −22.45
Mandibular molar (Mi/OLp − Pg/OLp)	−24.65	−25.32 to −23.99	−23.45	−24.16 to −22.73	−25.29	−25.88 to −24.69	−25.61	−26.32 to −24.88

was completed by August 1999. The last data collection was done in November 2000. The average age of the children was 9.7 (SD = 0.98) years for the treatment group and 9.8 (SD = 0.94) years for the control group.

We found that 14 (16%) of the children who were enrolled in the treatment group did not complete their course of Twin-block treatment. Some of these children could not wear the appliance, and they did not respond to treatment. One patient in the control group (0.01%) was lost to follow-up. Figure 1 illustrates the flow of patients through the study.

Analysis of the cervical spine maturational data showed that all subjects were classified as prepeak height velocity. Table I contains the data for the Pancherz analysis at the start and end of the trial, and Table II contains the data for change in Pancherz analysis variables. Figure 2 gives box plots to show the distribution of overjet and skeletal discrepancy measurements at the start and end of the study. Figure 3 illustrates the difference in proportion of overjet change that was due to either skeletal or dental change between the 2 groups. Figure 4 contains similar data for change in molar relationship.

The raw PAR scores were weighted with the UK weightings.[6] The mean pretreatment scores were 31.15 (95% CI 29.03-32.26) for the Twin-block group and 32.72 (95% CI 30.91-34.55) for the control group. At data collection 2, the mean posttreatment score for the Twin-block group was 18.04 (95% CI 16.24-19.84), whereas after the observation period the mean score for the untreated control group was 35.70 (95% CI 33.95-37.46). When we considered percentage change in PAR score, the treatment group had a mean percentage reduction of 42% (SD = 29.3), and the control group had an increase of 9% (SD = 21.1) (P = .001).

The results of the regression analysis are shown in Table III (final skeletal discrepancy according to Pancherz analysis), Table IV (final overjet), and Table V (final PAR). In all models, when the baseline data were taken into account, the only independent variable that had an effect on the outcome was the treatment group, apart from PAR, in which age and sex had an effect. In

Table II. Change in Pancherz variables

	Twin-block		*Control*		*Difference*	
	Mean	*95% CI*	*Mean*	*95% CI*	*Mean*	*95% CI*
Overjet (Is/OLp − Ii/OLp)	−6.63	−7.28 to −5.98	+0.30	+0.01 to +0.62	−6.93	−7.01 to −6.85
Molar relation (Ms/OLp − Mi/OLp)	−4.93	−5.65 to −4.20	−0.33	−0.56 to −0.095	−4.59	−4.69 to −4.51
Skeletal changes						
Maxillary base (A point to OLp)	+0.57	+0.16 to +0.97	+1.45	+1.09 to +1.81	−0.88	−0.94 to −0.82
Mandibular base (Pg/OLp)	+3.52	+2.80 to +4.23	+2.52	+1.89 to +3.14	+1.00	+0.89 to +1.11
Condylar head (Co/OLp)	+0.17	−0.27 to +0.60	+0.71	+0.32 to +1.10	−0.54	−0.61 to −0.47
Mandibular length (Pg/OLp + Co/OLp)	+3.35	+2.48 to +4.21	+1.80	+1.10 to +2.50	+1.55	+1.41 to +1.67
Dental changes						
Maxillary incisor (Is/OLp − SsOLp)	−2.30	−2.72 to −1.87	+0.73	+0.47 to +0.98	−3.03	−2.09 to −1.97
Mandibular incisor (Ii/OLP − Pg/OLp)	+1.38	+0.87 to +1.91	+0.65	+0.20 to +1.09	+2.03	+1.95 to +2.11
Maxillary molar (Ms/OLp − Ss/OLp)	−0.77	−1.29 to −0.25	+0.42	+0.16 to +0.68	−1.19	−1.26 to −1.12
Mandibular molar (Mi/OLp − Pg/OLp)	+1.21	+0.73 to +1.68	+0.32	−0.12 to +0.75	+1.51	+1.44 to +1.59

Change = data collection 2 − data collection 2. Difference = Twin-block − control.

all models, the baseline data were found to be correlated with the outcome of treatment (ie, the outcome was not independent of the start measurements). It appears that treatment contributes to reducing the discrepancy, but it did not totally eliminate it.

