

Original Article

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

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Submitted: 03-03-2023

Accepted: 24-05-2023

Abstract

Aim: The aim of this study was to assess the performance of moisture resistant, M-TEG-P containing universal adhesive (TMR-Aquabond0, YAMAKIN CO., Japan) in comparison to 10-MDP containing universal adhesive (Single Bond Universal Adhesive, 3M ESPE, USA) in geriatric patients with NCCLs. **Materials and methods:** 28 participants were enrolled in this study. NCCLs were restored using nano hybrid universal resin composites preceded with either Aquabond0 or Single bond universal adhesive. Restorations were assessed using the World Dental Federation (FDI) 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 ($P \leq 0.05$), survival rate was analyzed using Kaplan-meier and Log-rank test. **Results:** No statistically significant difference between the two groups was found for all outcomes $p > 0.05$. However, a statistically significant difference was found regarding survival analysis ($p = 0.034$) where 10-MDP containing adhesive showed higher survival rate than M-TEG-P phosphate containing universal adhesive. **Conclusion:** Both universal adhesives revealed acceptable 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-caries cervical lesions

I. INTRODUCTION

Dental adhesives and resin composites are without a doubt the first choice for restoring tooth tissue defects for their excellent esthetic and mechanical properties. Despite the great advances in dental adhesives, the dentin-resin interface is still the weakest zone due to several factors such as bond degradation, nano-leakage and gap formation

which might result in secondary caries around the tooth-restoration margins. Hence, improving bond durability is fundamental for increasing restoration longevity. Therefore, there was an increased demand for simplified adhesives with improved performance which led to the development of 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 humidity, caries-affected tissue, and the lack of retention due to extensive tooth loss that might contribute to adhesive-interface degradation. In addition, oral factors such as pH fluctuations and thermo-mechanical stresses may reduce restoration longevity *Santis et al., (2017)*.

Tooth wear is a universal physiological phenomenon, with slow irreversible progression. It is usually associated with aging and parafunctional habits. Their prevalence worldwide is 46.7% higher in geriatric patients *Santis et al., (2017)*. Non-carious cervical lesions (NCCLs) are ideal to assess the performance of adhesives. These lesions generally do not provide any macro-retention. Therefore, improper bonding will cause restoration loss. Loss of retention is the key for evaluating the performance of adhesives in NCCLs based clinical trials *Peumans et al., (2020)*.

Geriatrics implies medical support for elder adults, an age group difficult to define accurately. Despite there is no specific age to classify, patients older than 65 years are often described as geriatric patients. Also, from a chronological point of view, medical treatment of the elderly (geriatrics) begins from the age of 65 years old *Stefanacci R.G., (2022)*.

A greater 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) restoration 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 dental adhesion 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 occurs after application, and whose adhesion will not be susceptible to influence by the amount of moisture mixed into the adhesive layer *Yamakin et al., (2016)*. The M-TEG-P 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 adhesive application on the tooth surface. It also has shorter light activation time if 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 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 introduced universal adhesive also exhibits chemical adhesion to dentin, showing hydrolytic bond stability when compared to other functional monomers *Ranjitha et al., (2020)*

Due to the limited available clinical data, this trial was designed to assess the performance of two universal adhesives, 10-MDP containing universal adhesive and M-TEG-P containing universal adhesive. The null hypothesis tested was that the two adhesives would behave equally placed in NCCLs for geriatric patients over a 12-month follow up period.

