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CLASS II MALOCCLUSION CORRECTION BY TWO DIFFERENT INTERMAXILLARY ELASTICS PROTOCOLS: A RANDOMIZED CLINICAL TRIAL

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Abstract

Objective*: The effect of two different Class II elastics protocols on the inclination of the maxillary incisors.*

Materials and Methods*: A total of 20 patients were divided into two equal groups conventional group and early one. Cephalometric radiographs were taken before the treatment. For conventional group, elastics were inserted once the patients reached heavy rectangular stainless steel arch wires but in early group, all patients were instructed to wear light short Class II elastics from day one just after placement of full fixed pre-adjusted edge-wise appliance. All patients were instructed to wear Class II elastics 24 hours except while eating. After alignment, leveling, and Class I achievement; post-treatment cephalometric radiographs were taken.*

Results: Both groups showed statistically significant maxillary incisors retroclination in relation to SN plane (P <0.05). However, early group showed statistically significant maxillary incisors retroclination in relation to the palatal plane also (P <0.05).

Conclusion: Retroclination of the maxillary incisors as a compensatory effect of Class II elastics occurred in both groups (protocol independent).

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Introduction

Class II malocclusion is one of the major orthodontic problems. The dental and skeletal factors ranging from mild to severe provide the multiple characteristics of this malocclusion. Moreover, Class II division 1 is more common than division 2 (1).

There are several orthodontic techniques and appliances for class II malocclusion treatment; among these are Class II elastics. Class II elastics correct a Class II malocclusion by two actions: retraction and clockwise rotation of the maxillary arch, and protraction and clockwise rotation of the mandibular arch. This combination of anteroposterior and vertical effects corrects this malocclusion (2). The force levels of elastics range from light, medium, heavy, and extra heavy. The force value of elastics should be provided by the manufacturers for different sizes. It is recommended to stretch the elastic to three times the original internal diameter to achieve the force stated on the package (3). the regular change of elastics is very important because their force level decreases rapidly. So effective use

of elastics needs excellent patient cooperation.

In spite of their popularity, there are no significant data to determine the most convenient protocols to correct Class II malocclusion with Class II elastics. there are many variables related to Class II elastics such as the mode of elastics wear, the force value, the frequency of elastics changes, and also the proper timing for starting the elastics wear.

According to the 20 principles of Alexander's discipline, the premature use of Class II elastics can be very dangerous if used with light archwires that cannot control torque. these elastics can cause mandibular incisors proclination, maxillary incisors retroclination, mandibular molar extrusion, and alteration of the occlusal plane (4). Also, worsen smile esthetics due to increased gingival exposure (5). Therefore, Class II elastics should not be used until these factors are under control. Alexander used 1/2 inch; 6 Oz elastics extended from the maxillary lateral incisor ball hook to the mandibular first or second molar. Class II elastics traditionally run from the upper canine hook to the lower first or second molar hook on stainless steel rectangular wire. So, among orthodontists, the statement "Don't use elastics on a light wire " is acknowledged as not negotiable.

Sabrina Huang from Taiwan advocated the use of early light short elastics and she suggested the ELSE (Elastic, Light, Short, and Early) acronym some years ago as mentioned by Tom Pitts and Duncan Brown (6),(7). Recently, active early Protocol was introduced by Tom Pitts and Duncan Brown (8),(9),(10). This novel Protocol includes immediate light short elastics (ILSE) allowing the orthodontist to apply the elastics early from the first appointment. The authors mentioned the guiding principles of

ILSE which include: full-time wear, immediate elastics, and light force is better than a heavy one and they claim the active early protocol is efficient, effective, and predictable (11). However, these claims are based only on their case reports and clinical articles with no evidence.

Therefore, the main objective of this study is to evaluate whether the use of immediate light short Class II elastics can correct canine Class II malocclusion without significant side effects when compared to the conventional longer and heavier elastics used with passive rectangular stainless-steel wire.

