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ABSTRACT

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Introduction The aim of this study was to evaluate the effect of different treatments on lower incisor (L1) inclination in patients with Class II malocclusion.

Methodology 73 patients (39 females, 34 males) with Class II malocclusion were retrospectively collected from the postgraduate orthodontic clinic. All patients were treated at least with multibracket appliance (MBA) and Class II elastics (CLII) alone (control group), or in combination with the removable-functional appliance (RFA), fixed-functional appliance (FFA), or lingual arch (LA). Pre- and post-treatment L1-NB (mm), L1-GoGn (°) and L1-NB (°) values were analyzed. The analysis of the treatment effect in relation to the outcomes and time were done by the Propensity Score Matching (PSM) method using Cox regression and Survival analysis. **Results** Regarding L1-NB distance, patients treated only with CLII elastics have lower risk of incisor proclination, however, the risk may occur from the beginning of the treatment. FFA, RFA and LA present higher risk of incisor proclination, but this occurs later in time (hazard ratio HR= 0.4 RFA/0.22 FFA and LA). Concerning L1-GoGn angle, all treatments have high risk of proclination. However, RFA reduces the rate of risk (p=0.003) (HR=0.22), while FFA increases the rate of risk (HR=0.35).

Conclusion Multibracket orthodontic treatment with CLII elastics alone produces unfavorable labial incisor inclination rapidly. Combination treatment of RFA with CLII elastics delays the occurrence of proclination, while FFA highly increases the risk of proclination. The use of the lingual arch retains the position of the dentition for longer time, however once the lower incisor proclination occurs, it deteriorates fast.

KEYWORDS

Mandibular Incisor; Inclination; Class II Malocclusion

1. INTRODUCTION

From the early steps in orthodontic science, the position and inclination of the lower incisor has been considered essential in diagnosis, treatment planning and retention. In 1941 Holly Broadbent correlated normal dentofacial growth with incisor mandibular plane angle and set the basis for cephalometric analysis [1]. In 1943 Margolis was the first to correlate lower incisor inclination with chin position [2]. Tweed advocated that the mandibular incisors must always be positioned upright on the alveolar process in order to achieve harmony in the lower facial third [3].

Class II malocclusion is present in approximately one-third of the patients seeking orthodontic treatment [4]. Correction of Class II discrepancies

is achieved with a variety of extraction and nonextraction approaches, maxillary expansion, use of headgears, functional appliances, fixed-functional appliances, Class II elastics, with or without skeletal anchorage and other [5].

Systematic reviews (SRs) and meta-analyses (MAs) in Class II malocclusion patients treated with removable functional appliances revealed minor skeletal changes, while the effects of the treatment were mostly dentoalveolar, such as increased inclination of lower incisors and uprighting of the maxillary incisors [6-7]. Because the lack of success of functional appliances has been attributed under some circumstances to the lack of patient compliance regarding appliance wear, the treatment effects of fixed functional appliances (FFAs) were examined as well in other SRs or/and MAs and presented with

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similar results as far as the inclination of the lower incisors is concerned.

Further, the application of Class II elastics apart from the side effects that produces, such as extrusion of the lower first molars and of the upper incisors, their use is highly associated with proclination of the lower incisors and retroclination of the upper incisors [8].

A direct comparison of the effect of different therapeutic methods on lower incisor inclination seems not to have been examined thoroughly. Thus, the aim of this study was to evaluate the effect of different orthodontic treatment approaches taking also into consideration the possible influence of treatment time on the lower incisor inclination of patients presenting Class II discrepancy.

2. METHODOLOGY

A study sample of 73 patients (39 females and 34 males; mean age 13.2±4.1 years) was retrospectively collected in consecutive order from the Postgraduate Orthodontic Clinic. The patients' inclusion criterion was the Class II malocclusion with at least half cusp to full Class II canine and molar relationship and Class Il treatment approach, such as functional appliance, Class II elastics and other. Patients with extractions, stripping, surgical intervention or craniofacial anomalies were excluded. All patients were treated at least with the multibracket appliance (MBA) (Straight wire, Roth prescription) in both dental arches and Class II elastics, with or without another treatment, which preceded or followed, such as removablefunctional appliance (RFA), fixed-functional appliance (FFA), or lingual arch (LA).

