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Efficacy of the Sander bite-jumping appliance in growing patients with mandibular retrusion: a randomized controlled trial

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Structured Abstract

Objectives – The efficacy of functional appliances remains highly debated. This randomized controlled trial investigated the skeletal and dentoalveolar effects determined by the Sander bite-jumping appliance (BJA). The null hypothesis to be tested was that the appliance would not induce supplementary mandibular growth compared to untreated controls.

Setting and Sample Population – This study was carried out at the Section of Orthodontics, University of Naples Federico II, Italy. Forty-six patients receiving a clinical diagnosis of skeletal and dental class II due to mandibular retrusion were either allocated to a treatment (23 patients;15 boys, 8 girls; mean age ± SD: 10.9 ± 1.3 years) or to an untreated control group (23 patients;11 boys, 12 girls; mean age ± SD: 10.5 ± 1.2 years), by using a balanced block randomization.

Methods – Lateral cephalograms were taken before and after treatment and used for comparisons. Measurements were analyzed by descriptive statistics, univariate and multivariate statistical tests.

Results – Treated individuals had a significant increase in mandibular length (6.4 ± 2.3 vs. 3.5 ± 2.5 mm; $p < 0.001$), overjet reduction (−5.0 ± 2.9 vs. 0.3 ± 1.2 mm; $p < 0.001$) and molar relationship improvement (−5.3 ± 2.4 vs. 0.1 ± 1.1 mm; $p < 0.001$) compared to controls. The use of the appliance did not significantly affect jaw divergence. Proclination of lower incisors was slightly greater (3.0°, $p = 0.023$) in treated patients than in controls. The increase in mandibular length was not significantly influenced by cervical stage ($p = 0.40$).

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Conclusion – The BJA can effectively correct class II malocclusions by a combination of dentoalveolar and skeletal effects. The long-term stability of the correction needs to be evaluated.

Key words: bite jumping appliance; class II malocclusion; functional therapy; mandibular retrusion

Introduction

Most patients diagnosed as skeletal Class II present mandibular retrusion with the upper maxilla normally positioned or even retruded (1,2). The main treatment objective in these patients should be correction of dental and jaw sagittal relationships by advancing the mandible (3) rather than by distalizing the upper jaw and/or dentition, and obtaining at the same time an improvement of the impaired facial profile (4). In growing patients, this objective may be obtained by the use of functional appliances that posture the mandible forward and thus stimulate supplementary mandibular growth (5). Animal studies have previously shown that prolonged forward posturing of the lower jaw may induce temporomandibular joint remodelling and adaptation (6–8) and that the incremental mandibular growth obtained can be maintained in adult age (9). Also, human MR (Magnetic Resonance) studies (10,11) confirmed the possibility to obtain remodelling of the temporomandibular joint and increase of mandibular length.

However, the results of previous clinical trials testing the efficacy of functional appliances are not consistent. A recent review showed that the amount of supplementary mandibular growth obtained with treatment ranged from 0 to 5 mm per year (3). Differences between these studies might be related to the encouragement of *post hoc* deductions (12) and to the comparison with historical controls. Indeed, secular trends in craniofacial growth determined a significant mandibular length increase of Caucasians over a 50-year time span (13). Hence, historical controls may be not valid for comparisons with contemporary patients.

Randomized controlled trials (RCTs) are regarded as the best study design with which to test the efficacy of medical and dental interventions (14). In a systematic review concerning the treatment of prominent upper teeth in children it was reported that functional appliances may be effective in the short term (15). In a review of RCTs, Chen et al. concluded that the use of functional appliances for mandibular growth enhancement should be revaluated (16). Marsico et al. found that only four studies reached an acceptable methodological quality score (17), thus making them eligible for a meta-analysis. The conclusion of this meta-analysis was that functional appliances are associated with an

