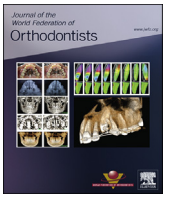
Journal of the World Federation of Orthodontists 8 (2019) 89–94

Contents lists available at ScienceDirect

Journal of the World Federation of Orthodontists

journal homepage: www.jwfo.org



Featured Review Article

An updated systematic review regarding early Class II malocclusion correction

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ARTICLE INFO

Article history:
Received 14 June 2019
Accepted 19 June 2019
Available online 14 August 2019

Keywords:
Class II malocclusion
Early treatment
Orthodontic appliance
Systematic review
Treatment outcomes

ABSTRACT

Background and aim: Class II malocclusion is one of the most common malocclusions in young children and a great deal of research on this topic has been undertaken. Despite this, there are still knowledge gaps on whether it is effective to treat these malocclusions early or what type of treatment should be performed. The aim of this article was to systematically review and update the quality of evidence for various treatment modalities considering Class II malocclusion correction before 10 years of age and with a focus on improvement of dental and skeletal relationships, soft tissue profile, relation to temporomandibular disorder (TMD), incidence on dental trauma, cost-effectiveness, and quality of life.
Material and methods: Four databases were searched, from January 1960 to April 2019. Inclusion criteria were randomized or controlled trials reporting short- or long-term effects on dental or basal relationships, soft tissue profile, associations to TMD, quality of life, incidence of trauma, or costs. The quality of evidence was scored according to Grading of Recommendations Assessment Development and Evaluation.
Results: A total of 300 publications were identified and 23 satisfied the inclusion criteria for full evaluation. The quality of evidence was high in 5 trials, moderate in 3, and low in 15.
Conclusions: From the short-term perspective, there is a high level of evidence that early treatment reduces overjet and improves the anterior-posterior skeletal relationship. There is insufficient evidence about whether early treatment can reduce the incidence of trauma, is cost-effective, provides improved soft tissue profile, improves oral health–related quality of life, or possesses a risk of developing TMD.
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1. Introduction

Class II malocclusion is one of the most common malocclusions in young children [1] and even though a great deal of research on this topic has been conducted, there are still knowledge gaps regarding whether it is effective to treat those malocclusions early or what types of treatment should be performed [2,3]. Nonetheless, a Cochrane review [2] presented that early correction with functional removable devices attained a statistically significant decrease in trauma incidence of incisors. Even if most research has addressed dental and skeletal treatment effects, some research efforts have also been focused on whether temporomandibular disorders (TMD) may cause or can be associated with Class II malocclusions [4], as well as if oral health–related quality of life [5] or psychosocial effects [6] can be affected by untreated Class II malocclusions. It has been presented that 8- to 10-year-old children with excessive overjet and Class II malocclusion reported significantly lower oral health–related quality of life compared with children with unilateral posterior crossbite or children with normal occlusion [5]. However, regarding TMD, the evidence was insufficient in considering if early treatment of Class II malocclusions is related to TMD development [3].

It also has been discussed whether, if at all, it is beneficial to treat Class II malocclusions that are in the mixed dentition early, or if treatment should be postponed to the permanent dentition. Those who prefer early treatment justify this because the treatment is easier to carry out, the growth can be better exploited, and early treatment will result in less damage to the teeth and surrounding tissues, as well as there being positive effects on children's self-esteem [7].

Funding: This survey was funded by the authors' academic institution. Faculty of Odontology, Malmö University, Malmö, Sweden.
Competing interest: Authors have completed and submitted the ICMJE Form for Disclosure of potential conflicts of interest. None declared.
Provenance and peer review: Commissioned; Internally peer reviewed.
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2212-4438/$ – see front matter © 2019 World Federation of Orthodontists.
https://doi.org/10.1016/j.ejwf.2019.06.002

In clinical research regarding different orthodontic interventions, it is primarily recommended to perform randomized controlled trials (RCTs) to minimize bias [8,9]. Consequently, using RCTs will diminish clinicians' or patients' preference for certain treatment, and, most important, by the random allocation process, confounding factors, factors over which we have no control during the trial, will affect the involved groups equally [10]. It is also a goal to ensure that the evidence-based research results are transformed into everyday clinical practice and assist the clinicians in delivering high-quality evidence-based care. However, it can be difficult for the busy clinician to read and analyze every article and then interpret the evidence. Instead, in estimating the entire quality of the research and disclosing conceivable knowledge gaps, a systematic review of research is a useful tool to help the clinician. The aim of this article was to systematically review and update the quality of evidence for various treatment modalities considering Class II malocclusion correction before 10 years of age and with a focus on improvement of dental and skeletal relationships, soft tissue profile, relation to TMD, incidence on dental trauma, cost-effectiveness, and quality of life.

