



# Clear aligner treatment in adult patients with class III malocclusion: lower distalization and class III elastics vs class III elastics alone – a RCT

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## Abstract

**Objectives:** to analyze the effects of clear aligner treatment in adult patients with moderate Class III malocclusion, comparing the lower molar distalization and Class III elastics protocol with the application of Class III elastics alone.

**Null hypothesis:** There is no significant difference between lower molar distalization and the use of Class III elastics alone in the correction of Class III disharmony.

**Trial Design:** Two-arm, parallel-group, randomized controlled trial with a 1:1 allocation ratio.

**Participants:** 31 adult patients with moderate Class III malocclusion were blindly assigned into two groups.

**Interventions:** Group 1 (7 f, 8 m; 19.1 ± 1.7 y) was treated with lower molar distalization combined with Class III elastics and dento-alveolar expansion. In Group 2 (9 f, 6 m; 19.7 ± 0.1.3 y) all subjects underwent Class III elastics and dento-alveolar expansion.

**Primary objective:** to evaluate changes in the position of the lower first molars and of the lower incisors at the end of both treatment protocols (i.e. lower molar distalization and Class III elastics vs Class III elastics).

**Secondary objectives:** to compare sagittal and vertical skeletal changes obtained at the end of treatment with both protocols.

**Outcome assessment:** a customized cephalometric analysis, including 16 dento-skeletal variables, was performed before (T0) and at the end of treatment (T1) with an average time interval of about 24 +/- 6 months.

**Randomization:** randomization sequence was generated with a 1:1 allocation ratio.

**Blinding:** cephalometric analysis and statistical comparisons were conducted by blinded operators.

**Results:** 30 patients completed treatment and were included in the final analysis (1 drop-out in Group 2). Group 1 revealed a significant improvement in vertical and sagittal position of both molars and incisors compared to Group 2 (respectively L6-MP, -2.8 mm and -0.6 mm; L6^MP, -0.7° and -2.5°, L6 crown-CoGo, -1.4 mm and -0.2 mm; L6 apex-CoGo, -3.3 mm and -1.5 mm; L1 crown-CoGo, -2.9 mm and + 1.9 mm; L1 apex-CoGo -1.7 mm and + 2.6 mm). Both groups showed a significant increase in upper incisor inclination (Group 1, + 2°; Group 2, + 2.7°), overjet (Group 1, + 1.6 mm; Group 2; + 1.3 mm), and overbite (Group 1, + 1.3 mm; Group 2; + 1.1 mm).

**Conclusions:** The lower molar distalization protocol combined with Class III elastics allowed a more significant improvement in occlusal relationships in the treatment of Class III malocclusion in adult patients, compared to a protocol that involves the use of intermaxillary elastics alone.

**Trial Registration number:** ClinicalTrials.gov NCT06859606.

**Keywords:** lower molar distalization; Class III malocclusion; clear aligner treatment

## Introduction

Class III malocclusion is considered one of the most challenging maxillofacial disorders in clinical practice [1–4] characterized by an antero-posterior discrepancy with mandibular protrusion, maxillary retrusion, or a combination of both. In adult patients, managing this condition is further complicated by the absence of residual skeletal growth, limiting therapeutic options to orthodontic interventions and, in some cases, surgical procedures. Diagnosis in Class III non-growing patients requires distinguishing between skeletal malocclusion and dento-alveolar discrepancy. The combination of orthognathic

surgery and orthodontic therapy represents the gold standard for more severe skeletal Class III disharmonies, leading to an improvement of both function and aesthetics [5–7]. On the other hand, in Class III cases characterized by a prevalent dental component or mild skeletal discrepancy, the malocclusion can be addressed with a dento-alveolar compensation [7]. In these cases, the clinical objectives are to achieve a proper canine and molar Class I relationship, as well as ideal values of overjet and overbite. The non-surgical orthopedic approach involves the application of Class III elastics or the distalization of the lower molars, which can improve the sagittal and the

