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A systematic review of cephalometric facial soft tissue changes with the Activator and Bionator appliances in Class II division 1 subjects

Carlos Flores-Mir and Paul W. Major
Orthodontic Graduate Program and Cranio-facial & Oral-health Evidence-based Group, Faculty of Medicine and Dentistry, University of Alberta, Canada

SUMMARY The objective of the present systematic review was to evaluate, through lateral cephalograms, facial soft tissue changes after the use of the Activator and Bionator appliances in Class II division 1 malocclusion subjects.

Several electronic databases (PubMed, Medline, Medline In-Process & Other Non-Indexed Citations, Cochrane Database, Embase, Web of Sciences, and Lilacs) were searched with the assistance of a senior health sciences librarian. Abstracts, which appeared to fulfil the initial criteria, were selected by consensus. The original articles were then retrieved. Their references were also hand searched for possible missing articles. Clinical trials, which assessed facial soft tissue changes with the use of either an Activator or a Bionator appliance without any surgical intervention or syndromic characteristics, were considered. A comparable untreated control group was required to factor out normal growth changes.

Five articles using the Activator and six using the Bionator fulfilled the selection criteria and quantified facial soft tissue changes. An individual analysis of these articles was undertaken and some methodological flaws were identified.

Based on the available evidence, a significant amount of controversy regarding the soft tissue changes produced by the Activator and the Bionator exists. Soft tissue changes that were reported as being statistically significant were of questionable clinical significance. Long-term, double-blinded, prospective randomized clinical trials are needed to confirm the findings. Three-dimensional quantification is also required to overcome current limitations in our understanding of the soft tissue changes obtained with the use of removable functional appliances.

Introduction

Class II division 1 malocclusions have been treated for more than a century with different removable functional appliances. A functional appliance is a removable or fixed appliance, which changes the mandible/maxilla interrelationship through forces generated by acrylic or wirework to the dentition and underlying structures. These forces are generated through stretching of muscles, fascia, and/or periosteum (Mills, 1991). Removable functional appliances can be classified into four groups (Macey-Dare and Nixon, 1999):

1. tooth-borne passive (e.g. Activator, Bass, Bionator),
2. tooth-borne active (e.g. Twin Block),
3. tissue-borne (e.g. Fränkel), and
4. combined (e.g. hybrid appliance).

These distinctive types of removable functional appliances produce changes through different mechanisms, but in essence they create a pattern of function which encourages a new morphological pattern in some of the dental and skeletal facial structures (Carels and van der Linden, 1987).

Among all the available passive tooth-borne functional appliances, the Activator and the Bionator are the most commonly used. Both appliances reposition the mandible in a more protrusive position, control the overbite, and modify dental eruption (Crokaert *et al.*, 1989; Macey-Dare and Nixon, 1999).

Aesthetic improvement is one of the main reasons for seeking orthodontic treatment (Peck and Peck, 1995; Vig *et al.*, 1999) and functional appliances are intended to improve occlusal relationships as well as facial profile (Pancherz and Anehus-Pancherz, 1994). Of the hundreds of reports evaluating the skeletal and dental changes produced by different removable functional appliances, only a relatively small proportion have analysed the soft tissue changes. Several individual studies have evaluated the soft tissue changes produced by the Activator or Bionator. Although some literature reviews (Bishara and Ziaja, 1989; Crokaert *et al.*, 1989; Mills, 1991; Petrovic *et al.*, 1991; Johnston, 1996; Barton and Cook, 1997; Rudzki-Janson and Noachtar, 1998; Macey-Dare and Nixon, 1999; Collett, 2000; McSherry and Bradley, 2000; Jacobs and Sawaengkit,

2002; Gill *et al.*, 2005) and systematic reviews (Aelbers and Dermaut, 1996; Chen *et al.*, 2002; Shen *et al.*, 2005) have focused on the effect of different functional appliances on skeletal and dental structures, no systematic review has specifically focused on the evaluation of soft tissue changes produced by the Activator and Bionator appliances. Therefore, the objective of the present systematic review was to evaluate facial soft tissue changes using lateral cephalograms after the use of the Activator and Bionator appliances in Class II division 1 malocclusion subjects.