2. Material and methods

The Goodman guidelines [11] were used to accomplish this systematic review. Thus, we started to denote a research question, and, further on, a plan for the literature search was assessed followed by the search itself and retrieval of papers. Last, information was interpreted to perform quality assessment of the papers and estimate the general evidence.

2.1. Research question

We denoted the following question: "How effective are various treatment modalities considering Class II malocclusion correction before 10 years of age and with a focus on the outcomes: improvement of dental and skeletal relationships, soft tissue profile, relation to TMDs, incidence on dental trauma, cost-effectiveness, and quality of life?"

2.2. The literature search

In consultation with a senior librarian, four electronic databases were searched from January 1960 through April 2019. The four databases were PubMed, Web of Science, Cochrane, and CINAHL, and five separate search syntaxes were devoted. Thus, the first one included Malocclusion, Angle Class II (MeSH term) and Orthodontic appliances (MeSH term) and Dentition, Mixed (MeSH term), followed by a second: Malocclusion, Angle Class II (MeSH term) and Orthodontic appliances (MeSH term) and Dentition, Mixed (MeSH term) and Costs and Cost Analysis (MeSH term), for the third: Tooth injuries (MeSH term) and/or Tooth fractures (MeSH term) and Malocclusion, Angle Class II (MeSH term) and Orthodontic appliances (MeSH term) and Dentition, Mixed (MeSH term), and the fourth search: Malocclusion, Angle Class II (MeSH term) and Orthodontic appliances (MeSH term) and Dentition, Mixed (MeSH term) and Temporomandibular Joint Dysfunction Syndrome (MeSH). Finally, the fifth syntax consisted Quality of Life (MeSH term) and/or Self Concept (MeSH term) and/or Patient Satisfaction (MeSH term) and Malocclusion, Angle Class II (MeSH term) and Orthodontic appliances (MeSH term) and Dentition, Mixed (MeSH term).

2.3. Collection of papers

The PICO model was set up as follows:

- Population: children starting the Class II malocclusion correction before the age of 10.
- Intervention: any orthodontic treatment for Class II malocclusion correction. For two-phase treatments, the first-phase treatment was included if it was started before the age of 10.
- Control: no treatment or children treated with another comparable orthodontic treatment method.
- Outcome: short- or long-term treatment outcomes as improvement of dental and skeletal relationships, soft tissue profile, relation to TMD, incidence on dental trauma, cost-effectiveness, and quality of life.

Using a pre-set protocol, three researchers independently decided the potential eligibility of randomized or prospective controlled trials. Retrospective controlled trials, case series, case reports, reviews, and opinions were excluded, as well as any trial considering treatment started after the age of 10. Articles were collected irrespective of the language in which they were published.

The titles and abstracts of all potentially relevant trials were first reviewed, and, following this, the full-text version of an article was retrieved if at least one of the three researchers deemed the publication to be relevant or if the title and abstract did not provide sufficient information. Diverging opinions among the three researchers were solved by consensus. The reference lists of articles deemed eligible were also hand-searched for additional studies.

2.4. Data collection, quality assessment, and estimation of general evidence

The three researchers extracted key data from the accepted trials and these data were compiled in a table. Following this, the quality of the selected papers was rated after predetermined criteria for methodology and study performance. The quality of every trial was categorized as high, moderate, and low [12]. To classify as high or moderate quality, the trial must have a sufficient number of subjects, appropriate control subjects, and a dropout rate below 30%. In addition, quality could be downgraded if there was absence of adaptation for possible confounders (selected subjects or only successful outcomes were presented) or contradiction of outcomes.

The quality or strength of the evidence was finally rated with the Grading of Recommendations Assessment Development and Evaluation (GRADE) tool [13].

