



Early treatment for Class II Division 1 malocclusion with the Twin-block appliance: A multi-center, randomized, controlled trial

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Introduction: The aim of this study was to evaluate the effectiveness of early orthodontic treatment with the Twin-block appliance for the treatment of Class II Division 1 malocclusion. This was a multi-center, randomized, controlled trial with subjects from 14 orthodontic clinics in the United Kingdom. **Methods:** The study included 174 children aged 8 to 10 years with Class II Division 1 malocclusion; they were randomly allocated to receive treatment with a Twin-block appliance or to an initially untreated control group. The subjects were then followed until all orthodontic treatment was completed. Final skeletal pattern, number of attendances, duration of orthodontic treatment, extraction rate, cost of treatment, and the child's self-concept were considered. **Results:** At the end of the 10-year study, 141 patients either completed treatment or accepted their occlusion. Data analysis showed that there was no differences between those who received early Twin-block treatment and those who had 1 course of treatment in adolescence with respect to skeletal pattern, extraction rate, and self-esteem. Those who had early treatment had more attendances, received treatment for longer times, and incurred more costs than the adolescent treatment group. They also had significantly poorer final dental occlusion. **Conclusions:** Twin-block treatment when a child is 8 to 9 years old has no advantages over treatment started at an average age of 12.4 years. However, the cost of early treatment to the patient in terms of attendances and length of appliance wear is increased. (Am J Orthod Dentofacial Orthop 2009;135:573-9)

We report the results of a 10-year randomized controlled trial examining the effectiveness of early orthodontic treatment with the Twin-block appliance. Over the past few years, there has been considerable debate on the merits of early orthodontic treatment for Class II Division 1 malocclusions. When a young child with a severe Class II malocclusion comes for assessment just after the eruption of the permanent incisors, orthodontists have a dilemma. This was succinctly put by Tulloch et al,¹ who asked "does treatment started in the mixed dentition before adolescence [early treatment], when followed by a second phase of treatment in the early permanent dentition during adolescence, provide superior results to single-phase treatment

delayed until adolescence [adolescent treatment]?" The proponents of early treatment stated that it normalizes the skeletal pattern and reduces the length of adolescent treatment in the permanent dentition. However, recent research in the United States suggested that few benefits are gained by this approach.^{1,2}

Although these studies used high levels of scientific investigation and were carried out rigorously, the findings have not been universally accepted. The methodology was criticized because the studies were done in single dental schools, with 1 to 4 operators, and the patients were recruited from screening exercises and offered incentives to cooperate with treatment. This issue was addressed, to a degree, in our articles on the first phase of our multi-center randomized trial about early treatment with the Twin-block appliance.^{3,4} The results showed that early treatment was effective and resulted in a reduction in overjet, a small amount of skeletal change, and an improvement in the child's self-esteem. Although these results were encouraging, they must be considered to be interim findings because the ultimate evaluation of early treatment should be after all orthodontic treatment, including treatment during adolescence. This was the aim of this study.

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MATERIAL AND METHODS

The treatment that we studied can be defined as either early or adolescent treatment. Early treatment is provided in 2 phases. The first is done when the child is in the transitional dentition. There is usually a period of inactivity followed by a final course of treatment when most or all of the permanent dentition has been established.

Adolescent treatment is treatment provided in 1 stage when most or all of the permanent dentition has been established; it is carried out with functional or fixed appliances. This group was the control group in our study. Under the study conditions, these patients could start treatment after a minimum of 15 months without treatment.

Thus, the only difference between the 2 groups was an earlier course of Twin-block functional appliance treatment when the child was in the mixed dentition.

This investigation had the following null hypotheses. There are no differences after all treatment between early or adolescent treatment with respect to (1) the anteroposterior relationship of the maxilla to the mandible, (2) the overjet, (3) the dental malocclusion as recorded by the peer assessment rating (PAR), (4) the child's self-esteem, (5) the process of treatment in terms of duration of orthodontic appliance wear and number of attendances at the clinic, and (6) the cost of treatment.

