

Effectiveness of olive oil local application in decreasing the period of alignment phase in non extraction orthodontic patients. A randomized controlled clinical trial.

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Background:

During the orthodontic treatment, the friction between the bracket and the archwire could prevent the action of forces required for a particular tooth movement ⁽¹⁾. Studies demonstrated that approximately 12 to 60% of the force used to move a tooth is dissipated in the form of friction ⁽²⁾. Consequently, a delay could occur in the biological response to orthodontic movement. The most important factors that may have an impact on friction are the composition of the bracket, the archwire alloy, the cross-sectional size of the arch-wire, the type of ligation system and the surface roughness of the bracket-archwire assembly ^(3,4).

In addition to the factors related to the orthodontic appliances, saliva is also considered a biological variable associated with friction, as it acts as a lubricant during sliding mechanics ⁽⁵⁾. This fact should be taken into account in laboratory studies that aim to evaluate the performance of the archwire-bracket combinations. However, in the majority of the research studies, the friction test has been conducted without the use of any lubricant ^(6,7,8,9), which does not represent the clinical reality where saliva is introduced

during the movement of the archwire on the bracket. To remedy this situation, distilled water has been used as a lubricant ⁽¹⁰⁾. Although in this case the test is conducted in the presence of a lubricant, water does not have the lubricating ability of natural human saliva ^(11,12).

It is well known that oil is a well-known lubricant. But how can we use it to decrease friction between brackets and wires? And which type of oil can we use safely in patients' mouths? Olive oil (OO) (*Olea europaea*, *Oleaceae*) is a fundamental component of the Mediterranean Diet; it is a mix of fatty acids such as oleic and linoleic acid, secoiridoids (oleuropein and oleocanthal), simple phenols (tyrosol and hydroxytyrosol), lignans (pinoresinol), flavonoids (apigenin), hydrocarbons (squalene), triterpenes (maslinic acid), and phytosterols (β -sitosterol) ^(13,14).

The large body of evidence supports the chemotherapeutic potential of substances found in OO, acting on different sides, such as inflammation, oxidative damage, and even epigenetic modulation ^(15,16). The consumption of OO should be suggested in a healthy diet instead of other types of oils. It looks worthy to determine the effect of the local application of olive oil on decreasing the friction between

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brackets and wires during orthodontic treatment.

Aim & Objectives:

Primary Outcome:

To detect the effectiveness of local usage of Olive Oil on orthodontic brackets during the alignment phase of orthodontic treatment in decreasing the duration of teeth alignment.

Secondary Outcome:

To examine the change in surface roughness of Nickel-Titanium arch wires when using Olive Oil as a lubricant and without the use of a lubricant.

Study Design:

The protocol was registered in ClinicalTrials.gov record no. 455. A Randomized Controlled Clinical Trial was performed according to CONSORT (consolidated standards of reporting trials) guidelines (Figure 1).

Selection and Exclusion of Subjects:

Patients who were enrolled in this study had the following criteria: age ranges from 15–20 years old; mild to moderate dental irregularities requiring non-extraction treatment; presence of all the permanent teeth at least up to the first molars; Good oral hygiene and periodontal health, and patients were excluded if they were requiring orthognathic surgery to correct skeletal discrepancies, were taking medications like NSAIDs or other anti-inflammatory drugs, had cleft lip or palate, hypodontia, or hyperdontia.

Ethical Regulations:

Written consent forms were obtained after informing the patients and/or their parents of the interventions and the possible effects associated with them.

Ethical approval for this clinical trial was obtained from the Ethics Committee of the Faculty of Dentistry, Minia University.

Treatment Subjects:

Sample size calculation was performed using *power (sample size) calculator* online software according to the formula for Superiority Trials with continuous outcomes with a margin of error of 5% and a confidence level of 90% and the mean outcome difference obtained from previous similar published trials^(17,18). The target sample size was determined to be 110 patients, including 10% dropout.

All patients were bonded with 22mil*28mil Roth orthodontic brackets. Patients were randomly allocated to two groups: the control group, where no olive oil was applied, and the patients, who were restricted from using Olive Oil in their food. The second group is the intervention group, where the patients were instructed to apply Olive Oil locally with a bond brush over the orthodontic brackets five times daily after each teeth brushing (Figure 2).

