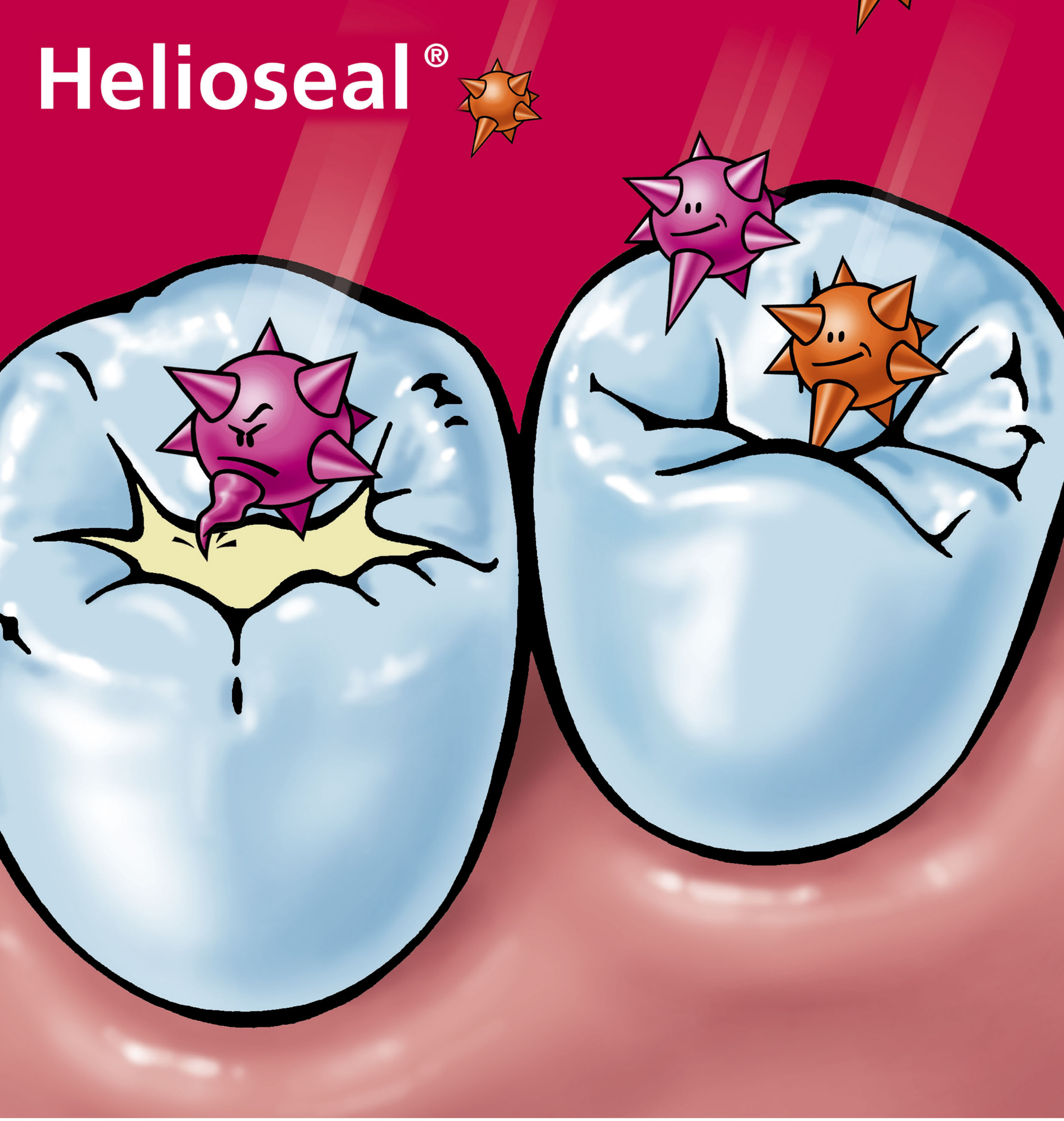
Helioseal®



Scientific Documentation

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1. Introduction

1.1 Fissure caries

Worldwide studies have shown that even good oral hygiene, reasonable eating habits and fluoridation are often not sufficient measures to prevent fissure caries. Given their morphology, fissures provide ideal niches for microorganisms to settle and grow and are often the starting point for the formation and development of caries. Even with excellent oral hygiene, plaque can only be removed from the occlusal surface up to the fissure entrance. Deeper regions of the fissure can usually not be reached with the bristles of a typical toothbrush and therefore present retention areas for plaque (Fig. 1) and carious lesions may easily form in these areas.

