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## Pharyngeal airway changes in pre-pubertal children with Class II malocclusion after Fränkel-2 treatment

### ABSTRACT

**Aim** To evaluate two-dimensional changes in pharyngeal airway dimensions in pre-pubertal children with a Class II malocclusion treated with a Fränkel-2 appliance compared to a matched non-treated control sample.

**Materials and Methods** Lateral cephalograms obtained from 28 consecutively treated pre-pubertal children before (T0) and after (T1) a one-year Fränkel-2 treatment were analysed. Fränkel-2 appliance was used for at least 18 hr/day during 12 months. The control group was matched as closely as possible. All the cases presented normal facial growth pattern. Sagittal and vertical cephalometric measurements assessing maxillary and mandibular skeletal positions,

as well as sagittal pharyngeal airway dimensions, were calculated. Intraclass correlation coefficient was calculated in order to determine reliability. Differences based on age for all the outcome variables at T0 were compared with an independent t-test. A MANOVA was used thereafter to determine if any factors and their interactions were associated with changes in the outcome variables. Differences between T1 and T0 were evaluated with either a t-student test or a Mann Whitney U test.

**Results** At T0 differences between groups were noted for several variables. These differences were considered during the follow-up statistical analysis. Changes between groups after treatment (T1-T0) were noted for SNB, PNS to Ba, McNamara Low and Middle to S (increase in treatment group), and ANB and AD1 to Ba (decrease in treatment group).

**Conclusions** Some pharyngeal two-dimensional airway dimensions changed in Class II malocclusion pre-pubertal patients during a one-year treatment with Fränkel-2 appliances.

**Keywords** Fränkel-2; Functional appliances; Oropharynx; Pharynx; Pre-pubertal; Upper airway dimensional changes.

### Introduction

Reduced oropharyngeal airway dimensions in some patients with skeletal Class II malocclusion associated with a significant retrusive mandible could lead to the development of breathing problems. Increases in upper airway dimensions and improvements in tongue resting position have been suggested as potential mechanisms to improve breathing patterns in selected individuals [Yassei et al., 2007; Jena et al., 2013; Restrepo et al., 2011]. However, increases in upper airway dimensions do not automatically imply better breathing function. Breathing is a complex function in which oropharyngeal dimensions is only one of the factors to be considered.

Some studies [Kim et al., 2010; Claudino et al., 2013; Alves et al., 2012; Ozbek et al., 1998] reported that individuals with retrognathic faces presented significantly smaller mean total upper airway dimensions compared to mesognathic faces. Pharyngeal airway dimensional changes were first investigated after functional orthopaedic treatment for growing patients with Class II malocclusion suggesting the existence of an association between mandibular forward reposition and an increase in oropharyngeal airway dimensions [Ozbek et al., 1998]. Subsequently, other studies suggested increases in oro- and/or nasopharyngeal airway dimensions in Class II malocclusion patients treated during peak of adolescent growth spurt with different

Class II correction appliances [Yassei et al., 2007; Jena et al., 2013; Hänggi et al., 2008; Kinzinger et al., 2011; Schütz et al., 2011; Lin et al., 2011; Han et al., 2014]. Only three of these studies [Yassei et al., 2007; Hänggi et al., 2008; Han et al., 2014] suggested that the quantified pharyngeal airway changes may be relatively stable in the long-term. In contrast, another study [Lin et al., 2011] found no significant changes in the sagittal dimensions of the pharyngeal airway in growing retrognathic patients treated with a modified Bionator.

So far only two studies [Restrepo et al., 2011; Gao et al., 2003] evaluated the changes of the oropharyngeal airway dimensions in patients with retrognathic faces treated with mandibular advancement appliances before peak of adolescent growth spurt. Patients treated with Klammt and Bionator were compared showing significant increase in nasopharyngeal dimensions [Restrepo et al., 2011]. Improvements of pharyngeal airway after Fränkel-2 treatment were reported in another study [Gao et al., 2003]. However, both studies did not have non-treated control groups to factor out normal developmental changes. It is expected that pharyngeal dimensions change continuously during craniofacial growth and development [Restrepo et al., 2011]. Therefore it can be argued that there is still need to clarify how those oropharyngeal changes in pre-pubertal samples treated with Class II appliances are different from the normal expected changes.