Intra oral scans were taken for the lower arch using the Medit I700 scanner immediately before brackets bonding (T0), after one month (T1), after two months (T2), after three months (T3), and after four months (T4).

Assessment of Efficacy:

Little's irregularity index⁽¹⁹⁾ was used to assess

the changes in dental alignment throughout the study. All measurements were taken digitally using Medit Design software on digital models obtained from intra oral scanning. The grid tool was used to fix the scene at each measurement time, making measurements more standardised. Intraoral scans were taken for the lower arch: immediately before brackets bonding (T0), after one month (T1), after two months (T2), after three months (T3), and after four months (T4) (Figures 3, 4).

Scanning Electron Microscope (SEM) Examination:

Scanning electron microscopic images were taken for the 0.018 inch NiTi wires that will be

used for teeth alignment to assess the changes in surface roughness of these wires. samples were selected for SEM model Prisma E (thermofisher company) attached with EDX unit to assess the surface topography. samples were fixed on aluminum stubs with standard diameter using a carbon double sticky tape. SEM examination of each sample was operated at an accelerating voltage 30 kV and the examination was done at 400X. Representative images of different samples were selected to analyze by Image J software version 1.53 (National Institute of Health, USA) to detect surface roughness parameters (Ra and Rq, Rv, Rp, Rpm, Rt, ...etc) from SEM images.