vertical occlusal relationship. Mandibular molar distalization allows to increase lower arch length with the achievement of the necessary space to correct a Class III relationship [8, 9]. However, bone density and root anatomy make lower molar distalization difficult to achieve [10]. In addition, one of the most frequent adverse effects is represented by the anterior anchorage loss with a worsening of lower incisor proclination and overjet values [11, 12]. Traditional appliances feature the use of open coil springs, inter arch elastics, and lip bumper device combined with fixed appliances [13]. Nowadays, the development of clear aligner technology provides new opportunities even in the management of complex malocclusion cases, including Class III discrepancies. In particular, lower molar distalization movements and intermaxillary elastics have been proposed as a valid clinical strategy to improve the occlusal relationship without requiring skeletal anchorage devices [9]. Only a limited number of studies have analyzed sagittal mechanics in the lower arch in the treatment of Class III malocclusion excluding the need for skeletal anchorage [14–16]. Horodynski et al. [16] pointed out the validity of clear aligners in lower molar distalization, suggesting the need of an over-correction during the planning phase to obtain more bodily movements of lower molars. Furthermore, Simon et al. [17] and Rossini et al. [18] concluded that the best accuracy and predictability of distalization movements are supported by the sequential staging and the presence of attachments on the tooth surfaces. However, scientific evidence is limited, and it is influenced by restrictions in terms of sample size, retrospective design, and lack of long-term observation. Hence, the aim of this prospective clinical trial was to evaluate the efficacy and efficiency of intermaxillary elastics combined with lower molar distalization by means of clear aligners in the treatment of mild Class III malocclusion in adult patients. More specifically, a randomized controlled trial (RCT) was conducted to evaluate the antero-posterior correction induced by Class III elastics combined with lower molar distalization and the application of Class III elastics alone. The possibility of achieving satisfying clinical outcomes without the use of skeletal anchorage was considered to avoid an invasive orthodontic approach.

## Materials and methods

### Trial design

This is a two-arm parallel balanced randomization trial. The Consolidated Standards of Reporting Trials (CONSORT) checklist was used to conduct and report this trial [19]. The study was approved by the ethical committee of the Hospital of Rome ‘Tor Vergata’ (protocol number 75/23) and informed consent was obtained on behalf of all enrolled participants. The trial was registered on ClinicalTrials.gov (registration number: NCT06859606).

### Subjects

Patients had to meet the following inclusion criteria: European ancestry, adult age ( $\geq 18$  years); permanent dentition including second permanent molars; skeletal Class I or slight Class III ( $-2^\circ < \text{ANB} < +2^\circ$ ); Wits appraisal of  $-1$  mm or less; normal skeletal divergency pattern ( $\text{SN}^\wedge\text{MP } 27^\circ\text{--}37^\circ$ ); anterior crossbite or incisor end-to-end relationship; Class III canine and molar relationship at baseline (T0), moderate lower arch crowding ( $\leq +4$  mm); good compliance with aligners and elastics ( $\geq 20$  hours/day). No discrepancy between centric

occlusion and centric relation (indicating pseudo-Class III malocclusion). Exclusion criteria included: severe skeletal Class III malocclusion ( $\text{ANB} < -2^\circ$ ); transversal maxillary deficiency; use of Temporary Anchorage Devices (TADs); extraction treatments other than third molars; periodontal disease or temporomandibular disorders (TMDs); craniofacial syndromes, malformations, and facial asymmetries.

## Interventions

Adult patients with Class III malocclusion were enrolled in this study and were recruited based on specific inclusion and exclusion criteria. Patients who met the criteria were provided with detailed information about the study’s objectives, procedures, potential risks, and benefits. Written informed consent was obtained from all participants before enrollment, in accordance with ethical guidelines. The patients enrolled in the study were randomly allocated into two groups.

### Group 1 (Lower Distalization Protocol)

Group 1 underwent the Lower Distalization Protocol, which included extraction of the lower third molars, transversal dento-alveolar coordination before starting treatment and a 50% sequential lower distalization with two teeth being distalized at a time. The distalization started with the movement of lower second molars, followed by the first molars halfway through the process, and so on. Once the canine reached the right position, the ‘en-masse’ retraction of the four incisors completed the treatment plan. The protocol comprised the use of Class III intermaxillary elastics to ensure the anchorage during the distalization movement.

### Group 2 (Non-Distalization Protocol)

Group 2 was treated by using a Non-Distalization Protocol, which featured extraction of the lower third molars before starting treatment, transversal dento-alveolar coordination, strategic interproximal reduction (IPR) in the anterior segment of the lower arch, and the addition of Class III elastics.

