

**ROLE OF THE FRICTION FREE DISTALIZE APPLIANCE (2FDA)<sup>PAT</sup> IN THE MOLAR DISTALIZATION: PHOTOELASTIC ANALYSIS AND ALKALINE-PHOSPHATASE (ALP) ACTIVITY ON FIRST MOLAR AND BICUSPID**

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Maxillary molar distalization is an increasingly popular option for the resolution of Class II malocclusions. This study describes the effects of one particular molar distalizing appliance, the Friction Free Distalize Appliance (2FDA), in a sample of 20 consecutively treated and growing patients to verify the osteoblastic activity in the compression and traction sites of both the molars and the bicuspids when used as the anchorage teeth. The 2FDA appliances were constructed utilizing a Nickel Titanium open coil spring of 200 gr force in order to distalize the maxillary first molar. The reaction force was controlled utilizing the principle of low/free friction. The results show that the resin around the root of the bicuspid did not discolour at all, which indicates an absence of a force load. On the other hand, on the molar, the resin around the root of the molar became discoloured due to the fact that an orthodontic force was involved with the tooth. To better understand whether the quantity of force that reached the tooth was able to produce osteoblastic recruitment in the sites of tension of the molar and the bicuspid, we quantified an enzyme, the alkaline phosphatase (ALP), present. This measurement allowed us to verify a regular increase of the ALP on the site of molar traction. We also elaborated a mathematical model to evaluate the quantity of force of reaction that produces the device on the bicuspid. Such force results as being 8.34 grams which equals half the pressure of the capillaries of the parodontal ligament (18 grams). The 2FDA appliance compares favourably with other intra-oral distalization devices for the resolution of patients with Class II malocclusions, and is the only distalizing appliance that does not determine osteoclastic/osteoblastic recruitment on the "anchorage tooth".

Class II malocclusion cases constitute a heterogeneous group of patients that represents a significant portion of all the patients who attend for orthodontic treatment. Class II malocclusion is not a single clinical anomaly. It can occur in various forms. In non-extraction Class II adult patients, maxillary molar distalization may be used to correct the molar relationship and to alleviate crowding in the maxillary arch. A variety of techniques for molar distalization have been suggested, including those that require patient compliance (1-10) and those that reduce the need for patient co-operation. In a survey by Sinclair (11), all responding orthodontists reported using molar distalization, and nearly all indicated that patient co-operation was the most significant problem encountered in distalizing maxillary molars.

Patients' adherence is said to be decreasing and co-operation with prescribed intraoral and extraoral devices (12-16). Consequently, many non-compliance fixed appliances have been developed to apply a distal force to the maxillary molars, with the purpose of diminishing the need for patient co-operation. (17-23) However, despite the effectiveness of many of these appliances in moving posterior teeth distally, they all produce a certain amount

of anterior anchorage loss—mesial movement of anchoring teeth, proinclination of maxillary incisors and produce some distal tipping of the maxillary molars. (24-27). International literature (28-36) reports a loss of anchorage between 15 and 65%; a molar tipping between  $-2.2^{\circ}$  and  $16.0^{\circ}$ ; and a bicuspid tipping between  $-4.3^{\circ}$  and  $2.4^{\circ}$ .

To try to minimize the adverse effects of the molar distalization with a non-compliance device, we recently developed a new distalize appliance named Friction Free Distalize Appliance (2FDA<sup>Pat</sup>). It has been proven that this new device can distalize maxillary molars with very few or, in several cases, without the disadvantages of the other methods.

The use of the Friction Free Distalize Appliance (2FDA), is clinically efficient, and in fact the measurements of the dental casts of 20 patients showed that there was a highly significant distal movement of the maxillary first and second molars on the right side of  $3.33 \text{ mm} \pm 1.46 \text{ mm}$  ( $p \leq 0.01$ ). The rate of maxillary molar distalization was  $0.66 \text{ mm} \pm 0.29 \text{ mm}$  per month on the test side.

