Systematic Review

Optimal force for maxillary protraction facemask therapy in the early treatment of class III malocclusion

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SUMMARY
BACKGROUND: The facemask is used to treat early class III malocclusion, in combination with expansion therapy. There is a great deal of controversy in literature regarding the effectiveness of protraction facemask treatment as studies report results anywhere from considerable changes to lack of any maxillary improvement. This controversy may be due to the fact that the process of placing the orthopaedic face mask on patients has, in part, been done empirically, without the use of literature containing the clinical parameters for facemask placement for maxillary protraction.

OBJECTIVE: To determine the optimal magnitude, duration, and direction that should be used in maxillary protraction facemask therapy.

SEARCH METHODS: A systematic search was carried out in the following databases: Medline, Google Scholar, Embase, Cochrane, Lilacs, Scielo, with no restriction placed on the year of publication, in English and Spanish, using MeSH terms and free-text terms.

SELECTION CRITERIA: Clinical trials, systematic reviews, meta-analysis, cohort studies, case-control studies, and cross-sectional studies were included, whereas literature reviews, case reports, case series, symposiums, compendiums, pilot studies, and expert opinions were excluded.

DATA COLLECTION AND ANALYSIS: Data selection and extraction were blinded and performed independently, and the methodology was evaluated using various scales.

RESULTS: A total of 223 articles were found. After eliminating repeated articles and those that did not meet the selection criteria, 14 remained for analysis. Regarding magnitude, there were values ranging from 180 to 800g per side; there were force vector direction values between 20 and 30 degrees below the occlusal plane or parallel to the occlusal plane; and a duration ranging from 10 to 24 hours of use per day.

CONCLUSIONS: There is no scientific evidence that would allow for the definition of adequate parameters for force magnitude, direction, and duration for maxillary protraction facemask treatment in class III patients.

Introduction

The facemask is a device commonly used to treat early class III malocclusion caused by maxillary deficiency and mandibular prognathism, and which is generally used in combination with expansion therapy. There is a great deal of controversy in literature regarding the effectiveness of protraction facemask treatment as studies report results anywhere from considerable changes to lack of any maxillary improvement (Wisth, 1984; Mermigos et al., 1990; Baik, 1995; Ngan et al., 1997; Williams et al., 1997; Baccetti et al., 1998; da Silva Filho et al., 1998; Gallagher et al., 1998; Kapust et al., 1998; Kiliçoglu and Kirliç, 1998; Pangrazio-Kulbersh et al., 1998; Sung and Baik, 1998; Turley, 2002). This controversy may be due to the fact that the process of placing the orthopaedic facemask on patients has, in part, been done empirically (Grandori et al., 1992), without the use of literature containing the clinical parameters for facemask placement for maxillary protraction.

Differences in magnitude, direction, and duration of force may produce different patterns of displacement and distribution of the mask in maxillofacial sutures of the nasomaxillary complex, which can lead to unexpected results (Tanne and Sakuda, 1991; Billiet et al., 2001).

The objective of this study was to determine the optimal force characteristics regarding magnitude, duration, and direction to be used in maxillary protraction facemask therapy in order to summarize the information related to this topic as well as identify the parameters that would facilitate clinical decision making.

Material and methods

Defining a question of clinical interest

Three questions were formulated in order to select the question that was most relevant and of greatest clinical interest:
• What is the ideal force with regard to magnitude, direction, and duration in maxillary protraction facemask therapy?
• What is the ideal direction of force in order to obtain movement of the maxilla?
• What is the protocol for introducing forces when installing the facemask?

These questions were sent to five local colleagues (Juan Upegui, Diana Barbosa, Luisa Villegas, Marcela Ruiz, Paola Botero) and five international colleagues (Tiziano Baccetti, Lorenzo Franchi, Peter Ngan, James McNamara, Jing Sugawara)—all experts in this field—with the objective of identifying which question, in their opinion, was the most relevant to be answered by means of a systematic review (Supplementary information S1).

Upon receiving the experts’ opinions, the following question was selected: what is the ideal force with regard to magnitude, direction, and duration in maxillary protraction facemask therapy in patients with class III malocclusion?

Search strategy

The systematic review involved the Cochrane Collaboration methodology (Clarke and Oxman, 2003) and was divided into four phases:

Phase 1: initial search. This was carried out with the objective of estimating the amount of information published on the topic being studied, as well as the quality (whether or not there were systematic reviews, randomized clinical trials, etc.). Another objective was to identify the most appropriate databases and the terms to be used in the search.

