Performance of Universal Adhesives containing M-TEG-P and 10-MDP in Non-Carious Cervical Lesions in Geriatric Patients: A One-year Randomized Clinical Trial

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Abstract

Aim: The aim of the present study was to evaluate the clinical performance of a moisture resistant, M-TEG-P phosphate monomer based universal adhesive (TMR-Aquabond0, YAMAKIN CO., Japan) compared to conventional 10-MDP containing universal adhesive (Single Bond Universal Adhesive, 3M ESPE, USA) in geriatric patients with NCCLs. Materials and methods: This randomized, double-blind clinical study enrolled 28 participants who met the inclusion criteria. NCCLs were restored using nano hybrid universal resin composites preceded with either Aquabond0 or Single bond universal adhesive. The restorations were evaluated using the FDI World Dental Federation criteria at baseline (1 week), 6 and 12 months, measuring fractures and retention, marginal adaptation, marginal staining, post-operative sensitivity and secondary caries. Categorical data was described as frequency and percentage, intergroup comparisons between interventions were performed using Chi-Squared test with statistical significance level set at (P ≤ 0.05), survival rate was analyzed using Kaplan-meier and Log-rank test. Results: There was no statistically significant difference between both groups, for all outcomes P>0.05. However statistically significant differences were found regarding survival analysis (P=0.034) where 10-MDP containing adhesive showed higher survival rate than M-TEG-P phosphate monomer based universal adhesive. Conclusion: Both universal adhesives presented acceptable clinical performance after 12 months of clinical service in NCCLs in geriatric patients. However, it should be noted that (Single Bond Universal, 3M ESPE, USA) showed a better survival rate.

Keywords: M-TEG-P, 10-MDP, Universal adhesives, Adhesive dentistry, Non carious cervical lesions

I. INTRODUCTION

Dental adhesives and resin composites are the first choice for tooth tissues defects due to their excellent esthetics and direct-filling capabilities. Despite great improvements in dental adhesives, the dentin-resin interface is still the weakest area in resin composite restorations due to dentinal bond degradation, micro-leakage and gap formation which provide an effective pathway for invasion of oral plaque biofilms and the development of secondary caries around the tooth-restoration margins. Therefore, improving the bond durability and preventing bacterial invasion are pivotal issues
for inhibiting secondary caries and increasing the restoration longevity. Therefore, there was an increasing demand for simplified adhesive systems which led to the development of a next generation dental adhesives termed universal adhesives

Wawrzynkiewicz et al., (2020).

When an adhesive is applied to the treated dentin, it is thought that osmotic pressure causes the interstitial fluid to leak from the dentinal tubule to the interface. It is very difficult to prevent moisture from penetrating into this adhesive, and there are many uncertainties as to how much moisture permeates an area of the cavity and to what extent it becomes a hindrance to adhesion

Sakamoto et al., (2016). Also, there are so many factors inherent to dentin, such as the presence of humidity, presence of caries-affected tissue, degree of demineralization, and lack of retention due to high tissue loss, have been associated with failure at the adhesive interface. In addition, external factors such as pH challenges, saliva, and thermal-mechanical stresses may contribute to reduced longevity of the restorations


Tooth wear is a universal physiological phenomenon, with slow irreversible progression. It is usually associated with aging and parafunctional habits. Non-carious cervical lesions (NCCLs) are type of tooth wear which occurs close to the cementoenamel junction (CEJ) despite the presence or absence of micro-organisms. The pooled prevalence of non-carious cervical lesions (NCCLs) worldwide is 46.7% higher in geriatric patients

Santis et al., (2017). NCCLs are the most ideal lesions to test the clinical effectiveness of adhesives in clinical trials. These lesions commonly do not provide any (or they provide minimal) macro-retention. Therefore, ineffective bonding will result in debonding and thus restoration loss. Loss of retention is the key objective parameter against which the bonding performance of adhesives in NCCL clinical trials is evaluated

Peumans et al., (2020).

Geriatrics refers to medical care for older adults, an age group that is difficult to define accurately. Despite there is no set age to define older age, patients older than 65 years are often described as geriatric patients. Also, from a chronological point of view, medical treatment of the elderly (geriatrics) starts from the age of 65 years old


A higher percentage of failures was observed in restorations placed in the cervical region compared to occlusal and anterior restorations, and the longevity of the restorations was unsatisfactory. Factors that lead to unsuccessful non-carious cervical lesion (NCCL) restorations is the differences of the tooth substrate that are being faced, including occluded dentinal tubules constituting the sclerotic formation, the presence of bacteria on the lesion surface and acid-resistant hyper-mineralized layers. All this serves as a barrier to the diffusion of primer and resin infiltration in a manner similar to the smear layer of intact dentin. As such, there is a need for new techniques and improvements in the adhesion of restorative materials to prolong the clinical longevity of restored cervical lesions

