



Effectiveness of treatment for Class II malocclusion with the Herbst or Twin-block appliances: A randomized, controlled trial

Kevin O'Brien, PhD, MSc, BDS, FDS, DOrthRCSEng,^a Jean Wright, MSc, BSc,^b Frances Conboy, MA, BA,^b YeWeng Sanjie, BDS, MSc,^c Nicky Mandall, PhD, BDS, FDSRCSEng, MOrthRCSEng,^d Stephen Chadwick, BDS, FDSRCSEdin, MOrthRCSEng,^e Ivan Connolly, BDS, FDSRCPSGlasg, FFDRCSIrel, MOrthRCSEng,^f Paul Cook, MSc, BChD, FDSRCPSGlasg, LDS, FDS, DOrth, MOrthRCSEng,^g David Birnie, BDS, FDSRCSEdin, FDS, MOrthRCSEng,^h Mark Hammond, MSc, BDS, FDS, RCPSGlasg, MOrthRCSEng,ⁱ Nigel Harradine, MB, BS, BDS, FDSRCSEdin, MOrthRCSEng,^j David Lewis, BDS, FDS, DOrthRCSEng, FRSH,^k Cathy McDade, BDS, FDSRCSEdin, DOrthRCSEng,^l Laura Mitchell, MDS, BDS, FDSRCPSGlasg, MOrthRCSEng, DOrthRCSEng,^m Alison Murray, BDS, MSc, FDSRCPSGlasg, MOrthRCSEng,ⁿ Julian O'Neill, BDS, MSc, FFDRCSIrel, MOrthRCSEng,^o Mike Read, BDS, FDSRCSEdin, DOrthRCSEng,^l Stephen Robinson, MSc, BDS, FDSRCPSGlasg, MOrthRCSEng,^h Dai Roberts-Harry, MSc, BDS, FDSRCPSGlasg, MOrthRCSEng,^g Jonathan Sandler, MSc, BDS, FDSRCPSGlasg, MOrthRCSEng,^p and Ian Shaw, PhD, MScD, BDS, FDS, DOrthRCSEng^q
Manchester, Chester, Portadown, Leeds, Portsmouth, Stourbridge, Bristol, Bolton, Bradford, Derbyshire, Kettering, Chesterfield, and Sunderland, United Kingdom

The aim of this study was to evaluate the effectiveness of Herbst and Twin-block appliances for established Class II Division I malocclusion. The study was a multicenter, randomized clinical trial carried out in orthodontic departments in the United Kingdom. A total of 215 patients (aged 11-14 years) were randomized to receive treatment with either the Herbst or the Twin-block appliance. Treatment with the Herbst appliance resulted in a lower failure-to-complete rate for the functional appliance phase of treatment (12.9%) than did treatment with Twin-block (33.6%). There were no differences in treatment time between appliances, but significantly more appointments (3) were needed for repair of the Herbst appliance than for the Twin-block. There were no differences in skeletal and dental changes between the appliances; however, the final occlusal result and skeletal discrepancy were better for girls than for boys. Because of the high cooperation rates of patients using it, the Herbst appliance could be the appliance of choice for treating adolescents with Class II Division 1 malocclusion. The trade-off for use of the Herbst is more appointments for appliance repair. (*Am J Orthod Dentofacial Orthop* 2003;124:128-37)

This article reports the results of a randomized clinical trial that evaluated the effectiveness of orthodontic treatment with either a Herbst or a Twin-block functional appliance.

Although the provision of early orthodontic growth modification treatment for Class II malocclusion has

been investigated with randomized trial methodology,¹⁻³ few controlled clinical trials have investigated the effects of orthodontic growth modification in early adolescence. These have been confined to evaluating the effects of the functional appliance phase of treatment.⁴⁻⁶ The authors of those studies concluded that

^aProfessor and chair, Unit of Orthodontics, University Dental Hospital of Manchester, United Kingdom.

^bResearch associate, University Dental Hospital of Manchester.

^cVisiting student (from Wuhan University, People's Republic of China), University Dental Hospital of Manchester.

^dLecturer in orthodontics, University Dental Hospital of Manchester.

^eConsultant orthodontist, Chester Royal Infirmary, previously Blackburn Royal Infirmary, Chester, United Kingdom.

^fConsultant orthodontist, Craigavon Area Hospital, Portadown, Northern Ireland, United Kingdom.

^gConsultant orthodontist, Leeds Dental Institute, United Kingdom.

^hConsultant orthodontist, Queen Alexandra Hospital, Portsmouth, United Kingdom.

ⁱConsultant orthodontist, The Corbett Hospital, Stourbridge, United Kingdom.

^jConsultant orthodontist, Bristol Dental Hospital, United Kingdom.

^kConsultant orthodontist, Bolton General Hospital, United Kingdom.

^lConsultant orthodontist, University Dental Hospital of Manchester, United Kingdom.

^mConsultant orthodontist, St Luke's Hospital, Bradford, United Kingdom.

ⁿConsultant orthodontist, Derbyshire Royal Infirmary, United Kingdom.

