

Soft Tissue Changes with Fixed Functional Appliances in Class II division 1

A Systematic Review

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ABSTRACT

Objective: To evaluate facial soft tissue changes after the use of fixed functional appliances in Class II division 1 malocclusion cases using a systematic review of the literature.

Materials and Methods: Several electronic databases (PubMed, Medline, Medline In-Process & Other Non-Indexed Citations, Cochrane Database, Embase, Web of Sciences, and Lilacs) were searched with the help of a senior Health Sciences librarian. Abstracts that appeared to fulfill the initial selection criteria were selected by consensus. The original articles were then retrieved. Their references were also hand-searched for possible missing articles. Clinical trials assessing facial soft tissue changes with the use of fixed functional appliances without any surgical intervention or syndromic characteristics were considered. A comparable untreated control group was required to factor out normal growth changes. Four articles using Herbst and one using Jasper Jumper fulfilled the selection criteria. An individual analysis of these articles was made and some methodological flaws were identified.

Results: Although fixed functional appliances produce some significant statistical changes in the soft tissue profile, the magnitude of the changes may not be perceived as clinically significant.

Conclusions: The conclusions from this systematic review should be considered with caution because only a secondary level of evidence was found. Long-term double-blinded prospective randomized clinical trials are needed. Three-dimensional quantification of the soft tissue changes is required to overcome current limitations in our understanding of the soft tissue changes obtained with the use of fixed functional appliances. (*Angle Orthod* 2006;76:712-720.)

KEY WORDS: Functional appliances; Soft tissue; Profile; Facial changes

INTRODUCTION

Class II division 1 malocclusions with a mandibular deficiency have been treated for more than a century

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with different types of functional appliances. Esthetics is one of the main reasons for seeking orthodontic treatment.¹ It has been suggested that maxillary, mandibular, and dental morphologies have an indirect effect on the perception of facial beauty.² It seems clear that at least Caucasians prefer a straight profile.³ Therefore, one of the goals of functional treatment is to attain a straighter profile from a starting retrognathic profile, characteristic of Class II division 1 patients.⁴ From the hundreds of reports emphasizing changes produced by functional appliance use, only a relatively small proportion reported soft tissue changes.

For Class II corrections, several removable functional appliances are available, but only a few fixed functional appliances exist (ie, Crossbow, Forsus, Herbst, Jasper Jumper, MARA). Fixed functional appliances have the advantage of not requiring patient compliance. They can also be used concurrently with brackets. Their disadvantages are that they are prone to breakage and difficult to clean or remove.⁵

Although literature reviews about skeletal and dental changes with the use of fixed functional appliances have been made, no such review has been made for the soft tissue changes. It has been shown that fixed functional appliances enhance mandibular growth and that they tend to produce a more horizontal condylar growth compared with removable functional appliances.⁶ A comparison of dentoalveolar and skeletal effects between Herbst and Twin Block⁷ showed that most of the changes were dental in nature, with proclination of mandibular incisors and retroclination of maxillary incisors, which can potentially alter the lip-profile relationship.

Because of the volume of new publications produced every year, the development of a systematic approach to search, identify, and summarize available evidence has become increasingly necessary. In the past, conventional literature reviews were written by people deemed experts on a particular topic. However, such reviews were based on the authority of the most popular lecturers and researchers rather than relying on the best available evidence and, therefore, prone to bias. Conversely, a systematic review can be defined as "a review that has been prepared using a systematic approach to minimize biases and random errors which is documented in a materials and methods section."⁸ The distinct advantage of the systematic review compared with the conventional literature review is the transparency and reproducibility of its literature search.⁹ In this manner, systematic reviews can both deduce consensus among previous research with minimized bias and identify topics requiring further research.

Although a significant improvement of the facial profile after fixed functional appliance use has been reported previously, no study has yet systematically reviewed these claims. The objective of this systematic review is to evaluate facial soft tissue changes after the use of fixed functional appliances in Class II division 1 malocclusion cases using lateral cephalograms. This will permit a distinctive differentiation between the changes reported on the basis of sound methodological study designs and the anecdotal reported information.