Materials and methods

A computerized search was conducted using Medline (from 1966 to week 1 of January 2006), Medline In-Process & Other Non-Indexed Citations (up to 12 January 2006), Lilacs (from 1982 to December 2005), PubMed (1966 to week 1 of January 2006), Embase (from 1988 to week 1 of 2006), Web of Science (1945 to week 1 of 2006), and all evidence-based medicine (EBM) reviews (Cochrane Database of Systematic Reviews, American College of Physicians Journal Club, database of abstracts of reviews of effects, and Cochrane database of trial registration; to the fourth quarter of 2005). The terms used in this literature search were 'Activator', 'Bionator', 'functional appliances', 'soft tissue', 'profile changes', and 'facial changes'. The selection and specific use for each term in every database search were made with the help of a senior librarian specialized in health sciences database searches (Table 1).

The following inclusion criteria were chosen to initially select potential articles from the published abstract results:

1. Human clinical trials,
2. Facial soft tissue changes evaluated through lateral cephalograms,
3. Activator and/or Bionator functional appliances to correct Class II division 1 malocclusions,
4. No syndromic or medically compromised patients,
5. No individual case reports or series of cases, and
6. No surgical intervention.

No attempts were made at this stage to identify studies which did not use adequate control groups to factor out growth changes. It was considered improbable that the abstracts would report sufficient 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 articles collected. The selection process was independently made by both authors and their results compared to settle discrepancies through discussion, except for the Lilacs database which was only evaluated by one of the researchers because of language limitation. If an article abstract did not provide sufficient information to make a decision, the actual article was obtained.

The articles ultimately selected were chosen with the following additional final inclusion criteria:

1. A comparable control group to factor out growth changes if the subjects were still growing, and

Table 1 Search results from different electronic databases.

Database	Keywords	Results	Selected	Percentage of total selected abstracts (30)†
PubMed	(1) functional appliance*; (2) activator OR bionator; (3) #1 OR #2; (4) soft tissue*; (5) facial change*; (6) profile change*; (7) #4 OR #5 OR #6; (8) #3 AND #7; (9) limit #8 to humans	101	17	53.3
Medline	(1) functional appliance$.mp; (2) activator.mp; (3) bionator.mp; (4) #1 OR #2 OR #3; (5) soft tissue$.mp; (6) facial change$.mp; (7) profile change$.mp; (8) #5 OR #6 OR #7; (9) #4 AND #8; (10) limit #9 to humans	104	16	56.7
Medline In-Process & Other Non-Indexed Citations	(1) functional appliance$.mp; (2) activator.mp; (3) bionator.mp; (4) #1 OR #2 OR #3; (5) soft tissue$.mp; (6) facial change$.mp; (7) profile change$.mp; (8) #5 OR #6 OR #7; (9) #4 AND #8	2	0	0
Embase	(1) functional appliance$.mp; (2) activator.mp; (3) bionator.mp; (4) #1 OR #2 OR #3; (5) soft tissue$.mp; (6) facial change$.mp; (7) profile change$.mp; (8) #5 OR #6 OR #7; (9) #4 AND #8	37	0	0
All EBM reviews (Cochrane Database of Systematic Reviews, ACP Journal Club, DARE, and CCTR)	(1) functional appliance$.mp; (2) activator.mp; (3) bionator.mp; (4) #1 OR #2 OR #3; (5) soft tissue$.mp; (6) facial change$.mp; (7) profile change$.mp; (8) #5 OR #6 OR #7; (9) #4 AND #8	15	4	13.3
Web of Science	(1) TS = (functional appliance* OR bionator OR activator) AND (soft tissue* OR facial change* OR profile change*) DocType = Article; Language = All languages; Database(s) = SCI-EXPANDED	18	5	16.7
Lilacs	(activator AND facial) + (bionator AND facial)	12	10	33.3
Hand search	Reference lists from selected articles		0	0

†Percentages do not add up to 100 as the same reference could be found in several databases.
EBM, evidence-based medicine; ACP, American College of Physicians; DARE, database of abstracts of reviews of effects; CCTR, Cochrane database of trial registration.