The measurement of the mean of the mesialization (anchorage lost) of the first right bicuspid was  $0.37 \text{ mm}$

*Key words: Class II, molar distalization, friction free, anchorage, non-compliance distalize appliance, alkaline-phosphatase, photoelastic resin*

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$\pm 0.005$  mm ( $p= 0.219$  n.s.) (Fig. 1)

The medium amount of space created was 6.4 mm, the real distalization of the first molar was 5.4, therefore the percentage of the distal movement obtained was 85.34%. From this mathematical proportion it is possible to calculate the percentage of the lost anchorage by subtracting the percentage of the molar distalization from 100. In this way the mesialization of the first premolar was 14.66%, which converted into millimeters was 0.37.

For this reason, the purpose of the present study is to evaluate the nature of bone metabolism in the distalization (the first molar zone) and anchorage site (the first bicuspid zone). We evaluated longitudinally the levels of alkaline phosphatase (ALP) activity in the gingival crevicular fluid (GCF) of the teeth included in the 2FDA appliance. It is known that bone turnover during orthodontic tooth movement is characterized by a continual and balanced process characterized by bone deposition at sites of tension and bone resorption on the pressure sites (38-39). It is also known that bone-forming cells have been shown to have ALP activity, (40) and changes in this activity have also been related to the time of treatment and the type of stress exerted on the periodontium (tension or compression) by the tooth movement. (41-42).

#### MATERIALS AND METHODS

*Appliance Design.* The 2FDA, which can be placed both in the upper and in the lower arch, is made up of: 1) a molar band (with a gingival tube, the slot size of which is .018" x .025" or .022" x .028") bonded to the upper molar to be distalized; 2) a coil spring, 5 mm long, and a Gurin screw or similar applied over each tube. (We use 3M Unitek nickel titanium 200g coil springs ); 3) a stainless steel wire (size: .016" x .022") extending from the first molar band to the first bicuspid band ending in a bayonet bend; 4) this sectional wire is solidarized to the first bicuspid by a double tube bracket. This bracket is made by two tubes that are placed one upon the other. The gingival tube has a rectangular shape with .018" x .025" size; the tube under the first one is round and contains a 3M Unitek Niti closed coil spring with 250 gr. of force, this coil is soldered onto the sectional wire. The 2FDA appliance is activated by sliding the Gurin screw close to the first molar once a month.

*Study population.* The subjects for this retrospective analysis of the 2FDA molar distalizing appliance consisted of twenty consecutively treated Class II orthodontic patients (11 females; nine males) obtained from the private practice of two clinicians. The mean age of the patients at the time of the initial records was 12.6 ( $\pm 2.1$ ).

The criteria for the subject selection included:

a) Need for non-extraction treatment (i.e. mild to moderate crowding); b) Molar distalization achieved only with the 2FDA in the first phase of treatment; c) availability of good quality radiographs and dental models (before treatment and after distalization); d) healthy systemic condition; e) no use of anti-inflammatory drugs in the month preceding the beginning of the study; f) probing depth values not exceeding 4 mm in the whole dentition; g) no loss of periodontal attachment exceeding

2 mm in any interproximal site; h) no radiographic evidence of periodontal bone loss after a full-mouth radiographic periapical examination; i) a full-mouth plaque score (FMPS) and a full-mouth bleeding score (FMBS)  $\leq 20\%$ .

FMPS and FMBS were recorded as the percent of tooth surfaces with the presence of supragingival plaque or bleeding within 15 seconds after probing with a 20 g controlled-force probe (Vivacare TPS Probe, Vivadent, Schaun, Lichtenstein).

During the 2 months preceding the baseline examination, all subjects received repeated oral hygiene instructions on the correct use of a toothbrush, dental floss, and an interdental brush. Moreover, 2 weeks before the baseline examination, all patients underwent a session of supra- and subgingival ultrasonic scaling. Finally, the study subjects were not allowed to take any anti-inflammatory drugs during the study in order to avoid unreliable results. (43-45). Informed consent was obtained from the patients or the parents of patients under 18 years of age prior to the commencement of the study, and the protocol was reviewed and approved by the Ethical Committee of the G. d'Annunzio University Medical Faculty.