Akarsu et al., (2020). Despite the outstanding clinical performance of many universal adhesives in dentin bonding and restorations durability in NCCLs, "Simplifying the method of adhesion" includes reducing or shortening the steps required for adhesion; for example, the wait time (decalcifying time) until the surface is etched after application of the adhesive to the tooth substance, or shortening the time required for visible light activation (light activation time) in the subsequent curing is highly needed in modern dentistry

Washino et al., (2016). Therefore, to improve bonding to dentin a novel adhesive containing M-TEG-P® phosphate monomer was introduced. This monomer succeeded in developing an adhesive whose components will not exhibit phase separation during the solvent volatilization that occur after application, and whose adhesion will not be susceptible to influence by the amount of moisture mixed into the adhesive layer

Yamakin Group., (2016). The M-TEG-P monomer containing universal adhesive (TMR-Aquabond0, YAMAKIN CO., Japan) has shorter decalcifying time which enables the next step of the process to be performed, solvent removal by air-blow immediately after the adhesive is applied on the tooth surface. It also has shorter light activation time as long as the LED lamp has a light amount of 1000mW/cm2 or more, AQUA- BOND can be cured and adhere well with good reproducibility with activation of ten seconds or more without any particular additional requirements. Furthermore, in the case of LED lamps with a light amount of
2400mW/cm² or more, adhesion by activation for three seconds or longer can be reliably achieved Washino et al., (2016). This recently developed universal adhesive has an additional chemical bonding potential between the functional monomers and the components of dentin. Studies have shown that this bond is more stable to hydrolytic degradation than other functional monomers Ranjitha et al. (2020)

Since there’s limited clinical data available and due to the increased popularity of universal adhesives has led us to the design of this clinical trial. The clinical performance of two universal adhesives, namely 10- MDP-containing universal adhesive (Single Bond Universal, 3M ESPE, USA) and M-TEG-P containing universal adhesive (TMR-Aquabond0, YAMAKIN CO., Japan) placed in NCCLs for geriatric patients was evaluated over a period of 12 months. The null hypothesis tested was that there is no difference in clinical performance between the two adhesives in regards to fractures and retention, marginal discoloration, marginal adaptation, secondary caries and post-operative sensitivity.

II. MATERIALS AND METHODS

A. Materials

The materials used are summarized in table (1) with their composition, lot number and manufacturer.

Table (1): Materials’ composition, lot number and manufacturer

<table>
<thead>
<tr>
<th>Materials</th>
<th>Composition</th>
<th>Lot Number</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Bond Universal Adhesive</td>
<td>MDP Phosphate Monomer, Dimethacrylate resins, HEMA, Vitrebond Copolymer, Filler, ethanol, water, initiators, silane</td>
<td>10420A</td>
<td>3M ESPE, 2510 Conway Avenue St. Paul, MN 55144-1000 USA Phone 1-800-634-2249 <a href="https://www.3M.com/dental">https://www.3M.com/dental</a></td>
</tr>
<tr>
<td>Etch-Rite™ XT</td>
<td>38% Phosphoric acid, Water, Synthetic amorphous silica, Polyethylene glycol</td>
<td>160728</td>
<td>PULPDENT Corporation 80 Oakland Street Watertown, MA 02472 USA <a href="https://www.pulpdent.com">https://www.pulpdent.com</a></td>
</tr>
<tr>
<td>Filltek™ Z250</td>
<td>Fillers: Nanohybrid silica/zirconia (82% by weight)</td>
<td>NC99452</td>
<td>3M ESPE, 2510 Conway Avenue St. Paul, MN 55144-1000 USA Phone 1-800-634-2249 <a href="https://www.3M.com/dental">https://www.3M.com/dental</a></td>
</tr>
<tr>
<td>TMR-AQUA BOND 0</td>
<td>M-TEG-P phosphate monomer, distilled water, methacrylate monomer, carboxylic monomer, photopolymerization initiator, ethanol, thickener</td>
<td>01062024</td>
<td>YAMAKIN CO., LTD. 1090-3 Otani, Kamibun, Kagamicho, Konan-shi, Kochi, 781-5451 Japan <a href="https://www.yamakin-global.com">https://www.yamakin-global.com</a></td>
</tr>
<tr>
<td>TMR Z FILL 10</td>
<td>methacrylate monomer, inorganic fillers (silica, alumina, and zirconia: average particle diameter &lt; 20µm), pigments, Inorganic filler content rate Approximately 55 vol%</td>
<td>01042126</td>
<td>YAMAKIN CO., LTD. 1090-3 Otani, Kamibun, Kagamicho, Konan-shi, Kochi, 781-5451 Japan <a href="https://www.yamakin-global.com">https://www.yamakin-global.com</a></td>
</tr>
</tbody>
</table>


B. Methods

- Trial Registration and Ethical Approval

The current study was registered in (clinicaltrials.gov), with trial registration number: NCT05029479. Ethical approval was obtained prior to the start of the study. The study was approved by Research Ethics Committee (REC), Faculty of Dentistry, Cairo University with identification number: 101021