2. Only a removable functional appliance was used.

The actual articles from the selected article abstracts were then independently evaluated by both authors. A consensus was reached regarding which articles fulfilled the final selection criteria and these were finally included in the systematic review. Studies that did not factor out growth in growing subjects were rejected at this stage and not considered further. It was considered important to factor out craniofacial growth in order to make an accurate assessment of the amount of true magnitude of the soft tissue changes. Failure to consider craniofacial growth changes would result in a potential overestimation of the amount of changes obtained. Simultaneous use of fixed 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 an article but rather was considered in the interpretation of the data.

Recognizing that more methodologically sound studies may provide more reliable conclusions, a methodological scoring process (Table 2) was developed to identify which selected studies would be most valuable. No attempt was made to imply that this evaluation tool has been properly validated. Previous reports (Juni *et al.*, 1999, 2001; Verhagen *et al.*, 2001) have shown that there is no sound evidence regarding the validity of the use of quality assessment of clinical trials, and they recommend that 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. When extra information was required for discussion or statistical analysis and, was not specifically stated in the article, contact with the authors was undertaken 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. Comparing the database results, Medline and PubMed showed the greatest diversity of finally selected abstracts (slightly more than 50 per cent). The same abstracts were selected from PubMed and Medline. All the abstracts selected from all EBM reviews and Web of Science were already included in Medline and PubMed. Lilacs, which included only Latin-American publications, accounted for a significant percentage (33 per cent) of the finally selected abstracts which did not appear in any other databases. None of the finally selected articles was missed in the electronic database searches.

From the 30 studies, which based on the abstracts seemed to be potentially useful, only 11 (37 per cent) actually fulfilled the final selection criteria after reading the complete article (Table 2). The remaining 19 articles were rejected due to the lack of an adequate control group to factor out expected normal growth changes (Table 3) or because they

Table 2 Methodological score of selected articles.

Articles	A	B	C	D	E	F	G	H	I	J	K	L	M	N	Total number of checks	Percentage of the total
Almeida *et al.*, 2001	√	√	≠≠	≠-	--	--	-	√	--	√	-	√	≠	≠≠	8	40
Cozza *et al.*, 2004	√	√	√√	√-	√-	--	-	√	--	√	-	√	-	≠≠	10	50
Forsberg and Odenrick, 1981	√	-	≠≠	√-	√≠	--	-	√	--	√	-	√	≠	≠≠	9	45
Gogen and Parlar, 1989	√	-	√≠	≠-	--	--	-	√	--	-	-	√	≠	≠≠	6.5	32.5
Henriques *et al.*, 2001	√	√	≠≠	≠-	--	--	-	√	--	√	-	√	≠	≠≠	9	45
Lange *et al.*, 1995	√	≠	√√	√-	–	--	-	√	--	√	-	√	≠	≠≠	9	45
Looi and Mills, 1986	√	√	√√	≠-	√√	--	-	√	--	√	-	√	≠	≠≠	11	55
Maltagliati *et al.*, 2004	√	√	≠≠	≠-	--	--	-	√	--	√	-	√	≠	≠≠	8	40
Mamandras *et al.*, 1989	√	√	≠≠	≠-	--	--	-	√	--	√	-	√	≠	≠≠	8	40
Morris *et al.*, 1998	√	√	√√	≠-	≠≠	√-	√	√	--	√	≠	√	≠	≠≠	12.5	62.5
Oliveira *et al.*, 1997	√	√	≠≠	≠-	≠≠	√-	-	√	--	√	-	√	≠	≠≠	10	50

Fulfilling of the methodological criteria: √ satisfactorily (1 check point); ≠ partially (0.5 check point); - did not (0 check point).
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.
H, Measurement method—appropriate to the objective.
I, Blind measurement—blinding (examiner, statistician).
J, Reliability—described.
K, Dropouts—included in data analysis.
L, Statistical analysis—appropriate for data.
M, Confounders—included in analysis.
N, Statistical significance level—*P* value stated, confidence intervals.

were published only as an abstract, thesis, or later as a full article (Table 4). A flow diagram of the literature search appears in Figure 1.

