

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 considered to be 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 there is saliva 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 we can use it to decrease friction between brackets and wires? and which type of oil we can use safely in patient mouth? 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 (pinorexinol), 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 local application of Olive Oil in decreasing the friction between brackets and wires during orthodontic treatment.

Aim & objectives:

Primary outcome:

To detect the effect 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 and stainless steel archwires when using Olive Oil as a lubricant and without usage of a lubricant.

Study Design:

A Randomized Controlled Clinical Trial will be performed according to CONSORT guidelines

Selection and Exclusion of Subjects:

Patients who will be enrolled in this study should have the following criteria:

1. The age of patients ranges from 15–20 years old.
2. Mild to moderate dental irregularity requiring non-extraction treatment.
3. Presence of all the permanent teeth at least up to the first molars.
4. Good oral hygiene, and periodontal health.
5. Patients will be excluded if they require 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 will be obtained after informing the patients and/or their parents of the interventions and the possible effects associated with them.

Ethics approval for this clinical trial was obtained from the Ethics Committee of 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.

Assessment of Efficacy:

Little's irregularity index ⁽¹⁹⁾ will be used to assess the changes in dental alignment throughout the study. All the measurements will be made on the study models reproduced from alginate impressions that will be taken for both arches: immediately before brackets bonding(T0), after one month(T1), after two months(T2), after three months(T3), and after four months(T4). All measurements will be done using an electronic digital caliper (Dentaurum, Inspringen, Germany) with an accuracy of 0.01 mm.

Scanning electron microscopic images will be taken for the NiTi wires that will be used for teeth alignment to assess the changes in surface roughness of these wires.

Adverse Events:

Any adverse effects that will be noticed or reported from patients resulting from Olive Oil usage will be reported.

Statistical analysis plan:

The means and standard deviations (mean ± SD) of the quantitative variables will be used to describe the relevant variables in the sample. Descriptive statistics (means, standard deviations, and percentages) will be calculated using SPSS v-20 (SPSS Inc., Chicago, IL, USA). Also inferential statistics in form of student’s t-test and repeated-measurements analysis, with the significance level of 0.05, will be used to analyze the outcome measurements.

Data management:

The data will be analyzed to get the statistical and clinical significance.

Project Timetable Flowchart:

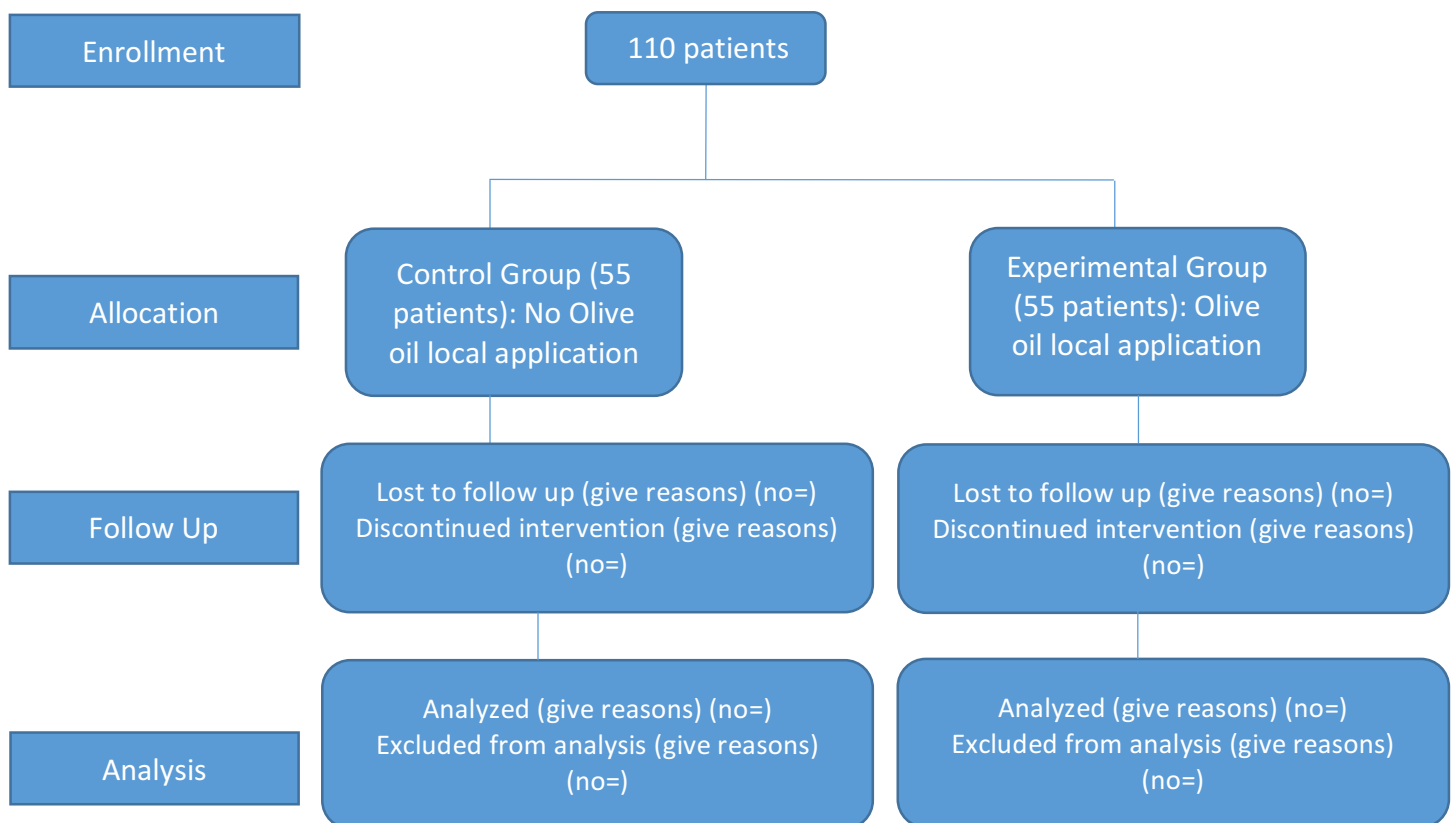


Figure (1): CONSORT Flow Diagram

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Supplements/Appendices :

Informed Consent Form

Personal Data:

Patient Name:

Age:

Address:

Mobile NO.:

Research Title:

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Volunteer Returned on Benefits:

The Volunteer will get all the orthodontic treatment for free.

Expected Side Effects of the treatment:

Regarding the Olive oil, no side effects are expected as the consumption of Olive Oil is suggested in a healthy diet instead of other types of oils.

While regarding the common side effects of orthodontic treatment are pain and ulcerations. Responsible Doctor: Ahmed Nasef, Lecturer of Orthodontics, Faculty of Dentistry, Minia University. Mobile No.: 01003383457

Volunteer Signature: _____

Doctor Signature: _____