Phase 2: systematic search. This was carried out in the following databases: Medline, Google Scholar, Embase, Cochrane, Lilacs, and Scielo, where the following MeSH terms were used: ‘class III malocclusion’, ‘Malocclusion, Angle class III’, ‘Reverse Pull Headgear’, ‘Protraction headgear’, ‘Therapy’, ‘Circummaxillary sutures’, ‘Anterior Crossbite’, ‘Techniques, Orthodontic Anchorage’; as well as the free-text terms: ‘Face mask’, ‘Facemask therapy’, ‘Maxillary retrognathia’, ‘Maxillary protraction’, ‘force’, ‘force intensity’, ‘biomechanics’, and ‘Force magnitude’. Detailed search strategies were performed by crossing the previously described terms (Supplementary information S2) in each of the databases selected according to the differences in the rules of syntax and controlled vocabulary (MeSH terms, free-text terms, or key words). This search was conducted between 28 March and 5 May of 2011.

Phase 3: manual search. References were taken from the articles selected in phase 2 that did not appear as a result of the search strategy.

Phase 4: contacting experts. A protocol of the review was sent to local and international colleagues, who were then asked to suggest further studies and information related to this topic.

Selection criteria

Inclusion criteria. Articles, clinical trials, systematic reviews, meta-analysis, cohort, case-control, and cross-sectional studies reporting patients with class III malocclusion, who had undergone facemask therapy with or without expansion.

Exclusion criteria. Articles, literature reviews, case reports, case series, symposiums, compendiums, pilot studies, and expert opinions. Studies on individuals with cleft lip and palate were excluded.

The search was limited to English or Spanish, with no restriction placed on the year of publication.

When selecting which articles were going to be a part of the systematic review, two of the researchers independently blind reviewed the title and abstract of each article found in the various searches. A third researcher compared the articles selected by the two reviewers and determined disagreements between them. A fourth researcher, along with the two other reviewers, chose which articles (from the discordant ones) would be included in the systematic review.

Data collection and analysis

Before analysing the articles, both researchers standardized data extraction as well as the evaluation of the methodological quality of the studies. Article reading was also performed blindly and independently and was recorded on a template designed for such a purpose (Supplementary information S3).

The following scales were used for the assessment of methodological quality:

Jadad (1996) Scale for clinical trials; Newcastle Ottawa Scale for cohort and case-control studies AMSTAR Scale for systematic reviews (Shea et al., 2007); the score recommended by Berra et al. (2008) was used for transversal studies.

No tools were used to assess the quality of in vitro studies as there are no such tools available.

After the critical reading of the articles, Cohen’s Kappa test was used to determine interobserver agreement between the two researchers that extracted the data. An index of 0.8 or higher was considered to be adequate for the review. This analysis was conducted using EPIDAT® version 3.1 (Xunta de Galicia, Pan American Health Organization, 2006).

Results

Search Results

The search strategies yielded 223 articles after eliminating the duplicates. One hundred and ninety-eight were excluded...
because they did not meet the inclusion criteria. Out of a total of 25 articles included, after a complete reading of the articles, 11 were excluded due to not meeting the inclusion criteria (Supplementary information S4) and 14 articles were included (Figure 1).

Four studies had the main objective of analysing one of the characteristics of force in particular (Tanne and Sakuda, 1991; Grandori et al., 1992; Alcan et al., 2000; Keles et al., 2002). They analysed the variations in direction and the location of force imposition on upward and outward maxillary rotation, but no study analysed force magnitude and duration. The 10 remaining studies simply mentioned these elements as a part of methodology, but it was not their objective (Ngan et al., 1996; Merwin et al., 1997; Baccetti et al., 1998; Ngan et al., 1998; Pangrazio-Kulbersh et al., 1998; Saadia and Torres, 2000; Suda et al., 2000; Keles et al., 2002; Kajiyama et al., 2004; Vaughn et al., 2005; Tortop et al., 2007). Table 1 describes the characteristics of the articles that were included. Two poor-quality controlled clinical trials (Keles et al., 2002; Vaughn et al., 2005) were found, as well as 12 moderate-to-high quality cohort studies (Tanne and Sakuda, 1991; Grandori et al., 1992; Ngan et al., 1996; Merwin et al., 1997; Baccetti et al., 1998; Ngan et al., 1998; Pangrazio-Kulbersh et al., 1998; Alcan et al., 2000; Saadia and Torres, 2000; Suda et al., 2000; Keles et al., 2002; Kajiyama et al., 2004; Tortop et al., 2007). Table 1 shows the results of each study on the main clinical findings regarding maxillary position, dentoalveolar angulation, and mandibular rotation.