Both protocols involved the use of Class III elastics to control the anterior anchorage and to prevent the possible incisor flaring. The instruction for the application of Class III elastics were provided when patients received their third set of aligners. During the same clinical appointment, the attachments were bonded. Overall, in both protocols, the first two sets of aligners were delivered without attachments. At the delivery of the third set, the attachments were bonded, Class III elastics were provided, and the aligner change interval was standardized to 7 days. In both groups, Class III elastics were applied on precision cutouts positioned at the level of upper first molars and lower canines. All patients were asked to wear aligners and Class III elastics (1/4 inch, 6 ounces) at least 22 hours per day with regular clinical checks in office every 4 weeks. During each four-week follow-up visit, clinical evaluation included the assessment of aligner fit, attachment integrity, and tooth movements. Specifically, the progression of treatment was compared to the digital planning sequence to verify consistency with the expected movements. The presence of all programmed attachments and the proper fitting of the aligners were considered indirect, but reliable indicators of patient compliance and treatment success. A follow-up interview with each patient was also carried out during the treatment to assess the level of compliance by means of a three-point (poor, moderate, good) Likert-type scale. The following criteria were considered: low compliance when the

patient wore the aligners for less than 16 h per day; moderate from 16 to 20 h per day; good when the aligners and elastics were worn full time as indicated [20–22]. The three-point Likert scale was chosen with the aim of simplifying the response process and minimizing potential confusion. This format was considered appropriate for the study population and the retrospective design, allowing for a straightforward classification of adherence levels.

Lateral cephalograms were taken at T0 (before treatment) and at the end of the clear aligner treatment (T1) with an average time interval of about 24 +/- 6 months.

## Outcomes

A customized digitization regimen and cephalometric analysis provided by Viewbox (software, dHAL software, Kifissia, Greece) was performed by a single experienced operator (FG) trained in cephalometric analysis. The operator was blinded to the group allocation of the examined patients to minimize bias. For each tracing, the customized cephalometric analysis included 16 dento-skeletal variables, comprising 8 angular and 8 linear ones (Figure 1). A table summarizing the cephalometric variables and their respective abbreviations was provided (Table 1). The detailed cephalometric analysis adopted allows for the comprehensive evaluation of dento-skeletal changes, providing valuable assessment of the effects of the treatment protocols. These measurements were crucial for the evaluation of the efficacy of the two treatment approaches, particularly in terms of their impact on sagittal and vertical skeletal relationships, as well as lower molar and

incisor positions. Magnification was standardized to an 8% enlargement for all radiographs in both treated samples.

## Sample size

In order to highlight a difference between the two treatment modalities of 1.5 degree for the ANB angle, considering a standard deviation (SD) of 1.8 [23], a two-tailed significance level of 5 percent, and a power of 80 percent, a sample size of 26 patients (13 per treatment) was required, taking into account a 10 percent withdrawal rate from the study.

## Randomization, allocation concealment and blinding

Allocation of patients to the two groups was determined by a computer-generated randomization list using Rv.0.1 software. Successively, the allocation information (randomization results) was concealed in opaque and sealed envelopes by the statistician (Figure 2). The clinicians could not be blinded about the treatment that they were providing. The study was blinded in regard to the statistical analysis: blinding was obtained by eliminating every reference to patient group assignment from the elaboration file.

## Statistical analysis

The evaluation of T1-T0 intergroup differences was assessed by means of the Student's *t*-test for paired data. In the presence of normally distributed data (Kolmogorov–Smirnov test), statistical intergroup comparisons were performed with independent sample *t*-tests. In case of not normally distributed data, statistical intergroup comparisons were carried out with the Mann–Whitney *t*-test. The significance level was set at  $P < 0.05$ . Twelve lateral cephalograms were randomly selected and then traced and measured at 2 times within 2 weeks by the same operator (FG). To enhance the reliability of the measurements and reduce potential bias, a second independent operator (CP) evaluated a random subset of 20% of the cephalometric tracings. Both operators underwent a calibration session prior to data collection, during which they analyzed the same set of radiographs and compared results to achieve methodological consistency. Inter- and intra-operator reliability were assessed using the intraclass correlation coefficient (ICC), with values above 0.90 considered to indicate excellent agreement [24].

## Results

Subject recruitment started in December 2022, while the observation follow-up was conducted until January 2025. All patients received the treatment assigned by randomization. Among the 31 patients randomly assigned to the two different protocols, there was one drop-out in Group 2, and no deviations from protocol (Figure 2). The final analyzed sample comprised 30 patients in Group 1 (7 females and 8 males with a mean age of  $19.1 \pm 1.7$  years) and 30 subjects in Group 2 (9 females and 6 males with a mean age of  $19.7 \pm 0.1.3$  years). Duration of active therapy was  $30 \pm 1$  months in the group 1 and  $24 \pm 0.8$  months in the group 2 (statistically not significant). The demographic data of the two groups are shown in Table 2. No significant intergroup differences were found for any of the cephalometric variables at T0 (Table 3). In Table 4, comparisons of the intragroup T0-T1 changes are reported. In both groups, an improvement of sagittal and vertical skeletal relationships, even if not statistically significant,