Fourteen hospital-based orthodontic specialists in the United Kingdom took part in the study. Each one had undergone basic specialty training followed by a 3-year period of further training in the treatment of severe malocclusions. All operators were based in their own orthodontic department in the National Health Service of the United Kingdom. In this system, orthodontists receive a salary, and treatment is provided at no direct cost to the patient and the family.

We based our sample size calculation on data from the University of North Carolina investigation.⁵ This showed that the mean duration of treatment for patients who had later treatment after early treatment was 25 months (SD, 11). It was decided that a meaningful difference between the treatment duration for children who did, or did not, receive early treatment was 6 months. To give a study a power of 80% and an alpha of 0.05, the sample size needed to be 60 in each group.

We used inclusion criteria of a minimum of 7 mm overjet (measured clinically), no craniofacial syndromes, and willingness of the patient and a parent to participate in the study. The patients had to be in the mixed dentition with at least the permanent incisors and first molars erupted, but there was no age criterion. These criteria were similar to those used in the North

Carolina study of early Class II treatment.¹ We followed the guidelines in the Declaration of Helsinki.⁶

When patients who satisfied the inclusion criteria attended the clinic, they were asked to take part in the investigation. If they consented, the orthodontist phoned the study center at Manchester University to provide details of the patient. After initial recording of the patient's data, he or she was randomized to receive early treatment with a Twin-block appliance (early treatment group) or to have treatment delayed for a minimum of 15 months from entry into the study (adolescent group). The randomization was prepared by minimization stratified on center and sex. Trial registration started in October 1996.

Treatment protocols

A modification of the Twin-block appliance, originally developed by Clark, was used in this study.⁷ 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 embrasures. A passive maxillary labial bow was also used to aid anterior retention and control the incisors if they were proclined. The jaw registration was taken with approximately 7 to 8 mm of 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 an 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 a 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 according to the operator's preference.⁷ The duration of this retention depended on the patient's cooperation and the operator's preference.

The patients in both groups were then kept under review in the clinics until the permanent dentition was more established and they were ready for any further treatment. This was then provided according to the operators' normal treatment protocols. No further randomization was carried out.

Data collection

Data were collected on the patients at the following points. Data collection 1 was when they entered the study. Data collection 2 was when their final appliances were removed.

The following data were collected by each orthodontist and sent to the study coordinating center in Manchester: study models of the teeth, cephalometric radiographs, the patient's self-esteem as measured by the Piers-Harris self-concept scale, the patient's treatment record, intraoral and extraoral photographs, and the patient's zip code (used to determine socioeconomic status according to the Carstairs index⁸).

The cephalograms were analyzed with the Pancherz analysis.⁹ The study casts were scored with the PAR with the United Kingdom weightings.¹⁰ The cephalograms and the study casts were scored with the examiner unaware of the patient's group. The examiner rescored 30 radiographs and study casts. The intraclass correlation coefficient was 0.9 for the PAR data.¹¹ The intraclass correlation coefficients for the cephalometric data ranged from 0.8 to 0.95, and the root mean squared ranged from 0.5 mm for A/OLp to 0.7 mm for Pg/OLp. These were acceptable levels of error.

Treatment process

Each patient record was examined, and we recorded the number of attendances and the appliances used, whether the patient completed all treatment, and whether extraction of permanent teeth was required during treatment.

All data were entered into computer databases by research assistants who were unaware of group allocation.

Incidence of trauma

The incidence of trauma to the incisors during the study period was recorded from a combination of examining data collection sheets, patient records, and anterior photographs and radiographs. We simply recorded whether trauma had occurred that had harmed the teeth; this was defined as visible signs of trauma—eg, a crack to the enamel or a dentin fracture. This was a simplified version of the method used in a similar trial.¹² A sample of 30 sets of records was reexamined, and reproducibility was calculated with the kappa statistic.¹³ This gave a kappa score of 0.95, which is a high level of agreement.