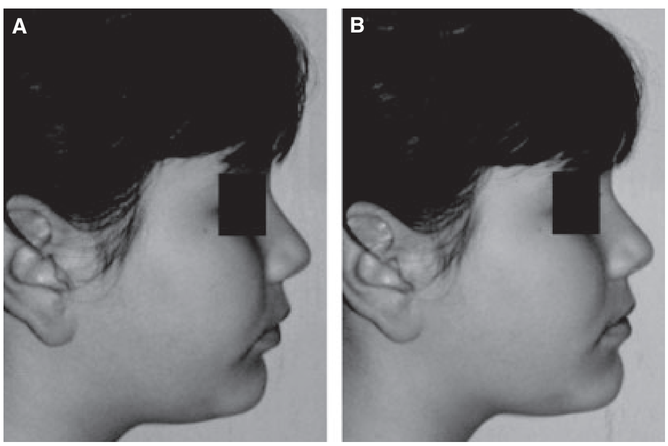

Fig. 1. Fraenkel maneuver. (A) Lateral photo at rest, (B) Lateral photo with Fraenkel maneuver.

average increase of mandibular growth amounting to approximately 1.8 mm, which was not considered clinically relevant.

The research methodology of previously published studies has also been questioned, because of the lack of a well-defined class II phenotype and the lack of appropriate controls used for comparisons (18). Although functional appliances should be electively prescribed to skeletal class II patients with a retruded mandible, the majority of previous RCTs did not consider mandibular features as inclusion criteria, and patients were selected mainly based on increased overjet and/or molar class II relationship. It is therefore possible that patients with either a skeletal class I pattern or a protruded maxilla were also included in study samples, which would have confounded the results (18,19). This latter scenario can also occur when cephalometric measurements rather than dental relationships are used as selection criteria (18).

It has been suggested that the orthopaedic correction of class II may be influenced by vertical craniofacial features (2). However, with only one exception (20), vertical diagnosis and divergence of the jaws were not taken into account in previous trials.

Another limitation of previous RCTs may be ascribed to inappropriate treatment timing, because functional appliances may be more effective when used close to the pubertal growth peak (21).

The aim of the present study was to carry out an RCT to test the efficacy of the Sander Bite Jumping Appliance (BJA, 22) in young individuals close to the pubertal growth peak who had been diagnosed as skeletal class II, with mandibular retrusion. The null hypothesis was that the tested appliance would not induce supplementary mandibular growth compared to untreated controls.

Material and methods

Study sample

Patients seeking an orthodontic consultation were screened by two specialists in orthodontics (RM and RT) at the Department of Oral Sciences, Section of Orthodontics, University of Naples Federico II, Italy, between April 2006 and June 2007. The patients were considered eligible when they presented a full class II molar relationships, overjet ≥ 6 mm, an age range of 10–13 years for boys and of 9–12 years for girls.

The Fraenkel maneuver (23) (Fig. 1) was used to assess the sagittal jaw discrepancy based on an aesthetic evaluation, as previously done by Illing et al. (24). The patients were asked to posture the mandible forward until a class I molar relationship was achieved. The maneuver was then repeated at least three times while encouraging the patients to keep the lips relaxed. Subjects that exhibited bimaxillary protrusion during the Fraenkel maneuver were excluded.

The following conditions were considered as further exclusion criteria: cervical vertebral maturation stage (CVMS) <2 or >3 (25), lack of parent's willingness to sign an informed consent form, sella-nasion to mandibular plane (Me-Go) angle equal to or greater than the normal value plus a standard deviation (26), periodontal diseases, orofacial inflammatory conditions, tooth agenesis, congenital syndromes, and previous orthodontic treatment.

The study protocol complied fully with the principles of the Helsinki Declaration and was approved by the Local Ethics Committee (reference number: 137/04).

Appliance

The appliance tested in this study was a Sander BJA (22). This appliance consists of an upper and lower acrylic plate. The core of the appliance tested is an expansion screw moulded with two robust prongs 13 mm long, which are embedded in the upper plate and positioned to form an angle of 60° with the occlusal plane (Fig. 2). The mid-portion of the lower plate has an inclined plane made of acrylic, which meets with the upper prongs when the mouth is closed, so that the patient is forced to posture the mandible forward. Stability and retention of both plates is obtained by means of Adams clamps; this is further increased by the use of a labial bow in the upper plate, and by covering the edges of the lower incisors and canines with