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

Materials	Composition	Lot Number	Manufacturer
Single Bond Universal Adhesive	MDP Phosphate Monomer, Dimethacrylate resins, HEMA, Vitrebond Copolymer, Filler, ethanol, water, initiators, silane	10420A	3M ESPE, 2510 Conway Avenue St. Paul, MN 55144-1000 USA Phone 1-800-634-2249 https://www.3M.com/dental
Etch-Rite™	38% Phosphoric acid, Water, Synthetic amorphous silica, Polyethylene glycol	160728	PULPDENT Corporation 80 Oakland Street Watertown, MA 02472 USA https://www.pulpdent.com
Filtek™ Z250 XT	Fillers: Nanohybrid silica/zirconia (82% weight) Matrix: BIS-GMA, UDMA, BIS-EMA, PEGDMA and TEGDMA (18% by weight)	NC99452	3M ESPE, 2510 Conway Avenue St. Paul, MN 55144-1000 USA Phone 1-800-634-2249 https://www.3M.com/dental
TMR-AQUA BOND 0	M-TEG-P phosphate monomer, distilled water, methacrylate monomer, carboxylic monomer, photopolymerization initiator, ethanol, thickener	01062024	YAMAKIN CO., LTD. 1090-3 Otani, Kamibun, Kagamicho, Konan-shi, Kochi, 781-5451 Japan https://www.yamakin-global.com
TMR Z FILL 10	methacrylate monomer, inorganic fillers (silica, alumina, and zirconia: average particle diameter < 20µm), pigments, Inorganic filler content rate Approximately 55 vol%	01042126	YAMAKIN CO., LTD. 1090-3 Otani, Kamibun, Kagamicho, Konan-shi, Kochi, 781-5451 Japan https://www.yamakin-global.com

MDP: Methacryloxydecyl dihydrogen phosphate, HEMA: 2-hydroxyethyl methacrylates, BIS-GMA: Bisphenol A-glycidyl methacrylate, UDMA: Urethane dimethacrylate, BIS-EMA: Bisphenol A ethoxylated dimethacrylate, PEGDMA: Polyethylene glycol dimethacrylate, TEGDMA: Triethylene glycol dimethacrylate, M-TEG-P: 10-methacryloyloxy tetraethylene glycol dihydrogen phosphate

B. Methods

• Trial Registration and Ethical Approval

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

• Study Setting and Design

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

• Sample Size Calculation

According to *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 M-TEG-P phosphate-based universal adhesive was (0.9), probability of score 5 was (0.1) with effect size $w=0.8$ ($n=13$). With an alpha (α) level of 0.05 (5%) and power=80%, the estimated sample size was 22 cases. Sample size was raised by (20%) to compensate for dropouts through follow-ups to a total of (28) cases; (14) per 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

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> - Geriatric patients of age ≥ 65 years - Patients committed to the whole study period - Males and Females - Patients complaining from compromised esthetics or sensitivity 	<ul style="list-style-type: none"> - Patients below 65 years old - History of allergy to any of the materials used - Infectious diseases - Inadequate oral hygiene - Severe Bruxism with more than 50% wear - Severe dysgnathia/traumatic occlusion

Table (3): Inclusion and exclusion criteria of teeth

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> - Non-carious cervical lesions score 2 and 3 according to DAW classification for NCCLs (<i>Loomba et al.,2014</i>) - Anterior and posterior teeth - Absence of periapical alterations 	<ul style="list-style-type: none"> - Non-vital teeth or teeth with pulp affection - Severe periodontal diseases - Active caries lesions - Teeth with Grade 3 mobility - Teeth with exposed pulp

• 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**)