^oConsultant orthodontist, Kettering General Hospital, United Kingdom.

^pConsultant orthodontist, Chesterfield Royal Hospital, United Kingdom.

^qConsultant orthodontist, Sunderland Hospital, United Kingdom.

Supported by the Medical Research Council (99410454).

Reprint requests to: Professor Kevin O'Brien, Professor and Chair, Orthodontic Unit, Department of Dental Medicine and Surgery, Higher Cambridge Street, Manchester M15 6FH, United Kingdom; e-mail, Kevin.O'Brien@man.ac.uk. Submitted, August 2002; revised and accepted, December 2002.

Copyright © 2003 by the American Association of Orthodontists.

0889-5406/2003/\$30.00 + 0

doi:10.1016/S0889-5406(03)00345-7

most of the correction of the malocclusion was due to dentoalveolar change and that there was a small but statistically significant amount of skeletal change.

One disadvantage of removable functional appliances is that extensive cooperation is needed, and discontinuation rates can vary between 9% and 15% with the Twin-block.^{5,7} One solution to noncompliance is to use fixed functional appliances, such as the Herbst appliance.⁸ It has been suggested that treatment that does not depend on compliance has become more popular during the last 2 decades.⁹ There have, however, been no randomized trials of the effectiveness of removable and fixed functional appliances that have followed the treatment through to completion with fixed appliance therapy. This was the aim of our study.

This investigation had the null hypothesis that there is no difference in effectiveness between Twin-block and Herbst appliances.

MATERIAL AND METHODS

Seventeen hospital-based orthodontic specialists in the United Kingdom (UK) took part in the study. Each had undergone basic specialty training followed by 3 years of advanced training in the treatment of severe malocclusions. All were based in orthodontic departments working in the National Health Service of the UK. In this system, the orthodontists are salaried, 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 80% power with an α of .05 on a clinically meaningful difference in peer assessment rating (PAR) scores of 15% between the study groups.¹⁰ The calculation showed that we needed to recruit 80 patients into each arm of the study to account for an estimated noncompletion rate of 15%.

The patient inclusion criteria for this investigation were overjet ≥ 7 mm, second premolars erupted, and no craniofacial syndrome.

The protocol was approved by the relevant ethics committees. We followed the guidelines of the Declaration of Helsinki.¹¹

When a patient who satisfied the inclusion criteria attended a study clinic, he or she was invited to enter the study. When consent was obtained from the child and the parent, the orthodontist gave patient details to the study center at Manchester University by telephone. After initial recording of the data, the patient was randomized to receive treatment with either a Twin-block or a Herbst appliance. At the beginning of the study, random number tables were used to prepare randomization lists, stratified by center and sex into permuted blocks.

We used a modification of the original Twin-block design, shown in Figure 1.^{6,12} This appliance consisted of maxillary and mandibular removable appliances retained with Adams clasps on the first permanent molars and first premolars. For additional retention, we used 0.9-mm ball clasps in the mandibular incisor interproximal areas and a 0.7-mm maxillary labial bow, which was only activated when the maxillary incisors 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 steeply inclined planes interlocked at about 70° to the occlusal plane. When necessary, compensatory lateral expansion of the maxillary arch was achieved by means of an expansion screw that was turned once per week. Reactivation of the blocks was carried out when necessary. All patients were instructed to wear the appliance for 24 hours per day (except during contact or water sports). They were asked to wear the appliance while eating, if possible.

The patients visited the orthodontic departments every 4 to 8 weeks. When the overjet was fully reduced, the operator and patient decided on whether to have a second phase of fixed appliance therapy. If patients did not have this second phase, their treatment was finished by grinding the blocks and reducing the wear of the Twin-block to permit the occlusion to settle to a good interdigitation.¹² If they proceeded to a second phase of treatment, fixed appliances were fitted and the treatment continued until the orthodontist and patient were satisfied with the final occlusion.

The Herbst appliance used was a cast cobalt chromium design, as described by Panerz (Fig 2).⁸ In this design, the Herbst framework was extended from the canines posteriorly to include all the erupted teeth. Where possible, the occlusion was advanced to an edge-to-edge relationship. The appliances were cemented with glass ionomer cement. After fitting of the appliance, preadjusted edgewise fixed appliances were placed as soon as practicable. The patients were seen every 4 to 8 weeks. During this phase of treatment, if the operator thought that it was necessary, the appliance was advanced with collars placed on the pistons. When the overjet was fully reduced, the Herbst appliance was removed and the treatment completed. The fixed appliances were removed when the orthodontist and patient were satisfied with the final occlusion.

A patient was classified as noncompliant for both the treatment groups if overjet was not reduced by at least 10% after 6 months or if he or she broke or damaged the appliance so that treatment was not practicable.

Data were collected on the patients at the following points: data collection 1 (DC1) was completed when



Fig 1. Design of Twin-block used in study.