In this study, a maxillary first molar undergoing distal movement from each patient was used as the test molar (TM), with the controlateral (CM) first molar used as control. In addition, the first bicuspid (that was included in the 2FDA appliance and was considered as the anchorage element) was also tested (TB), with its controlateral (CB) as control.

The test teeth TM and TB were used to bond the 2FDA appliance. Orthodontic bands (3M-Unitek, Monrovia, CA) were used to build the 2FDA appliance. To distally move the TM, a nickel-titanium calibrated open coil spring, (3M-Unitek, Monrovia, CA) exerting a constant force over its range of activation of 200 g was included in the 2FDA appliance. Moreover, the teeth from the maxillary incisors to the maxillary cuspid were left without any orthodontic appliance. The CM and CB teeth were also included in the fixed appliance with another 2FDA appliance, (this appliance was absolutely passive). The two orthodontic 2FDA appliances were placed in a single clinical session. No orthodontic appliance was placed on the mandibular arch.

*Evaluation of osteoblastic activity on mesial and distal sites of the first molar and first bicuspid Clinical monitoring and GCF collection.* At the mesial and distal aspects of the TM, CM, AM, TB, CB and AB teeth, GCF was collected for the ALP activity assay. In each sampling site, the presence or absence of dental plaque (PL), the probing depth (PD), and the presence or absence of bleeding on probing (BoP) were assessed as clinical monitoring. GCF was collected immediately before the appliance placement and activation, as described above, and at 1 hour and at 15, 30 and 45 days after placement. Clinical examination consisted of assessing the PL visually and assessing BoP within 15 seconds after probing with a 20-g controlled force probe and the PD in 6 sites per tooth (mesio-buccal, mid-buccal, disto-buccal, mesio-lingual, mid-lingual, and disto-lingual/palatal). Clinical data were always collected by the same operator. Contamination of the GCF samples was minimized by recording the plaque scores before carefully cleaning the tooth with cotton pellets, collecting GCF from the isolated area, and recording the PD and BoP as previously described by Griffiths et al. (46). These clinical parameters were assessed twice, at

baseline (before the orthodontic appliance was placed) and after 45 days.

Each crevicular site included in the study was isolated with cotton rolls. Before the GCF collection, any supragingival plaque was removed with cotton pellets (46) and a gentle air stream was directed toward the tooth surface for 5 seconds to dry the area. GCF was collected with n. 30 standardized sterile paper strips (Inline, Torino, Italy) inserted 1 mm into the gingival crevice and left *in situ* for 30 seconds. Care was taken to avoid mechanical injury. Immediately after collection, paper points were transferred to plastic vials. GCF total volume was determined for each sample as previously described. (47).

ALP activity was assayed spectrophotometrically (48) with a spectrophotometer at 405 nm (model 8453, Hewlett Packard, Waldgrohn, Germany). The cone sample was incubated at 30°C, with less than 0.05°C fluctuation, for 20 minutes in a substrate containing *p*-nitrophenyl phosphate (10 mmol/L), carbonate buffer (pH 10.2 ± 0.1 at 30°C), mannitol (200 mmol/L), and MgCl<sub>2</sub> (3 mmol/L), to a total volume of 1.0 mL. ALP hydrolyses *p*-nitrophenyl phosphate to *p*-nitrophenol and inorganic phosphate. The rate of increase in absorbance at 405 nm was monitored as the *p*-nitrophenol formed. We used 18.45 as the *p*-nitrophenol millimolar absorptivity and converted the absorbance into enzyme activity units (1 U = 1 μmol of *p*-nitrophenol released per minute at 30°C). Final results were reported as total ALP activity (mUnits/sample). The overall percentages of tooth sites positive for plaque (%PL +) and bleeding on probing (%BoP +) and the mean PD were calculated from the % PL +, % BoP +, and mean PD of each site at baseline and on day 45.