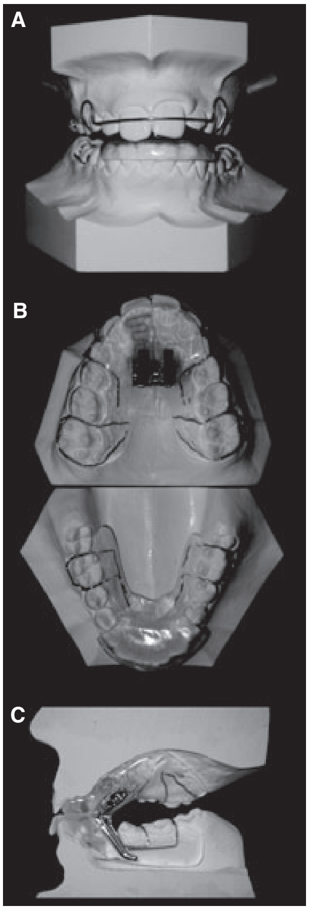

Fig. 2. Sander bite jumping appliance. (A) Frontal view, (B) Occlusal view, (C) Sagittal midsection.

acrylic in the lower plate. The initial wax bite registration was made with the mandible advanced by 4 mm. Subsequent reactivations of the appliance were obtained chair-side by adding a layer of acrylic 1.5 mm thick to the inclined plane of the lower plate. The timing of reactivation was determined in each patient based on the individual amount of improvement in sagittal dental relationships. The expansion screw was activated during treatment (one turn = 0.25 mm per week) as appropriate. The need for expansion was determined by comparing the transversal relationship of the upper and lower dentition in the initial models fitted in a class I molar relationship.

The patients were asked to wear the appliance 14 h/day, including sleep time, but not during meals. The patients were strongly motivated to wear the appliance consistently and were asked to record the daily wearing time in a diary.

Study design

The study was designed as an RCT. Enrolled patients were allocated to either a treatment (BJA) or control (CTR) group by balanced block randomization using gender as a stratifying factor. A custom-made Java script was used to generate the randomization procedure by a single investigator (SP) that was not involved in the clinical management of patients and control subjects. The randomization sequence was carefully concealed to the other investigators and was disclosed immediately after obtaining written informed consent. Patients allocated to the BJA group were treated with the BJA, whereas patients allocated to the CTR group did not receive any treatment and acted as passive controls. Patients allocated to the treatment group were seen every 5 weeks until a full class I molar relationship was achieved. The maximum treatment duration, however, was set at 18 months. The control patients were seen every 3 months for 12 months. The examiners involved in the recruitment process and in the treatment of patients (RM and RT) had been extensively trained in methodological and clinical procedures and calibrated for the assessment of Fraenkel maneuver outcomes. In particular, they underwent a preliminary calibration session using photographs of 30 untreated subjects with class II skeletal malocclusion. The clinicians were invited to evaluate independently the photographs and to assess if the patient showed bimaxillary protrusion when the mandible was postured forward. The percentage of agreement was 96.7%. In only one case out of thirty the examiners presented different assessments. The Cohen's K was 0.89, indicating a very good agreement (27).

Cephalometric measurements

The objective of cephalometric analysis was to assess the dentoalveolar, sagittal, and vertical changes. Lateral standardized cephalograms in the intercuspal position were obtained with the same X-ray equipment with standardized settings. The cephalograms were taken in centric relation at the start (T0) and end (T1) of the treatment in the BJA group and at the end of control period (12 months) in the control group. A 5-cm ruler was included in each radiograph. Cephalometric landmarks, lines, and measurements are shown in Fig. 2. A single examiner (AG) performed all of the cephalometric measurements using Dolphin Imaging 11.0 software (Chatsworth, CA, USA).

The measuring points, reference points, and lines used are shown in Fig. 3 and were defined following Pancherz's method (28). Variables for dental changes within the maxilla and within the mandible were calculated as follows: is/OLp minus Ss/OLp, change in position of the maxillary central incisor within the maxilla. Ii/OLp minus Pg/OLp, change in position of the mandibular central incisor within the mandible. Ms/OLp minus Ss/OLp, change in position of the maxillary permanent first molar within the maxilla. Mi/OLp minus Pg/OLp, change in position of the mandibular permanent first molar within the mandible.

For all of the linear measurements, the OL and the OLp of the initial radiograph were used as a reference grid. The grid was then transferred from the pretreatment to the posttreatment radiograph by superimposing on the nasion–T point line, with the T point as the registering point (Fig. 3). All of the measurements were made parallel to the OL. Differences in T1–T0 linear measurements were recorded according to Pancherz's method (28).

