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Durability of a low shrinkage TEGDMA/HEMA-free resin composite system in Class II restorations. A 6-year follow up

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ABSTRACT

Objective. The objective of this randomized controlled prospective trial was to evaluate the durability of a low shrinkage and TEGDMA/HEMA-free resin composite system in posterior restorations in a 6-year follow up.

Methods. 139 Class II restorations were placed in 67 patients with a mean age of 53 years (range 29–82). Each participant received at random two, as similar as possible, Class II restorations. In the first cavity of each pair the TEGDMA/HEMA-free resin composite system was placed with its 3-step etch-and-rinse adhesive (cmf-els). In the second cavity a 1-step HEMA-free self-etch adhesive was used (AdheSe One F). The restorations were evaluated using slightly modified USPHS criteria at baseline and then yearly during 6 years. Caries risk and parafunctional habits of the participants were estimated.

Results. Three molar teeth showed mild post-operative sensitivity during 3 weeks for temperature changes and occlusal forces. After 6 years, 134 Class II restorations were evaluated. Twenty-one restorations, 8 cmf-els (11.4%) and 13 ASE-els (20%) failed during the 6 years ($p < 0.0001$). The annual failure rates were 1.9% and 3.3%, respectively. The main reasons for failure were fracture followed by recurrent caries. Most fractures and all caries lesions were found in high risk participants.

Significance. The Class II resin composite restorations performed with the new TEGDMA/HEMA-free low shrinkage resin composite system showed good durability over six years.

1. Introduction

Despite the increasing use of resin composites, there are still several remaining problems to be solved. During curing of the monomers, a network of polymers is formed, which becomes rigid due to increasing cross-linking of the polymer chains. The free curing contraction for resin composites varies from 1.0% to 5.0% [1]. In the pre-gel phase, the material is able to flow and stresses are relieved. Post-gel polymerization results in stresses in the material and tooth structures and their interfaces, which may affect the interfacial adaptation and durability of restorations [2–6]. The magnitude of shrinkage

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stress depends on many factors like resin matrix formulation, amount of filler used in the resin composite and degree of conversion. Cuspal movement during polymerization may be perceived as post-operative pain [7–9]. Increasing C-factor may result in greater stresses due to the larger number of bounded surfaces. Posterior Class I and II cavities will therefore show high stress formation. A few low shrinkage resin composites have been developed and marketed during the last years [10–12].

Biocompatibility of dental materials is an important consideration for the patient and clinician. Many in vitro studies have shown that the polymerization reaction, producing the cross-linked polymer matrix from the dimethacrylate resin monomers, is never complete. It has been reported that of the methacrylate groups, 25%–60% may remain unreacted and about 10% of the available groups are free to diffuse out in the oral cavity [13,14]. Adverse reactions may be expected in sensitive operators or patients due to the release of non-polymerized monomers. Clinical studies have shown that dental resin composites may induce local and systematic adverse effects, which are caused by methacrylate (co)monomers [15]. Two frequently used methacrylate monomers TEGDMA (Triethyleneglycol-dimethacrylate) and HEMA (2-hydroxyethyl-methacrylate) eluate from different resin composites, compomers, resin modified glass ionomers and adhesives and have been shown to be responsible for several cytotoxic reactions [16–20]. The diluent monomer TEGDMA show biological significant properties, like low molecular weight, relatively high hydrophilicity and detergent activity in liposomes. It can penetrate all biological compartments, the extracellular and intracellular space, including cell nuclei and membranes. The monomer showed chemical–biological interactions with many cell structures or processes like inhibition of cell growth and decrease of the intracellular glutathione level [18,19,21,22]. The quantity of TEGDMA leaching from restorative materials is predominantly dependent on the monomer–polymer conversion. But in addition, chemical processus like erosion, enzymatical hydrolytic disintegration and alcoholysis as well as physical processus like wear may also contribute to a release of degradation products from the polymerized resin in time [23]. Geurtsen and Leyhausen [18] concluded that it should be the aim of future studies to replace TEGDMA with more biocompatible diluent monomers. HEMA is frequently present in dental adhesives, resin-modified glass ionomers and poly-acid modified resin composites. In adhesives, in amounts from 30% to 55%, it reduces viscosity, promotes diffusion of co-monomers by expanding the demineralized collagen [24–26] and enhances bond strength to dentin [24]. Omission of HEMA in adhesives may lead to phase separation between water and the adhesive monomers [27–29]. It has been shown that HEMA inhibited intracellular tyrosine phosphorylation [20], induced cell growth inhibition and cycle perturbation [30] and is a potent inducer of apoptotic cell death [31]. Cell mutation has been observed after exposure to both TEGDMA and HEMA [32,33] as well as increased intracellular concentrations of reactive oxygen species (ROS) [22,34]. Exposure to low concentrations of the monomers for a prolonged time reduced the rate of cell proliferation possibly as result of DNA damage [35].