The aim of the present study was therefore to perform a retrospective study in order to assess two-dimensional changes in some pharyngeal airway dimensions in pre-pubertal Caucasian children with Class II malocclusion treated with Fränkel-2 appliances compared to normal expected changes in untreated matched pre-pubertal children with Class II malocclusion.

## Materials and methods

Appropriate ethical approval from Canada was secured by the Health Research Ethics Board of University of Alberta (Pro00057279) and by Burlington Growth Center, University of Toronto, in May 2015. In Italy, the approval was granted by the Health Research Ethics Board of the Second University of Naples (currently named University of Campania "Luigi Vanvitelli") (No. 0014474), in July 2015.

### Sample characteristics

The treated group comprised 28 consecutively treated pre-pubertal patients (15 girls, 13 boys) with Class II malocclusion recruited between July 2013 to July 2015. No sample size calculation was conducted as this was a convenience sample. Lateral cephalograms were taken before (T0) and at the end of active Fränkel-2 based treatment (T1). Total treatment time was  $1.22 \pm 0.26$  years.

The inclusion criteria were as follows.

- Class II Division 1 malocclusion diagnosed at baseline according to the presence of all following signs: bilateral

Group	Sample size			Average age (yr/mo)	
	Tot.	M	Fe	T0	T1
Treated	28	13	15	$8.40 \pm 0.64$	$9.61 \pm 0.68$
Control	21	14	7	$8.47 \pm 0.51$	$9.80 \pm 0.60$

TABLE 1 Characteristics of participants.

full- or half-cusp Class II molar relationship, increased overjet (> 4 mm), skeletal sagittal relationship of Class II (ANB angle >4°) associated with retrognathic mandibles (SNB angle <78°).

- Cervical Vertebral Maturation [Baccetti et al., 2005] stage either 1 or 2 at both T0 and T1.
- Good general health without known growth or nutritional related problems.
- Caucasian ancestry.
- Treatment with Fränkel-2 appliance, constructed according to the design recommended by Fränkel and Fränkel [1989].
- Good compliance: only patients wearing Fränkel-2 appliance for at least 18 hours/day to discriminate between lack of effect due to the treatment protocol and poor patients' compliance.

The exclusion criteria were the following:

- Previous orthodontic treatment.
- Severe craniofacial or dental anomalies (e.g., agenesis, craniofacial syndromes).
- Absence of adequate pre- or post-treatment records.

The untreated group consisted of 21 pre-pubertal children (14 males and 7 females) closely matched to the treated group based on age, ancestry, cervical vertebral maturation stage, sex and observation period. The inclusion criteria were similar except that no treatment was provided. Characteristics of both groups are depicted in Table 1.

### Cephalometric analysis

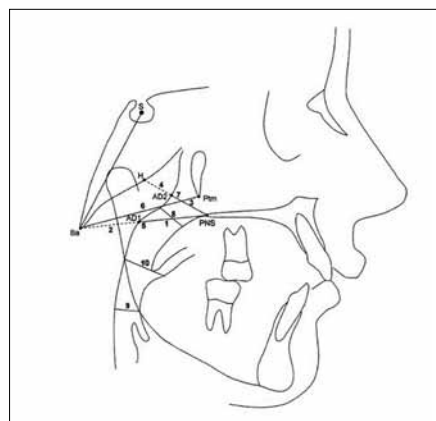
Lateral cephalograms for each subject in both groups at T0 and T1 were analysed by using a standardised protocol, with an 8% magnification factor. Three sagittal and one vertical cephalometric measurements were used to assess the maxillary and mandibular skeletal positions. Specific variables to evaluate the sagittal nasopharyngeal and oropharyngeal airway dimensions were chosen according to the definitions of McNamara [1984] and Martin et al. [2006] depicted in Figure 1 and Table 2. All measurements were calculated at both T0 and T1.

