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Title:

Long-term dentoskeletal changes of class II growing patients treatment with the PUL appliance. A Prospective Controlled Study.

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Abstract

Background: Class II is one of the most common malocclusions. The prevailing aspect in Class II patients is a mandibular deficiency. Various removable and fixed functional therapies are used in order to enhance the mandibular growth or position.

The aim of this prospectively controlled study was to evaluate long-term dentoskeletal changes obtained by a functional appliance for Class II.

Methods: Prospective controlled study, based on a sample size calculation. 26 Class II Division 1 patients (11.8 ± 1.5 years) were consecutively treated with the PUL appliance and a multi bracket appliance (PG), they were compared to a sample of 26 Class II untreated patients (11.5 ± 0.8 years) (CG).

Lateral cephalograms were taken before and after the PUL therapy, and after multibracket treatment.
Interaction Analysis was carried out to test whether the PUL parameters in treatment groups were different according to the acquisition times, using the Linear Mixed-Effects Model.

Results: Significant ANB, Overjet and WITS differences existed in treatment groups according to the time. In particular, comparing to T1 Vs T0, the relative difference (RD) means in the control group were -0.34, -0.31 and 0.17 for ANB, Overjet and WITS, respectively. The corresponding RD means in the treated group PG were -1.58, -4.27 and -2.38. Comparing to T2 Vs T0, the RD means in the control group were -0.36, -0.51 and 0.63 for ANB, Overjet and WITS, respectively. While the corresponding RD means in the treated group were -2.08, -5.12 and -2.50.

Conclusion: The PUL appliance successfully corrected class II malocclusion. The long term correction was mainly due to dentoalveolar effects: therapy success was 91% for overjet correction and 76% for ANB correction. During the post functional appliance period, overjet was stable in 77% of the treated subjects, and ANB in 74% of the treated subjects.

Keywords: Orthodontics, Mandibular Advancement, Orthodontic Appliances

Introduction

Class II malocclusion is one of the most common characteristics in young orthodontic patients, as it affects nearly a third of the population.[1-4] A mandibular deficiency represents the prevailing aspect in this malocclusion,[5,6] and various removable and fixed functional therapies are used in order to enhance the mandibular growth or position.[7-12]
Different key factors should be considered in growing class II patients treatment, and the focus should be on the: 1) enhancement of mandibular length related to treatment timing/growth spurt 2) kind of appliances 3) long term stability.
Thus, the main points should be on the efficiency and the efficacy of treatment. Different clinical studies and reviews/meta analyses have investigated these issues, most of the

time considering the overall points separately. The main reason for using functional removable appliances is to establish muscular balance, eliminate oral dysfunctions, and allow a proper length of both the maxilla and the mandible [13]. Different studies have been performed in order to evaluate mandibular changes, associated with the use of several functional appliances to propel forward the mandible, such as Frankel [14, 15], Bionator [16], Bass appliance [17], Herbst [18], Sander Bite Jumping [19], etc. Many studies have found changes in mandibular length and position, both in the sagittal and vertical plane [14–19]. However, when studies are analyzed together in systematic reviews and meta-analysis, controversies appear. Some reviews have found no statistically or clinically significant differences between groups treated with functional appliances and controls [20], while other authors have observed those differences to be statistically significant [21]. Additionally, studies have found other results for the treatment with functional appliances, such as secondary statistically significant mandibular elongation and changes in the facial profile, due to incisal inclination [22].

A meta-analysis published in 2016 researches the stability of class II treatment using fixed functional appliances (FFAs).[23] The research included only studies containing data on the changes occurring during a non-active post treatment period of at least one year. Even if they found 76 different available appliances to correct class II malocclusion, there was the possibility to perform a meta-analysis only for the Herbst treatment, which resulted in a good dentoskeletal long term stability, without clinically relevant changes over time.

The Removable Functional Appliances (RFAs) are the alternative to FFAs; a review of the literature on long term studies on RFAs produces as a result a few papers,[24-31] even though this topic is really important to better understand the efficacy and stability of class II therapy. As Koretsi et al. recently reported, these appliances are effective in improving the malocclusion, even if the effects are mainly dentoalvelar,[32] but it was impossible, in this meta-analysis, to get long term data on RFAs treatment, due to lack of adequate studies.

