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ORIGINAL ARTICLE

Efficacy of a moisture-tolerant material for fissure sealing: a prospective randomised clinical trial

N. Schlueter · J. Klimek · C. Ganss

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Abstract
Objectives Fissure sealings offer nearly complete protection against fissure caries, provided that they are adequately applied, for composite-based sealants with sufficient moisture control. This is not always attainable, particularly in children with low compliance. To counter this problem, a moisture-tolerant sealant has been developed. The present randomised clinical trial compared such a moisture-tolerant material (Embrace) with a conventional sealant (Helioseal).
Material and methods In 55 participants (mean age, 10± 3 years), corresponding molar pairs were sealed with either Embrace or Helioseal. Retention, quality of sealing, and caries were clinically examined, both tactilely and visually, immediately and after 1 year.
Results After 1 year, 93 % of Helioseal sealings were complete, whereas 60 % of Embrace sealings showed partial and 13 % complete loss. The surface quality of Embrace was significantly worse than that of Helioseal. After the use of Embrace, the sealant margin was noticeable as a slight (distinct) step in 36 % (15 %). The visual (tactile) examination showed a rough surface in 78 % (33 %) in the case of Embrace. The Helioseal surfaces were shiny (smooth) in all cases (all differences between Helioseal and Embrace, $p \leq 0.001$). Caries was found only after the use of Embrace (4 %, n.s. compared to Helioseal).
Conclusion The moisture-tolerant material Embrace was distinctly inferior to Helioseal because Embrace showed weaknesses in retention and surface quality.
Clinical relevance Even if a moisture-tolerant sealant would be desirable in particular for children with low compliance, the tested material does not represent an alternative to the standard preparation.

Keywords Fissure sealing · Clinical trial · Prophylaxis · Retention

N. Schlueter (✉) · J. Klimek · C. Ganss
Department of Conservative and Preventive Dentistry,
Dental Clinic of the Justus Liebig University,
Schlangenzahl 14,
35392 Giessen, Germany
e-mail: nadine.schlueter@dentist.med.uni-giessen.de

Introduction

Fissure sealants were introduced in the 1960s. Whilst in the 1980s, less than 10 % of children and adolescents had fissure sealings, the prevalence of sealed teeth increased to approximately 40 % amongst the 12–15-year-old age group at least in the USA [1]. As a result of regular use of pit and fissure sealings, the prevalence of fissure caries was reduced by 87 % on 12-month and 60 % on 48–54-month follow-up [2]. Fissure sealings have not only been used for prevention but also for managing non-cavitated occlusal dentine caries. In comparison to unsealed teeth, sealed dentine lesions showed no progression [3]. Both facts, the reduction in caries prevalence and the reduction of progression of non-cavitated dentine caries, provide a strong argument for the use of sealants. However, the success of sealings is undoubtedly dependent on the retention of the sealant in the fissure, indicated by a reduced success rate in cases with an increased rate of loss [2].

The retention of resin-based or composite materials is often better than that of, e.g., glass ionomer cements, provided that sufficient moisture control is performed with cotton rolls or,

ideally, with rubber dam [4]. However, moisture control is often only possible to a limited extent, particularly in children with low compliance. Contamination of acid-conditioned surfaces with saliva is quite possible and may result in a reduced tensile bond strength [5, 6], leading to a reduced success rate of sealant retention. Therefore, a material combining the attributes of resin-based sealants, in particular good retention and good physical properties, with moisture tolerance and ease of handling would be desirable. Recently, a sealing material has been developed whose hydrophobic matrix has been supplemented with hydrophilic groups (di-, tri-, and multifunctional acrylate monomers). This should lead not only to a higher tolerance towards moisture but also to an improved miscibility with water. Concomitantly, an easier application after the common acid-etch technique is promoted. According to the manufacturers' recommendations, the surfaces of the teeth to be sealed must not be dried after the etching procedure because the moisture is necessary for activation of the sealing material, subsequently leading to a chemical reaction between the sealant and the dental hard tissue. In contrast to other sealants [7], even contamination with saliva should have no negative impact on bond strength of this material [8].