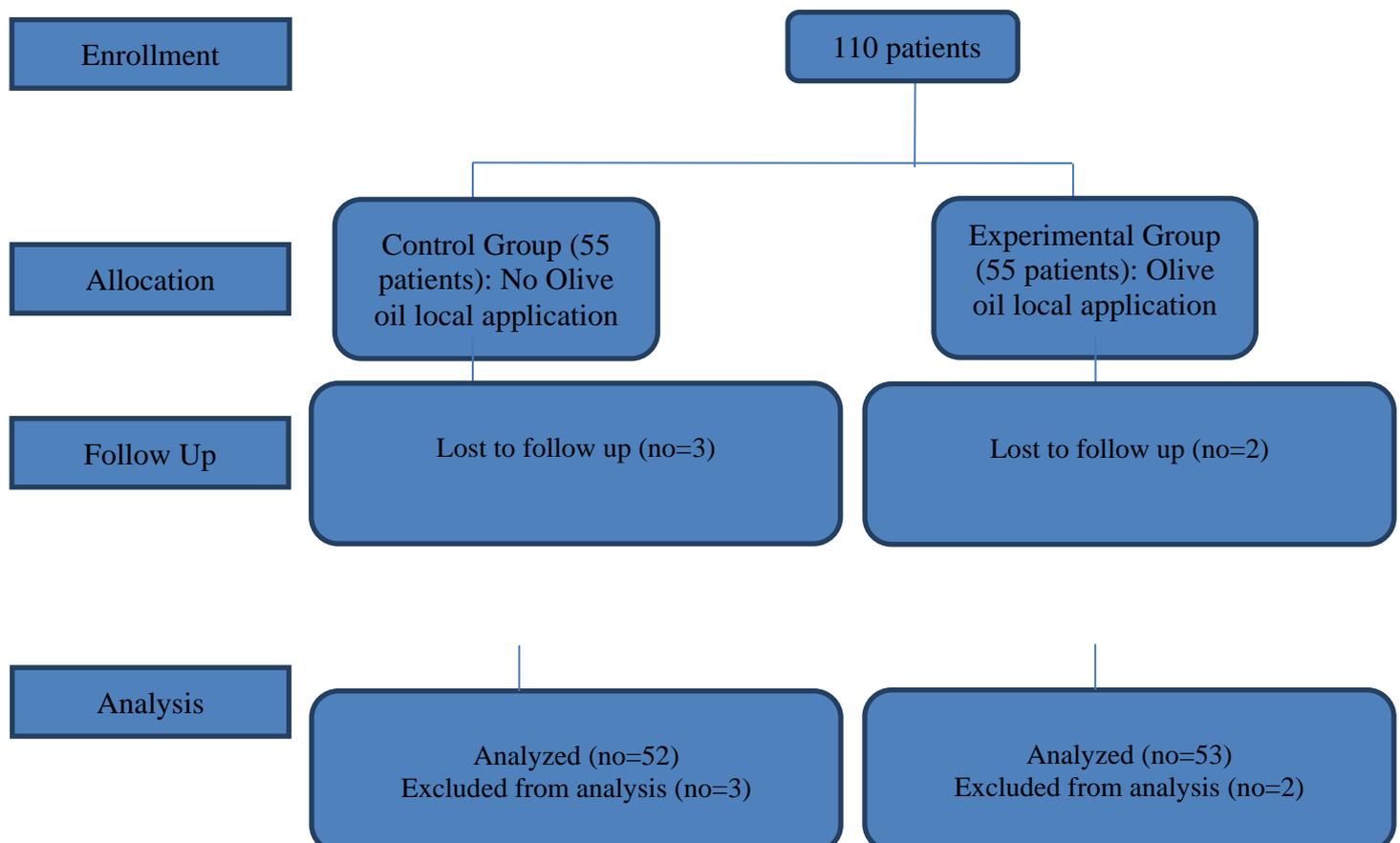


Figure (1): project timetable flow chart.



Figure (2): local Olive Oil application.



Figure (3): usage of Grid tool to standardize the scene at each measurement time.

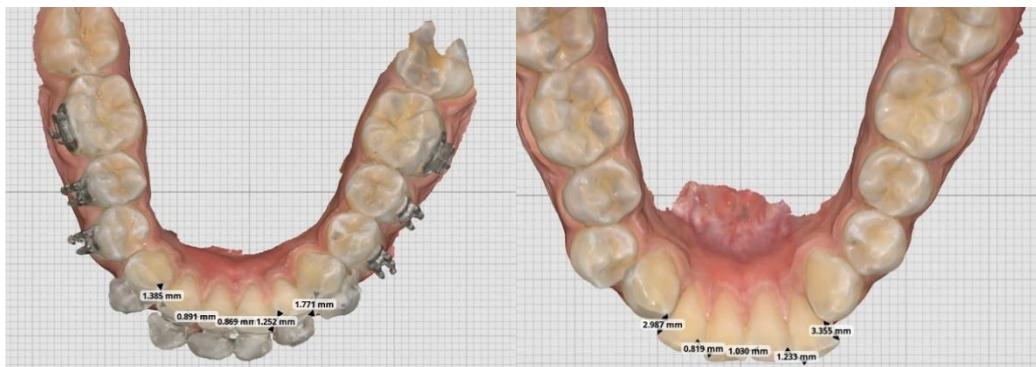


Figure (4): digital marginal ridges measurements.

Results:

Statistical Analysis Results:

The analysis of the data was carried out using the IBM SPSS version 20.0 statistical package software (IBM; Armonk, New York, USA). Normality of the data was tested using the Shapiro-Wilk test. Data were expressed as mean \pm SD for parametric quantitative data. Independent samples t-test for parametric

quantitative data between the two groups. Paired samples t-test for parametric quantitative data within the same group. Data was represented in tables and a bar chart. A p-value less than 0.05 was considered significant. The study began with one hundred and ten patients (fifty-five patients in each group) but five patients (three patients from control group and two patients from intervention group)

missed multiple follow up so they were excluded from analysis.

Regarding the control group, little's irregularity index began with a mean (5.59 mm ± 0.60) and decreased to (0.71mm ± 0.48) (table 1) while in the intervention group; little's irregularity index began with a mean (5.48 mm

± 0.58) and decreased to (0.07 mm ± 0.08) (table 2). Significant difference at (T2&T3) between control group and intervention group. Insignificant difference at (T1) between control group and intervention group (Table I, II) (Figure 5).

Table I: Independent samples t-test for parametric quantitative data between the two groups.