The interobserver agreement for the assessment of methodological quality of the articles was 1.0, which indicates that both researchers had a near perfect agreement.

Force magnitude

None of the 14 selected articles had the specific objective of answering the question ‘What is the best force magnitude to obtain maxillary protraction?’ These studies simply included data in their methodology, which reported forces, per side, as high as 500g (as reported by Tanne and Sakuda, 1991; Grandori et al., 1992; Keles et al., 2002; Vaughn et al., 2005) and as low as 180–250g (as reported by Suda et al., 2000). Calculating global measurements is not feasible (see Table 1) due to the heterogeneity of the studies.

Force vector direction

Ten studies described the force vector direction in the methodology, but did not explain why a specific direction was chosen (Ngan et al., 1996; Merwin et al., 1997; Baccetti et al., 1998; Pangrazio-Kulbersh et al., 1998; Saadia and Torres, 2000; Suda et al., 2000; Keles et al., 2002; Kajiyama et al., 2004; Vaughn et al., 2005; Tortop et al., 2007), and four specifically evaluated force direction in protraction therapy (Tanne and Sakuda, 1991; Grandori et al., 1992; Alcan et al., 2000; Keles et al., 2002; see Table 1).

Alcan et al., 2000 stated that force must be oriented parallel to the Frankfort horizontal plane, which allows to avoid using the jaw as an anchor, hence, reducing the potentially adverse effects on the temporomandibular joint. This force direction, however, does not avoid maxillary rotation.

Tanne and Sakuda, 1991 propose that the force vector direction be parallel to the occlusal plane, stating that the distribution of the stress produced when applying this force is due to the compressive stresses found in the bones around the maxillofacial sutures, in addition to the tensile stresses in the maxillary bone. These biomechanical changes in the sutures cause the counterclockwise rotation and forward displacement of the nasomaxillary complex in the most efficient manner.

Keles et al., 2002 wanted to examine the effect of varying the force direction on maxillary protraction. They evaluated two force vector directions. In group 1, force was applied intraorally from the canine region, at a 30 degree angle to the occlusal plane (below the centre of resistance of the maxilla). In group 2, force was applied with a modified extraoral facial arch, 20 mm above the maxillary occlusal plane (with the objective of approaching the centre of resistance of the maxilla). The results showed both force systems were equally effective to protract the maxilla. However, in group 1, it was observed that the maxilla advanced forward with a counterclockwise rotation, whereas, in group 2, the anterior translation of the maxilla occurred without rotation, indicating that this method can be used effectively on patients with class III malocclusion combined with an anterior open bite.

Duration

None of the 14 studies specifically focused on investigating how long the maxillary protraction facemask should be used each day. The information was taken from the methodology section and it was found that duration varied from a minimum of 10 hours (Suda et al., 2000; Kajiyama et al., 2004) up to all day (Vaughn et al., 2005;
Table 1  Characteristics and methodological quality of included articles. SNA, sella-nasion angle; palatal plane/SN, palatal plane angle/sella-nasion; PE, palatal expansion; W/o PE, without palatal expansion; EM, early mixed dentition group; LM, late mixed dentition group; DD, deciduous dentition group.

