The effect of the Er: YAG laser on the clinical success of hydrophilic fissure sealant: a randomized clinical trial

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Introduction

The term fissure sealant is used to describe a material that is applied to pits and fissures that are susceptible to caries, forming a micromechanically bonded layer on the enamel and preventing the growth of cariogenic bacteria. Traditionally, the retention of the sealant is maintained by etching the enamel using various concentrations of phosphoric acid (1). Cueto and Buonocore (2) published their first paper on the successful application of sealants for pits and fissures in 1967. According to their study, at the end of one year, caries incidence was decreased by 87%, and 71% of the sealants were fully retained.

The efficacy of sealants for caries prevention depends on the long-term retention of the material (3). Retention rates show variation due to proper isolation of the working field, viscosity of the sealant, roughening of the enamel surfaces, and use of the adhesive system.

The most widely used enamel conditioning procedure is acid etching that selectively erodes the hydroxyapatite rods prior to resin based fissure sealant application. However, there are some disadvantages of acid
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etching, such as the removal of superficial enamel, formation of various etching depths, and high sensitivity to water or saliva contamination and demineralization, which cause the enamel to be susceptible to caries and produce unsatisfactory bonding (4-6). Therefore, alternative methods have been proposed for the preparation of the enamel.

Laser etching has been suggested as a pretreatment method to roughen the enamel. It has the advantage of cleaning, conditioning and decontamination of barely accessible fissures only in one step, and it is a painless procedure that does not involve vibration or heat (6,7). Studies confirmed that, the use of a laser changes the calcium/phosphorus ratio, making the tooth structure more stable and resistant to acid attacks (8).

Contamination by saliva is often experienced in pediatric patients, which deteriorates the quality of adhesion between the enamel and fissure sealant in pediatric dentistry (9). Hydrophilic sealants were introduced that bond effectively to moist enamel surfaces to overcome this problem. UltraSeal XT™ hydro™ is a new moisture-tolerant, self-adhesive, light-cured hydrophilic pit and fissure sealant. This material is reported to chase moisture into the pits and fissures, eliminating moisture related failures (10). There are many in vitro studies investigating the effect of Er:YAG lasers on hydrophilic fissure sealants. The number of clinical studies comparing the retention rates of fissure sealants applied using conventional acid etching, laser etching or the combination of laser and acid etching are limited (11-13). The results of the studies still have the conflicting results if Er:YAG laser is a useful tool for enamel surface conditioning prior to placement of fissure sealants. While some authors reported that acid and laser etching provided similar results in terms of sealant retention rate (14,15), some of them suggested the use of acid after laser application and reported that the application of laser did not eliminate the need for acid etching (16). Moreover, a recently published in-vitro study showed that bond strength of a sealant to phosphoric acid etched enamel was significantly higher than that Er:YAG laser etched enamel (17).

The aim of this study was to evaluate the effect of the Er:YAG laser on the clinical success of a hydrophilic fissure sealant over 12 months. The null hypothesis tested herein was that the Er:YAG laser had not improve the clinical success in terms of retention rates and caries development rates of a hydrophilic fissure sealant.

Subject and Methods

The protocol and consent form for this study were reviewed and approved by the Aydın Adnan Menderes University Faculty of Dentistry Ethics Committee (ADUDHF2018/048-2017/089). The study was registered (Protocol Registration Receipt NCT03718689) at http://www.clinicaltrial.gov. Written informed consent was obtained from the parents of the participants.

The participants were selected from the patients attending the Adnan Menderes University Faculty of Dentistry. The treatment procedures, possible side effects and benefits were explained to the participants/caregivers. Written informed consent was obtained from participants/caregivers, who signed the informed consent prior to participation.

Patients eligible to participate were healthy individuals aged 7-11 years with at least three non-curious first permanent molars requiring fissure sealant. The inclusion criteria for the study were as follows:

- Good general health and having a high caries risk with a dmft (decayed, missed and filled tooth) value between 4 to 6
- Fully erupted permanent first molar teeth with deep, narrow fissures
- No detectable occlusal or proximal caries
- Children with satisfactory cooperative behaviour (18) (Frankl score 3 or 4)

The exclusion criteria for the study were as follows:
- The presence of systemic pathology or history of allergic reaction to the materials used in the study
- Having hypomineralized areas, such as fluorosis or molar incisor hypomineralization

The plaque and debris were removed using a polishing brush and pumice. Caries status was assessed using a DIAGNOdent pen (DIAGNOdent 2190, KaVo, Biberach, Germany) at the occlusal and proximal sites. Teeth having DIAGNOdent readings of 12 or less at the occlusal site and 7 or less at the proximal site were included in the study.