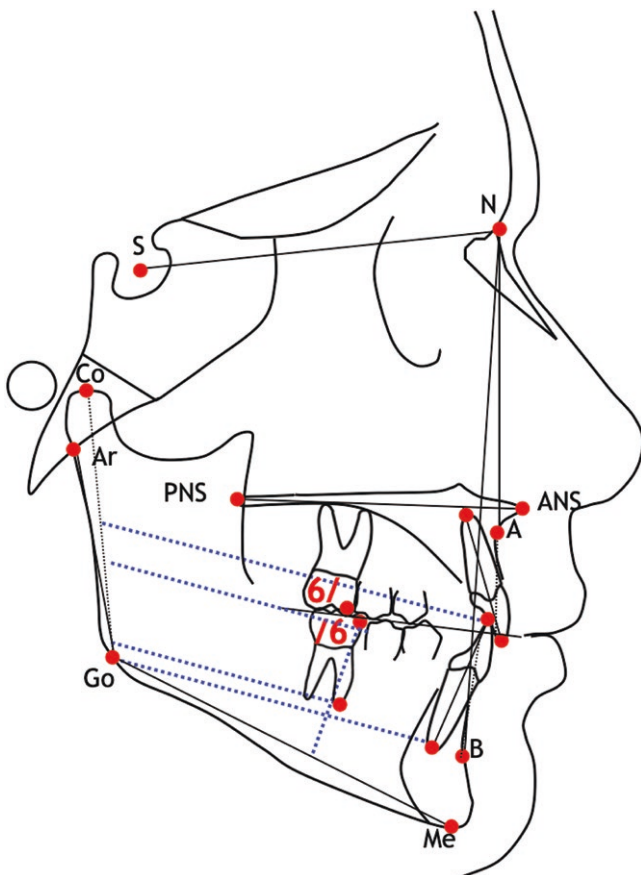
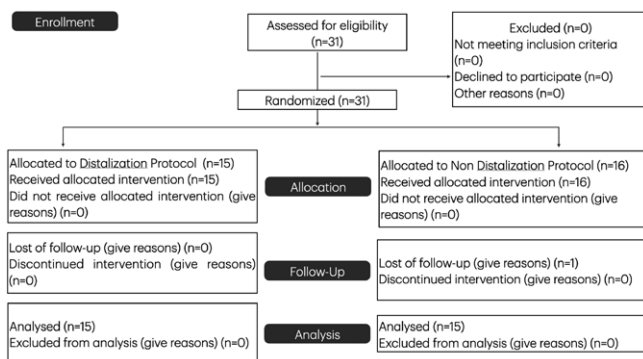


Figure 1. Cephalometric variables used in the analysis.

**Table 1.** Dento-skeletal variables and their definition.

Variables	Definition
SNA (°)	Maxillary sagittal position. Angle between Sella, Nasion, and A-point of the maxilla
SNB (°)	Mandibular sagittal position. Angle between Sella, Nasion, and B-point of the mandible
ANB (°)	Maxillo-mandibular discrepancy Angle formed by A-point, Nasion, and B-point
Wits (mm)	Maxillo-mandibular discrepancy Distance between the perpendicular projection of A and B-points on the occlusal plane
SN <sup>^</sup> MP (°)	Skeletal divergency Angle between the Sella-Nasion and the Mandibular Plane
Gonial Angle (°)	Mandibular angle Angle between the mandibular ramus (Ar-Go) and mandibular body (Go-Me)
IncSup <sup>^</sup> SN (°)	Upper incisor inclination Angle between the upper incisor and the Sella-Nasion line
IMPA (°)	Lower incisor inclination Angle between the lower incisor and the mandibular plane
Overjet (mm)	Horizontal incisor overlap Horizontal distance between the upper and lower incisors
Overbite (mm)	Vertical incisor overlap Vertical distance between the upper and lower incisors
L6—MP (mm)	Vertical position of lower first molar Distance from the lower first molar to the mandibular plane
L6 <sup>^</sup> MP (°)	Lower first molar inclination Angle formed by the lower first molar axis and the mandibular plane
L6 crown— CoGo (mm)	Lower first molar antero-posterior position Perpendicular distance from the lower first molar vestibular mesial cusp to the Condilion- Gonion Line
L6 apex— CoGo (mm)	Lower first molar antero-posterior position Perpendicular distance from lower first molar mesial apex to the Condilion- Gonion Line
L1 crown— CoGo (mm)	Lower incisor antero-posterior position Perpendicular distance from the lower incisor incisal edge to the Condilion- Gonion Line
L1 apex—CoGo (mm)	Lower incisor antero-posterior position Perpendicular distance from lower incisor apex to the Condilion- Gonion Line