<table>
<thead>
<tr>
<th>Author</th>
<th>Sample</th>
<th>Sample age (years)</th>
<th>Force used per side</th>
<th>Direction of occlusal plane</th>
<th>Time (h)</th>
<th>Skeletal changes (SNA in degrees)</th>
<th>Dentoalveolar changes (palatal plane/SN in degrees)</th>
<th>Type of study/Methodological quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suda et al. (2000)</td>
<td>60</td>
<td>9–10</td>
<td>180–250g</td>
<td>30°</td>
<td>10</td>
<td>1.6° (0.4)</td>
<td>2.21° (0.5)</td>
<td>Cohort/Moderate</td>
</tr>
<tr>
<td>Pangrazio-Kulbersh et al. (1998)</td>
<td>17</td>
<td>8</td>
<td>200–300g</td>
<td>30°</td>
<td>14–16</td>
<td>1.24°</td>
<td>1.59°</td>
<td>Cohort/High</td>
</tr>
<tr>
<td>Tortop et al. (2007)</td>
<td>28</td>
<td>11</td>
<td>300g</td>
<td>20°</td>
<td>16</td>
<td>With PE: 3° (0.4)</td>
<td>With PE: 1.5° (1.4)</td>
<td>Cohort/Moderate</td>
</tr>
<tr>
<td>Acan et al. (2000)</td>
<td>17</td>
<td>12</td>
<td>375g</td>
<td>Parallel to Frankfort horizontal plane</td>
<td>17</td>
<td>2.29° (2.53)</td>
<td>4.5° (6.24)</td>
<td>Cohort/High</td>
</tr>
<tr>
<td>Merwin et al. (1997)</td>
<td>30</td>
<td>5–8 and 9–12</td>
<td>380g</td>
<td>30°</td>
<td>12–14</td>
<td>1.4° (3.4)</td>
<td>3.4° (9.0)</td>
<td>Cohort/High</td>
</tr>
<tr>
<td>Ngin et al. (1998)</td>
<td>20</td>
<td>8</td>
<td>380g</td>
<td>30°</td>
<td>12</td>
<td>1.3° (3.3)</td>
<td>3.4° (7.8)</td>
<td>Cohort/Moderate</td>
</tr>
<tr>
<td>Ngu et al. (1996)</td>
<td>30</td>
<td>8</td>
<td>380g</td>
<td>30°</td>
<td>12</td>
<td>1.37° (2.96)</td>
<td>2 to 3° (estimate)</td>
<td>Cohort/Moderate</td>
</tr>
<tr>
<td>Saadia and Torres (2000)</td>
<td>112</td>
<td>Younger than 9 and older than 9 years</td>
<td>395g</td>
<td>30°</td>
<td>14</td>
<td>EM: 3.58 mm (2.26)*</td>
<td>EM: 4.14 mm (2.43)*</td>
<td>Cohort/Moderate</td>
</tr>
<tr>
<td>Baccetti et al. (1998)</td>
<td>29</td>
<td>6–10</td>
<td>400g</td>
<td>Parallel to occlusal plane</td>
<td>14</td>
<td>EM: 1 mm (0.8)</td>
<td>EM: 1.51 mm (0.91)</td>
<td>Cohort/Moderate</td>
</tr>
<tr>
<td>Kajiyama et al. (2004)</td>
<td>63</td>
<td>5–8</td>
<td>400g</td>
<td>30°</td>
<td>10–12</td>
<td>DD: 4.16° (2.60)</td>
<td>DD: 9.3° (12.91)</td>
<td>Cohort/Moderate</td>
</tr>
<tr>
<td>Vaughan et al. (2005)</td>
<td>46</td>
<td>5–10</td>
<td>300–500g</td>
<td>15–30°</td>
<td>24</td>
<td>With PE: 3.02° (0.68)</td>
<td>With PE: 1.27° (1.94)</td>
<td>Clinical Trial/Poor</td>
</tr>
<tr>
<td>Keles et al. (2002)</td>
<td>20</td>
<td>8</td>
<td>500g</td>
<td>30°</td>
<td>16</td>
<td>W/o PE: 2.78° (0.67)</td>
<td>W/o PE: 1.44° (0.39)</td>
<td>Clinical Trial/Poor</td>
</tr>
<tr>
<td>Tanne and Sakuda (1991)</td>
<td>6</td>
<td>12</td>
<td>500g</td>
<td>Parallel to occlusal plane</td>
<td>Does not specify</td>
<td>Does not specify</td>
<td>Does not specify</td>
<td>Cohort/Moderate</td>
</tr>
<tr>
<td>Grandori et al. (1992)</td>
<td>5</td>
<td>9–13</td>
<td>500g</td>
<td>20°</td>
<td>Does not specify</td>
<td>Does not specify</td>
<td>Does not specify</td>
<td>Cohort/Moderate</td>
</tr>
</tbody>
</table>

*Data are expressed in millimetres.
see Table 1). On average, most studies report a prescribed facemask use of 12–16 hours per day for a 9–12 month period (Ishii et al., 1987; Baik, 1995; Gallagher et al., 1998; Kim et al., 1999; Turley, 2002; Cha, 2003; Kama et al., 2006).

Discussion

This study sought the best evidence that showed the magnitude, direction, and duration of the ideal force when installing the facemask for maxillary protraction. It was not possible to determine global average measurements for force duration and magnitude due to the heterogeneity of the studies, as well as because of the lack of information in some of them. However, with the objective of providing new information of clinical interest, the discussion is focused on the analysis of each of the included studies regarding the maxillary protraction values obtained. This correlation allowed us to determine, by clinical judgment, but not by evidence, the values of magnitude and duration that can yield greater maxillary protraction.