The examiner had been extensively trained in electronic cephalometric analysis and was blinded to the patients' name and allocation. The dates of the radiographs were also concealed from the examiner during the measurements. T0 and T1 radiographs were randomly submitted to the examiner. The cervical stage was determined on the T0 cephalogram by the same examiner (AG) according to the cervical vertebral maturation (CVM) method for the assessment of skeletal growth (25).

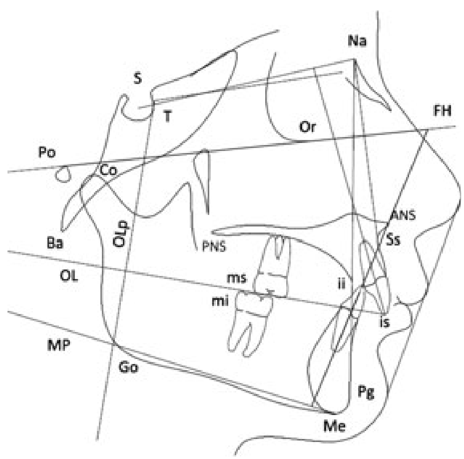

Fig. 3. Cephalometric evaluation of changes with treatment/observation periods. *Landmarks:* ANS (anterior nasal spine), the tip of the anterior nasal spine; Ba (basion), the midsagittal point of the anterior margin of the foramen magnum; Co (condyle), most superoposterior point on the curvature of the condylar head; where there was a double projection to two points, the midpoint was used; ii (incision inferius), incisal tip of the most prominent mandibular central incisor; is (incision superius), incisal tip of the most prominent maxillary central incisor; mi (molar inferius), distal contact point of the mandibular permanent first molar determined by a tangent perpendicular to the occlusal line (OL) - where there was a double projection to two points, the midpoint was used; ms (molar superius), distal contact point of the maxillary permanent first molar determined by a tangent perpendicular to the OL - where there was a double projection to two points, the midpoint was used; Pg (pogonion), most anterior point on the bony chin determined by a tangent perpendicular to the OL; Ss (subspinale), deepest point on the anterior contour of the maxillary alveolar projection; Sella (S), center of the hypophyseal fossa; N (Nasion), most anterior point of the junction of the nasal and frontal bone (frontonasal suture); Or (Orbitale), lowest point of the inferior margin of the orbit; Po (Porion), most superior point on the anatomical external auditory meatus; Go (Gonion), midpoint of the curvature at the angle of the mandible; Me (Menton), most inferior point of the mandibular symphysis; PNS (posterior nasal spine): the tip of the posterior nasal spine; T (T point), most superior point of the anterior wall of the sella turcica at the junction with the tuberculum sella. *Reference lines*: FH (Frankfurt horizontal), line connecting the P point to the Or point; MP (mandibular plane), line connecting the Me point to the Go point; SN (sella nasion line), line through S and N; OL (occlusal line), line through the is point and the distobuccal cusp of the maxillary permanent first molar; OLp (occlusal line perpendicular), line perpendicular to the OL through the T; PP (palatal plane), line connecting ANS and PNS. *Linear distances/skeletal landmarks*: Ss/OLp, position of the maxillary base;. Pg/OLp, position of the mandibular base; Co/OLp, position of the condylar head; Pg/OLp + Co/OLp, sagittal mandibular length. *Linear distances/dental landmarks:* is/OLp, position of the maxillary central incisor; ii/OLp, position of the mandibular central incisor; ms/OLp, position of the maxillary permanent first molar; mi/OLp, position of the mandibular permanent first molar.

Statistical analysis

The determination of sample size was based upon previous estimates of changes in mandibular length (Pg/OLp) during growth (21). By setting type I error at 0.05 and type II error at 0.20 (80% power), it was found that at least 19 patients per group were needed to detect an increase in mandibular length ≥ 2.0 mm. Data were analysed by conventional descriptive statistics. Absolute cephalometric changes were converted to relative changes over a 15-month period, and between-group differences were compared by means of independent samples T-test. Data were also analysed by means of analysis of variance entering group (BJA vs. CTR), cervical stage (CVMS 2 or 3) and gender as factors. The primary outcome was sagittal mandibular length (Pg/OLp + Co/OLp) change with treatment/observation periods. Secondary outcomes were dental relationship changes with treatment/observation periods, changes in the position of the upper maxilla, and changes in divergence of the jaws with treatment/observation periods (Table 1).