3. Results

In total, 300 publications were identified, of which 75 were completely judged. After analysis according to the inclusion/exclusion criteria, 23 publications remained to be qualified for the evaluation of trial quality (Fig. 1).

Fifteen publications [14–28] were judged to be of low quality, and were not considered in the final analysis and assessment of evidence. These publications were graded as being of low quality because only successful treatments were reported, historical controls were used, the inclusion criteria were unclear, the subjects were insufficiently described, or unclear methodologies were used. Consequently, eight publications [6,29–35] and all RCTs, remained to be qualified for the final analysis, and, of these, five were considered [6,29–32] to be of high and three [33–35] of moderate quality (Table 1). Four of the publications were produced in the United States [29,32,33,35], three in the United Kingdom [6,30,31], and one in Sweden [34]. The trials from the United States consisted of two populations and two trials [29,32] comparing the Bionator together with headgear treatment with no treated control children, whereas the other two publications used Bionator or headgear/bite

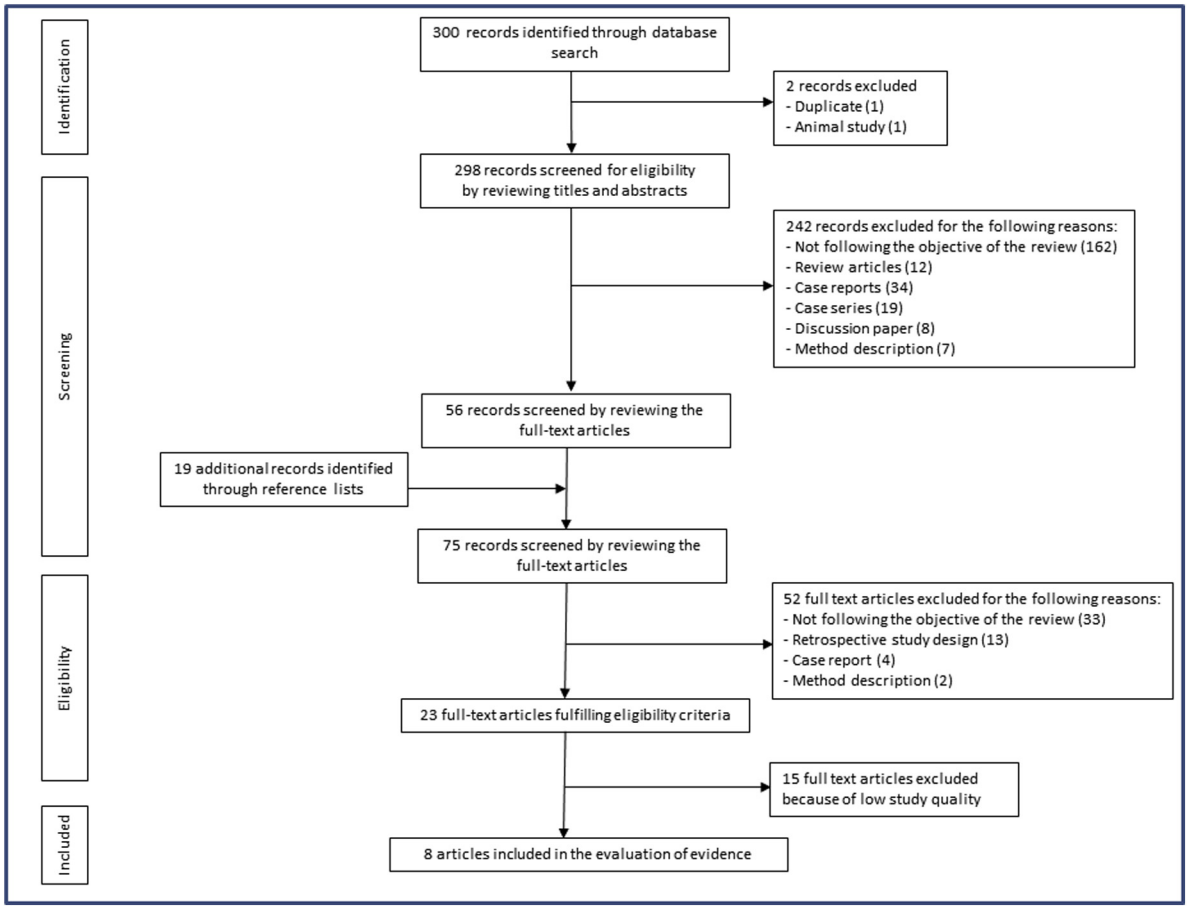

Fig. 1. The varying phases and the flow of identified publications in this review.

plane and untreated controls for comparisons [3,35]. In the publications from the United Kingdom [6,30,31], the same study population was used in all three trials and treatment of the twin-block was compared with untreated children. Finally, in the Swedish trial [34], activator and headgear treatment were compared with untreated control children.