MATERIALS AND METHODS

A computerized search was conducted using Medline (from 1966 to week 1 of August 2005), Medline In-Process & Other Non-Indexed Citations (up to August 12, 2005), Lilacs (from 1982 to July 2005), Pubmed (1966 to week 1 of August 2005), Embase (from 1988 to week 32 of 2005), Web of Science (1945 to week 32 of 2005), and all EBM reviews (Cochrane Database of Systematic Reviews [CCTR], ASP Journal

Club, Database of Abstracts of Reviews of Effects, and CCTR) (to the second quarter of 2005) databases. Terms used in this literature search were "functional appliances," "soft tissue," "profile" or "facial changes," and "human studies." The selection and specific use of each term inside every database search were made with the help of a senior librarian who specialized in Health Sciences database searches (Table 1).

The following inclusion criteria were chosen to initially select potential articles from the published abstract results: human clinical trials; facial soft tissue changes; fixed functional appliances to correct Class II division 1 malocclusions; nonsyndromic or medically compromised patients; no individual case reports or series of cases; and no surgical intervention.

No attempts were made at this stage to identify which studies did not use adequate control groups to factor out growth changes. It was considered improbable that the abstracts would report enough information regarding control groups. This would potentially exclude some articles.

All the article abstracts that appeared to meet the initial inclusion criteria were selected, and the actual articles were collected irrespective of the language in which they were published. The selection process was independently conducted by two researchers, their results compared and any discrepancies settled through discussion. The Lilacs database articles were evaluated only by one of the researchers because of language limitations. If an article abstract did not provide enough information to make a decision, the actual article was obtained.

The articles ultimately selected were chosen with the following additional inclusion criteria: evaluation of soft tissue changes through lateral cephalograms; a comparable control group to factor growth changes if required; and only fixed functional appliances used.

The actual articles from the selected article abstracts were independently evaluated by two researchers. A consensus was reached regarding which articles fulfilled the final selection criteria and were to be included in the systematic review. Articles that did not factor out growth when required (growing samples) were rejected at this stage. Factoring out craniofacial growth in the analysis was considered important to make an accurate assessment of the amount of treatment produced soft tissue change. Failure to consider craniofacial growth changes would result in a potential overestimation of the amount of change produced by the treatment. Simultaneous use of fixed banded appliances was considered a confounder and a reason for exclusion. Although measurement error is needed for a correct interpretation of the clinical significance of the findings, it was not considered a reason to reject

TABLE 1. Abstract Search Results from Different Electronic Databases^{a,b}

Database	Key Words	Results	Selected	% of Total Selected Abstracts (9)*
PubMed	(1) functional appliance*; (2) orthodontic appliances, functional; (3) Crossbow or Forsus or Jasper Jumper or Herbst or MARA; (4) #1 or #2 or #3; (5) soft tissue*; (6) facial change*; (7) profile change*; (8) #5 or #6 or #7; (9) #4 and #8; (10) limit #9 to humans	97	5	55.6
Medline	(1) functional appliance\$.mp; (2) EXP orthodontic appliances, functional/; (3) (Crossbow or Forsus or Jasper Jumper or Herbst or MARA).mp; (4) #1 or #2 or #3; (5) soft tissue\$.mp; (6) facial change\$.mp; (7) profile change\$.mp; (8) #5 or #6 or #7; (9) #4 and #8; (10) limit #9 to humans	87	5	55.6
Medline In-Process & Other Non-Indexed Citations	(1) functional appliance\$.mp; (2) EXP orthodontic appliances, functional/; (3) (Crossbow or Forsus or Jasper Jumper or Herbst or MARA).mp; (4) #1 or #2 or #3; (5) soft tissue\$.mp; (6) facial change\$.mp; (7) profile change\$.mp; (8) #5 or #6 or #7; (9) #4 and #8	1	0	0
Embase	(1) functional appliance\$.mp; (2) EXP orthodontic appliances, functional; (3) (Crossbow or Forsus or Jasper Jumper or Herbst or MARA).mp; (4) #1 or #2 or #3; (5) soft tissue\$.mp; (6) facial change\$.mp; (7) profile change\$.mp; (8) #5 or #6 or #7; (9) #4 and #8; (10) limit #9 to humans	13	0	0
All EBM reviews (Cochrane Database of Systematic Reviews, ACP Journal Club, DARE and CCTR)	(1) functional appliance\$.mp; (2) EXP orthodontic appliances, functional/; (3) (Crossbow or Forsus or Jasper Jumper or Herbst or MARA).mp; (4) #1 or #2 or #3; (5) soft tissue\$.mp; (6) facial change\$.mp; (7) profile change\$.mp; (8) #5 or #6 or #7; (9) #4 and #8	10	1	11.1
Web of Science	TS = (functional appliance* or Crossbow or Forsus or Jasper Jumper or Herbst or MARA) and (soft tissue* or facial change* or profile change*) DocType = Article; Language = All languages; Database(s) = SCI-EXPANDED	28	5	55.6
Lilacs	[(Crossbow or Forsus or Jasper Jumper or Herbst or MARA) and facial]	8	3	33.3
Hand-search	Reference list from selected articles		0	0

^a EBM indicates evidence-based medicine; ACP, American College of Physicians; DARE, Database of Abstracts of Reviews of Effects; and CCTR, Cochrane Database of Trial Registration.