- Study Setting and Design

This study took place in the clinics of the Faculty of Dentistry Cairo University. This is a randomized clinical trial with two groups and parallel, 1:1 allocation ratio, trial framework is equivalence frame. The participants were randomly assigned to each of the two groups (n= 14). The FDI criteria was adopted to evaluate the tested materials as baseline, 6 months, and 12 months.
- **Sample Size Calculation**

A power analysis was designed to have adequate power to apply statistical test of the research hypothesis to evaluate novel moisture resistant, M-TEG-P phosphate monomer-based universal adhesive compared to light cured universal adhesive for restoration of NCCLs after 12 months regarding fracture and retention. According to the results of *Haak et al., (2019)* in which the probability of score 1 for fracture and retention of restorations performed using light cured universal adhesive was (0.99), probability of score 5 was (0.01) with effect size $w=0.98$ (n=9). If the estimated probability of score 1 for fracture and retention of restorations performed using novel moisture resistant, M-TEG-P phosphate monomer-based universal adhesive was (0.9), probability of score 5 was (0.1) with effect size $w=0.8$ (n=13). By adopting an alpha ($\alpha$) level of 0.05 (5%), power=80%. The predicted sample size was a total of 22. Sample size was increased by (20%) to account for possible dropouts during follow-up intervals to be total of (28) cases i.e. (14) for each group. Sample size calculation was performed using G*Power 3.1.9.2 using chi square test.

- **Eligibility Criteria**

**Table (2): Inclusion and exclusion criteria of participants**

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geriatric patients from age 65 years and above</td>
<td>Lack of written informed consent to participate</td>
</tr>
<tr>
<td>Patients willing to commit to the whole period of the study</td>
<td>Patients below 65 years old</td>
</tr>
<tr>
<td>Males and Females included</td>
<td>Allergies to components of the materials used</td>
</tr>
<tr>
<td>Patients complaining from compromised esthetics or sensitivity</td>
<td>Infectious diseases</td>
</tr>
<tr>
<td>-</td>
<td>Mucosal diseases with unclear diagnosis</td>
</tr>
<tr>
<td>-</td>
<td>Inadequate oral hygiene</td>
</tr>
<tr>
<td>-</td>
<td>Severe Bruxism with more than 50% wear</td>
</tr>
<tr>
<td>-</td>
<td>Severe dysgnathia/traumatic occlusion</td>
</tr>
</tbody>
</table>

**Table (3): Inclusion and exclusion criteria of teeth**

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-carious cervical lesions score 2 and 3 according to DAW classification for NCCLs (<em>Loomba et al., 2014</em>)</td>
<td>High caries activity</td>
</tr>
<tr>
<td>Anterior and posterior teeth</td>
<td>Non-vital pulp</td>
</tr>
<tr>
<td>Absence of periapical alterations</td>
<td>Severe periodontal diseases</td>
</tr>
</tbody>
</table>

- **Recruitment**

Patients were recruited from the clinic of Conservative Dentistry Department, Faculty of Dentistry Cairo University, where there was a continuous and high patient flow from which eligible patients could be selected to fulfill the eligibility criteria one month before intervention. Patients were recruited by convenient consecutive sampling until reaching the target sample size. *(Figure 1)*
• **Sequence Generation and Allocation Concealment**

Random Sequence generation: Simple randomization was done by generating numbers from 1:28 using Random Sequence Generator, Randomness and Integrity Services Ltd (https://www.random.org/) either intervention or comparator group. Each generated random number from 1-14 represents the intervention and from 15-28 is the comparator. The operator chose between numbers in an opaque sealed envelope, which was arranged by a contributor who wasn’t involved in any of the phases of the clinical trial.

• **Masking/blinding**

This is a triple blinded study where the volunteers/patients and the assessors were blinded, and the statistician was blinded as well. The operator could not be blinded to material assignment because of the difference in the application protocol of the restorative materials, which prohibited blinding of the operator.

• **Clinical Procedures**

**Field Preparation**

Local anesthesia was administered to the patients (ARTINIBSA 40 mg/ml + 0.01mg/ml solution for injection, Inibsa, Spain). Shade selection was done under appropriate conditions.
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Cavities to be restored were isolated with rubber dam (Nic Tone, Expertech Solutions, Bucharest, Romania) to ensure moisture control of the operative field and lack of contamination of the cavities. Subgingival clamps were used for stabilization and impervious isolation of the teeth (TOR VM Dental Manufacturing Company, Russia).

**Cavity Preparation Steps**

Round bur in a high-speed hand piece (NSK high speed hand-piece Pana Air FX PAF-SU-M4, Japan) with air/water coolant were used to prepare class V cavity preparations (according to lesion depth and width) and a yellow-coded abrasive diamond used to prepare the incisal bevel. Any tooth suffered from pulpal exposure was excluded from the study.

