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Class II Growth Modification: Evidence of Absence or Absence of Evidence?

Abstract: The capacity for dentofacial orthopaedics to modify the growth of the jaws and face in the management of Class II malocclusion has been the subject of much debate over the past century. It is only recently, following the publication of randomized controlled trials, that answers based on high level evidence can be provided. This article aims to review the recent literature in order to provide some clarification on the important issues relating to Class II growth modification, including: immediate treatment effects, long term stability of skeletal changes, the effects of differing orthopaedic appliances and the importance of treatment timing.

Clinical Relevance: Class II growth modification, particularly through the use of functional appliances, is now widely practised and it is important that clinicians adopt an evidence-based approach to its clinical application.

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Dentofacial growth modification involves an attempt to alter the underlying hard or soft tissues and bring about permanent skeletal and dento-alveolar change. Functional appliances are commonly the method of choice for the treatment of a developing Class II skeletal problem, and aim to restrain maxillary and enhance mandibular growth. Functional appliances can be defined as fixed or removable orthodontic appliances, which use the forces generated by the stretching of muscles, fascia or periodontium to bring about change to the existing skeletal or dental relationship.¹

It is generally accepted that functional appliances can correct Class II malocclusions with great rapidity and the clinical efficacy of such appliances is not in dispute (Figure 1). However,

Skeletal	Restriction of forward and downward growth of the maxilla. Enhancement of mandibular growth. Redirection of condylar growth. Remodelling of glenoid fossa to a more anterior position.
Dento-alveolar	Retroclination of upper incisors. Proclination of lower incisors. Inhibition of mesial and vertical development of maxillary teeth. Encouragement of mesial and vertical movement of mandibular molars.
Soft tissue	Removal of lip trap and improved competence. Removal of adaptive tongue activity. Removal of soft-tissue pressure from cheeks and lips.

Table 1. Theories on the mode of action of functional appliances.

their specific mode of action has been the subject of much debate and the proposed theories are outlined in Table 1.

The frequently asked question is can functional appliances modify growth? In this era of evidence-based dentistry, we

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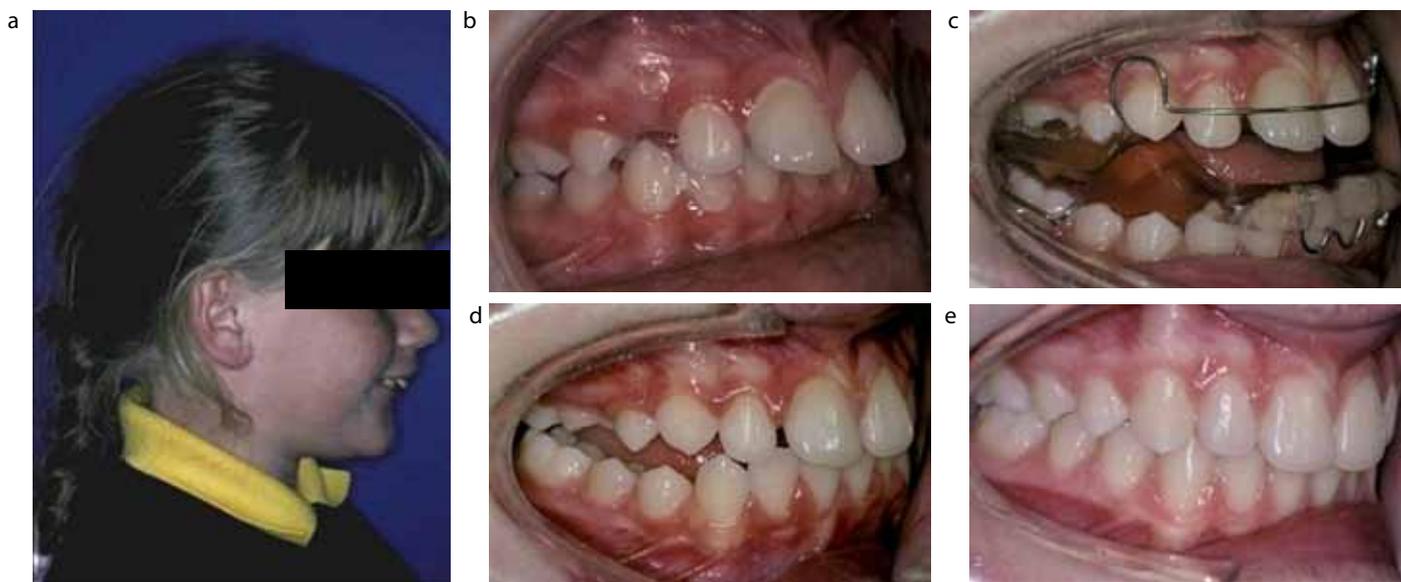