Fig 2. Design of Herbst appliance used in study.

each patient entered the study, and the final data collection (DC2) occurred when the treatment was completed. The following were collected by each orthodontist and sent to the study coordinating center:

- Study models
- Cephalometric radiographs
- The patient's postal code, used to obtain data on the patient's level of social deprivation, according to the Carstairs index¹³
- A questionnaire that gathered information on the patient's perception of the appliance, directed at the effect of the appliance on (1) speaking, eating, drinking, and appearance; (2) schoolwork; (3) relationships with friends; (4) relationships with their families; and (5) hobbies and interests. This was given to the patients 4 months after the Herbst or Twin-block appliances were fitted.
- The number of visits required to complete treatment, additional appointments for appliance repairs, the number of appliance repairs made, duration of treatment, and date of birth, obtained from each patient's chart

The cephalograms were corrected for magnification and analyzed with the Pancherz analysis.⁸ The study casts were scored with the PAR with the UK weightings.¹⁰ Cephalograms and study casts were both scored with the examiner unaware of the group to which the patient had been allocated. The examiner rescored 30

sets of study casts and 20 cephalograms, and error was evaluated with the intraclass correlation coefficient (ICC) and Student *t* test. This showed no bias for the PAR index and 0.92 for the ICC. 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 (standard deviation 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.

We also recorded the stages of maturation of the cervical spine from the pretreatment cephalograms, according to the method described by Hassel and Farman.¹⁴ Thirty sets of radiographs were reanalyzed, and error was evaluated with the κ statistic, giving a κ value of 0.94; this was acceptable.

Data analysis was performed with SPSS 10.0 (SPSS, Chicago, Ill) and was restricted to generation of descriptives and regression analyses on (1) the process of treatment; (2) factors influencing whether the patient completed the functional appliance phase of the treatment; (3) the final anteroposterior skeletal discrepancy, as calculated by the Pancherz analysis (defined as A/OLp – Pg/OLp); (4) the posttreatment overjet; and (5) the final PAR score.

We carried out an intention-to-treat analysis of the data, and the results of all patients were analyzed

Table I. Details of variables that were entered into different regression analyses

Independent variables assessed at start of modeling process	Type of regression				
	Logistic regression	Linear regression (Sums of squares Type II)			
	Failure to complete (yes/no)	Natural logarithm of duration of functional treatment in months	Skeletal discrepancy measured by Pancherz analysis	Overjet	PAR score
Baseline value				V	V
Treatment group	F(2)	F(2)	F(2)	F(2)	F(2)
Center	F(13)	F(13)	F(13)	F(13)	F(13)
Gender	F(2)	F(2)	F(2)	F(2)	F(2)
Age	F(3)	V			
Carstairs social deprivation index	F(2)	V	V	V	V
Pretreatment cephalometric values (A/OLp, Pg/OLp, max/mand plane)			V	V	V
Time from registration to DC2 cephalograms			V	V	V
Spine maturation	F(4)	F(4)	F(4)	F(4)	F(4)
Treatment × center	F(2) × F(13)	F(2) × F(13)	F(2) × F(13)	F(2) × F(13)	F(2) × F(13)
Gender × center	F(2) × F(13)	F(2) × F(13)	F(2) × F(13)	F(2) × F(13)	F(2) × F(13)

F, Factor (number of levels); V, continuous variable.

regardless of the outcome of treatment. Details of the type of regression and the independent variables assessed during the modeling process are shown in Table I. No interim modeling of the data was carried out.

We initially considered center × treatment group and gender × treatment group interaction terms in all models.¹⁵ Simpler models were then found by removing nonsignificant variables. When variables were removed, the regression coefficients were compared with the previous model to ensure stability of effect.

Data on the patients' perceptions of their appliances were analyzed with the Wilcoxon-Mann-Whitney test.

RESULTS

A total of 215 patients were enrolled in the study: 110 (62 girls and 48 boys) were allocated to receive treatment with the Twin-block, and 105 (55 girls and 50 boys) to the Herbst group (Fig 3). Enrollment started in March 1997 and was completed by June 1998. DC2 was done in September 2001. The average age of the children was 12.41 (95% confidence interval [CI] 12.17-12.63) and 12.74 (95% CI 12.48-12.99) years for the Twin-block and Herbst appliance groups, respectively. The number of patients entered by each department ranged from 4 to 39. In the largest department, 2 operators treated the patients. The mean deprivation scores for the patients ranged from -1.18 to 3.68, with high scores representing higher levels of deprivation.

Details of the treatment process are given in Table II.

Analysis with the Wilcoxon-Mann-Whitney test showed no difference in the total duration of treatment between the Herbst and the Twin-block groups ($P = .53$). However, the patients who wore the Twin-block appliance spent more time in the functional appliance phase of treatment ($P < .0005$), and they had slightly more routine appointments ($P < .04$). When we considered the number of additional appointments that were needed because of breakage or debonding of the appliances, it seemed that there were considerably more appointments for the Herbst appliance group ($P < .0005$).