In addition it has been observed that TEGDMA and HEMA are common sensitizers with a high sensitizing potential [36–38]. The lower the molecular weight of the monomer, the higher the biophase penetration risk and allergic potential. The risk of allergic reactions increases due to unwary handling of the non-cured resin monomers [39]. Fast penetration of uncured monomers through the skin and gloves cause contact dermatitis in dental staff [40]. Patients with diagnosed allergies for HEMA and/or TEGDMA should not receive dental materials which can release these monomers.

Recently a TEGDMA/HEMA-free resin composite system was developed with low volumetric shrinkage and low contraction stress [40]. In its 3-step etch-and-rinse adhesive, smaller hydrophilic monomers were omitted resulting in a more hydrophobic resin layer, which is less prone to water absorption and hydrolytic degeneration [41,42]. The HEMA substitution for Bis EMA, which represents high molecular weight may result in reduced toxicity.

Clinical effectiveness of the resin composite system in Class V non carious cervical lesions was reported recently in a 5-year follow up [43], but no clinical study reported the durability in Class II restorations.

The aim of the present randomized controlled prospective study was to investigate the clinical longevity of Class II restorations performed with the TEGDMA/HEMA-free resin composite system. The 3-step etch-and-rinse TEGDMA/HEMA-free adhesive of the system was compared with a HEMA-free 1-step self-etch adhesive. The null hypothesis tested was that the adhesives showed similar clinical performance when used with the 1-step self-etch adhesive.

2. Materials and methods

2.1. *Experimental design*

The study was a randomized controlled prospective trial. In an intra-individual comparison each participant received one pair of similar sized Class II resin composite restorations. The two restorations in each pair were performed with the TEGDMA/HEMA-free low shrinkage resin composite (els; Saremco AG, Rebstein, Switzerland), and bonded either with the TEGDMA/HEMA-free 3-step etch-and-rinse adhesive of the system (cmf, Saremco) or a single-step HEMA-free self-etching adhesive in a pen delivery system (AdheSE One F, Vivadent Ivoclar, Schaan, Liechtenstein; ASE). The els resin composite does not contain co-monomers of low molecular weights and showed the lowest contraction stress of marketed resin composites [40,41].

During 2009, adult patients attending the Public Dental Health Service clinic at the Dental School Umeå, who at the yearly examination did need two Class II restorations were asked to participate in a clinical follow up. No patients were excluded because of caries risk, bruxing habits or not acceptable oral hygiene. All patients were informed on the background of the study and each participant provided informed consent to participate in the study. The study design followed the requirements outlined in the CONSORT 2010 statement. All participants were informed on the background

Table 1 – Distribution and size of the experimental restorations.

Surfaces	Maxilla		Mandibula		Total
	Premolars	Molars	Premolars	Molars	
2 surfaces	20	32	15	22	89
3 surfaces	3	7	5	11	26
>3 surfaces	2	12	1	9	24
Total	25	51	21	42	139

of the study, which was approved by the ethics committee of the University of Umeå (Dnr 07-152M).

Reasons for placement of the resin composite restorations were carious lesions, fracture of old fillings or replacements due to esthetic or other reasons. No Class I cavities were included because of the relative good durability of these restorations. Operative procedures were performed under local anesthesia if necessary. Sixty-seven patients, 33 female and 34 male, with a mean age of 53 years (range 29–82) participated in the study. One hundred and thirthy-nine Class II restorations were placed in 46 premolars and 93 molars by one experienced operator (JvD) (Table 1). All, except 5 patients, received at random two restorations with the two restorative techniques. The 5 participants received also one more Class II restoration with the cmf adhesive. All teeth were in occlusion. The majority of cavities had dentin bordered proximal cervical margins.