The descriptive statistics of the sample are shown in Tab. 1. Pre-treatment and post-treatment lateral cephalograms were analyzed with the use of the Viewbox 4 software (dHal Software, Athens, Greece) to measure the inclination and position of the lower incisors at the beginning and at the end of the treatment. The angles between the lower incisor (L1) and the Nasion-B point line (L1-NB°), the Go-Gn

line (L1-GoGn°) and the distance between L1 and Nasion-B point line (L1-NB mm) were examined. The total treatment time and also the treatment time of each appliance was available from the patients' records. More specifically, the date of application of the MB, CLII, RFA, FFA or LA and the total active treatment of each appliance were retrieved. Also, crowding was evident in 35 patients (47,9%), while 38 patients (52,1%) had no crowding (Tab. 2).

Table 2. Descriptive statistics of the sample regarding the presence of crowding in the lower arch in the different treatment groups.

MBA+CLII		No other treatment	+ FFA	+ RFA	+ LA	Total
Crowdin	Yes	23	3	2	7	35
	No	16	7	15	0	38
Total		39	10	17	7	73

An analysis of the treatment effect in relation to the outcomes and the implementation of time was done by the propensity score matching (PSM) method using Cox regression and Survival analysis [9]. In randomized clinical trials (RCTs) treatment groups and/or control groups are balanced for the baseline characteristics of participants between groups with no systematically difference between them. With the use of PSM the differences between groups can be estimated and the distribution of the baseline characteristics can be balanced to be similar between the groups [10]. In the orthodontic field, orthodontic treatments are not static with a direct treatment effect. Instead, different types of treatments, appliances or methods are used during a long period of time and usually there are differences between a specific treatment effect and the time of application of the corresponding treatment. The treatment effect is affected by the time period of the treatment. The involvement of time in the orthodontic treatment effect can be studied and analyzed using two statistical tools, which are very common in medical science; the Survival analysis and the Cox regression analysis. Survival analysis is a statistical technique to analyze a "time to event outcome variable", where the

Table 1. Descriptive statistics of the sample. CLII Tx time: Time of Class II elastics wear during treatment; Total Tx Time: Total treatment duration; L1-NB (mm): distance between the lower incisor (L1) and Nasion-B point line; L1-GoGn°: angle between L1 and the Nasion-B point line; L1-GoGn°: angle between L1 and the Go-Gn line.

Variable Treatment	N	Age Mean (±SD)	Sex Male %	CLII Tx Time Mean (±SD)	Total Tx Time Mean (±SD)	L1-NB (mm) Mean (±SD)	L1-NB (°) Mean (±SD)	L1-GoGN (°) Mean (±SD)
MBA + CLII	39	14.1 (±5.18)	46.15%	13 (±8.2)	37.6 (±16.3)	2.73 (±1.58)	25.5 (±6.44)	98.3 (±6.40)
MBA + CLII + FFA	10	13.8 (±1.93)	60%	11 (±10.9)	34.4 (±8)	4 (±2.43)	30.8 (±8.36)	107 (±8.44)
MBA + CLII + RFA	17	11.4 (±1.46)	47.06%	16.4 (±10.7)	48.6 (±16.1)	3.93 (±2.35)	28.3 (±6.03)	102 (±5.02)
MBA + CLII + LA	7	11.1 (±1.07)	71.42%	11.2 (±13.4)	47.7 (±19.9)	2.70 (±1.63)	26.8 (±8.15)	99.7 (±9.08)



outcome variable are the treatments that have been used in a study and the event is the goal achievement of the treatment. The Cox (Proportional Hazards) regression is a statistical method for studying the effect of multiple variables upon the time an event takes to happen.