Figure 1. An example of a case successfully treated with the Twin-block: (a) pre-treatment facial profile; (b) pre-treatment overjet; (c) Twin-block appliance *in situ*; (d) post-functional overjet correction; (e) final occlusal result on completion of fixed appliance therapy and (f) post-treatment facial profile.



aim to review the recent orthodontic literature which has sought to answer this pertinent question. Evidence will also be reviewed with regard to the effects of differing functional appliances and the implication of treatment timing on functional appliance treatment outcomes.

Research hierarchy

The methods used to study growth modification have been shown to have a considerable impact on the conclusions drawn.² Study design is of particular importance.

Many of the early studies were undertaken on animal subjects, with one notable study³ on *Macaca mulatta* monkeys demonstrating an average mandibular length increase



Figure 2. Hierarchy of research evidence. (Source: Copyright SUNY (State University of New York). 2004. Guide to research methods: The evidence pyramid. <http://library.downstate.edu/EBM2/2100.htm>)

of 5–6 mm using functional appliances compared with untreated controls. However, with reference to research hierarchy, animal studies form one of the lowest levels of evidence (Figure 2) because it is difficult to correlate the data from animals to human subjects for the following reasons:

- The difference between species;
- The frequent use of animals without a skeletal Class II discrepancy; and
- The unrealistic, prolonged full-time

wear protocols employed.

Human retrospective studies, with or without a control, form the large body of the available literature on functional appliances. However, their internal validity is poor for the following reasons:

- They often only include successfully treated cases (selection bias);
- They are frequently undertaken by an enthusiast who does not represent the average clinician (performance bias); and

RCT	Groups	Mean age (yrs)	Results: Mean changes	Comments
New Zealand ^{4,5,6}	Un-tr. control (n=17) Fränkel (n=13) Harvold (n=12)	11.6	ANB (°): No SD control (-0.36; sd 0.71) vs. combined tr. groups (-0.88; sd 0.93) OJ (mm): SD control (0.21; sd 1.21) vs. combined tr. groups (-3.65; sd 3.34)	18 months of tr. Unsure of allocation concealment Assessor blinding 16% drop out rate Poor reporting on withdrawals
North Carolina (Phase 1) ⁷	Delayed tr. control (n=61) Bionator (n=53) Headgear (n=52)	9.4	ANB (°): SD control (-0.17; sd 0.73) vs. Bionator (-0.93; sd 0.99); SD control vs. Headgear (-1.07; sd 0.73) OJ (mm): SD control (-0.09; sd 0.98) vs. Bionator (-2.66; sd 1.81); SD control vs. Headgear (-1.50; sd 1.36)	15 months of tr. Unsure of allocation concealment Assessor blinding 5% drop out rate for phase 1 Good reporting on withdrawals
Florida (Phase 1) ⁸	Delayed tr. control (n=78) Bionator (n=79) Headgear-biteplane (n=92)	9.6	Apical base & OJ (mm): (<i>Johnston's pitchfork analysis</i>) Significantly greater Sk. Class II and OJ correction in tr. groups vs. control -absolute values not provided, results presented diagrammatically	Up to 24 months tr. Allocation concealment Assessor blinding 23% drop out rate for phase 1 Good reporting on withdrawals
UK multi-centre(i) (Phase 1) ⁹	Delayed tr. control (n=84) Twin-block (n=89)	9.8	Apical base & OJ (mm): (<i>Pancherz analysis</i>) Significantly greater Sk. Class II (mean difference: 1.88) and OJ (mean difference: 6.93) correction in Twin-block group vs. control	Up to 15 months tr. Allocation concealment Assessor blinding <2% drop out rate for phase 1 Good reporting on withdrawals

n = number of subjects included in final analysis; SD = significant difference (P < 0.001); sd = standard deviation.