2.2. *Clinical procedure*

After removal of the old restorations and/or caries excavation according to the principles of adhesive dentistry, the operative field was carefully isolated with cotton rolls and suction device. No bevel was placed. For all cavities a thin metallic matrix was used and carefully wedging was performed with wooden wedges (Kerr/Hawe Neos, Switzerland). No $Ca(OH)_2$ base or other base material was used. The cavities in each individual pair were randomly distributed to the two test adhesives, before the operative procedure started, by throwing dice. In this way, an intraindividual comparison was possible of the adhesive systems.

After rinsing of the cavities with water, application of the respective adhesive was performed according to the manufacturer's instructions (Table 2). Curing was performed with a well controlled light curing unit for at least 10 s (Astralis 7, Vivadent; Demetron light meter, Kerr, Orange, CA, USA). The low shrinkage resin composite (els, Saremco) was applied in all cavities in layers of maximally 2–3 mm with if possible, an oblique layering technique using selected resin composite instruments (Hu Friedy). Every increment was light cured for 20–40 s. After checking the occlusion/articulation and contouring with finishing diamond burrs, the final polishing was performed with the Shofu polishing system (brownie).

2.3. *Evaluation*

The restorations were blindly evaluated and scored by using slightly modified US Public Health Service criteria at baseline (after performance of the restorations) and then yearly during the 6 year follow up (Table 3) [44]. During the evaluations, the evaluators had neither knowledge of which study the evaluated RC restorations belonged to nor of the earlier recall evaluation scores. Cohen-kappa values performed during the follow up were >86%. Bite-wing radiographs were taken at the yearly recalls. The participants were asked at their next visit and at all recalls if they had experienced symptoms in the region of the experimental teeth The caries risk of each participant and their parafunctional habits activity at baseline and during the follow ups was estimated by treating clinician by means of clinical and socio-demographic information routinely available at the annual clinical examinations, e.g. incipient caries lesions, former caries history, frequency, dietary habits, oral hygiene, medications, salivary properties and symptoms related to bruxing activity [45,46]. All patients were informed about the follow up evaluations according to the rules at the PDHS clinic at the Dental School Umeå. Concomitant treatment was given to the patients in conformity with normal clinical routines at the clinic. Patients were instructed to contact the clinic immediately if any discomfort occur.

2.4. *Statistical analysis*

The characteristics of the restorations are described by descriptive statistics using cumulative relative frequency distributions of the scores. The experimental and control restorative techniques were compared intra-individually with the non parametric Friedman two-way analysis of variance test [47]

3. Results

Three molar teeth (1 cmf, 3 ASE) showed post-operative sensitivity during the first 3 weeks for temperature changes and occlusal forces. Two male patients with 2 pair of restorations (2P, 2M) could not be evaluated during the whole 6 year follow up due to death of both participants during the third and fifth year, respectively, of the follow up. After 6 years, 135 restorations were evaluated.

Twenty-one Class II molar restorations failed during the 6 years (15.6%), 8 cmf/els (11.4%) and 13 ASE/els (20.0%). This resulted in annual failure rates (AFR) of 1.9% and 3.3%, for cmf and AES respectivelly and a significant difference in overall durability between the two adhesives ($p < 0.001$).

The cumulative failure frequencies, years of failure and reasons for failure are shown in Table 4. The scores at baseline, 3 and 6 years for the evaluated restorations are given as relative cumulative frequencies in Table 5. The main reason for failure was resin composite fracture (9), followed by a combination of resin fracture/secondary caries (4) and cusp fracture (4). Eleven of the failures were observed in male and ten in

Table 2 – Resin composites and adhesive system used.