The regression for log duration of the time of the functional appliance phase is shown in Table III. We found a significant interaction between center and duration of the functional phase. This was studied by dividing the centers into 2 groups according to the duration of the functional phase. This led to the following findings:

- The use of a Twin-block appliance increased the duration of treatment by a factor of 2.2 months compared with the Herbst appliance in centers with shorter treatment times, compared with a factor of 1.5 months in centers with longer duration.
- Patients who were classified as being at cervical spine development stage CVs1 spent 1.4 times longer in their functional appliance than those in the later developmental stages.
- There was a correlation between socioeconomic status and duration of treatment regardless of appliance.

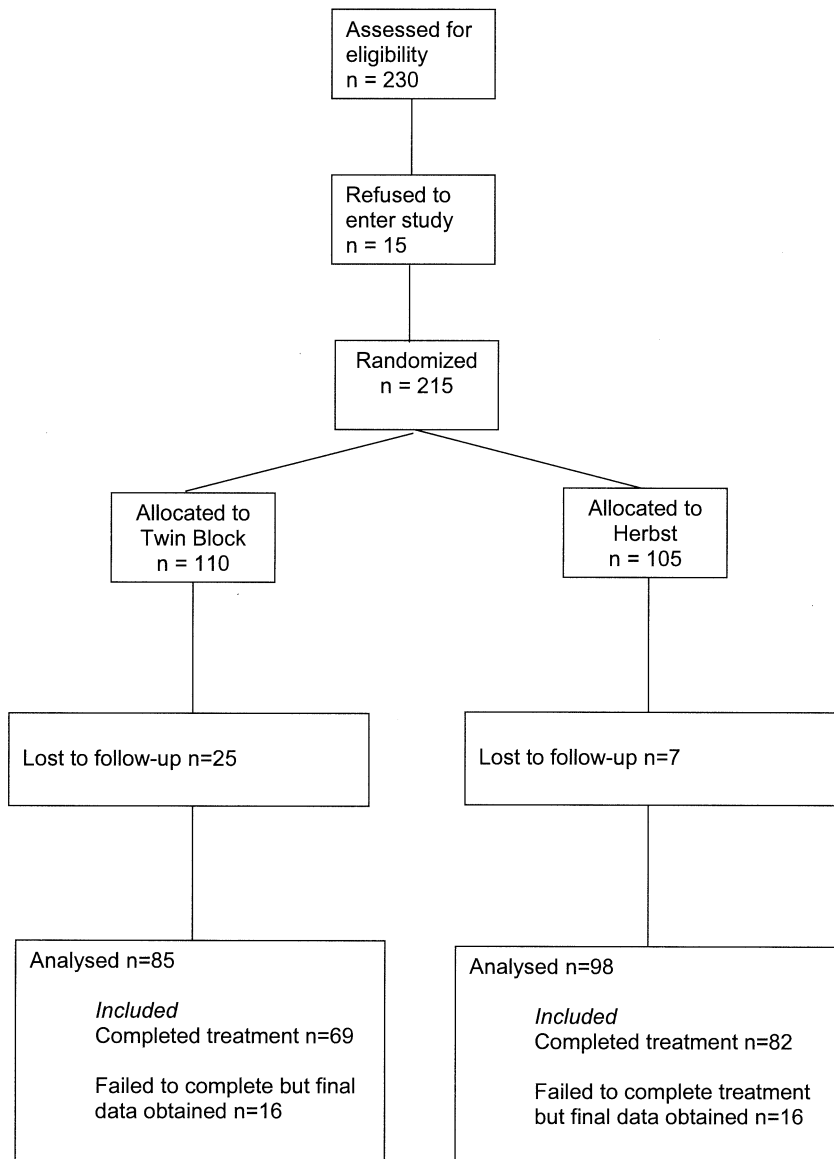


Fig 3. Flow chart of patients in study.

The 2 appliances differed significantly in cost. The average costs were \$350 for the Herbst and \$80 for the Twin-block.

We found that 37 (33.6%) of the children in the Twin-block group and 18 (12.9%) of the Herbst patients did not complete the functional appliance phase of treatment ($P = .01$). None of the noncompliant patients received a second phase of fixed appliance treatment. The regression analysis of this data is shown in Table IV.

This shows that fitting with a Twin-block appliance increased a patient's chance of not completing the functional appliance phase of treatment by 2.4 times,

compared with a Herbst appliance. There was also an effect of the patient's level of social deprivation. This suggested that a child in the least-deprived quartile of our population had 4 times the chance of completing treatment than did a child in the most deprived quartile, regardless of the appliance.

By using a cutoff value of the predicted probability from the regression of 0.35, 58.7% of those not completing and 70.1% of those completing functional treatment were correctly predicted by this regression.

