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Mandibular advancement appliances for sleep-disordered breathing in children: A randomized crossover clinical trial

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ABSTRACT

Objective: To test the short-term effectiveness of a mandibular advancement splint (MAS) for the management of sleep-disordered breathing (SDB) in children.

Methods: Eighteen SDB children were enrolled in a crossover randomized clinical trial and assigned to a treatment sequence starting either with an Active or a Sham MAS. Each appliance was worn for three weeks and treatment periods were separated by a two-week washout. Home-based polysomnographic data were collected before and after each treatment period. In addition, blood samples were collected at the end of each treatment period to assess serum levels of insulin-like growth factor-1 (IGF-1).

The apnea-hypopnea index (AHI) and snoring time represented the main outcome variables. Secondary outcomes included IGF-1 levels, and questionnaire scores for quality of life and behavior.

Results: Compared to the Sham MAS, the wearing of the Active MAS resulted in a significant reduction in overall AHI (-37%; 95% CI = 15–53%; $p = 0.002$) and supine AHI (−4.1 events per hour; 95% CI = 1.8–6.4; $p < 0.001$). Mean snoring time per night was shorter with the Active MAS than with the Sham MAS (−46.3 min; 95% CI = 14.5–78.1; $p = 0.004$). Wearing of the Active MAS improved the ratings of quality of life and behavior ($P \leq 0.028$), but there was no evidence that it influenced IGF-1 levels ($P = 0.172$).

Conclusion: Wearing an Active MAS overnight, over a short period can be beneficial for SDB children, resulting in a clinically relevant reduction of supine AHI.

1. Introduction

Sleep-disordered breathing (SDB) encompasses a continuous spectrum of disorders, ranging from primary snoring to obstructive sleep apnea (OSA). The health impact of SDB in children has become increasingly recognised [1,2]. Whilst most authors report a 10% prevalence of habitual snoring in children [3], the prevalence of OSA in children ranges from 1 to 4% [2,4,5]. SDB has been associated with growth disorders, daytime sleepiness, educational and behavioral problems, and nocturnal enuresis [6]. In the most severe cases, OSA may have life-threatening consequences, such as cardiorespiratory failure [1,6].

Enlarged adenoids and tonsils are the most common cause of OSA in children therefore the first line and most common treatment for pediatric OSA is adenotonsillectomy [7]. The incidence of adenotonsillectomy has increased in the past few decades, as the indication for surgery has markedly shifted from recurrent infection to upper airway obstruction [8,9]. Although significant improvements in SDB are observed following adenotonsillectomy, the cure rate of OSA after operation (defined as a post-adenotonsillectomy AHI < 1 event/h) ranges from 27% to 60% [10,11].

Orthodontic and craniofacial anomalies have often been reported in pediatric OSA. A mutual interaction has been reported between the nasopharyngeal airway and the craniofacial complex [12]. Jaw malposition and anomalies are associated with changes in airway morphology and respiratory problems [13–17]. Reciprocally, obstruction of the airways has an influence on the development of the stomatognathic system [18]. Because of this association, oral appliances, such as mandibular advancement splints have also been widely used for the treatment of OSA in patients with dentofacial anomalies [19]. These appliances increase the posterior oropharyngeal airway and reduce the upper airway collapsibility by holding the mandible in a protruded position during sleep. Furthermore, the appliance may trigger stretch receptors, which in turn activate the airway supporting muscles [19] increasing airway patency.

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Previous studies have shown that oral appliances are better tolerated than continuous positive air pressure (CPAP), which is currently considered the first-line treatment option for adult OSA, due to improved comfort, quietness, and portability [20]. Mandibular advancement splints (MAS) are the most widely used oral appliance for treating SDB in adults. In children, they are widely used to improve facial appearance in growing children with retruded mandible [21] but they are hardly used for SDB treatment [20,22–25]. To date, there are only few studies testing the efficacy of MAS in children, which suffer from methodological flaws, including lack of randomisation and lack of adequate control conditions, such as the use of a placebo-like or sham appliance. A Cochrane review [24] concluded that there is not enough evidence to support the use of oral appliances and functional orthopedic appliances for the treatment of OSA in children. This conclusion was also reached by two recent systematic reviews and a meta-analysis, confirming that the current evidence is limited, but the potential for MAS to be effective for treating pediatric OSA was indicated [22,23]. Thus there is a strong need to carry out well-designed randomized controlled trials (RCTs) to investigate both the efficacy and effectiveness of mandibular advancement appliances in children affected with SDB [24,26–28].

The aims of this study were to test the short-term effectiveness of MAS appliances for the management of SDB in children and their effect on quality of life, behavior, and growth hormone levels.

2. Materials and methods

2.1. Study design

This study was carried out as a crossover randomized clinical trial. Each participant wore an Active and a Sham MAS appliance overnight for three weeks. Treatment periods were separated by a two-week washout period.