Material	Composition	Type	Application steps	Manufacturer
cfm	*cmf etch*: buffered phosphoric acid (pH = 1.5) *cmf primer*: metacrylated phosphoric salt, alcohol, aceton, CQ, co-initiator *cmf bonding*: hydrophilic ethoxylated Bis-GMA, silanized barium glass, CQ, co-initiator.	3-step etch-and-rinse light curing adhesive system	• Etch for 15 s enamel and dentin • Rinse for maximally 10 s • Air dried carefully for ca 5 s. • The cmf primer was applied using a rubbing motion for 30 s, followed by a careful 5 s air blowing to remove solvent. Light cure 20 s • The cmf bonding was applied using a rubbing motion for 20 s • Light cure for 20 s	Saremco AG, Rebstein, Switzerland
AdheSE One F	Bis-acrylamide derivative, bis-methacrylamide dihydrogenphosphate, amino acid acrylamide, hydroxyalkyl methacrylamide 20–40%, water alcohol solvent 20–30%, stabilizers, initiators. highly dispersed silicon dioxide, pH 1.4 fillers <5%, potassium fluoride	single-step self-etching, light-cured, nano-filled, with fluoride release in a pen delivery system	• Dry surface • An adequate amount of AdheSE One F was directly applied to the cavity with the VivaPen. • The adhesive was brushed into the entire surface for 30 s. • Air blow for more than 5 s until a glossy, immobile liquid film appeared. • Light-cure for 10 s.	Vivadent Ivoclar, Schaan, Liechtenstein
els (extra low shrinkage)	Bis-GMA, Bis-EMA, IBMA, catalysts, inhibitors, pigment filler: Ba glass, Ba-Al-B-Si glass, silanized, ø 0,7 μm, max. 2,6 μm, 74 wt%, 50 vol.%.	low shrinkage resin composite volume shrinkage 2.3%, shrinkage stress after 30 min: 2.6 MPa	Applied in 2–3 mm layers, oblique when possible. Light cured 20–40 s per layer	Saremco, Switzerland

Abbreviations: HEMA 2-hydroxyethyl-methacrylate, 4-MET 4-methacryloxyethyl trimetellitic acid, IBMA, isobornylmethacrylate, PENTA Phosphoric acid modified acrylate resin, TCB resin carboxylic acid modified dimethacrylate, TEGDMA triethyleneglycol dimethacrylate, Bis GMA bisphenol A-glycidyl methacrylate, Bis EMA Bisphenol A ethoxylate dimethacrylate, UDMA urethane dimethacrylate; CQ camphoroquinon.

Table 3 – Modified USPHS criteria for direct clinical evaluation (van Dijken [44]).

Category	Score		Criteria
	Acceptable	Unacceptable	
Anatomical form	0		The restoration is contiguous with tooth anatomy
	1		Slightly under- or over-contoured restoration; marginal ridges slightly undercontoured; contact slightly open (may be self-correcting); occlusal height reduced locally
		2	Restoration is undercontoured, dentin or base exposed; contact is faulty, not self-correcting; occlusal height reduced; occlusion affected
		3	Restoration is missing partially or totally; fracture of tooth structure; shows traumatic occlusion; restoration causes pain in tooth or adjacent tissue
Marginal adaptation	0		Restoration is contiguous with existing anatomic form, explorer does not catch
	1		Explorer catches, no crevice is visible into which explorer will penetrate
	2		Crevice at margin, enamel exposed
		3	Obvious crevice at margin, dentin or base exposed
		4	restoration mobile, fractured or missing
Color match	0		Very good color match
	1		Good color match
	2		Slight mismatch in color, shade or translucency
		3	Obvious mismatch, outside the normal range
		4	Gross mismatch
Marginal discoloration	0		No discoloration evident
	1		Slight staining, can be polished away
	2		Obvious staining can not be polished away
		3	Gross staining
Surface roughness	0		Smooth surface
	1		Slightly rough or pitted
	2		Rough, cannot be refinished
		3	Surface deeply pitted, irregular grooves
Caries	0		No evidence of caries contiguous with the margin of the restoration
		1	Caries is evident contiguous with the margin of the restoration

female participants. Sixteen participants were estimated as having high caries risk and nineteen showed mild to severe parafunctional habits during the observation period. Five of seven caries lesions were observed in high caries risk participants and eight of eleven fractures (cusp and material) occurred in bruxing participants.