Cost analysis

A cost analysis was carried out from the perspectives of the health care provider (National Health Service) and the children in the study. Data were collected from the start to the end of all treatment. We included data on scheduled and unscheduled clinic attendances, and data on both the distance traveled and the travel time for each child. We then calculated the costs using the following information.

1. The clinic attendances were costed by using the national average cost per visit of \$257 for the first visit and \$147 for subsequent visits, according to the Department of Health reference costs.¹⁴ These unit costs included staff, overhead, equipment and facilities, and treatment. Costs were discounted at 3.5%.¹⁵ The costs of travel were estimated at \$0.31, which is the national average cost for public transport per kilometer.¹⁶
2. The time costs were estimated as the national average (median) pay per hour (Office of National Statistics).¹⁷ The travel and time costs included only the costs for the child. However, some children had traveled with at least 1 family member, but data on the proportion of children traveling with an adult were unavailable. This meant that the time and travel costs for the patient were a minimum estimate of the likely costs in routine practice.

The costs were estimated in United Kingdom pounds sterling for the year 2005/06 and converted to US dollars by using purchasing-power parities for 2005/06.¹⁸

Statistical 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 generation of descriptives and regression analyses of the following: (1) the relationship of the maxilla to the mandible measured with the Pancherz analysis (Pg/OLp minus A/OLp), (2) the final overjet derived from the Pancherz analysis,⁹ (3) the final PAR score, (4) the Piers-Harris self-esteem score, (5) the process of treatment, (6) the incidence of extractions, (7) the incidence of trauma, and (8) the cost of treatment.

We carried out an intention-to-treat analysis, so that the data from all patients, regardless of treatment outcome, were included. This comprised an analysis of all patients who entered the trial and for whom baseline and final records were available. There were some missing Carstairs and PAR baseline data because of imperfect models. We imputed these data using baseline mean values as described by White and Thompson.¹⁹

The treatment effects for the continuous outcomes were estimated by regression (analysis of covariance, ANCOVA) models allowing for treatment center, age at baseline, age at start of second period, sex, socioeconomic status (Carstairs), and baseline value when appropriate. The baseline PAR score was also included in the models for attendance, duration of treatment, and cost. Logistic regression models were fitted for