Recently, a new functional device called PUL was introduced to treat skeletal class II young patients,[33] an appliance consisting of two different components, one for the upper jaw

and the second one for the lower jaw. The two parts are connected by two telescoped rods incorporating a stainless steel coil spring, which is activated to enhance the mandibular position.

The aim of this study was to describe a functional device for Class II Division I malocclusions called PUL and to evaluate long-term dentoskeletal changes obtained with this removable appliance in comparison with a longitudinal untreated Class II group patients in the treatment of Class II Division I young patients.

Methods

This prospective controlled study included 26 patients who underwent PUL therapy for the treatment of Class II Division I malocclusion. All subjects gave informed written consent and the following inclusion criteria were considered:ANB ≥ 5 degrees

1. Overjet > 5 mm at the start of treatment
2. Full Class II molar relationship
3. No missing teeth (extracted or agenesis)
4. Growing patient
5. No syndromic or medically compromised patients
6. No use of other appliances before or during the period of functional treatment

The exclusion criteria were: patients affected by systemic diseases, bone pathology, tooth agenesis, premature loss of permanent teeth, poor hygiene and previous orthodontic treatment.

The "Department of Surgical and Diagnostic Sciences" of Genoa University approved this clinical research with the approval number 63816. All clinical procedures on humans described in the present manuscript were carried out with the approval of the responsible Ethics Committee and in accordance with national law and the Helsinki Declaration of 1975 (in its current revised form).[35]

All patients firmed a Informed Consent for treatment and a Consent to report individual data.

Treated Group

The patients who met inclusion criteria were 26 (15 boys and 11 girls; treated group, TG); patients were consecutively treated at one single private practice with the "propulseur universal light" (PUL) appliance (Figure 1) and subsequently underwent to a multibracket orthodontic treatement.

Their mean age was 11.8 ± 1.5 years, and the average PUL treatment time was 9.2 ± 1.1 months; while the multibracket therapy lasted for 1.2 ± 0.3 years. Patients were instructed to wear the removable appliance full-time except for eating, sports, and tooth brushing. The PUL appliance is a removable device. The device consists of an upper and lower component thermoformed on patient dental cast.

The two parts could have different auxiliaries such an expansion screw, an actionable TMA omega loop or lip bumper. A telescoped rod incorporating a stainless steel coil spring is activated to enhance the mandibular position and connects the two components. These springs are described as shock absorber to protect the TMJ.

Lateral cephalograms of the TG group were taken before the start of the treatment (T0) and upon completion (T1) of functional treatment and after multibracket therapy (T2).

Multibrackets therapy was carried out with an MBT prescription to complete the treatment. No mandibular protraction appliances were used during the fixed appliance period.

Control Group

The control group (CG) was obtained from 26 (15 boys and 11 girls) untreated Class II Division 1 patients (11.5 ± 0.8 years); these patients' data came from AAOF legacy (Michigan, Oregon, Burlington, Denver, Iowa, ForsythTwin, Mathews collections). Untreated patients data were-matched in sex, age, pubertal stage, and malocclusion with the TG group of patients. Mean observation time was 2.7 ± 1.2 years.

Cephalometric measurements:

The X-rays of all patients were collected at the Orthodontics Department, XXXX University, and were blindly traced and measured with regard to the provenience of the group by two clinicians. Tracings were hand-made on an acetate film (3M Unitek, Monrovia, Calif) with an HB mechanical pencil (0.3-mm lead; Staedtler, Nuernberg, Germany), using a cephalometric protractor for angular measurements,

whereas the linear values were evaluated with an electronic caliper (S.A.M.A. Italia S.r.l, Viareggio, Italy) with a precision of 0.02 mm. Customized cephalometric examination, including measurements from the analysis of Jacobson,[35] McNamara,[36] Ricketts[37] and Steiner,[38] was used. Skeletal maturity was assessed using the cervical vertebral maturation (CVM) method[39] before and after treatment by two calibrated operators at the University of XXXXX (MM and ASB). In case of disagreements, the observer resolved the staging together. Cephalograms from the two groups showed different magnification values (5.6% to 10%), and were all normalized. The success rate of the treated group was defined as final overjet < 2 mm and as final ANB < 4mm.