4. Discussion

Dental resin composites are complex mixed materials, which consist of an organic polymerizable matrix, reinforcing fillers, a silane coupling agent and various additives. One of their main disadvantages is that polymerization after light irradiation never is completed and continues at least another 24 hours. Uncured comomoners and additives released by diffusion through dentin into the pulp and by saliva, will remain in the surrounding tissues and become bioavailable for metabolism [14]. Apart from the elution of residual monomers and additives immediately after placement, diverse chemical reactions like solvolysis (enzymatical), hydrolysis, and alcoholysis as well as physical processes like wear and erosion promote a constant disintegration and dissolution of resin polymers. TEGDMA and HEMA are probably the two co-monomers that contribute most to the severe cytotoxic effects and allergic reactions. [18,42,48]. Reichl et al showed

Table 4 – Not-acceptable restorations and reasons for failure during the 6 years follow up. cmf = cmf/els, ASE = AdheSE One F/els, RC = resin composite.

	1 year		2 year		3 year		4 year		5 year		6 year		Total
	cmf	ASE	cmf	ASE	cmf	ASE	cmf	ASE	cmf	ASE	cmf	ASE	
RC fracture		1	1		1	2			2	1		1	9
RC fracture and caries								2			2		4
Caries				1				1		1		1	4
Cusp fracture		1					2	1					4
Cumulative absolute frequencies	0	2	1	3	2	5	4	9	6	11	8	13	21
Cumulative relative frequencies (%)	0	3.0	1.4	4.5	2.8	7.7	5.7	13.9	8.6	16.9	11.4	20.0	

Table 5 – Scores for the evaluated posterior restorations at baseline (139), 3 years (137) and 6 years (135) of the cmf/els (cmf) and AdheSE One F/els (ASE) restorations given as relative frequencies (%).

		0	1	2	3	4
Anatomical form	cmf baseline	94.4	7.3	0	0	
	ASE baseline	97.0	3.0	0	0	
	cmf 3 years	97.2	1.4	0	1.4	
	ASE 3 years	92.3	1.5	0	6.2	
	cmf 6 years	94.3	0	0	5.7	
	ASE 6 years	83.1	3.0	0	13.9	
Marginal adaptation	cmf baseline	100	0	0	0	0
	ASE baseline	100	0	0	0	0
	cmf 3 years	95.8	2.8	0	0	1.4
	ASE 3 years	90.8	1.5	1.5	1.5	4.7
	cmf 6 years	82.9	11.4	0	0	5.7
	ASE 6 years	63.1	15.4	7.7	15	12.3
Color match	cmf baseline	26.4	69.4	4.2	0	0
	ASE baseline	31.3	61.2	7.5	0	0
	cmf 3 years	23.9	71.7	4.3	0	0
	ASE 3 years	19.7	73.8	6.5	0	0
	cmf 6 years	21.2	72.7	6.1	0	0
	ASE 6 years	13.5	73.0	13.5	0	0
Marginal discoloration	cmf baseline	100	0	0	0	
	ASE baseline	100	0	0	0	
	cmf 3 years	95.8	2.8	1.4	0	
	ASE 3 years	95.1	3.3	1.6	0	
	cmf 6 years	81.8	6.1	12.1	0	
	ASE 6 years	69.2	21.2	9.6	0	
Surface roughness	cmf baseline	100	0	0	0	
	ASE baseline	100	0	0	0	
	cmf 3 years	98.6	1.4	0	0	
	ASE 3 years	100	0	0	0	
	cmf 6 years	84.8	12.1	3.1	0	
	ASE 6 years	82.7	17.3	0	0	
Caries	cmf baseline	100	0			
	ASE baseline	100	0			
	cmf 3 years	100	0			
	ASE 3 years	98.5	1.5			
	cmf 6 years	98.5	1.5			
	ASE 6 years	90.8	9.2			

that unpolymerized TEGDMA and HEMA remain chemically and physically unchanged and can leach up to 30d [42]. It has been stated that for biocompatibility reasons these monomers should be avoided in dental biomaterials, especially in patients with diagnosed allergies [49]. To replace these monomers in resin composite systems have been the goal of novel research projects [38]. Several HEMA-free adhesives have been marketed during the last years and acceptable clinical retention and durability have been shown for some of these products in Class V NCCLís, and also in posterior restoration studies [43]. However, the TEGDMA monomer and other low molecular weight monomers are still used in most marketed resin composites [41].

