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SCIENTIFIC SECTION

Is early class III protraction facemask treatment effective? A multicentre, randomized, controlled trial: 15-month follow-up

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Objective: To investigate the effectiveness of early class III protraction facemask treatment in children under 10 years of age.

Design: Multicentre, randomized controlled trial.

Setting: Eight UK hospital orthodontic units.

Subjects and methods: Seventy-three patients were randomly allocated, stratified for gender, into an early class III protraction facemask group (PFG) (n=35) and a control/no treatment group (CG) (n=38).

Outcomes: Dentofacial changes from lateral cephalograms and occlusal changes using the peer assessment rating (PAR). Self-esteem was assessed using the Piers–Harris children's self-concept scale, and the psychosocial impact of malocclusion with an oral aesthetic subjective impact scores (OASIS) questionnaire. Temporomandibular joint (TMJ) signs and symptoms were also recorded. The time points for data collection were at registration (DC1) and 15 months later (DC2).

Results: The following mean skeletal and occlusal changes occurred from the class III starting point: SNA, PFG moved forwards 1.4° (CG forward 0.3°; P=0.018); SNB, PFG moved backwards −0.7° (CG forward 0.8°; P<0.001); ANB, PFG class III base improved +2.1° (CG worsened by −0.5°; P<0.001). This contributed to an overall difference in ANB between PFG and CG of 2.6° in favour of early protraction facemask treatment. The overjet improved +4.4 mm in the PFG and marginally changed +0.3 mm in the CG (P<0.001). A 32.2% improvement in PAR was shown in the PFG and the CG worsened by 8.6%. There was no increased self-esteem (Piers–Harris score) for treated children compared with controls (P=0.22). However, there was a reduced impact of malocclusion (OASIS score) for the PFG compared with the CG (P=0.003), suggesting treatment resulted in slightly less concern about the tooth appearance. TMJ signs and symptoms were very low at DC1 and DC2 and none were reported during active facemask treatment.

Conclusions: Early class III orthopaedic treatment, with protraction facemask, in patients under 10 years of age, is skeletally and dentally effective in the short term and does not result in TMJ dysfunction. Seventy per cent of patients had successful treatment, defined as achieving a positive overjet. However, early treatment does not seem to confer a clinically significant psychosocial benefit.

Key words: Class III skeletal pattern, early orthopaedic treatment, protraction facemask, randomized controlled trial

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Introduction

The prevalence of class III malocclusion in Europeans is 3–8%,[1–4] with 42–63% exhibiting maxillary retrusion with or without a prognathic mandible.[5] Orthopaedic treatment for class III skeletal problems is aimed at reducing or redirecting mandibular growth and enhancing maxillary growth. One option is a functional appliance; however, retrospective studies suggest they have no skeletal effect.[6–9] A second option is to use a chin cup, but response to this treatment is not reported as orthopedic *per se*. There is no effect on the maxilla or cranial base, and the reduction in chin prominence is primarily because of a downward and backward mandibular rotation.[10–12] Two studies have shown that when a combined chin cup and maxillary protraction headgear is used there is approximately 2° of maxillary protrusion, 1° of mandibular retrusion and an overall jaw relation improvement of 3°.[13,14]

Where the aetiology of the class III skeletal pattern is a retrusive maxilla, then protraction headgear would be the treatment of choice. In the UK, early protraction facemask treatment has not been in widespread use, possibly because of the lack of long term evidence to convince clinicians that patients will not outgrow the class III correction.

Previous studies in this area have involved prospective designs, but many have been retrospective investigations with matched controls. Overall, these studies have shown that protraction headgear has an orthopaedic effect with an increase in SNA of up to 2°. ANB also improved in some studies to around 3°, often secondary to a downwards and backwards mandibular rotation. This, as well as dental changes, resulted in an average 6 mm improvement in positive overjet.[15–23] In addition, younger children under 10 years old, are reported to respond more favourably as, theoretically, the circumaxillary sutures are more amenable to orthopaedic protraction.[5,24–27] However, this is not always clear cut, as other authors have not detected improved treatment outcomes in younger patients.[28,29]

Whilst there is a lack of prospective literature investigating early protraction facemask treatment, there have been two systematic reviews and meta analyses on existing retrospective and prospective studies.[21,30] The latter review compared orthopaedic class III treatment effect with control groups and suggested a mean forward movement at SNA of 1.4°, backward movement of SNB −1.3° and a combined improvement in ANB of 2.6°.

The aim of this multicentre, prospective, randomized clinical trial was to investigate the effectiveness of early class III orthopaedic treatment in children under 10 years of age. This was in an attempt to assess the long term effectiveness of early class III orthopaedics, which, up until now, has mainly been retrospectively reported and may therefore have over-estimated treatment effectiveness.

The working hypotheses tested were that early class III orthopaedic treatment with a protraction facemask compared with control will lead to differences in:

- skeletal or dental relationships;
- psychosocial well being;
- temporomandibular joint (TMJ) pain dysfunction.

Subjects and methods

Study setting

Patients were recruited through UK orthodontic departments at five district general hospitals and three teaching hospitals. Patient recruitment was optimized by writing to all general dental practitioners, who referred to each unit, explaining the type of patient we were looking to recruit. Additionally, the consultant orthodontist in each centre screened up to five local primary schools for suitable children in the 8–9 years old age group. Multicentre and local ethical and Research and Development approval was obtained (MREC reference: 03/8/2).

Sample size calculation

Initial calculations, based on expected changes in SNA and ANB, derived from previous protraction facemask literature resulted in extremely small sample sizes ($n=3$ per group). Therefore, this sample size calculation was based on an expected occlusal improvement as measured by the peer assessment rating (PAR).[31] Ngan *et al.*[32] showed that a significant majority of patients treated with a protraction facemask, had a PAR score improvement of at least 30%. We then estimated that our treated patients might be expected to achieve a mean PAR score improvement of 25%. This was set slightly lower than 30% because there was a possibility that previous retrospective data might have overestimated treatment success. No patient in the control group was expected to show any improvement in class III skeletal pattern, so the improvement in PAR was set at 0%.

It was determined that a sample size of 23 in each group (protraction and control) would have a 90% power to detect a difference in means of 0.25 (difference between a test group mean PAR reduction of 25% and a control group mean PAR reduction of 0%) assuming a common standard deviation of 0.25 using a two group test with a

0.05 two sided significance level. Thus, a total sample size of 46 patients was needed for the trial. In order to allow for long-term attrition, 73 patients were recruited.

Inclusion criteria

The following inclusion were applied

- seven to nine years old at the time of registration
- three or four incisors in crossbite in the intercuspal position
- clinical assessment of a class III skeletal problem.

A lateral cephalogram was not considered to be ethically justified to screen patients prior to the study; therefore inclusion was based on clinical rather than radiographic assessment of skeletal pattern. The initial examination was carried out by ensuring that the patient was in the retruded contact position and the emphasis was placed on detecting a retrusive maxilla rather than a protrusive mandible, since protraction facemask treatment is aimed at correcting a class III skeletal pattern where the actiology is maxillary protrusion.

Exclusion criteria

The following exclusion criteria were applied:

- child of non-Caucasian origin
- cleft lip and palate and/or craniofacial syndrome
- a maxillo-mandibular planes angle greater than 35° or lower face height greater than 70 mm[33]
- previous history of TMJ signs or symptoms
- lack of consent.

Patient assignment

Patients eligible for inclusion were approached and written informed consent was obtained from the patient and parent. The patient was then randomly allocated to the protraction facemask group (PFG) or control/no treatment group (CG). The randomization list was generated in randomization blocks of 10 with stratification according to gender. Stratification meant that a separate randomization list was generated for girls and boys, since gender was considered to be a potential confounding factor. This was because girls and boys will grow at different times during the study and, thus, potentially confound class III skeletal measurements. The computer generated randomization sequence was concealed centrally and each clinician telephoned a research assistant there to receive the treatment allocation after each patient was registered.

Data collection

Data were collected at the following time points:

- DC1: baseline data at trial registration
- DC2: 15 months after baseline data collection.

A 15 month data collection point was agreed to give clinicians time to carry out the protraction facemask treatment for 6 to 12 months, as necessary, and also allowing for a few weeks delay going into active treatment after trial registration.

The following records were collected at each time point:

- lateral cephalometric radiograph in intercuspal position
- study models with wax bite recorded in the intercuspal position
- Piers–Harris children's self-concept scale
- oral aesthetic subjective impact score (OASIS)
- a standardized clinical examination for TMJ dysfunction.

Control group

Following collection of DC1 records the patients allocated to the control group received no clinical intervention. They were recalled 15 months after registration for collection of DC2 records.

Clinical intervention for patients in the active treatment group

Rapid maxillary expansion (RME) (Figure 1). A bonded maxillary acrylic expansion device was placed as outlined by Baccetti *et al.*[24] This consisted of a metal framework and a midline expansion screw to which 3 mm acrylic was adapted. The appliance was modified, if needed, with acrylic extending over the upper incisor edges to increase appliance retention. One vestibular hook was located, on each side, in the upper deciduous first molar position, for elastic traction. The appliance was cemented with glass ionomer cement, but if it later debonded, it was re-cemented with composite, following acid etching of the buccal and palatal cusps of the upper first permanent molars. For patients with posterior crossbites, the expansion screw was activated one quarter turn (0.25 mm) per day until the lingual cusps of the upper posterior teeth approximated the buccal cusps of the lower posterior teeth. If no transverse change was required the maxillary splint was still activated once a day for 7–10 days in order to disrupt the circum-maxillary sutures.