Table 2. Summaries of RCTs investigating the immediate effects of functional appliances.

■ Their results may have been derived from incomplete case records (information bias).

Consequently, such studies may overestimate treatment effectiveness.

For studies without an untreated control group it is not possible to differentiate true treatment effects from normal growth changes. When a control has been incorporated, it is often based on historic data sets, such as the well known 'growth studies' which may no longer be valid for today's population. Even for prospective studies, unless the control group has been selected by random allocation, there are no assurances that

groups for comparison are balanced for confounding variables, known or unknown, and that any observed differences can be reliably attributed to treatment effects.

Consequently, prospective, randomized controlled trials (RCTs) are considered the 'gold standard' for study design when investigating treatment effectiveness of functional appliances and these will be the main focus of this article (Figure 3).

Immediate effects

Four recent RCTs⁴⁻⁹ investigating

the immediate effects of functional appliances, through the incorporation of an untreated control group, are summarized in Table 2.

With the exception of the New Zealand Trial,^{4,6} it can be seen that functional appliances produced statistically significant growth modifying effects. However, these effects tended to be modest, up to 1° ANB reduction⁷ or 1.9 mm improvement in skeletal relations⁹ compared with untreated controls, and therefore may not be considered clinically significant.

When assessing the

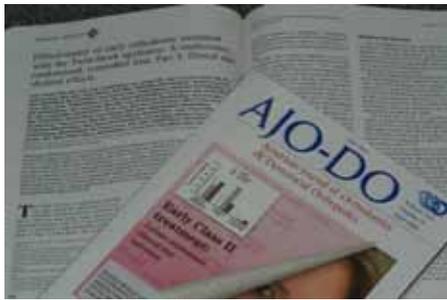


Figure 3. RCTs assessing Class II growth modification treatment effectiveness have emerged in recent years.

source of skeletal change, the trials investigating the Bionator appliance both showed no effect on maxillary growth but approximately 1 mm of annualized mandibular growth enhancement.^{7,8} Conversely, the Twin-block appliance produced 0.9 mm of maxillary growth restriction and 1 mm of mandibular growth enhancement at the 15 months data collection point.⁹

It should be noted that these trials all reported great variation in skeletal response to functional appliances, with some participants reacting much more and others much less favourably than the controls. This would imply that it is difficult to predict from the outset how well an individual

will respond to treatment. Currently, the best pre-treatment indicator of possible treatment success with the Twin-block appliance is a deep overbite.¹⁰

Compared with untreated controls, net overjet correction with functional appliance therapy ranged from 2.5 mm⁷ to 7 mm.⁹ If it has been established that skeletal effects are small, dento-alveolar effects must be the main contributor to this treatment change. The UK multi-centre RCT concluded that overjet correction was in fact a result of 27% skeletal change and 73% dento-alveolar change.⁹ Maxillary incisor retroclination was the most notable dento-alveolar functional appliance effect contributing to overjet reduction, which is consistent with the New Zealand RCT.⁶

Long term stability

Fundamental to the success and acceptance of any dentofacial growth modification technique is the ability to produce favourable skeletal changes that are retained over the long term.

Evidence from non-randomized studies, using matched untreated historic datasets as controls, generally suggests that the mandible experiences acceleration of growth

during functional appliance therapy, but slower growth thereafter, ultimately resulting in the same amount of total mandibular growth as the controls.¹¹⁻¹³ There is some evidence to suggest that maxillary restraint, unlike mandibular enhancement, is maintained and, in fact, continues to a small degree post-treatment.¹² However, this study was undertaken on young children and involved a demanding treatment protocol of 5 months of headgear-Herbst appliance, followed by a 3 to 5 year period of Activator retention.

