Evaluation of enamel demineralization during clear aligner orthodontic treatment with QLF compared to conventional fixed appliances: a randomized clinical trial

Materials and Methods:

Study design and settings

This was a prospective randomized clinical trial of two arms conducted at the postgraduate Dental Teaching Clinics/ Jordan University of Science and Technology (JUST).

Before starting, an ethical approval was obtained from the institutional Review Board (IRB) of JUST and King Abdullah University Hospital (IRB# 27/98/2016).

Sample size was determined to be at least 19 patients (per group) to yield a power of 80% in detecting 2.0% difference change in lesion fluorescence (ΔF). These assumptions were based on a previous in vitro trial on permanent teeth using the same QLF system.[10]

Participants

All participants were informed verbally and in writing about the study and received an informed consent letter to read and sign at home.

The inclusion criteria consisted of healthy patients from both genders aged (17 – 24 years), class I malocclusion with mild to moderate crowding (≤ 5 mm), non-extraction treatment plan, optimum oral Hygiene before treatment as determined by clinical examination: Plaque Index 1 or less, Gingival Index 1 or less and less than 1.5 score of the ΔR_{30} value in the QLF images.

measured by the QLF images, healthy gingiva without signs of gingivitis and/or periodontitis, maximum of 3 restored teeth and absence of defective enamel formation in the form of

hypocalcification or hypoplasia. Patients with poor oral hygiene, defective enamel, extensive restorations and salivary glands diseases were excluded.

Out of 113 examined patients, a total of 49 patients fulfilled the selection criteria and agreed to participate in the study.

Randomization

The participants were randomly assigned into one of the following study groups according to a simple randomization method using a coin toss by the patient; the text side of the coin indicating treatment with CA (Group 1) and the head side of the coin indicating orthodontic treatment with FA (Group 2).

Intervention

In Group 1, patients received treatment with clear aligners (EON Aligner®, Minneapolis, USA). This group composed of 27 participants; 7 males and 20 females with a mean age of 21.2 years. Group 2 comprised 22 patients received orthodontic treatment with FA (3M Unitek Gemini Metal Brackets, Monrovia, USA). This group included 3 males and 19 females with a mean age of 21.3 years.

Orthodontic therapy took place once the patients' oral hygiene status was assessed to be adequate to support treatment with either CA or FA therapy.

All participants received strict oral hygiene regime instructions and dietary advice; they were informed that it is of paramount importance to brush their teeth at least twice a day and preferably after each meal, and to spend at least 3–4 minutes while brushing every time. For the

aligners group, patients were instructed not to eat while wearing the appliance and to brush their teeth and aligners before wearing them back.

The risks associated with poor oral hygiene practice while undergoing orthodontic treatment (such as periodontal problems and the development of WSLs) were explained to the participants along with a prescription for a fluoridated toothpaste (over the counter toothpastes with~1500 ppm fluoride concentration), mouth rinse (Over-the-counter solutions of 0.05% sodium fluoride (230 ppm fluoride) for daily rinsing), interdental and orthodontic brushes. The previous instructions were re-enforced similarly in the two groups during the course of the study just before the commencement of the treatment and at all the consequent appointments. The participants` compliance with the given oral hygiene instructions was assessed by the clinical evaluation at each appointment and judged by the visual inspection for the amount of plaque accumulation along with gingival examination for any signs of inflammation (gingival enlargement and bleeding on probing).

All the recruited patients undertook the orthodontic therapy normally with monthly appointments for the appliances adjustment and follow-up. No changes to methods after trial commencement occurred.

For the CA Group, the composite resin attachments (3M Unitek Transbond LR Adhesive) were placed after teeth preparation with 37% phosphoric acid etching for 20-30 seconds, followed by primer application (3M Unitek Transbond XT Primer) and light curing. Excess composite resin was removed with plastic instrument before curing. Bonding the brackets for the FA Group was carried on by etching the enamel surface with 37% phosphoric acid for 20-30 seconds, followed by priming (3M Unitek Transbond XT Primer) and adhesive resin application (3M Unitek

Transbond XT adhesive). Excess composite resin flash was carefully removed before light curing.