Protraction face mask (Figure 2). A commercially available adjustable facemask was used (TP Orthodontics),

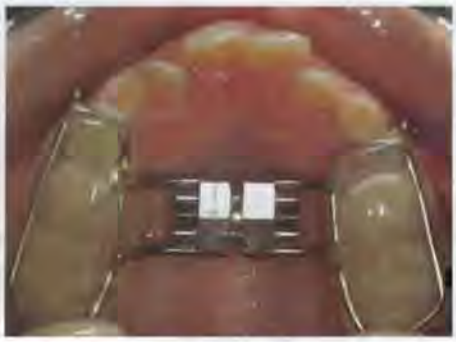

Figure 1 RME design for protraction facemask

which had bilateral vertical rods connected to both chin and forehead pads. This design is adjustable vertically to customize the fit. If patients experienced chin reddening, ventilation holes were drilled through the plastic chin pad or soft padding was added. Elastics were connected bilaterally to the adjustable midline crossbow in a downwards and forwards direction. Patients were asked to wear the facemask for 14 hours per day, continuously, during the evening and night. A co-operation calendar was used in an attempt to increase treatment compliance, although this was not formally statistically evaluated.

Extra oral elastics of increasing strength were used (3/8″ 8 oz elastics for 1–2 weeks; then 1/2″ 14 oz elastics; then 5/16″ 14 oz elastics) until a force of 400 g per side was delivered.[24] The direction of elastic traction was downwards and forwards 30° from the vestibular hooks on the bonded maxillary expander to the adjustable crossbar of the facemask. Additionally, the elastics could be crossed over to prevent catching or interference with the corners of the lips.

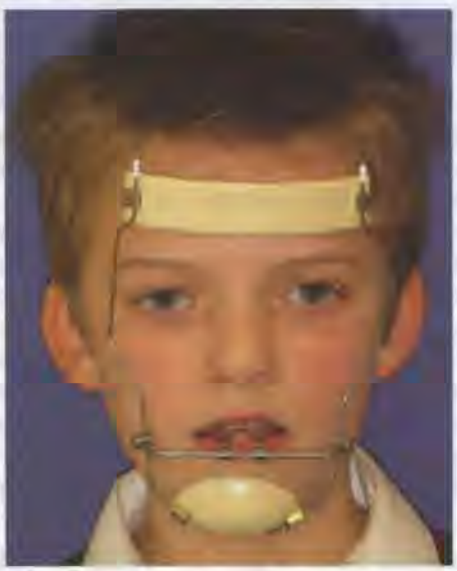

Figure 2 Protraction facemask

Clinical end point. End of active treatment was defined as when the facemask treatment had achieved a correction of the incisal relationship to class I or positive overjet, class I molars and/or a correction of the class III skeletal pattern to a clinically apparent class I skeletal relationship.

Once the active treatment had finished, none of the patients in the PFG received any form of retention. A functional appliance is sometimes used to try to maintain the protraction facemask correction; however, because our study was specifically looking at the effect of the protraction facemask, the additional use of a functional appliance would have been a confounding factor.

Most patients would have had active facemask treatment for a considerably shorter time than 15 months. When the active facemask treatment had finished, the clinician waited until the 15 months data collection 2 (DC2) time point for record collection. This 15 months period enabled completion of facemask treatment whilst allowing for delays between registration and fitting the appliances. Therefore, at DC2, no patient had RME still cemented in place or was still receiving active protraction facemask treatment.

Outcomes measures

Cephalometric and occlusal measurements. The lateral cephalograms were traced by an experienced clinician (NS) who was blinded as to group allocation. To determine the rotations of the maxillary and occlusal planes superimposition of the DC1 and DC2 lateral cephalometric radiographs was undertaken by another author (IS) using Bjork's structural method which employs the anterior zygomatic process as the reference landmark.[34,35] PAR scores[31] were measured by a calibrated examiner (R McD). Overjet measurements were recorded from study models, with a steel millimetre ruler, by an experienced examiner (NM).

Overjet and lateral cephalogram measurements were carried out twice and a mean value calculated to reduce random error. Intra-examiner reliability was assessed by re-measuring 20 radiographs and 20 overjet scores and 30 PAR scores, 1 week apart.

Psychosocial measures. The Piers–Harris children's self-concept scale used was the short form consisting of 60 questions (compared with previous longer form of 80 questions) and it has been previously validated.[36] It was used to evaluate self-concept, which may have been

influenced by receiving early class III treatment. Psychosocial/oral health related quality of life effects of treatment were assessed using the OASIS,[37] which sums the impact of concern about appearance of teeth, including nice comments, unpleasant comments, teasing, avoidance of smiling, covering the mouth because of the teeth and self-perceived aesthetic component of the Index of Orthodontic Treatment Need.[38] Both questionnaires have previously been shown to have very good internal consistency or internal reliability.[36,37] Therefore, no repeatability assessment was made by asking study participants to repeat the questionnaire a few weeks after baseline or 15 month time points.

TMJ examination. All the orthodontists involved in the trial received training from a TMJ specialist before the start of the trial to ensure that the TMJ examination was standardized. This TMJ specialist also advised that an examination appropriate for this age group of children should assess pain (lateral and intra-auricular), clicking, crepitus, locking, muscle tenderness (temporalis, masseter, and lateral pterygoid), and restriction of jaw movement (maximum opening and lateral movement). In addition, the presence of forward mandibular displacement on closure was recorded.

TMJ signs or symptoms were recorded at DC1 to ensure no patients might be treated with protraction facemask that may exacerbate any TMJ problems through potential downwards and backwards rotation at the chin point. No patients were excluded at baseline because of pre-existing TMJ signs or symptoms. Any TMJ signs or symptoms occurring during active facemask treatment were recorded in the notes and further standardized recordings were taken at 15 months.

Blinding. It was not possible to blind the clinician or the patient in this study; however, the trial was single-blind, as the researchers measuring the radiographs and study models and the statistician were blind to the treatment/control allocation until the data were analysed and the code broken. Ideally the clinician collecting the records at the 15 month DC2 time point would have also been blinded as to group allocation; however this was not attempted, because only one operator was involved at each centre. They will have had the patient's notes in front of them and it was also likely that they would have remembered who had received protraction facemask treatment.

Patients leaving the study or refusing treatment. We collected as much data as possible on patients who dropped out of the study to reduce possible assessment bias. If a subject failed to co-operate during treatment and the clinician decided to stop the treatment the data were still collected. An 'intention to treat' analysis was carried out, therefore if a patient was allocated to the treatment group, but then subsequently failed to have the protraction facemask fitted, they were kept in the treatment group.

Statistics

Descriptive statistics were generated and the changes occurring between baseline (DC1) and 15 month follow-up (DC2) calculated. The data were checked for normality. Multiple linear regression models were fitted to the dependent variables (DC2) with DC1 data and group as covariates. Chi square tests were conducted for TMJ signs and symptoms and all analyses were conducted at the 0.05 level of significance.

Results

Table 1 shows high intra-examiner reliability for both the cephalometric and study model measurements. Root mean square values suggested that random error was within acceptable limits (root mean square: cephalometric values range 0.05 to 0.10°; PAR=1.35; overjet=0.13 mm). Calibration for the PAR score examiner showed a very small mean difference of −0.07; 95% confidence intervals for the difference −1.60 to +1.47.

A flow chart showing the recruitment and passage of participants through the trial is shown in Figure 3. A total of 73 children were recruited to the trial (38 CG and 35 PFG). Mean time for active protraction facemask treatment was 8.6 months (SD 3.5 months).

Pretreatment equivalence

There was no apparent difference between groups for age, gender or presence of posterior crossbite. The mean age at baseline in the CG was 9.0 years (SD 0.8 years) and in the PFG was 8.7 years (SD 0.9 years). There were 22 (56.4%) females in the CG and 17 (43.6%) in the PFG. There were also similar numbers of males in both groups (CG 16, 47.1%; PFG 18, 52.9%). Mean age at DC2 was 10.3 years (SD 0.8 years) for CG and 10.0 years (SD 0.9 years) in the PFG. At baseline, 19 out of 35 (54%) children in the PFG, and 18 out of 38 (47%) children in the CG had a posterior crossbite. In addition the groups appeared similar for all cephalometric variables and study model/occlusal measurements at DC1. Piers–Harris and OASIS questionnaires

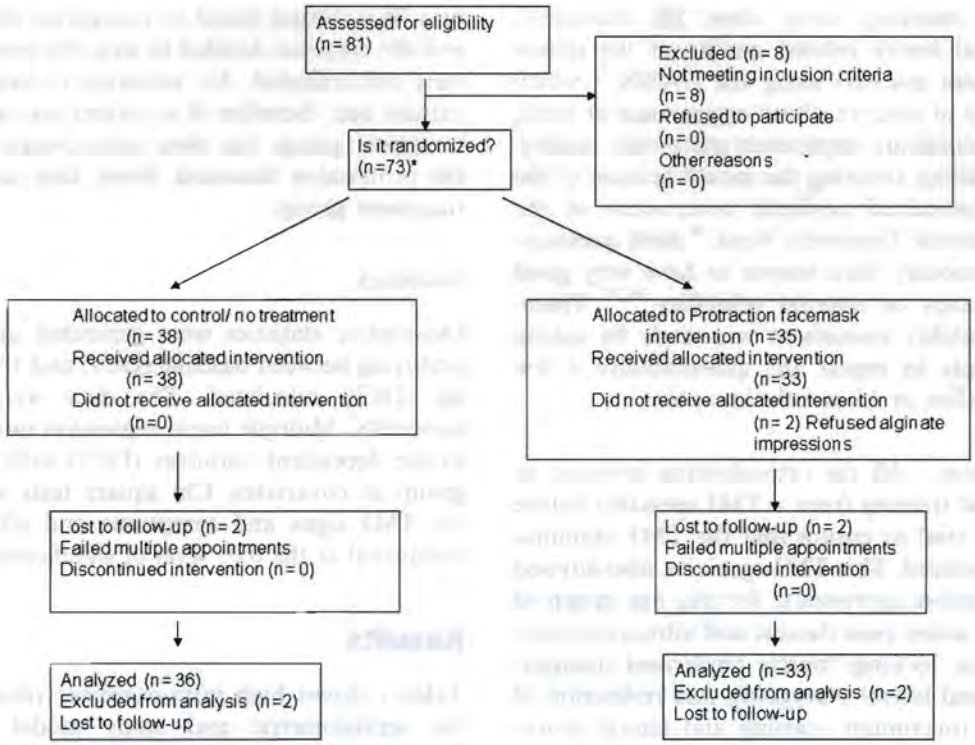

Figure 3 Trial profile

also showed similar DC1 scores for both groups. The presence of TMJ signs and symptoms was low at DC1, in both groups (Table 2).