Sample size determination

The sample size required was determined to be 132 teeth (44 teeth per group) using G-power software based on a study by Karman et al (14) for a power of 95% (α=0.05, 1-β=0.95).

Randomization

A total of 132 permanent first molars from 44 patients, three in each patient, were included in the study. They were randomly assigned using block allocation. A table of random numbers was used to assign the teeth for the groups.

Groups and procedures

In the acid group (Group A-control), teeth were etched with 35% phosphoric acid (Vocociid®, Voco Products, Cuxhaven, Germany) for 20 seconds, rinsed and lightly air-dried as suggested by the manufacturer. UltraSeal XT® hydro™ (UltraSeal XT® hydro™, Ultradent Products, South Jordan, Utah, USA) was then applied by a previously calibrated operator and light-cured for 20 seconds with an LED curing unit (Monitex Ti-Lite Gt 1500, New Taipei, Taiwan). Then, the sealants were clinically checked for adequacy, and the occlusion was checked with an articulation paper.

In the laser group (Group L), teeth were etched with an Er:YAG laser system (LightWalker STE-E, Fotona Medical Lasers, Ljubljana, Slovenia) using a noncontact handpiece (RO2) with the following settings: the wavelength was 2.94 µm, the power was 3.6 W, the energy output was 180 mJ, a short pulse duration, the frequency was 20 Hz, and the beam spot size was 0.6 mm. The Er:YAG laser applied to fissures at a working distance of 1-2 mm aligned perpendicularly to the target area with water cooling (air/water ratio of 6/4). The duration of exposure depended on the time needed to guide the laser beam evenly across the pits and fissures to be irradiated (14). During the laser application, the operator, patient and parent wore protective glasses. The teeth were then air-dried, and UltraSeal XT® hydro™ that is a moisture-activated, self-adhesive, acrylate-based hydrophilic fissure sealant was applied as described for group A.

In the acid and laser group (Group A+L), teeth were etched with an Er:YAG laser and phosphoric acid, and the fissure sealant was applied as described above.
Follow-up

An examiner who was unaware of which etching protocol was used independently evaluated the sealants at baseline and at 3-, 6-, 9-, and 12-month follow-up visits. At the beginning of the study, the kappa value was calculated to test intra-examiner reproducibility. The kappa value was high (0.93) and showed strong intra-examiner agreement. The teeth were assessed using a mouth mirror and explored for new caries formation and retention of the fissure sealants. Sealant retention was recorded according to Simonsen’s Criteria as follows: 1 was total retention (TR), 2 was partial retention (PR), and 3 was total loss (TL) (15). Partial retention or total loss was noted as failure and total retention was noted as success for survival analysis.

Each sealant was evaluated for the presence or absence of caries formation. Loss of enamel translucency along the margins and softness at the base of the exposed fissures were noted as caries presence. In case of a partial or total loss of the sealants were observed, they were noted as failure and we evaluated the teeth found to be successful in the follow-up periods. However, when partial or total loss of the sealant was observed, such sealants were repaired or replaced in the same appointment and those teeth excluded from the study.

Statistical analysis

Data were analyzed with SPSS 24.0 (SPSS 24.0 for Windows, SPSS Inc., Chicago, IL, USA). Pearson’s chi-square tests were used to evaluate differences in the retention rates of sealants applied with different etching techniques for each evaluation period at a 5% level of significance. The total retention rates at baseline and all recall times for each group were compared using Cochran’s Q test and Dunn’s Multiple Comparison test. The intra-examiner reproducibility was determined using Cohen’s kappa statistics by re-examining 10 patients one week after the examination period. Additionally, Kaplan-Meier survival analysis and log-rank tests were used to estimate the probability of the etching protocol’s success.

Results

A total of 132 teeth were sealed in 44 patients (19 girls and 25 boys) and all patients attended all visits, resulting in a recall rate of 100%. An equal number of fissure sealants were applied to the maxillary and mandibular teeth. There was no statistically significant difference in retention rates of the sealants in terms of jaw type (p>0.05). The mean age of the participants was 8.97±1.62. The age distribution of the sample was as follows: 7 years old (27.3%), 8 years old (20.5%), 9 years old (9.1%), 10 years old (13.6%), 11 years old (29.5%).