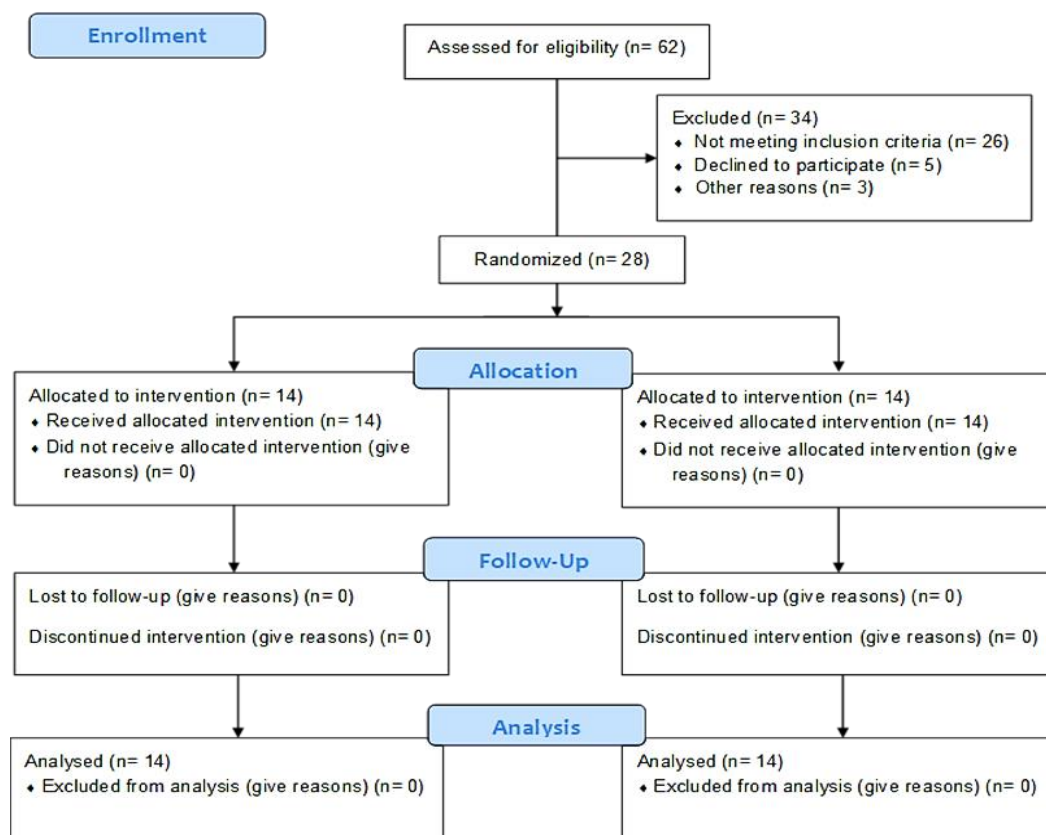


Figure (1): CONSORT flow diagram

• Sequence Generation and Allocation Concealment

Simple randomization was performed by generating numbers from 1:28 using Random Sequence Generator and Integrity Services Ltd (<https://www.random.org/>). Each random number generated from 1-14 represents the intervention while from 15-28 represents the comparator. The numbers were secured in sealed and obscured envelopes, organized by a contributor who did not participate in any other clinical trial phase.

• Masking/blinding

This is a triple blinded study where the volunteers, assessors, as well as the statistician. The operator cannot be blinded due to different application protocol of the restorative materials.

• Clinical Procedures

Field Isolation

After local anesthesia was administered (ARTINIBSA 40 mg/ml + 0,01mg/ml, Inibsa, Spain), cavities to be restored were isolated with

rubber dam sheets (Nic Tone, Expertech Solutions, Bucharest, Romania), subgingival clamps (TOR VM Dental Manufacturing Company, Russia) and floss ligatures as needed.

Cavity Preparation Steps

A round bur in a high-speed hand piece (NSK high speed hand-piece Pana Air FX PAF-SU-M4, Japan) with air /water coolant was used for surface roughening of the cavities and a yellow-coded, fine grit, diamond stone was used to prepare the incisal bevel.

Material Application Steps

Intervention (M-TEG-P universal adhesive)

Materials were placed upon manufacturer instructions as follows: selective enamel etching was performed where 38% phosphoric acid etching gel (Pulpdent, Etch-Rite, USA) was applied on all enamel margins for 15 seconds. Rinsing followed by gentle air dryness was performed to remove excess moisture without desiccating the dentin. M-TEG-P universal adhesive (TMR-Aquabond0, YAMAKIN CO., Japan) was applied to the

prepared cavity surfaces with a micro brush. Gentle air-blowing was performed to spread the adhesive into a thinner layer. Afterwards, the adhesive was cured with a light curing unit for ten seconds using LED light intensity 1200 mW/cm² (Woodpecker i-LED, Woodpecker Co., Ltd, Guilin, Guangxi, China). Universal nanocomposite (TMR-Z Fill 10,

YAMAKIN CO., Japan) restorative material was placed into the prepared cavity in 2mm thick increments and light cured for 20 seconds. After light curing, shape contouring was done with fine and extra-fine diamond abrasives, followed by sequential discs for further restoration finishing and polishing (**Figure 2**).