		Control group N= 50	Intervention group N= 49	p value
T0	Mean ± SD (Range)	5.59 ± 0.60 (4.5 – 6.5)	5.48 ± 0.58 (4.6 – 6.6)	0.357
T1 (after 1 month)	Mean ± SD (Range)	2.65 ± 0.39 (2.0 – 3.3)	2.59 ± 0.32 (2.1 – 3.2)	0.437
T2 (after 2 month)	Mean ± SD (Range)	1.53 ± 0.32 (0.9 – 2.3)	1.05 ± 0.19 (0.5 – 1.4)	<0.0001*
T3 (after 3 month)	Mean ± SD (Range)	0.71 ± 0.48 (0 – 1.8)	0.07 ± 0.08 (0 – 0.2)	<0.0001*

- *: significant level at p value <0.05

Table II: Paired samples test for parametric quantitative data within the same group.

	p value	
	Control group	Intervention group
T0 Vs T1	<0.0001*	<0.0001*
T0 Vs T2	<0.0001*	<0.0001*
T0 Vs T3	<0.0001*	<0.0001*
T1 Vs T2	<0.0001*	<0.0001*
T1 Vs T3	<0.0001*	<0.0001*
T2 Vs T3	<0.0001*	<0.001*

- *: significant level at p value <0.05

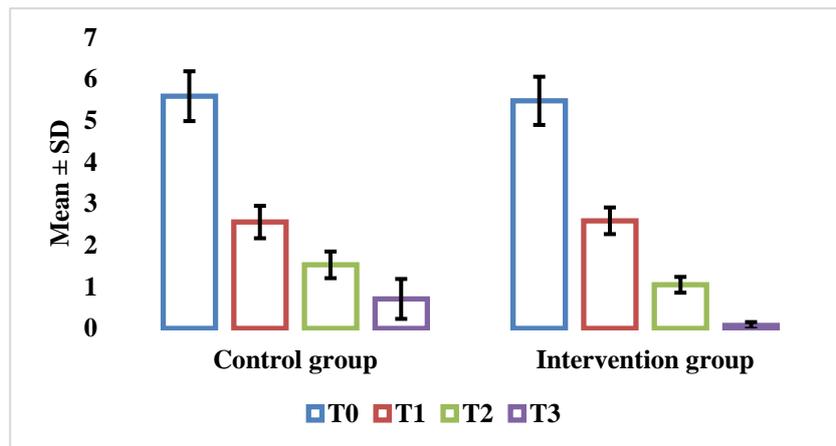


Figure (5): Bar chart representation of control group and intervention group.

**Scanning Electron Microscope Results:
(Roughness Results from Analysis of SEM
Images)**

Average Roughness (Ra): the mean of Ra changed from (18.92±2.61) in the control group and (10.84±0.27) in the intervention group, and the difference between the two groups was statistically highly significant (P-value < 0.001).

Maximum Profile Peak Height (Rpm): the mean of Rpm changed from (206.46±6.36) in

the control group and (196.38±4.69) in the intervention group, and the difference between the two groups was statistically significant (P-value < 0.05).

Therefore, we can say that the intervention group achieved a clearer improvement in the roughness profile than the control group, either in the result of average roughness or in the maximum profile peak height results (Table III) (Figure 6, 7, 8).

Table III: Mean ±SD of average roughness (Ra) and the maximum profile peak height (Rpm) for the control and control groups.

	Control	Intervention	P-value*
Ra	18.92±2.61	10.84±0.27	0.000 ^{HS}
Rpm	206.46±6.36	196.38±4.69	0.007 ^S

-* P-value for comparing between the two time intervals under the same bar.

-* P-value for comparing between the two kind of bars at the same time interval.

- S= Statistically significant at $P \leq 0.05$

- NS= Non-significant $P > 0.05$.