An agreement of 95% was found between the researchers in assessing the data extraction and quality scores of the included publications.

3.1. Dental and skeletal relationships

Overjet was reduced compared with untreated subjects when early treatment of twin-block, Bionator, activator, or headgear was performed [30,32,34,35]. In addition, twin-block also corrected the molar relation [30].

Large individual variations were found in skeletal changes and improvements [30,32,34,35] and a significant mean skeletal improvement of 2 mm was found for twin-block treatment [30], but this improvement was not considered clinically significant.

It was also reported that early treatment with headgear could restrain the maxillary forward growth, whereas Bionator increased the mandibular forward position [32]. Moreover, when compared with untreated children, early treatment with Bionator and headgear/bite plane corrected the apical base relation and predominantly by mandibular forward position and without any maxillary restricted growth [35]. On the other hand, Jakobsson [34] presented a restricted maxillary forward growth when headgear and activator treatment were carried out. However, no support for mandibular forward position was found or that the condylar growth was intensified [34].

3.2. Soft tissue profile

One trial evaluated the soft profile changes after early twin-block treatment of Class II malocclusion [31]. After judgment by other children and teaching personnel, the facial profile was defined to improve after treatment, predominantly because of diminished overjet and decreased visible incisors.

3.3. TMDs

No publications could be found that had investigated the relation between early Class II malocclusion correction and TMD.

3.4. Incidence on dental trauma

It was found that early Bionator treatment could diminish trauma incidence [29] but another trial could not find this connection [33]. Likewise, it must be recognized that, before the age of 10, many children have experienced incisor trauma [33] even if most injuries before or under treatment may be of minor extent [29,33].

3.5. Cost-effectiveness

One trial reported that early treatment with Bionator appliance may have some impact on diminishing the frequency of trauma,