Table 1 Reliability (limits of agreement and intraclass correlation coefficients)

	Mean diff	SD	Limits of agreement	ICC
SNA	0.3	0.4	−0.5 to 1.1	0.99
SNB	0.2	0.4	−0.6 to 1.0	0.99
ANB	0.1	0.5	−0.9 to 1.1	0.95
Maxillary rotational change	0.2	2.1	−4.4 to 4.0	0.81
Occlusal plane rotation	0.1	3.5	−6.9 to 7.1	0.72
MM angle	0.0	0.3	0.6 to 0.6	1.00
Percentage lower face height	0.3	0.8	−1.3 to 1.9	0.95
Upper incisor maxillary plane	0.0	0.5	1.0, −1.0	1.00
Lower incisor mandibular plane	−0.1	0.3	0.5, −0.7	1.00
Inter-incisal angle	0.2	0.5	1.2, −0.8	1.00
Overjet	0.2	0.6	1.4, −1.0	0.98
Weighted PAR	0.1	1.9	3.9, −3.7	0.98

Cephalometric changes DC1 to DC2

Skeletal and dental changes over time are shown in Table 3. In the CG, SNA moved forwards a small amount (0.3°) and is likely to be a reflection of normal growth. In the PFG, SNA was protracted, on average, 1.4° and this was statistically significantly different to the CG (regression $P=0.03$). SNB moved forwards in the CG, as would be expected with growth and, in comparison, B point moved backwards 0.7° in the PFG (regression $P<0.001$). This contributed to an overall difference in ANB between PFG and CG of 2.6° (regression $P<0.001$).

The occlusal plane showed a statistically significant upwards and forwards rotation in the PFG ($P<0.001$). This group also exhibited a downwards and backwards rotation of the maxilla compared with the CG ($P<0.001$). The maxillary–mandibular (MM) angle increased a small amount in the PFG compared with CG ($P=0.004$), but this was not reflected in a statistically significantly greater increase in the percentage lower face height ($P=0.73$). The only incisal change of note was more retroclination of the lower incisors for the PFG compared with CG (−4.9° versus −1.2°) (regression $P=0.001$).

Table 2 Percentage of temporomandibular joint signs and symptoms at baseline (DC1) and 15-month follow-up (DC2) for the control and protraction groups

		DC1		DC2	
%		Control	Facemask	Control	Facemask
Lateral pain	Right	2.6	0.0	5.4	0.0
	Left	0.0	2.9	2.6	0.0
Intra-articular pain	Right	0.0	0.0	0.0	0.0
	Left	2.6	2.9	0.0	0.0
Click	Right	5.3	5.7	2.6	9.1
	Left	2.6	5.7	0.0	9.1
Crepitus	Right	5.3	0.0	15.8	3.0
	Left	2.6	5.7	7.9	3.0
Locking, loss of movement or temporalis spasm		0.0	0.0	0.0	0.0
Masseter spasm		0.0	2.9	0.0	0.0
Lateral pterygoid spasm		2.6	8.6	5.3	3.0

Study models/occlusal changes DC1 to DC2

Table 3 also shows overjet change and occlusal improvement measured using the PAR index. The mean treatment effect on overjet in the PFG was 4.4 mm compared with a CG mean change of 0.3 mm (regression $P<0.001$). Treated cases had a large variation in treatment response, having either no overjet change or up to a maximum of 9 mm improvement. A 32.2% improvement in PAR was shown in the PFG and the CG worsened by 8.6%. Importantly, 23 out of 33 children treated with protraction facemask had a positive overjet at DC2, equivalent to a 70% treatment success.

Piers–Harris children's self-concept scale and OASIS psychosocial outcome questionnaires DC1 to DC2

Table 4 highlights changes in self-concept over time from DC1 to DC2, where a negative value indicates a drop in self-concept and a positive value a rise in self-concept. Overall, small increases and decreases were

Table 3 Cephalometric and occlusal outcomes

	DC1, mean (SD)		DC2, mean (SD)		DC2 minus DC1, mean change (SD)		
	Control	Protraction	Control	Protraction	Control	Protraction	***P value
SNA	78.5 (2.5)	78.8 (2.6)	78.8 (2.8)	80.2 (3.0)	0.3 (2.0)	1.4 (2.1)	**0.018**
SNB	80.9 (2.9)	80.6 (2.9)	81.7 (2.9)	79.9 (2.6)	0.8 (1.4)	−0.7 (1.5)	**<0.001**
ANB	−2.4 (2.0)	−1.9 (1.8)	−2.9 (2.1)	0.2 (2.2)	−0.5 (1.5)	2.1 (2.3)	**<0.001**
SN/maxillary plane	8.3 (3.2)	8.2 (3.5)	8.0 (2.8)	7.7 (2.9)	−0.3 (2.5)	−0.5 (2.3)	0.65
Maxillary rotational change (superimposition)					2.1 (2.3)*	2.3 (2.6)**	**<0.001**
Occlusal plane rotation (superimposition)					1.6 (3.0)**	2.9 (4.2)*	**<0.001**
Maxillary–mandibular angle	26.0 (4.8)	26.3 (4.3)	25.8 (5.3)	28.1 (3.8)	−0.2 (2.6)	1.8 (3.2)	**0.004**
Percentage lower face height	54.4 (2.6)	54.9 (1.8)	55.0 (2.6)	55.3 (1.8)	0.6 (1.1)	0.4 (2.0)	0.73
Upper incisor/maxillary plane	109.6 (10.7)	108.9 (5.5)	113.4 (6.7)	111.8 (6.5)	3.8 (8.2)	2.9 (6.4)	0.34
Lower incisor/mandibular plane	86.5 (7.1)	87.1 (6.5)	85.3 (7.7)	82.2 (5.8)	−1.2 (4.3)	−4.9 (4.1)	**0.001**
Inter-incisal angle	137.9 (11.1)	138.4 (9.4)	136.5 (11.2)	138.0 (8.5)	−1.4 (7.7)	−0.4 (6.8)	0.50
Overjet (mm)	−2.2 (1.6)	−2.3 (1.2)	−1.9 (1.9)	2.1 (2.9)	0.3 (1.6)	4.4 (2.7)	**<0.001**
Weighted PAR	31.3 (10.4)	33.8 (8.4)	34.0 (9.9)	22.9 (11.1)	2.7 (6.8) (or 8.6% worse)	−10.9 (12.7) (or 32.2% improved)	**<0.001**

*Rotation upwards and forwards.
**Rotation downwards and backwards.
***Bold values denote statistically significant results.

Table 4 Piers–Harris children's self-concept scale scores

Piers–Harris value (maximum possible score)	DC1, mean (SD)		DC2, mean (SD)		DC2 minus DC1, mean change (SD)		
	Control	Protraction	Control	Protraction	Control	Protraction	*P* value
Piers–Harris total score (60)	48.9 (8.6)	51.0 (7.3)	48.1 (8.7)	51.7 (7.2)	−0.8 (5.7)	0.7 (4.7)	0.22
Behaviour adjustment (14)	11.7 (2.8)	13.1 (1.2)	12.5 (2.2)	13.0 (1.6)	0.8 (1.8)	−0.1 (1.4)	0.30
Intellectual and school status (16)	12.9 (3.3)	14.0 (2.2)	12.4 (3.3)	13.5 (2.7)	−0.5 (2.7)	−0.5 (2.0)	0.68
Physical appearance and attributes (11)	8.5 (1.6)	8.5 (2.2)	7.5 (2.3)	8.4 (2.2)	−1.0 (2.2)	−0.1 (1.6)	0.10
Freedom from anxiety (14)	11.1 (3.3)	11.5 (1.7)	11.2 (3.0)	11.5 (2.1)	0.1 (2.0)	0.0 (1.9)	0.92
Popularity (12)	9.8 (2.7)	9.6 (2.5)	9.9 (2.4)	10.0 (2.1)	0.1 (1.4)	0.4 (1.5)	0.52
Happiness and satisfaction (10)	8.8 (1.5)	8.9 (1.2)	8.6 (1.1)	8.7 (1.1)	−0.2 (1.5)	−0.2 (1.4)	0.77

shown in both groups that were not statistically significantly different ($P>0.05$).