An important limitation of observational studies in relation to non-randomized study designs is the treatment selection bias. Due to that limitation, the baseline characteristics of the study population could dramatically differ for each treatment group [10-13]. Direct estimations about the treatment effect without considering these sources of heterogeneity can lead to bias estimations about the treatment effects [14]. Propensity score can be estimated by a logistic regression model that predicts the treatment assignment given the observed baseline characteristics. This method gives the opportunity to evaluate the treatments through relatively homogeneous population groups. It is worth mentioning that the considerable amount of differences in the sample size of the groups of this study is balanced with the use of PSM, which takes this inequality into account. For example, crowding differences between patient groups were balanced with the use of different statistical weights among groups. Randomized clinical trials are the goal standard for estimating casual effectiveness by assigning treatments independently from covariates. The process of propensity score simulates the process of RCTs with the limitation that the unobserved confounders have no way to be adjusted [15].

3. RESULTS

AFirst the Propensity Score of the 73 patients was computed with the Average Treatment Effect (ATE) method to compare outcomes among the treatments. Treatment outcomes were categorized into "accepted" or "not accepted" according to the value of the outcome and the relationship with the physiological mean values. More specific, the value of outcome is referred to the post-treatment value of the lower incisor inclination. Accepted outcomes had a post-treatment incisor inclination value within the mean ± Standard Deviation (SD) value of each measurement, while not accepted outcomes lay beyond the SD values and exceeded the mean value. The ATE method was also used to compute Propensity Scores for the population and a Cox proportional hazard model was implemented to assess the impact of the treatments on the above outcomes. The group of patients treated with MBA/Class II elastics and no other treatment were used as reference group to estimate the effect of the other treatments. For the above method we had two groups of patients, those who had an accepted outcome (normal lower incisor inclination) and those who had a non-accepted outcome (lower incisor proclination), according to the post-treatment incisor inclination value.

3.1 Patients with an accepted outcome Patients with an accepted outcome presented an accepted post-treatment lower incisor inclination

value. Tab. 3 and Figs. 1, 2, 3 show the results of the Cox regression analysis.

Table 3. Prognostic performance of different treatments on the lower incisor inclination for the accepted outcome (post-treatment normal incisor inclination) after adjusting with ATT Propensity Score.

Treatments/		L1-NB	L1-NB	L1-GoGN	
Outcomes		(mm)	(°)	(°)	
	Coef	-1.15	-1.48	-1.12	
	Hazard				
FFA	Ratio	0.31 (0.07-1.41)	0.23 (0.02-2.07)	0.32 (0.04-2.46)	
	(CI)				
	p value	0. 1312	0.36	0. 276	
	Coef	-3.39	-2.71	-0.98	
	Hazard				
RFA	Ratio	0.03 (0.003-0.33)	0.07 (0.01-0.31)	0.37 (0.05-2.69)	
	(CI)				
	p value	0.00371**	0.000618***	0.260	
	Coef	-1.37	1.77	-1.62	
	Hazard				
LA	Ratio	0.25 (0.05-1.29)	0.17 (0.01-2.88)	0.2 (0.01-3.32)	
	(CI)				
	p value	0.09813	0.22	0.12	

*p<0.05, **p<0.01

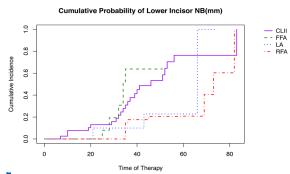


Figure 1. Reverse Kaplan-Meier is presented for the cumulative probability of Lower Incisor NB (mm) for the endpoint with normal inclination.

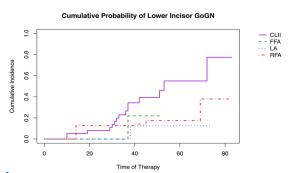


Figure 2. Reverse Kaplan-Meier is presented for the cumulative probability of Lower Incisor-GoGN angle for the endpoint with normal inclination.