2.2. Participants and setting

This study took place between May 2014 and December 2015, and was conducted at the Discipline of Orthodontics, School of Dentistry, University of Otago, Dunedin, New Zealand. Ethical approval was granted by the University of Otago Human Ethics Committee [H14/054]. The trial was registered in the Australian New Zealand Clinical Trials Registry (ACTRN12614001013651). The full protocol including sample size estimation has been published elsewhere [29]. We aimed to recruit at least 18 participants.

2.3. Recruitment

Advertisements were placed in local newspapers and on community noticeboards to invite children whose parents reported their child snored regularly and loudly to participate in the study. Thirty-one parents contacted the research team with expressions of interest, and were sent information sheets by mail. Twenty-two respondents presented to the Dental School for a clinical screening, and their parents were asked to complete the Pediatric Sleep Questionnaire (PSQ). Individual height and weight measurements were taken at the first appointment to calculate the body mass index (BMI), and an oral examination was performed. Tonsil size and oropharyngeal patency were visually inspected and scored according to Mallampati [30]. Dental impressions were taken using alginate impression material (Orthotrace, Cavex Holland BV, Haarlem, The Netherlands), and poured with stone (Ortho Stone & Ortho Plaster, Nobilium Company, New York, USA) to obtain study and work models. Additional records that were collected included intra-oral and extra-oral photographs and lateral cephalograms (Carnex Tome Ceph, SOREDEX, Tuusula, Finland) in maximum intercuspal position. The cephalometric landmarks and measurements assessed are illustrated in Fig. 1.

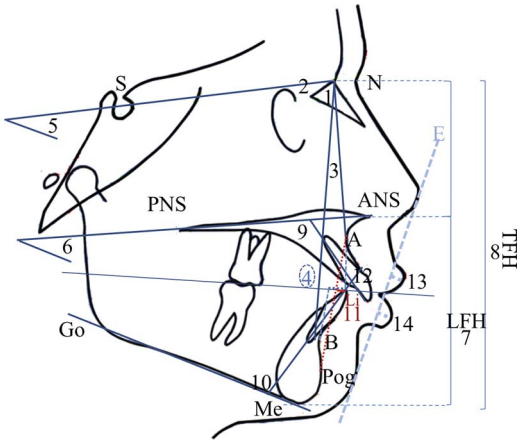

Fig. 1. Cephalometric measures used in the study.
Cephalometric landmarks and measurements used to describe the dentofacial features of participants enrolled in the trial.
SNA (deg) the angle formed by the planes sella-nasion and nasion-point ASNB (deg) the angle formed by the planes sella-nasion and nasion-point BANB (deg) the angle formed by the planes nasion-point A and nasion-point BWits appraisal (mm) distance between the projection of points A and B on the occlusal planeSN-MP (deg) the angle between the mandibular plane and sella-nasionMMPA (deg) the angle formed between the palatal (ANS-PNS) and mandibular planesLower face height (LFH) (ANS-Me) (mm) measured by the distance from ANS to mentonTotal face height (TFH) (N-Me) (mm) measured by the distance from N to mentonUIA the angle formed by the long axis of the upper incisor and the maxillary planeLIA the angle formed by the long axis of the lower incisor and the mandibular planeLi-APog (mm) distance between the tip of the lower incisor (Li) and (A-Pog)Interincisal angle (deg) the angle formed by the long axis of the upper and lower incisorUpper lip relation to Ricketts E line (mm) measured by the distance between labrale superius (Ls) to Ricketts E lineLower lip relation to E line (mm) measured by the distance between labrale inferius (lower lip) to Ricketts E line

Eligible participants had to meet the following inclusion criteria: age range from 8 to 12 years, and; parental report of loud snoring for three or more nights per week.

Exclusion criteria were: previous orthodontic treatment, craniofacial and genetic syndromes (*e.g.* cleft lip and/or palate), neuromuscular disorders, and Class III incisor and/or skeletal relationship as confirmed by lateral cephalometric radiograph (ANB angle $\leq 0^{\circ}$) [31].

2.4. Randomization

Participants enrolled in the trial were randomly assigned to one of two sequences involving either the Active MAS treatment being delivered first followed by the Sham MAS, or the opposite order.

Randomization was performed using computer-generated blocks of size 4 for the two treatments. Allocation was concealed using opaque envelopes, which were only disclosed immediately after enrolment by a member of the research team (MF). Participant flow is illustrated in Fig. 2.

Participants were not made aware of whether the appliance they received was the Active or the Sham appliance.

2.5. Oral appliances

Clark's Twin-Block [32] was chosen as the active intervention for this RCT to be used as an Active MAS, based on the results of a pilot study, which aimed to compare the retention and comfort of different MAS designs [29]. Treatment was always provided by the same member of the research team (GI).

2.5.1. Twin-Block MAS design

This consisted of two removable upper and lower acrylic plates, each with matching surfaces, which encourage the lower jaw to posture forward as the upper and lower teeth come together [33]. Bilateral

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