Data suggest that the patients treated with the Twin-block thought that their speech and sleep patterns had changed, and they felt embarrassed about their

Table II. Treatment process data

	<i>Twin-block</i>	<i>Herbst</i>	P (<i>Mann-Whitney</i>)
Number of visits			
Total	16.05 (14.35 to 17.76) n = 56	20.21 (18.57 to 21.86) n = 70	.0005
Functional phase	8.64 (7.71 to 9.57) n = 50	9.09 (8.24 to 9.93) n = 70	.0005
Regular visits	5.63 (5.00 to 6.25)	4.50 (4.05 to 4.94)	.04
Emergency visits	1.55 (1.02 to 2.09)	4.29 (3.51 to 5.06)	.0005
Fixed phase—only patients receiving fixed phase	11.53 (9.95 to 13.10) n = 36	12.77 (11.48 to 14.06) n = 61	.23
Time in treatment (months)			
Functional phase	11.22 (9.58 to 12.86) n = 56	5.81 (5.13 to 6.48) n = 70	.0005
Fixed phase—only patients receiving fixed phase	14.81 (12.63 to 16.99)	16.29 (14.57 to 18.01)	.292
Total treatment time	21.99 (19.50 to 24.49)	20.84 (18.88 to 23.27)	.53

Data are presented as mean (95% CI).

Table III. Results of regression duration of treatment when functional appliance was in place (months) as dependent variable

<i>Significant variables</i>	<i>Coefficient</i>	<i>95% CI for coefficient</i>	P
Treatment group (Twin-block)	2.17	1.71 to 2.75	<.0005
Center (1)	1.43	1.11 to 1.83	.044
Cervical spine staging (1)	1.42	1.03 to 1.95	.029
Carstairs social deprivation index	0.97	1.57 to 0.99	.038
Treatment (Twin-block) × center (1)	0.68	0.46 to 1.00	.049
Constant	3.96	3.29 to 4.76	<.005
Time in functional phase (months)	Twin-block (n = 56)	Herbst (n = 70)	
Center = 1	12.01 (8.75 to 15.27)	7.09 (5.93 to 8.25)	
Center = 2	10.70 (8.88 to 12.53)	4.90 (4.17 to 5.63)	

Log duration of treatment was used in the model. These figures have been converted back from log scale.

Table IV. Regression analysis on dependent variables of patients who did not complete functional appliance phase of treatment

<i>Significant variables</i>	<i>Regression coefficient</i>	<i>Odds ratio for noncompletion of functional treatment</i>	<i>95% CI of odds ratio</i>	P
Treatment (Twin-block)	0.868	2.38	1.178 to 4.83	.018
Deprivation score				.087
Level 1 (lowest)	-1.376	0.253	0.08 to 0.77	
Level 2	-0.150	0.861	0.35 to 2.12	
Level 3	-0.089	0.915	0.38 to 2.23	
Compared with Level 4 (highest deprivation score)	0	1		
Constant	-1.315	0.268		.001

appliance. Importantly, they also believed that these factors influenced their relationships with family (Mann-Whitney $P < .001$). When we evaluated these factors for the Twin-block patients who did not complete the functional appliance phase of treatment, it seemed that they felt that the problems with eating influenced their schoolwork, and they were more embarrassed with their families than were the patients who

completed the functional phase (Mann-Whitney $P < .001$). Similarly, Herbst appliance patients who did not complete phase I treatment reported more problems with eating (Mann-Whitney $P < .005$).

Analysis of the cervical spine maturational data showed that the patients could be classified into the following groups: Cvs1 = 19 (8%), Cvs2 = 53 (24%), Cvs3 = 66 (30%), Cvs4 = 40 (18%), Cvs5 = 1

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

	Twin-block (n = 63)				Herbst (n = 67)			
	Before		After		Before		After	
	Mean	95% CI	Mean	95% CI	Mean	95% CI	Mean	95% CI
Overjet (Is/OLp - Ii/OLp)	+10.29	+9.77 to +10.81	+4.05	+3.42 to +4.68	+9.33	+8.76 to +9.90	+3.53	+3.20 to +3.85
Molar relation (Ms/OLp - Mi/OLp)	+1.96	+1.52 to +2.42	-1.66	-2.29 to -1.02	+1.27	+0.77 to +1.76	-1.76	-2.35 to -1.17
Maxillary base (A point to OLp)	+71.46	+70.50 to +72.42	+73.31	+72.11 to 74.51	+72.10	+70.92 to +73.19	+73.33	+72.06 to +74.60
Mandibular base (Pg/OLp)	+71.72	+70.49 to +72.95	+76.14	+74.65 to +77.64	+72.56	+71.09 to +73.83	+76.22	+74.55 to +77.88
Skeletal discrepancy (A point to OLp - Pg/OLp)	-0.26	-1.03 to +5.09	-2.83	-3.68 to +1.99	-0.46	-1.32 to +0.41	-2.89	-3.68 to -1.92
Condylar head (Co/OLp)	-13.40	-14.08 to -12.71	-14.36	-15.14 to -13.57	-13.22	-13.93 to -12.55	-13.52	-14.23 to -12.80
Mandibular length (Pg/OLp + Co/OLp)	+58.32	+56.90 to +59.74	+61.78	+60.01 to +63.56	+59.34	+57.64 to +60.79	+62.70	+60.83 to +64.56
Maxillary incisor (Is/OLp - Ss/OLp)	+9.40	+8.93 to +9.87	+6.29	+5.6 to +7.02	+8.50	+8.00 to +8.99	+6.07	+5.43 to +6.72
Mandibular incisor (Ii/OLp - Pg/OLp)	-1.15	-1.96 to -0.37	-0.59	-1.54 to +0.35	-1.29	-2.19 to -0.38	-0.35	-1.27 to +0.57
Maxillary molar (Ms/OLp - Ss/OLp)	-21.48	-22.07 to -20.89	-21.08	-21.73 to -20.42	-21.80	-22.30 to -21.30	-21.32	-22.10 to -20.26
Mandibular molar (Mi/OLp - Pg/OLp)	-23.71	-24.55 to -22.88	-22.25	-23.24 to -21.26	-23.53	-24.30 to -22.76	-22.46	-23.39 to -21.53