A new methacrylate-free resin composite was introduced in 2007 based on silorane monomers with traditional filler particles. The resin composite polymerized through a ring-opening polymerization process which reduced the volume shrinkage to less than 1%. A meta-analysis of 11 clinical studies showed acceptable performance for the silorane-based material and similarly to methacrylate-based resin composites [12]. The authors concluded that low polymerization was not the most important factor deciding the clinical effectiveness of a resin composite system in posterior cavities. It has been suggested for many years that stress generation at tooth/resin composite interfaces and the resulting interfacial deficiencies remain one of the most important reasons for clinical failure [40]. The claim that minimizing the shrinkage stresses may lead to improvements in the success rate and survival of restorations can be found in many scientific articles [50,51] However, clinical evidence has been missing that shrinkage stress plays such an important clinical role [10]. The investigated resin composite in this study, with both low shrinkage and low shrinkage stress but also with low flexural strength, flexural modulus, and compressive strength [40,43], showed good clinical durability. The low annual failure rates observed were similar but not superior to those observed in other studies of several resin composites with higher shrinkage stress [40,52,53]. This finding is in agreement with the statement in Magno et alís meta-analysis and earlier reported findings, that low shrinkage stress is an important advantage and certainly plays a role for the durability of the restoration, but not as the main factor. [10,12,54].

Table 6 – Published annual failure rates of the in Umeå and Copenhagen tested restorative systems in Class II restorations after 6 year follow up periods. AFR = annual failure rate.

Classification	Restorative system (study follow up years)	Year of publica-tion (reference no)	Failures at 6 years (%)	AFR (%)	Manufacturer
Resin composite system low shrinkage, HEMA/TEGDMA free	els/cmf	2016	11.4%	1.9	Saremco AG, Rebstein, Switzerland
	els/AdheSE (6 years)		20.0%	3.3%	Ivoclar/Vivadent, Schaan, Liechtenstein
Resin composite, low shrinkage	InTen-S/Excite	2015 [10]	12.8%	2.1%	Ivoclar/Vivadent, Schaan, Liechtenstein
Resin composite, microhybrid	Point 4/Optibond Solo Plus (15 years)		14.3%	2.4%	Kerr Corp, Orange, USA
Resin composite, nanofilled	Ceram X/Xeno III	2015 [52]	10.1%	1.7%	DeTrey/Dentsply, Konstanz, Germany
	Ceram X/Excite (8 years)		5.8%	1.0%	
Resin composite, nanofilled highly filled hybrid	Tetric Evo Ceram	2014 [53]	13.6%	2.3%	Ivoclar/Vivadent, Schaan, Liechtenstein
	Tetric Ceram (10 years)		10.2%	1.7%	
Resin composite, hybrid	Spectrum TPH/Prime&Bond (8 years)	2014 [55]	15,0%	2.5%	Dentsply DeTrey, Konstanz.
Resin composite, hybrid	Gradia Direct Posterior/G-Bond	2013 [56]	8.5%	1.4%	GC, Tokyo, Japan
Resin composite, Giomer	Beautifil/FLbond (6 years)		17.7%	3.0	Shofu, Kyoto, Japan
Resin composite, highly filled hybrid small-particle	Tetric Ceram/Excite	2011 [57]	14.0%	2.3%	Ivoclar/Vivadent, Schaan, Liechtenstein
	Tetric Ceram/Tetric flow/Excite (7 years)		12.3%	2.1%	
Resin composite, fiber reinforced	Alert/Bond-1	2006 [58]	12.8%	2.1%	Jeneric/Pentron, Wallingford, CT, USA
	Nulite/NS Bond Universal Adhesive (6 years)		25.0%	4.2%	Nulite Systems International PTY Ltd, Hornsby, Australia
Ca-aluminate cement	Doxadent (3 years)	2005 [59]	21% after 3 years	7.0%	Doxa, Uppsala, Sweden
Resin composite (sandwich)	Z100/Vitremer (7 years)	2004 [60]	19%	3.2%	3M, St Paul, MN, USA
Resin composite smart material	Ariston (3 years)	2002 [61]	26% after 3 years	8.7%	Ivoclar/Vivadent, Schaan, Liechtenstein
Resin composite inlay	Brilliant/Brilliant duo cement	2000 [54]	11.5%	1.9%	Brilliant DI, Coltène AG, Altstätten, Switzerland
Resin composite	Fullfil/GC lining/enamel bond (11 years)		14.7%	2.5%	DeTrey, Konstanz, Germany