**Intervention group Application “M-TEG-P phosphate monomer based universal adhesive” (TMR-Aquabond0, YAMAKIN CO., Japan):**

The material was applied according to manufacturer instructions as follows: Following the selective enamel etching protocol, the prepared enamel margins were conditioned using 38% phosphoric acid etching gel (Pulpdent, Etch-Rite, USA) for 15 seconds. The surfaces were rinsed and dried with compressed air to remove all excess moisture without desiccating the dentin structure. (TMR-Aquabond0, YAMAKIN CO., Japan) was placed on a disposable dispensing dish and a sufficient amount of the product was applied to the whole inside of the cavity with a disposable applicator brush by rubbing for five seconds (active application). At this point, the adhesive layer was spread into a thinner layer and the whole adherence surface was dried sufficiently to ensure proper infiltration of the adhesive into the dentinal tubules. After drying, adhesive was cured with a dental light curing unit for ten seconds using LED light intensity 1200 mW/cm² (Woodpecker i-LED, Woodpecker Co., Ltd, Guilin, Guangxi, China). Then, universal nanocomposite (TMR-Z Fill 10, YAMAKIN CO., Japan) restorative material was filled into the cavity in increments up to 2mm thick and light cured for 20s. After light curing, shape was corrected, fine grained and extra-fine diamond tips, and sequential polishing discs were used for restoration finishing during the same appointment (Figure 2).

**Comparator group application “10-MDP containing universal adhesive” (Single Bond Universal Adhesive, 3M ESPE, USA):**

The material was applied according to manufacturer instructions as follows: Following the selective enamel etching protocol, the prepared enamel margins were conditioned using 38% phosphoric acid etching gel (Pulpdent, Etch-Rite, USA) for 15 seconds. The surfaces were rinsed and dried with compressed air to remove all excess moisture without desiccating the dentin structure. Single Bond Universal, 3M ESPE, USA was placed on a disposable dispensing dish and a sufficient amount of the product was applied to the whole inside of the cavity with a disposable applicator brush and rubbed for 20 seconds (active application). The adhesive was air dried gently for approximately five seconds to evaporate the solvent and to ensure proper infiltration of the adhesive into the dentinal tubules. After drying, adhesive was light cured with a dental light curing unit for ten seconds using LED light intensity 1200 mW/cm² (Woodpecker i-LED, Woodpecker Co., Ltd, Guilin, Guangxi, China) then nanohybrid

![Figure (2): Selective enamel etching, adhesive and resin composite application of intervention group](image-url)
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composite (3M™ ESPE™ Filtek™ Z250XT, USA) was filled into the cavity in increments up to 2mm thick and light cured for 20 seconds. After light curing, shape was corrected, and restorations were finished and polished in accordance with normal practice. Fine grained and extra-fine diamond tips, and sequential polishing discs were used for restoration finishing during the same appointment (Figure 3).

**Figure (3):** Selective enamel etching, adhesive and resin composite application of control group

- **Outcomes**

The restorations were evaluated using the FDI “World Dental Federation” criteria at baseline (1 week after restoration placement), 6 and 12 months, measuring fractures and retention, marginal adaptation, marginal staining, post-operative sensitivity and secondary caries (Figure 4).

**Figure (4):** FDI criteria for evaluating restorations
Statistical Analysis

Data was analyzed using Medcalc software, version 19 for windows (MedCalc Software Ltd, Ostend, Belgium). Categorical data was described as frequency and percentage, intergroup comparisons between interventions was performed using the Chi-Squared test with statistical significance level set at (P ≤ 0.05), intragroup comparison within each intervention was performed using the Chi-Squared test with statistical significance level set at (P ≤ 0.016) after Bonferroni correction. Relative risk was used to assess the clinical significance. Survival rate was analyzed using Kaplan-meier and Log-rank test. The confidence limit was set at 95% with 80% power and all tests were two tailed.

III. RESULTS

1. Demographic Data

This study was conducted on (28) participants with non-carious cervical lesions that were randomly allocated to the intervention and the comparator arms (n=14). After 12 months 28 participants completed the follow-up with 100% retention rate. Regarding gender, there was 16 males and 12 females in the current study, in the Aquabond group there was 4(28.6%) males and 10(71.4%) females, while in the Single bond universal group there were 12(85.7%) males and 2(14.3%) females, there was statistically significant difference between both groups regarding gender (P = 0.0027). Mean age of the participants in the current trial was 65.5±2 years; mean age within Aquabond group was 65.7±1.2 years, while within the Single bond universal group mean age was 65.3±2.7 years, there was no statistically significant difference between both groups regarding age (P=0.595). According to teeth distribution in the dental arches, there were 7 maxillary incisors, 3 maxillary canines, 4 maxillary premolars, 1 maxillary molar, 3 mandibular incisors, 1 mandibular canine and 9 mandibular premolars in the current study, there was no statistically significant difference between both groups regarding teeth distribution (P = 0.0751). Distribution of teeth is shown in Table (4).