Method error

Intraclass correlation coefficients (ICC) were calculated for linear and angular measurements for 15 randomly selected cephalograms.

Traces were performed by the same operators in one time after a 4-week interval. For angular measurements, the mean ICC value was greater than 0.92, for linear variables the value was greater than 0.88.

Sample size

The sample size estimation calculated that 24 patients for each group achieve 80% power to detect a mean increase in ANB of 1.47 in the test group (functional appliance), with an estimated standard deviation of differences of 2.42 and with a significance level (alpha) of 0.05

using a t-test. The sample size calculation was performed on the basis of results from a recent study.[33]

Statistical analysis.

Continuous variables are given as means ± standard deviations (SD) and range, whereas categorical variables as number and/or percentage of subjects. The fifteen PUL parameters were considered as primary outcome measurements. Outcome baseline differences among treatment groups were tested by the Student's t-Test. In order to investigate the associations of the PUL parameters with treatment groups and placement times the Linear Mixed-Effects (LME) model was performed. Considering that two treatment groups were evaluated and three different placement times were taken into account, an Interaction Analysis was also carried out to test whether, the PUL parameters in treatment groups were different according to the placement times, once again, using the LME Model. The Likelihood Ratio (LR) test was used as a test of statistical significance and in each LME model, the sampling units were considered to be random factor. The analysis of the PUL parameter Absolute Differences (AD) was performed to test whether the PUL parameter AD means in treatment groups were different comparing Time T1 vs Time T0 and Time T2 vs Time T0, respectively.

The estimated p-values were adjusted for multiple comparisons by the Bonferroni correction method and when the adjusted p-value less than 0.05, the differences were selected as significant. Data were acquired and analysed in R v3.2.3 software environment.[40]

Results

A total of 52 (30 male and 22 female) subjects were considered in this study. Twenty-six patients represented the control group (CG), while 26 (50.00%) subjects had the PG treatment. The baseline PUL distribution in the treatment groups, with a summary of tests used, were reported in Table 1.

Result are expressed as Mean (Standard Deviation); p-value = Student's t-Test p-value adjusted by using Bonferroni method.

Significant baseline SArGo and Summa differences between treatment groups were observed (p-value: 0.0422 and 0.0399, respectively). In particular, the SArGo and Summa means had -7.45 and -9.31 significant decrease from patients belonging to the control group to patients that received the PUL treatment. The distribution of the PUL parameters on the considered span of time and in the two groups were reported in Table 2.

The ANB, Overjet and WITS means were 5.56 (SD=1.83), 4.77 (SD=2.99) and 4.51 (SD=4.45), respectively.

The time and treatment group effects on PUL parameters are briefly reported (data not shown): a significant time effect on ANB, Overjet, PFH_AFH.1, SNB, WITS, Co.Gn and Co.ptA were observed (p-values: <0.0001, <0.0001, 0.0003, <0.0001, 0.0121, <0.0001, and <0.0001, respectively). In particular comparing ANB and Overjet means at T1 and T2 with that at T0, significant ANB and Overjet decreases were observed, while significant increases were estimated for SNB, WITS, Co.Gn and Co.ptA (data not shown). Moreover, a significant PFH_AFH.1 increase was only observed comparing means at T2 with that at T0. Regarding treatments, significant PG effects on the WITS, X1inf.MP, ArSN, SArGo, Gonial.Angle and Summa PUL parameters were estimated (p-values: 0.0001, 0.0098, 0.0273, 0.0082, 0.0027 and 0.0036, respectively). Taking patients in Control CG treatment as reference, significant increase of 2.98, 3.29, 4.73 and -4.11, -5.28, -4.71 and -6.55 significant decreases were estimated in subject having PG treatment, for PFH_AFH.1, WITS, X1inf.MP, ArSNWITS, SArGo, Gonial.Angle and Summa PUL parameters, respectively. The Interaction Analysis demonstrated that significant ANB, Overjet and WITS differences existed in treatment groups according to the time (Table 3; p-values for interaction: 0.0105, <0.0001 and 0.0006, respectively).