^b Asterisk indicates that percentages do not add up to 100% because the same reference could be found in several databases.

TABLE 2. Studies that Fulfilled Initial Selection Criteria But Were Later Rejected

Authors	Reason(s) for Rejection
Eicke and Wieslander ²⁰	Only photos used
Schutz et al ¹⁷	No control group
Schutz et al ¹⁸	No control group
Soytarhan and Isiksal ¹⁹	No control group

an article but was considered in the interpretation of the data.

Knowing that more methodologically sound studies may provide more reliable conclusions, a methodological scoring process was developed to identify which selected studies would be most valuable (Table 2). No attempt was made to imply that this evaluation tool has been properly validated. Previous reports¹⁰⁻¹² have shown that there is no sound evidence about the validity of the use of quality assessments of clinical trials, and they recommend researchers examine individually the influence of key components of methodological quality.

The reference lists of the retrieved articles were also hand-searched for additional relevant publications that may have been missed in the database searches. In cases where extra information was required for discussion or statistical analysis, and was not specifically stated in the article, contact with the authors was sought to obtain the required information.

RESULTS

The search results and the final number of abstracts selected according to the initial selection criteria from the various databases are provided in Table 1.

From the nine studies which based on the abstracts seemed to be potentially useful, only five^{4,13-16} (56%) actually fulfilled the final selection criteria after reading the complete article. Of these five studies, three^{4,15,16} were done with adolescents and two^{13,14} with adults. From the remaining four articles, three¹⁷⁻¹⁹ were rejected because of the lack of an adequate control group to factor out expected normal growth changes and one²⁰ because it only used lateral extraoral photos

TABLE 3. Flow Diagram of the Literature Search

Manual search 0 papers		Electronic search 116 abstracts
↓		↓ → excluded 107
Potentially appropriated to be included 0 papers	→ ↓ ←	Potentially appropriated to be included 9 papers
	9 potential papers	
	↓ → excluded 3 lack of control group	
	↓ → excluded 1 Only photos were used	
	5 papers finally selected	

TABLE 4. Methodological Score for the Clinical Trials

I. Study Design (11 ✓)
A. Objective—objective clearly formulated (✓)
B. Population—described (✓)
C. Selection criteria—clearly described (✓); adequate (✓)
D. Sample Size—considered adequate (✓); estimated before collection of data (✓)
E. Baseline characteristics—baseline characteristics (✓); similar between groups (✓)
F. Timing—prospective (✓); long-term follow-up (✓)
G. Randomization—stated (✓)
II. Study Measurements (4,✓)
H. Measurement method—appropriate to the objective (✓)
I. Blind measurement—blinding (examiner ✓, statistician ✓)
J. Reliability—described (✓)
III. Statistical Analysis (5,✓)
K. Dropouts—included in data analysis (✓)
L. Statistical analysis—appropriate for data (✓)
M. Confounders—included in analysis (✓)
N. Statistical significance level— <i>P</i> value stated (✓); confidence intervals (✓)
Maximum number of ✓s = 20

(Table 2). A flow diagram of the literature search is shown in Table 3.

A methodological quality checklist (Table 4) was developed to evaluate the methodological soundness of the selected articles and the application of the same is provided in Table 5. Further details about the methodology of the selected studies can be found in Table 6.

The following data represent a summary of the soft tissue changes stated in each individual study. Please refer to Table 7 for specific information about the measurements used and the magnitude of the changes.

Jasper Jumper

An increase in the nasiolabial angle, a more retruded position of *Labrale Superius* relative to the vertical reference plane, and a protrusion of *Labrale Inferius* relative to Esthetic Plane (E-plane) were found. No changes were found in the H-angle, upper lip relative to the E-plane, and lower lip relative to the vertical reference plane.¹⁶

Herbst

All studies^{4,13–15} reported significant changes in the facial angles related to a soft tissue menton protrusion. Regarding the nose-base angulation, no significant changes were found.¹⁵ *Subnasale*, but not the nose tip, was more retrusive after treatment.¹⁵

Contradictory results have been reported regarding the anteroposition of the upper lip. Whereas one study⁴ reported a retrusion, another¹⁴ reported a protrusion. Studies^{4,14,15} consistently reported no change to the lower lip and the soft tissue menton.