Figure 1 represents the flow chart of the patients and first permanent molars included in this study. Caries were not observed in any of the sealed teeth throughout the 12-month follow-up period, and none of the teeth exhibited total loss of sealant. Retention rates of the groups at baseline and 3-, 6-, 9-, 12-, month recalls and comparison of the sealant retention rates of the groups at each time interval and intragroup comparisons with baseline for total retention rates for each group is displayed in Table 1. Figure 2 shows the sealant retention distribution along with total retention and partial and total loss of sealants at all follow-up periods.

Table 1. Retention rates of the groups at baseline and 3-, 6-, 9-, 12-, month recalls and comparison of the sealant retention rates of the groups at each time interval and intragroup comparisons with baseline for total retention rates for each group

| Group | Baseline, n (%) | 3-Months, n (%) | 6-Months, n (%) | 9-Months, n (%) | 12-months, n (%) |
|-------|----------------|----------------|----------------|----------------|-----------------|
|       | A | L | A+L | A | L | A+L | A | L | A+L | A | L | A+L | A | L | A+L |
| TR    | 44 (100) | 44 | 44 | 44 | (97.7) | 43 | (95.5) | 39* | (88.6) | 37* | (84.1) | 38* | (86.4) | 35* | (79.5) | 33* | (75) | 35* | (79.5) | 32* | (72.7) | 26* | (59.1) | 29* |
| PR    | 0 | 0 | 0 | 0 | (1.2) | 0 | (1.2) | 0 | (1.2) | 0 | (1.2) | 0 | (1.2) | 0 | (1.2) | 0 | (1.2) | 0 | (1.2) | 0 | (1.2) | 0 | (1.2) | 0 | (1.2) |
| TL    | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 |
| p value | 1.00 | 0.77 | 0.82 | 0.83 | 0.40 |

TR, total retention; PR, partial retention; TL, total loss; A; acid; L; laser; A+L, acid and laser. *Significant difference in comparison with baseline according to Cochran’s Q test for total retention rates in each group (p<0.05)
At the 3-month follow up, the total retention rate of sealants in Group A and Group L was 97.7%, which was not significantly different from Group A+L with a total retention rate of 95.5% (p>0.05). At the 6-month follow up, the total retention rates of sealants in Group A, Group L and Group A+L were 88.6%, 84.1%, and 86.4%, respectively, and the difference between the groups was not statistically significant (p>0.05).

At the 9-month follow up, the retention rate of sealants in Group A and Group A+L were 79.5%, while it was 75% for Group L. There were no significant differences in the retention rates among the three groups at any of the evaluation times (p>0.05).

At the 12-month follow up, the total retention rates of sealants in Group A, Group L and Group A+L were 72.7%, 59.1%, and 65.9%, respectively, and the differences among groups were not statistically significant (p>0.05).

Differences between baseline and each recall time within each group are displayed in Table 1. There were no statistically significant differences between the baseline and 3-month recall for the groups (p>0.05). For all groups, significant differences were observed between the baseline and 6-month recall, 9-month recall and between the baseline and 12-month recall (p<0.05) (Table 1).

Figure 3 shows cumulative survival analysis of the groups. The Kaplan-Meier survival analysis and log-rank (Mantel-Cox) test revealed that there were no significant differences in retention rates of the sealants among three groups (p>0.05).

Discussion

The present study compared the clinical performance of hydrophilic fissure sealant applied using conventional acid etching, an Er:YAG laser or a combination of an Er:YAG laser and acid etching in terms of the retention rate and caries formation over a 12-month period.

Fissure sealant applications are considered as effective method for preventing caries formation on occlusal surfaces of newly erupted posterior teeth (19). The fissure sealant material should penetrate to the roughened enamel surface for successful retention. Penetration of resin material depends on the etching and wetting ability of the enamel, the surface tension of the fissure sealant material and the degree of (20). Newly erupted teeth are less mineralized and have less resistance to acid attacks because maturation is not completed (19). Poor behaviour of child during the sealant application may interrupt the sealant retention rates. In this study, we used rubberdam isolation to eliminate the saliva contamination and Er:YAG laser for etching procedure. The complicated study protocol could not be tolerated in the younger age group. Moreover, the caries risk evaluation in terms of dmft value (dmft:4-6) was an inclusion criteria for the study. Therefore, patients with high caries risk aged 7-11 years who could cope with this study protocol were selected for the study.

In vivo and in vitro studies confirmed that DIAGNOdent pen in noncavitated occlusal lesions indicate that the device can diagnose caries lesions with high sensitivity (21-23). Therefore, the DIAGNOdent pen was used in this study to detect caries at the beginning of the study.