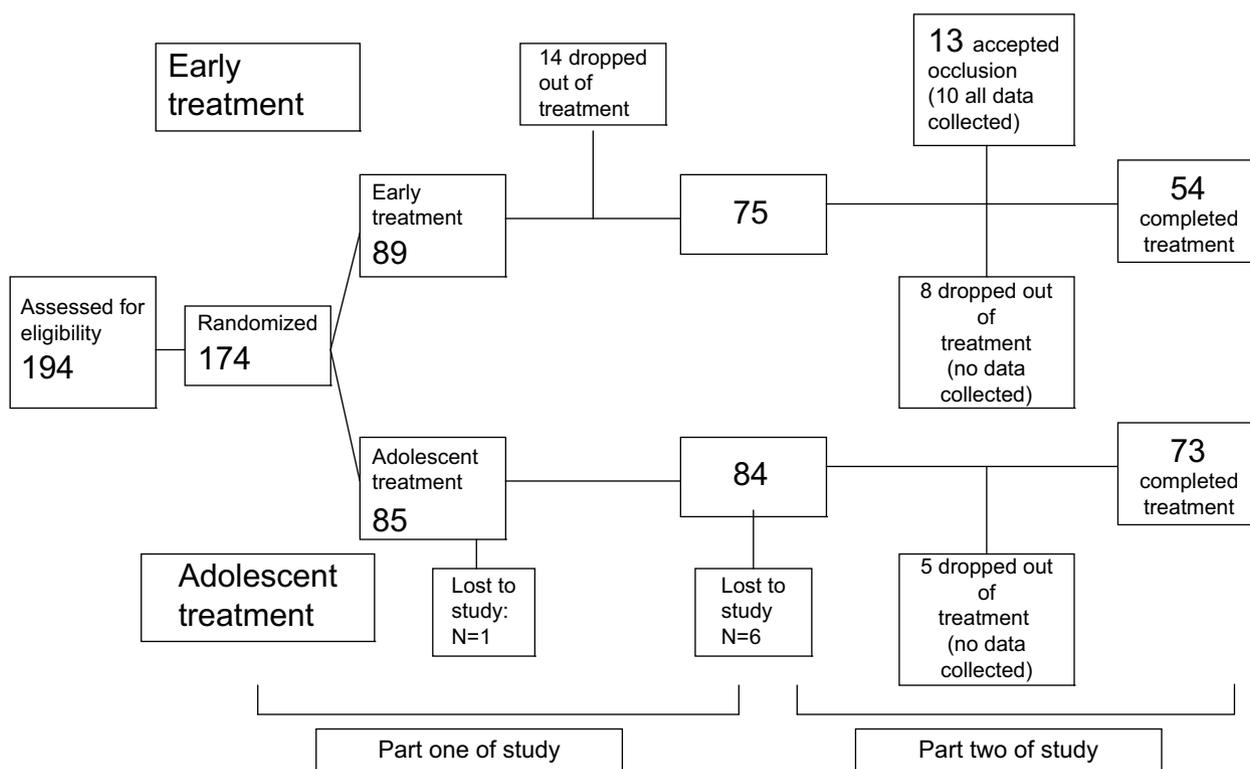


Fig. Flow of the patients through the study.

the binary outcomes of whether the child had extractions and new dental trauma to estimate the treatment effect with the same covariables as above, including the baseline PAR score. Residual analyses assessed the assumptions about the use of multiple linear regression and logistic regression. We did not carry out pre-treatment univariate analysis of the variables that we measured, because this is not a currently recommended statistical practice.^{20,21}

RESULTS

One hundred seventy-four patients were enrolled at the start of the project; of these, 89 (41 girls, 48 boys) were allocated to early treatment, and 85 (39 girls, 46 boys) to later treatment (control). Enrollment started in March 1997 and was completed by August 1999.³ The last data collection was in July 2006. At the start of the study, the average ages of the children were 9.7 years (SD, 0.98) for the early treatment group and 9.8 years (SD, 0.94) for the adolescent treatment group. The flow of the patients through the study is shown in the Figure. Not all records had been collected for each patient; this is reflected in the number of subjects reported in the tables. These also show that data loss was similar for both groups.

Of the patients who had early Twin-block treatment, 13 accepted their occlusion and declined further treatment, whereas none of the control subjects accepted their occlusion after the 15-month period.

The average ages at the start of treatment for the patients who had treatment in the permanent dentition were 12.1 years (SD, 1.0) for the adolescent group and 12.41 years (SD, 1.16) for the early treatment group. Apart from the later start of treatment in the control group, there were also some differences in the appliances used for the 2 groups. Of those treated early with the Twin-block, 42 (64%) were subsequently treated with fixed appliances; only 6 (9%) were treated with a further Twin-block and fixed appliances, and 5 (8%) were treated with a further Twin-block only. In the adolescent treatment group, 45 (61%) were treated with Twin-block and fixed appliances, 14 (19%) with fixed appliances only, and 14 (19%) with Twin-block only. Analysis of extractions showed that 27% of the early treatment group and 37% of the adolescent treatment group had extractions. However, this was not significantly different logistic regression model, treatment effect: odds ratio 1.32 (95% CI, 0.91-1.90), *P* = 0.14.

The cephalometric data are shown in Table I. For the purpose of inclusion of uniform data in systematic

Table I. Descriptive cephalometric data before and after the study (Panherz analysis⁹)

	Twin-block (n = 63)		Control (n = 65)		Treatment effect Twin-block – control (95% CI)
	Before Mean (SD)	After Mean (SD)	Before Mean (SD)	After Mean (SD)	
Overjet					0.96 (0.31, 1.61)
Is/OLp – ii/OLp	10.77 (2.47)	4.33 (2.19)	10.30 (2.45)	3.37 (1.42)	
Maxillary base					-0.44 (-2.28, 1.40)
A/OLp	70.19 (3.93)	74.02 (5.06)	70.84 (3.29)	74.46 (5.35)	
Mandibular base					-2.15 (-4.63, 0.33)
Pg/OLp	69.87 (5.04)	76.79 (7.20)	71.14 (4.54)	78.94 (6.84)	
Skeletal discrepancy (A/OLp – Pg/OLp)	-0.32 (3.18)	2.77 (4.54)	0.30 (3.03)	4.48 (4.14)	-1.71 (-3.25, -0.18)