Further details concerning the methodology of the selected studies are shown in Table 5.

Activator

Five studies (Forsberg and Odenrick, 1981; Looi and Mills, 1986; Gogen and Parlar, 1989; Mamandras *et al.*, 1989; Cozza *et al.*, 2004) evaluated the soft tissue changes obtained with the use of an Activator. The specific measurements are shown in Table 6.

No changes in the naso-labial (SnLs SnNBt) and labio-mental (SiLi SiM′) angles were observed (Looi and Mills, 1986), but a mild protrusion (1.8 degrees) of menton was reported (Cozza *et al.*, 2004). Neither the tip (Forsberg and Odenrick, 1981) nor the base (Looi and Mills, 1986) of the nose underwent any change. Contradictory results were found regarding the position of the upper lip, the lower lip, and menton. Some studies (Forsberg and Odenrick, 1981; Looi and Mills, 1986; Gogen and Parlar, 1989) reported upper lip retrusion (−1.1 to −3 mm) but others no change (Mamandras *et al.*, 1989; Cozza *et al.*, 2004). Contradictory changes in upper lip thickness and length were also reported, but no changes in the lower lip or soft tissue menton were noted (Looi and Mills, 1986).

Table 3 Articles excluded due to a lack of a control sample to factor out normal changes.

Kamonji, 1980
Luder, 1982
Jonas, 1984
Remmer *et al.*, 1985
Marin *et al.*, 1989
Fourka, 1990
Deguchi, 1991
Weichbrodt and Ingervall, 1992
Hirschfelder and Fleischer-Peters, 1993
De Clerck and Timmerman, 1994
Freitas and Vigorito, 1999
Almeida *et al.*, 2000
Zhou *et al.*, 2001
Singh and Thind, 2003

Table 4 Publications excluded because they were published only as an abstract, thesis, or later as a full article.

Morris, 1995
Dominguez and Vigorito, 1997
Almeida, 2000
Brangeli, 2000
Almeida-Pedrin, 2003

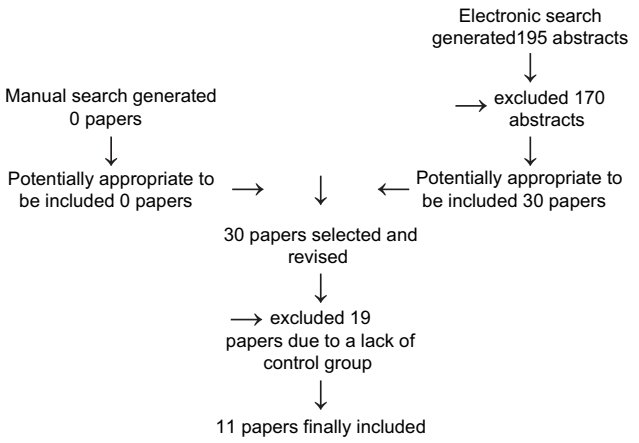

Figure 1 Flow diagram of the literature search.

Bionator

Six studies (Lange *et al.*, 1995; Oliveira *et al.*, 1997; Morris *et al.*, 1998; Almeida *et al.*, 2001; Henriques *et al.*, 2001; Maltagliati *et al.*, 2004) evaluated the soft tissue changes using a Bionator. The measurements used are shown in Table 7.

Contradictory results were reported for the facial angles. One of the studies (Henriques *et al.*, 2001) did not report any changes in facial convexity, one a diminution (−2.2 degrees; Morris *et al.*, 1998), and one augmentation (2.7 degrees; Lange *et al.*, 1995). Regarding the labio-mental angle, a large increase (17 degrees; Lange *et al.*, 1995) and no change (Morris *et al.*, 1998) were observed. No studies reported a significant naso-labial angle change (Lange *et al.*, 1995; Oliveira *et al.,* 1997; Almeida *et al.*, 2001; Henriques *et al.*, 2001). Total face height and lower face thirds were augmented (Morris *et al.*, 1998; Henriques *et al.*, 2001).