**Data treatment.** The %PL + and % BoP + were considered to be ordinal data; therefore, Friedman's test (49) was used to evaluate the statistical significance of the differences in the clinical data from the experimental categories at baseline and on day 45. When significant interactions were found, a Wilcoxon paired signed rank test was performed. Changes in %PL+ and %BoP+ within the experimental groups were similarly tested by Wilcoxon paired signed rank test as a *post hoc* procedure. The statistical significance of the differences in PD of the experimental categories at baseline and on day 45 was evaluated with a 1-way repeated measures ANOVA; when significant interactions were found, a Bonferroni-corrected paired Student *t* tests as *post hoc* procedure was performed for pair-wise comparisons. Changes in PD within the experimental groups were tested by paired Student *t* tests as *post hoc* procedure. When appropriate, to statistically assess differences in clinical conditions between mesial and distal aspects of the same experimental tooth at the same experimental session, data obtained from the site corresponding to the GCF sampling area were tested.

PL and BoP were processed as dichotomous data with a McNemar test, whereas the PD scores were processed with a paired Student *t* test. The measurements of GCF volume were recorded for all the teeth at each sampling time and were expressed as a single score for each experimental group throughout the study; 1-way repeated measures ANOVA and Bonferroni-corrected paired Student *t* tests were used to examine the significance of differences in GCF volume among the experimental categories. The means and SDs of measurements for ALP activity values were calculated and arranged in a 2 x

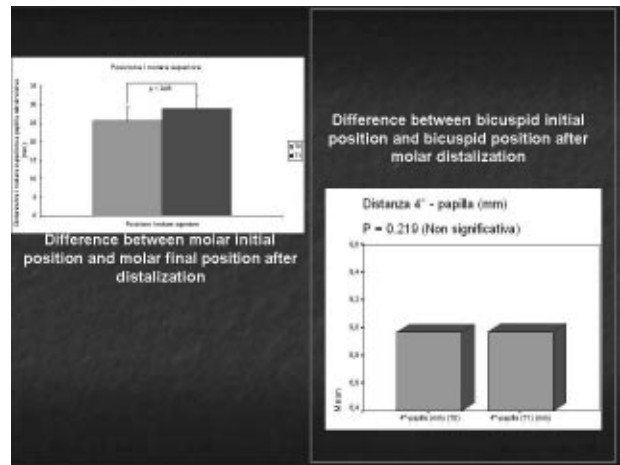


Fig 1. The clinical results of degree of molar distalization and bicuspid list anchorage.

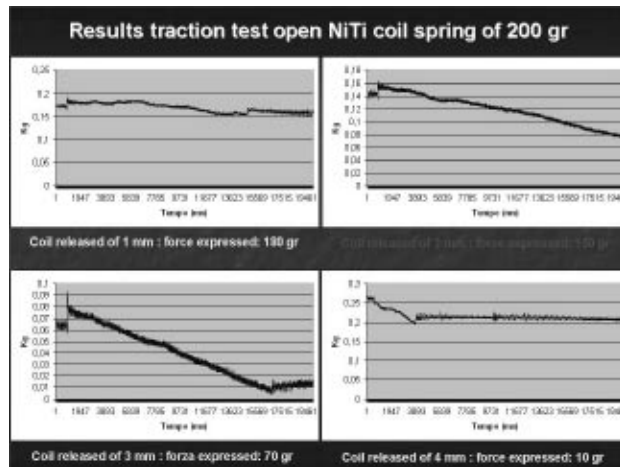


Fig. 2. Test to the dynamometer to quantify the practiced force in the distalization of the molar from the open coil spring of 5 mm in length when it is released by 2 mm.

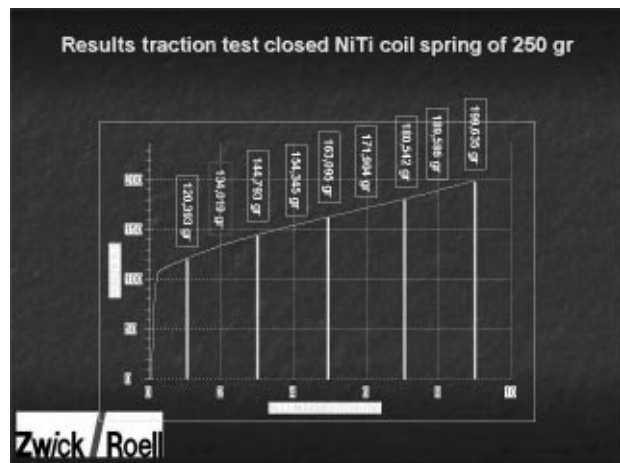


Fig. 3. Test by the dynamometer to quantify the practiced force on the bicuspid, from the closed coil spring of 5 mm of length when it is activated by 2 mm.