Force magnitude

Orthodontics and orthopaedics have always faced the great challenge of finding the optimal force to obtain adequate results. The optimal force in maxillary protraction therapy can be defined as the lowest force with the least duration that produces the greatest skeletal movement and least dental movement. The results shown in the articles are discussed comparing which force magnitude is required to meet these criteria.

Low forces: below 300g

Only two studies were found within this range of force: Suda et al. (2000) report positive effects regarding skeletal movement in patients, without palatal expansion, and with the use of a chin cup. They describe that the sella-nasion A point (SNA) shows an average maxillary movement of 1.6 degrees (SD±0.4) and report a proclination of upper incisors of 2.21 degrees (SD±0.5). Pangrazio-Kulbersh et al. (1998), show a maxillary movement of 1.24 (SD±0.6) according to the SNA, and an upper incisor proclination of 2.35 degrees (SD±0.76).

Although it can be observed that both studies achieve maxillary protraction, this is not enough to make the decision of using low forces in protraction therapy as there is co-intervention, such as the use of the chin cup in the study by Suda et al. (2000). Despite reporting positive results for skeletal effects, the study by Pangrazio-Kulbersh et al. (1998) does not allow to determine whether the force applied per side was of 200g, which would be among the low forces, or 300g, which is on the low end of medium forces, as the authors do not specify when they use each force.

Medium forces: between 300 and 400g

Out of the 14 selected studies, 9 used a medium range of force. There is a variety of studies anywhere from poor-quality clinical trials, such as that of Vaughn et al. (2005) to moderate-to-high quality cohort studies (Ngan et al., 1996; Merwin et al., 1997; Baccetti et al., 1998; Ngan et al., 1998; Alcan et al., 2000; Saadia and Torres, 2000; Kajiyama et al., 2004; Tortop et al., 2007). Each of these, in one way or another, analysed the effects of the facemask, but as mentioned earlier, the studies are not compatible due to the different methodologies used. It is also of extreme importance to keep in mind that many of the studies do not only use the facemask, but that there are other variables such as performing palatal expansion or not, as well as the age factor, which has an effect on the full movement the maxilla can reach.

The study by Alcan et al. (2000) included patients who underwent palatal expansion and report a maxillary movement of 2.29 (SD±2.53) based on the SNA, with marked dental effects, where the upper incisors were proclined 4.5 degrees (SD±6.24) and the lower incisors were retroclined −3 degrees (SD±1.03).

The studies by Ngan et al. (1996, 1998) and Merwin et al. (1997) used a force of 380g on patients, where palatal expansion was used. Unlike the study by Alcan et al. (2000), the patients had an average age of 8 years and were instructed to wear the appliance 12–14 hours a day. They report having reached a maxillary forward movement of 1.3–1.6 degrees (SD±3.3; 1.8 to 2.1 mm), according to SNA. Regarding the dental effects, Ngan et al. (1996, 1998) observed a labial movement of the maxillary incisors of 3.4 degrees (SD±7.8) and toward lingual movement of the mandibular incisors of −5.2 degrees (SD±5.6). Therefore, we can observe that there were greater dental effects in the study by Alcan et al. (2000) regarding the proclination of upper incisors based on the average, which could possibly be due to the age differences of the patients in each sample. In the study by Merwin et al. (1997), two age groups were analysed (under 8 and over 8 years). They found that in those under 8, correction reaches 52% for skeletal movement [maxillary forward movement of 1.4 degrees (SD±3.4) according to SNA] and 48% for dental movement [proclination of upper incisors of 4.6 degrees (SD±9.0) and retroclination of lower incisors of −1.4 degrees (SD±6.6)]. In children over 8, correction reaches 63% for skeletal movement [maxillary forward movement of 1.9 degrees (SD±3.4) according to SNA], and 37% for dental movement [proclination of upper incisors of 3.8 degrees (SD±3.2) and retroclination of lower incisors of −2.7 degrees (SD±3.5)], which can be corroborated by the studies by Ngan et al. (1996, 1998), which also show that greater skeletal effects can be obtained in patients over 8 (maxillary forward movement of 1.9–2.0 mm; SNA: 1.3–1.6 degrees) with less dental effects (proclination of upper incisors of 3.4 degrees).
Saadia and Torres (2000) used a force of 395g per side in patients who underwent palatal expansion and were divided into children under 9 and over 9 (up to 12 years old), and were instructed to wear the device 14 hours a day. They report significant skeletal effects for children aged 3–9 years, with a lower maxillary forward movement than what was reported by Alcan et al. (2000) with very similar dental effects, which could be due, as mentioned earlier, to the age differences of the patients included in each sample.