Material and methods

The ethics committee at the Faculty of Dentistry Ain-Shams University approved the study design after reviewing the study protocol. No financial conflicts of interest were declared. The study was self- funded by the principle investigator.

Twenty patients participated in this study (15 females and 5 males). They have been selected from the outpatient clinic of the orthodontic department, faculty of Dentistry, Ain-Shams University. Patients were selected according to the following inclusion criteria: Permanent dentition stage with fully erupted permanent teeth (excluding third molars), increased overjet, Dental Class II malocclusion, and orthodontic treatment plan involves the use of a pre-adjusted edgewise fixed orthodontic appliance with a non-extraction approach. Subjects were excluded from the study if they have a gummy smile, obvious periodontal disease and gingival recession or vulnerable patients (orphans, subjects with mental disorders…. etc.). Participants who met the eligibility criteria were invited to participate inthis study.

Sample size calculation

The sample size was calculated based on continuous response variables from independent control and experimental subjects with 1 control(s) per experimental subject. Based on previous studies (12),(13) the response within each subject group was normally distributed with a standard deviation of

9.3. If the true difference in the experimental and control means is 13.6, we will need to study 9 experimental subjects and 8 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. The effect size is 1.43 (Fig 1).

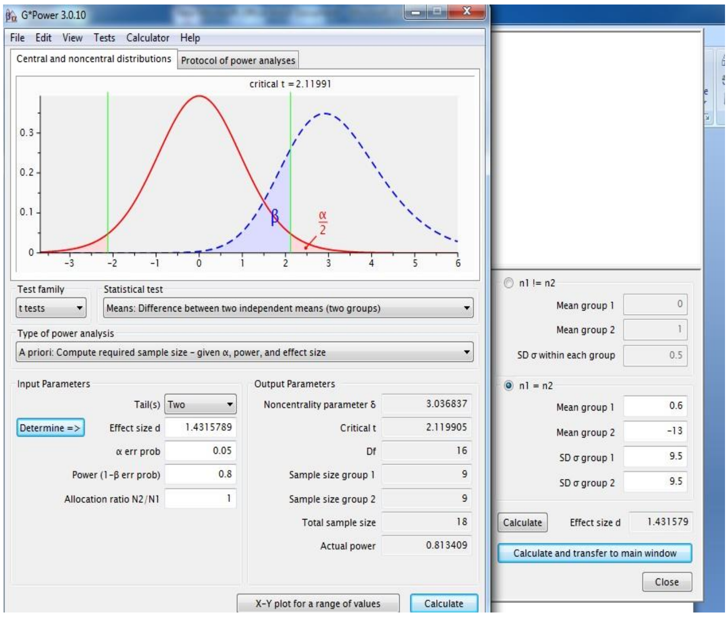

Figure 1: Sample size calculation.

Accordingly, a sample size of 20 patients was selected and divided into two groups:

Group 1: early group, 10 patients

Group 2: conventional group, 10 patients

Randomization and Allocation Concealment

Patients who met the inclusion criteria and approved participation in the study were randomly allocated to either early or conventional groups. A colleague not involved in the clinical trial, generated randomization sequences using the computer software which generated random number sequences that were done in blocks (block size: 10 participants) to ensure a 1:1 allocation ratio. Each subject was given a number in the order in which he/she showed up for diagnosis. Allocation of the subjects into either early group or conventional group was performed by matching that number with the generated sequence. The allocation sequence was concealed from the investigators of the study (Fig 2). The CONSORT flow-chart summarizes the process of enrollment, allocation, follow-up, and analysis of the recruited sample (Fig 3).