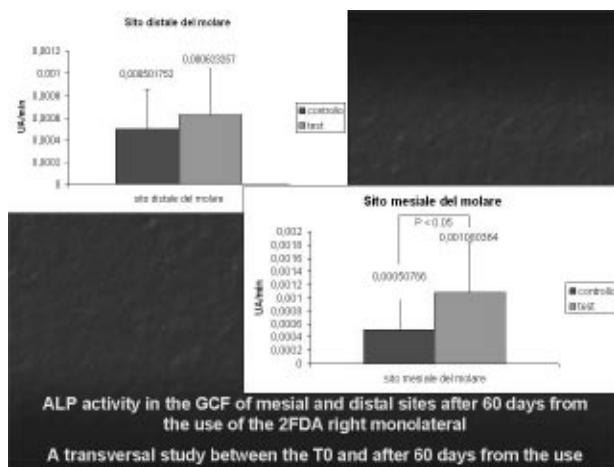


Fig. 4. ALP activity on mesial site (traction site) and on distal site (compression site).

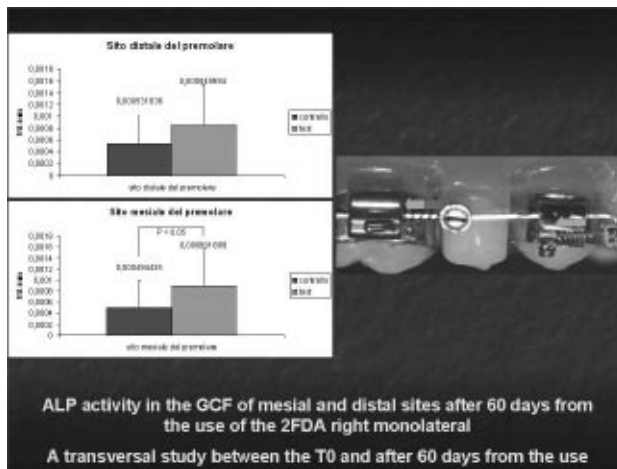


Fig. 5. ALP activity on mesial site (compression site) and on distal site (traction site). The explanation for which it increases the osteoblastic activity on the site of compression is explained by the biomechanics of the appliance. In fact the direction of action of the closed coil spring is backwards. To the periodontal receptors of the mesial site (of compression), relative information is sent as an action of traction; vice versa for the distal site. The 2FDA are then able to turn the site of compression into one of traction inducing an osteoblastic production more important than that of osteoclastic. Therefore, the supposition that the bicuspid progress toward the mesial direction, losing anchorage, does not exist.

6 x 3 matrix, reflecting the sampling site (mesial or distal), the time points, and the 3 treatments. These 3 factors were used in a repeated measure 3-way ANOVA (50) to assess the data of GCF ALP activity. Furthermore, to test the simple main effect of each factor, 1-way repeated measures ANOVAs were performed to evaluate the significance of differences in ALP activity among the experimental groups at each time point and across times within each group in both mesial and distal sites. Bonferroni-corrected paired Student t tests were used as a pair-

wise comparison procedure when appropriate. The significance of differences in ALP activities between mesial and distal sites for the teeth categories at each time point were assessed with a paired Student t test as a *post hoc* procedure. ALP value less than 0.05 was accepted as being statistically significant.

*Evaluation of the reaction force on the first bicuspid by photoelastic resin and a mathematical model.* A molar and a bicuspid were put into the photoelastic resin. At different times, a non-compliance distal appliance was inserted. Once a traditional appliance, and another time a 2FDA device. The purpose was to verify, by the change in coloration of the resin, the different load which involved the anchorage bicuspid submitted to stress.