In particular comparing to T1 Vs T0, the relative difference (RD) means in control CG group were -0.34, -0.31 and 0.17 for ANB, Overjet and WITS, respectively. While the corresponding RD means in group PG were -1.58, -4.27 and -2.38. Comparing to T2 Vs T0, the

RD means in control CG group were -0.36, -0.51 and 0.63 for ANB, Overjet and WITS, respectively. While the corresponding RD means in group PG were -2.08, -5.12 and -2.50. Finally, a graphical representation of the significant PUL parameter values in treatment groups according to placement time were reported in Figure 2.

Discussion Long term studies on results of functional appliances are as relevant as difficult to execute, but they can provide a prospective on the effectiveness of therapies that can help clinicians to better understand the expected results when the malocclusion is treated. This study shows the limitation that it was not set to evaluate the result of the therapy considering the pubertal growth spurt, and a subgroup analysis was therefore not indicated due to the poor case distribution. The other limitation could be the use of historical case control patients, but the decision to have untreated patients in a long term perspective is ethically doubtful, since these patients do need a treatment before growth is completed. This cephalometric investigation was set on the base of specific criteria to obtain a more efficient evaluation of the effects of treatment with the PUL, analyzing the differences with an observational data from untreated Class II malocclusion. In PG group ANB, Overjet and WITS decreased significantly according to the time: in particular comparing T1 vs T0, the corresponding RD means in PG group were -1.58, -4.27 and -2.38, while comparing T2 vs T0, the corresponding RD means in group PG were -2.08, -5.12 and -2.50. Class II correction in long term was mainly due to dentoalveolar effects. A perfect matching was not possible, because significant baseline SArGo and Summa differences between treatment groups were observed (p-value: 0.0422 and 0.0399, respectively). Particularly, these values were higher for patients belonging to the control group and this could suggest that patients who received the PUL treatment were slightly less facially divergent than the controls. According to Franchi et al.[41] values of CoGoMe lower than 125.5 degrees are predictive of a better individual responsiveness to class II treatment, and even though our cephalometric evaluation did not take into account this specific angle, it seems reasonable to consider that on average the treated group was made of good responders. In fact, the present study found that the functional appliance produced a correction of sagittal intermaxillary relationships, with a statistically significant reduction in ANB angle and Wits, and a significant decrease of overjet. These results appeared as stable after multibracket treatment. On the other hand, no significant differences were found for what concerns skeletal growth indicators, such as Co.Gn and Co.ptA. Within the functional appliance period, PUL established an average increase of 4.45 mm in Co.Gn, which is relevant from a clinical point of view, but the control group seemed to recover this difference during the subsequent period. Even though it looks like the whole growth potential was exploited during the functional appliance period in the treated group, we are not allowed to look at the functional appliance as an 'orthopedic catalyst', because no data on pubertal growth could be matched. PUL appears to be effective in correcting Class II malocclusion in long term, mainly with dentoalveolar effects, in accordance with what was suggested by a recent systematic review and meta-analysis, that is the skeletal effects of removable functional appliances are minimal and of negligible clinical importance when these are compared with untreated individuals.[33]

Conclusions

The treatment of Class II skeletal malocclusion in growing patients with the PUL appliance revealed, in the long-term, the following results: therapy success was 91% for overjet correction and 76% for ANB correction. During the post functional appliance period, overjet was stable in 77% of the treated subjects, and ANB in 74% of the treated subjects. Significant ANB, Overjet and WITS differences existed between the group treated with the PUL appliance and the untreated control according to the time: particularly, in the treated group ANB, Overjet and Wits decreased of -1.58, -4.27 and -2.38 respectively between completion of the functional treatment and baseline and of -2.08, -5.12 and -2.50 between completion of the multibracket phase and the baseline. Long term class II correction was mainly due to dentoalveolar effects.
No long-term vertical changes were found.

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Notes

The manuscript is not being considered for publication in another journal.