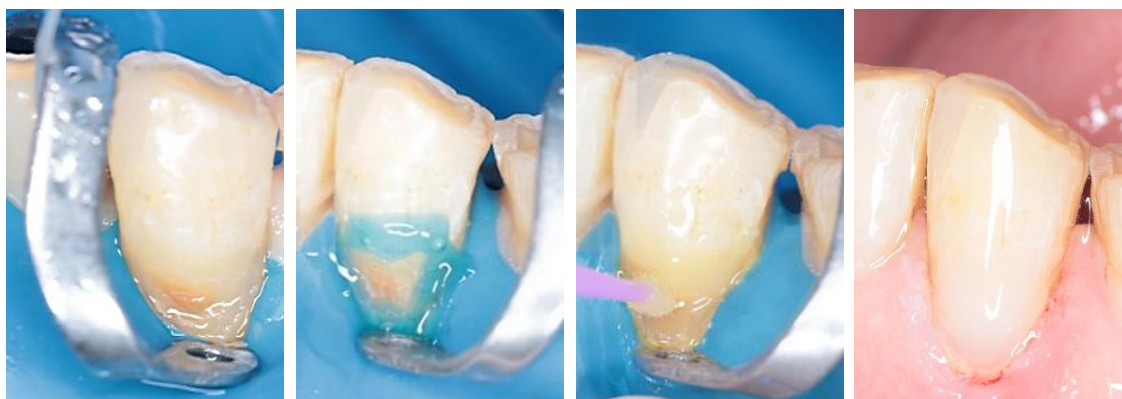


Figure (2): Field isolation, selective enamel etching, bonding and resin composite application of the intervention group

Comparator (10-MDP universal adhesive)

Materials were placed upon manufacturer instructions as follows: selective enamel etching was performed where 38% phosphoric acid etching gel (Pulpdent, Etch Rite, USA) was applied on all enamel margins for 15 seconds. Rinsing followed by gentle air dryness was performed to remove excess moisture without desiccating the dentin. 10-MDP universal adhesive (Single Bond Universal, 3M ESPE, USA) was placed on the prepared cavity surfaces with a micro brush with active rubbing for 20 seconds. The adhesive was gently air dried for

five seconds to evaporate the solvent. Afterwards, the adhesive was cured with a light curing unit for ten seconds using LED light intensity 1200 mW/cm² (Woodpecker i-LED, Woodpecker Co., Ltd, Guilin, Guangxi, China). Nanohybrid composite (3M™ ESPE™ Filtek™ Z250XT, USA) was placed into the prepared cavity in 2mm thick increments and light cured for 20 seconds. Afterwards, shape contouring was done with fine and extra-fine diamond abrasives, followed using sequential discs for further restoration finishing and polishing (**Figure 3**).



Figure (3): Field isolation, selective enamel etching, bonding and resin composite application of the control group

Outcomes

The restorations were assessed using the World Dental Federation (FDI) criteria at baseline

(1 week after placement), 6 and 12 months, measuring fractures and retention, marginal adaptation, marginal staining, post-operative sensitivity and secondary caries (**Figure 4**).