**Figure 2.** Study flow chart.

was observed. A significant increase of upper incisor inclination was found in both Group 1 (IncSup<sup>^</sup>SN, + 2°) and Group 2 (IncSup<sup>^</sup>SN, + 2.7°). A great reduction of IMPA was observed when lower distalization was applied (Group 1, -2.9°) whereas a slight significant decrease occurred in Group 2 (-1.1°). Overjet and Overbite significantly improved in both groups (respectively, + 1.6 mm and + 1.3 mm in Group 1; + 1.3 mm and + 1.1 mm in Group 2). Significant changes were observed in terms of molar and incisor position only in Group 1 (L6-MP, -2.8 mm; L6 crown-CoGo, -1.4 mm; L6

apex-CoGo, - 3.3 mm; L1 crown-CoGo, -2.9 mm; L1 apex-CoGo, -1.7 mm). Table 5 reports the treatment effects in the T0-T1 interval between Group 1 and Group 2. No statistically significant differences were found for any of the sagittal and vertical skeletal variables between the two groups. Group 1 showed a greater significant reduction of lower incisor inclination (IMPA, -2.9°) when compared with Group 2 (IMPA, - 1.1°). On the other hand, both groups revealed a similar increase and improvement of upper incisor inclination (IncSup<sup>^</sup>SN; Group 1, + 2°; Group 2, + 2.7°), overjet (Group 1, + 1.6 mm; Group 2; + 1.3 mm), and overbite (Group 1, + 1.3 mm; Group 2; + 1.1 mm). Significant differences were found in terms of molar and incisor position and tipping. Indeed, Group 1 highlighted a significant improvement of lower molar vertical position and tipping when compared with Group 2 (respectively L6 -MP, -2.8 mm and -0.6 mm; L6<sup>^</sup>MP, -0.7° and -2.5°). Furthermore, an improvement of the antero-posterior position of the lower first molar was observed in Group 1 (L6 crown -CoGo, -1.4 mm; L6 apex-CoGo, -3.3 mm) with respect to Group 2 (L6 crown-CoGo, -0.2 mm; L6 apex-CoGo, -1.5 mm). Significant differences were also revealed in terms of antero-posterior position of lower incisors with a greater improvement in Group 1 (L1 crown-CoGo, -2.9 mm; L1 apex- CoGo -1.7 mm), with Group 2 showing an L1 crown -CoGo of + 1.9 mm and an

**Table 2.** Demographics of the Group 1 (Lower Distalization Protocol) and Group 2 (Non-Distalization Protocol).

Variables	Group 1 n = 15 (7 f, 8 m)		Group 2 n = 15 (9 f, 6 m)		P
	Mean	SD	Mean	SD	
Age T0, y	19.1	1.7	19.7	1.3	NS
Age T1, y	21.7	1.5	21.7	1.2	NS
T1-T0, y	2.6	1.0	2	0.8	NS

y, years; f, females; m, males; SD, standard deviation; NS, not significant.  
T0 indicates before treatment; T1 indicates the end of the clear aligner treatment  
Descriptive statistics were calculated by means of Mann-Whitney U test.