Tables

Outcome variables	Total	Group		p-value
		Control CG	PG	
ANB	6.29 (1.49)	5.85 (1.43)	6.73 (1.43)	0.4655
Overjet	6.47 (2.93)	5.36 (1.66)	7.58 (3.49)	0.0900
X1_sup_PP	110.52 (6.32)	109.07 (5.81)	111.96 (6.59)	1.0000
PFH_AFH.1	64.41 (4.83)	62.75 (4.2)	66.06 (4.93)	0.1819
SNA	81.92 (3.49)	81.79 (2.95)	82.04 (4.02)	1.0000
SNB	75.62 (3.22)	75.94 (2.93)	75.31 (3.52)	1.0000
WITS	5.19 (4)	6.3 (5.27)	4.08 (1.49)	0.7209
Co.Gn	107.85 (6.34)	108.04 (5.86)	107.65 (6.9)	1.0000
Co.ptA	88.88 (5.7)	88.96 (6.68)	88.81 (4.64)	1.0000

Diff	18.97 (6.27)	19.09 (7.75)	18.85 (4.48)	1.0000
X1inf.MP	95.79 (5.07)	94.53 (3.11)	97.04 (6.28)	1.0000
ArSN	124.79 (7.55)	123.09 (4.14)	126.5 (9.65)	1.0000
SArGo	140.38 (9.11)	144.1 (5.32)	136.65 (10.6)	0.0422
Gonial.Angle	125.06 (6.83)	127.7 (5.12)	122.42 (7.39)	0.0676
Summa	390.23 (11.28)	394.89 (5.77)	385.58 (13.46)	0.0399

Table 1: Baseline characteristics in whole population (N=52)

Outcome variables	Total	Group		Time		
		Control CG	PUL	T0	T1	T2
ANB	5.56 (1.83)	5.61 (1.7)	5.51 (1.97)	6.29 (1.49)	5.33 (1.84)	5.07 (1.95)
Overjet	4.77 (2.99)	5.09 (1.61)	4.45 (3.89)	6.47 (2.93)	4.18 (2.5)	3.66 (2.78)
X1_sup_PP	110.29 (6.5)	109.01 (6.36)	111.56 (6.42)	110.52 (6.32)	110.35 (6.15)	110 (7.1)
PFH_AFH.1	64.98 (4.86)	63.49 (4.08)	66.47 (5.14)	64.41 (4.83)	64.91 (4.89)	65.62 (4.88)
SNA	81.87 (3.62)	82 (2.99)	81.74 (4.18)	81.92 (3.49)	81.76 (3.8)	81.95 (3.63)
SNB	76.31 (3.33)	76.38 (2.79)	76.23 (3.8)	75.62 (3.22)	76.42 (3.48)	76.88 (3.21)
WITS	4.51 (4.45)	6.56 (5.23)	2.45 (2.01)	5.19 (4)	4.08 (4.71)	4.25 (4.63)
Co.Gn	110.99 (8.37)	110.1 (6.03)	111.87 (10.15)	107.85 (6.34)	111.85 (11.34)	113.26 (5.28)

Co.ptA	90.76 (6.07)	90.95 (7.44)	90.58 (4.34)	88.88 (5.7)	90.83 (6.05)	92.58 (5.99)
Diff	20.22 (8.78)	19.15 (8.65)	21.29 (8.83)	18.97 (6.27)	21.02 (11.79)	20.68 (7.31)
X1inf.MP	96.31 (5.26)	94.66 (3.89)	97.95 (5.92)	95.79 (5.07)	96.68 (5.41)	96.45 (5.35)
ArSN	124.44 (10.92)	122.08 (11.8)	126.81 (9.47)	124.79 (7.55)	125.51 (7.5)	123.03 (15.68)
SArGo	140.83 (8.24)	143.47 (5.75)	138.19 (9.45)	140.38 (9.11)	140.54 (7.91)	141.58 (7.73)
Gonial.Angle	125.19 (6.33)	127.55 (5.12)	122.83 (6.58)	125.06 (6.83)	125.41 (6.84)	125.11 (5.32)
Summa	391.11 (9.4)	394.38 (5.63)	387.83 (11.16)	390.23 (11.28)	391.46 (8.55)	391.62 (8.21)

Table 2: Descriptive statistics in whole population (N=52)

Outcome Variables	p-value for Interaction	Post-hoc analysis			
			Treatment		
		Contrast	Mean Control Group	Mean PUL Group	p-value
		T1 vs T0	-0.34	-1.58	0.0196
ANB	0.0105	T2 vs T0	-0.36	-2.08	0.0040
		T2 vs T1	-0.02	-0.50	0.8594
		T1 vs T0	-0.31	-4.27	<0.0001
Overjet	<0.0001	T2 vs T0	-0.51	-5.12	<0.0001
		T2 vs T1	-0.20	-0.85	0.6234
		T1 vs T0	1.01	-1.35	