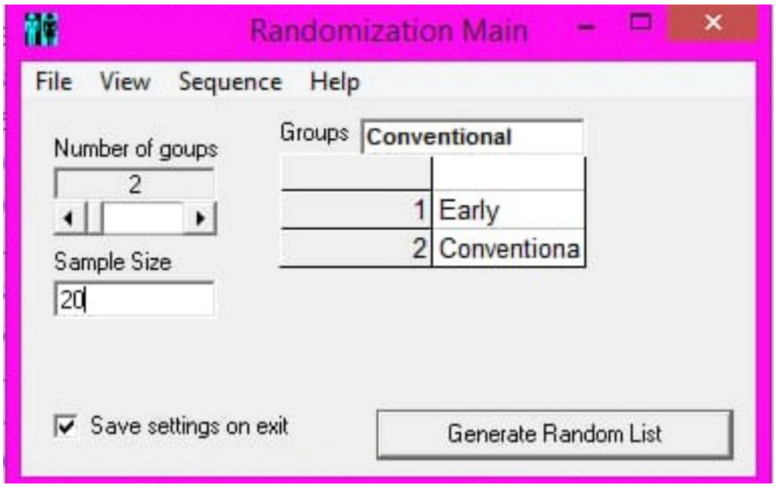

Figure 2: Sample Randomization.

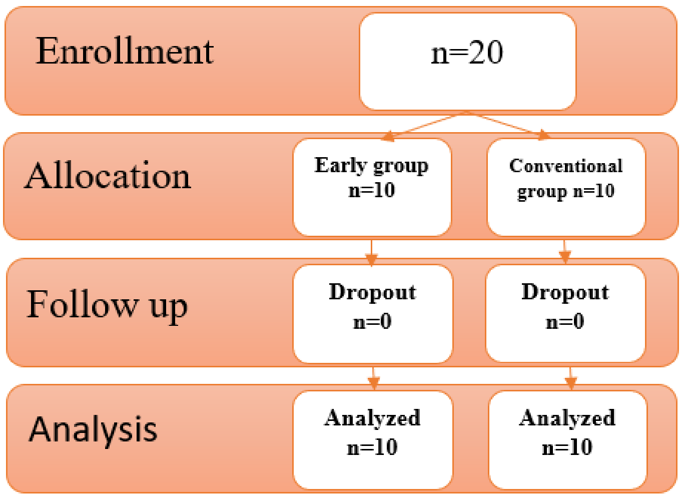

Figure 3: The CONSORT flow-chart.

Participants who agreed toparticipate were given a full detailedexplanation of the study before any procedure and an informed consent was signed by the participants before their enrollment in the study in which the aim of the study and the methodology were clearly described.

Interventions

Pre-adjusted edgewise full fixed orthodontic appliance 0.018-Inch slot Roth prescription was placed. Proper elastics size and force level was selected using a force gauge to be in the range of 2 - 3.5 Oz for the early group and 4 – 5 Oz for the late group. Immediate light short elastics were inserted from the maxillary canine hook to the mandibular second premolar hook immediately after appliance placement in the early group (Figure 4). In the late group, elastics were inserted from the maxillary canine hook to the mandibular first molar hook after reaching 0.016×0.022-inch stainless steel archwires (Figure 5). Glass ionomer cement was used for disarticulation of occlusion at the central fossa of lower first molars in both groups.

All patients were fully motivated by interactive discussion including the effectiveness, simplicity, cost-benefit ratio and esthetic concerns of Class II elastics. In addition, possible alternative treatment modalities were discussed including the need for extraction or extra appliances. Patients were instructed to wear the Class II elastics regularly and change them every 12 hours. Regular follow up was done at 4-weeks intervals and WhatsApp messages were sent “home follow up” to enhance patients’ compliance. The records including cephalometric radiograph and standardized smile photos were taken before the treatment and repeated once proper alignment and leveling was achieved along with Class I buccal segment relationship.

Figure 4: Immediate light short class II elastic

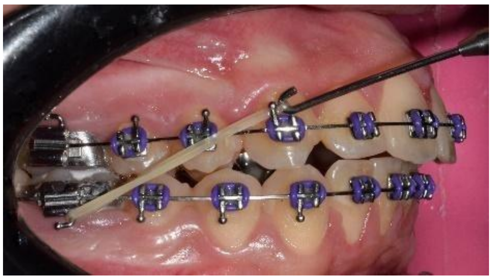

Figure 5: Conventional Class II elastics

Outcomes

The outcomes for this study include the assessment of dental, skeletal, and soft tissues changes before and after treatment. Cephalometric analysis was done using Dolphin version 11.54 software.13 Landmarks were identified on the digital images and dental, skeletal, and soft tissue measurements were then performed.