DISCUSSION

Skeletal versus dental change

One of the most important morphologic findings of this study was that early intervention with a Twin-block appliance successfully reduced dental overjet, molar discrepancies, and severity of malocclusion. This was achieved by a combination of dental and skeletal change. Interestingly, the amounts of overjet and molar change that were attributable to skeletal change were 27% and 41%, respectively, and this was made up of growth modification of both the mandible and the maxilla to a similar degree. Even though the skeletal change was statistically significant, it amounted to only 1.9 mm, which might not be considered to be clinically significant or useful. In addition, the overlap of the box plots for skeletal discrepancy (Fig 1) suggests that there was considerable similarity between the 2 groups, at both the start and the end of the study. This finding is similar to that of Tulloch et al.[1] This is in contrast to the dental measurements, for which there is no overlap. Furthermore, when the regression analyses for the cephalometric variables were evaluated, it was evident that the model for the final overjet explained 77% of the variation in the sample, and yet the model for the final skeletal discrepancy explained a much smaller proportion of the variation (54%). This suggests that although the Twin-block appliance appears to produce some skeletal change, a substantial amount of this change was due to other factors. We can conclude that this probably reflects individual variation in growth that is not influenced by orthodontic "growth modification" treatment. As a result, we can conclude that the most important changes resulting from treatment were dentoalveolar.

When we analyzed the data, we fitted models that included the initial baseline values of the outcome measures and the time between data collection stages. There are several reasons for this. First, this takes into account any pretreatment variation that could influence the outcome of treatment. Second, this reflects the current statistical practice of not running multiple tests

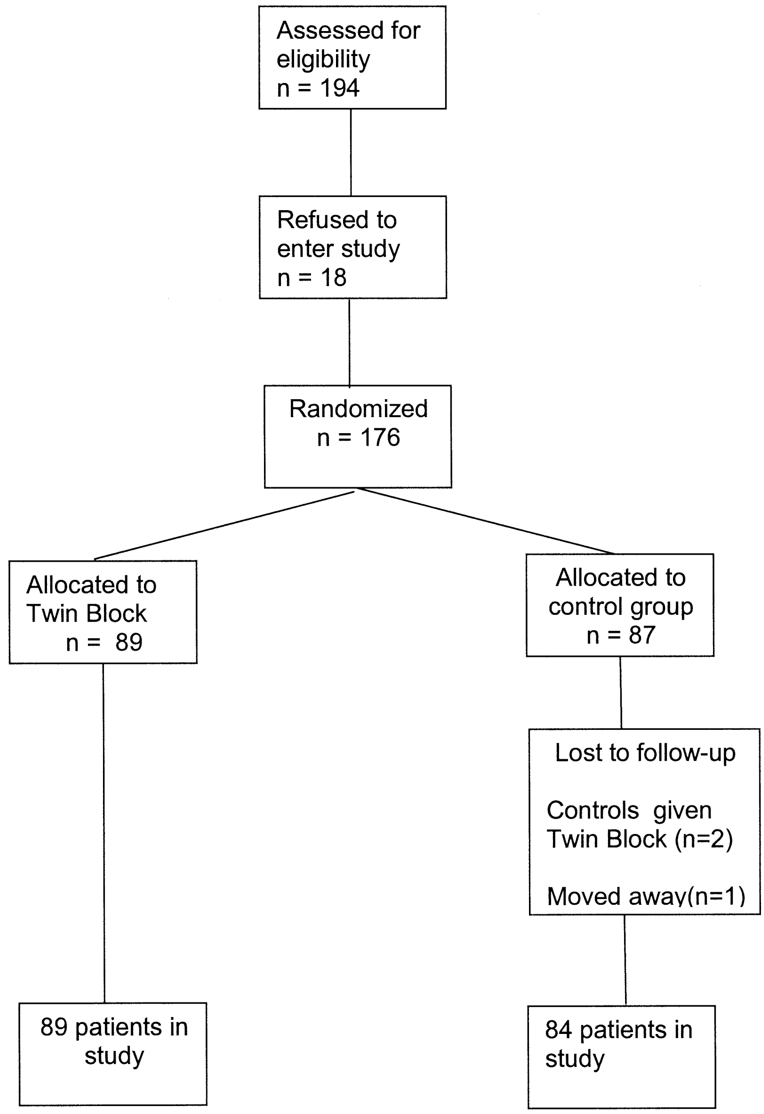

Fig 1. Flow of patients through study.

between the treatment and control group variables, with the risk of false positives.[12] Finally, the fitting of time takes into account any differences in the timing of data collection stages between patients and avoids the need to annualize our data.