The analysis showed that RFA treatment results in a statistically significant achieve effect of L1-NB (mm) and the L1-NB (°) (p=0.00371 and 0.000618 respectively). The negative sign of the regression coefficient (coef) in the tables shows that the probability of each additional treatment to reach the desired accepted result for every outcome reduces the effect of Class II elastics. For example, regarding the L1-NB (mm) value, the RFA treatment decreases the cumulative probability of producing an accepted

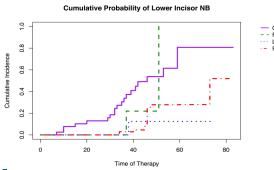


Figure 3. Reverse Kaplan-Meier is presented for the cumulative probability of Lower Incisor-NB angle for the endpoint with normal inclination.

3.2 Patients with a non-accepted outcome

Patients with a non-accepted outcome presented a non-accepted post-treatment lower incisor inclination value. Further analysis was conducted in this group of patients and these were the most important results. Specifically, the Average Treatment Effect on the Treated (ATT) Propensity Score was computed for the group who exceeded the accepted values and presented incisor proclination. Survival analysis was conducted to examine the risk of labial incisor inclination among the different treatments. Regarding the L1-NB (mm) measurement, according to the Kaplan-Meier graph (Fig. 4) patients treated only with C1 II have lower risk of exceeding the I1-NB Kaplan-Meier of Lower Incisor NB(mm)

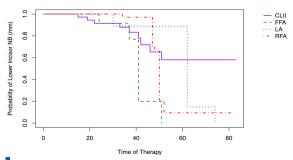


Figure 4. Kaplan-Meier curve is presented for patients with Lower Incisor-NB (mm) for the proclined endpoint.

However, this risk may occur from the beginning, during the first weeks of application of the Class II elastics. On the other hand, RFA, FFA, and LA present a higher risk of producing a not accepted outcome of the L1-NB (mm) value compared to CLII alone during the treatment, but this happens later in time than the CLII. Moreover, RFA causes a not accepted L1-NB (mm) value in a later time compared to all the other treatments.

Specifically, RFA has a higher rate of increasing the probability of lower incisor proclination with a hazard ratio of 0.4 compared to FFA and LA, which have a hazard ratio of 0.22. This means that once the risk occurs, RFA can deteriorate the L1-NB (mm) value in a shorter time period.

Regarding the L1-GoGn (°) measurement, according to the Kaplan-Meier graph (Fig. 5) patients treated with CLII, RFA, FFA and LA have all high risk of producing lower incisor proclination.

Likewise, for CLII alone treatment the risk may occur from the beginning, during the first weeks of application of the Class II elastics. In contrast, RFA, FFA and I A have the probability to produce the Kaplan-Meier of Lower Incisor GoGN

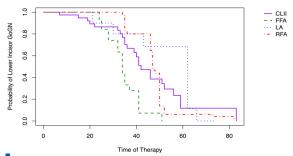


Figure 5. Kaplan-Meier curve is presented for patients with Lower Incisor-GoGN angle with proclined endpoint.

Especially the RFA treatment reduces the rate of risk with a statistical significance of p=0.00269 compared to the other treatments, with a hazard ratio of 0.22. On the other hand, FFA has an increased rate of risk for proclination with a hazard ratio of 0.35.

Lastly, regarding the L1-NB (°) measurement, according to the Kaplan-Meier graph (Fig. 6) patients treated with CLII, RFA, FFA and LA have all again high

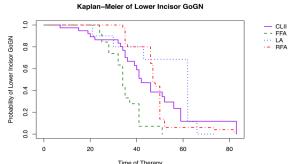


Figure 6. Kaplan-Meier curve is presented for patients with Lower Incisor-NB angle with proclined endpoint.

The risk for labial inclination is the same as for L1-GoGn (°) measurement. RFA reduces the rate of risk with a statistical significance of p=0.0465 compared to the other treatments, with a hazard ratio of 0.3. FFA on the other hand has an increased rate of risk for increasing lower incisor inclination with a hazard ratio of 0.5.