Contradictory results were found for the antero-posterior position of the upper lip, lower lip, and soft tissue pogonion. Retrusion of the upper lip (−0.89 to −1.4 mm; Lange *et al.*, 1995; Almeida *et al.*, 2001) or no change (Morris *et al.*, 1998; Henriques *et al.*, 2001) was reported. For the lower lip, a protrusion (2.2–4.9 mm; Almeida *et al.*, 2001; Henriques *et al.*, 2001) or no significant change (Lange *et al.*, 1995; Morris *et al.*, 1998) was observed. Finally, soft tissue pogonion was found to be more protrusive (0.9 mm; Lange *et al.*, 1995; Henriques *et al.*, 2001) or unchanged (Morris *et al.*, 1998).

A vertical increase was reported for upper lip, lower lip, and soft tissue menton measurements (Lange *et al.*, 1995). The locations of the cephalometric points are shown in Figure 2. Definitions of the cephalometric points used in this study are defined elsewhere (Athanasiou, 1995).

Discussion

The present systematic review was performed to analyse the soft tissue changes produced with the use of the Activator and Bionator appliances in Class II division 1 malocclusion subjects.

A significant number (25 per cent) of the finally selected studies appeared only in the Lilacs database. This finding shows the need for comprehensive database searches for systematic reviews in all possible languages. Previous studies have also raised this issue (Sutton *et al.*, 2000; Clarke, 2002).

Table 5 Key details about the selected articles.

Study	Sample size	Untreated sample	Appliance	Treatment length
Almeida *et al.*, 2001	22 (11M/11F; 10 y 8 m)	22 (11M/11F; 8 y 7 m)	Bionator	1 y 4 m
Cozza *et al.*, 2004	40 (20M/20F; 10 y)	30 (15M/15F; 10 y)	Activator	1 y 9 m
Forsberg and Odenrick, 1981	47 (25M/22F; 10 y 9 m)	31 (16M/15F; 10 y 5 m)	Activator	1 y 11 m
Gogen and Parlar, 1989	18 (10 y 10 m)	18 (11 y 5 m)	Activator	1 y 5 m
Henriques *et al.*, 2001	25 (13M/12F; 10 y 11 m)	24 (14M/10F; 10 y)	Bionator	1 y 6 m
Lange *et al.*, 1995	30 (10 y 6 m)	30 (10 y 6 m)	Bionator	1 y 6 m
Looi and Mills, 1986	30 (15M/15F; 11 y 6 m)	22 (14M/8F; 11 y 8 m)	Activator	4 y 2 m
Maltagliati *et al.*, 2004	25 (13M/12F; 10 y 11 m)	24 (14M/10F; 10 y)	Bionator	1 y 6 m
Mamandras *et al.*, 1989	32 (14M/18F; 10 y 7 m)	12 (5M/7F; 10 y 7 m)	Activator	1 y 7 m
Morris *et al.*, 1998	18 (9M/9F; 11y 8 m)	20 (13M/7F; 11 y 2 m)	Bionator	9 m
Oliveira *et al.*, 1997	10 (10 y 9 m)	10 (10 y 9 m)	Bionator	11 m

M, male; F, female; y, years; m, months.

Table 6 Articles pertaining to Activators.

			Cozza *et al.*, 2004	Forsberg and Odenrick, 1981	Gogen and Parlar, 1989	Looi and Mills, 1986	Mamandras *et al.*, 1989
Face	Subnasale	SnLs SnNBt				NS	
	ST pogonion	N′Pg′TrOrpS	1.78				
	Sulcus inferious	SiLLt SiMt				NS	
Nose	Pronasale horizontal	Prn-NA		NS			
	Subnasale horizontal	Sn-TrSN*pS				NS	
Upper lip	Sulcus superious horizontal	Ss-OpS	NS				
		Ss-SN*pS				−2.2	
		Ss-SNpS					NS
	Labrale superious horizontal	Ls-SN*pS				−3	
		Ls-PrnPg′	NS	−1.6	−1.1		
		Ls-OpS	NS				
		Ls-SNpS			−1.9		
		Ls-SNpS					NS
	Upper lip thickness	LsU1				1.6	
		SsA				−1.1	
	Upper lip length	SnSts				NS	
		SsLs				−0.8	
Lower lip	Labrale inferious horizontal	Li-SN*pS				NS	
		Li-PrnPg′	NS	−0.8			
		Li-OpS	NS				
		Li-SNpS					1.1
		Li-SNpS			NS		
	Sulcus inferious horizontal	Si-OpS	3.37				
		Si-SN*pS			NS		3
	Lower lip thickness	SiB				NS	
		StiM				NS	
	Lower lip length	LiLI				NS	
		SiLi				NS	
Menton	ST pogonion horizontal	Pg′-OpS	2.77				
		Pg′-NA		1.9			
		Pg′-SN*pS				NS	
		Pg′-SNpS			NS		1.2
	ST pogonion thickness	Pg′Pg				NS	