The aim of the present study was to compare the moisture-tolerant fissure sealing material with a standard resin-based sealant by examining parameters such as retention and quality of the sealings as well as the occurrence of caries. Assessment was performed immediately and at a 1-year follow-up, both visually and tactilely. The null hypothesis was that there is no difference between the two materials.

Participants, materials, and methods

Participants

The trial was planned as a prospective, randomised study with a split mouth design. The observation period per participant was 1 year. The study was conducted in a dental practice in the area of Giessen and was supervised by the Department for Conservative and Preventive Dentistry in the Dental Clinic of the Justus-Liebig University in Giessen. Participants were outpatients in the dental practice. Inclusion criteria were informed consent by parents or legal guardians, no serious diseases, no allergies against dental materials, acceptable compliance during treatment, sufficient moisture control, willingness for check-ups, and indication for a prophylactic fissure sealing at corresponding molars in one jaw. The indication was the presence of a non-stained fissure with a complex relief that was without caries, as well as no caries on the proximal surfaces. Fissure sealing was performed at least 6 months after tooth eruption.

The study was performed in accordance with Good Clinical Practice guidelines and conformed to the Declaration of Helsinki. It was approved by the local ethics committee (Ethik-Kommission des Fachbereichs Medizin der Justus-Liebig-Universität Giessen, application no. 67/05). The report of the study follows the CONSORT guidelines.

Interventions

Two different sealants were compared (for composition, see Table 1): the moisture-tolerant material Embrace™ WetBond (GABA GmbH, Loerrach, Germany) and the conventional resin-based sealing material Helioseal® (Vivadent, Schaan, Lichtenstein), which was the control. Fissures were cleaned prior to sealing using pumice slurry, a rubber cup (Pro-Cup, art. no. 991/30, KerrHawe, Bioggio, Switzerland), and a small dental probe. For relative moisture control, cotton rolls were used. Etching was performed with phosphoric acid (37 %, Total Etch, Vivadent, Schaan, Liechtenstein). The sealants were applied with a small ball-shaped plugger and a dental probe. Light curing was performed with a halogen light curing unit (Translux CL, Heraeus Kulzer, Hanau; power output, 850 mW/cm^2).

For an overview of procedures, see flow chart in Fig. 1. All parents or legal guardians gave written informed consent for their children (hereafter, parents and children are referred to as participants). The entire study consisted of a total of three appointments per participant. During the first appointment, participants were informed about the procedures. During the second appointment, the fissure sealings were performed according to the manufacturers' instructions (see Fig. 1). Sealing was generally started in the first quadrant in the maxilla and in the third quadrant in the mandible. Directly after the sealing procedure, the sealings were examined (E1). Finally, fluoridation with a varnish (Duraphat, GABA GmbH, Loerrach, Germany) was performed according to the German guidelines for pit and fissure sealing.

Table 1 Composition of the sealants used as declared by the manufacturer and from the Materials Safety Data Sheets

Helioseal	Embrace
• 58.3 % Bisphenol A-Glycidyl methacrylate (Bis-GMA)	• Contains di-, tri-, and multifunctional acrylate monomers
• 38.1 % Triethylene glycol dimethacrylate (TEGDMA)	• No Bisphenol A-Glycidyl methacrylate (Bis-GMA)
• 2.0 % titanium dioxide	• No Bisphenol A-Dimethacrylate (Bis-DMA)
• 1.6 % initiators, catalysts, and stabilizers	• Sodium fluoride
• Not filled	• Glass-filled (filler by weight, 36.6 %)
	• Amorphous silica
• Solubility in water, 3.4 μg/mm³	• Solubility in water, nil
• Water sorption, 57.7 μg/mm³	• Water sorption, no data
• Film thickness, no data	• Film thickness, 12 μm