Table 1
Studies included in the evaluation of evidence

Author, year	Study design	Study population	Outcome measures	Results	Study quality/Comments
Tulloch et al. 1997 [32]	RCT	53 Bionator 9.4 ± 1.0 years 52 Headgear 9.4 ± 1.0 years 61 Controls 9.4 ± 1.2 years	Cephalometrics: Antero-posterior skeletal discrepancies Dental relations: Overjet, overbite Mandibular length	Overall, early treatment showed a reduction in overjet and a 75% chance for improving the jaw relationship. Basal improvement was achieved through different mechanisms. Headgear resulted in maxillary restraint and Bionator in forward positioning and increased length of the mandible. Great individual response to treatment and difference in growth were registered in both the treatment and control groups.	High + Randomized study design + Sample size calculations + Intention-to-treat approach + Attrition <20% + Method error analysis
O'Brien et al. 2003 [30]	RCT	89 Twin-block 9.7 ± 0.98 years 85 Controls 9.8 ± 0.94 years	Cephalometrics: Antero-posterior skeletal discrepancies Dental relationships: Overjet, incisor and molar positioning PAR-score	Twin-block treatment resulted in a reduction of overjet, 70% of the correction due to dentoalveolar changes. Skeletal improvement after early treatment with Twin-block was on average 2 mm, the result of a similar degree of growth modification in the maxilla and the mandible. PAR-score was reduced by 42% in the treated group whereas in the controls PAR-score was increased by 9%	High + Randomized study design + Multicenter + Control of confounders (age, gender, treatment) + Attrition <20% + Sample size calculations + Intention-to-treat approach + Blinding when analyzing + Method error analysis
O'Brien et al. 2003 [6]	RCT	89 Twin-block 9.7 ± 0.98 years 87 Controls 9.8 ± 0.94 years	Piers-Harris Children's Self-concept Scale. Childhood Experience Questionnaire. Perceptions of the Benefits of Orthodontic Treatment Scale	At onset and at 15 months follow-up, both groups reported medium- to high self-esteem. Twin-block treatment resulted in an increased self-concept and a reduction in negative social experience.	High + Randomized study design + Multicenter + Sample size calculations + Intention-to-treat approach + Blinding when analyzing - Attrition > 20% (28% for Twin-block, 22% for controls)
Koroluk et al. 2003 [29]	RCT	52 Bionator 9.4 ± 1.0 years 50 Headgear 9.4 ± 1.0 years 61 Controls 9.4 ± 1.2 years	Incidence of trauma Estimations regarding: Extent of trauma Required trauma treatment Costs	Trauma to maxillary incisors was found in all groups. Most injuries were minor and related costs were estimated as low. Treatment with Bionator might reduce the incidence of trauma, but should be initiated soon after eruption of maxillary incisors to be effective. It was estimated that the expected cost of trauma per child was less for patients who had early growth modification treatment than for patients whose treatment was delayed until their permanent dentition. However, early 2-phase orthodontic treatment is usually more expensive than a single-phase treatment approach.	High + Randomized study design + Sample size calculations + Intention-to-treat approach + Attrition <20%
O'Brien et al. 2009 [31]	RCT	20 Twin-block 8–10 years 20 Controls 8–10 years Randomly selected from O'Brien et al. 2003	Attractiveness graded by Likert scale	After twin-block treatment, the profile was rated as more attractive when compared to untreated controls. Visible front teeth and large overjet had negative impact on profile perception.	High + Randomized study design + Multicenter + Sample size calculations + Blinding when analyzing + Method error analysis
Jakobsson 1967 [34]	RCT	20 Headgear 8.5 years 20 Activator 8.5 years 20 Controls 8.5 years	Cephalometrics: Antero-posterior skeletal discrepancies Dental relations: Overjet, overbite Mandibular length	Early treatment reduced overjet. Activator and headgear treatment appeared to affect positioning of the maxilla, most pronounced by headgear treatment. Both treatments significantly increased facial height. Activator treatment had an effect within the dento-alveolar area of the mandible, but no support for an orthopaedic effect was found.	Moderate + Randomized study design + Method error analysis + Attrition <20% - No sample size calculations - No blinding when analyzing - No intention-to-treat approach
Keeling et al. 1998 [35]	RCT	90 Headgear/biteplane 9.7 years 78 Bionator 9.7 years 81 Controls 9.5 years	Cephalometrics: Antero-posterior skeletal discrepancies Dental relationships: Overjet, incisor and molar positioning Significance of retention relapse	Bionator and headgear groups showed significantly more skeletal Class II correction than untreated controls. Early treatment with headgear resulted in significant dental Class II correction, affecting maxillary incisors and molars. Treatment with Bionator or headgear/biteplane showed no effect on maxillary growth but both appliances enhanced mandibular anterior growth. Skeletal changes were stable 1 year after treatment but relapse was evident for dental changes.	Moderate + Randomized study design + Blinding when analyzing - Attrition >20% - Pretreatment performed in treatment (approximately 50%) and control (approximately 10%) groups, unclear method

(*Continued on next page*)

Table 1 (*Continued*)

Author, year	Study design	Study population	Outcome measures	Results	Study quality/Comments
Chen et al. 2011 [33]	RCT	93 Headgear/biteplane 9.7 years 87 Bionator 9.7 years 81 Controls 9.5 years	Modified Ellis injury classification	A significant number of children (25%) had already experienced incisor trauma before treatment were initiated. No correlation was found between initial overjet and the prevalence of trauma. Early orthodontic treatment did not significantly affect the incidence of trauma. Most injuries before and after treatment were minor, consisting of enamel fractures.	Moderate + Randomized study design + Blinding when analyzing - Attrition >20% - Pretreatment performed in treatment (approximately 50%) and control (approximately 10%) groups, unclear method - No adjustment for confounders (lip closure, socioeconomics, leisure activities)

RCT, randomized controlled trial.

and, by this means, health care costs could be reduced [29]. Otherwise, no other cost-effectiveness trials could be found.