Table II. Mean PAR scores (SD), Piers-Harris scores (SD), attendances in phases 1 and 2, and duration of treatment for phases 1 and 2 for both groups of patients who had posttreatment data

		Early treatment		Adolescent treatment	
		n	Mean (SD)	n	Mean (SD)
PAR score	Pretreatment	63	31.91 (9.13)	70	32.55 (7.85)
	Posttreatment		10.25 (10.67)		6.30 (6.17)
Piers-Harris score	Pretreatment	62	60.33 (11.99)	70	61.78 (12.86)
	Posttreatment		68.87 (8.32)		68.04 (10.09)
Attendances in phase 1 (n)		66	11.48 (4.34)	72	None
Attendances in phase 2 (n)		66	13.47 (5.54)	72	18.33 (8.44)
Total attendances (n)		66	22.11 (9.00)	72	18.33 (8.44)
Duration of treatment in phase 1 (d)		64	527 (208)	73	None
Duration of treatment in phase 2 (d)		64	435 (344)	73	744 (397)
Total duration of treatment (d)		64	968 (428)	73	744 (397)
Total clinical cost of attendances (2005/06 \$)		65	3282 (1131)	74	2398 (1123)
Total travel cost of attendances (public transport) (2005/06 \$)		65	105 (87)	73	136 (146)
Total time cost of attendances (2005/06 \$)		65	531 (322)	74	419 (280)
Total costs (2005/06 \$)		64	3913 (1388)	73	3018 (1400)

reviews, we also included data using more conventional methods. The means (and standard deviations) for ANB angle at the end of the study were 4.0° (2.0) and 3.8° (2.2) for the early and later treatment groups, respectively. The descriptive data on PAR scores, self-esteem, process, and costs of treatment are included in Table II, with the treatment effects from the regression models for all continuous primary outcomes shown in Table III. There was no evidence from the residual analyses that the assumptions underlying the use of multiple linear regression and logistic regression were not upheld. The results suggest that, after all treatment, the only differences between the groups were treatment duration and final PAR score; there were no differences in skeletal pattern and self-esteem. The early treatment group had significantly higher PAR scores at the end of treatment ($P = 0.002$). When we examined the process data, it appeared that the patients who had early treatment had

statistically significantly fewer attendances in phase 2 than did the adolescent treatment group ($P < 0.001$), but when we combined these with the visits that were necessary in phase 1, they attended statistically significantly more times than did the adolescent treatment group ($P < 0.016$). Similarly, when the duration of treatment was evaluated, we found that the early treatment group had statistically significantly longer overall treatment times than the adolescent treatment group ($P < 0.001$). The cost of treatment was also greater ($P < 0.001$) for the early treatment group; this additional cost averaged approximately \$900.

Eleven children experienced new dental trauma, 4 (8%) in the early treatment group and 7 (14%) in the adolescent treatment group. This difference was not statistically significantly different logistic regression model, treatment effect: odds ratio 1.37 (95% CI, 0.70-2.72), $P = 0.36$.

Table III. Treatment effects and 95% CI for the primary outcomes in the study, fitting the regression models, with ages at baseline and start of phase 2, sex, center, Carstairs index, and baseline value where appropriate, with the baseline PAR score included in the models for attendance