Classification	Esthetic Property 1. Staining margin	Functional Properties		Biological Properties	
		2. Fractures and retention	3. Marginal adaptation	4. Postoperative (hyper-) sensitivity	5. Recurrence of caries
1. Clinically very good	1.1 No marginal staining.	2.1 Restoration retained, no fractures/ cracks.	3.1 Harmonious outline, no gaps, no discoloration.	4.1 No hypersensitivity.	5.1 No secondary or primary caries
2. Clinically good (after correction very good)	1.2 Minor marginal staining, easily removable by polishing.	2.2 Small hairline crack.	3.2.1 Marginal gap (50 µm).	4.2 Low hypersensitivity for a limited period of time.	5.2 Very small and localized demineralization. No operative treatment required
			3.2.2 Small marginal fracture removable by polishing.		
3. Clinically sufficient/ satisfactory (minor shortcomings with no adverse effects but not adjustable without damage to the tooth)	1.3 Moderate marginal staining, not esthetically unacceptable.	2.3 Two or more or larger hairline cracks and/or chipping (not affecting the marginal integrity).	3.3.1 Gap < 150 µm not removable.	4.3.1 Premature/ slightly more intense.	5.3 Larger areas of demineralization, but only preventive measures necessary (dentin not exposed).
			3.3.2. Several small enamel or dentin fractures.	4.3.2 Delayed/weak sensitivity; no subjective complaints, no treatment needed.	
4. Clinically unsatisfactory (repair for prophylactic reasons)	1.4 Pronounced marginal staining; major intervention necessary for improvement.	2.4 Chipping fractures which damage marginal quality; bulk fractures with or without partial loss (less than half of the restoration).	3.4.1 Gap > 250 µm or dentin/base exposed.	4.4.1 Premature/ very intense.	5. 4 Caries with cavitation (localized and accessible and can be repaired.
			3.4.2. Chip fracture damaging margins.	4.4.2 Extremely delayed/weak with subjective complaints.	
			3.4.3 Notable enamel or dentin wall fracture.	4.4.3 Negative sensitivity intervention necessary but not replacement.	
5. Clinically poor (replacement necessary)	1.5 Deep marginal staining not accessible for intervention.	2.5 (Partial or complete) loss of restoration.	3.5 Filling is loose but <i>in situ</i> .	4.5 Very intense, acute pulpitis or nonvital. Endodontic	5.5 Deep secondary caries or exposed dentin that is not

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 ($p \leq 0.05$), intragroup comparison within each intervention was performed using the Chi-Squared test with statistical significance level set at ($p \leq 0.016$) after Bonferroni correction. Relative risk was used to assess 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.

RESULTS

1. Demographic Data

This study was conducted on 28 participants that were randomly assigned to the two arms ($n=14$). After 12 months, 28 participants completed the follow-up with a 100% retention

rate. Regarding gender, there was 16 males and 12 females in the current study, in the M-TEG-P universal adhesive 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 M-TEG-P universal adhesive 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 the two 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

Teeth distribution	M-TEG-P Universal Adhesive	10-MDP Universal Adhesive	Total
Maxillary incisors	4(57.1%)	3(42.9%)	7(25%)
Maxillary canines	2(66.7%)	1(33.3%)	3(10.7%)
Maxillary premolars	3(75%)	1(25%)	4(14.3%)
Maxillary molars	1(100%)	0(0%)	1(3.6%)
Mandibular incisors	2(66.7%)	1(33.3%)	3(10.7%)
Mandibular canines	0(0%)	1(100%)	1(3.6%)
Mandibular premolars	2(22.2%)	7(77.8%)	9(32.1%)
Mandibular molars	0(0%)	0(0%)	0(0%)
Total	14 (50 %)	14 (50 %)	28

2. Clinical Evaluation

Intergroup comparison between both adhesives revealed no statistically significant difference for all outcomes at all follow-up intervals ($p>0.05$). Intragroup comparison within M-TEG-P universal adhesive revealed no significant difference between follow-up intervals regarding 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 a 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).