3.6. Quality of life

In one trial, it was presented that twin-block treatment may ameliorate self-concept and negative social experiences among children who have undergone early treatment of Class II malocclusions [6].

3.7. Strength of evidence

Because no long-term trials have been performed regarding early treatment of Class II malocclusions, only evidence considering the short-term effects can be defined. Nonetheless, four trials, two of high [30,32] and two of moderate evidence [34,35], were found, and even if treatments were performed with different treatment modalities (functional appliances or headgear treatment), there exists a high degree of evidence that early Class II malocclusion corrections resulted in reduced overjet. Furthermore, moderate evidence exists that early treatment of Class II malocclusions with twin-block, activator, or Bionators enhance forward position of the mandible [30,32,35].

Because too few publications are available regarding early Class II malocclusion correction on the tissue profile, incidence on trauma, cost-effectiveness, and oral health–related quality of life, and no existing trials regarding relation to TMD, the evidence from these aspects is insufficient.

4. Discussion

The most important results from this updated systematic review were that a high level of evidence exists that early Class II malocclusion treatment with functional appliance in the short-term reduces overjet and improves the skeletal anterior-posterior relationship. In addition, a moderate level of evidence was found that headgear might restrict maxillary forward growth in the short-term. However, any conclusions of long-term effects or stability after early treatment cannot be drawn because overall long-term follow-up trials are lacking. In addition, because too few or no trials were published, the evidence was insufficient considering early treatment impact on soft tissue profile, quality of life, incidence of trauma, and cost-effectiveness. Finally, even if no publication could be found that had explicitly investigated the relation between early Class II malocclusion correction and TMD, it can be noted that existing research, in general, does not emphasize a risk of developing TMD when Class II malocclusions are treated [36].

It was a disappointment that high-quality research on early Class II malocclusion correction has been carried out to only a relatively small extent. Moreover, the trials on this topic are relatively old, that is, the latest trial was performed 8 years ago and the oldest was carried out 52 years ago.

The most common reasons for excluding trials in this review were that they had a retrospective study design and a large age span of included individuals, that is, the children could be much older than 10 years, and thus did not receive early treatment.

It was remarkable that three [6,30,31] of the five high-quality publications had used identical or exploited the same individuals for their material, and, in addition, the other two publications [29,32] used a uniform study population for their two trials. From a methodological point of view, this can be considered problematic, because, overall, a fairly small number of individuals were evaluated. Furthermore, no aggregation of individuals could be accomplished in a meta-analysis because there were obvious differences in the type of treatments and methodology performed. Nevertheless, the results of this systematic review are in line with a previous systematic review [37], although that overview has less extensive issues, that is, without evaluating trauma incidents, relation to TMD, cost-efficiency, and impact on oral health–related quality of life.

The consistency of the three researchers in this systematic review was very high (95%), and if disagreement existed, this was resolved by discussion until consensus was achieved. Some possible reasons for the good agreement were the use of the Goodman's guidelines [11], which has clear and well-defined criteria, and that all three researchers were familiar with this model.

The GRADE tool for scoring evidence can categorize study quality as high, moderate, or low. When few or no relevant trials of high quality exist, the summary evidence becomes insufficient, but it is still important to understand that insufficient evidence does not always mean lack of effect. Regardless of this, all the existing results must be valued, and to fill in knowledge gaps, it is always strongly recommended to carry out new robust and well-designed trials within the field.

5. Conclusions and clinical implications

Although early treatment of Class II malocclusions has been debated in the orthodontic profession and among clinical researchers, the following can be stated:

- From a short-term perspective, there is a high level of evidence that early treatment of Class II malocclusions reduces overjet and improves the anterior-posterior skeletal relationship, and, primarily, the position of the mandible becomes more anterior.

- A moderate level of evidence exists indicating that early treatment with headgear in the short-term leads to decreased overjet and could restrain the maxillary forward growth.
- There is insufficient evidence that early treatment can reduce the trauma incidence, if the treatment is cost-effective or can provide an improved soft tissue profile, improved oral health–related quality of life for the children, or possesses a risk of developing TMD, and, therefore, based on these aspects, new high-quality clinical research is motivated and urgent.
- Finally, knowledge gaps exist regarding whether early treatment of Class II malocclusions is stable over the long-term, implying that long-term follow-up trials are also warranted.

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