**Table 3.** Descriptive statistics and statistical comparisons of the starting forms.

Variables	Group 1 n = 15 (7 f, 8 m)		Group 2 n = 15 (9 f, 6 m)		Group 1 vs Group 2			
	Mean	SD	Mean	SD	Diff	pValue	95 CI	
							Low	Upp
SNA (°)	80.9	2.3	81.6	2.9	-0.7	0.959	-2.053	0.653
SNB (°)	80.4	2.2	80.7	1.6	-0.3	0.548	-1.294	0.694
ANB (°)	0.5	1.2	1.3	1.7	-0.8	0.039	-1.560	-0.040
Wits (mm)	-1	1.4	-1.2	1.9	0.2	0.250	-0.363	1.363
SN <sup>^</sup> MP (°)	31.5	2.3	32	1.7	-0.5	0.057	0.455	2.545
Gonial Angle (°)	132.1	2.8	130.6	2.9	1.5	0.046	0.027	2.973
IncSup <sup>^</sup> SN (°)	106.8	0.3	104.3	2.3	2.5	0.049	1.652	3.348
IMPA (°)	93.2	1.4	91.6	2.2	2.7	0.845	1.747	3.653
Overjet (mm)	1	1.5	0.9	0.7	-0.8	0.741	-0.505	0.705
Overbite (mm)	0.1	1.1	0.3	1.8	0.7	0.605	-0.971	0.571
L6—MP (mm)	27.8	2.7	28.4	1.6	-0.6	0.299	-1.747	0.547
L6 <sup>^</sup> MP (°)	79.3	1.6	80.5	2.1	-1.2	0.015	-2.165	-0.235
L6 crown—CoGo (mm)	42.9	3.2	44	0.8	-1.1	0.072	-2.305	0.105
L6 apex—CoGo (mm)	37.1	2.1	35.9	1.7	1.2	0.018	0.213	2.187
L1 crown—CoGo (mm)	62.8	3.1	65.5	0.4	-2.7	0.007	-3.842	-1.558
L1 apex—CoGo (mm)	54.5	0.1	56.1	2.1	-1.6	0.023	-2.468	-0.932

\*P < 0.05.

SD, standard deviations; Diff., differences; CI, confidence interval

MP, mandibular plane

Starting forms comparison was performed with Kruskal- Wallis and Tukey post-hoc tests.

L1 apex-CoGo of + 2.6 mm. Compliance assessment of the selected patients (use of aligners and elastics) highlighted a good/moderate level of cooperation in all subjects of both groups (Table S1). A Spearman correlation analysis was performed to investigate the association between patient compliance (assessed through a three-point Likert scale) and the variation in ANB angle from T0 to T1. The analysis revealed a statistically significant association between patient compliance scores and the improvement in ANB angle ( $r = 0.37$ ;  $P = 0.0045$ ), suggesting that higher levels of compliance were related to greater dento-skeletal changes. The inter and intra-observer reproducibility, carried out by the Intraclass Correlation Coefficients (ICCs), showed an excellent agreement for all measurements, with ICC values ranging between 0.957 and 0.986, and statistically significant p-values (Table S2). The highest consistency was observed across both angular and linear measurements. Minimal variations were

detected between repeated assessments, with differences as low as  $0.1^\circ$  for the ANB angle and  $0.2^\circ$  for the IMPA. For linear variables, variations started from 0.2 mm for overbite and 0.3 mm for L6-MP.

## Discussion

Lower molar distalization and Class III elastics represent valid clinical strategies in the management of mild and moderate Class III malocclusion cases, avoiding extraction protocols or skeletal anchorage devices [9]. However, only a limited number of studies have analyzed sagittal mechanics in the lower arch, and, when available, they are influenced by the limitations in terms of sample size, retrospective design, and lack of long-term observation [16]. The randomized controlled trial aimed to compare the outcomes of two different treatment approaches: Lower Distalization Protocol with sequential molar

**Table 4.** Descriptive statistics and statistical comparisons of the intragroup T0-T1 changes.

Variables	Group 1 n = 15 (7 f, 8 m)				Diff	P Value	Group 2 n = 15 (9 f, 6 m)				Diff	P Value
	T0		T1				T0		T1			
	Mean	SD	Mean	SD			Mean	SD	Mean	SD		
SNA (°)	80.9	2.3	81.3	1.1	0.4	0.984	81.6	2.9	81.9	2.7	0.3	0.043
SNB (°)	80.4	2.2	80.2	1.8	-0.2	0.008	80.7	1.6	80.4	1.6	-0.3	0.984
ANB (°)	0.5	1.2	1.1	1.6	0.6	0.242	1.3	1.7	1.3	1.7	0	0.656
Wits (mm)	-1	1.4	-0.6	1.6	0.4	0.543	-1.2	1.9	-1.3	0.9	-0.1	0.006
SN <sup>^</sup> MP (°)	31.5	2.3	30.1	1.6	-1.4	0.987	32	1.7	32.3	0.8	0.3	0.009
Gonial Angle (°)	132.1	2.8	132.3	1.9	0.2	0.008	130.6	2.9	132	1.9	1.4	0.756
IncSup <sup>^</sup> SN (°)	106.8	0.3	108.8	0.4	2	0.004*	104.3	2.3	107	1.2	2.7	0.002*
IMPA (°)	93.2	1.4	90.3	2.2	-2.9	0.000*	91.6	2.2	90.5	1.2	-1.1	0.000*
Overjet (mm)	1	1.5	2.6	0.6	1.6	0.001*	0.9	0.7	2.2	0.4	1.3	0.000*
Overbite (mm)	0.1	1.1	1.4	0.3	1.3	0.000*	0.3	1.8	1.4	1.5	1.1	0.000*
L6—MP (mm)	27.8	2.7	25	2.2	-2.8	0.002*	28.4	1.6	27.8	1.2	-0.6	0.536
L6 <sup>^</sup> MP (°)	79.3	1.6	80	1.9	-0.7	0.008	80.5	2.1	78	1.7	-2.5	0.007
L6 crown—CoGo (mm)	42.9	3.2	41.5	1.7	-1.4	0.002*	44	0.8	43.8	0.6	-0.2	0.894
L6 apex—CoGo (mm)	37.1	2.1	33.8	2	-3.3	0.000*	35.9	1.7	34.4	1.2	-1.5	0.654
L1 crown—CoGo (mm)	62.8	3.1	59.9	2.8	-2.9	0.001*	65.5	0.4	67.4	0.4	1.9	0.543
L1 apex—CoGo (mm)	54.5	0.1	52.8	1.2	-1.7	0.000*	56.1	2.1	58.7	2.4	2.6	0.765