- HS= Highly significant at $P \leq 0.001$

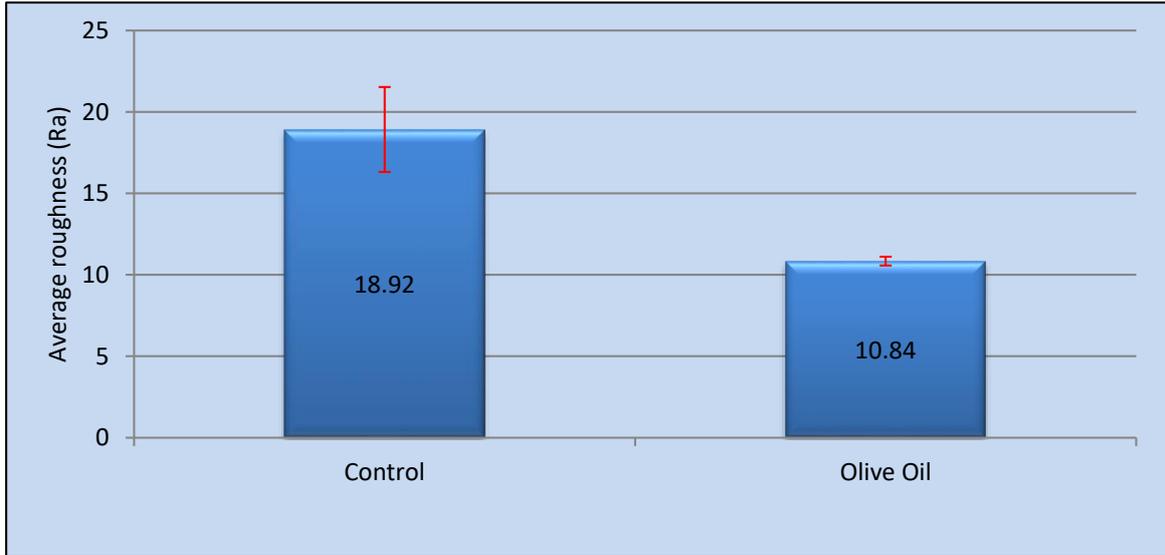


Figure (6): Bar chart representing the mean and SD of average roughness (Ra) for the control and intervention groups.

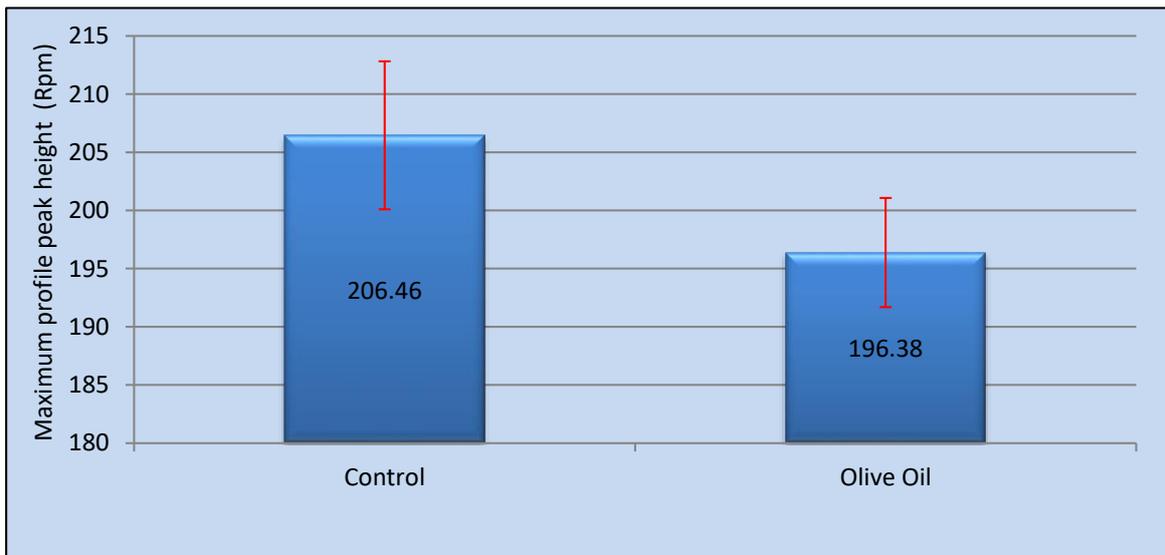


Figure (7): Bar chart representing the mean and SD of the maximum profile peak height (Rpm) for the control and intervention groups.