SN* perpendicular to a corrected SN (+7°); NS, not significant.

Art students, dental students, and parents of orthodontic patients did not perceive any significant soft tissue differences in subjects treated with two types of removable functional appliances (Activator and Fränkel; O'Neill *et al.*, 2000) in comparison with untreated controls. Therefore, although some statistically significant soft tissue changes were found after the use of the Activator or Bionator appliances, the clinical significance, at least from a layperson's perspective, is questionable.

Another problem found in this systematic review was that the level of evidence from the selected reports was low. Only two (Looi and Mills, 1986; Morris *et al.*, 1998) of the final selected studies obtained a methodological score higher than 50 per cent. Only one (Morris *et al.*, 1998) of

Table 7 Articles pretaining to Bionators.

			Almeida *et al.*, 2001	Lange *et al.*, 1995	Morris *et al.*, 1998	Henriques *et al.*, 2001	Oliveira *et al.*, 1997	Maltagliati *et al.*, 2004
Face	Subnasale	SnLs SnNBt	NS	NS		NS	NS	NS
		SnPg′ SnNBt			NS			
		GlSn SnPg′		−2.2		NS		−1.3
		N′Sn SnPg′			2.7			
	Sulcus inferious	SiLLt SiMt		17.4	NS			
		N′Pg′ Pg′Ls			−3.2			
	Face heights	Gl-Sn			NS	NS		NS
		Sn-M′			3.4	2.7		2.3
		Pg′N′			3.5	3.5		
		Sn-StS				NS		
		StI-M′				−2		
Nose	Subnasale horizontal	Sn-SN*pS		NS	NS			
	Subnasale vertical	Sn-TrOr		1.2				
Upper Lip	Sulcus superious horizontal	Ss-SN*pS		−1.1	NS			
		Ss-SN*Gl				NS		NS
	Sulcus superious vertical	Ss-TrOr		2.1				
	Labrale superious horizontal	Ls-Pg′Sn	−0.9	−1.1				
		Ls-PrnPg′			NS			
		Ls-SN*pS	NS	−1.4	NS			
		Ls-SN*pGl				NS		NS
	Labrale superious vertical	Ls-TrOr		1.8				
	Upper lip thickness	SsA			NS			
	Upper lip length	SnSts			NS			NS
Lower Lip	Labrale inferious horizontal	Li-Pg′Sn	3.4	NS				
		Li-PrnPg′		NS	NS			
		Li-SN*pS			NS			
		Li-SN*pGl				2.2		2.2
	Labrale inferious vertical	Li-TrOr		2.8				
	Sulcus inferious horizontal	Si-SN*pS		NS	NS			
		SI_SN*PGl				4.9		3.6
	Sulcus inferious vertical	Si-TrOr		4.1				
	Lower lip thickness	SiB			NS			
		StiM′			NS			
	Lower lip height	StiM′						1.9
Menton	ST pogonion horizontal	Pg′-SN*pS		0.9	NS			
		Pg′-SN*pGl				NS		3.0
	ST pogonion vertical	Pg′-TrOr		3.3				

SN* perpendicular to a corrected SN (+7°); NS, not significant.

those was an actual randomized clinical trial. More methodologically sound trials are required to attain the best possible level of evidence (double-blinded, randomized clinical trials) to understand the soft tissue changes produced by these types of functional appliances.

