The Evaluation Of The Efficiency Of Micro-osteoperforation

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STUDY PROTOCOL

The aim of this study was to evaluate the effectiveness of micro-osteoperforations (MOP) performed in the alignment stage.

This was a 2-arm parallel-group, randomized,controlled trial with a 1:1 allocation ratio

The protocol of the study was approved by Izmir Katip Çelebi University Clinical Research Ethics Committee dated 18.05.2016 (no: 94) and T.C. Ministry of Health, Turkey Pharmaceuticals and Medical Devices Agency dated 09.09.2016 (document number: 228 418) was approved by decision.

Based on Mehr's (1) study, the dependent sample t-test using the G * Power 3.1 software program (Franz Faul, Universität Kiel, Germany) showed that 24 patients had an effect width of d = 1.05 and α = 0.05 significance level. it was determined that the number of samples formed 80% power. Assuming a 15% exclusion rate, a total of 28 patients (14 patients) were included in the study.

The patients who applied to the Department of Orthodontics of the Faculty of Dentistry of Izmir Katip Çelebi University and who were found to comply with the study criteria were informed verbally and in writing. Written informed consent was obtained from patients and parents who agreed to participate in the study. A total of 28 patients (12 males and 16 females) aged between 12 and 27 years, with a diameter of more than 5 mm in terms of the Little irregularity index, were included in the study. The study groups were composed of 14 patients (4 boys, 10 girls) in the MOP applied (MOP +) group and 14 patients (8 boys, 6 girls) in the MOP not applied (MOP-) group.

The following inclusion and exclusion criteria were considered in the selection of patients to be treated: Inclusion Criteria:
• All permanent teeth have been removed (except the 3rd molars)
• Presence of more than 5 mm crowding in the lower arc according to Little irregularity index (1)

• Gingival and periodontal indices less than 1
• Good oral hygiene
• Patient and / or guardian volunteering to participate in the study Exclusion Criteria:
• Congenital missing or pulled teeth
• Severe skeletal malocclusion
• Systemic disease
• Presence of periodontal disease
• Radiographic determination of bone loss

• Gingival pocket depth of more than 4 mm • Previous orthodontic treatment

Table 1 presents the gender, age distribution and baseline Little irregularity index data of the patients. Table 1: Gender distribution by groups, mean age and perceptions.

GROUPS	**MOP+**		**MOP-**		**TOPLAM**		**p**
	n	**%**	**n**	**%**	**n**	**%**	0,252

Female	10	71,4	6	42,9	16	57,10	
Male	4	28,6	8	57,1	12	42,90	
total	14	100	14	100	28	100	
	x̄	ss	x̄	ss	x̄	ss	**p**
Little irregularit y index	9,99	2,63	8,87	1,50	9,42	2,17	0,179
age (years)	17,21	3,76	15,29	1,77	16,25	3,05	0,095

n: number of individuals x̄ : average, ss: standard deviation, $p<0,05$

Oral hygiene procedures were explained visually with videos and applied on the model to all patients before the treatment and in the session where the brackets were applied. It was told that they should brush their teeth at least 3 times a day, then use an interface brush, pay attention to the foods that will cause caries and avoid acidic beverages. Periodontal status of the individuals included in the study before the treatment was evaluated with the help of periodontal measurements. Oral hygiene of the individuals included in the study was checked at each session and necessary suggestions were made.

The pre-treatment routine orthodontic recordings of the individuals included in the study were performed by taking plaster model, intraoral and extraoral photographs, panoramic and lateral cephalometric radiographs and evaluations according to inclusion criteria.

In each study, clinical periodontal parameters were measured with periodontal sonde just before (T0) and after the leveling (T1) treatment. Gingival thickness measurements were performed with an

ultrasonic device (Pirop® Ultrasonic Biometer A- Scan, Echo - Son, Krancowa, Poland).