### Statistical analysis

Statistical analysis was performed with Statistical Package for the Social Sciences (SPSS version 22.Q, SPSS Inc., Chicago, USA). The mean values and standard deviation were calculated. The normality of the variable distributions was tested. Age at T0 and T1 was compared with an independent t-test. All the outcome variables were also analysed through an independent t-student test to determine differences at baseline (T0). A MANOVA was used to determine if any factors (group, sex, age at T0

**TABLE 2**  
Definitions for the cephalometric measurements of the airways.

	Cephalometric measurements	Definition
1.	PNS-AD1 Lower airway thickness	Distance between PNS and the nearest adenoid tissue measured through the PNS-Ba line (AD1)
2.	AD1-Ba Lower adenoid thickness	Soft-tissue thickness at the posterior nasopharynx wall through the PNS-Ba line
3.	PNS-AD2 Upper airway thickness	Distance between PNS and the nearest adenoid tissue measured through a perpendicular line to S-Ba from PNS (AD2)
4.	AD2-H Upper adenoid thickness	Soft-tissue thickness at the posterior nasopharynx wall through the PNS-H line (H, Hormion, point located at the intersection between the perpendicular line to S-Ba from PNS and the cranial base)
5.	PNS-Ba	Total lower sagittal depth of the bony nasopharynx
6.	Ptm-Ba	Posterior sagittal depth of the bony nasopharynx
7.	PNS-H	Total upper airway thickness
8.	McNamara's upper pharynx dimension	Minimum distance between the upper soft palate and the nearest point on the posterior pharynx wall
9.	McNamara's lower pharynx dimension	Minimum distance between the point where the posterior tongue contour crosses the mandible and the nearest point on the posterior pharynx wall
10.	Middle airway Space	Minimum distance between the posterior border of the tongue and the posterior pharyngeal wall, through the tip of the soft palate



**FIG. 1**  
Cephalometric measurements of the airways.

for treated and control groups ( $T_0 = 8.4 \pm 0.57$  and  $T_1 = 9.7 \pm 0.64$ ).

**Before treatment**

At  $T_0$ , significant differences were noted between the control and the treated groups. The following measurements were greater in the treated group before treatment was provided: PNS-AD1 (by  $3.39^\circ$ ,  $p = 0.003$ ), AD2-H (by  $2.28^\circ$ ,  $p = 0.017$ ), PNS to Ba (by  $3.94$  mm,  $p = 0.031$ ), Ptm to Ba (by  $3.75$  mm,  $p < 0.001$ ), PNS-H (by  $3.65$  mm,  $p = 0.001$ ), McNamara Lower (by  $2.44$  mm,  $p < 0.001$ ) and Middle airway Space (by  $2.46$  mm,  $p = 0.011$ ), whereas the McNamara Upper measure was smaller in treatment group by  $1.96$  mm,  $p = 0.023$ , as reported in Table 3.

According to the MANOVA, group ( $p < 0.001$ ) was the only factor associated with the changes in the outcome variables. Therefore, differences between  $T_1$  and  $T_0$  for every outcome variable were analysed through individual independent Student t-test dividing the sample by group.

**After treatment**

Differences between groups ( $T_1-T_0$ ) were noted for SNB (increase in treatment group by  $1.90^\circ$ ,  $p < 0.001$ ), ANB (decrease in treatment group by  $2.62^\circ$ ,  $p < 0.001$ ), AD1 to Ba (decrease in treatment group by  $0.38$  mm,  $p = 0.026$ ), PNS to Ba (increase in treatment group by  $1.67$  mm,  $p = 0.012$ ), McNamara Lower (increase in treatment group by  $2.41$  mm,  $p < 0.001$ ) and Middle airway Space (increase in treatment group by  $2.08$  mm,  $p = 0.004$ ), as reported in Table 3.

**Discussion**

This study was undertaken to evaluate two-dimensional changes in oro- and nasopharyngeal airway dimensions in pre-pubertal Caucasian children with Class II malocclusion treated with a Fränkel-2 appliance compared with an untreated matched sample. A claimed advantage of

or age at  $T_1$ ) or their interactions were associated with changes in the outcome variables. Differences between  $T_1$  and  $T_0$  for every outcome variable were analyzed through an independent t-student test and a Mann Whitney U test when data was not normally distributed.

A p-value below 0.05 was indicative of statistical significance.

**Method error**

The evaluators were trained. The cephalograms of the treated and untreated groups were hand traced by one researcher and verified by a second researcher. Ten radiographs (five treated and five untreated) chosen at random were retraced and re-measured by the same operators at least 4 weeks apart in order to determine reliability of the method through Intra class Correlation Coefficients (ICC).

**Results**

Intra-rater reliability was excellent  $ICC = 0.99$  ( $0.99, 0.99$ ), representing an excellent consistency. Inter-rater reliability, representing agreement between evaluators, was also very good  $ICC = 0.97$  ( $0.95, 0.99$ ). Mean ages were similar at  $T_0$

managing upper airway dimensions at this developmental stage is that further craniofacial developmental problems associated with respiratory problems could be avoided or at least minimised [Restrepo et al., 2011].