Table 5 shows changes in OASIS score from DC1 to DC2 where a negative value shows a reduced impact of malocclusion and a positive value an increased impact over time. The PFG children were statistically significantly 'less concerned' by their malocclusion at DC2, compared with the CG (regression $P=0.003$). Again, although statistically significant, the values show a fairly small clinical difference of four points between groups.

TMJ outcomes DC1 to DC2

Table 2 shows the number of children with TMJ signs or symptoms. This was low for both groups at both time points with $\leqslant 3\%$ of patients having intra-articular pain, locking, loss of movement or temporalis/masseter spasm. There was no history of condylar trauma or TMJ arthritis. Lateral TMJ pain and lateral pterygoid spasm was also $\leqslant 8.6\%$, at both time points, in either group. Clicking tended to increase slightly in the PFG at DC2 and crepitus tended to increase in the CG by DC2. This is reported as a trend only as the numbers in the cells were too low to run a chi square statistical test. Maximum mouth opening in control and treatment groups at both DC1 and DC2 was between 40.9 and 42.9 mm and lateral movement between 9.0 and 10.4 mm. Importantly, no TMJ signs or symptoms were detected in the PFG during active treatment.

Table 6 shows the percentage of subjects, with or without mandibular displacement on closure, at both time points. Over time, the CG had increased numbers of children with a forward mandibular displacement (52.6 to 70.3%). Conversely, the PFG showed fewer cases with a forward mandibular displacement at DC2 (52.9 to 21.9%; Pearson chi square value 16.1, 1 df, $P<0.001$). A reflection of the success of protraction facemask treatment is also eliminating any forward mandibular displacement on closure.

Table 5 Mean OASIS score at baseline (DC1) and DC2 (15 months) and change score over time (DC2 minus DC1)

	Control, mean (SD)	Protraction, mean (SD)	*P* value
OASIS DC1	20.7 (7.4)	20.6 (6.7)	
OASIS DC2	21.0 (6.6)	16.9 (4.7)	0.003
OASIS change, DC2 minus DC1'	0.3 (6.6)	−3.7 (7.7)	

Table 6 Mandibular displacement on closure at DC1 and DC2

	DC1		DC2	
%	No	Yes	No	Yes
Control	47.4	52.6	29.7	70.3
Facemask	47.1	52.9	78.1	21.9

Discussion

This prospective multicentre randomized controlled trial found that early protraction facemask treatment lead to significantly favourable skeletal and dental changes in young patients with class III malocclusion compared with untreated controls in the short term. Figures 4 and

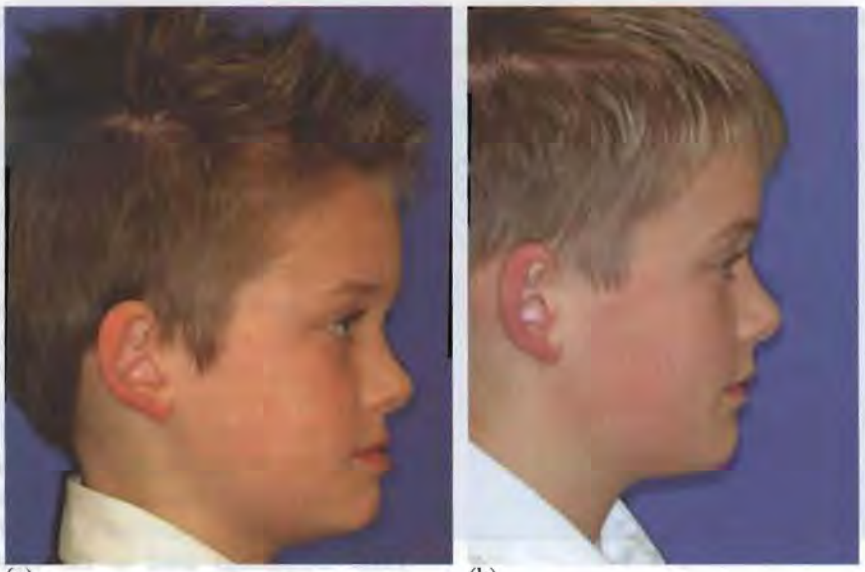

Figure 4 Facial profile (a) before protraction headgear treatment (baseline, treatment by SL) and (b) after protraction headgear treatment (15-month follow-up)

5 show a patient at baseline and following protraction facemask treatment at 15-month follow-up.

Skeletal effect

Overall for this trial, it is interesting to compare the results with previous meta analyses.[21,30] Table 7 compares changes attributable to protraction treatment from Kim *et al.*[21] and our study. Importantly, this table does not show treatment effects compared with controls. Overall, this trial seemed to show smaller skeletal treatment changes but this may be because the studies included in the systematic review were retrospective, and may have overestimated treatment effects.

Table 8 compares our data with the systematic review by Jager *et al.*[30] where comparison is made with a control group. In this systematic review, account was taken of growth changes in the control group by subtracting from treatment changes. Care should be taken in comparing this data, as many control groups consisted of class I children. In addition, studies included in these meta-analyses include samples from Europe, USA, China, and Japan where skeletal characteristics and growth patterns are different and treatment response may also vary. Despite these caveats, the mean differences between protraction treatment and controls from the meta-analysis by Jager *et al.*[30] were very similar to our trial. It is noteworthy that the larger changes in SNB suggested in Table 8 are because differences between protraction and control groups are being compared, and controls will worsen with growth.

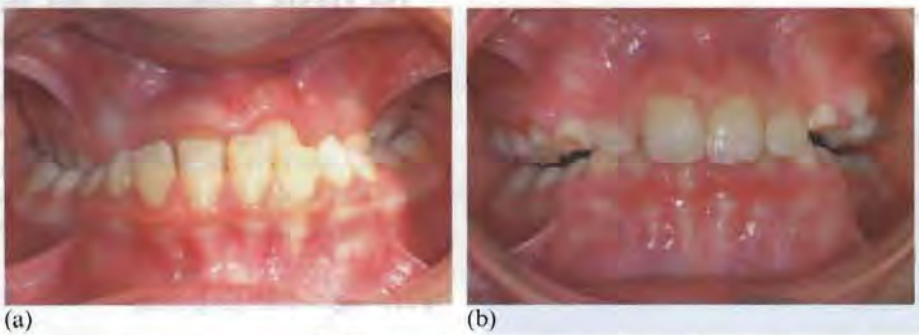

Figure 5 (a) reverse overjet before protraction headgear treatment (baseline, treatment by SL) and (b) positive overjet after protraction headgear treatment (15-month follow-up)

Table 7 Comparison of data from this trial and the systematic review by Kim *et al.*[21] for the effect of protraction facemask treatment

Cephalometric variable	This trial (protraction facemask group)	Kim *et al.* (1999)[21]
SNA	1.4	1.7
SNB	−0.7	−1.2
ANB	2.1	2.8
Maxillary rotational change	2.3 downwards and backwards	0.8 upwards and forwards
Maxillary–mandibular angle	1.8	1.5
% lower face height	0.4	...
Upper incisor/maxillary plane	3.0	2.8
Lower incisor/mandibular plane	−4.8	−2.9

A recent systematic review[39] further highlights shortcomings of previous retrospective and prospective studies as: no sample size calculation, sample bias, lack of method error analysis, lack of blinding, no information on dropouts and deficient or absent statistical analysis. As a result of differing cephalometric analyses and treatment details including timing and duration, this most recent systematic review did not attempt a quantitative analysis of cephalometric outcomes.

Occlusal effect

Ngan *et al.*[16] reported a mean treatment improvement in overjet of 6.2 mm which is slightly higher than the average of 4.4 mm in the PFG for this study. However, when the difference is calculated relative to CG, the PFG improvement is reduced to 4.1 mm. Also, the variability of treatment response in this study was large; some treated patients achieving no change, and others, up to 9 mm improvement in overjet. This evidence would support an orthodontist in offering early protraction facemask treatment, because there is always the chance that a patient will respond extremely favourably, whilst simultaneously cautioning that such change is not guaranteed.

Table 8 Comparison of data from this trial and the systematic review by Jager *et al.*[30] where effects of protraction facemask treatment are compared with controls

Cephalometric variable	This trial*	Jager *et al.* (2001)[30]
SNA	1.1	1.4
SNB	−1.5	−1.3
ANB	2.6	2.6
Upper incisor/maxillary plane	0.9	1.6
Lower incisor/mandibular plane	−3.7	−3.7

*Calculation of the differences between change occurring in protraction facemask group and controls (Table 3).

In this trial, treatment was successful in 70% of patients, defined as having a positive overjet at DC2. However, when we ran a multiple linear regression analysis, there were no predictive factors to establish which patients might respond favourably to early treatment.

When PAR scores are considered, Ngan and Yiu[32] showed a mean improvement in weighted PAR of 21.5 points from baseline to immediately after treatment. In our study, a mean reduction in weighted PAR of 10.9 points was observed in the PFG from baseline to 15-month follow-up. Direct comparison of these data with Ngan and Yiu[32] should be made with care as the time points for data collection were different and different PAR weightings used in the USA may make direct comparison of the data invalid.