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

Outcome	Follow up	M-TEG-P Universal Adhesive						10-MDP Universal Adhesive						p-value
		N	Success			Failure		N	Success			Failure		
			1	2	3	4	5		1	2	3	4	5	
Fracture and Retention	Baseline	14	14(100%)	0(0%)	0(0%)	0(0%)	0(0%)	14	14(100%)	0(0%)	0(0%)	0(0%)	0(0%)	1.0000
	6 Months	14	13(92.9%)	0(0%)	0(0%)	0(0%)	1(7.1%)	14	12(85.7%)	2(14.3%)	0(0%)	0(0%)	0(0%)	0.2187
	12 Months	14	13(92.9%)	0(0%)	0(0%)	0(0%)	1(7.1%)	14	12(85.7%)	2(14.3%)	0(0%)	0(0%)	0(0%)	0.2187
	p-value		0.3749							0.1979				
Outcome	Follow up	M-TEG-P Universal Adhesive						10-MDP Universal Adhesive						p-value
		N	Success			Failure		N	Success			Failure		
			1	2	3	4	5		1	2	3	4	5	
Marginal Adaptation	Baseline	14	14(100%)	0(0%)	0(0%)	0(0%)	0(0%)	14	14(100%)	0(0%)	0(0%)	0(0%)	0(0%)	1.0000
	6 Months	14	12(85.7%)	1(7.1%)	0(0%)	1(7.1%)	0(0%)	14	8(57.1%)	6(42.9%)	0(0%)	0(0%)	0(0%)	0.2921
	12 Months	14	5(35.7%)	4(28.6%)	2(14.3%)	3(21.4%)	0(0%)	14	4(28.6%)	7(50%)	3(21.4%)	0(0%)	0(0%)	0.4315
	p-value		0.0092*							0.0010*				
Outcome	Follow up	M-TEG-P Universal Adhesive						10-MDP Universal Adhesive						p-value
		N	Success			Failure		N	Success			Failure		
			1	2	3	4	5		1	2	3	4	5	
Postoperative Sensitivity	Baseline	14	11(78.6%)	3(21.4%)	0(0%)	0(0%)	0(0%)	14	14(100%)	0(0%)	0(0%)	0(0%)	0(0%)	0.0719
	6 Months	14	11(78.6%)	3(21.4%)	0(0%)	0(0%)	0(0%)	14	12(85.7%)	2(14.3%)	0(0%)	0(0%)	0(0%)	0.6280
	12 Months	14	8(57.1%)	5(35.7%)	1(7.1%)	0(0%)	0(0%)	14	9(64.3%)	5(35.7%)	0(0%)	0(0%)	0(0%)	0.5016
	p-value		0.5046							0.0112*				
Outcome	Follow up	M-TEG-P Universal Adhesive						10-MDP Universal Adhesive						p-value
		N	Success			Failure		N	Success			Failure		
			1	2	3	4	5		1	2	3	4	5	
Secondary Caries	Baseline	14	14(100%)	0(0%)	0(0%)	0(0%)	0(0%)	14	14(100%)	0(0%)	0(0%)	0(0%)	0(0%)	1.0000
	6 Months	14	14(100%)	0(0%)	0(0%)	0(0%)	0(0%)	14	14(100%)	0(0%)	0(0%)	0(0%)	0(0%)	1.0000
	12 Months	14	14(100%)	0(0%)	0(0%)	0(0%)	0(0%)	14	14(100%)	0(0%)	0(0%)	0(0%)	0(0%)	1.0000
	p-value		1.0000							1.0000				
Outcome	Follow up	M-TEG-P Universal Adhesive						10-MDP Universal Adhesive						p-value
		N	Success			Failure		N	Success			Failure		
			1	2	3	4	5		1	2	3	4	5	
Marginal Staining	Baseline	14	14(100%)	0(0%)	0(0%)	0(0%)	0(0%)	14	14(100%)	0(0%)	0(0%)	0(0%)	0(0%)	1.0000
	6 Months	14	8(57.1%)	5(35.7%)	1(7.1%)	0(0%)	0(0%)	14	8(57.1%)	6(42.9%)	0(0%)	0(0%)	0(0%)	0.7384
	12 Months	14	4(28.6%)	3(21.4%)	4(28.6%)	2(14.3%)	1(7.1%)	14	4(28.6%)	7(50%)	3(21.4%)	0(0%)	0(0%)	0.1489
	p-value		0.0053*							0.0010*				

3. Survival Analysis

Overall survival of M-TEG-P and 10-MDP universal adhesives in cervical restorations was assessed after 12 months. Four restorations failed after 12 months in M-TEG-P universal adhesive 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**).