Table (4): Teeth distribution among groups

<table>
<thead>
<tr>
<th>Teeth distribution</th>
<th>Aquabond Universal Adhesive</th>
<th>Single Bond Universal Adhesive</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary incisors</td>
<td>4(57.1%)</td>
<td>3(42.9%)</td>
<td>7(25%)</td>
</tr>
<tr>
<td>Maxillary canines</td>
<td>2(66.7%)</td>
<td>1(33.3%)</td>
<td>3(10.7%)</td>
</tr>
<tr>
<td>Maxillary premolars</td>
<td>3(75%)</td>
<td>1(25%)</td>
<td>4(14.3%)</td>
</tr>
<tr>
<td>Maxillary molars</td>
<td>1(100%)</td>
<td>0(0%)</td>
<td>1(3.6%)</td>
</tr>
<tr>
<td>Mandibular incisors</td>
<td>2(66.7%)</td>
<td>1(33.3%)</td>
<td>3(10.7%)</td>
</tr>
<tr>
<td>Mandibular canines</td>
<td>0(0%)</td>
<td>1(100%)</td>
<td>1(3.6%)</td>
</tr>
<tr>
<td>Mandibular premolars</td>
<td>2(22.2%)</td>
<td>7(77.8%)</td>
<td>9(32.1%)</td>
</tr>
<tr>
<td>Mandibular molars</td>
<td>0(0%)</td>
<td>0(0%)</td>
<td>0(0%)</td>
</tr>
<tr>
<td>Total</td>
<td>14 (50 %)</td>
<td>14 (50 %)</td>
<td>28</td>
</tr>
</tbody>
</table>

2. Clinical Evaluation

Intergroup comparison between both adhesives revealed no statistically significant difference for all tested outcomes at all follow-up periods (P>0.05). Intragroup comparison within Aquabond revealed no statistically significant difference between follow-up periods for fracture and retention, postoperative hypersensitivity, secondary caries (P>0.05), while there was statistically significant difference for marginal adaptation and marginal staining (P<0.016). Intragroup comparison within single bond universal revealed statistically significant difference between follow-up periods for marginal adaptation, postoperative hypersensitivity, and marginal staining (P<0.016), while there was no statistically significant difference for fracture and retention, and secondary caries (P>0.05). Intergroup and Intragroup comparison between the two groups at different time intervals is shown in Table (5).
### 3. Survival Analysis

Overall survival of Aquabond and Single bond universal adhesives in cervical restorations was assessed after 12 months. Four restorations failed after 12 months in Aquabond group due to scoring 4 or 5 in marginal staining, marginal adaptation, and fracture and retention. Kaplan-Meier analysis was used to obtain survival curves, comparison of survival curves was performed using Logrank test, there was statistically significant difference between both adhesives (P = 0.034123). (Figure 5)

**Table (5):** Intergroup and Intragroup comparison between the two groups at different time intervals

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Follow up</th>
<th>Aquabond Universal Adhesive (M-TEG-P)</th>
<th>Singel Bond Universal Adhesive (10-MDP)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Success 1 2 3 4 5</td>
<td>Success 1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Fracture and Caries</td>
<td>Baseline</td>
<td>14(100%) 0(0%) 0(0%) 0(0%) 0(0%)</td>
<td>14(100%) 0(0%) 0(0%) 0(0%) 0(0%)</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td>6 Months</td>
<td>13(92.9%) 0(0%) 0(0%) 0(0%) 1(7.1%)</td>
<td>14(85.7%) 2(14.3%) 0(0%) 0(0%) 0(0%)</td>
<td>0.2187</td>
</tr>
<tr>
<td></td>
<td>12 Months</td>
<td>13(92.9%) 0(0%) 0(0%) 0(0%) 1(7.1%)</td>
<td>14(85.7%) 2(14.3%) 0(0%) 0(0%) 0(0%)</td>
<td>0.2187</td>
</tr>
<tr>
<td>Marginal Adaption</td>
<td>Baseline</td>
<td>14(100%) 0(0%) 0(0%) 0(0%) 0(0%)</td>
<td>14(100%) 0(0%) 0(0%) 0(0%) 0(0%)</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td>6 Months</td>
<td>12(85.7%) 1(7.1%) 0(0%) 1(7.1%) 0(0%)</td>
<td>14(85.7%) 6(42.9%) 0(0%) 0(0%) 0(0%)</td>
<td>0.2921</td>
</tr>
<tr>
<td></td>
<td>12 Months</td>
<td>5(35.7%) 4(28.6%) 2(14.3%) 3(21.4%) 0(0%)</td>
<td>14(28.6%) 7(50%) 3(21.4%) 0(0%) 0(0%)</td>
<td>0.4315</td>
</tr>
<tr>
<td>Postoperative Sensitivity</td>
<td>Baseline</td>
<td>14(100%) 0(0%) 0(0%) 0(0%) 0(0%)</td>
<td>14(100%) 0(0%) 0(0%) 0(0%) 0(0%)</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td>6 Months</td>
<td>11(78.6%) 3(21.4%) 0(0%) 0(0%) 0(0%)</td>
<td>14(85.7%) 2(14.3%) 0(0%) 0(0%) 0(0%)</td>
<td>0.6280</td>
</tr>
<tr>
<td></td>
<td>12 Months</td>
<td>8(57.1%) 5(35.7%) 1(7.1%) 0(0%) 0(0%)</td>
<td>14(64.3%) 5(35.7%) 0(0%) 0(0%) 0(0%)</td>
<td>0.5016</td>
</tr>
<tr>
<td>Secondary Caries</td>
<td>Baseline</td>
<td>14(100%) 0(0%) 0(0%) 0(0%) 0(0%)</td>
<td>14(100%) 0(0%) 0(0%) 0(0%) 0(0%)</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td>6 Months</td>
<td>14(100%) 0(0%) 0(0%) 0(0%) 0(0%)</td>
<td>14(100%) 0(0%) 0(0%) 0(0%) 0(0%)</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td>12 Months</td>
<td>14(100%) 0(0%) 0(0%) 0(0%) 0(0%)</td>
<td>14(100%) 0(0%) 0(0%) 0(0%) 0(0%)</td>
<td>1.0000</td>
</tr>
<tr>
<td>Marginal Staining</td>
<td>Baseline</td>
<td>14(100%) 0(0%) 0(0%) 0(0%) 0(0%)</td>
<td>14(100%) 0(0%) 0(0%) 0(0%) 0(0%)</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td>6 Months</td>
<td>14(100%) 0(0%) 0(0%) 0(0%) 0(0%)</td>
<td>14(100%) 0(0%) 0(0%) 0(0%) 0(0%)</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td>12 Months</td>
<td>4(28.6%) 3(21.4%) 4(28.6%) 2(14.3%) 1(7.1%)</td>
<td>14(28.6%) 7(50%) 3(21.4%) 0(0%) 0(0%)</td>
<td>0.1489</td>
</tr>
</tbody>
</table>