The purpose was to understand how much reaction force arrived on the anchorage tooth. With 2FDA we were able to analyze the force produced by the open coil spring used to distalize the molar when this last was unloaded by 2 mm, and how much force produced the closed coil spring when it was activated by 2mm (Fig. 2, 3). Thus, knowing the forces practiced by the 2 coil springs and the quantity of deflection of each, it was possible to realize a mathematical model ( $K_{pm} \Delta x_{pm} - K_m \Delta x_m / 2$  where  $K_{pm}$  = coefficient of elasticity of the closed coil spring,  $K_m$  = coefficient of elasticity of the open coil spring and  $\Delta x$  = variation of length of the coil spring) that allowed us to quantify the reaction force that arrived on the bicuspid anchorage tooth.

## RESULTS

*Evaluation of osteoblastic activity on mesial and distal sites of the first molar and first bicuspid.* The clinical parameters had similar scores in both experimental sites at baseline, without any statistically significant differences. On day 45, all clinical parameters of the TMs, CMs, TBs and CBs were significantly worse than at the baseline; conversely, in the AMs, the parameters did not show significant changes. At this point in the experiment, the cross-sectional analysis also showed a significant difference in the clinical parameters from the 2 groups. The pair-wise comparison tests showed that the significance was due to the differences in the clinical data from the AMs compared with those from the TMs, CMs, TBs and CBs. Within these TMs, CMs, TBs and CBs group parameters there were no statistically significant differences between the mesial and distal sites. The means and SDs of GCF volume in microliters for each experimental group were  $0.14 \pm 0.08$  in the TMs,  $0.14 \pm 0.07$  in the CMs, and  $0.12 \pm 0.06$  in the AMs, with a significant difference between the groups (1-way ANOVA;  $P \leq 0.01$ ). GCF volume was significantly greater in the TMs and TBs compared with the CMs and CBs ( $P \leq 0.01$ ). The 3-way repeated measures ANOVA reveals that the subjects demonstrated significant differences in GCF ALP activity levels between the time points (F-ratio = 13.23;  $P \leq 0.01$ ), the treatments (F-ratio = 37.07;  $P \leq 0.01$ ), and the sites (F-ratio = 11.46;  $P \leq 0.01$ ). In addition, the interactions of treatments with times (F-ratio = 7.83;  $P \leq 0.01$ ) and with sites (F-ratio = 6.43;  $P \leq 0.02$ ) were

also significant.

One-way ANOVA showed a statistically significant change in enzyme activity only in the TM and TB groups, in mesial sites, among the repeated samplings during the study period (Fig. 4, 5). Results of pair-wise comparisons show a significantly greater enzymatic activity in mesial sites from the TM group from day 1 to the end of the experiment, as compared with the baseline. Conversely, in the CM and CB group, over the study period no significant statistical difference in ALP activities was seen from day 1 to the end of the experiment, as compared with the baseline. At baseline and at 1 hour, in both distal and mesial sites, ALP activity was similar in the all groups, without significant differences (1-way ANOVA). In distal sites, statistically significant differences both between the TMs and CMs and between TBs and CBs were seen from day 1 to the end of the experiment.

*Evaluation of the reaction force on the first bicuspid by photoelastic resin and a mathematical model.* The photoelastic resin showed that with the traditional non-compliance distalize appliance the resin around all the bicuspid root was completely discoloured. Therefore, the majority of the reaction force was directed on the tooth. Instead, with the 2FDA, the resin around the root of the bicuspid remained absolutely transparent. No force involved the root of the first bicuspid.

Meanwhile, on the molar, the load of the force was more evident with the 2FDA than with a traditional non-compliance distalize appliance. The explanation for this can be found in the different quantity of force that loads the molar and the bicuspid, as underlined by the mathematical model previously described.