The success of fissure sealants increases with the quality of adhesion between sealant and enamel. The adhesion and retention of sealant are provided mainly from micromechanical interlocking that exists between the resin and enamel (24). The enamel surface is then roughened to increase the surface area for the micromechanical interlocking of the sealant (14). Lasers have been introduced as an alternative to acid etching for surface preparation for use with fissure sealants (9). There are controversial findings in the literature on the effectiveness of lasers in conditioning the enamel before fissure sealant application. Baygin et al. (25) and Shahabi et al. (26) reported that laser conditioning may be an alternative to conventional acid etching but does not eliminate the need for acid etching prior to placement of a fissure sealant. According to the results of the present study, the retention rate was 72.7% in Group A, 59.1% in Group L and 65.9% in Group A+L. Our study agrees with Baygin et al’s and Shahabi et al’s studies because the highest retention rate was seen in the acid etching group, and the lowest retention rate was observed in the laser group without statistically significant difference. Moreover, when the laser was used in combination with acid etching, the retention rate increased from 59.1% to 65.9%. Contrary to our study, Durmus et al. (27) stated that fissure sealants placed with the Er:YAG laser combined with acid etching showed significantly higher retention rates than those placed acid etching alone. The different results might have been due to different laser output characteristics, types of fissure sealant material and experimental designs.
SEM images of the Er:YAG laser-conditioned permanent enamel revealed uneven areas and modified hydroxyapatite crystals. The superficial micromorphology of the laser-conditioned enamel is due to the microexplosive ablation process, which characterizes the nonselective thermal effect of the Er:YAG laser (28). The fact that the laser beam is pulsed and does not have a continuous structure creates areas that are not exposed to laser radiation between the pulses. This irregular structure is thought to adversely affect the bond strength of the fissure sealant (29,30). For this reason, etching the surfaces with phosphoric acid after laser applications is recommended for roughening the areas that are not exposed to the laser, thus forming a regular structure (31).

Energy parameters used for laser conditioning (power, pulse velocity, working distance, tip diameter) have a significant effect on bond strength. However, there is no consensus on the optimal laser parameters. In this study, the parameters determined by the laser manufacturer for enamel etching were used (wavelength: 2.94 μm, power: 3.6 W, energy: 180 mJ, frequency: 20 Hz, and pulse time: 50 μs). Üşümez et al. (32) evaluated the shear bond strength of orthodontic brackets for conditioning with different energy parameters of an Er: Cr: YSGG laser and 37% orthophosphoric acid. In the study, the bond strength values obtained with 1 W were found to be significantly lower than the values obtained with acid etching. There was no statistically significant difference between the bond strength values obtained with 2 W and those obtained from acid etching.

Prabakar et al. (33) placed UltraSeal XT® hydro™ to fissures of mandibular first permanent molars following acid etching and they stated that the retention rate was 78.3% of The UltraSeal XT® hydro™ at three months follow-up. In this study, retention rate of the acid etch group was 97.7% at three months follow up.

Laser conditioning techniques have gained popularity in recent years. The laser conditioning process has several advantages, such as being less time consuming, removing debris more effectively, reaching narrow fissures and increasing acid resistance of the enamel (6,25,34). However, the disadvantage of this method is that the type of laser and the energy parameters have not yet been optimized. In addition, many commercial resin based fissure sealants are produced for applying on acid-etched enamel surfaces. The development of specific materials for laser-conditioned surfaces may be suitable for increasing the longevity of fissure sealants. The present study found no significant differences between the three enamel conditioning methods. Therefore, the null hypothesis should be accepted.

**Conclusion**

Etching with the Er:YAG laser, phosphoric acid or a combination of both methods provided similar results in clinical success rate of hydrophilic fissure sealant.

**Ethics Committee Approval:** The protocol and consent form for this study were reviewed and approved by the Adnan Menderes University Faculty of Dentistry Clinical Investigations Ethics Committee (ADUDHF2018/048-2017/089). The study was registered (Protocol Registration Receipt NCT03718689) at http://www.clinicaltrial.gov. Written informed consent was obtained from the parents of the participants.

**Informed Consent:** The informed consents were provided by the participants.

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**Author contributions:** SK and HY participated in design of the study. SK and HY participated in generating the data for the study. SK and HY participated in gathering the data for the study. HY participated in the analysis of the data. HY wrote the majority of the original draft of the paper. SK and HY participated in writing the paper. All authors approved the final version of this paper.

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