In order to investigate the long term stability of growth modifying effects of functional appliances comprehensively, a prolonged longitudinal RCT, with complete treatment denial to the control group, would be required. Understandably, for ethical reasons, such a trial has not been performed.

Our best evidence arises from two longitudinal RCTs^{14,15} which investigated the effectiveness of 2-phase treatment for Class II malocclusion. In both trials, the untreated control group initially used to investigate the effectiveness of early functional or headgear therapy subsequently received fixed appliance treatment in adolescence (1-phase treatment).

RCT	Active Treatment Groups	Treatment Timing	Significant Cephalometric Differences (P < 0.05)
Illing <i>et al</i> ¹⁷	Bass-headgear (n=13) Bionator (n=18) Twin-block (n=16)	Adolescence	Skeletal: Twin-block greater maxillary restriction than Bass-headgear Twin-block greater total A-P correction than Bass-headgear Dental & Occlusal: Bass-headgear less lower incisor advancement than Bionator No difference between appliances for OJ
UK multi-centre (ii) ¹⁸	Twin-block (n=85) Herbst (n=98)	Adolescence	Skeletal: No A-P differences Dental & Occlusal: No OJ differences
Lee <i>et al</i> ¹⁹	Twin-block (n=28) Dynamax (n=28)	Adolescence	Skeletal: Greater mandibular enhancement with Twin-block Greater total A-P correction with Twin-block Greater increase in total anterior face height with Twin-block Dental & Occlusal: No OJ differences

Table 3. Summaries of RCTs comparing the Twin-block with other functional appliances. n = number of subjects included in final analysis.

Treatment outcomes were then compared to the early functional and headgear groups after they had also received fixed appliance treatment in adolescence (2-phase treatment).

They concluded that, at the end of fixed appliance treatment, there were no significant differences between 1-phase and 2-phase treatment for all anteroposterior and vertical skeletal^{14,15} or dental¹⁴ measurements. Beneficial growth modifying effects from early functional appliance or headgear treatment were not maintained after fixed appliance treatment in adolescence. This was despite one of the trials initially reporting that the skeletal gains from early functional appliance or headgear/biteplane treatment remained stable after one year follow up.⁸

Further, 2-phase treatment did not result in any difference in final PAR score, time in fixed appliances, or the proportion of complex treatments involving extractions or orthognathic surgery when compared to 1-phase treatment.¹⁴

The body of evidence therefore appears to suggest, particularly for early treatment, that the small skeletal gains achieved with functional appliances are purely temporary and not maintained in the long term. Nonetheless, the short-term average growth enhancement may usefully assist overjet reduction and molar correction.

Comparing appliances

Headgear versus functional appliances

Class II growth modification with headgear versus functional appliances has been investigated in three RCTs.^{7,8,16} Both the North Carolina⁷ and Florida⁸ trials compared the Bionator appliance with headgear in pre-adolescent children. They were in agreement that no significant difference existed between appliances for the total small amount of immediate skeletal correction achieved. Conversely, headgear in a mixed sample of pre-adolescent and adolescent participants produced a significantly greater reduction in ANB compared with the Fränkel appliance, mean difference 1.3° over two years.¹⁶ However, this should be interpreted with caution as no significant difference for change in the Wits measurement was found between the groups.

This literature is not wholly in agreement with regard to the differing sources of skeletal correction

and appears dependent on which cephalometric measures are compared. However, the evidence suggests that significantly greater maxillary restraint is achieved with headgear and significantly greater mandibular enhancement is achieved with functional appliances.^{7,16}

Twin-block versus other functional appliances

RCTs have also been undertaken to compare the effectiveness of different functional appliances.^{4,5,17,18,19} Trials comparing the Twin-block, which is considered the most popular functional appliance within the United Kingdom,²⁰ are of particular interest and are summarized in Table 3.