Reichl et al showed that of several investigated adhesive systems, cmf used in this study was the only adhesive which did not release HEMA and TEGDMA. They reported that the above discussed silorane adhesive system released both HEMA and TEGDMA. This resin composite system was recently withdrawn from the market. Reichl et al concluded that cmf can be used as adhesive system for patients with diagnosed allergies for HEMA and/or TEGDMA. Mine et al. [49] reported that the adhesive showed good microtensile bond strength to enamel, but significantly lower to dentin compared to the golden standard 3-step etch-and-rinse Optibond FL. They concluded that the overall bonding effectiveness of the new adhesive was reasonable and comparable with bond strengths recorded for other recently marketed adhesives tested in the same way[49]. Longevity results of restorations placed in Class V non-carious lesions showed also that the clinical retention of the studied TEGDMA/HEMA-free adhesive in low stress bearing localizations was highly acceptable and in line with the better etch-and-rinse adhesives [43].

The Class II restoration is the most stress bearing restoration. The present six year results were obtained for extensive Class II restorations. Class I restorations were not included as have been the case in many earlier posterior resin composite studies. Clinical posterior restoration studies including Class I restorations show lower AFRís, depending on the ratio Class I/Class II restorations. The present six year follow up showed a significant difference between the two experimental groups. The etch-and-rinse adhesive showed a 1.9% annual failure rate compared to 3.3% for the self-etch adhesive group. The hypotheses was therefore rejected. The higher failure rate of the self etch adhesive was surprising due to the fact that the same adhesive applied by brush showed rather good initial in vitro bond strength. Not at least because other HEMA-free self adhesives have shown rather good results in posterior restorations [43]. The clinical handling characteristics, estimated as rather poor during the placement of the restorations, may have resulted in an inferior wetting of the cavity explaining partly the higher failure rate. Also an aging effect of the interfacial adhesive bond may have influenced the outcome.

During the years rather large differences in longevity for Class II restorations have been reported. The design of many published clinical studies did include a high selection of participants by excluding risk patients, like caries risk and/or bruxing participants. In these participants the majority of failures can be expected. To avoid selection bias, all participants attending the PDHS clinic, who were in need of Class II restorations, were asked to participate. The best comparison of the success rate of the HEMA-TEGDMA-free resin composite system with those of other traditional resin composite systems containing low molecular weight monomers, is by observing clinical studies with the same study design and patient selection. Table 6 presents posterior resin composite studies performed by our research groups in Umeå and Copenhagen and published in international reviewer based dental journals, of which the majority was published during the last 10 years [10,52–61]. Studies investigating Class II restorations-only, where their 6 year failure rates and annual failure rates are shown. The results of two new restorative materials with early high catastrophic failure rates are included, indicating the need of shorter follow up times for new materials. The 88.6% success rate observed after 6 years with the TEGDMA/HEMA-free resin composite system is in line with those of highly acceptable resin composite systems with traditional monomers. This shows that it is very well possible to exchange both HEMA and TEGDMA from the resin composite system without changing the clinical durability. However, the good clinical results were only observed when els was combined with the cmf adhesive system. The resin composite els did not shown optimal biomechanical properties in earlier in vitro studies [41], but combining the resin composite with the HEMA/TEGDMA free adhesive resulted in good durability. This adhesive has shown excellent clinical results in Class V NCCL lesions [41].

The main reason for failure was material fracture followed by recurrent caries. This is in accordance with recent findings in most of the clinical follow up [62,63]. The high relative frequency fractures observed may be explained partly by the high percentage of participants with parafunctional habits. But also by the inclusion of a high frequency extense “amalgam cavities” in molar teeth, which increase the total fracture risk. Wear was not observed to be a clinical problem, despite suggestions in the literature that wear may be a significant mode of failure in larger restorations, especially in patients with bruxing and clenching habits [64]. This confirms findings from recent reviews of clinical studies published during the last years [62,63].

It can be concluded that Class II resin composite restorations performed with the new TEGDMA/HEMA-free low shrinkage resin composite system showed good durability similar to hybrid or nanofiller resin composite systems containing HEMA, TEGDMA or other low molecular weight monomers, with high effectiveness.

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