Fluorescence images of all patients were recorded for the maxillary and mandibular anterior and premolar teeth before orthodontic treatment and after 3 months from bonding the appliances with the QLF system (Inspektor Research BV, Amsterdam, The Netherlands). The images were captured through a customized software (QA2 version 1.18, Inspektor research B.V., Amsterdam, The Netherlands) using a Canon EOS 550D with Canon 60mm f/2.8 USM macro lens and Biluminator™ Tube with the following specifications: 112 mm length and 70 mm diameter, blue illumination 12 high performance LED, white illumination 4 LED and QLF special high-pass yellow Filter system. Three images were captured at each occasion (Frontal, Right and Left) for every patient to examine the extent of mineral content for all bonded teeth.

To increase the reproducibility of the QLF imaging technique, the distance between the patients and the lens was nearly constant in all occasions and several images were taken in each view to attain good quality images for analysis.

The size and orientation of the images was adjusted through a special application of the software. All the QLF images were taken in a dark room with the patients seated in a dental chair with a fixed position.

QLF images were judged visually for signs of decalcification, which appears as dark areas surrounded by bright green fluorescing sound tooth tissue. The QLF images were then analyzed using customized software (QA2 version 1.18, Inspektor research B.V., Amsterdam, The Netherlands) to calculate 3 parameters for WSL; the surface area of the WSL (in Pixels), the

average lesion fluorescence loss (ΔF%) reflecting mineral loss in percent and the deepest point in the lesion expressed as ΔF_{Max} (%).

Additionally, one parameter was measured for plaque; ΔR_{30} (%) which is the number of pixels on the total tooth area that have red fluorescence intensity 30% above the red fluorescence of a clean tooth surface calculated in percent (ΔR_{30}/SurfaceArea*100).

Presence or absence of lesions was scored on a per-surface base in each patient. In detected lesions, the fluorescence loss and lesion area were determined by using the system's analysis software. A patch was drawn around the lesion site with its borders on sound enamel (Figure 1a). Inside this patch, the fluorescence level of sound tissue was reconstructed by using the fluorescence radiance of the surrounding sound enamel (Figure 1b). Then the percentage difference between the reconstructed and the original fluorescence levels was calculated. Contour points were used to outline the lesion surface area in pixels².

The amount of plaque was calculated using the same software (QA2) by drawing a patch around all the teeth in the image field (Figure 2).

Capturing and analyzing QLF images along with orthodontic treatment for all the participants was carried out by the first author (Z.A) of the study. Due to the nature of the study, blinding was not possible since the appliance is shown in the images. Nevertheless, data assessment and analysis were blinded as they were performed solely by the second author (S.A).

Twenty pictures were randomly selected from the patients' list and re-analyzed after 20 days interval from the initial analysis to determine measurement error in this study. The method error was calculated using Dahlberg's double determination formula. Houston coefficient of reliability was also calculated.

Houston's coefficient of reliability was above 90 per cent. The values of Dahlberg error were 0.8% for ΔF, 12.6 pixels for lesion area, and 1.1% ΔR_{30} for plaque measurements.

Mean and standard deviation for all the measured parameters pretreatment (T0) and three months after the commencement of treatment (T1) were calculated using the Statistical Package for the Social Science (SPSS version 19, Chicago, IL, USA).

Chi square test was used to detect if there was a difference in the number of newly developed WSLs in each group and compare between the two groups regarding the incidence of new lesions during the treatment.

Paired t-test was used within each group to determine the changes in all measured parameters within groups. Independent Student’s t-test was used to check differences between the two groups regarding mineral change, lesion area and amount of plaque.

P value was set at 0.05 level.