#### DISCUSSION

*Evaluation of osteoblastic activity on mesial and distal sites of the first molar and first bicuspid and evaluation of the rate of the reaction force on the first bicuspid.* The evaluation of the osteoblastic activity by monitoring the alkaline phosphatase (ALP), statistically underlines ( $p \leq 0.05$ ) a meaningful enzymatic increase at the site of tension (mesial site) of the molar test (TM group) both in comparison to the T0 and in comparison to the molar control (CM group). This is in accord with the physiology of the dental movement: in the bone remodelling in the site of tension the osteoblastic activity has to prevail to allow an apposition of the bone. Vice versa, in the site of compression an osteoclastic activity prevails to allow the tooth to move in the direction imposed by the orthodontic force. Around the first bicuspid, tooth anchorage of the appliance, the site of traction is the distal site, while that of compression is the mesial one.

The statistic analysis of the enzymatic activity of the ALP statistically underlines ( $p \leq 0.05$ ) a meaningful increase of the enzyme on the compression site (mesial).

Such data results in contrast with the physiology of the dental movement, for which the osteoblastic activity has to be reduced in favour of an osteoclastic one in the compression site. This results from the direction of the application of the orthodontic force.

These results are justifiable according to the biomechanics of the appliance. The presence of the closed coil spring on the first bicuspid turns the mesial site of the bicuspid from a compression site into a traction site. This is possible because the coil spring once activated (open) aims to return (because of its elasticity) to its initial position producing stimuli of traction in the periodontal receptors of the mesial site of the first bicuspid.

This data allows us to better understand the clinical results related to the measurement of the loss of anchorage. In fact, loading the site of compression on the anchorage tooth leads to a prevalence of an osteoblastic activity or an apposition of bone, otherwise it is not possible for the same tooth to move mesially. It may induce movements of rotation and/or of tipping but not of translation of the tooth which represents the true loss of anchorage.

To better justify the 2FDA innovative philosophy, we should underline that the quantity of the reaction force that involves the first bicuspid is low. This data is confirmed both by experimentation effected on photoelastic resin and from the realization of a mathematical model which made it possible for us to calculate the quantity of reaction force that involves the anchorage tooth.

The 2FDA experimentation on the photoelastic resin underlined that there is no discoloration and therefore no load around the first bicuspid, unlike the traditional non-compliance distalize system. This allows us to deduce that if no force involves the tooth, it will not be possible to move it. In order to clarify how much of the force of reaction involved the anchorage tooth we used a mathematical model (see Results.) which allowed us to show that such force was equal to 8.34 grams. In relation to the original 75 grams of the force of reaction, this value represents 11% of all the reaction force. Such data seem to explain both the clinical and enzymatic result related to the loss of anchorage. In fact, 8.34 grams is equal to half of the pressure of the capillary pressure of the periodontal ligament (18 grams) (51), and is an insufficient force to induce the secretion of the pre-osteoclastic and pre-osteoblastic vasoactive substances.

In conclusion, the Friction Free Distalize Appliance (2FDA) is a fixed appliance designed to produce distalization of maxillary first molars. This device constitutes an effective and predictable method for the correction of a Class II malocclusion for which no patient co-operation is required.

The present study produced the following findings regarding the use of the 2FDA appliance for the distal

movement of maxillary first molars during the correction of Class II malocclusions.

1. Class II molar relationships were corrected to Class I in about five months.
2. The distalizing force on the maxillary molar resulted in 88.64% molar distalization and 11.36% reciprocal anchorage loss measured at the maxillary first premolar. This division is more favorable than that reported in studies on other intraoral methods of molar distalization
3. The maxillary first molars were moved distally an average of 3.3 mm on side test. Net distalization was less than that seen with the pendulum.
4. Anchorage loss, measured at the first premolars, was 0.43 mm one side test.
5. Evaluation of osteoblastic activity on mesial and distal sites of the first molar and first bicuspid showed a statistical change in enzyme ALP activity only in the mesial site of the first molar and first bicuspid of the test group.

It is important to note that the mesial site of the molar is the tension site of a tooth subordinate to orthodontic force, for this reason it is normal that the activity of this enzyme is higher than the base-line.

Instead, is not normal that the ALP activity increases at the mesial site of the first bicuspid because this site represents a compression site of a tooth subordinate to orthodontic force. The hypothesis of this event is explained in the Discussion section.

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