\*P &lt; 0.05.

SD, standard deviations; Diff., differences; CI, confidence interval

MP, mandibular plane

Intragroup differences for T0-T1 interval were assessed by mean of the Student's t-test for paired data. If data were not normally distributed, the Mann-Whitney test was performed.

**Table 5.** Descriptive statistics and statistical comparisons of the intergroup T0-T1 changes.

Variables	Group 1 n = 15 (7 f, 8 m)		Group 2 n = 15 (9 f, 6 m)		Diff	P Value	95% CI	
	Mean	SD	Mean	SD			Lower	Upper
SNA (°)	0.4	1	0.3	0.5	0.7	0.012	0.291	1.109
SNB (°)	-0.2	1.4	-0.3	0.2	0.4	0.743	-0.417	0.617
ANB (°)	0.6	1.6	0	1.2	0.6	0.059	-1.225	0.025
Wits (mm)	0.4	0.9	-0.1	0.2	0.3	0.006	0.163	0.837
SN <sup>^</sup> MP (°)	-1.4	1.6	0.3	0.7	-1.7	0.006	-3.195	-1.005
Gonial Angle (°)	0.2	0.6	1.4	1.1	-2.3	0.007	-2.658	-1.742
IncSup <sup>^</sup> SN (°)	2	2.2	2.7	0.7	-0.7	0.102	-1.544	0.144
IMPA (°)	-2.9	1.2	-1.1	1.7	-1.8	0.000*	-6.760	-5.240
Overjet (mm)	1.6	0.4	1.3	0.8	0.3	0.071	-0.027	0.627
Overbite (mm)	1.3	0.1	1.1	1.3	0.2	0.404	-0.277	0.677
L6—MP (mm)	-2.8	1.1	-0.6	0.7	-2.2	0.000*	1.202	3.198
L6 <sup>^</sup> MP (°)	-0.7	1.5	-2.5	1.2	1.8	0.000*	1.098	2.502
L6 crown—CoGo (mm)	-1.4	0.2	-0.2	0.3	-1.2	0.000*	-2.200	-2.068
L6 apex—CoGo (mm)	-3.3	2.1	-1.5	1.4	-1.8	0.004*	-0.722	1.122
L1 crown—CoGo (mm)	-2.9	1.1	1.9	0.6	-4.8	0.000*	-6.258	-5.342
L1 apex—CoGo (mm)	-1.7	0.5	2.6	1.2	-4.3	0.000*	-3.567	-3.532

\*P &lt; 0.05.

SD, standard deviations; Diff., differences; CI, confidence interval

MP, mandibular plane

Intragroup differences for T0-T1 interval were assessed by mean of the Student's t-test for paired data. Statistical intergroup comparisons were performed with independent samples t-tests for normally distributed data. If data were not normally distributed, the Mann-Whitney test was performed.