Psychosocial outcomes

The impact of malocclusion on self-concept and psychosocial parameters has not previously been assessed in early class III protraction facemask treatment. The improvement in self-concept that we had hoped to see following treatment was not evident. This may be because factors contributing to self-concept are multifactorial, and the effect of orthopaedic treatment alone was not strong enough to influence Piers–Harris scores. It is also noteworthy that the Piers–Harris children's self-concept scale, although robustly developed with input from children aged 7 years and upwards, with demonstrable content, construct and criterion validity, does not specifically measure self-esteem related to the face and occlusion. Other more recently developed questionnaires do assess oral health impact, but contain questions related to facial and dental pain, which are also not directly relevant to orthodontic outcomes. There is therefore a need to develop measures to reflect orthodontic psychosocial outcomes.

The OASIS questionnaire did show a statistically significant change with PFG children being less concerned and perceiving less impact from their malocclusion at DC2. However, a difference between PFG and CG of four points may not be clinically significant. Further work is needed to develop psychosocial measures that could be more effective in detecting treatment advantages, as perceived by patients.

TMJ signs and symptoms

TMJ signs and symptoms were both very low at DC1 and DC2. No evidence was seen with regard to the

theoretical risk of a reciprocal downwards and backwards force at the chin point causing TMJ problems during protraction facemask treatment.

A drawback to the study design was that we did not carry out a repeatability test for TMJ measurements. This was partly owing to logistical reasons of recalling patients for an additional appointment and also that the patient may have presented with different TMJ signs or symptoms a number of weeks later.

Study design and analysis

All patients in the PFG had RME prior to placing protraction forces. Patients with posterior crossbites were expanded to allow for some overcorrection as previously described. Patients without posterior crossbite turned the expansion screw once a day, for 10 days. At the time of starting this trial, a meta-analysis by Jäger *et al.*[30] suggested that SNA and ANB changes were significantly greater when RME was used to release the circum-maxillary sutures. Therefore, we decided to use RME on every treated patient, which also standardized the clinical intervention. Since then, it has been shown that the success of protraction headgear is not influenced by the use of RME.[40,41]

Data for this trial were presented as change from baseline to 15-month follow-up for PFG and CG. Information was not collected immediately after the end of active protraction facemask treatment, as this would be at different times for each patient and the data would have had to be annualized. Annualization relies on a projection of average treatment change or growth change over 1 year. For example, if treatment was completed in 5 months, average treatment change would then be used to predict the cephalometric values for that patient at 1 year. Statistically, we were not advised to use this approach, particularly as the same prediction would not be used in the control group.

Patients presenting with a class III skeletal pattern in retruded contact position, but who also had a forward mandibular displacement on closure, were not excluded from the trial. This was because the main treatment aim was to orthopedically protract the maxilla. Ethically, it was not justified to take two lateral cephalograms (one in retruded contract position and one in intercuspal position) at each data collection, in view of this not being routine practice in younger patients, and the added radiation dose. Gravely[42] concluded that no forward mandibular displacement persisted cephalometrically after initial disengagement of the incisors. The forward displacement was counteracted by a backward displacement of the condyles during further closure.

At DC2 a significant number of treated patients no longer had a forward mandibular displacement. It was tested to see whether these patients had larger treatment improvement in SNB that could have been postural, compared with treated patients who did not have a forward displacement at baseline. There was no statistically significant difference in SNB improvement between patients with and without a forward mandibular displacement at DC1 (P=0.095).

It would have been useful to evaluate the proportion of skeletal and occlusal changes occurring with a Pancherz analysis. However, as statistically significantly more occlusal plane rotation occurred in the PFG compared with the CG (mean difference 4.5°), it was decided not to use an analysis that relies on the occlusal plane as a stable reference point.

Lastly, with reference to sample size, it has been shown that the study had sufficient power to detect a difference between PFG and CG for cephalometric outcomes. It is evident that the confidence intervals were fairly wide so the data should be cautiously interpreted. Despite this, the key clinical message would be that at 15-month follow-up, early protraction facemask treatment has a 70% success rate in achieving a positive overjet. This information should be helpful to parents and patients when making the decision whether to embark on early protraction facemask treatment.

The patients in this randomized clinical trial are undergoing long term prospective follow-up until they are 15 years old. This will enable us to report on long term skeletal and dental stability of early protraction facemask treatment and to evaluate whether it reduces the need for orthognathic surgery.

Conclusions

- Early class III orthopaedic treatment, with protraction facemask, in patients under 10 years of age, is skeletally and dentally effective in the short term.
- Seventy per cent of patients had successful treatment, defined as achieving a positive overjet.
- There were no resultant TMJ problems.
- Early treatment does not seem to confer a clinically significant psychosocial benefit.

Contributors

Nicky Mandall was responsible for the study design, obtaining funding, co-ordination of the trial, data collection at two centres, data analysis and critical revision, drafting and approval of the final report. The

following authors were part of the clinical trial team and were responsible for patient screening, recruitment, treatment, follow-up, data collection, critical revision and approval of the final report: Richard Cousley, Andrew DiBiase, Fiona Dyer, Simon Littlewood, Rye Mattick and Spencer Nute. Barbara Doherty was responsible for the day-to-day running of the study, data reminders and collection, co-ordination and data entry. The following authors were responsible for data collection and analysis, critical revision and final approval of the report: Nadia Stivaros, Ross McDowall, Inderjit Shargill. Helen Worthington was responsible for data analysis, interpretation, critical revision and approval of the report. Nicky Mandall is the guarantor.

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SCIENTIFIC SECTION

Is early class III protraction facemask treatment effective? A multicentre, randomized, controlled trial: 3-year follow-up

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Objective: To investigate the effectiveness of early class III protraction facemask treatment in children under 10 years of age at 3-year follow-up.

Design: Multicentre randomized controlled trial.

Subjects and Methods: Seventy-three patients were randomly allocated, stratified for gender, into early class III protraction facemask group (PFG) ($n=35$) and a control/no treatment group (CG) ($n=38$).

Outcomes: Dentofacial changes were assessed from lateral cephalograms and occlusal changes using the peer assessment rating (PAR). Self-esteem was assessed using the Piers–Harris children's self-concept scale, and the psychosocial impact of malocclusion with oral aesthetic subjective impact score (OASIS) questionnaire. Temporomandibular joint (TMJ) signs and symptoms were also recorded. The time points for data collection were at registration (DC1), 15 months later (DC2) and 3 years post-registration (DC3).

Results: The following mean skeletal and occlusal changes occurred from the class III starting point to DC3 (3-year follow-up): SNA, PFG moved forwards $+2.3^{\circ}$ (CG forward $+1.6^{\circ}$; $P=0.14$); SNB, PFG moved forwards $+0.8^{\circ}$ (CG forward $+1.5^{\circ}$, $P=0.26$); ANB, PFG class III base improved $+1.5^{\circ}$ (CG stayed about the same at $+0.1^{\circ}$; $P=0.001$). This contributed to an overall difference in ANB between PFG and CG of $+1.4^{\circ}$ in favour of early protraction facemask treatment. The overjet was still improved by +3.6 mm in the PFG and changed a small amount +1.1 mm in the CG (P=0.001). A 21% improvement in PAR was shown in the PFG and the CG worsened by 8.4% ($P=0.02$). There was no increase in self-esteem (Piers–Harris score) for PFG compared with the CG ($P=0.56$) and no statistically significant difference in the impact of malocclusion (OASIS) between groups in terms of the changes from DC1 to DC3 ($P=0.18$). TMJ signs and symptoms were very low at DC1 and DC3.

Conclusions: The favourable effect of early class III protraction facemask treatment undertaken in patients under 10 years of age, is maintained at 3-year follow-up in terms of ANB, overjet and % PAR improvement. The direct protraction treatment effect at SNA is still favourable although not statistically significantly better than the CG. Seventy per cent of patients in PFG had maintained a positive overjet which we have defined as ongoing treatment success. Early protraction facemask treatment does not seem to influence self-esteem or reduce the patient's personal impact of their malocclusion at 3-year follow-up.

Key words: Class III skeletal pattern, early orthopaedic treatment, protraction facemask, randomized controlled trial

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Introduction

The effects of early protraction facemask treatment for children under 10 years of age are widely documented and systematically reviewed.[1–3] The initial mean treatment effect is reported as being a 1.7° protraction of A point and a 2.8° ANB improvement. Where early class III treatment is compared with untreated controls, it is suggested a

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mean forward movement at SNA of 1.4° and an ANB improvement of 2.6° occurs.

These data were recently compared with the early results of our multicentre randomized controlled trial,[4] which suggested similar, but slightly smaller protraction facemask treatment effects. This may be because of its prospective randomized design, with a concurrent matched control group, which overcomes the possibility of selection bias and thus improved results sometimes reported in retrospective research.

While short-term data of treatment effectiveness are clinically useful, it is important to evaluate outcomes in the medium and long term. We may then advise our patients not only of the likelihood of early protraction facemask treatment success, but whether they are likely to outgrow the initial correction. This paper is the second in a planned series of three, which prospectively evaluates the effects of early protraction facemask (PFG) with an untreated control (CG). This paper will report the 3-year follow-up for this multicentre randomized controlled trial.

The aim of this multicentre prospective randomized clinical trial was to investigate the effectiveness of early class III orthopaedic protraction facemask treatment in children under 10 years of age. The working hypothesis was that early class III orthopaedic treatment with a protraction facemask compared with an untreated control, will lead to differences in (1) skeletal and dental relationships; (2) psychosocial well being; and (3) temporomandibular joint (TMJ) pain dysfunction.

Subjects and methods

A short summary of the subjects and methods for this clinical trial will be presented here, as they have been described in detail in the 15-month follow-up report.[4]

Study setting

Following multicentre and local Ethical and Research and Development approval, patients were recruited at eight UK hospital orthodontic departments through general dental practitioner referrals or following primary school screening.