When we consider the results of the other randomized, controlled trials that have evaluated the effect of early treatment, our findings are in broad agreement with the study of Tulloch et al,[1] who concluded that the bionator produced a mandibular change of approximately 1 mm, with little influence on the maxilla. The study by Keeling et al[2] came to similar conclusions regarding the magnitude of growth modification change, with the bionator resulting in a small increase in mandibular growth.

There may be several reasons for the Twin-block's small restraining effect on maxillary growth. One suggestion is that this might have occurred because of the labial bow on the Twin-blocks. This design was adopted because all the operators used labial bows on their Twin-blocks to increase retention and to control the maxillary incisors. As a result, the labial bow might have retroclined the maxillary incisors, and the position of A point might have been influenced. However, if we consider the studies by Keeling et al[2] and Tulloch et al,[1] the latter investigators used a bionator without a labial bow, and the former used a fitted labial bow, yet their results were very similar.

The use of a labial bow has been discussed by Clark,[8] who suggests that a labial bow should not be

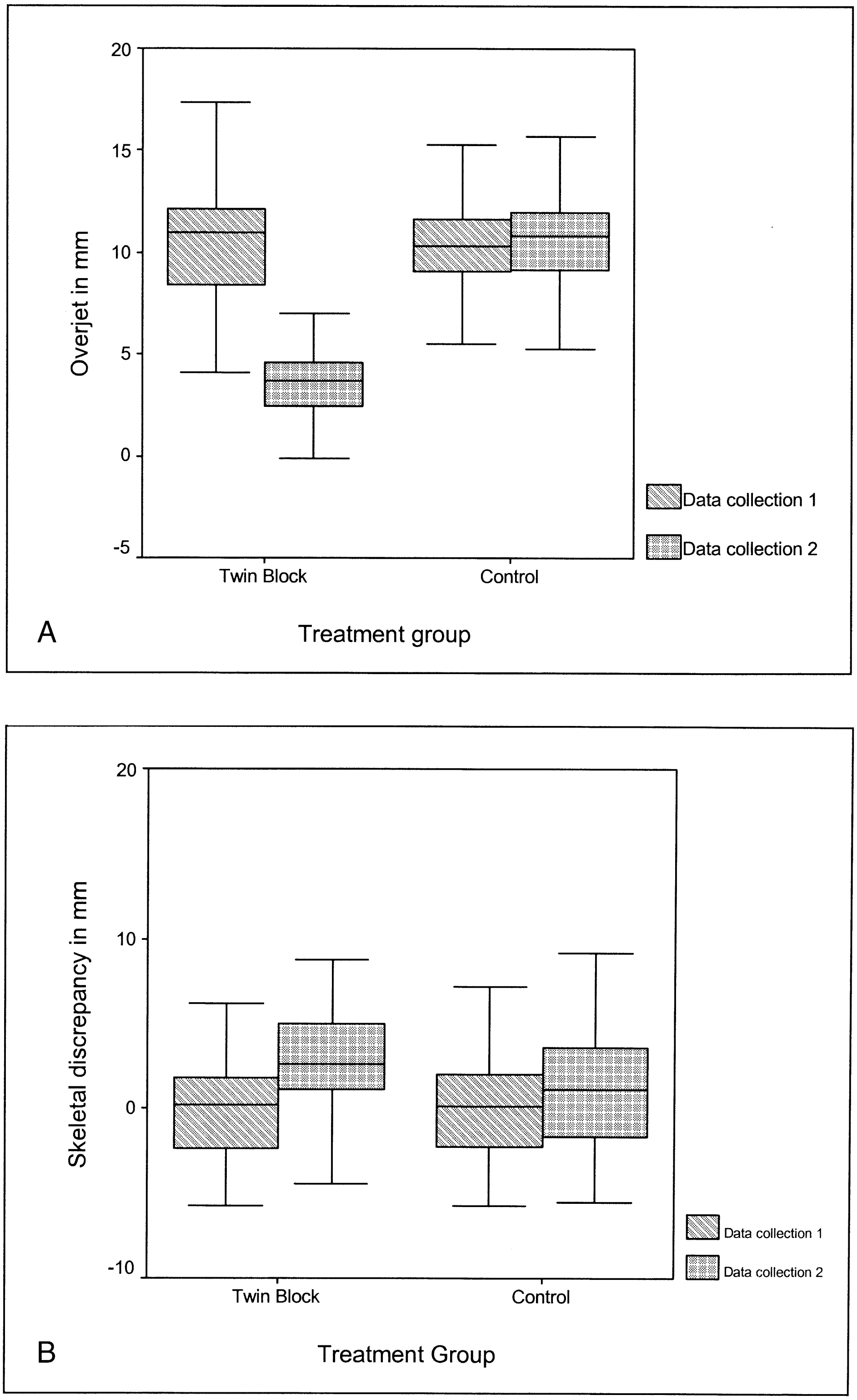

Fig 2. Box plots to illustrate variation in response to treatment for **A**, overjet and, **B**, skeletal discrepancy according to Pancherz analysis (A/OLp − Pg/OLp).

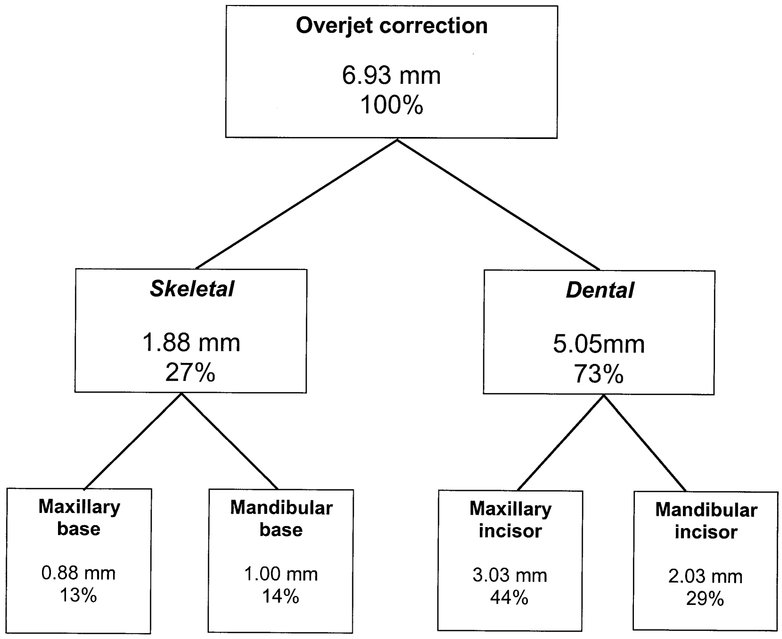

Fig 3. Contribution of dental and skeletal change to difference in overjet change (Twin-block group − control group).

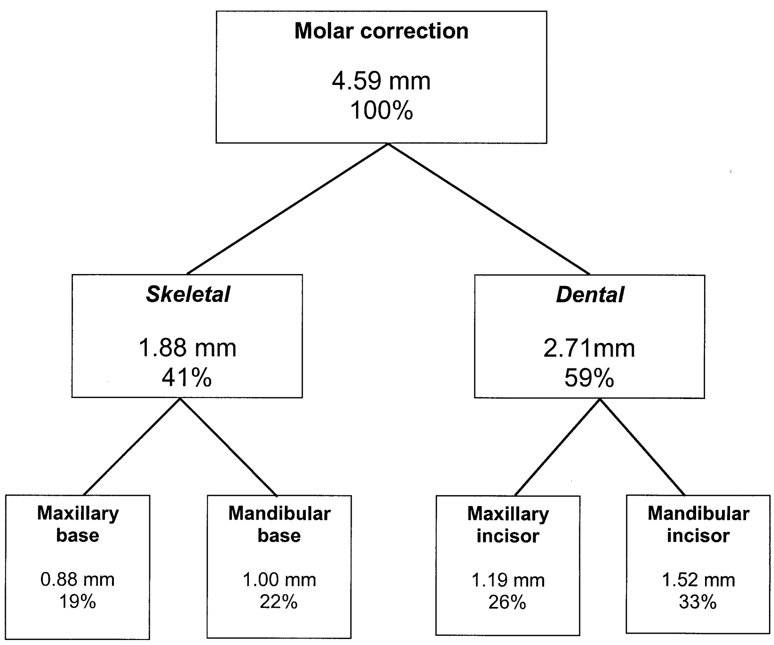

Fig 4. Contribution of dental and skeletal change to difference in molar correction (Twin-block group − control group).

used because, by retroclining the maxillary incisors, the amount of potential skeletal change is reduced. However, there is no scientific evidence for this suggestion. Furthermore, when our data are examined, it can be seen that our patients on average had proclined maxillary incisors, and, at the end of Twin-block treatment, the incisor angulation was normal and not over-retroclined.