Although an increase of the lower facial third is associated with functional appliance treatment (Alexander *et al.*, 1999; Bardinet *et al.*, 2003), only one (Lange *et al.*, 1995) of the selected studies reported soft tissue vertical changes. Skeletal vertical changes are an important component of functional appliances (Falck and Kobel, 1985; Lange *et al.*, 1995; Morris *et al.*, 1998); therefore, they should be discussed with the patients.

The importance of posture in assessing soft tissues cephalometrically also has to be considered. Some studies use vertical lines based on natural head position changes, while others use vertical lines from heads positioned with Frankfort parallel to the floor to evaluate soft tissue changes. This makes comparison between measurements questionable.

Reference structures used to quantify soft tissue changes have to be carefully considered. For example, the aesthetic plane is not a good reference plane to quantify changes in the lips. Simultaneous changes in soft tissue pogonion or pronasale could create the impression of lip changes that are really non-existent. One study (Nalbantgil *et al.*, 2005) reported that if the aesthetic plane was not used and instead a linear distance to a vertical line through sella, then a significant retroposition of the upper lip was found but there was no lower lip change. If the aesthetic plane was used as a reference, then no significant antero-posterior change of the upper lip, but a significant protrusion of the lower lip, was observed.

Future studies should consider three-dimensional (3D) analysis of the soft tissue changes produced by the Activator and Bionator. Conventional orthodontic frontal and lateral cephalometric analyses do not seem capable of comprehensive evaluations of 3D changes. Use of stereophotogrammetry or a laser surface scanner will

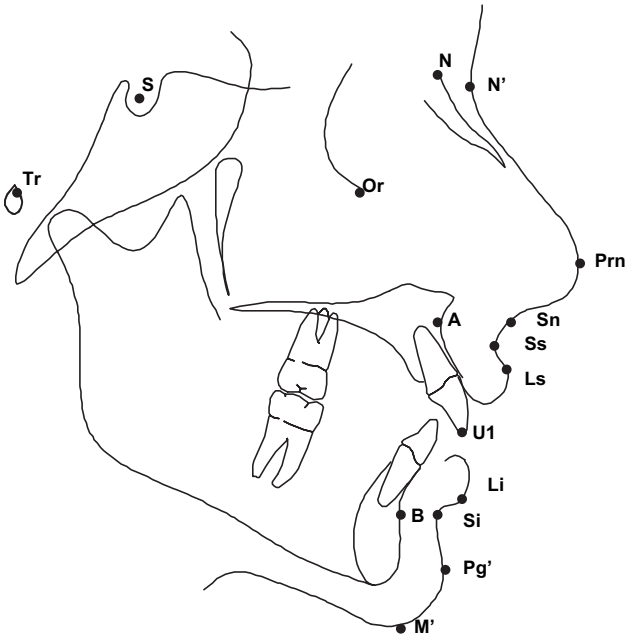

Figure 2 Cephalometric points (Athanasiou, 1995). S, sella; N, nasion; N′, soft tissue nasion; Tr, tragus; Or, orbitale; Prn, pronasale; Sn, subnasale; Ss, stomion superious; Ls, labrale superious; Li, labrale inferious; Si, stomion inferious; Pg′, soft tissue pogonion; M′, soft tissue menton; A, point A; B, point B; U1, tip of the upper incisor.

overcome the current limitations. A very limited number of studies evaluating 3D soft tissue changes after functional treatment have been published (Illing *et al.*, 1998; Morris *et al.*, 1998; McDonagh *et al.*, 2001). Their main limitations were failing to use a normal non-treated control group and presenting the results as visual changes rather than actual volumetric changes.

Conclusions

Based on the available evidence, there is significant controversy regarding the soft tissue changes produced by the Activator and the Bionator.

For the studies that supported significant changes, the nature of reported changes was of questionable clinical significance.

Address for correspondence

Dr Carlos Flores-Mir
Faculty of Medicine and Dentistry
Room 4051A,
Dentistry/Pharmacy Centre
University of Alberta
Edmonton
Alberta T6G 2N8
Canada
E-mail: carlosflores@ualberta.ca

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