A single operator (IC), who was blinded to patient allocation (i.e. the allocation was masked to him in the dataset) performed the statistical analyses. Statistical significance was set at $p < 0.05$. All of the analyses were performed with commercial software (SPSS 20.0, IBM).

Data were analysed according to the intention-to-treat principle.

Results

Of the 110 individuals screened, sixty-one individuals were recruited and 49 excluded according to the inclusion/exclusion criteria (Fig. 4) Thirty-one individuals were allocated to BJA group and thirty to CTR group.

Six individuals did not receive allocated intervention (group BJA), and nine were lost to follow up (two in BJA group and seven in CTR group). Figure 4 (CONSORT flow diagram) demonstrates patient flow through the clinical trial.

The final sample comprised 23 patients (15 boys, 8 girls, mean age ± SD = 10.9 ± 1.3 years) allocated to the BJA group and 23 individuals (11 boys, 12 girls, mean age ± SD = 10.5 ± 1.2 years) allocated to the CTR group. The two groups were very similar at the baseline with regard to all skeletal and dentoalveolar variables (Table 1).

The mean (±SD) treatment duration was 14.5 months (±3.5 months). None of the patients reported any significant adverse effects, with the exception of mild discomfort experienced during the first week of treatment and the occurrence of a few oral ulcers. The majority of patients complied well with the appliance; the reported average wearing time was 12.1 ± 3.8 h per day.

Skeletal and dental measurements at T0 and T1 and their relative changes over time are reported in Table 1. Sagittal skeletal relationships were improved in the treatment group. The treatment determined a significant increase of mandibular length in treated individuals as compared to controls (Pg/OLp + Co/OLp = + 2.9 mm; 95% CI, 1.4–4.3 mm) as a result of increased mandibular base (Pg/OLp = +2.1 mm; 95% CI, 0.9–3.2 mm) and increased Co/OLp (+0.8 mm; 95% CI, −0.2–1.8 mm). The increase in mandibular length was not significantly influenced by cervical stage ($p = 0.40$). The BJA did not appear to cause significant maxillary restraint compared to controls (Ss/OLp = −0.3 mm; 95% CI, −1.7–1.0 mm). The treatment did not determine any clinically and statistically relevant clockwise rotation of the lower jaw as compared to controls (MP-FH, + 1.0°; 95% CI, −0.5 – 2.6 °; SN-MP, +1.1°; 95% CI −0.3 – 2.6°; PP-MP, −0.9°; 95% CI −0.1 – 2.9°).

The appliance determined an improvement of sagittal dental relationships as compared to controls, by producing a significant overjet reduction (−5.3 mm; 95% CI −6.7 – −4.1 mm), a minor proclination of the lower incisors (IMPA, + 3.0°; 95% CI 0.4 – 5.6°) and a slight retroclination of the maxillary incisors (U1/SN, −5.4°; 95% CI −8.3 – 2.5°).

Similar results were obtained by using analysis of variance after adjusting for gender and CVMS (Table 1).

Discussion

The aim of this trial was to evaluate the possible effects of functional therapy on mandibular length changes in individuals treated with BJA and untreated controls who presented very similar craniofacial characteristics at baseline. The study was designed as a randomized controlled trial and included concurrent untreated controls

Table 1. **Cephalometric measurement before (T0) and at the end (T1) of treatment/observation periods. Descriptive statistics for the variables examined and between-group (BJA vs. CTR) comparisons. Absolute cephalometric changes (T1–T0) are converted to relative changes over a 15-month period (see statistical methods). Linear measurements are in mm. Significance level was set at *p* < 0.05. Bold type: statistically significant**