DISCUSSION

The present systematic review was performed to systematically analyze the soft tissue changes that were produced by fixed functional appliances in Class II division 1 malocclusions. Despite the extensive amount of published studies regarding therapeutic effects produced by fixed functional appliances, almost exclusively with the use of the Herbst appliance, only a few clinical trials fulfilled the selection criteria. Furthermore, the level of evidence found in them was low. The use of properly designed clinical trials with an ad-

TABLE 5. Methodological Score of Selected Articles^a

Articles	A	B	C	D	E	F	G	H	I	J	K	L	M	N	Total Number of Checks	% of the Total
Pancherz and Anehus-Pancherz ⁴	✓	—	✓✓	✓—	✓≠	—✓	—	✓	—	✓	—	✓	≠	≠≠	11	60
Nalbantgil et al ¹⁶	✓	—	✓✓	≠—	✓≠	—	—	✓	—	✓	—	✓	≠	≠≠	9.5	45
Ruf and Pancherz ¹³	✓	✓	≠≠	≠—	✓≠	✓—	—	✓	—	✓	—	✓	✓	≠≠	11	60
Ruf and Pancherz ¹⁴	✓	≠	≠≠	✓—	✓≠	—	—	✓	—	✓	—	✓	✓	≠≠	10	50
Ursi et al ¹⁵	✓	✓	✓✓	✓—	✓≠	—	—	✓	—	✓	—	✓	≠	≠≠	11	60

^a A to N indicates methodological criteria in Table 4; ✓, fulfilled satisfactorily the methodological criteria (1 check point); ≠, fulfilled partially the methodological criteria (0.5 check point); —, did not fulfill the methodological criteria (0 check point).

TABLE 6. Key Details About the Selected Articles^a

Study	Year	Sample Size	Nontreated Sample	Selection	Error	Appliance	Tx Length	Measure- ments
Nalbantgil et al ¹⁶	2005	15 (7M/8F; 15 y 2 mo SD 9 mo)	15 (6M/9F; 15 y 1 mo SD 1 y)	Retrospective, based on available rec- ords	Yes	Jasper Jumper	NS	Ceph
Pancherz and Anehus-Pancherz ⁴	1994	69 (49M/ 20F; 12 y 6 mo SD 1 y 2 mo)	24 (NSM/ NSF; age 11 y 4 mo SD 9 mo)	Retrospective, based on available re- cords	Yes	Herbst	Seven mo SD 1 mo Long-term 5–10 y in 44 subjects	Ceph
Ruf and Pancherz ¹³	1999	18 (4M/10F; 18 y 5 mo SD NS)	NA	Prospective, consecutive	Yes	Herbst	8.5 mo SD NS	Ceph
Ruf and Pancherz ¹⁴	2004	23 (4M/19F; 26 y SD NS)	NA	Retrospective, based on available re- cords	Yes	Herbst	One y 9 mo SD NS	Ceph
Ursi et al ¹⁵	2000	35 (14M/ 21F; 9 y 10 mo SD NS)	29 (19M/ 10F; 10 y 9 mo SD NS)	Retrospective, based on available rec- ords	Yes	Herbst	One y 9 mo SD NS	Ceph

^a M indicates male; F, female; NS, not stated; NA, not applicable. y = years; mo = months

equate nontreated control group, if growth is expected, is the only scientific approach to quantify changes produced by therapeutic appliances. Consideration of retrospective clinical trials, series of cases, or case reports is prone to bias and exaggeration of changes attained.⁹ This has been shown in a randomized clinical trial about the Herbst compared with retrospective studies.⁷

Jasper Jumper

The Jasper Jumper is a relatively new fixed functional appliance,²¹ and therefore the number of published clinical trials^{16,22–25} is small. Only one¹⁶ of these studies fulfilled the selection criteria. Contradictory results were found because the significance of changes in the lip positions depended on the reference plane used. The change of the upper lip was associated with

an increase in the nasolabial angle. These results are consistent with the results from the selected Herbst studies. No direct comparison with other Jasper Jumper studies was feasible.