It is evident that within each trial the differing appliances were equally effective in overjet reduction. Greater reductions were achieved by the Twin-block in all trials, but did not reach significant levels. Equally, when compared with the Twin-block, the Herbst and Bionator appliances were as effective for skeletal correction.^{17,18} However, the Bass-headgear combination and Dynamax appliance were found to be significantly inferior to the Twin-block, with average ANB changes 2.3° and 0.9° less than the Twin-block, respectively.^{17,19} However, the latter result may not be clinically significant.

If there is little difference between functional appliances for skeletal and overjet correction, perhaps outcome measures that assess treatment efficacy and patient perceptions are of more importance. For example, it has been shown that the Herbst appliance, when compared with the Twin-block, achieves functional treatment effects significantly quicker, has a smaller noncompliance rate (13% versus 34%) and produces fewer problems with eating and speaking.¹⁸ However, the Twin-block costs less to produce and requires approximately three times fewer emergency appointments than the Herbst appliance.¹⁸

Twin-block design

In an attempt to minimize unwanted dento-alveolar effects and generate more skeletal change, design modifications to the Twin-block have been made and investigated. One RCT²¹ compared the effects of Twin-block treatment with an initial edge-to-edge bite to that of incremental advancement, using a series of 2 mm acetal spacers and advancement screws. Incremental bite advancement produced no advantages

over maximum advancement, with no significant differences for final overjet and skeletal discrepancy, treatment duration or patient compliance.

Although not strictly a RCT, a prospective study,²² involving random allocation of age and gender matched participants, compared a conventional Twin-block without a labial bow to a modified Twin-block. The incorporation of a maxillary incisor torquing spring, reduced bite-block height and incremental advancement significantly reduced maxillary incisor retroclination, but did not enhance mandibular growth or limit vertical skeletal changes when compared with the conventional design.

Lower level evidence also suggests that the incorporation of high-pull headgear and torquing spurs to the Twin-block can significantly increase maxillary restraint and reduce vertical skeletal changes.²³ Currently, there is no high quality evidence to support the statement that lower incisor capping reduces lower incisor proclination.

Treatment timing

It is widely hypothesized that the effectiveness of functional treatment depends on the growth rate of the mandible. Growth rates can be described as pre-peak, peak and post-peak with reference to the pubertal growth spurt. The evidence surrounding this topic is conflicting. Data, largely from retrospective studies, appear to indicate that the greatest skeletal response occurs during, or slightly after, the onset of the pubertal peak in growth velocity.²⁴⁻²⁶ However, evidence from one RCT,²⁷ assessing skeletal maturity using hand-wrist radiographs, and two further RCTs,^{18,21} assessing skeletal maturity using the cervical vertebral maturation (CVM) method, have failed to demonstrate any relationship between stage of skeletal maturity and skeletal response to functional treatment in growing participants. Either these methods of measuring maturation have limited validity or the outcome of treatment is not related to skeletal maturation.

Interestingly, one of these RCTs¹⁸ did report that the duration of time for functional appliance treatment was significantly shorter during the pubertal peak in growth velocity. This suggests that, although growth enhancement may not be increased, the increased rate of normal mandibular growth accompanying this stage of skeletal maturity helps to ensure that

functional correction of the malocclusion occurs quicker.

There are, of course, other important considerations relating to the timing of functional treatment. For example, the likelihood of compliance, with one RCT²¹ highlighting that patients aged 12.3 years or less are three times more likely to complete Twin-block treatment than older patients.

Trauma is a further consideration. It has been reported that the proportion of children sustaining accidental damage to their permanent incisors increases with age from 5% at age 8 to 11% by age 12,²⁸ and that overjets greater than 9 mm are at increased risk of sustaining trauma.²⁹ Therefore, undertaking early functional treatment to minimize this risk appears logical. However, new evidence from the UK multi-centre RCT investigating the effectiveness of early treatment for Class II malocclusion challenges this belief.³⁰ They found no significant difference in the prevalence of trauma between children receiving early treatment and those receiving treatment in adolescence only, 8% versus 14%, respectively. Interestingly, this supports earlier data from the North Carolina RCT.³¹ But it must be acknowledged that trauma figures were lower within the early treatment groups for both trials, and did not reach significant levels, which may be a reflection of group sizes.