Measurement	Group BJA n = 23 CTR n = 23	T0 (mean ± SD)	T1 (mean ± SD)	T1–T0 (mean ± SD) 15 months	T-TEST *p* between groups	ANOVA *p* between groups
Overjet (is/OLp – ii/OLp)	BJA	8.0 ± 1.9	3.6 ± 1.3	−5.0 ± 2.9	**<0.001**	**<0.001**
	CTR	7.6 ± 1.6	7.8 ± 1.8	0.3 ± 1.2		
Molar relation (ms/OLp − mi/OLp)	BJA	2.3 ± 1.0	−2.5 ± 1.4	−5.3 ± 2.4	**<0.001**	**<0.001**
	CTR	2.1 ± 1.0	2.1 ± 1.0	0.1 ± 1.1		
Maxillary Base (Ss point to OLp)	BJA	68.8 ± 4.0	70.0 ± 4.0	2.2 ± 1.9	0.604	0.710
	CTR	69.2 ± 3.7	71.2 ± 4.5	2.5 ± 2.5		
Mandibular base (Pg/OLp)	BJA	68.1 ± 5.4	73.3 ± 6.0	5.6 ± 2.2	**0.001**	**0.001**
	CTR	69.1 ± 6.0	72.0 ± 6.6	3.5 ± 1.6		
Condylar head (Co/OLp)	BJA	14.5 ± 3.0	15.4 ± 2.9	0.7 ± 1.7	0.132	**0.038**
	CTR	14.8 ± 3.3	14.8 ± 3.4	0.0 ± 1.7		
Mandibular lenght (Pg/OLp + Co/OLp)	BJA	82.7 ± 6.7	88.7 ± 6.9	6.4 ± 2.3	**<0.001**	**<0.001**
	CTR	83.9 ± 5.2	86.8 ± 6.5	3.5 ± 2.5		
Mandibular length (Co − Pg)	BJA	98.8 ± 6.6	105.5 ± 7.0	7.2 ± 3.2	**<0.001**	**<0.001**
	CTR	99.6 ± 4.9	102.7 ± 5.7	3.8 ± 2.7		
Mandibular height (Co − Go)	BJA	49.1 ± 4.2	52.9 ± 5.5	4.2 ± 3.7	0.169	0.219
	CTR	49.4 ± 4.5	51.6 ± 4.8	2.7 ± 3.3		
Maxillary incisor (is/OLp − Ss/OLp)	BJA	7.4 ± 2.1	6.3 ± 1.9	−1.4 ± 1.5	**<0.001**	**<0.001**
	CTR	7.9 ± 2.4	8.5 ± 2.4	0.8 ± 1.8		
Mandibular incisor (ii/OLp − Pg/OLp)	BJA	0.0 ± 1.9	0.2 ± 2.0	0.2 ± 1.4	0.096	0.056
	CTR	0.9 ± 2.3	0.5 ± 2.4	−0.5 ± 1.2		
Maxillary molar (ms/Olp − Ss/OLp)	BJA	−28.8 ± 7.7	−30.3 ± 8.2	−1.9 ± 1.8	**0.002**	**0.001**
	CTR	−32.3 ± 5.5	−32.2 ± 6.2	0.1 ± 2.2		
Mandibular molar (mi/OLp − Pg/OLp)	BJA	−31.1 ± 8.3	−31.2 ± 8.6	0.0 ± 1.5	0.065	0.101
	CTR	−34.1 ± 5.4	−34.8 ± 5.8	−0.8 ± 1.3		
SN-MP (°)	BJA	29.3 ± 5.5	30.1 ± 5.5	0.8 ± 2.2	0.125	0.173
	CTR	30.3 ± 5.5	30.2 ± 4.7	−0.28 ± 2.7		
MP-FH (°)	BJA	22.7 ± 3.5	22.8 ± 3.6	0.1 ± 2.1	0.171	0.126
	CTR	22.9 ± 4.6	22.1 ± 4.2	−0.9 ± 3.0		
U1/SN (°)	BJA	109.0 ± 6.8	103.9 ± 6.3	−5.7 ± 5.8	**0.001**	**0.001**
	CTR	106.3 ± 6.0	105.9 ± 6.0	−0.3 ± 3.8		
IMPA (°)	BJA	96.9 ± 6.1	99.6 ± 5.2	3.3 ± 3.7	**0.023**	**0.016**
	CTR	99.6 ± 6.3	99.8 ± 5.4	0.3 ± 4.9		
L1_FH (°)	BJA	60.4 ± 4.6	57.6 ± 5.2	−3.4 ± 4.5	**0.010**	**0.003**
	CTR	57.5 ± 4.8	58.0 ± 5.2	0.6 ± 5.6		
PP-MP (°)	BJA	24.9 ± 4.2	25.0 ± 4.5	0.2 ± 2.6	0.070	0.059
	CTR	26.1 ± 5.1	25.2 ± 5.1	−1.1 ± 2.4		