Fig. 1: The bristles of the toothbrush cannot reach the fissure bed (Picture courtesy of Prof. Dr Zimmer).

The teeth most at risk of fissure caries are molars, incisors with deep foramina caeca and more rarely premolars [1]. The surface enamel areas in fissures are thin and partially discontinuous near the pulp, therefore carious lesions in these areas can quickly penetrate the dentin.

Such risk factors help to explain why occlusal caries still accounts for up to 90% of all caries amongst children and teenagers, even in countries where a sharp overall decrease in caries has been achieved [2] [3] [4]. Ripa *et al.* reported that the percentage of first molars with occlusal caries or restorations increased by an annual rate of around 10% after a three year period [5].

There are therefore good reasons to seal susceptible fissures in children and adults to protect them from caries. The US National Institute of Health strongly recommends the sealing of fissures and foramina to lower the incidence of caries further below the margin already achieved by fluoridation or other measures [4]. Fissure sealing plays a key role in caries prevention. Long-term studies clearly substantiate their efficacy, as can be seen in Figure 2. Increased numbers of sealings result in a decrease in occlusal caries [6].

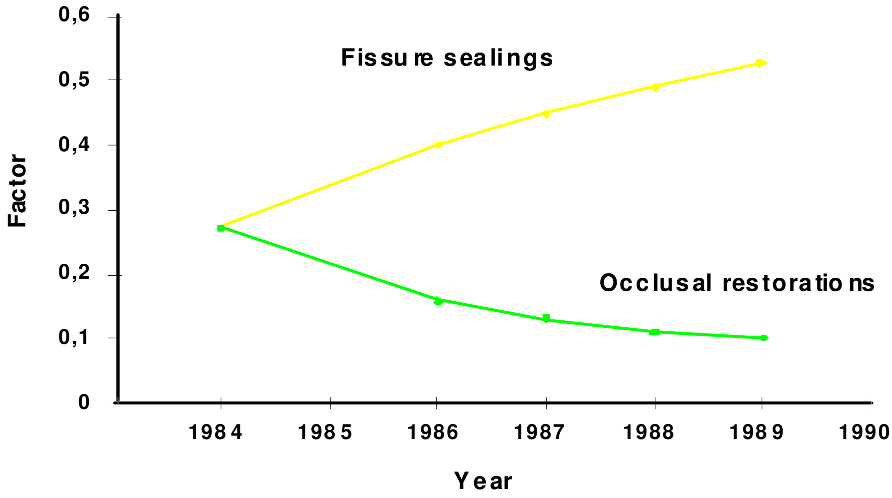

Fig. 2: Increase in the number of fissure sealings and decrease in occlusal caries in permanent teeth between 1984 and 1990 [6].

1.2 Indication for fissure sealing

Fissure sealings are suitable for both children and adults. The caries risk depends on the host and the bacteria. It is therefore essential to consider patient-specific factors, such as behavioural patterns, systemic influences and dental history. However, none of these factors is age-dependent [7]. Fissure sealing is indicated for the following areas:

• Pits and fissures of the molars and premolars

• Foramina caeca of anteriors

Preventive resin restoration therapy using fissure sealants may be indicated for initial carious lesions that do not warrant more invasive treatment [8] [1].

In children, sealing should be performed early and as soon as the entire occlusal table is visible and free of soft tissue [9]. The highest success can be achieved if the fissures are sealed four to six months after the eruption of teeth [10]. If the sealant is applied too early, the quality of the sealing may be hampered due to the position of the teeth or incomplete exposure of the occlusal surface [11]. Figure 3 below indicates an erupted tooth that is not yet suitable for sealing as the occlusal surface is still partially covered with soft tissue. The teeth shown in Fig. 4 are fully erupted and therefore perfectly suitable for sealing.