Herbst

Much has been written about the skeletal and dental effects produced by the use of the Herbst appliance as shown by a few literature reviews.^{26–30} However, very few studies have dealt with immediate soft tissue changes^{4,13–15,17–20} and even fewer with long-term changes.⁴

Soft tissue changes in growing subjects

A significant improvement of the facial profile after Herbst appliance use has been reported previous-

TABLE 7. Reported Soft Tissue Measurements from the Finally Selected Studies^{a,b}

			Pancherz- stable group ⁴	Pancherz- relapse group ⁴	Ruf and Pancherz ¹³	Ruf and Pancherz ¹⁴	Ursi et al ¹⁵	Nalbantgil et al ¹⁶
Face	Pronasale	N'Prn^PmPg' TrOrpN^PmPg'	1.6	0.9		1		NS ^c
	Subnasale	SnPg'^SnNBt SnLs^SnNBt N'Sn^SnPg'					NS	3.5
Nose	Sulcus Superious	N'Ss^SsPg'	3.4	3.3	2.8 ^d	3.1	3.5	
	Pronasale horizontal	Prn-TrOrpN					NS	
	Subnasale horizontal	Sn-TrOrpN					-1.5	
Upper lip	Labrale Superious horizontal	Ls-PrnPg'	-1.5	-2		1.1		NS
		Ls^TrOrpN					NS	
		Ls-TrOrpN					-2	
Lower lip	Labrale Inferious horizontal	Ls-TrOrpS						-3.1
		Li-PrnPg'	NS	NS		NS		1.2
		Li-TrOrpN					NS	
Menton	ST Pogonion horizontal	Ls-TrOrpS						NS
		Pg'-TrOrpN					NS	

^a In the third column the abbreviations are as follows: - indicates linear measurement (in mm); ^, angle; and p, perpendicular to.

^b See Figure 1 for definition of cephalometric points.

^c NS indicates not significant.

^d No statistical comparison.

ly.^{20,31-34} The selected articles^{15,35} consistently report an increase in different facial angles, which is correlated to an improvement in the facial profile. This improvement is not the product of a more forward position of the lower lip but more likely a retrusion of the upper lip. A possible explanation may be the restriction of the maxillary growth that appears to happen with the use of the Herbst,^{32,34,36} although the magnitude does not seem to be large. It should be noted, however, that one study³⁷ did not report any significant change in maxillary position. A more detailed analysis using measurements with reference structures not so prone to growth or treatment changes (N perpendicular to Frankfort) showed that the anteroposterior position of the upper lip gets less prominent but the inclination of the lip per se does not change,¹⁵ which is explained by a similar posterior reposition of both *Subnasale* and *Labrale Superious*. Most likely, a combination of skeletal and dental changes produced these changes.²⁶⁻³⁰

No significant changes were reported for the lower lip and the soft tissue *Pogonion* in any of the two selected studies,^{15,35} regardless of the measurements used. These results are contradictory to the numerous studies^{31,34,36-38} that have reported an increase in mandible growth (either by increase of condylar growth or by changes in the gonial angle) with the use of the Herbst appliance. Changes like those should have displaced the *Pogonion* forward with the consequent forward movement of the soft tissue *Pogonion*. The reported²⁶⁻³⁰ lower incisor protrusion produced by the Herbst treatment did not appear to be associated with

the protrusion of *Labrale Inferious* in these studies. The soft tissue adaptability to hard tissue changes has been shown to be a complex, not linear association.³⁹

Only one long-term study (more than 1 year after active use of Herbst) about the soft tissue changes produced by Herbst appliance was found. Five to 10 years after the completion of the active phase of treatment, an increase of the facial convexity was reported if the nose was included.⁴ If the nose was not included, the facial convexity was reduced in a stable group and remained unchanged in a relapse group.⁴ Also, a retrusion of both lips was observed.⁴

Soft tissue changes in nongrowing subjects

Two^{13,14} of the selected studies evaluated changes in young adults. The observed changes in the soft tissues were similar in nature and direction compared with the changes in growing individuals. An improvement in the facial profile was associated with a retrusion of the upper lip but not a forward position of the lower lip. A possible explanation is a significant dental retrusion of the upper incisors combined with a protrusion of the lower incisors similarly to the ones reported⁷ recently in a randomized clinical trial. Because both lips are supported more significantly by the upper incisors, changes in the anteroposterior position of the upper incisors more significantly affects the lip position than do changes in the lower incisors. No long-term studies about the effects of Herbst treatment in young adults have been found.