X1_sup_PP	1.0000	T2 vs T0	-1.19	0.15	
		T2 vs T1	-2.20	1.50	
		T1 vs T0	0.53	0.46	
PFH_AFH.1	1.0000	T2 vs T0	1.67	0.75	
		T2 vs T1	1.14	0.29	
		T1 vs T0	0.18	-0.50	
SNA	1.0000	T2 vs T0	0.45	-0.38	
		T2 vs T1	0.27	0.12	
		T1 vs T0	0.52	1.08	
SNB	1.0000	T2 vs T0	0.82	1.69	
		T2 vs T1	0.29	0.62	
		T1 vs T0	0.17	-2.38	0.0005
WITS	0.0006	T2 vs T0	0.63	-2.50	0.0008
		T2 vs T1	0.46	-0.12	1.0000
		T1 vs T0	1.78	6.23	
Co.Gn	1.0000	T2 vs T0	4.40	6.42	
		T2 vs T1	2.62	0.19	
		T1 vs T0	2.05	1.85	
Co.ptA	1.0000	T2 vs T0	3.93	3.46	
		T2 vs T1	1.88	1.62	
		T1 vs T0	-0.27	4.38	

Diff	1.0000	T2 vs T0	0.47	2.96	
		T2 vs T1	0.74	-1.42	
		T1 vs T0	0.24	1.54	
X1inf.MP	1.0000	T2 vs T0	0.14	1.19	
		T2 vs T1	-0.10	-0.35	
		T1 vs T0	0.70	0.73	
ArSN	1.0000	T2 vs T0	-3.72	0.19	
		T2 vs T1	-4.43	-0.54	
		T1 vs T0	-1.36	1.69	
SArGo	1.0000	T2 vs T0	-0.52	2.92	
		T2 vs T1	0.83	1.23	
		T1 vs T0	0.38	0.31	
Gonial.Angle	1.0000	T2 vs T0	-0.83	0.92	
		T2 vs T1	-1.22	0.62	
		T1 vs T0	-0.26	2.73	
Summa	0.5023	T2 vs T0	-1.25	4.04	
		T2 vs T1	-0.99	1.31	