Before treatment (T0), the treated group, which included more skeletal Class II than the controls, showed a tendency for a larger total upper airway thickness (PNS-H) due likely to a larger upper adenoid thickness (AD2-H). Pre-pubertal children could have adenoids at their maximum size due to differences in the timing of peak of the lymphoid growth compared to craniofacial growth [Hänggi et al., 2008]. This could lead to a temporary functional influence predisposed by natural anatomical conditions [Kim et al., 2010]. The study group also showed a greater total lower nasopharynx depth (PNS-Ba) due to a larger lower airway thickness (PNS-AD1) when compared with controls. Finally, at baseline, the study group showed a larger lower pharynx dimension (McNamara Lower) and middle airway space, but a smaller upper pharynx dimension (McNamara Upper). Why these differences were present could not be hypothesised. These differences draw a different initial picture between the two samples that had to be controlled statistically.

After treatment (T1-T0), the apparent positive impact of Fränkel-2 therapy on upper airway dimensions could not be explained just by the quantified skeletal changes. It has been suggested that underlying mechanisms that influence breathing function in growing children are complex and not quantified in this study. Different tongue posture likely caused by increased genioglossal muscle tonus or other soft tissues changes may play an important role and maybe induced by forward positioning of the mandible during Fränkel-2 treatment [Hänggi et al., 2008].

The problem with this hypothesis is that it may explain changes at the oropharyngeal level, but not necessarily at the nasopharyngeal level. Available literature [Yassei et al., 2007; Hänggi et al., 2008; Han et al., 2014] suggested that changes in pharyngeal airway dimensions following functional appliance therapy may be maintained in the long-term.

Only two previous studies [Restrepo et al., 2011; Gao et al., 2003] evaluated pharyngeal dimensions in pre-pubertal children during Class II malocclusion treatment reporting that the changes obtained in the nasopharynx after treatment may have been a combination of growth changes and the result of the appliance effects. In our study, differences between T1-T0 showed in the study group significant greater skeletal Class II decreases (ANB reduction by 2.62°,  $p < 0.001$ ) due to forward positioning of the mandible (SNB increase by 1.90°,  $p < 0.001$ ), as previously reported [Fränkel and Fränkel, 1989; Perillo et al., 1996; Perillo et al., 2011; Perillo et al., 2013; Perillo et al., 2013].

The current study group showed significant decrease in lower adenoid thickness (AD1 to Ba) and increase in total lower sagittal depth of the bony nasopharynx (PNS-Ba) compared to controls. As these children were likely near their adenoid tissue peak growth, pharyngeal and middle airway space dimensions, which are closely located to adenoid tissue, become larger after the advancement of the mandible, as previously suggested [Restrepo et al., 2011]. The specific physiology of those changes has not been assessed in this study as the actual changes may be at least partially a reflection of adenoid tissue shrinking.

In addition, in the study group the minimal distance behind the tongue (McNamara Lower) improved by 1.75

