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A 15-year randomized controlled study of a reduced shrinkage stress resin composite

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ABSTRACT

Objectives. The aim of this randomized controlled study was to evaluate the long term effectiveness of a reduced shrinkage stress resin composite in Class II restorations. The material was compared intra-individually with a microhybrid resin composite.

Materials and methods. Each of 50 patients with at least one pair of two similar sized Class II cavities participated (22 female, 28 male, mean age 43 years, range 18–64). Each participant received in each pair, in a randomized way, one Class II restoration performed with a reduced shrinkage stress resin composite (InTen-S) and the other restoration with a microhybrid resin composite restoration (Point 4). Both restorations were placed with an etch-and-rinse bonding system and an oblique layering technique. A total of 106 restorations, 33 premolar and 73 molars, were placed. The restorations were evaluated blindly each year using modified USPHS criteria. The overall performance of the experimental restorations was tested after intra-individual comparison using the Friedmanís two-way analysis of variance test. The hypothesis was rejected at the 5% level.

Results. At 15 years, 91 restorations were evaluated. The drop out frequency was 15 restorations (5 male, 3 female participants; 2 premolar and 13 molar restorations). Except for 2 participants, who reported slight symptoms during a few weeks after placement, no postoperative sensitivity was observed at the recalls. The overall success rate at 15 years was 77%. Twenty-one non acceptable restorations were observed during the 15 years follow up, 10 InTen-S (21.7%) and 11 Point 4 (24.4%) restorations ($p > 0.05$). Annual failure rates for the resin composites were 1.5% and 1.6%, respectively. The main reasons for failure were secondary caries (8) and resin composite fracture (7). The differences between premolar vs. molar restorations and between restorations in male vs. female participants were not significant. Significant differences were observed between 2-surface vs. 3-surface restorations.

Significance. During the 15-year follow up, the reduced shrinkage stress resin composite showed a good clinical durability in Class II cavities, but not significantly better than the control microhybrid resin composite. Secondary caries and material fracture were the main reasons of failure.

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1. Introduction

Resin composites have replaced amalgam in modern adhesive dentistry. Acceptable longevity has been shown in short and long term retrospective and longitudinal prospective evaluations [1–7]. One of the remaining problems of resin based composites has been stated to be their polymerization shrinkage, which may influence the durability of restorations [8–10]. The magnitude of shrinkage depends on factors like resin matrix formulation, amount of filler used in the resin composite and degree of conversion. The free curing contraction for resin composites varies from 2.0% to 5.0% with post-gel contraction values as low as 0.2% to 2.0% [8]. Depending on the concentration, the type and the flexibility of the reacting groups, polymerization shrinkage is manifested as shrinkage stress when monomer molecules are converted into a polymer network. In the pre-gel phase, the material is able to flow and stresses are relieved. Post-gel polymerization results in stresses in the tooth structures and tooth–material bonding interfaces. Contraction forces exceeding the bond strength at the tooth-restoration interface affect the interfacial adaptation [11,12]. Bacterial microleakage may follow interfacial debonding, resulting in marginal staining, pulpal inflammation or secondary caries [13]. Cuspal movement during polymerization may be perceived as post-operative pain [14–16].

Different application techniques and light curing protocols have been suggested to reduce the effect of contraction stress [17–21]. No significant difference in durability was observed when a low-shrinkage hybrid resin composite with reduced shrinkage stress was compared to a control hybrid resin composite in a 5-year follow up of Class II restorations [22]. No long-term clinical study investigated this factor. The aim of this clinical randomized study was to evaluate the 15 year effectiveness of these Class II restorations made with the reduced shrinkage stress resin composite and compared intra-individually with a microhybrid resin composite. The hypothesis tested was that durability of posterior Class II restorations with the reduced shrinkage stress resin composite would be in favour to these made with the microhybrid resin composite.

2. Materials and methods

2.1. *Experimental design*

The study is a two-centre randomized controlled trial. In an intra-individual comparison each participant received at least one pair Class II resin composite restorations. The two restorations in each pair were of approximately the same size, one performed with an experimental low shrinkage resin composite, marketed as InTen-S (IvoclarVivadent, Schaan, Liechtenstein), and one with a control microhybrid resin composite (Point 4; Kerr, West Collins Orange, CA, USA). The low shrinkage resin composite with reduced shrinkage stress (InTen-S) contains barium glass and ytterbium trifluoride filler, 74 wt% and 51 vol% with a particle size between 0.2 and 7.0 μm. The inclusion of special copolymer fillers resulted in a 81.9 filler w%. As defined do hybrid resin composites combine microfiller particles (0.04-μm fumed silica) with microfine glass fillers with an average particle size diameter of less than 2 μm. Point 4 is a microhybrid resin composite that contains approximately 76% inorganic filler by weight and 57 vol% with an average particle size of 0.4 μm [22].

During the first part of 2000, all adult patients, who needed at least two similar sized Class II resin composite restorations, attending the Public Dental Health clinics of the two authors at the Dental School Umeå (JvD) and the Folktandvården Seminariegatan Skellefteå (AL), were asked to participate in the follow up study [22]. The teeth to be included had to be in occlusion and should have at least one synergist and one neighbouring tooth. Pregnant patients, dental personal and -students, and patients with partial prosthesis or orthodontic apparatus were excluded. No participant was excluded because of high caries activity, periodontal condition or parafunctional habits. All the patients invited, participated in the study. Twenty-two women and 28 men, with a mean age of 43 years (18–64 years), were included in the study. Each patient provided informed consent to participate in the study, which was approved by the ethics committee of the University of Umeå, Sweden. The checklist of the CONSORT statement, an evidence-based minimum set of recommendations for reporting randomized trials, was followed. Reasons for placement of the resin composite restorations were secondary caries, fracture of old amalgam fillings or replacement because of aesthetic or other reasons. The participants were not aware of the cavity the experimental materials were placed.

Operative procedures were performed by two operators experienced with adhesive dentistry and familiar with the tested materials [22]. Local anesthesia was used if necessary. After removal of the amalgam restoration and/or caries excavation, the cavities were rinsed by water. Before the operative procedure started, the cavities within each participant were randomized to the test systems by throwing dice. The distribution and the number of surfaces of the 106 restorations are given in Table 1. No rubberdam was used. The operative field was isolated with cotton rolls and suction device. For all cavities a thin metallic matrix (stainless steel, 0.038 mm; TopDent, DAB, Stockholm; Tofflemire matrix system) was used and carefully wedging was performed with wooden wedges (Hawe Neos, Bioggio, Switzerland). No calcium hydroxide base material was placed and no bevels were prepared. The cavities were cleaned by a careful rinsing with water, before they were conditioned with 37% phosphoric acid (Ultradent Prod Inc, South Jordan, Utah, USA). The enamel was first acid etched for 10 s, after which the dentin and enamel was etched for another 5 s. For the InTen-S restorations the enamel-dentin bonding

Table 1 – Distribution of the experimental restorations.

Surfaces	Mandible		Maxilla		
	Premolars	Molars	Premolars	Molars	
2-surfaces	10	26	17	32	85
3-surfaces	4	7	5	5	21
	14	33	22	37	106