DENTAL MATERIALS 33 (2017) 944–953

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.intl.elsevierhealth.com/journals/dema

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

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ARTICLE INFO

Article history:
Received 3 February 2017
Received in revised form
10 April 2017
Accepted 28 April 2017

Keywords:
Adhesive
Clinical
HEMA
Low shrinkage
Posterior
Resin composite
TEGDMA

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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http://dx.doi.org/10.1016/j.dental.2017.04.021

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