Sample size calculation

The sample size calculation was based on expected peer assessment rating (PAR)[5] changes where a sample size of 23 children in the PFG and 23 in the CG would have a 90% power to detect a difference in means of 0.25 (the difference between a PFG mean PAR reduction of 25% and a CG mean PAR reduction of 0%) assuming a common standard deviation of 0.25 using a two group test with a 0.05 two-sided significance level. Therefore, a total sample size of 46 children was needed for the clinical trial.

Inclusion criteria

- seven to nine years of age at the time of registration;
- three or four incisors in crossbite in the intercuspal position;
- clinical assessment of a class III skeletal problem in the retruded contact position with emphasis on the presence of a retrusive maxilla.

Exclusion criteria

- child of non-Caucasian origin;
- cleft lip and palate and/or craniofacial syndrome;
- a maxillo-mandibular planes angle greater than 35° or lower face height greater than 70 mm;[6]
- history of TMJ signs or symptoms;
- lack of consent.

Patient assignment

Following child and parent written consent, patients were randomly allocated to PFG or CG. The randomization list was stratified for the potential confounding effect of gender to take into account the possibility that boys and girls would grow at different times during the study. The randomization sequence was concealed centrally and the group allocation only revealed after each patient was registered for the trial.

Data collection

Data collection (DC) was carried out at DC1 (baseline at trial registration), DC2 at 15-month follow-up and DC3 at 3-year follow-up. At each time point, we collected:

- lateral cephalogram in the intercuspal position;
- study models;
- questionnaires: Piers–Harris children's self-concept scale[7] and oral aesthetic subjective impact score (OASIS);[8]
- clinical signs and symptoms of TMJ dysfunction.

Clinical intervention

Following the collection of DC1 records, patients randomly allocated to the PFG were treated according to a standardized protocol summarized in Table 1 and Figures 1 and 2.[4] The patients allocated to the CG received

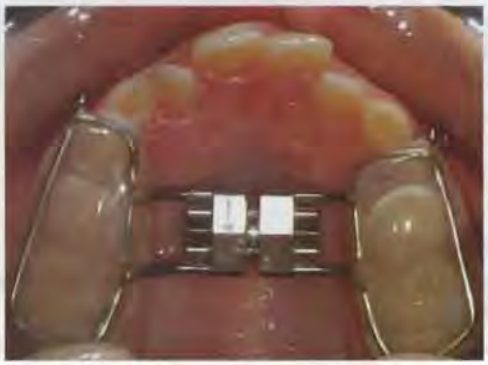

Figure 1 RME device

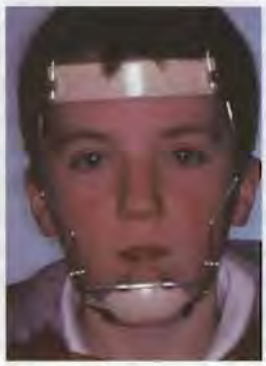

Figure 2 Protraction facemask (TP Orthodontics)

no clinical intervention. All patients were then recalled 15 months post-registration for data collection 2 (DC2) and 3 years post-registration for data collection 3 (DC3).

Clinical end point

The end of active treatment was defined as when the facemask treatment had achieved a correction of the incisal relationship to class I or positive overjet, class I molars and/or a clinical correction of the class III skeletal pattern. Once the active treatment had finished, none of the patients in the PFG received any form of retention. Although a functional appliance may be used to try to maintain the protraction facemask correction, this study excluded this option because it would have been a potential confounding factor.

Outcome measures

Cephalometric and occlusal measurements

The lateral cephalograms were traced by one author (NS) who was blinded as to group allocation. To determine the rotations of the maxillary and occlusal planes, superimposition of the DC1 and DC3 lateral cephalometric radiographs was undertaken by another author (IS) using Bjork's structural method, which employs the anterior zygomatic process as the reference landmark.[9,10] Weighted PAR scores[5] were measured by a calibrated examiner (R McD). Overjet measurements were recorded from study models, with a steel millimetre ruler, by author NM. Overjet and lateral cephalogram measurements were carried out twice and a mean value calculated to reduce random error. Intra-examiner reliability was assessed by re-measuring 20 radiographs and 20 overjet scores and 30 PAR scores, 1 week apart.

Psychosocial measures

The previously validated short form Piers–Harris children's self-concept scale was used.[7] Psychosocial/oral health related quality of life effects of treatment were assessed using OASIS.[8] Both questionnaires have previously been shown to have very good internal consistency or internal reliability.

TMJ examination

All of the orthodontists involved in this trial had received training from a TMJ specialist before the start of the trial

Table 1 Summary of the clinical intervention: Protraction facemask treatment.

Clinical intervention	Design and application
Rapid maxillary expansion (RME)	Bonded RME with 3-mm acrylic placed over a metal framework[24] Vestibular hook located adjacent to upper first deciduous molars Activation ¼ turn (0.25 mm) once a day for 7–10 days
Protraction facemask 'TP orthodontics'	Vertically adjustable for custom fit Elastics connected to midline crossbow Wear for 14 h per day
Extra oral elastics	⅜ inch, 8 oz for 1–2 weeks, then ½ inch 14 oz, then 5/16 inch 14 oz elastics to finally deliver 400 g per side
'TP orthodontics'	Elastic traction direction 30° downwards and forwards

to ensure that the TMJ examination was standardized and appropriate for younger children. TMJ signs or symptoms were recorded to ensure no patients might be treated with protraction facemask that may exacerbate TMJ problems through potential downwards and backwards rotation at the chin point. No patients were excluded on this basis, either at baseline or during facemask treatment.

Blinding

This trial was single blind, as the researchers measuring the radiographs and study models and the statistician were blind to the treatment/control allocation until the data were analysed and the code broken. Ideally, the clinician collecting the records at the 15-month DC3 time point would also have been blinded as to group allocation. However, this was not attempted, because only one operator was involved at each centre. They will have had the patient's notes available and it was also likely that they would remember who had received protraction facemask treatment.

Patients leaving the study or refusing treatment

We collected as much data as possible on patients who dropped out of the study to reduce possible assessment bias. If a subject failed to cooperate during treatment and the clinician decided to stop the treatment, the data were still collected. An 'intention to treat' analysis was carried out. Therefore, if a patient was allocated to the treatment group, but then subsequently failed to have the protraction facemask fitted, they were kept in the treatment group. Further analysis was carried out to compare baseline characteristics for patients who dropped out of the study compared with those left in to assess the possibility of attrition bias.

Statistical analysis

Descriptive statistics were generated and the data checked for normality. The changes occurring between DC1 and DC3 were calculated. Multiple linear regression models were fitted to the dependent variables (DC3) with DC1 data and group as covariates. All analyses were conducted at the 0.05 level of significance.

Results

Complete records were available for 63 patients out of 73 representing an 86% follow-up. Intra-examiner reliability for cephalometric and study model measurement was high and there were no apparent difference between groups at DC1 for age, gender and presence of posterior crossbite, as previously reported.[4] A trial profile is shown in Figure 3. The mean age of patients at DC3 was 12.1 years (SD: 0.9) in the PFG and 12.3 years (SD: 0.8) in the CG. In the PFG, there were 15 boys (50%) and 15 girls (50%) and in the CG, there were 15 boys (45%) and 18 girls (55%). Figures 4 and 5 show an example of a patient from the PFG at baseline, 15-month and 3-year follow-up where treatment changes were successfully maintained.

Cephalometric changes DC1 to DC3

Skeletal and dental changes over time are shown in Table 2. The statistically significant treatment effect (PFG) maintained at 3-year follow-up was a mean ANB improvement of 1.5° compared with almost no improvement (0.1°) in the CG. Thus, the ANB difference between groups was 1.4° in favour of protraction facemask treatment (regression $P=0.001$). There was a tendency for the PFG to maintain a more protrusive A point (2.3°) compared with the CG (1.6°) and a more retrusive B point (PFG 0.8°)(CG 1.5°), but none of these effects, on their own, were statistically significant (regression P value SNA=0.14; SNB=0.26). Cephalometric superimposition suggested that the maxilla had rotated downwards and backwards in the PFG (4.1°) and the functional occlusal plane had rotated upwards and forwards (2.8°) (regression $P<0.001$). Lastly, there was no statistically significant effect of increased MM angle or increased % lower face height or incisor inclination in the PFG compared with the CG.

Study models/occlusal changes DC1 to DC3

Table 2 summarizes occlusal changes from DC1 to DC3. The PFG still exhibited a mean overjet improvement of 3.6 mm compared with the CG change of +1.1 mm (regression $P=0.001$). There was almost a 30% difference between PFG and CG weighted PAR scores with PFG maintaining a 21% improvement and CG worsening by an average 8.4% (regression $P=0.02$). Where treatment success was defined as maintaining a positive overejet at DC3, 70% of patients in the PFG achieved this.