Fig. 3: Unsuitable molar for sealing

Fig. 4: Suitable molars for sealing

In adults, sealing may be indicated if high bacterial counts (mutans streptococci and lactobacilli) are present. Lactobacilli, which are mainly responsible for the progression of caries, require retention sites and niches for their survival as they do not have the ability of mutans streptococci to adhere to the smooth surfaces of the teeth. A significant correlation between carious lesions and the lactobacilli count in both adults and children has been observed. Children with cavities in need of restoring demonstrate clearly higher lactobacilli counts than children with restored cavities. A high lactobacilli count is also an indicator of high sugar intake [12]. In these patients, bacterial counts can be clearly reduced by sealing potential retention sites.

Sealing may also be indicated as a preventive measure for patients who enjoy a diet rich in simple carbohydrates or patients who are on certain medications. Even if the diet of diabetes patients is low in sugars, they have an increased risk of developing caries, because they may experience low salivary flow as well as increased glucose levels in the oral cavity or a loss of local defence mechanisms [13]. Xerostomic patients, i.e. those patients with poor salivary flow due to e.g. medication, radiation treatment, stress or autoimmune diseases, are especially at risk as the natural protective mechanisms of saliva, e.g. buffer capacity and provision of remineralizing ions, are reduced and consequently not sufficiently effective. Fissure sealing is also recommended for these cases.

Preventive resin restorations refer to a minimally invasive treatment of the pits and fissures before the sealant is applied. Such a treatment may be warranted if a questionable discoloration is present and possibly when the teeth to be sealed erupted several years previously [9]. Flowable composites are for instance suitable for preventive resin restorations [14].

1.3 Method of protection

Fissure sealing is a non-invasive preventive measure which seals off pits and fissures with an impermeable resin layer. This layer prevents food and bacteria from entering the deep and narrow crevices of the fissure (see Fig. 5). The supply of substrates to bacteria that may already be below the sealant is also cut off thus hampering bacterial metabolism and preventing the bacteria from producing enough acids to cause further demineralisation [15]. Fissure sealing not only protects those regions prone to caries, but it can also stop the progression of initial lesions. [16]. In a comparison between a sealed with an unsealed fissure, only about 2% of the bacteria were still viable a month after sealing [17].

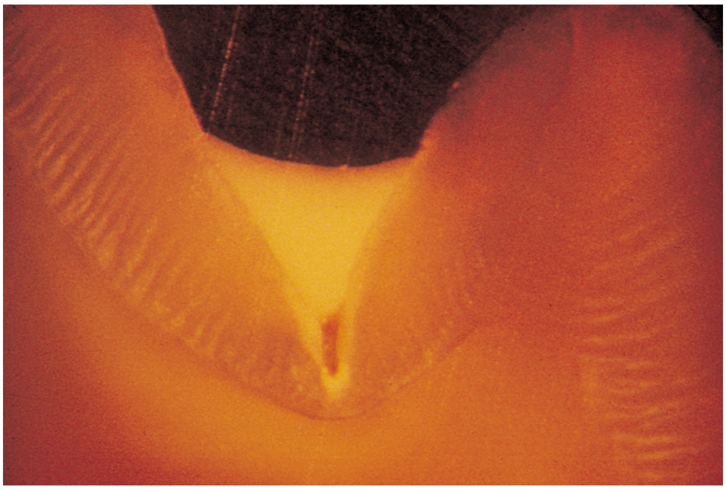

Fig. 5: The sealant forms a smooth hygienic surface. If the sealing is tight, the microorganisms are cut off from the supply of substrates and are no longer viable.

In addition, the resin layer creates smooth surfaces which are less susceptible to plaque retention than fissures and pits and allow improved oral hygiene. Fissure sealing therefore reduces the number of available retention sites and inhibits the viability of the microorganisms.

Fissure sealants can reduce the risk of developing occlusal caries by approximately 70 to 90% if the following requirements are met [17]:

- The sealant fully wets the surface of the fissures and pits, but it is not absolutely necessary to fill the fissure completely.
- The sealant forms a strong and durable bond with the enamel surface.
- Mechanical, thermal or chemical stimuli do not cause the material to crack or become more porous.