movement (Group 1), and Non-Distalization Protocol with dento-alveolar compensation (Group 2). The findings highlighted the effectiveness of mandibular distalization using clear aligners combined with Class III elastics in achieving more significant sagittal and vertical improvements in the treatment of Class III malocclusion in adult patients. No significant differences were revealed for any of the sagittal skeletal variables when the two groups were compared as well as a greater but not significant vertical control was observed in Group 1 (SN<sup>∧</sup>MP, -1.4°). A potential side effect of molar uprighting and distalization is the relative extrusion of the molars, which may lead to the development of premature dental contacts and a worsening of the vertical relationship [14]. The bite-block effect of aligner thickness, combined with the planning of intrusion forces during lower molar distal movement, allows the improvement of lower molar vertical position [14]. On the contrary, Group 2 showed a slightly increased vertical relationship. It is likely that during transversal movements the crown tipping of the posterior teeth may have led to an increase of the dento-alveolar height. Concerning the detected dental variables, in Group 1, the Lower Distalization Protocol favored a substantial improvement in lower molar vertical and antero-posterior position (L6-MP, -2.8 mm; L6<sup>∧</sup>MP, -0.7°; L6 crown-CoGo, -1.4 mm; L6 apex-CoGo, -3.3 mm), and a significant control of lower incisor inclination (IMPA, -2.9°). In line with our results, Rota et al. [14] concluded that clear aligners, when combined with intermaxillary elastics, can facilitate bodily movement of lower molars, although minor tipping effects might still occur. Moreover, in a recent systematic review, Horodyski et al. [16] underscored the effectiveness of clear aligners in mandibular molar distalization mechanics reporting a maximum crown distal movement ranging from 1.16 mm to 2.03 mm, and a root distal movement ranging from 0.83 mm to 1.58 mm at the level of the first molar. However, a discrepancy between the expected and achieved movements was observed, with a prevalence of distal tipping. For this reason, the authors highlighted the importance of planning over-correction movements to minimize tipping and ensure bodily translation. Even Han et al. [9] suggested overcorrected mechanics to promote more bodily translation limiting the tipping movements observed. Concerning lower incisor inclination changes observed in the study, the significant reduction evidenced in Group 1 contrasts with the side effects commonly associated with traditional Class III treatments, where anterior anchorage loss often exacerbates incisor inclination. On the contrary, the Non-Distalization Protocol adopted in Group 2 determined a lower control of incisor inclination with a decrease by 1.1° of the value of IMPA. This outcome reinforces the findings by Rota et al. [14], who reported the effectiveness of the Class III elastics in lower molar distalization treatment for a better control of anterior anchorage. Hence, the difference observed between the two analyzed groups in terms of anterior anchorage could be explained by the greater amount of space recovered through the antero-posterior movements of the posterior segments. Overall, the effectiveness and the predictability of distalization mechanics depends on patient compliance and on the biomechanical properties of aligners. As claimed by Horodyski et al. [16], the adherence to aligner wear protocols significantly impacts success rates. In this study, the monitoring of compliance contributed to favorable outcomes. As a matter of fact, the positive correlation between compliance and ANB improvement observed in our sample highlights the potential impact of patient adherence

on dento-skeletal outcomes obtained. This finding underlines the importance of patient cooperation when planning clear aligner therapy.

### Limitations

Limitations of the present investigation include the relatively small sample size and the short-term follow-up. However, the innovative nature of the study lies in its prospective design, which allows for a more precise evaluation of clinical outcomes and the identification of temporal changes, providing a significant advantage over retrospective analyses. While significant cephalometric changes were detected, long-term studies with larger cohorts are needed to validate these results and assess their stability over time. Further analyses are necessary to explore individual variations in dento-skeletal response to the lower distalization protocol and Class III elastics in the treatment of adult Class III patients. Nevertheless, the findings suggest no major concerns regarding the generalizability of results from a future definitive RCT with an appropriately sized sample.

Another limitation of this study was the need of patient's compliance, which could have determined heterogeneity of results. On the other hand, however, this fact increases the possibility of extrapolating the results to the ordinary clinical routine. Moreover, the sample size may not be adequate for some variables. As a matter of fact, it was calculated considering the ANB angle as the primary variable.

### Conclusions

- The lower distalization protocol combined with Class III elastics allows a more significant improvement in occlusal relationships in the treatment of Class III malocclusion in adult patients, compared to a protocol that involves the use of intermaxillary elastics alone.
- Sequential staging of movements ensures a more effective and predictable control of antero-posterior movements, reducing the risk of undesired distal tipping.
- The combination of lower molar distalization with Class III elastics provide a better control of the anterior limit compared to the Non-Distalization Protocol.

### Conflict of interest

The Authors report a funding relationship between themselves and Align Technology. However, Align Technology had no role in the design of the study, in the collection, analyses or interpretation of data, in the writing of the manuscript, or in the decision to publish the results.

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### Data Availability

The data underlying this article will be shared on reasonable request to the corresponding author.

## Supplementary material

Supplementary material is available at *European Journal of Orthodontics* online.

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