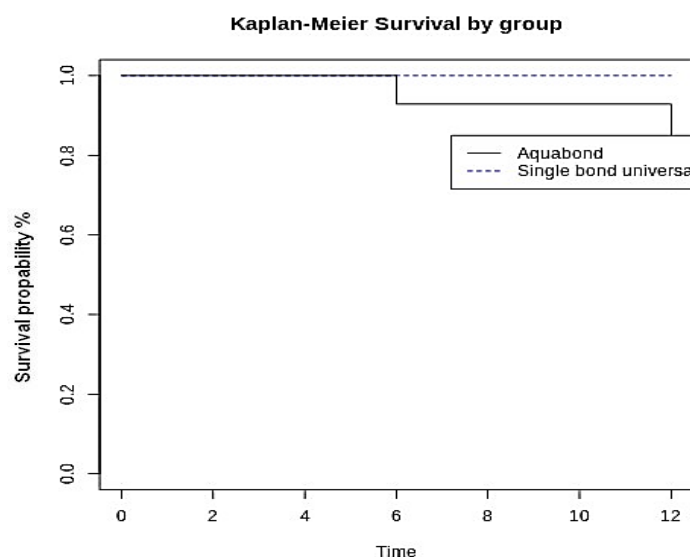


Figure (5): Survival analysis of M-TEG-P and 10-MDP universal adhesives after 12 months

IV. DISCUSSION

There are a lot of factors inherent to dentin and several external factors that contribute to failure at the interface. Consequently, clinical studies are required to assess the longevity of adhesive restorations exposed to the different oral conditions *Santis et al., (2017)*.

The gained interest in simplified and less technique sensitive adhesion resulted in developing more versatile adhesive systems, termed "universal" or "multi-mode", which are simplified adhesives implemented either in etch-and-rinse mode, self-etch mode or even after selective enamel etching protocol *Zanatta et al., (2019)*.

Enamel and dentin require different adhesive approaches due to different inherent tissue characteristics. Usually, adhesives used in dentin are self-etch due to their less aggressive acid conditioning, reducing collagen collapse liability after air dryness. On the other hand, enamel requires phosphoric acid etching to promote retention. Therefore, selective enamel etching has been implemented to restore cavities involving enamel and dentin *Zanatta et al., (2019)*. After evaluating studies of 1-5 years clinical follow up, selective enamel etching prior to universal adhesives improves the clinical performance of resin composite and reduces restoration loss *Shinohara et al., (2020)*.

The American Dental Association recommends clinical studies on non-carious cervical lesions to evaluate adhesives as they are non-retentive, and retention depends mainly on the

adhesive *Follak et al., (2021)*. NCCLs have special inherent characteristics, such as increased sclerosis, high occlusal forces stressing on the cervical tooth area, limited retentive cavity design, and margins extending to dentin, rendering them ideal to test adhesives *Ruschel et al., (2018)*.

Universal adhesives exhibit functional monomers that improve the bond strength by chemically adhering to the tooth structure. 10-methacryloyloxydecyl dihydrogen phosphate (10-MDP) is now an integral entity in dental adhesives. It has high affinity to the hydroxyapatite calcium, which is improved by the stability and low solubility of the calcium salts formed, rendering it a desired constituent in adhesives *Ruschel et al., (2018)*. The 10-Methacryloyloxydecyl dihydrogen phosphate (MDP), interacts with hydroxyapatite crystals by a dual mechanism: First, stable ionic bonding with calcium forming nano-layered MDP-Ca salts with hydroxyapatite at the interface. This nano-layering greatly improves bond durability. *Perdigão et al., (2019)*.

Hydrolytic degradation of the hybrid layer reduces dentin bond strength with eventually loss of the adhesive joint. 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 among the hydrophobic and the hydrophilic monomers, which may result in improper resin infiltration, voids at the interface and reduced 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 shortcomings 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 leak 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, the added M-TEG-P monomer claimed to have succeeded in developing an adhesive whose components will not exhibit phase separation during solvent volatilization that occurs 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 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 (Aquabond0, YAMAKIN CO., Japan) doesn't require time for demineralization and can be cured immediately after application *Yamakin et al., (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) resulted in significantly lower formation of monomer-calcium salts and tensile bond strength than 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 compared to 2-MEP have more stable chemical bonding which is enhanced by their high dentin wettability and due to their fairly long spacer chain, increasing the separation of methacrylate and phosphate functional groups. It is demonstrated that monomers showing weak

hydroxyapatite interaction are less likely to create high initial bond strength and durability, compared to those with superior chemical interaction *Van Landuyt et al., (2008)*. These findings are important in leading future formulations of functional monomers, which should be designed to a long and hydrophobic spacer, to realize stable chemical interaction and higher bond durability *Feitosa et al., (2013)*.