1.4 Properties of fissure sealants

1.4.1 Chemical properties

Most fissure sealants on the market are filled or unfilled, one- or two-component materials. Most of them contain methacrylate, e.g. bis-GMA, as the resin base. In addition to resin-based sealants, glass-ionomer cements are also used for fissure sealing. There are fissure sealants with or without fluoride release and self- or light-cured ones. Self-curing (chemically curing) fissure sealants incorporate a catalyst, usually benzoyl peroxide, which initiates polymerization. Light-curing sealants are polymerized with the help of an appropriate light source. The polymerization of these sealants is also initiated by a catalyst (e.g. camphorquinone), which absorbs light of a specified wavelength.

Most fissure sealants – including the Helioseal products – are light-cured. Generally, the tooth structure has to be conditioned with etching gel prior to applying the sealant.

1.4.2 Shade

Fissure sealants are available in a variety of different shades, such as white, transparent or colours that are specifically matched to the natural colour of teeth. Other colours such as red and colour-changing sealants are also offered.

The clinical application and evaluation at recall are facilitated if a sealant is clearly visible because it is pigmented, e.g. white [18] [2]. Tooth-coloured sealants offer favourable esthetic properties, but may be difficult to differentiate from the enamel at the recall.

Transparent sealants offer superior esthetics. Although they are also difficult to differentiate from the tooth structure, they offer a transparent surface through which any untoward changes in the fissure, e.g. discoloration which may indicate incipient carious processes, can be observed. In addition, colour-changing sealants, e.g. Clinpro Sealant/3M/Espe, are also available. Clinpro Sealant is pink when dispensed from the syringe and turns opaque cream upon polymerization. The colour change is irreversible.

1.4.3 Fluoride

Fissure sealants are available with or without fluoride. Fissure sealants contain various types of fluoride compounds, e.g. fluorosilicate glass, fluoridated methacrylic acid and sodium fluoride. The caries protective effect of fluoride is a well-documented and generally accepted fact [19; 20]. Fluoride is known to:

- promote remineralization processes and hamper demineralization processes

- increase enamel resistance

- reduce plaque growth and plaque activity

Hydroxyapatite $[Ca_3(PO_4)_2]_3{\cdot}Ca(OH)_2$ is the principal component of enamel. By exposing hydroxyapatite to fluoride ions, fluorapatite is formed ($[Ca_3(PO_4)_2]_3{\cdot}Ca(F)_2$), which is considerably less susceptible to being dissolved by acids than hydroxyapatite. The results of numerous studies substantiate the fact that fluoride is incorporated into the enamel and increases enamel resistance when fluoridated materials are used [21].

Continual exposure to small quantities of fluoride is the optimal situation. It is therefore of great benefit if materials, such as fissure sealants, which are in long-term contact with the teeth continuously release small quantities of fluoride [22].

In vitro studies have shown that the depth of lesions is significantly lower after application of a sealant containing fluoride than after using a sealant without fluoride [23]. Furthermore, fluoride offers a protective effect at the margins, i.e. the area adjacent to non-sealed enamel. Consequently, fluoride may reduce the risk of caries development even if seals are broken or damaged [24].

1.5 The Helioseal family

Ivoclar Vivadent offers three light-curing fissure sealants, which are clearly distinctive from each other and are indicated for different clinical requirements:

Helioseal®

Helioseal is the original fissure sealant from Ivoclar Vivadent. Small amounts of titanium dioxide give this material its typical white shade, facilitating the evaluation of the seal and retention at recall appointments. In addition, Helioseal is distinct for its excellent flow properties.

Helioseal® F

Helioseal F is also shaded white, facilitating the clinical application and evaluation of the marginal seal and retention at recall appointments (see Fig. 6). Helioseal F comprises 40% inorganic fillers including a fluorosilicate glass which slowly releases fluoride ions over time. The viscosity of Helioseal F is slightly higher than that of Helioseal because of its filler content. This ensures the stability and homogeneity of the material. Helioseal F offers dual protection against caries by combining mechanical block and depot fluoride action.

Helioseal® Clear

Helioseal Clear is a clear transparent fissure sealant which is particularly suitable for dentists and patients demanding a superior esthetic finish (see Fig. 7). The material optimally flows into fissures due to its low viscosity. The colourless transparent shade enables the clinician to easily identify possible changes under the sealant at recall appointments.