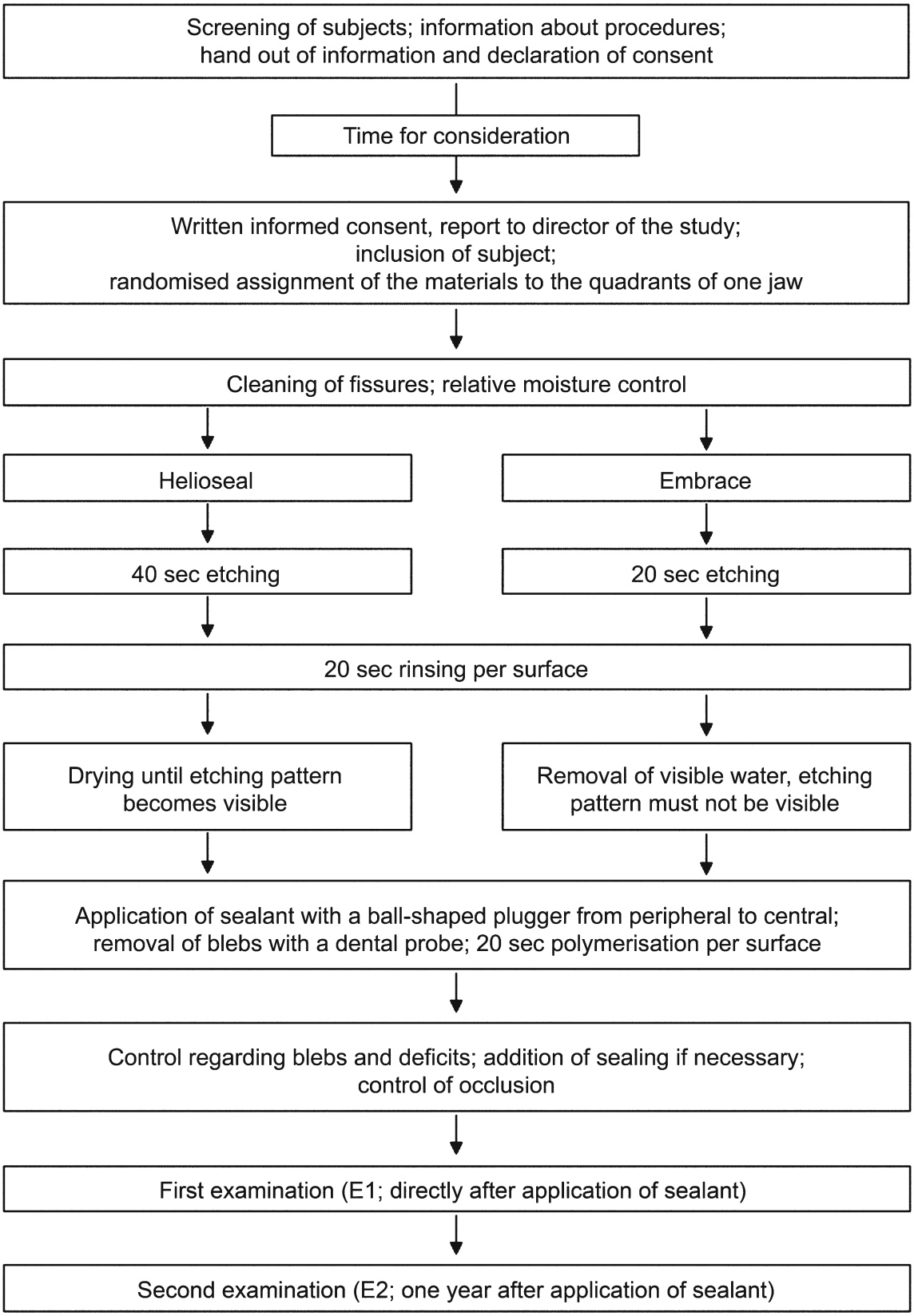

Fig. 1 Flow chart of the study procedures. *E1* represents the examination directly after the application of the sealant, *E2* represents the examination 1 year after the sealing procedure

After 1 year, the participants were invited back for a second examination (E2) of the sealings by the clinical investigator.