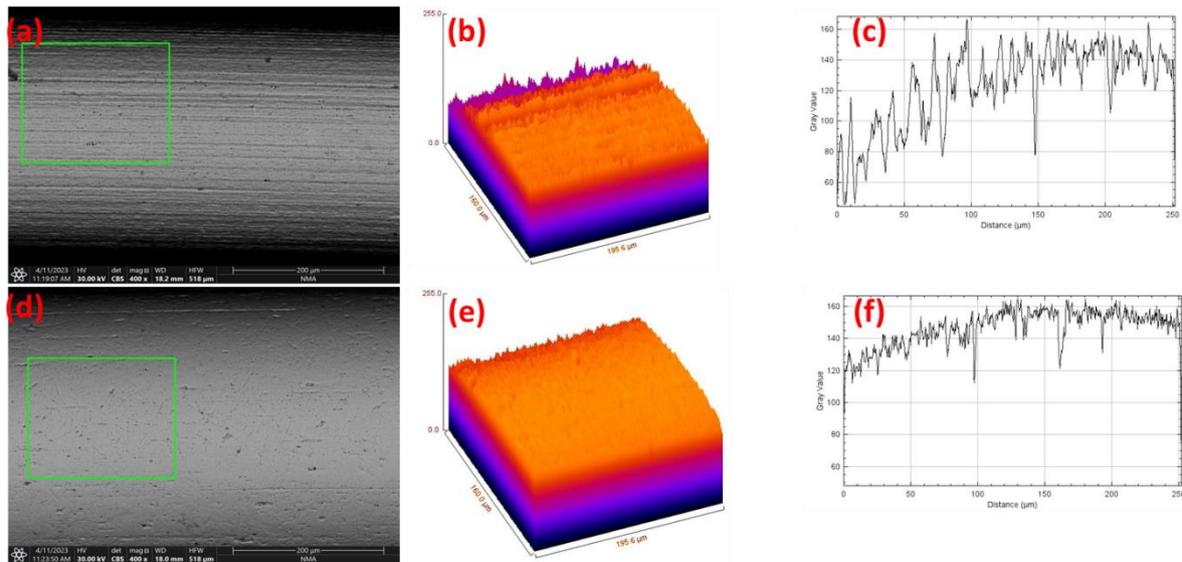


Figure (8): SEM and image analysis results of the for control (a, b, and c) and intervention (d, e, and f) groups. The SEM results at magnification 400X (a and d), the surface plot (b and d), plot profile (c and f).

Adverse Events:

No adverse effects that were noticed or reported from patients resulting from Olive Oil usage.

Discussion:

Understanding the biology underlying orthodontic tooth movement has great clinical implication. Active orthodontic treatment often lasts 18 to 24 months, which is a significant time commitment. Since the 1890s, there has been a significant interest in accelerating tooth movement to reduce treatment time. Customized brackets and wires have substantially increased the effectiveness of treatment; yet, these advancements cannot indefinitely shorten treatment as we are ultimately limited by the biological response during orthodontic tooth movement⁽²⁰⁾.

Another trend is the increase in adult patients requesting orthodontic treatment. An average orthodontist treated 125 adult patients in 2014,

compared to 41 adult patients in 1989, according to the 2015 AAO Economics of Orthodontics Survey. This has been a significant growth rate in recent years. Since adults are not growing and have significantly slower rates of local tissue metabolism and regeneration than teenagers, they can benefit the most from accelerated orthodontic treatment. Adult patients are additionally more vulnerable to periodontal issues and other time-dependent adverse effects (such as dental hygiene-related issues, root resorption, etc.). Accelerating treatment for adults has further practical advantages. Numerous surgical and nonsurgical methods have been used to hasten tooth movement because remodeling of the alveolar bone is a crucial part of orthodontic tooth movement. These methods work by interfering with the biological pathways that control the activity of bone cells (osteoclasts, osteoblasts, and osteocytes), which are the main components of remodeling⁽²¹⁾.

Over a century of clinical testing has gone into the development of surgical methods for accelerating orthodontic therapy. It was once thought that moving teeth faster was accomplished by reducing the resistance posed by the surrounding cortical bone by using the early methods, which involve alveolar osteotomy alone or in conjunction with corticotomy to create a movable "bony block". These methods have a high risk of periodontal disease, are exceedingly intrusive, and increase tooth morbidity. Modern approaches have abandoned the concept of the bony block, and selective alveolar corticotomy has become the reproducible gold standard. Rather than the movement of a bony block containing a tooth, Wilcko et al. were the first to hypothesize that rapid tooth movement following corticotomy may be caused by a demineralization-reminerization process that results in a regional acceleratory phenomenon (RAP) of bone remodeling. The degree of hyalinization of PDLs has a deleterious impact on RAP in addition to bone density. Increased macrophage chemoattraction is a result of corticotomy. These macrophages cause the hyaline zone to vanish earlier than normal, which speeds up tooth movement near the corticated alveolar area. In bones, RAP typically lasts between 4-6 months. Recent approaches have improved on minimally invasive techniques that don't require a flap, like piezoelectricity and corticision, which are more attractive because there are fewer potential side effects ⁽²²⁾.