Error measurement

Interobserver and intraobserver reliability was evaluated by using ICC (interclass correlation coefficient). Interobserver reliability (Inter Class Coefficient) was used to evaluate the agreement between 2 observers and revealed excellent agreement (α = >0.9) in all measurements. Intraobserver

4 Dolphin Imaging and Management Solutions, Chatsworth, Calif. USA.

reliability (Inter Class Coefficient) was used to evaluate the agreement between 2 readings of the same observer and revealed excellent agreement (α = >0.9) in all measurements

Statistical analysis

Statistical analysis was performed with SPSS 205, Graph Pad Prism6 and Microsoft Excel 20167.All quantitative data were explored for normality by using Shapiro Wilk and Kolmogorov Normality test and presented as minimum, maximum, means and standard deviation (SD) values. Shapiro Wilk and Kolmogoro v were used for normality exploration. Paired t test was used to compare between pre and post measurements and Independent t test was used to compare between both groups.

RESULTS

Dental cephalometric measurements

Table 1 shows dental cephalometric measurements in both groups and comparison between them. Comparison between both groups was performed and revealed insignificant difference in all measurements as P>0.05.

Table (1) Mean difference and standard deviation between pre and post of dental cephalometric measurements in both groups and comparison between them using Independent t test:

Measurements			Group 1 (Early)		Group 2 (Conventional)		Difference (Independent t test)				
			MD	SD	MD	SD	MD	SEM	95% CI Lower	95% CI Upper	P value
Sagital	Angular	U1/SN	-7.87	5.76	-6.57	3.65	1.3	2.16	-3.23	5.83	0.55 ns
		U1/NA	-7.76	6.54	-5.07	4.25	2.69	2.47	-2.49	7.87	0.29 ns
		U1/PP	-7.21	5.77	-3.02	5.18	4.19	2.45	-0.96	9.34	0.10 ns
		L1/MP	5.85	4.91	4.71	5.26	-1.14	2.28	-5.92	3.64	0.62 ns
	Linear	U1/NA	-2.85	2.63	-2.09	2.14	0	1.31	-2.75	2.75	1.00 ns
		L1/NB	1.49	1.24	1.46	2.07	-0.03	0.76	-1.63	1.57	0.97 ns

M: mean, SD: standard deviation, MD: mean difference, SEM: standard error mean, CI: confidence interval, *Significant at P<0.05

5 Statistical Package for Social Science, IBM, USA.
6 Graph Pad Technologies, USA
7 Microsoft Co-operation, USA.

Skeletal cephalometric measurements

Table (2) shows the skeletal cephalometric measurements in both groups and comparison between them. The comparison revealed insignificant difference in all measurements except MP/SN and PP/SN angles with P value

Table (2): Mean difference and standard deviation between pre and post of skeletal cephalometric measurements in both groups and comparison between them using Independent t test:

Measurements			Group 1 (Early)		Group 2 (Conventional)		Difference (Independent t test)				
							MD	SEM	95% CI		P value
			MD	SD	MD	SD			Lower	Upper	
Vertical	Angular	MP/SN	0.6	1.36	3.26	2.55	2.66	0.91	0.74	4.58	0.01*
		PP/SN	0.7	1.8	3.12	1.95	2.42	0.84	0.66	4.18	0.01*
		OP/SN	2.8	2.89	4.11	1.88	1.31	1.09	-0.98	3.6	0.25 ns
	linear	PFH / AFH Ratio	-0.42	1.26	-0.92	2.95	-1.34	1.02	-3.47	0.79	0.20 ns
		LAFH/ AFH Ratio	-0.05	1.21	1.55	2.03	-1.5	0.75	-3.07	0.07	0.06 ns

Min: minimum, Max: maximum, M: mean, SD: standard deviation, MD: mean difference, SEM: standard error mean, CI: confidence interval, *Significant at P<0.05

Soft tissue measurements

Table 3 shows soft tissue measurements in both groups and comparison between them. The comparison between them revealed insignificant differences in all measurements as P value > 0.05.