Piers–Harris (self-esteem) and OASIS psychosocial outcome questionnaires DC1 to DC3

Piers–Harris scores and scores of the domain (Table 3) were compared between PFG and CG from DC1 to DC3. There were tiny changes in self-esteem over time and no statistically significant increase in self-esteem as a result of protraction facemask treatment. Although OASIS scores at DC3 (Table 4) tended towards a reduced impact of malocclusion PFG (−2.0 points) compared with increased impact in the CG (+1.4

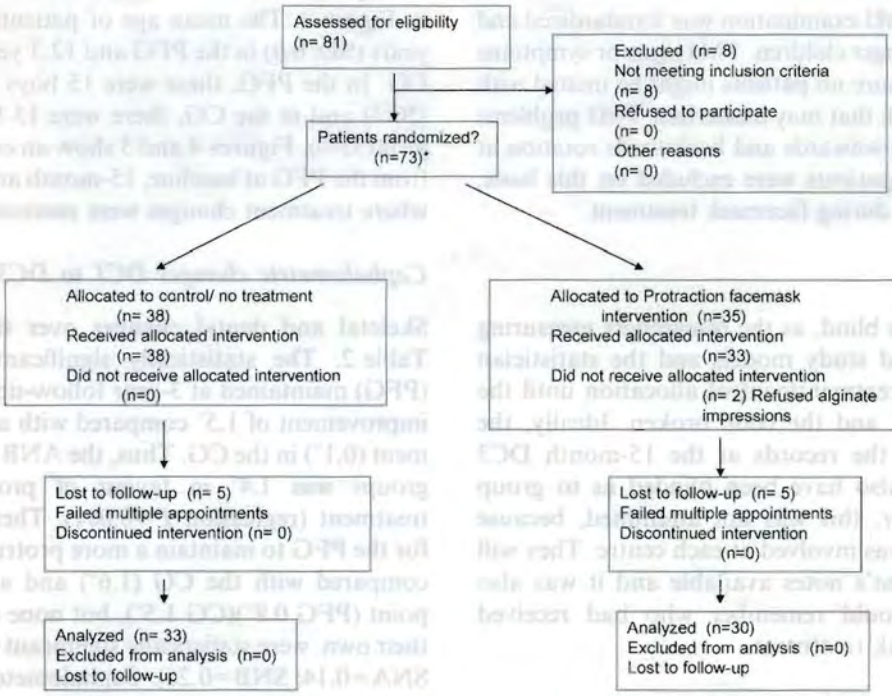

Figure 3 Trial profile

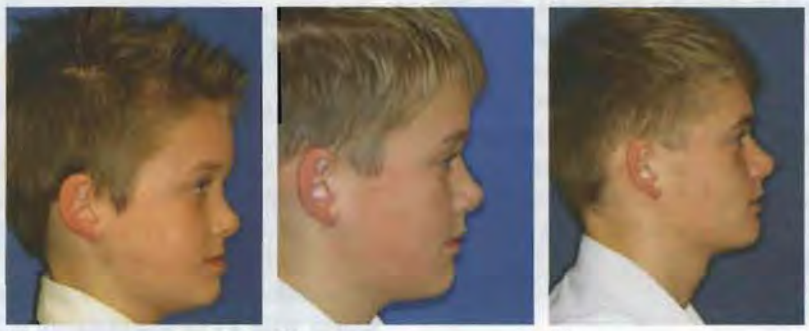

Figure 4 Profile images of (a) baseline, (b) 15-month follow up after protraction facemask treatment and (c) 3-year follow up Courtesy of author Simon Littlewood

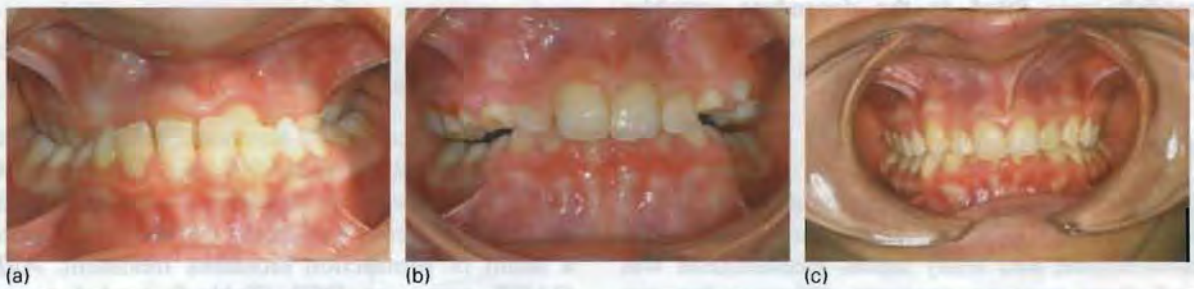

Figure 5 (a) Baseline occlusion, (b) 15-month follow up after protraction facemask treatment and (c) 3-year follow up Courtesy of author Simon Littlewood

points), this was not statistically significant (regression $P=0.18$).

TMJ outcomes DC1 to DC3

Table 5 confirms the low prevalence of TMJ signs and symptoms at both time points; therefore, no statistical analysis was carried out. Crepitus was the most frequently observed sign at DC3. Patients with forward mandibular displacement on closure were also evaluated. As would be expected, patients in the CG stayed fairly constant from DC1 (52.6%) to DC3 (50.0%). In the PFG, this variable reduced from 52.9% at DC1 to 21.9% at DC3.

The elimination of any forward mandibular displacement with protraction facemask treatment may suggest that these patients had an enhanced improvement in B point. Therefore, within the PFG, we compared the SNB improvement in patients with and without forward mandibular displacement at baseline. Improvement at SNB was no better for patients whose mandibular displacement had been eliminated by protraction facemask treatment compared with treated patients who still had a forward displacement at DC3 (Chi-square value 3.26, $P=0.66$).

Treatment effects of PFG compared with CG at DC2 and DC3.

Table 6 shows the statistically significant treatment effects occurring at DC2 and those that were maintained at DC3. Where there had been statistically significant changes for SNA, SNB and ANB at 15 months (DC2), at DC3, only ANB was still significant. The other statistically significant treatment effects seen at DC2 and maintained at DC3 were overjet, percentage PAR improvement and both maxillary and functional occlusal plane rotations.

Discussion

Skeletal and dental effects

Three-year follow-up of patients randomly allocated to treatment (PFG) or control (CG) indicates that some skeletal and dental effects of early protraction facemask treatment are maintained until children are 12 years old. These include improvements in ANB, overjet, maxillary and occlusal plane rotations and weighted PAR score. Favourable changes in SNA and SNB were not in themselves statistically significant, but the combined

Table 2 Cephalometric and occlusal outcomes.

	DC1	DC1	DC3	DC3	DC3→DC1	DC3→DC1	
	mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean change (SD)	Mean change (SD)	
	CG	PFG	CG	PFG	CG	PFG	*P* value
SNA	78.3 (2.5)	78.7 (2.5)	79.9 (3.6)	81.0 (2.9)	1.6 (2.6)	2.3 (2.1)	0.14
SNB	80.9 (2.9)	80.5 (2.8)	82.4 (4.0)	81.3 (3.0)	1.5 (2.3)	0.8 (1.5)	0.26
ANB	−2.6 (2.0)	−1.8 (1.8)	−2.5 (2.5)	−0.3 (1.9)	0.1 (1.9)	1.5 (2.0)	**0.001**‡
Sn/MxP	8.5 (3.1)	8.7 (3.2)	7.5 (4.1)	7.0 (2.9)	−1.0 (3.5)	−1.7 (2.5)	0.43
Maxillary rotational change (superimposition)					4.3* (2.8)	4.1† (4.1)	**<0.001**‡
Functional occlusal plane rotation (superimposition)					2.6† (4.7)	2.8* (4.8)	**<0.001**‡
MM angle	25.7 (4.8)	26.5 (4.4)	26.5 (6.1)	27.7 (4.1)	0.8 (3.9)	1.2 (3.1)	0.67
%LFH	54.2 (2.5)	55.0 (1.8)	54.8 (2.9)	55.2 (1.5)	0.6 (1.9)	0.2 (1.3)	0.57
UI/MxP	110.3 (11.0)	109.1 (5.7)	115.8 (6.6)	114.3 (5.9)	5.5 (9.5)	5.2 (6.8)	0.43
LI/MdP	86.2 (7.3)	86.9 (6.5)	85.5 (8.0)	85.4 (6.1)	−0.7 (4.7)	−1.5 (3.4)	0.38
Inter incisal angle	137.6 (11.5)	138.1 (9.2)	132.5 (10.7)	132.9 (8.9)	−5.1 (8.2)	−5.2 (7.9)	0.70
Overjet	−2.2 (1.6)	−2.2 (1.3)	−1.1 (2.8)	1.4 (2.8)	1.1 (2.6)	3.6 (2.6)	**0.001**‡
Weighted PAR	31.0 (10.6)	34.1 (8.5)	33.6 (10.6)	27.0 (12.0)	−2.6 (10.2)	7.1 (14.3)	**0.02**‡
					8.4% worse	21% improved	

*Rotation upwards and forwards.
†Rotation downwards and backwards.
‡Bold values denote statistically significant results.

effect meant that ANB was still statistically significantly improved in the PFG compared with the CG. This is important because although this treatment is known to be clinically and statistically effective in the short term, understanding longer term clinical benefit is useful to clinicians and patients when making treatment choices.

As expected, the protraction facemask treatment effects reduced over time as the patient grew older as a result of a continued class III growth pattern. We would not have expected the initial treatment effects to be totally maintained and it is, therefore, perhaps surprising that 70% of treated patients maintained a positive overjet at DC3, the same value observed at DC2. Interestingly, this cannot be explained by increased dentoalveolar compensation in the PFG between DC2 and DC3.

Table 3 Piers–Harris children's self-concept scale scores.