The Helioseal fissure sealants can be light-cured with all types of light-curing units (halogen, laser, plasma, LED) which offer a light intensity of more than 300 mW/cm^2 and emit light in the wavelength range between 400 nm and 500 nm. The light intensity of some LED lights in particular tends to be lower than the stipulated light intensity, in which case the illumination time has be extended to be longer than 20 seconds.

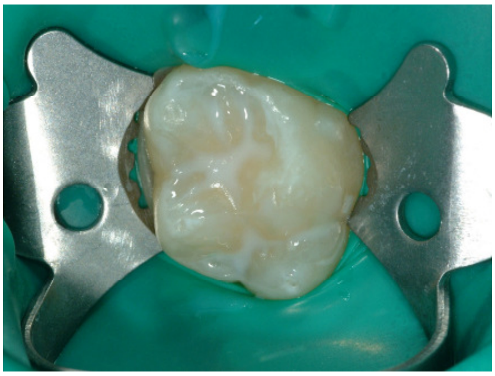

Fig. 6: Sealing with Helioseal F

Fig. 7: Sealing with Helioseal Clear (Courtesy picture of Prof. Dr S. Twetman)

2. Composition

Composition in percent by weight:

	Helioseal	Helioseal F	Helioseal Clear
Bis-GMA	58.3	11.8	60.0
TEGDMA	38.1	23.4	39.3
UDMA	-	23.4	-
Fluorosilicate glass, silicon dioxide	-	40.5	-
Titanium dioxide	2.0	0.6	-
Stabilizers, catalysts	1.6	0.3	0.7

Physical values:

	Helioseal	Helioseal F	Helioseal Clear
Vickers hardness 0.5/30	180 N/mm^2	240 N/mm^2	-
Refractive index n_D^{25}	1,5122	-	-
Flexural strength	77 MPa	88 MPa	95 MPa
Modulus of elasticity	2400 MPa	3200 MPa	2700 MPa
Depth of cure	2.4 mm	3.3 mm	5.5 mm
Sensitivity to light	80 s-	48 s	29 s
Film thickness	-	23 µm	28 µm
Fluoride release	-	7 $ng/cm^2/d$	-
Shear bond strength on etched bovine enamel	16.9 MPa	20.6 MPa	
Water absorption	57.7 $µg/mm^3$	54.3 $µg/mm^3$	-
Water solubility	3.4 $µg/mm^3$	4.5 $µg/mm^3$	-

3. *In vitro* investigations

3.1 Fluoride release of Helioseal F

In addition to purely mechanical protection, fissure sealants containing fluoride offer the additional benefit of localized fluoride release, strengthening the enamel and increasing its resistance to acid attacks. The fluoride source contained in Helioseal F is fluorosilicate glass, which, unlike sodium fluoride, ensures a continuous slow release of fluoride over time.

The amount of fluoride released by a sealant such as Helioseal F can be measured in laboratory tests. The fluoride release is high in the first 24 hours and then drops to a lower concentration, which is continuously released over a long period of time (see Fig. 8) [25; 26].