As above, only the combination of CLII with FFA increases the probability of proclination, while the combination with RFA and LA seems to reduce the probability of risk of proclination.

As for the treatment time, CLII alone produces unfavorable treatment effects more rapidly compared to all combinations. Table 4 shows the effect sizes of survival analysis.



Table 4. Prognostic performance of treatments for L1-NB (mm), L1-NB ("), L1-GoGN (") for the not accepted outcome (post-treatment lower incisor proclination) after adjusting with ATT Propensity Score.

Treatments/ Outcomes		L1-NB (mm)	L1-NB (°)	L1-GoGN (°)	
	Coef	-1.5	-0.68	-1.06	
	Hazard				
FFA	Ratio	0.22 (0.03-1.61)	0.5 (0.12-2.17)	0.35 (0.08-1.5)	
	(CI)				
	p value	0.137	0.36	0.157	
	Coef	-0.9	-1.2	-1.51	
	Hazard				
RFA	Ratio	0.4 (0.06-2.52)	0.3 (0.09 - 0.98)	0.22 (0.08-0.59)	
	(CI)				
	p value	0.333	0.0465	0.00269**	
	Coef	-1.5	0.87	-1.08	
	Hazard				
LA	Ratio	0.22 (0.02-3.12)	0.42 (0.11-1.56)	0.34 (0.09-1.33)	
	(CI)				
	p value	0.265	0.19	0.12	

^{*}p<0.05, **p<0.01

3.3 Treatment time

It is worth mentioning that the treatment time of the CLII elastics wear was studied separately for each combination treatment, so as to determine whether the treatment time of the CLII elastics in the combined treatments with other appliances affects the final outcome. After the statistical analysis it appeared that the treatment time of CLII elastics in the combination treatments does not affect statistically significant the outcome (p-values of 0.765, 0.907, 0.498 for lower incisor NB, lower incisor NB (mm) and lower incisor GoGn respectively).

4. DISCUSSION

TAs already known, studies comparing dentoskeletal alterations in treated Class II patients with those of untreated subjects, revealed significant retroclination of maxillary incisors and protrusion and proclination of lower incisors [16-18].

Despite the limitation of this study regarding the considerable amount of differences in the sample size of the groups, the use of the PSM method, which takes into account those differences, seemed to have clearly depicted the probability of risk for lower incisor proclination between the investigated treatment approaches.

The use of intermaxillary elastics is well documented in the literature, which claims that they are effective in correcting the anteroposterior relationship of the dentition, although undesirable side effects can occur [19-22]. Most authors mention adverse results from the horizontal vector of force, which has been shown to rotate or mesially tip the mandibular first molars, procline the mandibular anterior teeth, and displace the entire lower dental arch anteriorly [19,21,23,24]. Systematic reviews revealed that

Class II elastics are effective in correcting class II malocclusions and that their effects are primarily dentoalveolar, such as flaring of mandibular incisors and loss of mandibular anchorage. In this study it was evident that multibracket appliance with Class II elastics treatment is associated with the highest risk of lower incisor proclination compared to the other treatments under investigation.

To overcome the lower incisor proclination side effect, different types of appliances have been proposed to reinforce the anchorage in the molar region and thus, overcome the mandibular dental side effects. For example, the development of the lingual arch is attributed to the efforts of Lloyd S. Lourie [25] and John V. Mershon [26]. It is considered that the lingual arch can resolve lower incisor crowding by maintaining the arch perimeter [27]. The aim of including the lingual arch in the treatment of Class II malocclusion is mostly to enhance mandibular anchorage and minimize the side effects of Class II elastics, such as molar rotation and lingual tipping and protrusion of mandibular incisors [28]. In this study it was confirmed that the use of the lingual arch, when used with MBA and Class II elastics can retain the mandibular incisors for a longer period of time compared to MBA and Class II elastics alone. This means that the lingual arch retains the probability of risk for a longer period of time, meaning that the lower incisors may remain stable during treatment before reaching the not accepted proclined endpoint. However, once the risk with the use of LA occurs, then the incisors may deteriorate fast. Concluding, there is a timepoint after which the lower incisor inclination may deteriorate very fast and abruptly when lingual arch and Class II elastics are used.