Table VI. Change in Pancherz analysis variables

	Twin-block		Herbst	
	Mean	95% CI	Mean	95% CI
Overjet (Is/OLp - Ii/OLp)	-6.24	-5.47 to -7.00	-5.80	-6.42 to -5.18
Molar relation (Ms/OLp - Mi/OLp)	-3.62	+5.07 to +6.69	-3.03	-3.53 to -2.53
Skeletal changes				
Maxillary base (A point to OLp)	+1.85	+1.2 to +2.49	+1.22	+0.70 to +1.74
Mandibular base (Pg/OLp)	+4.42	+3.63 to +5.20	+3.66	+2.89 to +4.43
Condylar head (Co/OLp)	-0.96	-0.51 to -1.39	-0.30	-0.67 to +0.08
Mandibular length (Pg/OLp + Co/OLp)	+3.46	+2.45 to +4.47	+3.36	+2.51 to +4.21
Dental changes				
Maxillary incisor (Is/OLp - Ss/OLp)	-3.11	-2.31 to -3.91	-2.43	-3.00 to -1.85
Mandibular incisor (Ii/OLp - Pg/OLp)	+0.56	-0.29 to +1.13	+0.94	+0.37 to +1.51
Maxillary molar (Ms/OLp - Ss/OLp)	+0.40	-0.21 to +1.02	+0.48	-0.19 to +1.14
Mandibular molar (Mi/OLp - Pg/OLp)	+1.45	+0.66 to +2.55	+1.07	+0.61 to +1.53

(0.004%), and Cvs 6 = 0. It was not possible to categorize 35 patients (16%) because the radiographs were not clear in the cervical spine area. The cephalometric data at the start and end of treatment are shown in Table V, and Table VI contains the data for cephalometric change.

The mean pretreatment PAR scores were 34 (95% CI 31.74-36.25) for the Twin-block group and 31.14 (95% CI 28.92-33.36) for the Herbst group. At the end of all treatment, the mean scores were 10.57 (95% CI 7.86-13.28) for the Twin-block group and 7.28 (95% CI 5.87-8.70) for the Herbst patients. When we considered

Table VII. Regression analysis on final skeletal discrepancy according to Pancherz analysis (A/OLp – Pg/OLp)

Significant variables	Coefficient	95% CI for coefficient	P
Pretreatment skeletal discrepancy	0.86	0.72 to 1.0	<.0005
Sex (female)	-1.6	-2.5 to -0.7	<.001

For regression analysis, n = 147, P < .0005, adjusted R² = 0.58.

change in score, the Twin-block group had a mean percentage reduction of 40 (SD = 29.3) and the Herbst patients had a decrease of 39 (SD = 21.1).

None of the variables that we considered for the final overjet regression was significant. However, a satisfactory model was formulated for the final skeletal discrepancy; this is shown in Table VII. This shows that the final skeletal discrepancy was influenced by the pretreatment discrepancy. It seems that treatment contributes to reducing the discrepancy, but it did not totally eliminate it. Importantly, the sex of the patients had an effect in the model, suggesting that girls had less skeletal II discrepancy than did boys at the end of treatment, regardless of the appliances.

We also constructed a satisfactory model for final PAR score (R² = 0.35, P = .001). The only variable that had an effect in this model was gender, with a β coefficient of 6.5 (95% CI 2.64-10.43).

DISCUSSION

The likelihood of patient cooperation is one of the most important factors influencing the choice of orthodontic treatment. This randomized clinical trial showed that cooperation with the Herbst appliance was greater than that with the Twin-block. The noncompletion rate with the Twin-block was twice that of the Herbst.

A considerable advantage of a prospective study is that the dropout or failure rate can be accurately measured. Other prospective investigations show dropout rates with Twin-block appliances of 15%,⁵ 17%,⁷ and even 50%.¹⁶

Although the level of noncompliance with the Twin-block was disappointing, even when the functional appliance was attached to the patient's teeth, the discontinuation rate was still rather high. It was not possible for us to compare our results with other studies in which compliance depended on treatment because, surprisingly, noncompliance data have not been reported.^{8,9} In our study, the main reason for discontinuation of treatment was persistent debonding of the Herbst appliance; this does not seem to be related to any

operator or patient factors. We can therefore conclude that, even when a functional appliance is fixed to the teeth, the probability that this treatment will be unsuccessful is 12.9%.