This randomized clinical study evaluated the performance of two different adhesive systems, conducted on 28 participants with non-carious cervical lesions, randomly assigned to each group (n=14). After 12 months, 28 participants fulfilled 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 follow up; 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 10-MDP universal adhesive as our study regarding retention rates after 12 months follow up. *Follak et al., (2021)* showed that 10-MDP universal adhesive has better clinical performance after 6 months follow up regarding retention rates. *Yoshida et al., (2012)* observed significant chemical interaction between the MDP and hydroxyapatite, forming stable nanolayering which explains the high bond stability. Our results were in disagreement with *Gonçalves et al., (2021)* who reported statistically significant difference in 10-MDP containing universal adhesive regarding retention rate after 12 months and up to 3 years follow-up. This may be attributed to applying the universal adhesive without selective enamel etching resulting in higher debonding rates.

Concerning marginal adaptation, no significant difference was found between the two adhesives within different follow up intervals; baseline, 6 and 12 months but there was statistically significant difference between different follow-up periods within M-TEG-P and 10-MDP universal adhesive groups. This is in agreement with *Follak et al., (2021)* who also encountered failure in the restoration bonded by 10-MDP adhesive 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 10-MDP universal adhesive 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 after 6, 12 and 18 months follow up, this disagreement may be attributed to the different application techniques between the studies as they applied 10-MDP universal adhesive in total-etch mode 30 seconds to enamel and 15 seconds to dentin then removed excess water using absorbent paper, to leave a moist dentin surface while in our study the adhesive 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 at follow up intervals; baseline, 6 and 12 months. Intragroup comparison within M-TEG-P universal adhesive have shown no statistically significant difference between different follow-up intervals but there was statistically significant difference within 10-MDP universal adhesive between different follow-up intervals and this may be attributed to the effective adhesion of the novel M-TEG-P universal adhesive 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. On the contrary to our results *Zanatta et al., (2019)* recorded no or very few cases of post-operative sensitivity and this may be due to different in methodologies as in both studies they applied 10-MDP universal adhesive 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 intervals; baseline, 6 and 12 months. Intragroup comparison within M-TEG-P and 10-MDP universal adhesives 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 intervals: baseline, 6 and 12 months. Intragroup comparison within M-TEG-P and 10-MDP universal adhesives have shown statistically significant difference between different follow-up periods. There was three times more risk for marginal staining (score 4 and 5) of M-TEG-P universal adhesive when compared to 10-MDP universal adhesive after 12 months. Our results agreed with *Zanatta et al., (2019)* who stated that there was a statistically significant difference regarding marginal staining in 10-MDP adhesive 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 10-MDP adhesive 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 10-MDP-based universal adhesive with and without selective enamel etching after 1- and 3-year follow-up. This difference in results may be because they applied a thin protective coating (Finishing Gloss, 3M ESPE St. Paul, USA) onto the restoration surface.

In reference to the survival rate, overall survival of M-TEG-P and 10-MDP universal adhesive-based resin composite restorations assessed after 12 months, 4 restorations failed after 12 months in M-TEG-P universal adhesive 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 M-TEG-P universal adhesive (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 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 carried out on different populations and with different follow up periods.

The 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 M-TEG-P and 10-MDP containing universal adhesives showed acceptable 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 limited available research, more clinical studies comparing the performance of M-TEG-P containing universal adhesives with other universal adhesives are recommended.
2. Clinical trials assessing the performance of M-TEG-P universal adhesives in different clinical scenarios should be emphasized, using the new material in several clinical situations, 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 such as Scanning Electron Microscopy (SEM) or Quantitative Margin Analysis (QMA).

Conflict of Interest:

The authors declare no conflict of interest.

Funding:

This research received no funding grant from any agency in the commercial, not-for-profit or public sectors.

Ethics:

This study was granted approval by the Research Ethics Committee, Faculty of Dentistry, Cairo University with approval ID number: 10102.

VII. REFERENCES

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