* p < 0.05
* * p < 0.01
* * * p < 0.001
IV. DISCUSSION

There are a lot of factors inherent to dentin, such as the presence of humidity, presence of caries-affected tissue and the depth of demineralization that are known to have been accompanied by the failure of the adhesive interface. In addition, external factors, such as pH challenges, saliva, and thermal-mechanical stresses, contribute to reducing the longevity of the restorations. Consequently, clinical studies are needed to evaluate the longevity of adhesive restorations exposed to all the oral conditions and preferably to be tested in similar conditions Santis et al., (2017).

The interest in more simplified and less technique sensitive adhesion resulted in the development of more versatile adhesive systems, called "universal adhesives" or "multi-mode adhesives", which are simply single-step adhesives that can be applied in etch-and-rinse and self-etch modes or even after selective enamel etching protocol Zanatta et al., (2019).

Enamel and dentin always require different adhesive strategies due to different inherent tissue characteristics. Usually, the adhesives used in dentin are self-etch which provide less aggressive acid conditioning; this decreases the liability of collagen fibrils collapse after air drying. Enamel, needs etching with phosphoric acid to increase retention. As a result, the so-called selective etching technique has been adopted to restore cavities involving both enamel and dentin Zanatta et al., (2019). After evaluating studies of 1-5 years clinical follow up, the selective enamel etching prior to universal adhesive application in NCCLs improves clinical performance of composite resin and lower loss of retention with selective enamel etching observed after 3 years follow up Shinohara et al., (2020).

The American Dental Association recommends clinical studies on non-carious cervical lesions to evaluate the adhesive systems’ performance as they are non-retentive lesions, and the restoration retention depends primarily on the adhesive performance Follak et al.,(2021). NCCLs have special inherent characteristics, including increased sclerosis of the dentin substrate, high occlusal forces that stress the cervical third of teeth, decreased retention form, and margins that extend to dentin not only in enamel, render them the ideal substrate to challenge the retention ability of adhesive systems Ruschel et al.,(2018).

Universal adhesives contain functional monomers that can enhance the bond strength by chemical adhesion to the tooth structure. One of these monomers, namely, the 10-methacryloyloxydecyl dihydrogen phosphate (10-MDP), has been part of the composition of dental adhesives. It has high affinity for calcium in the hydroxyapatite crystals, which is amplified and stabilized by the low solubility of the calcium salt of the acidic molecule, rendering it a desirable component in the adhesive systems Ruschel et al.,(2018). The 10-Methacryloyloxydecyl dihydrogen phosphate (MDP), has been shown to interact with hydroxyapatite crystals by a dual

\[ \text{Figure (5): Survival analysis of Aquabond and Single bond universal after 12 months} \]
adhesion mechanism: First, stable ionic bonding to calcium is formed through a nano-layered structure of MDP-Ca salts at the interface with hydroxyapatite. Such hydrophobic nano-layering improves the long-term durability of dentin and enamel bonding. 

Perdigão et al., (2019).