It is difficult to explain the high discontinuation rates that we found. The most plausible reason must be that this study was carried out in a "real world" setting, rather than a dental school with 1 or 2 operators. The setting of treatment might have had an influence. All treatment was provided at no cost to the child and parents; it could be suggested that paying a fee would ensure cooperation, but this is conjecture.

Another finding of note was the effect of social deprivation on completion rates of phase I treatment. It seemed that if a child resides in an area of high social deprivation, this markedly increased the likelihood of not completing treatment. This has not been detected in any other orthodontic investigation, because studies of factors that influence cooperation have concentrated on orthodontist-patient interactions.^{17,18} Our only other source of comparable data is to consider the influence of social deprivation on the uptake of dental care in the UK. It has been suggested that social deprivation can result in poor attendance, problems in keeping appointments, and relapse in oral care; these factors might then make the operator more likely to stop treatment.¹⁹ Because these findings can probably be extrapolated to orthodontic treatment, they might explain our findings.

This finding can be considered to be important, because it suggests that if a study includes only children from higher socioeconomic backgrounds, the results are likely to be biased toward successful treatment. This implies that all studies would have more generality if an assessment of socioeconomic status were included as an independent variable.

In all clinical investigations, it is important to gather information on the perceptions of the consumers of care. When the patients had worn their appliances for 4 months, we found differences between the 2 appliances. It appeared that the Twin-block, perhaps because of the bulky acrylic blocks, caused more problems than did the Herbst in eating and speaking. Arguably, the patient might repeatedly remove the appliance, thus influencing the ultimate success of treatment. Furthermore, it seems that the information patients currently receive (that a new appliance will be uncomfortable for only a few days) does not reflect their actual experience.

It seems that the Herbst appliance was more effective at reducing overjet in phase I of treatment. Unfortunately, this did not lead to shorter overall treatment times, because the second phase of fixed appliance treatment was longer. There may be several reasons for

this; the most likely is that any trimming of the Twin-blocks during the later months of phase I treatment results in correction of dental features, thus reducing the complexity of any fixed appliance therapy. In contrast with the Herbst, the second phase may be more complex because of persistence of such features as posterior lateral open bites.

The duration of the functional appliance phase of treatment was influenced by a factor that was attributable to the treatment center. We could not identify any variable that could explain this finding, and it appears that this is an unexplained effect of treatment center. This is not unusual for multicenter studies and reflects the pragmatic nature of this investigation.

We were disappointed to find that the Herbst appliance was prone to damage resulting in debonding and fractured components. This has not been reported in the literature. However, an unpublished thesis showed much higher breakage and debonding rates.²⁰ As a result, it could be suggested that the trade-off for the increased compliance rate is that the patient must return to the clinician for several appliance repairs during the functional phase of treatment.

Evaluation of the morphologic effects of the appliances shows that most of the changes were dental; the maxillary incisors were retracted and the mandibular incisors were proclined. In addition, the skeletal changes were less than those reported in retrospective investigations.^{8,9}

When we consider the dental effects of the appliances, treatment group was not significant in explaining the final overjet, and we conclude that both treatments are equally effective at reducing overjet. We did, however, succeed in fitting a model for the final PAR score. It appears that there was more residual malocclusion for boys than for girls, and the difference of 6 PAR points is clinically significant. This could have resulted in differences in cooperation between girls and boys. This is worth further investigation.

When the data on final skeletal discrepancy are evaluated, a minus value for the Pancherz skeletal discrepancy means that a patient is less Class II than if he or she had a positive value. Interpretation of the regression for the effect of sex with the β coefficients suggests that, after treatment, girls were 1.6 mm less Class II than were boys, regardless of whether they received Twin-block or Herbst treatment.

It is difficult to explain these effects. They could be due to different developmental stages of the boys and girls in the study. However, the cervical spine growth staging did not have an influence in the model. Another reason could be potential differing levels of cooperation (as suggested for the difference in PAR scores); nev-

ertheless, this was not counteracted by the use of the Herbst appliance that did not depend on compliance.

We also found that the initial skeletal discrepancy influenced the outcome. It appears that the initial discrepancy was not totally counteracted by the effects of the treatment. This is a similar finding to that from our study on the effects of early orthodontic treatment with the Twin-block.²¹ In addition, we also found that when we included maxillary/mandibular plane angle as a measure of vertical proportion in the regression, it did not have an effect in the model. This suggests that the orthodontic clinical perception that patients with reduced facial heights or large skeletal discrepancies respond better to functional appliances is not correct.

Another important finding was the possible effects of stage of maturation of the cervical spine. It has been suggested that the best time to provide treatment is between CVs3 and CVs4, because this coincides with peak growth of the mandible.^{22,23} Although the results of the analysis of the duration of time in functional appliance data seem to reinforce this finding, this was not found for our data on skeletal discrepancy, and neither did this explain the different final skeletal relationships between girls and boys. As a result, our data do not support this theory, and it requires investigation in other prospective studies.

The Herbst appliance has some advantages over the Twin-block, mostly concerning increased compliance. Nevertheless, the trade off for these benefits is the additional cost of appliance construction and the extra visits for appliance repair. This will ultimately determine the uptake of this technique. This study adds to our knowledge of the effects of functional appliances; however, its findings might not be totally applicable to other countries or health care systems. Other researchers should repeat this methodology in other locations.