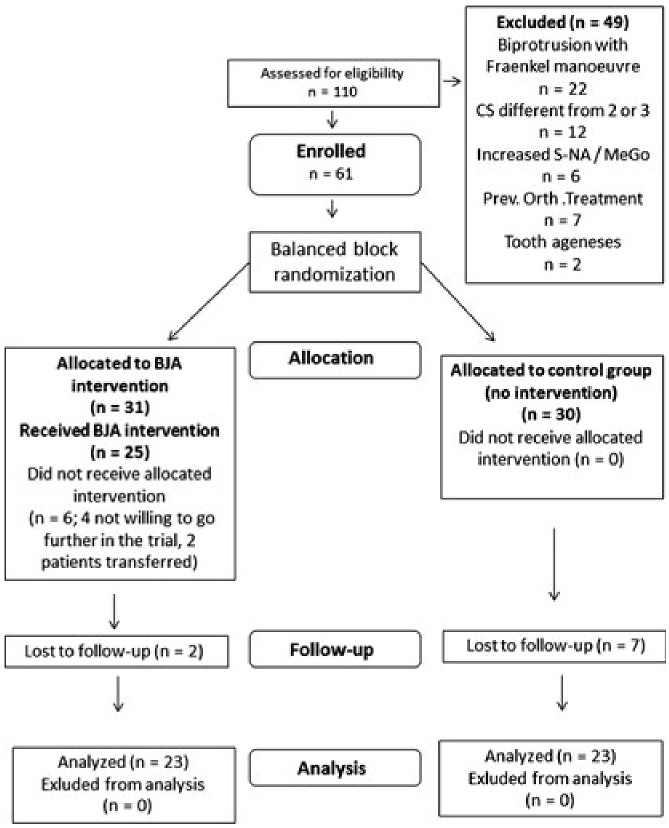

Fig. 4. CONSORT flow diagram. Diagram of patient flow through the trial.

for comparisons. This design allowed avoiding the risk of biases due to the use of historical controls (13).

Our results indicate that intervention with the BJA produced a statistically significant increase in mandibular length, reduced dental overjet, and improved molar relationship. A between-group difference of 2.1 mm in mandibular base (Pg/OLp) changes was measured. Furthermore, the total mandibular increment (Co/Pg) obtained is greater than the average values reported in a recent meta-analysis by Marsico et al. (17), and greater than that produced by the Twin-block appliance in 18 months of treatment or by the Herbst appliance in RCT studies (29,30). It is also greater than that produced by the Harvold activator or the Fränkel Regulator (0.69 mm and 1.32 mm, respectively) (31), in RCTs. A possible explanation for the greater mandibular response observed in our sample treated with BJA is the use of long sliding prongs that maintain an active protrusive effect during both day and night (32). Indeed, young individuals often present mouth breathing at night (33), and the electromyographic activity of the masseter at night is reduced compared to during the day (34). Therefore, it is to be expected that appliances with shorter sliding plates or prongs might exert a reduced protrusive effect on the lower jaw at night. However, further studies are needed to address this point. Moreover, patients might benefit from a nocturnal use of the appliance because of the more active bone turnover (35) and the reported growth-promoting effect of functional type orthopaedic appliance during rest (36).

The increase in the mandibular length observed in our study is clinically relevant, as it represents 51% of the molar relationship correction. Moreover, it should be pointed out that in our sample, a slight overcorrection of the molar relationship was achieved. Hence, it is possible that we underestimated the ratio between mandibular length change and molar relationship correction. Similar to the Twin-block appliance (29), the BJA exerted an irrelevant constraint on upper jaw growth (0.34 mm).

The BJA was also not associated with a significant proclination of the lower incisors (Ii/OLp minus Pg/OLp, 0.7 mm), which was less than that produced by other fixed or removable functional appliances (28, 30, 37). This could be due to the acrylic coverage of the lower incisors and canines.