The study conducted by Kajiyama et al. (2004) used 400g of force per side as well as a modified maxillary protractor without palatal expansion in patients divided according to their type of dentition (deciduous dentition, early mixed dentition). Their results show greater skeletal effects in deciduous dentition, whereas small advances are observed in mixed dentition, unlike what was reported by Saadia and Torres (2000). It should be noted that the article explains that the dental effects upon deciduous dentition are not precise as the patients are in the midst of the transition from deciduous to permanent teeth and the measurements are unreliable. In deciduous dentition, there was a maxillary forward movement of 4.16 degrees (SD ±2.60) according to SNA with an exaggerated dental movement, where the upper incisors had a proclination of 9.3 degrees (SD ±12.91), and the lower incisors had a retroclination of −5.38 degrees (SD ±7.25). In mixed dentition, there was a maxillary forward movement of 1.48 degrees (SD ±1.93) according to SNA, with smaller dental changes than those obtained with deciduous dentition, but still much higher than those in other studies (Ngan et al., 1996, 1998; Merwin et al., 1997; Alcan et al., 2000; Saadia and Torres, 2000), with an upper incisor proclination of 8.23 degrees (SD ±6.37) and a lower incisor retroclination of −4.57 degrees (SD ±7.10).

This study, therefore, is the one with greatest dental effects, which could be attributed to the fact that palatal expansion was not used along with the maxillary protractor.

Baccetti et al. (1998) used 400g of force per side with patients who were divided according to their type of dentition (early mixed dentition, late mixed dentition). Palatal expansion was performed and patients were instructed to wear the facemask 14 hours a day. In the group with early mixed dentition, they report a maxillary forward movement of 3.58mm (SD ±2.26), as well as a forward movement of upper incisors of 4.14mm (SD ±2.43) and a backward movement of lower incisors of −1.13mm (SD ±1.24). In the late mixed dentition group, there was a maxillary forward movement of 1mm (SD ±0.8; much lower than what was obtained for early mixed dentition), as well as a forward movement of upper incisors of 1.51mm (SD ±0.91) and a backward movement of lower incisors of −1.98mm. This shows the scarce dental and skeletal effects obtained in late mixed dentition. It should be noted, however, that the article does not offer data in degrees, as most measurements reported are linear, making it difficult to establish precise and reliable comparisons with the other studies.

The study conducted by Vaughn et al. (2005) used forces ranging from 300 to 500g per side in patients who wore the facemask 24 hours a day. They compared groups with or without palatal expansion in patients aged 5–10 years. They report a greater maxillary movement in patients with expansion, where the maxilla moved 1.67mm, compared with 1.41mm in the group without expansion. There were also significant differences regarding SNA, where there was a movement of 3.02 degrees (SD ±0.68) in the group with expansion, and 2.78 degrees (SD ±0.67) in the group without expansion. Also, there were greater dental effects in the group without expansion, with a proclination of upper incisors of 1.44 degrees (SD ±0.39) versus 1.27 degrees (SD ±1.94) in the group with expansion. It should be pointed out that although this is one of the studies with greatest maxillary protraction and least dental effects, the force magnitude cannot be supported since it does not specify whether 300g of force were applied per side, which would be within the medium force range, or 500g, which is on the low end of high forces. The study was also of poor methodological quality.

The study by Tortop et al. (2007) is similar to the one carried out by Vaughn et al. (2005) as they also evaluated the effects of the facemask with or without palatal expansion. They used a force of 300g per side in patients aged 10–11 years and were instructed to wear the appliance 16 hours a day. They report a greater maxillary movement in the group with expansion, with an SNA of 3 degrees (SD ±0.4) versus 2 degrees (SD ±0.5) in the group without expansion. With respect to dental effects, there was a proclination of 1.5 degrees (SD ±1.4) in the group with expansion compared to 2 degrees (SD ±1.2) in the group without expansion. This indicates that greater skeletal effects along with lesser dental effects can be obtained when using palatal expansion, which agrees with the results reported by Vaughn et al., despite the age differences of the patients.

In light of the aforementioned data, although these studies support the effectiveness of maxillary protraction with medium forces, the differences in the results, like obtaining more or less protraction with greater or lesser dental effects, could be due to various factors such as: differences in study design, appliance design, treatment duration, number of hours of facemask use per day, use or not of palatal expansion, and of course, age—one of the most influential factors regarding the effects of force on skeletal structure.

High forces: 500g and higher

Three of the 14 selected articles used a force of 500g (Tanne and Sakuda, 1991; Grandori et al., 1992; Keles et al., 2002).