A lot of studies have been conducted in order to evaluate the skeletal and dental changes that account for the Class II correction in subjects treated with Class II elastics compared with subjects treated with removable or fixed functional appliances [29-31]. These studies suggested that either there was no statistically significant difference between the two treatment modalities or if there was any, it did not last in the long term [32]. These results indicate that the final outcome of the treatment of Class II malocclusion might be similar independently of the orthodontic device used.

However, the risks of incisor proclination varied among treatments at this study. Compared to the use of MB and CLII alone, only the combination of MB and CLII with FFA increases the probability of incisor proclination, while the combination of MB and CLII with RFA or LA seems to reduce the probability of risk of proclination. This probably means that the use of RFA reduces the total time of Class II elastics wear, leading to more favorable results.

Systematic reviews and meta-analysis concluded that the treatment of Class II malocclusion with FFAs

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was associated with more pronounced soft tissue and dentoalveolar changes, including significant proclination and protrusion of mandibular incisors

This is in accordance with our study and moreover, it was evident that FFA treatment has the highest risk of producing mandibular incisor proclination among all treatments under investigation.

5. CONCLUSION

Multibracket appliance (MBA) orthodontic treatment with Class II elastics alone is associated with the high risk of producing unfavorable mandibular incisor proclination, which takes place more rapidly when compared to the combination treatment of Class II elastics with the other appliances under investigation.

Removable appliance treatment in combination with MBA and Class II elastics reduces the risk and delays the occurrence of proclination,

- Fixed functional appliance treatment in combination with MBA and Class II elastics highly increases the risk of proclination.
- The use of the lingual arch in combination with MBA and Class II elastics retains the probability of risk at the early stages of treatment, however a high risk of incisor proclination occurs abruptly later in time.

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6. ABBREVIATIONS

CLII: Class II elastics

RFA: Removable functional appliance

FFA: Fixed functional appliance

LA: Lingual arch

MBA: Multibracket appliance

HR: Hazard ratio

PSM: Propensity score matching **RCT:** Randomized clinical trial

Tx: Treatment

ATE: Average treatment effect

SD: Standard deviation

CONFLICT OF INTEREST

None to declare.

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AUTHOR CONTRIBUTIONS

AT, MT: Data collection and interpretation, manuscript writing; AC: Conceptualization, methodology, manuscript writing, reviewing and editing; MAP: Conceptualization, methodology, supervision, reviewing and editing.

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Questions

1. There is a higher risk of mandibular incisor proclination when:

- □a. Fixed functional appliances are combined with multibracket appliance treatment;
- □b. Removable appliances are combined with multibracket treatment and Class II elastics;
- □c. Removable appliance alone are used;
- □d. Lingual arch is used.

2. Which appliance retains the inclination of the lower incisors at the early stages of treatment?

- □a. The multibracket appliance;
- □b. The fixed functional appliance;
- □c. The removable appliance;
- □d. The lingual arch.

3. When does the risk of mandibular incisor proclination increase during treatment?

- □a. At the early stages of multibracket appliance treatment;
- □b. At the later stages of multibracket and Class II treatment, where lingual arch is used;
- □c. At the early stages of treatment, where lingual arch is used;
- □d. At the early stages of fixed functional treatment.

4. Which combination treatment delays the occurrence of lower incisor proclination?

- □a. The combination of fixed functional appliance and multibracket appliance;
- □b. The combination of Class II elastics with multibracket appliance;
- □c. The combination of removable appliance, followed by multibracket appliance and Class II elastics;
- □d. The combination of fixed functional appliance, multibracket appliance and Class II elastics.



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