CONCLUSIONS

From this study, we can conclude that:

1. Patient cooperation with the Herbst appliance is better than that with the Twin-block.
2. Phase I treatment is more rapid with the Herbst appliance, but overall duration of treatment is similar to that with the Twin-block.
3. The Herbst appliance is prone to debonding and component breakage.
4. There are no differences in the dental and skeletal effects of treatment between the 2 appliances, but there was a marked sex effect: girls responded to treatment better than boys.

The authors thank the patients for taking part in this study and the supporting staff for their additional work at the treatment centers.

REFERENCES

1. Tulloch JFC, Philips C, Proffit WR. Benefit of early Class II treatment: progress report of a two-phased randomized clinical trial. *Am J Orthod Dentofacial Orthop* 1998;113:62-72.
2. Keeling SD, Wheeler TT, King GJ, Garvan CW, Cohen DA, Cabassa S, et al. Anteroposterior skeletal and dental changes after early Class II treatment with bionators and headgear. *Am J Orthod Dentofacial Orthop* 1998;113:40-50.
3. Ghafari J, Shofer FS, Jacobsen-Hunt U, Markowitz DL, Laster LL. Headgear versus functional regulator in the early treatment of Class II, Division 1 malocclusion. *Am J Orthod Dentofacial Orthop* 1998;113:51-61.
4. Nelson CN, Harkness M. Mandibular changes during functional appliance treatment. *Am J Orthod Dentofacial Orthop* 1993;104:153-61.
5. Illing HM, Morris DO, Lee RT. A prospective evaluation of Bass, bionator and Twin-block appliances. Part 1—the hard tissues. *Eur J Orthod* 1998;20:501-16.
6. Lund I, Sandler PJ. The effects of Twin-Blocks: a prospective controlled study. *Am J Orthod Dentofacial Orthop* 1998;113:104-10.
7. Harradine NWT, Gale D. The effects of torque control spurs in twin-block appliances. *Clin Orthod Res* 2000;3:202-9.
8. Panchez H. The mechanism of Class II correction in Herbst appliance treatment. *Am J Orthod* 1982;82:104-13.
9. Franchi L, Baccetti T, McNamara JA. Treatment and posttreatment effects of acrylic splint Herbst appliance therapy. *Am J Orthod Dentofacial Orthop* 1999;115:429-38.
10. Richmond S, Shaw WC, O'Brien KD, Buchanan R, Jones R, Stephens CD, et al. The development of the PAR index (Peer Assessment Rating): reliability and validity. *Eur J Orthod* 1992;14:125-39.
11. World Medical Association. Ethical principles for medical research involving human subjects (Declaration of Helsinki). Available at: http://www.wma.net/e/policy/17-c_e.html. Accessed May 2, 2003.
12. Clark WJ. *Twin-block functional therapy*. London: Mosby-Wolfe; 1995.
13. Carstairs V. Multiple deprivation and health state. *Community Med* 1981;3:4-13.
14. Hassel B, Farman AG. Skeletal maturation evaluation using cervical vertebrae. *Am J Orthod Dentofacial Orthop* 1995;107:58-66.
15. Senn S. Some controversies in planning and analysing multicentre trials. *Stat Med* 1998;17:1753-65.
16. Baton S, Cook PA. Predicting functional appliance treatment outcome in Class II malocclusions—a review. *Am J Orthod Dentofacial Orthop* 1997;112:282-6.
17. Sinha PK, Nanda RS, McNeil DW. Perceived orthodontist behaviors that predict patient satisfaction, orthodontist-patient relationship, and patient adherence in orthodontic treatment. *Am J Orthod Dentofacial Orthop* 1996;110:370-7.
18. Nanda RS, Kieri MJ. Prediction of cooperation in orthodontic treatment. *Am J Orthod Dentofacial Orthop* 1992;102:15-21.
19. Pavi E, Kay EJ, Shepherd KW. The effect of social and personal factors on the utilisation of dental services in Glasgow, Scotland. *Community Dent Health* 1995;12:208-15.
20. Tse ELK. A comparative study of the skeletal and dental effects of a modified Herbst appliance and traditional Herbst in Southern Chinese—a prospective study [thesis]. Hong Kong: University of Hong Kong; 1994.
21. O'Brien KD, Wright J, Conboy F, Sanjie Y, Mandall N, Chadwick S, et al. Effectiveness of early orthodontic treatment with the Twin-block appliance: a multicenter, randomized, controlled trial: Part I. Dental and skeletal effects. *Am J Orthod Dentofacial Orthop* 2003 (in press).
22. Franchi L, Baccetti T, McNamara JA. Mandibular growth as related to cervical vertebral maturation and body height. *Am J Orthod Dentofacial Orthop* 2000;118:335-40.
23. Baccetti T, Franchi L, Toth LR, McNamara JA. Treatment timing for Twin-block therapy. *Am J Orthod Dentofacial Orthop* 2000;118:159-70.