Tanne and Sakuda (1991) who researched the distribution of stress on the craniofacial complex produced by an orthopaedic force and evaluated the morphological skeletal changes produced by maxillary protraction therapy. They report that the direction and the point of force application
are important to induce a more efficient maxillary growth and anterior displacement. However, this study does not provide sufficient quantitative data to know the exact maxillary movement that can be obtained, in addition to having a sample of only six patients that lacks representativity and therefore does not allow for the extrapolation of the results.

Keles et al. (2002) evaluated the effects of applying force in different directions on the protraction of the maxilla, and therefore formed two groups. In the first group, force was applied from the canine region at a 30 degree angle below the occlusal plane. In the second group, force was applied extraorally 20 mm above the maxillary occlusal plane. They had a sample of 20 patients with a mean age of 8 years, who underwent palatal expansion and were instructed to wear the facemask 16 hours a day. The results show an effective maxillary movement where the SNA increased 3.11 degrees (SD ± 1.05) with a proclination of upper incisors of 3.56 degrees (SD ± 4.59) in group 1 and an SNA of 3.09 degrees (SD ± 1.7) with a proclination of upper incisors of 8 degrees (SD ± 3.77) in group 2, showing clearly greater dental effects in group 2. It can be concluded, therefore, that if a greater skeletal effect is desired along with minimal dental effects, the direction of the force vector should run as close as possible to the centre of resistance.

At this point, it is worthwhile to compare the results obtained in the study by Keles et al. (2002) with those obtained by Tortop et al. (2007) in the group that underwent palatal expansion. Both studies had subjects aged 8–10 years who wore the facemask 16 hours a day for 6–8 months, but differed in the force magnitude used—500g versus 300g, respectively. It can be observed that the results obtained at the skeletal level with a force magnitude of 500g are similar to those obtained with a medium force of 300g, obtaining a maxillary movement of 3 degrees based on the SNA. However, greater dental effects are reported when using 500g of force since Tortop et al. (2007) reported a proclination of upper incisors of 1.5 degrees versus 8 degrees reported by Keles et al. (2002), which is far from meeting the concept of optimal force.

It should be noted that literature reports in vitro studies using forces between 500 and 800g (Itoh et al., 1985; Hata et al., 1987; Billiet et al., 2001). These studies used experimental models, and there are no cephalometric data to quantitatively observe the effects produced. Hence, there is insufficient evidence to support the use of such intense force in humans that could potentially produce undesired collateral effects.

Although there is no conclusive evidence, if we consider optimal force to be the smallest force that produces the greatest amount of skeletal movement along with the least amount of dental movement, it could be concluded that it is more efficient to use 300–400g of force since they produce similar effects to those produced by greater forces, without the biological wear and tear caused by greater forces.

**Force vector direction**

There is a vast amount of studies on facemasks, but only seven studies offer an explanation and discuss the importance of the direction of the force vector. A standard for the most appropriate direction cannot be established not only because the methodological differences amongst studies do not allow it but also because it all depends on the desired clinical effect. Therefore, establishing only one protraction facemask pattern is not the objective but rather to take into account the vertical component that accompanies the sagittal plane, which is what the force vector direction actually depends on.

Considering all of the above, if a parallel movement is desired, Keles et al. (2002) found that when applying force 20 mm above the maxillary occlusal plane (with the objective of approaching the centre of resistance of the maxilla) there will be an anterior translation of the maxilla without rotation, which is indicated for patients with class III malocclusion and an anterior open bite. This is in accordance with the concept expressed by Billiet et al. (2001), which states that the centre of resistance of the maxilla is located below the zygomatic process of the maxillary complex and a force vector applied through this region initially induces pure translation of the maxilla.

In order to minimize the counterclockwise rotation of the maxilla, Grandori et al. (1992) propose using a combination of a forward and downward force vector to protract the maxilla. Itoh et al. (1985) suggest the same in their in vitro study. On the other hand, in their in vitro study, Hata et al. (1987) suggest that applying 5 mm of force above the palatal plane is especially recommended when the rotation of the maxilla is contraindicated. However, in cases of a deep bite where it is necessary to open the bite, a protraction force on the maxilla with an anterior force component is recommended. If a counterclockwise rotation is desired, the results of the study by Tanne and Sakuda (1991) are quite helpful as they propose that the direction of the force vector should be parallel to the occlusal plane, resulting in counterclockwise rotation and the forward displacement of the nasomaxillary complex.