Table (3): Mean difference and standard deviation between pre and post of soft tissue cephalometric measurements in both groups and comparison between them using Independent t test:

Measurements		Group 1 (Early)		Conventional		MD	SD	95% CI		P value
		MD	SD	MD	SD			L	U	
soft tissue measurements	Ls- E line	-0.11	0.96	-0.2	0.94	0.09	0.43	-0.81	0.99	0.84
	Li- E line	0.45	1.32	0.41	1.37	0.04	0.6	-1.22	1.3	0.95
	Upper lip thickness	-0.5	1.64	-0.48	1.48	-0.02	0.7	-1.49	1.45	0.98
	Upper lip strain	1.24	1.79	0.66	2.7	0.58	1.03	-1.57	2.73	0.58

Min: minimum, Max: maximum, M: mean, SD: standard deviation, MD: mean difference, SEM: standard error mean, CI: confidence interval, *Significant at P<0.05

Discussion

Incisor inclination and position

Class II elastics caused a statistically significant maxillary incisors retroclination for both groups. For the early group, the change in maxillary incisors inclination was due to true incisors retroclination in relation to both Sella Nasion (SN) and palatal planes (PP). Maxillary incisors showed statistically significant retroclination by -7.87±5.76º with SN and -7.21±5.77º with PP. Comparing these findings to the case report by Linda Tseng and Chris Chang, early elastics usage caused retroclination of the maxillary incisors which was similar to our findings but the change in the inclination was by -13 degrees which was more when compared to our results as the patient in their case report was full cusp Class II relationship (13). On the other hand, the case series were reported by El-Bokle et al showed no change in one patient, and proclination of the maxillary incisors in the second patient (14). This was related to two reasons. First, the different treatment maneuver as they depend mainly on bite raisers with advancement of the mandible to correct Class II malocclusion not by the effect of the elastics as the

patients included in the study were growers. So, the treatment targeted the skeletal rather than dentoalveolar effects. Second, they started to place the Class II elastics after reaching to 0.014×0.025- inch Nickle Titanium arch wires which help to control the torque by the help of its rectangular cross section.

For conventional group, maxillary incisors also showed a statistically significant retroclination in relation to the SN plane by -6.57±3.65º. On the other hand, no statistically significant change was noted in relation to the palatal plane. Similarly, Janson et al in a systematic review (2013) reported that conventional Class II elastics caused significant retroclination of upper incisors (5) and Jayachandran et al (2016) study also showed significant retroclination by -6.41±9.17º (15).

Comparing both groups, significant differences were noted. As the maxillary incisors significantly retroclined in relation to the palatal plane only in the early group. This can be caused by the early use of elastics on round undersized arch wires which caused uncontrolled rotation of the incisors with significant retroclination.

On the other hand, there was no statistically significant differences between the two groups for the change in maxillary incisors' inclination in relation to SN plane. The maxillary incisors were retroclined by -7.87±5.76º and -6.57±3.65º in the early and conventional group, respectively. This can be caused by the finding that the palatal plane showed a significant clockwise rotation in the conventional group which resulted in maxillary incisors retroclination in relation to SN plane. Accordingly, the net result of maxillary incisors retroclination in relation to SN plane in the conventional group was the sum of both significant clockwise rotation of the palatal plane and minimal incisors retroclination in relation to its basal bone.

Our justification for these findings was that rectangular arch wires with larger cross section provide less play and more torque control so that maxillary incisors tipped lingually until binding of arch wire edges with bracket slot happened (16),(17) and the higher force transmitted to maxillary arch caused significant clockwise rotation of the palatal plane. This can explain why the net change in incisors' inclination to SN plane did not show significant differences between the two groups.