	T0		p <sup>a</sup>	T1		p <sup>a</sup>	T0-T1		p <sup>a</sup>
	Control	Treatment		Control	Treatment		Control	Treatment	
SNA	81.07 (SD=4.26)	80.04 (SD=2.71)	.305	81.05 (SD=4.11)	79.25 (SD=2.62)	.089	-0.02 (SD=1.81)	-0.79 (SD=0.67)	.079
SNB	75.29 (SD=3.80)	73.37 (SD=2.45)	.053	75.31 (SD=3.47)	75.29 (SD=2.41)	.979	0.02 (SD=1.28)	1.92 (SD=0.83)	<.001
ANB	5.79 (SD=1.76)	6.66 (SD=1.45)	.064	5.71 (SD=1.88)	3.96 (SD=1.09)	.001	-0.08 (SD=1.17)	-2.70 (SD=0.79)	<.001
Pal-Mdb	26.48 (SD=5.00)	26.54 (SD=3.61)	.962	26.74 (SD=4.30)	25.93 (SD=3.87)	.494	0.26 (SD=2.42)	-0.61 (SD=0.27)	.155
PNS-AD1	16.17 (SD=3.71)	19.56 (SD=3.73)	.003	16.79 (SD=4.39)	22.40 (SD=3.42)	<.001	0.62 (SD=3.15)	2.84 (SD=0.57)	.303
AD1-Ba	23.81 (SD=4.92)	24.35 (SD=4.38)	.684	23.74 (SD=5.29)	23.90 (SD=4.31)	.904	-0.07 (SD=8.36)	-0.45 (SD=7.07)	.026
PNS-AD2	12.88 (SD=3.27)	14.26 (SD=2.95)	.129	14.09 (SD=3.79)	16.56 (SD=2.67)	.010	1.21 (SD=7.00)	2.30 (SD=6.58)	.537
AD2-H	11.71 (SD=2.80)	13.99 (SD=3.43)	.017	12.09 (SD=3.26)	13.38 (SD=2.82)	.146	0.38 (SD=2.15)	-0.61 (SD=1.25)	.072
PNS-Ba	39.98 (SD=3.08)	43.92 (SD=2.91)	<.001	40.52 (SD=3.60)	46.13 (SD=2.97)	<.001	0.54 (SD=2.69)	2.21 (SD=0.90)	.012
Ptm-Ba	40.05 (SD=3.58)	43.78 (SD=2.65)	<.001	41.43 (SD=2.03)	44.82 (SD=2.72)	<.001	1.38 (SD=2.10)	1.04 (SD=0.61)	.478
PNS-H	24.59 (SD=2.53)	28.25 (SD=2.36)	<.001	26.17 (SD=3.27)	29.98 (SD=2.29)	<.001	1.58 (SD=2.26)	1.73 (SD=0.99)	.759
McNamara's Upper pharynx	9.38 (SD=3.28)	7.42 (SD=2.55)	.023	10.07 (SD=3.35)	8.99 (SD=2.30)	.187	0.69 (SD=3.14)	1.57 (SD=1.31)	.240
McNamara's Lower pharynx	9.14 (SD=1.96)	11.58 (SD=2.74)	.001	8.48 (SD=1.96)	13.33 (SD=2.83)	<.001	-0.66 (SD=2.85)	1.75 (SD=0.75)	<.001
Middle airway Space	12.38 (SD=2.51)	14.84 (SD=3.67)	.011	12.19 (SD=3.23)	16.73 (SD=3.50)	<.001	-0.19 (SD=2.88)	1.89 (SD=1.07)	.004

<sup>a</sup>:  $p < .05$  ;  $P < .01$  ;  $P < .001$  ; not significant. SD= Standard Deviation

**TABLE 3**  
Mean and SD of all measures for the two assessment time points and for observed period in treated and control groups.



mm on average during the observation period. Even though this seems to be a small increase, it may be nevertheless clinically significant, considering that it has been claimed that a 0.8 mm increase with a mandibular advancement device may have a positive effect on breathing problems [Battagel et al., 1999]. Again, no direct extrapolation should be made that increases in some of the measured dimensions do automatically represent an improvement in breathing patterns. Breathing is a complex multivariable function that cannot be simplified as only depending on a dimensional obstruction case.

### Limitations

No proper sample size calculation was made as all the available treated group records were used. Control group sample size was smaller than the treated group due to a lack of available matching records. Moreover, the pre-treatment differences in oropharyngeal dimensions between control and treated groups implies that the groups were not equal. However, this was controlled statistically.

All the cases were considered to have normal facial growth direction. Any possible effect of vertical craniofacial skeletal pattern on upper airway dimensions was not considered in this study.

The airway dimensions were evaluated by using two-dimensional radiographic methods where overlapping of anatomic structures can be misleading especially in evaluating posterior nasopharyngeal airway [Major et al., 2006]. Three-dimensional imaging could be a more adequate assessment method. Nevertheless, current radiographic imaging techniques only represent a snapshot that may be reflective of temporal soft tissue positions. Therefore, this snapshot may represent different positions of the soft tissues in various moments that may not be uniquely representative.

Because of the retrospective nature of the available records no adequate functional breathing assessment was conducted.

The actual explanation of the origin of the portrayed changes at both oro- and nasopharyngeal level cannot be explained solely by the skeletal or dental changes.

### Conclusions

Within the limitation of the study, some pharyngeal two-dimensional airway dimensions among this sample of pre-pubertal patients changed during Fränkel-2 treatment even when normal expected changes were factored out.

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