	DC1	DC1	DC3	DC3	DC3 minus DC1	DC3 minus DC1	
	CG	PFG	CG	PFG	CG	PFG	
Piers–Harris	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean change (SD)	Mean change (SD)	*P* value
Piers–Harris total	49.9 (8.1)	50.3 (6.8)	50.3 (6.9)	51.3 (8.7)	0.4 (7.2)	1.0 (5.6)	0.56
Behaviour	11.8 (2.9)	13.0 (1.3)	12.7 (2.3)	12.8 (2.7)	0.9 (3.1)	−0.2 (2.5)	0.73
Intellect/school	12.7 (3.2)	13.7 (2.3)	12.5 (3.1)	13.2 (3.3)	−0.2 (3.0)	−0.5 (2.3)	0.95
Physical	8.7 (1.7)	8.3 (2.2)	8.9 (1.9)	8.8 (2.6)	0.2 (2.0)	0.5 (2.1)	0.77
Freedom from anxiety	11.2 (3.3)	11.4 (1.7)	11.5 (2.4)	11.7 (2.6)	0.3 (2.3)	0.3 (1.8)	0.97
Popularity	9.8 (2.8)	9.5 (2.5)	10.5 (1.6)	10.4 (2.3)	0.7 (2.1)	0.9 (2.1)	0.69
Happiness	8.8 (1.5)	8.8 (1.2)	9.1 (1.1)	8.7 (1.3)	0.3 (1.8)	−0.1 (1.3)	0.23

Table 4 OASIS scores.

	Control	Protraction	
OASIS score	Mean (SD)	Mean (SD)	*P* value
DC1	20.7 (7.6)	20.8 (6.6)	
DC2 (15 months)	22.1 (7.3)	16.9 (4.4)	**0.001**
DC3 (3 years)	22.5 (8.3)	18.3 (5.2)	**0.02**
Mean change DC2 minus DC1	0.8 (6.5)	−4.2 (8.1)	**0.01**
Mean change DC3 minus DC1	1.4 (9.5)	−2.0 (9.1)	0.18

Table 5 Temporomandibular joint signs and symptoms.

%		DC1 CG	DC1 PFG	DC3 CG	DC3 PFG
Lateral pain	Right	2.6	0.0	0.0	0.0
	Left	0.0	2.9	2.8	0.0
Intra articular pain	Right	0.0	0.0	0.0	0.0
	Left	2.6	2.9	2.8	0.0
Click	Right	5.3	5.7	5.6	12.5
	Left	2.6	5.7	5.6	9.4
Crepitus	Right	5.3	0.0	11.1	9.4
	Left	2.6	5.7	8.3	18.8
Locking		0.0	0.0	2.8	0.0
Loss of movement or temporalis spasm		0.0	0.0	0.0	0.0
Masseter spasm		0.0	2.9	2.8	3.1
Lateral pterygoid spasm		2.6	8.6	5.6	3.1

One treatment effect that did seem to be progressive was the downwards and backwards rotation of the maxilla in the PFG from 2.3° at DC2 to 4.1° at DC3. This was not in agreement with a systematic review,[1] which found that the maxilla rotated upwards and forwards. This may be explained by differences in methodology as in the systematic review, the authors studied rotational changes of the palatal plane ANS to PNS and these are not stable structures,[11] whereas Bjork's structural method[10] is the one suggested for measuring maxillary rotational change.

In addition, it was not clear whether all studies in the systematic review had used a 30° downwards elastic force. This difference in findings may be explained by the point of force application at the vestibular hooks being below the centre of resistance of the maxilla, and also anterior to it in our trial. A downwards elastic force may then appear to result in a downwards and backwards maxillary rotation. The functional occlusal plane rotation of around 3° upwards and forwards in this trial is similar to the earlier systematic review where they suggest posterior tooth extrusion as a reason for the occlusal plane rotation.

Many published studies report immediate treatment effects with relatively little longer term follow-up. Deguchi *et al.*[12] published a 3-year follow-up of early protraction facemask treatment compared with retrospective matched controls. When normal growth in the control group was taken into account, the treatment group had a mean ANB improvement of 1.6° which is remarkably similar to this study (Table 6). This is despite methodology differences such as the mean age of treatment being 4 years 2 months and the added use of a removable retainer activated for crossbite correction as required for 1 year following facemask treatment.

Weighted PAR scores were followed up for 2 years following protraction facemask treatment by Ngan and Yiu.[13] It is difficult to compare actual weighted PAR changes with our study, as it is likely that different weightings were used. However, our percentage-weighted PAR improvement reduced over time: DC2 (32.2%) to DC3 (21%), and this could not be explained by a relapse in overjet or posterior crossbite, whereas Ngan's study showed an improvement over a 2-year follow-up from post-treatment (56%) to 2 years (63%). This difference in trend is difficult to explain, but it is possible that additional treatment for 1 year with a functional appliance, in the latter study, could enhance the protraction facemask occlusal effects. Further literature is available to compare longer term follow-up (5 years and longer) of protraction facemask effects and this will be compared in the next paper of our 6-year follow-up data.[14–20]

TMJ signs and symptoms and psychosocial outcomes

TMJ signs and symptoms were low throughout this clinical trial. There was a trend of increased crepitus at DC3; however, it is unlikely that this could be attributed to the protraction facemask treatment, since the increase occurred in both PFG and CG.

No statistically or clinically significant psychosocial benefit of early protraction facemask treatment was observed at DC3 which also broadly reflects the DC2 findings. Reasons for this, such as multi-factorial influences on self-esteem and the lack of availability of questionnaires that specifically investigate facial and occlusal concerns, have been previously discussed.[4] Perhaps the 6-year follow-up, currently being undertaken, may show psychosocial benefit in the PFG when

Table 6 Statistically significant effects of PFG compared with the CG at DC2 and those maintained at DC3 (in bold).

	PFG	PFG
	DC2 (degrees)	DC3 (degrees)
SNA	**1.1**	0.7
SNB	**−1.5**	−0.7
ANB	**2.6**	**1.4**
Maxilla rotation	**4.4** down and backwards	**4.1** down and backwards
Functional occlusal plane		
Rotation	**4.5** up and forwards	**2.8** up and forwards
MM angle	**1.6**	0.4
L/MdP	**−3.7**	−0.8
Overjet (mm)	**4.1**	**2.5**
% weighted PAR (difference between PFG improvement and CG worsening)	**40.8**	**29.4**

peer group pressure becomes more important between 12 and 15 years of age.

Study design

The study design has been discussed in detail in Part 1 of this clinical trial.[4] Recent literature suggesting that rapid maxillary expansion (RME) does not enhance protraction facemask treatment[21,22] would be useful if this study were being planned now. All our treated patients activated their RME for at least 10 days to standardize the clinical intervention and, theoretically, release the circum-maxillary sutures. Overall, we did not consider that this changing evidence was likely to affect the validity of our data.

The presence or absence of an anterior mandibular displacement on closure at the start of protraction facemask treatment will always be an important factor to consider. As Gravely[23] suggested that no forward mandibular displacement persisted cephalometrically between retruded and intercuspal position, we continued to take only one lateral cephalogram in intercuspal position at the 3-year follow-up. In addition, our analysis did not show any additional SNB improvement in patients whose forward mandibular displacement had been eliminated by protraction facemask treatment compared with those without pre-treatment displacement.

As with any long-term follow-up, some patients dropped out of this study ($n=10$), resulting in a risk of attrition bias. For example, the drop-outs may be the patients whose treatment was less successful, so biasing the data towards an enhanced treatment effect. Therefore, the baseline characteristics of the patients remaining in the study and the dropouts were compared. The start age, gender, SNA, SNB, ANB and overjet of the dropouts were no different to those patients still in the study which suggests that there is no attrition bias ($P=0.58$–0.98).

Lastly, we will consider clinical and statistical significance. Although treatment effects may be statistically significant, it is important to assess whether they are also clinically significant. What constitutes a clinically significant change has not been well defined in orthodontics. It is difficult to quantify, particularly with cephalometric values, at what point treatment benefit still outweighs treatment burden or risks. It is suggested that the statistically significant effects seen in the PFG at 3-year follow-up are also clinically significant and a proportion of patients will experience skeletal and occlusal improvement over and above the mean values quoted if their biological response is favourable. However, the more important clinical question is whether this early treatment reduces the need for orthognathic surgery. The 6-year follow-up data currently being collected will attempt to answer this question.

Conclusions

At 3-year follow-up:

- Early class III orthopaedic treatment, with a protraction facemask, in patients under 10 years of age, is skeletally effective; however, only the combined bimaxillary skeletal effect reflected in ANB measurements, was clinically or statistically significant.
- Seventy per cent of patients still presented with a positive overjet in the PFG and they had a PAR improvement of 21% compared with the CG who worsened by just over 8%.
- Early protraction facemask treatment does not seem to confer a clinically significant psychosocial benefit.
- There were no TMJ signs or symptoms that could be attributed to the early protraction facemask treatment.

Contributors

Nicky Mandall was responsible for the study design, obtaining funding, coordination of the trial, data collection at two centres, data analysis and critical revision, writing and approval of the final report. The following authors were part of the clinical trial team and were responsible for patient screening, recruitment, treatment, follow-up, and data collection: Richard Cousley, Andrew DiBiase, Fiona Dyer, Simon Littlewood, Rye Mattick and Spencer Nute. Barbara Doherty was responsible for the day-to-day running of the trial, data collection and data entry. The following authors were responsible for data measurements and calculations: Nadia Stivaros, Ross McDowall, Inderjit Shargill, Amreen Ahmad, and data supervision: Tanya Walsh. Helen Worthington was responsible for data analysis and interpretation. All authors were responsible for critical revision and final approval of the report. Nicky Mandall is the guarantor.

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