The treatment was associated with a retrusion of the upper incisors of about 2.2 mm. The total overjet correction was on average 5.4 mm (Initial OVJ = 8.0 mm). Hence, it could be argued that the overjet was not completely corrected in our study sample. Following Clark's suggestions for the Twin-block appliance, we did not activate the labial bow of the BJA in order to avoid a dental constraint on mandibular growth stimulation (38). Although there is no scientific evidence in support to this suggestion, it may be expected that the orthopaedic effects would have been limited by reducing the overjet, with retrusion of the upper incisors and/or proclination of the lower incisors, because of limitation of mandibular advancement.

If maximum advancement of the chin point is a desired goal of treatment, the clockwise rotation of the jaws during treatment should be minimized (2, 20). The BJA did not have a significant effect on the divergence of the jaws. This is probably related to the forward position of the prongs, and to their inclination (60°), which produces a more vertical-reacting force on the upper jaw, preventing a clockwise rotation of the jaws.

Contrary to a previous report (21), the treatment response was not influenced by the cervical stage. Differences in the sample selection among the studies and the biomechanics of the appliances might account for this discrepancy and need to be further addressed.

This study suffers from a number of limitations, which may limit generalizability of the findings.

First, the recruitment of our skeletal class II patients was based on the use of the Fränkel maneuver. However, although this maneuver relies on a subjective evaluation of the profile, it was preferred to conventional cephalometric criteria, as their validity for sagittal jaw diagnosis is highly questionable (18, 39–42). To overcome the subjective nature of this clinical maneuver, the examiners involved in our trial underwent a calibration session, and duplicate measurements were used to estimate their agreement, which was very good (27).

Previous trials investigating the efficacy of functional appliances have used an increased overjet, sagittal molar relationship, ANB angle, and Wits apparaisal as eligibility criteria for class II patients (20, 24, 29–31). Increased overjet, however, can be also found in Class I patients showing proclination of the upper incisors and/or lingual inclination of the lower incisors (19). Class II molar relationships may be not necessarily the consequence of a Class II skeletal pattern (18). An increased ANB angle does not necessarily indicate a Class II skeletal imbalance (40). As matter of fact, the use of SNA and SNB angles for the assessment of jaw position has been questioned, because the poor reliability of the Nasion point. Changes of this point can affect SNA, SNB, and ANB angles, making impossible to determine the type of skeletal imbalance in Class II patients (41). Also, the Wits appraisal for the assessment of anteroposterior jaw relationship has been questioned (42). Finally it should be considered that cephalometric norms are based on historical samples that may differ significantly from current populations.

In this study, we took the divergence of the jaws into account for sample selection, since it can considerably affect the cephalometric sagittal evaluation (Co/OLp + Pg/OLp) of the lower jaw before treatment and influence the treatment response (2). It is plausible that a long-face subject with clockwise rotation of the lower jaw would have a reduced sagittal increment of the mandible after treatment compared to individuals with normal or small angles. If advancement of the chin point is an objective of treatment, the divergence of the jaws should be taken into account.

Finally, a recent Cochrane review (15) indicated that the additional growth obtained by various functional appliances might be lost over time. Further studies should be performed to test the efficacy of BJA on the long-term.

Conclusions

The results of the present RCT reveal that BJA is effective in determining supplementary mandibular growth in young individuals as selected in the present study. The side effects of this appliance, such as clockwise rotation of the jaws, sagittal upper jaw growth control and proclination of the lower incisors were minimal.

Even if a significant component of class II correction might be obtained by an incremental growth of the mandible using this device, further studies should be performed to address the long-term effects produced by the BJA.

Clinical relevance

This study aimed to assess whether a functional therapy performed by means of the Sander Bite Jumping Appliance (BJA) induced supplementary mandibular growth in skeletal class II patients. In order to improve the internal validity of the trial, we have used strictly defined selection criteria. Indeed, the patients recruited in this trial showed skeletal class II jaw relationships that improved upon forward posturing of the mandible, were close to the growth peak, and did not present a severe hyperdivergent jaw pattern.

The trial provided evidence that BJA determined a statistically and clinically significant increase of mandibular growth, as the mandibular skeletal change represented 51% of the total class II correction. The findings support the short-term efficacy of BJA for the treatment of skeletal class II in a specific subset of patients. Long-term stability of the correction, however, needs to be evaluated.

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