Hydrolytic degradation of one or both components of the hybrid layer can cause loss of dentin bond strength and eventually loss of the adhesive joint/interface. For the resin monomer infiltration, water is mandatory to help in the expansion of the dentin collagen scaffold. Yet, excess moisture may cause phase separation between the hydrophobic and the hydrophilic monomers, which may result in irregular resin infiltration, blisters or voids at the interface and can reduce monomer conversion. This will consequently reduce the bond durability, increase the enzymatic degradation of the exposed collagen, and the hydrolysis of the poorly polymerized adhesive. To overcome these shortcoming newer modifications of the adhesive have been developed. The novel and newly introduced universal adhesive used in this study is claimed to overcome the moisture involved in dental adhesion such as moisture during cavity preparation, tissue fluids that leaks out of the dentinal tubules due to capillary action and osmotic pressure on the adhesive interface, gingival fluid seepage and the water that may be introduced when removing the adhesive solvent by air-blowing. In the composition of this adhesive, they added M-TEG-P monomer and claimed to have succeeded in developing an adhesive whose components will not exhibit phase separation during the solvent volatilization that occur after application, and whose adhesion will not be susceptible to influence by the amount of moisture mixed into the adhesive layer. M-TEG-P amphiphilic phosphate monomer claimed to be efficient in removing the smear layer on the surface of the enamel and dentin, or the calcium component as the smear plug, and forms a preferable surface for adhesion. Therefore, this novel adhesive can adhere immediately after application, and the adhesiveness gently increases with time due to controlled demineralization. So, this novel adhesive (YAMAKIN TMR- Aquabond0, Japan) doesn’t require time for demineralization and can be cured immediately after application. 

Yamakin Group, (2016).

The length of the spacer chain (number of carbons) is claimed to influence the ionic bond greater than its hydrophilicity. It was found that 2-MEP (shorter chain), MTEP, and CAP-P (hydrophilic spacer) provided a significantly lower formation of monomer-calcium salts and tensile bond strength than did 10-MDP and 12-MDDP. But surprisingly, MTEP and CAP-P, which are more hydrophilic monomers and contain ester and ether groups within their spacer chains, both can remain on the dentin surface after rinsing. Remarkably, the more hydrophilic functional monomer (MTEP) formed fewer but more rinse-resistant monomer-Ca salts. MTEP and CAP-P as compared with that of 2-MEP have more stable chemical bonding which may have been improved by their better wettability onto dentin and due to a relatively long spacer chain, thereby increasing the separation of the methacrylate and phosphate functional groups. It has been demonstrated that monomers having weak interaction with hydroxyapatite are less prone to produce high initial bond strength and durability, compared with those with a higher chemical interaction. 

Van Landuyt et al., (2008). These findings are important to guide the formulation of future functional monomers, which should be structured by a long and hydrophobic spacer, to achieve more stable chemical interaction and longer adhesive-dentin interface bond durability Feitosa et al., (2013).

The present randomized clinical trial evaluated the performance of two different adhesive systems. This study was conducted on (28) participants with non-curious cervical lesions that were randomly allocated to the intervention and the comparator arms (n=14). After 12 months 28 participants completed the follow-up with a 100% retention rate.

Regarding fractures and retention, there was no statistically significant difference between the two adhesives and also intragroup comparison within both groups at the different follow up periods; baseline, 6 and 12 months. This was in accordance with Ruschel et al., (2018) and Zanatta et al., (2019) who attributed that there is no significant difference between resin composite restorations placed using same universal adhesive as our study (SBU) regarding retention rates after 12 months follow up. Follak et al., (2021) showed
that SBU has better clinical performance than Prime & Bond Elect after 6 months follow up regarding retention rates. Yoshida et al., (2012) observed a significant chemical interaction between the MDP available in SBU adhesive system and hydroxyapatite of dental substrate, forming a stable nanolayer which explains high bond stability. Our results were in disagreement with Gonçalves et al., (2021) who reported statistically significant difference in SBU regarding retention rate after 12 months and up to 3 years follow-up period and this may be attributed to the application of this universal adhesive without selective enamel conditioning presenting high initial debonding rates.

Concerning marginal adaptation, there was no statistically significant difference between the two adhesives within different follow up periods; baseline, 6 and 12 months but there was statistically significant difference between different follow-up periods within Aquabond0 and Single Bond Universal groups. This is in agreement with Follak et al., (2021) who also encountered failure in the restoration bonded by SBU regarding marginal adaptation (3 restorations) after 6 months. These results were also similar to Gonçalves et al., (2021) who discovered that there was statistically difference within SBU groups when applied with selective enamel etching after 12 months and up to 3 years follow-up period regarding marginal defects and surface texture. But, this was in disagreement with Zanatta et al.,(2019) who reported acceptable marginal adaptation for SBU after 6, 12 and 18 months follow up , this disagreement may be attributed to the different application techniques between the studies as they applied SBU in total-etch mode 30 seconds to the enamel and 15 seconds to the dentin then removed excess water with absorbent paper, leaving a moist dentin surface while in our study SBU was applied in selective enamel etching mode and we used compressed air to remove all excess moisture.