The most recent paper from the UK multi-centre trial is of particular importance with reference to treatment timing.³⁰ It provides further support to the two earlier RCTs,^{14,15} previously alluded to, that 2-phase treatment, incorporating early intervention, cannot normally be justified in the management of Class II malocclusion. They found no difference between early Twin-block treatment, followed by treatment in adolescence, compared to adolescent only treatment with respect to skeletal pattern, extraction rate and self-esteem. Importantly, those who had early treatment had more attendances, received treatment for longer and incurred more costs than the adolescent treatment group. Interestingly, they also had a significantly poorer final occlusal outcome.

Perhaps, therefore, the only indication for early functional treatment is on psychosocial grounds. It has been shown that early functional treatment increases self-concept, reduces negative social experiences and improves

self-esteem compared with no early intervention.³² However, these gains are considered to be transient, as no difference in self-esteem was subsequently identified between this early treatment group and the controls once both groups had received treatment in adolescence.³⁰ Nonetheless, receiving these psychosocial gains early may be of particular benefit to children who are severely bullied or teased.

Discussion

We have endeavoured to review the available literature, focusing on high level evidence, in order to provide some clarification on the important issues relating to Class II growth modification, and in particular the use of functional appliances.

Many of our findings are in broad agreement with the recent and more formal Cochrane review.³³ As highlighted within their review, comparisons between different trials are particularly difficult to perform owing to a lack of uniformity in trial design. Notably, trials differ in the number and age of participants, clinical setting, treatment protocols, data collection intervals and outcome measures. The wide variation in cephalometric measures used, with or without annualization, makes trial comparison particularly troublesome. This lack of standardization should be taken into account when interpreting the findings of our review. In order to maximize research quality and facilitate trial comparison, such that meta-analysis can be performed to provide stronger statistical power to detect true effects, it is hoped that future RCTs adhere to the recommendations of the Cochrane review.³³ These focus on trial uniformity and reporting according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines.³⁴

The limited ability of functional appliances to modify growth, as reported in the reviewed RCTs, is not universally accepted throughout the orthodontic community.³⁵ Some clinicians would argue that there continues to be an absence of evidence on the grounds that trial results do not necessarily reflect their own clinical experiences. The inherent inaccuracy of cephalometry and the questionable validity of cephalometric measures used to quantify skeletal and dental changes have been proposed as reasons for this disparity.³⁵ It has also been suggested that the tendency to focus on the small mean skeletal changes often obscures the wide variability reported, and the potential for a greater than average beneficial effect in an individual.³⁵ While there may be some

truth in these statements, the consistency of findings between RCTs, the utilization of the best research methodology available at the time and the 'real world' approach of the most recent trials means that their evidence cannot be ignored. Until we can identify the factors that will guarantee a greater than average functional appliance response in an individual, we can only assume that a short term, limited average growth modifying effect will result.

Conclusion

Based on this review of the literature it can be concluded that:

- Functional appliances are effective in the management of Class II malocclusion in children.
- Overjet correction is principally by dento-alveolar change as opposed to skeletal change.
- A small degree of skeletal growth modification is achieved, but may not be of clinical significance.
- Long term stability of any skeletal correction is considered poor.
- The choice of functional appliance, when compared to the Twin-block, should not necessarily be based on the ability to correct overjet or skeletal relations, but on other operator and patient-related factors.
- More evidence is required to clarify whether in fact coinciding functional treatment with the pubertal growth spurt actually produces greater skeletal effects.
- Early orthodontic treatment followed by a later phase of adolescent treatment (2-phase) does not confer any benefits over adolescent only treatment (1-phase) in the management of Class II malocclusion.
- Severe bullying or teasing may be the only strong indicator to undertake early functional appliance treatment.

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CPD Answers for January 2010

1. C, D
2. A, B
3. A, B, C
4. A, B, C
5. A, B, C
6. A, D
7. A, B