All clinical examinations were performed under relative moisture control with cotton rolls and after thorough drying of the tooth surfaces. Examination was performed without magnification aid and included a tactile examination and a visual examination. All tactile examinations were made with a small dental probe.

Evaluation criteria

Criteria for clinical examination, both visual and tactile, were quality and retention of the sealing as well as the incidence of caries (for details, see Table 2). Criteria for the assessment of retention were: fissure sealing complete—no part of the sealant was lost; partial loss of fissure sealing—all cases in which previously sealed areas were exposed; and total loss of fissure sealing—the complete fissure is free of sealant. The results of each examination were entered into a standardised documentation sheet.

Responsibilities

The study director was responsible for the study logistics and the randomisation procedure (C.G.). Performance of the sealing, investigation at both time points, and data recording were carried out by the clinical investigator (A.M.). The investigator was carefully trained and calibrated for all procedures and for examinations. The twofold examination of 12 participants revealed an intra-examiner kappa value of 0.94.

Sample size

A difference of 15 % between both sealants was assumed (α=0.05; β=0.20) [4]. Sample size calculation revealed a group size of 48; considering dropouts or withdrawals (15 %), a sample size of n=55 was targeted.

Randomisation

Randomisation was performed in terms of allocation of the sealing material to one of the quadrants within the same jaw. The allocation after reporting of the included participants was performed by the study director using a previously created randomisation list (http://graphpad.com/quickcalcs/randomize2.cfm).

Blinding

Examination after 1 year was blinded with respect to initial data and randomisation (allocation of the sealing material). In order to do this, separate sheets were used for immediate examinations and 1-year follow-up examinations, whereas the sheets of the immediate examination were kept by the study director during the second examination.

Statistical analysis

Statistical analysis was performed at the end of the study. No interim analysis was performed. All statistical procedures were performed with IBM SPSS Statistics 19.0 (Armonk, NY, USA). The data were discrete and ordinal scaled; therefore, the Wilcoxon test was used to compare the results between the two sealing materials. To compare the results for one sealant used in separate jaws, the Mann–Whitney test was performed. The level of significance was set at 0.05.

Results

A total of 55 subjects participated in the study, which were recruited within a period of 3 months. All participants kept the appointment for the second examination (E2) at the

Table 2 Evaluation criteria for the examinations of fissure sealings directly and 1 year after application

Criteria for examination	
Retention	Fissure sealing complete
	Partial loss of fissure sealing
	Total loss of fissure sealing
Quality	
Air inclusion	Number (sampling with a dental probe)
Surface	Tactile: smooth/rough (sampling with a dental probe) optical: shiny/matte appearance
Junction sealing–tooth	Not noticeable/slight step/distinct step (sampling with a dental probe)
Staining of the margin	Yes/no
Caries in pit and fissures	Cavitation
	And/or opacity at fissures
	And/or distinct undermining, opaque discoloration

intended time point. The mean age of participants was 10± 3 years. A total of 28 pairs of molars in the maxilla and 27 pairs in the mandible were sealed. No deviations from the protocol and no side effects occurred.

At baseline (E1), no air inclusions were found after sealing with Helioseal. The surfaces were smooth and shiny in 100 % of cases. No step and no discolouration were found at the sealant margin, and all sealings were complete. After sealing with Embrace, one sealing was found to have one air inclusion (2 %), and one sealing was found to have two air inclusions (2 %) at baseline. In one case (2 %), the tactile assessment revealed a rough surface and a slight step between the sealing material and the surface of the dental hard tissue. Visually, the surface was shiny, without discolouration and complete in 100 % of cases.

The results of the clinical assessments after 1 year are displayed in Table 3. Retention, which was assessed using tactile and visual examinations of the surface quality and tactile examination of the sealant margin, was found to be significantly worse ($p \leq 0.001$) after the use of Embrace. Differences between the maxilla and mandible were found after the use of Embrace on visual assessment of the surface quality and on tactile assessment of the surface of the sealant margin. The results for these criteria were significantly ($p \leq 0.05$) worse in the mandible than in the maxilla.