Table III. Regression analysis on final skeletal discrepancy

Significant variables	*Coefficient*	*95% CI for coefficient*	P
Treatment group	1.94	1.16 to 2.72	<.0005
Pretreatment skeletal discrepancy	0.83	0.70 to 0.97	<.0005

For regression analysis, n = 146, $P < .0005$, adjusted $R^2 = 0.54$.

Table IV. Regression analysis on final overjet

Significant variables	*Coefficient*	*95% CI for coefficient*	P
Treatment group	−6.99	−7.63 to −6.35	<.0005
Overjet at baseline	0.59	0.46 to 0.72	<.0005

For regression analysis, n = 147, $P < .0005$, adjusted $R^2 = 0.77$.

Table V. Regression analysis on peer assessment rating

Significant variables	*Coefficient*	*95% CI for coefficient*	P
Treatment group	−16.77	−18.85 to −14.70	<.0005
Weighted PAR at baseline	0.48	0.36 to 0.60	<.0005
Age	1.38	0.29 to 2.47	.014
Sex (male)	2.41	0.34 to 4.48	.023

For regression analysis, n = 153, $P < .0005$, $R^2 = 0.70$.

It is also useful to compare our results with 2 retrospective investigations that have evaluated the effect of early Twin-block treatment. In both, the amount of skeletal change that contributed to overjet correction was reported as 50%, and this does not reflect our finding.[13,14] There could be several reasons for this, but the most likely is that retrospective investigations, because of the inherent selection bias, tend to overestimate the effects of treatment. Furthermore, these studies used the same historical control group, and these values might not be comparable to contemporary UK children.

When we consider the findings of the several randomized trials, we can conclude that early treatment with a functional appliance does not, on average, change the Class II skeletal pattern of a child to a clinically significant degree.

Patient compliance

In evaluating the effects of any treatment, patient compliance must be considered, and our noncooperation rate of 16% was similar to that in other investigations. For example, in a prospective cohort study of British children treated with Twin-blocks, the noncompliance rate was reported as 17%.[15] Other results from a randomized, controlled trial showed that 42% of boys and 24% of girls discontinued treatment with Fränkel appliances.[3] It therefore seems that for a fairly high proportion of patients undergoing early Twin-block treatment, the treatment will not be successful.

We used an intention-to-treat analysis, in which all patient records were analyzed, regardless of the outcome of treatment. It could be suggested that this approach underestimates the size of the treatment effect, because it includes data derived from patients who did not complete treatment. However, this is the recommended practice for randomized, controlled trials, because this approach evaluates the average effectiveness of treatment for the average patient who might be suitable for the type of care under evaluation. As a result, the study findings are relevant to all the patients who started treatment, rather than to only those who complied with the treatment.[16]

As with the other randomized, controlled trials that have investigated this question, this study is being extended to evaluate the stability of these changes and the effect of the provision of any treatment when the children are in their early teenage years.

The second article on this study will report the psychosocial effects of providing early Twin-block treatment to this group of children.

CONCLUSIONS

In a multicenter setting in the UK, early orthodontic treatment with the Twin-block appliance resulted in substantial reduction in the overjets of children with Class II malocclusion. This was mainly due to dentoalveolar change, with a small element of favorable skeletal change. The magnitude of the patient's initial discrepancy was related to the outcome of treatment. This study reinforces the findings of other, similar randomized, controlled trials that suggest that early functional appliance treatment does not, on average, influence the Class II skeletal pattern to a clinically significant degree.

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CORRECTION

The name of Mladen M. Kuftinec, DMD(Harv), DStom, ScD, was inadvertently omitted from the authors of "Condyle-fossa modifications and muscle interactions during Herbst treatment, Part 2. Results and conclusions" (Voudouris JC, Woodside DG, Altuna G, Angelopoulos G, Bourque PJ, Lacouture CY, Kuftinec MM, Am J Orthod Dentofacial Orthop 2003;124:13-29). This article, with the color foldout, has been reprinted and is being mailed with this issue.