In order to evaluate the changes in the dental arch until the leveling phase was completed, each session was taken from the lower jaw and plaster models were obtained. Afterwards, digital models were created from plaster models using 3D scanning device (3Shape R700 TM Scanner, Copenhagen, Denmark).

In our study, bracketing was performed by using MBT system brackets (Mini Master Series® 2, American Orthodotics, Sheboygan, WI, USA) with 0.022x0.028 inch slots in both groups. After bracketing and before MOP administration, patients were asked to rinse their mouth twice with chlorhexidine mouthwash, each lasting for 1 minute. In the first session, MOP application was performed with Propel® (Ossining, NY, USA) driver under local anesthesia in the areas where the dental movement was requested in accordance with the manufacturer's instructions.

Propel® is a disposable device specially designed for micro-osteoperforation. The device includes a 1.5 mm thick perforation tip. It has a depth setting of 3, 5 and 7 mm and the LED depth indicator warns when the desired depth is reached. The device was removed from its sterile packaging and, after adjusting the desired depth, was gently placed on the gum and then turned clockwise with gentle pressure. When the desired skin was reached, the LED indicator was removed by turning it counterclockwise with the indicator illuminated. Micro-osteoperforations were performed directly and atraumatically in the keratinized gum at two or three points, 3 mm between canine canine, 5 mm between canine molar, and 7 mm deep in the posterior region and 1.5 mm in diameter in the alveolar bone (2).

In each group of patients using conventional fixed orthodontic braces, leveling with 0.014 inch nickel titanium (Ni-Ti, American Orthodontics, Sheboygan, WI, USA) arc wire was started. All patients were called for monthly visits and each session was measured and a plaster model was formed until the leveling phase was completed. Ni-Ti (American Orthodontics, Sheboygan, WI, USA) wires of 0.014 inch, 0.016 inch, 0.016x0.022 inch and finally 0.019x0.025 inch were used, respectively, depending on the leveling condition. In both groups, arc wires were connected to the slots by prefabricated steel wire ligatures.

In order to evaluate the clinical efficacy of micro-osteoperforation, the following variables were evaluated in both groups at the beginning of treatment and after completion of the leveling:

• Cephalometric measurements

• Periodontal measurements

• Amount of entanglement and width of tooth arch

• Leveling time

• Pain values and patient satisfaction

Evaluation of Hard and Soft Tissue Changes

Angular and linear measurements were performed on lateral cephalometric films taken at the beginning and after treatment.

Lateral Cephalometric Radiography

The lateral cephalometric radiographs used in the study were taken with cephalometric x-ray device (Orthopantomograph, OP300, Scanora / Instrumentarium, Tuusula, Finland) in the Department of Oral

Diagnosis and Radiology of Izmir Katip Celebi University Faculty of Dentistry. Lateral cephalometric radiographs; natural head position, teeth in centric occlusion and lips in resting position. In order to perform cephalometric analysis, 24 points were determined and 9 cephalometric planes were created. A total of 13 measurements were performed using 4 skeletal, 6 dental and 3 soft tissues using Dolphin Imaging software (version 11.8, Dolphin Imaging, Chatsworth, CA, USA).

Cephalometric Points Evaluated in the Study

The points to be used for cephalometric analysis were grouped into 3 groups as skeletal, dental and soft tissue points.

Evaluation of Periodontal Tissues

Gingival index (GI), plaque index (PI), pocket depth (PD), probing bleeding (PB) and gingival thickness (GT) were measured when immediately before placing the bracket (T0) and after completion of the leveling procedure (T1) in all patients in the study, Periodontal measurements were performed by a single researcher in order to provide standardization. Probing was performed using the Williams periodontal probe (Hu Friedy®, Chicago, IL, USA) with a diameter of 0.5 mm and a guide line at 1-2-3- 5-7-8-9-10 mm on it to facilitate measurement. The measurements were recorded in clinical forms of each patient.

The gum thickness was measured using an ultrasonic measuring device (Pirop® Ultrasonic Biometer, A- Scan, Echo - Son, Krancowa, Poland) at the midline of the tooth, perpendicular to the tooth, in the middle of the keratinized gingival width (3).