Discussion

The retention of sealings after 1 year was found to be 74–96 % in a review of the literature of the ADA [9] and 79–92 % in a review of the Cochrane Collaboration [2]. We found the retention rate for Helioseal to be high and within the above-mentioned ranges with a complete retention rate of 93 %. The retention rate after the use of Embrace, however, was substantially lower with only 27 % complete retention. The low retention rate was accompanied by the high rate of tactile margins.

As both materials are resin sealants, the natural surfaces were conditioned with phosphoric acid prior to sealing following the manufacturers' recommendations. The etching period was different for the two sealants. However, there is no evidence that differences in the etching duration, in a range of 15 to 60 s, have any significant impact on the success or retention rate of fissure sealants [10]. Therefore, the differences in retention between both sealants were most likely not due to the differences in etching time.

The marked difference in retention was surprising because Embrace had previously been shown to create bonds with high tensile strength under in vitro conditions, which were comparable to that of a resin cement [11]. A central difference between the present and the cited study was that in the previous study, Embrace was used as a self-adhesive resin cement for indirect restorations. Therefore, whereas natural enamel surfaces were treated in the present study, prepared surfaces, mainly dentine, came into contact with the material in the previous study. A recent review on bonding effectiveness and stability [12] revealed that using self-etching adhesives on dentine is a very promising option.

The reason for the low retention rate of Embrace on enamel in our study is not clear. Two reasons could play a

Table 3 Results of clinical examination after 1 year

Results after 1 year		Helioseal (%)	Embrace (%)
Retention*	Fissure sealing complete	93	27
	Partial loss of fissure sealing	7	60
	Total loss of fissure sealing	0	13
Air inclusion	One inclusion	2	2
Tactile assessment of surface quality *	Smooth	100	55
	Rough	0	33
	No assessment due to total loss	0	13
Visual assessment of surface quality*	Shiny	100	9
	Matte	0	78
	No assessment due to total loss	0	13
Tactile assessment of the junction sealing–tooth*	Not noticeable	93	36
	Slight step	7	36
	Distinct step	0	15
	No assessment due to loss	0	13
Staining of the margin	No	100	87
	Yes	0	0
	No assessment due to loss	0	13
Caries	Yes	0	4

*$p \leq 0.001$, significantly different between both sealing materials

role. On the one hand, moisture control in the fissures was quite difficult to achieve. The manufacturer recommends using the material on surfaces that are moist enough such that no etching pattern is visible but dry enough such that water is not visible in the fissures. Clinically, these recommendations were difficult to achieve. While drying the fissure with the air syringe, the etching pattern became increasingly visible. Leaving the etching pattern masked by humidity implied pooling or drops of water in the fissures. The markedly poor retention as well as the matte appearance of the moisture-tolerant material could have been due to these weaknesses in clinical handling. On the other hand, the moisture tolerance is, even only little information about the composition of Embrace can be found (Table 1), most likely related to the presence of hydrophilic monomers, which allows forming bonds in the presence of water. Such monomers, however, lead to higher water sorption, which in turn can increase water solubility and a higher disintegration in the oral environment due to a lower cross-link density network [13]. The poor retention of Embrace was associated with tactile margins and a rough surface. Both of these characteristics can represent areas for higher retention of plaque. From a preventive perspective, this plaque retention may indicate worse long-term success, in particular, if one considers the development of caries.

The moisture-tolerant sealant may possibly unfold its full potential better if dentine is exposed. Dentine is hydrophilic and shows a somewhat uniform moistness after preparation. Due to the substitution of the sealant matrix with hydrophilic groups, the material acquires a more amphiphilic character, which in general increases the ability to bond to dentine [12].

Conclusion

The moisture-tolerant fissure sealing material Embrace was inferior to the sealant Helioseal in nearly all examined categories and therefore does not represent an alternative to the standard preparation.

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Conflict of interest None.

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