



# Is early treatment for Class II malocclusion effective? Results from a randomized controlled trial

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**T**he early treatment of severe Class II malocclusion remains a surprisingly controversial issue despite the publication of 3 large randomized controlled trials in the United States.<sup>1-3</sup> Perhaps a main reason is the belief that these trials were carried out on selected populations who received treatment at dental schools. As a result, these

studies measured the efficacy of treatment—treatment delivered in “ideal” conditions. But what is the effectiveness of the treatment—how does it fare in the real world of orthodontic practice outside dental schools?

We recently attempted to address this problem in a large multicenter trial in the United Kingdom.<sup>4</sup> Importantly, the treatment was provided by many operators using the most popular functional appliance in this country—the Twin-block. The results of this study were recently published in the *AJO-DO*, and I will describe here only the main findings and some preliminary data on the long-term follow up.

Fourteen hospital-based orthodontic specialists in the United Kingdom took part in the study. Each had undergone basic specialty training and 3 years of higher training in the treatment of severe malocclusions. All operators were based in orthodontic departments, working in the National Health Service. In this system, the orthodontist receives a salary, and treatment is provided at no direct cost to the patient and family.

Our inclusion criteria were a minimum of 7 mm

overjet, no craniofacial syndromes, and willingness of the patient and parent to participate. We followed the guidelines in the Declaration of Helsinki. When patients who satisfied the inclusion criteria attended the clinic, they were asked to participate in the study. If they consented, the orthodontist phoned the study center at Manchester University to provide details of the patient. After initial recording of patient data, each patient was randomized to receive treatment with a Twin-block appliance or to have treatment delayed for at least 15 months. The randomization was prepared at the start of the study by using prearranged random number tables with a block stratification on center and sex.

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

When the overjet had been fully reduced, the patients were instructed to continue wearing the appliances as retainers at night only, or they were fitted with a retainer with a steep inclined biteplane, depending on the operator's preference.

One hundred seventy-four children aged 8 to 10 years with Class II Division 1 malocclusions were randomly allocated to receive treatment with the Twin-

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block or to the untreated control group. Data were collected at the start of the study and 15 months later.

The results showed that early treatment with the Twin-block appliance reduced overjets, corrected molar relationships, and reduced the severity of the malocclusions. Most of this correction was due to dentoalveolar changes and small amounts of favorable skeletal change. It appears that early treatment with the Twin-block appliance is effective in reducing overjet and severity of malocclusion. The small change in the skeletal relationship was not considered to be clinically significant. Importantly, 18% of the children did not complete their treatments.<sup>4</sup>

We also considered the sociopsychological effects of the treatment. We found that early treatment with Twin-block appliance increased the patients' self-concepts and reduced negative social experiences. The children also reported benefits from treatment that might be related to improved self-esteem. These results were encouraging because it was the first time that any sociopsychological benefit of early treatment has been reported.<sup>5</sup>

The study continued until the children had completed phase 2 treatment. Operators treated the children according to their normal treatment protocols—a pragmatic, real-world approach. We provided treatment to 2 groups of patients: a group that had received early intervention and a group that had not. We aimed to learn whether early treatment resulted in (1) the need for phase 2 treatment, (2) differences in skeletal pattern or final dental occlusion, and (3) less incisal trauma. Finally, were the differences in self-esteem stable after phase 2 treatment?

The provisional results of the study were interesting and highly relevant to our clinical practice, but they are only provisional and will be published in due course. Nevertheless, these data indicate that, at the end of phase 2 treatment, there were no differences between the patients who had early treatment and those who did not for any variable that we evaluated. We concluded

that our results agree with those of previous studies. It appears that early orthodontic treatment for Class II malocclusion does not confer an advantage, apart from a transitory change in self-esteem.

Importantly, the design and the setting of this study counteract many criticisms of previously published investigations; it adds to the increasing evidence on early orthodontic treatment. Yet, this remains a controversial issue, and many will not agree with or support our findings. In this respect, we should consider the level of scientific evidence that is often used to argue against this type of research. This has frequently been at the level of personal opinion, case report, and retrospective investigation.<sup>6</sup> I suggest that, to bring some order to the debate, at the end of all presentations and articles on this issue, presenters and authors should clearly state the level of scientific evidence that underpins their beliefs. If it is not at the level of a systematic review or a randomized controlled trial, then that belief should not be supported.

#### REFERENCES

1. Wheeler TT, McGorray SP, Dolce C, Taylor MG, King GJ. Effectiveness of early treatment of Class II malocclusion. *Am J Orthod Dentofacial Orthop* 2002;121:9-17.
2. Tulloch JF, Proffit WR, Phillips C. Outcomes in a 2-phase randomized clinical trial of early Class II treatment. *Am J Orthod Dentofacial Orthop* 2004;125:657-67.
3. Ghafari J, Shofer FS, Jacobsen-Hunt U, Markowitz DL, Laster LL. Headgear versus functional regulator in the early treatment of Class II, Division 1 malocclusion. *Am J Orthod Dentofacial Orthop* 1998;113:51-61.
4. O'Brien K, Wright J, Conboy F, Sanjie Y, Mandall N, Chadwick S, et al. Effectiveness of early orthodontic treatment with the Twin-block appliance: a multicenter, randomized, controlled trial. Part 1: Dental and skeletal effects. *Am J Orthod Dentofacial Orthop* 2003;124:234-43.
5. O'Brien K, Wright J, Conboy F, Sanjie Y, Mandall N, Chadwick S, et al. Effectiveness of treatment for Class II malocclusion with the Herbst or Twin-block appliances: a randomized, controlled trial. *Am J Orthod Dentofacial Orthop* 2003;124:128-37.
6. Feather AL. Early mixed dentition orthodontics: a common sense approach. *Pacific Coast Society of Orthodontists Bulletin* 2004; 36-9.