Although surgical methods have been found to accelerate orthodontic tooth movement, nonsurgical procedures have always been

preferred by clinicians and patients due to their minimally invasive nature. These methods include systemic and local delivery of biological molecules as well as innovative physical stimulation technologies like photobiomodulation, resonance vibration, magnetic field forces, cyclic forces, light electrical currents, and low-intensity laser irradiation. All of these techniques have produced positive results with varying degrees of success. Prostaglandins, for example, are endogenously produced substances that affect bone remodeling. Exogenous application of these substances has specifically been tested for accelerating tooth movement, but the results were disappointing because local administration of these agents was linked to an increased risk of root resorption and pain. Epidermal Growth Factor (EGF), Parathyroid Hormone (PTH), 1,25-Dihydroxyvitamin D3, and Osteocalcin are a few new substances that are now being studied in animal trials. Some of these substances have shown promising acceleration effects, but further research is still needed to determine their safety and effectiveness in humans. Due to their non-invasive nature and lack of discomfort, physical stimulation procedures are becoming more popular with both patients and orthodontists. Before they are widely used in clinical settings, their clinical efficacy must be proven, and more research from randomised studies is required ⁽²³⁾.

This study aimed to detect the effectiveness of local usage of Olive Oil in decreasing the time needed for orthodontic alignment. Little's irregularity index was used to assess the changes in dental alignment throughout the

study. All measurements were taken digitally using Medit Design software on digital models obtained from intra oral scanning. Angus Burns et al⁽²⁴⁾; reported that measurements taken on digital casts, increased the reliability of Little's irregularity index.

Comparing the changes in little's irregularity index between the control group and the intervention group, we can figure out that the usage of Olive Oil as a lubricant during the alignment phase results in faster alignment of teeth, which is apparently due to a decrease in frictional force at the bracket-wire interface. The insignificant difference in values of little's irregularity index between the control group and the intervention group after one month (T1) indicates that the importance of lubricant is more evident after the beginning of orthodontic movement than when initiating it. Regarding the analysis of orthodontic wires surface roughness, we can say that the intervention group achieved a clearer improvement in the roughness profile than the control group, either in the result of average roughness or in the maximum profile peak height results. According to Fabrício Anderson et al.⁽²⁵⁾, there was no significant interaction between the wire cross-section and the condition of lubrication ($p=0.901$). Also, Fabrício Anderson concluded that, irrespective of whether lubricants were used or not, there was a significant increase in friction with an increase in the cross-section of the wire ($p<0.001$). Another study by A. Dridi et al.⁽²⁶⁾, The friction tests were conducted on an adequately developed device under dry and lubricated conditions. Human saliva, olive oil, Aloe Vera oil, sesame oil and sunflower oil

were used as biolubricants. The friction force was examined as a function of the ligation method and oil temperature. It was found that under oil lubrication, the friction behavior in the archwire/bracket assembly was the best. The SLB ligation was better than the conventional ligation system. The enhancement of the frictional behavior with natural oils was linked to their main components: fatty acids. Renata C. et al.⁽²⁷⁾, evaluated the effect of different lubricants on friction between orthodontic brackets and archwires. They showed that, no significant interaction between bracket type and lubricant ($P = .324$). The friction force obtained with passive self-ligating brackets was lower than that obtained with active brackets ($P < .001$). Friction observed in the presence of artificial saliva did not differ from that generated under lubrication with natural human saliva, as shown by the Tukey test. Higher friction forces were found with the use of distilled water or when the test was performed under dry condition (i.e., with no lubricant).

Conclusion:

1. Local application of Olive Oil decreased the alignment phase duration.
2. Local application of Olive Oil decreased the surface roughness of the used arch-wires during orthodontic treatment.
3. Local application of Olive Oil decreased the friction at the bracket-wire interface.

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