Properties of Pirop® Biometer:
1. The device measures from 0.25 to 6 mm.
2. It shows sensitivity up to 0.01 mm.
3. It has an A-scan tip at a frequency of 20 MHz (4).

4. It transmits 10 ultrasonic waves to the application area and works on the principle of giving 10 gum thickness measurements by automatically calculating the distance traveled in mm as a result of the reflection of the ultrasonic waves from the hard tissue.

5. Automatically subtracts the average value from 10 measurements and reflects the results to the 5.7- inch LCD touch screen with standard deviation.

With a 45 degree angle between the holding portion and the tip device, the conical tip 1.7 mm in diameter perpendicular to the teeth, without stressing the soft tissue, the measurement was carried out by applying to the mucosal outer surface. If the standard deviation of the 10 automatic mean values exceeds 0.05 mm, the gum thickness measurement was repeated.

Evaluation of Digital Model

In our study, nickel titanium (Ni-Ti, American Orthodontics, Sheboygan, WI, USA) wires were applicated to the patients in appointments according to the current situation. Each session is used to record the current situation until the session in which 0.019x00.25 inch Ni-Ti wire is attached; T0 (start, n = 28), T1 (second session, n = 28), T2 (third session, n = 28), T3 (fourth session, n = 28), T4 (fifth session, n = 28), T5 (sixth session, n (MOP +) = 7, n (MOP -) = 9) plaster model was obtained from patients. In both groups, a smaller number of models were obtained in the T5, since some of the patients had previously inserted 0.019x00.25 inch Ni-Ti wire.

Plaster models were converted to digital models using a scanning device (3Shape R700 TM Scanner, Copenhagen, Denmark). Dental models were performed on digital models with the software program (OrthoAnalyzer TM, Copenhagen, Denmark).

In order to analyze changes in dental arches; Intermolar distance, intercanine distance, arc length, arc depth and Little perpendicularity index measurements were made in horizontal plane.

Points Used in Model Analysis

1) L6F (right and left): Central fossas of the lower molar teeth

2) L3T (right and left): Tubercule tips of the lower canine teeth

3) L6MCP (right and left): Mesial contact points of the lower molar teeth

4) L1-1CP: The intersection of the contact points of the lower central incisors

5) L1MCP, L2MCP, L3MCP: Lower central, lateral and canine tooth mesial contact points

6) L1DCP, L2DCP: Distal anatomical points of the lower central and lateral teeth

Measurements in Model Analysis

1) Intermolar distance: Distance between right and left L6F

2) Intercanine distance: Distance between right and left L3T

3) Lower arc length: Sum of the distance between the contact points of the lower incisors (L1-1CP) and the mesial contact points (L6MCP) of the right and left lower molars

4) Lower arc depth: The distance between the intersection of the contact points of the lower incisors (L1-1CP) and the line connecting the mesial contact points (L6MCP) of the right and left lower molars.

5) Little irregularity index: Measure the distance between the teeth in the mandibular anterior region from the canine tooth's mesial (L3MCP) to the canine's mesial (L3MCP) on the other side with its own anatomical contact points (L1MCP, L2MCP, L1DCP, L2DCP) in the horizontal plane and add five measured values obtained (5).

Evaluation of Leveling Times

In assessing the leveling time in the lower jaw, the Little irregularity index was considered (5). The time from the beginning of treatment (T0) until the leveling was completed (T1: Little irregularity index falling below 1 mm) was calculated in days (6).

Evaluation of Pain and Patient Satisfaction During Treatment

A questionnaire was performed to assess pain and patient satisfaction at the beginning of treatment (T0), 1 hour later (T1), 12 hours later (T2), 7 (T3), 14 (T4) and 28 (T5) days (5). Visual analog scale (VAS) method was used for pain scoring, there is a range of 0–10, “no pain - unbearable pain” symbolizes information.

References

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