The clinical significance of this finding is that early elastics is preferably used in cases with proclined incisors in relation to the palatal plane. On the contrary, for patients with normal incisor's inclination, it is recommended to wait till reaching the heavy stainless-steel arch wires and use other

maneuvers such as adding a compensating curve to the wire to maximize torque control and avoid significant lingual tipping of the incisors. This should be considered during the treatment planning stage.

Another consideration is that the lingual tipping of the maxillary incisors with early elastics may predispose the teeth to orthodontically induced inflammatory root resorption(18). This warrants further research.

Regarding the mandibular incisors, early group showed statistically significant mandibular incisors proclination by 5.85±4.91º and protrusion by 1.49±1.24º. This is similar to the findings of previous studies.(14) On the other hand, Linda Tseng et al (13) showed minimal change in lower incisors inclination.

In the conventional group, mandibular incisors showed statistically significant proclination with insignificant protrusion. Meistrell et al (19), Nelson et al (20),(21),(22) , Uzel et al (23), and Janson et al (5),(24) reported similar findings. Comparing both groups, the results showed statistically insignificant differences. Thus it can be clinically recommended to consider using a long-term or indefinite retention for cases treated with Class II elastics with intentional or non-intentional change of more than 2mm in lower incisors position, according to clinical guidelines of the British orthodontic society(25).

Skeletal vertical change

The horizontal planes including the mandibular, palatal and occlusal planes showed clockwise rotation. This rotation was probably caused by the line of action of Class II elastics away from the center of resistance of the maxillary and mandibular arches, causing the generation of moments that caused clockwise rotation of the arches. For the early group, only the occlusal plane showed a statistically significant clockwise rotation by 2.80 ± 2.89 degrees. In the conventional group, all three horizontal planes rotated clockwise with 4.11 ± 1.88 degrees clockwise rotation in the occlusal plane. No significant differences were found in the occlusal plane inclination changes between the two groups.

Comparing our results to studies done by Li et al (26) and Tovseint BC (27) their results agreed with ours. Their results showed significant steepening in occlusal plane after treatment. The results of Meistrell et al (28) Study disagreed to ours as it showed statistically insignificant change in occlusal plane inclination.

Regarding the changes in the mandibular plane and palatal plane inclination, only conventional group showed statistically significant clockwise rotation which was similar to Nelson et al (1999) (20) although they applied mild force of 1-2 ounces only. Others like Meistrell et al (28) concluded that no significant change in mandibular plane angle was observed. The explanation of the differences between the different studies including ours was that the age range and force level used both have a great impact on the inclination of the planes.

In the current study, the conventional group showed a significant increase in anterior facial height which was matched with the significant mandibular rotation and significant extrusion for lower first molar when compared to early group which showed insignificant change. Again, this was believed to be caused by the higher force range. Nelson et al studies showed similar results(20),(21). It is important to note that there is close relationship between the sagittal and vertical dimensions of malocclusion. This was emphasized by Schudy (29) who clearly showed that clockwise rotation of the mandibular plane can position the chin relatively backwards, deteriorating an already deficient mandible. Thus, adequate control of the vertical dimension is an important pre-requisite for the clinical success of treatment of Class II malocclusion.

Soft tissue changes

For soft tissues changes, Janson et al in their systematic review(5) mentioned that there was a lack of evidence regarding the soft tissues changes caused by Class II elastics. The results of our study showed statistically insignificant soft tissues changes within each group as well as no significant changes between the two groups. This is contrary to the finding of Falcao et al (30) who reported that both the upper and lower lips were retruded in response to Class II elastics. Regarding upper lip thickness, Combrink et al results (31) showed increase in lip thickness following the use of Class II elastics.

Conclusions

1- Retroclination of the maxillary incisors as a compensatory effect of Class II elastics occurred in both groups (protocol independent).

2- Early protocol showed true retroclination of maxillary incisors compared to relative retroclination in Convensional protocol.

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