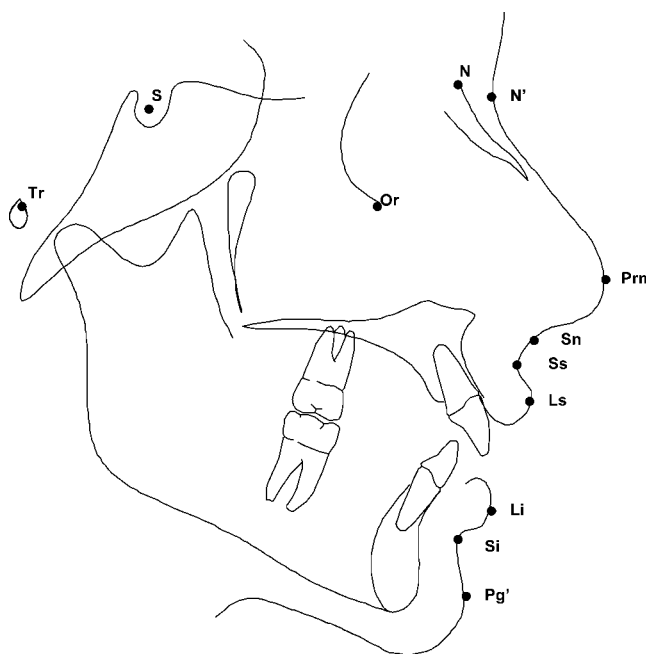


FIGURE 1. Cephalometric points. S, Sella; N, Nasion; N', Soft tissue Nasion; Tr, Tragus; Or, Orbitale; Prn, Pronasale; Sn, Subnasale; Ss, Stomion Superius; Ls, Labrale Superius; Li, Labrale Inferius; Si, Stomion Inferius; Pg' Soft tissue Pogonion.

General considerations about the reported results

A previous study⁴⁰ showed that art students, dental students, and parents of orthodontic patients did not perceive any significant changes in subjects treated with the two types of removable functional appliances. No similar evaluation was found for fixed functional appliances; therefore, although some statistically significant soft tissue changes were found after the use of Herbst appliances, the clinical significance is still questionable. A detailed esthetic judgment of the face should be carried out using the patient's frontal face view during conversation, with their facial expressions and smiling.⁴¹ Conventional orthodontic lateral cephalometric analysis is not capable of this kind of evaluation. A frontal cephalometric analysis is also not useful because of the lack of soft tissue structures to do the superimposition with hard tissue structures. Use of stereophotogrammetry or laser surface scanner may likely overcome these limitations.

A very limited number of studies evaluating three-dimensional soft tissue changes after functional treatment have already been published.⁴²⁻⁴⁴ Their main limitations are failure to use a normal nontreated control group and presenting the results as visual changes rather than actual volumetric changes.

Although an increase of the lower third of the face is associated with functional appliance treatment, none of the selected studies reported any soft tissue vertical

measurements. Vertical changes are an important component of functional appliances as shown for some removable functional appliances in studies factoring out growth.^{43,45,46}

Several different measurements have been used to evaluate the soft tissue changes after fixed functional treatment. Some of these have to be considered carefully because reference structures were used that could potentially change the end result of the treatment. For example, the esthetic plane (E plane) is not a good reference plane to quantify changes in the lips because simultaneous changes in the soft tissue Pogonion or Pronasale could create the impression of lip changes that are really nonexistent. As already discussed, in one study,¹⁶ if the E plane was not used, then a significant repositioning of the upper lip was found and no change was found for the lower lip. If the E plane was used as a reference, then no significant anteroposterior change of the upper lip, but a significant protrusion of the lower lip, was found.

Future studies in this area should consider a three-dimensional comparison of the soft tissue changes produced from the Herbst appliance against a nontreated control group. A double-blinded randomized clinical trial should be the format of choice because it will give the best possible scientific evidence. This is obviously also the case for the other fixed functional appliances (Crossbow, Forsus, Jasper Jumper, and MARA) reported in the literature.

CONCLUSIONS

The following systematic review conclusions should be considered with caution because only a secondary level of evidence was found. Long-term prospective double-blinded randomized clinical trials are needed to support these conclusions.

- An improvement of the facial convexity was found.
- Changes produced by fixed functional appliances seem to restrict the forward movement of the upper lip.
- No change in the anteroposterior position of the lower lip and soft tissue menton was found.
- Soft tissue changes are similar between nongrowing young adult and growing adolescent samples.

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