	Treatment effect (SE) (adolescent, early treatment)	95% CI	P value
Skeletal discrepancy (n = 127)	0.217 (0.312)	-0.402, 0.835	0.489
Overjet (n = 127)	-0.546 (0.175)	-0.893 to -0.200	0.002
PAR score (n = 132)	-2.329 (0.751)	-3.819, -0.839	0.002
Piers-Harris score (n = 131)	-0.919 (0.767)	-2.439 to 0.606	0.23
Attendances in phase 2 (n) (n = 138)	3.843 (0.666)	2.526, 5.161	<0.001
Total attendances in phases 1 and 2 (n) (n = 138)	-1.815 (0.739)	-3.279, -0.351	0.016
Duration of treatment in phases 1 and 2 (d) (n = 136)	-104 (32)	-167, -41	<0.001
Total clinical, travel, and time costs (2005/06 \$) (n = 138)	-445 (139)	-718, -171	0.001

DISCUSSION

These results suggest that there are minimal benefits of early "functional" or "growth modifying" treatment in the transitional dentition. Treatment starting at this age simply increased the number of patient attendances, and the duration and the cost of treatment, and resulted in poorer final occlusion.

This finding is similar to those of other studies that evaluated the effects of early treatment. In addition, it provides evidence of little difference in the effects of early treatment whether in ideal conditions in 1 dental school or in the real-world setting of specialist care in the United Kingdom. Furthermore, there does not seem to be a difference in the results of similar studies involving treatment with the bionator and this study with the Twin-block.^{1,2}

Although we can suggest that early treatment has limited advantages, we should consider the interim findings immediately after early treatment. These showed that early treatment results in reduction in overjet, favorable (but small) change in skeletal pattern, and meaningful improvement in the self-esteem of the treated group. As clinicians, we must evaluate whether the additional course of treatment justifies these interim changes that are not necessarily stable.

A relevant finding was that 13 patients in the early treatment group declined further treatment; they were satisfied with their occlusion. Because we did an intention-to-treat analysis, and they remained in the data analysis, they did not influence the overall effectiveness of treatment for any analyzed variable. Nevertheless, we can conclude that 1 benefit of early treatment is that almost 15% of the patients did not need more complex treatment in adolescence. Whether this justifies early treatment for a child with a Class II Division 1 malocclusion can be determined by the patient, the parents, and the orthodontist.

It was interesting to find clinical differences between the 2 groups in PAR scores, since the final occlusal result for the patients who received early treatment was inferior to that of the adolescent group. When we compared this finding with another clinical trial of early treatment, we found some differences between the studies.²² First, our patients' pretreatment PAR scores were higher, suggesting greater severity of dental malocclusion. After treatment, our adolescent group had a score that was similar to those of studies in the United States; however, our early treatment group was not finished to such a high standard.^{1,22} It is difficult to suggest reasons for this, since differences are unlikely in the operators' expertise in the 2 countries. One reason could arise from the different systems of payment in the United Kingdom, with care provided at no direct cost to the patient or the parent. It might be that payment influences the motivation of US patients and that the early treatment group maintained high levels of cooperation. In the United Kingdom, the burden of 2 courses of treatment might have caused patient burnout, and cooperation was lost. This, however, is purely conjecture.

Most of the adolescent group also had a Twin-block functional appliance followed by fixed appliances; some of these patients were also still in the late mixed dentition at the start of treatment. The differences in the results can therefore be attributed largely to the older age at which the adolescent group started treatment rather than to a fundamentally different modality of treatment.

Importantly, this and other studies provide information that we should use as evidence to our patients on the effects of treatment. They and their parents can now make an informed decision on whether to undergo the additional effort and cost of an earlier start of treatment, which necessitates a midtreatment pause and provides no long-term benefit, when compared with 1 course of treatment during adolescence.

CONCLUSIONS

From this multi-center, randomized, controlled trial using a contemporary functional appliance, we concluded the following.

1. Early orthodontic treatment with the Twin-block appliance followed by further treatment in adolescence at the appropriate time does not result in any meaningful long-term differences when compared with 1 course of treatment started in the late mixed or early permanent dentition.
2. There are definite disadvantages to the 2-phase approach including increased burdens for the patient in terms of attendance, costs, length of treatment, and an inferior final occlusal result.
3. This study reinforces similar conclusions of other randomized controlled trials. Early treatment for Class II malocclusion is not normally justified.

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