As for postoperative sensitivity, our study showed no statistically significant difference between both groups within different follow up periods; baseline, 6 and 12 months. Intragroup comparison within Aquabond0 have shown no statistically significant difference between different follow-up periods but there was statistically significant difference within Single bond universal between different follow-up periods and this may be attributed to the effective adhesion of our novel adhesive (TMR-Aquabond0, YAMAKIN CO., Japan) to both enamel and dentin even when it was adhered under moist conditions so, it does not require excessive dryness to dentin substrate which may cause postoperative sensitivity. In the contrary to our results Zanatta et al.,(2019) recorded no or very few cases of postoperative sensitivity and this may be due to different in methodologies as in both studies they applied SBU to moist dentin with only blotting excess water unlike our study where we used compressed air to remove excess moisture and for deeper resin infiltration.

Regarding secondary caries, there was no statistically significant difference between both adhesives for different follow up periods; baseline, 6 and 12 months. Intragroup comparison within Aquabond and Single bond universal have shown no statistically significant difference between different follow-up periods. This was also reported by Zanatta et al., (2019), Shinohara et al., (2020), Gonçalves et al. (2021) and Follak et al., (2021).

As for marginal staining, our study showed no statistically significant difference between the two adhesives within different follow up periods: baseline, 6 and 12 months. Intragroup comparison within Aquabond and Single bond universal have shown statistically significant difference between different follow-up periods. There was three times more risk for marginal staining (score 4 and 5) of Aquabond when compared to Single bond universal after 12 months. Our results agreed with Zanatta et al., (2019) who stated that there was a statistically significant difference regarding marginal staining in SBU group at 6, 12 and 24 months follow up. Our findings were in disagreement with Haak et al.,(2019) who discovered no significant increase in marginal staining in SBU group applied using selective enamel etching technique after 6, 12 and 36 months, this disagreement may be attributed to the different populations included in our current study and their study as they included young age participants whose teeth may have different structure than geriatric patients included in our current study. Also, in disagreement with Gonçalves et al., (2021) who verified that there was no statistically significant difference regarding...
marginal staining in resin composite restorations applied by SBU adhesive with and without selective enamel etching at the 12 months and 3-year follow-up this difference in results may be because they applied thin protective coating (Finishing Gloss, 3M ESPE St. Paul, USA) onto the restoration surface and photocured it for 20 s.

With reference to the survival rate, overall survival of (TMR-Aquabond0, YAMAKIN CO., Japan) and (Single Bond Universal, 3M ESPE, USA) resin composite cervical restorations assessed after 12 months, 4 restorations failed after 12 months in Aquabond group due to scoring 4 or 5 in marginal staining, marginal adaptation and fracture and retention. There was a statistically significant difference between both adhesives regarding survival rate.

At the end of the current study, failure rate for (TMR-Aquabond0, YAMAKIN CO., Japan) after 12 months clinical service was 4/14 = 28% (more than 10%) while failure rate for (Single Bond Universal, 3M ESPE, USA) was 0%. Therefore, the null hypothesis was rejected. There was no statistically significant difference between both adhesives regarding fractures and retention, marginal adaptation, post-operative hypersensitivity, marginal discoloration and secondary caries. However, statistically significant differences were found regarding survival rate. Studies in agreement or disagreement with our results are mainly related to the 10-MDP containing universal adhesive (Single Bond Universal, 3M ESPE, USA), as there were no available clinical trials on our M-TEG-P monomer containing novel adhesive (TMR-Aquabond0, YAMAKIN CO., Japan) and this gives an indication to the clinical importance of our study. It’s recommended that further studies on M-TEG-P monomer containing universal adhesives should be performed on different populations and with different follow up periods.

Limitations of this study that were encountered were mainly the small sample size and short follow up time, so further investigations with larger sample sizes and longer follow up periods are advocated to obtain more reliable results.

V. CONCLUSION

Under the limitations of this study, it can be concluded that both adhesives, M-TEG-P and 10-MDP containing universal adhesives showed acceptable clinical performance after 12 months of clinical service in non-carious cervical lesions (NCCLs) in geriatric adults. Both adhesives showed similar results and performed equally in the present study. However, it should be noted that 10-MDP containing universal adhesive showed a higher survival rate.

VI. RECOMMENDATIONS

1. Due to the limited available research, more clinical trials comparing the clinical performance of M-TEG-P containing universal adhesives with other universal adhesives are recommended.

2. Clinical trials testing the performance of M-TEG-P monomer containing universal adhesives in other clinical indications are encouraged, utilizing the new material in various clinical applications, different age groups, restoring carious lesions and for different follow up periods.

3. More clinical trials measuring bonding performance of M-TEG-P containing universal adhesives using different measuring tools as Scanning Electron Microscopy (SEM) or Quantitative Margin Analysis (QMA) are recommended.

Conflict of Interest:
The authors declare no conflict of interest.

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Ethics:
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VII. REFERENCES


- **Haak, R., Werner, M. S., Schneider, H., Häfer, M., & Schulz-Kornas, E. (2022).** Clinical Outcomes and Quantitative Margin Analysis of a Universal Adhesive Using a Randomized Clinical Trial over Three Years. *Journal of Clinical Medicine*, 11(23).