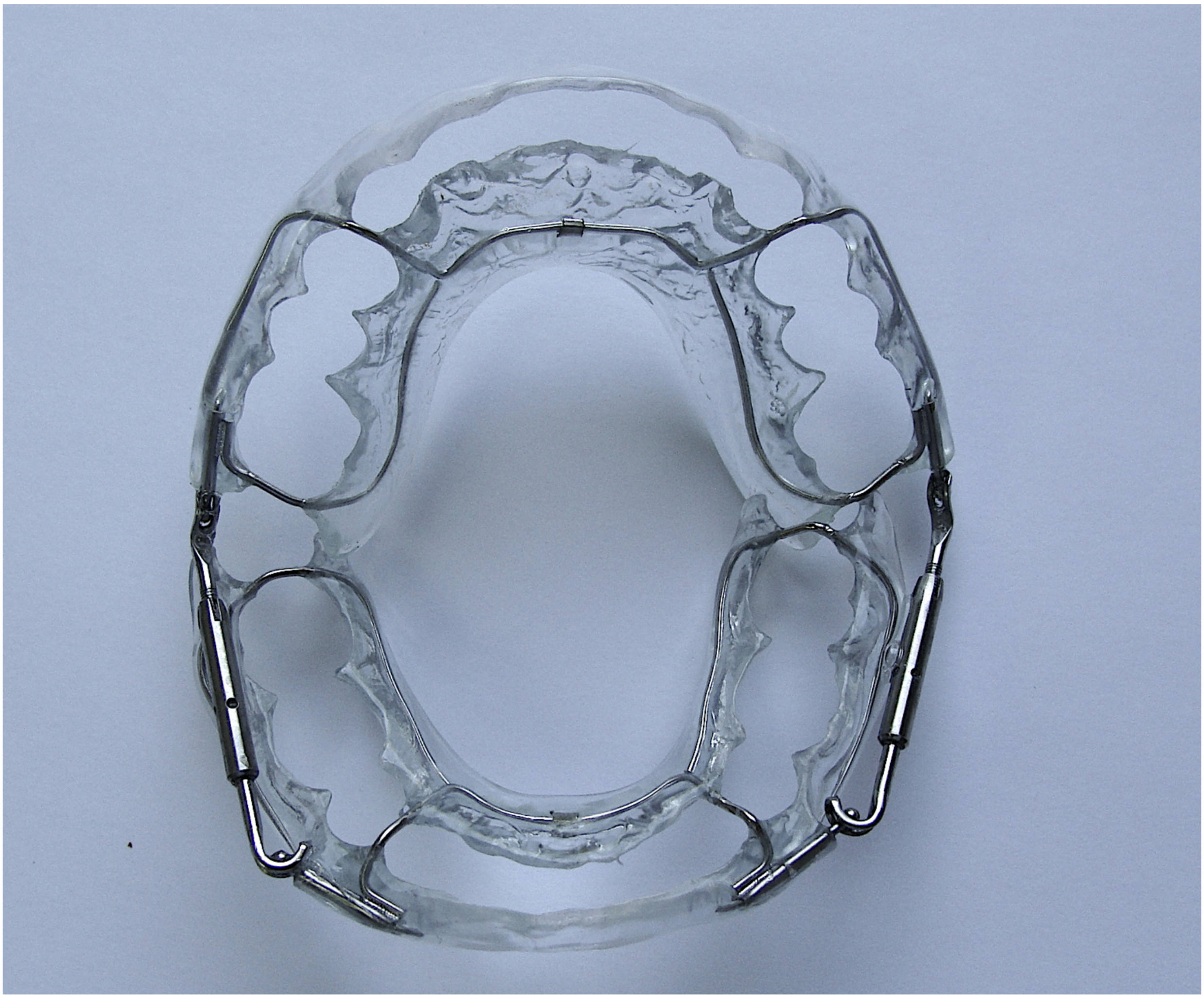
Table 3: the summary of the interaction analysis output with the Absolute Differences assay. **P-value for Interaction:** likelihood ratio test p-value for evaluating interaction

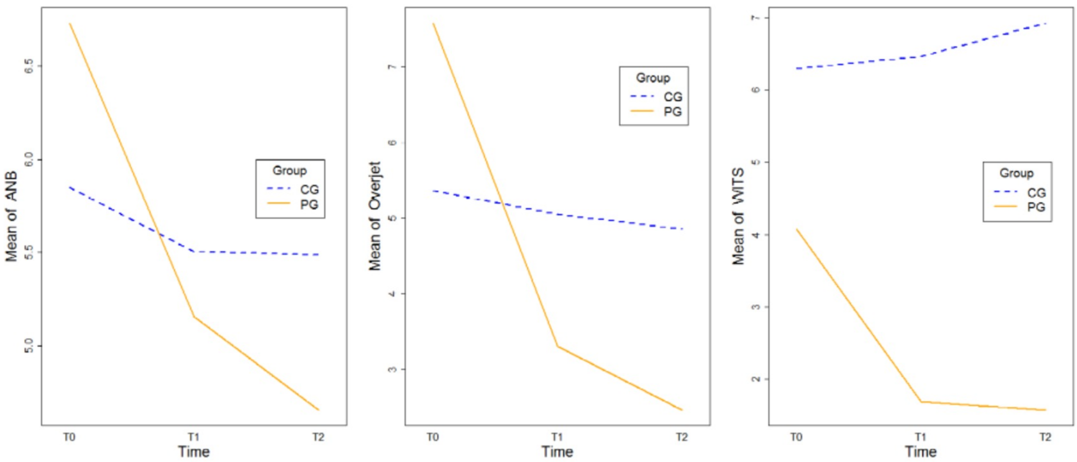
between Group of treatment and Time using mixed-effect model; **Contrast**: contrast taken in to account; **p-value**; t test p-value. All p-values were adjusted by using Bonferroni method.

Title of Figures

Figure 1: the PUL appliance

Figure 2: the significantly different parameter values in treatment groups




Mean of ANB
Time
T0
T1
T2
Group
CG
PG
Mean of Overjet
Mean of WITS