At this particular point, there are not enough studies to validate each of the assertions made regarding force vector direction, but what can be said is that it is not possible to establish a standard direction as everything depends on the desired clinical effect.

**Treatment Duration**

There is a great amount of controversy surrounding this point as there is a large quantity of combinations of magnitude and time of use of the device. In order to analyse what the articles reported regarding the various amounts of facemask use per day, a classification was established based on the hours of use found in the literature.
Under 11 hours

This classification includes the study conducted by Suda et al. (2000) with 10 hours a day (which does not allow for comparison since the maxillary protraction therapy was combined with the use of a chin cup). The study by Kajiyama et al. (2004), with 10–12 hours of use a day for 10 months, reported a significant forward movement of the maxilla in deciduous dentition, with SNA changes of 4.16 degrees, and marked dental effects with a proclination of the upper incisors of 9.3 degrees, whereas there was small forward movement in early mixed dentition with SNA changes of 1.48 degrees, however marked dental effects were observed similar to those found in deciduous dentition with a proclination of the upper incisors of 8.23 degrees. Nonetheless, the measurements made by the authors are not reliable due to individuals’ transition from deciduous to permanent teeth.

Twelve to 14 hours

In this category, we found the studies by Ngan et al. (1996, 1998), with 12 hours of facemask use per day for 6–8 months, and by Merwin et al. (1997), with 12–14 hours of facemask use per day for 6 months. Both studies obtained similar results. However, they report small effects on a skeletal level and very large effects on a dental level, which is not compatible with the concept of optimal force.

The studies conducted by Saadia and Torres (2000) and Baccetti et al. (1998) had patients use the facemask for 14 hours a day for 6–12 months. The study by Baccetti et al. (1998) does not provide data in degrees, which makes it impossible to compare with other studies. The study by Saadia and Torres (2000) had patients use the facemask for 14 hours a day for 6–12 months depending on the subjects’ age [3–6 years (for 6 months), 6–9 years (for 9 months), and 9–12 years (for 12 months)], and showed SNA increments with slight dental effects. They also observed a proclination of the upper incisors and a retroclination of the lower incisors. Although the study by Saadia and Torres (2000) approaches an optimal force, the studies with 12–14 hours of daily facemask use did not obtain significant skeletal effects as what can be obtained with 14–16 hours of facemask use, which is discussed below.

Fourteen to 16 hours

Pangrazio-Kulbersh et al. (1998) report daily facemask use of 14–16 hours for 10 months showing SNA increments of 1.24 degrees and with a proclination of the upper incisors of 1.59 degrees. Despite small dental effects, there were also very small skeletal effects as well as offering little clarity regarding when the device was used for 14 or 16 hours. Studies like the ones by Tortop et al. (2007) and Keles et al. (2002) indicate facemask use for 16 hours a day for 6–8 months and report SNA increments of 3 degrees but show great differences with respect to the force magnitude used [300g by Tortop et al. (2007) versus 500g by Keles et al. (2002)] and the age of the patients included in the sample (10–11 years in the Tortop et al. (2007) study versus 8 years in the one by Keles et al. (2002)). Regarding dental effects, the study by Tortop et al. (2007) reports less dental effects with a proclination of the upper incisors of 1.5 degrees versus 8 degrees reported by Keles et al. (2002). When analysing this time range, it can be observed that the study by Tortop et al. (2007) reached a significant skeletal effect with minimal dental effects, which makes the difference between the studies reporting 12–14 hours of use, regardless of the fact that they also observed little dental effects.

Over 16 hours

Alcan et al. (2000), with 17 hours of facemask use for 3 months, reported SNA changes of 2.29 degrees with marked dental effects. Vaughn et al. (2005) reported facemask use 24 hours a day for 6 months and observed SNA increments of 3 degrees with few dental effects. These results are similar to those reported by Tortop et al. (2007) and Keles et al. (2002), who had patients use the facemask for 16 hours a day.

After analysing the results of the articles regarding the time of facemask use, it is observed that the studies requiring 16 hours of use obtain greater maxillary protraction with minimal dental effects, which is similar to what is obtained when using the apparatus for 24 hours. We suggest, by clinical consensus, that the facemask should be used 14–16 hours a day.

Conclusions

The studies included in this systematic review are hard to compare due to methodological and biomechanical differences regarding apparatus design, the use or not of palatal expansion, the location of protraction force application, subjects’ ages, treatment duration, treatment end points, and control groups. There is no scientific evidence that would allow for the definition of adequate parameters for force magnitude, direction, and duration for maxillary protraction facemask treatment in class III patients.

Supplementary material

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