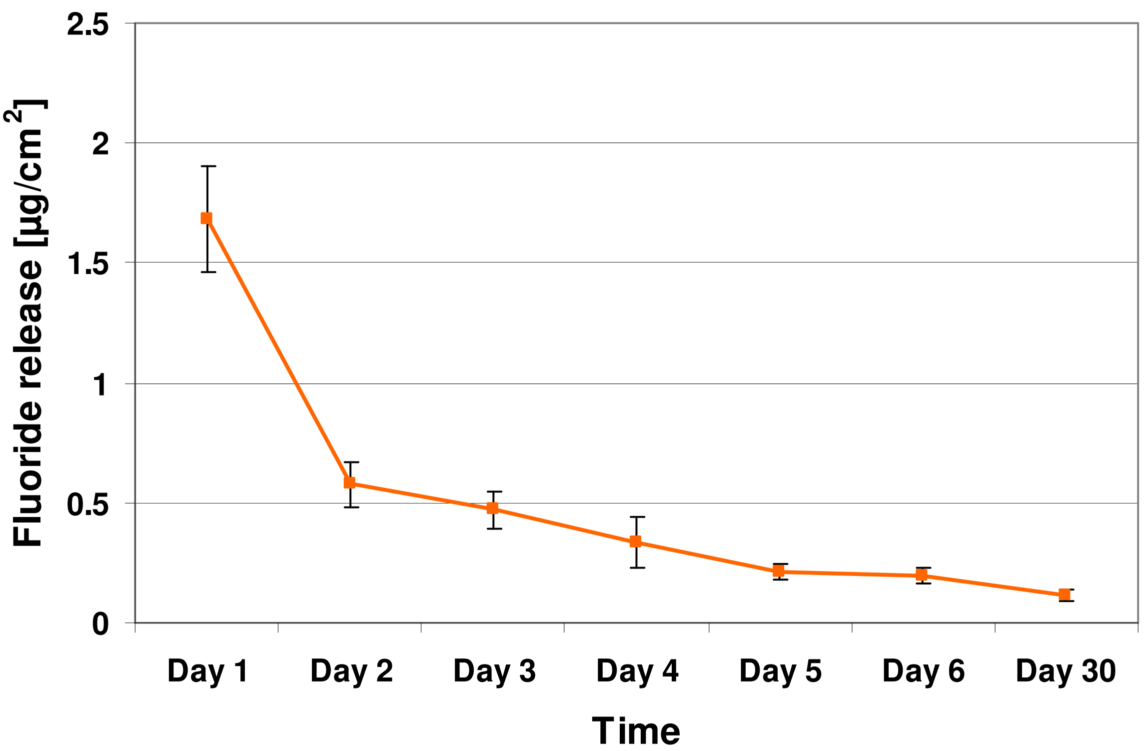

Fig. 8: Fluoride release of Helioseal F over 30 days [25]

If the amount of fluoride released over six months is added up in the chart in Figure 9. The continuous release of fluoride results in a steadily increasing amount of released fluoride over time [27]. The physical properties of the material are not affected in the process, because the fluoride is released only in small quantities over a long period of time.

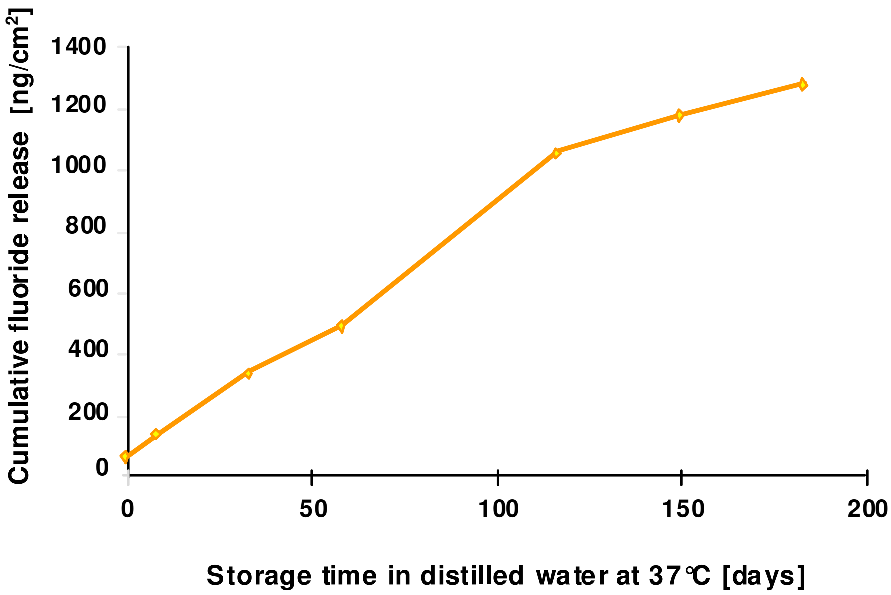

Fig. 9: Cumulative fluoride release of Helioseal F; mean value of 20 specimens [27].

3.2 Adhesion to enamel

The retention of a sealant is, among other factors, determined by its capability of bonding to the enamel. Enamel adhesion was also the subject of laboratory tests. Scanning electron microscopic studies of extracted teeth showed that Helioseal penetrated even the deepest portions of the fissures and consequently enabled an optimal bond between the etched enamel and material [28].

A comparison of the bonding values of two different sealants (Helioseal and Concise) did not show any significant differences between the two materials [29]. The objective of another study was to investigate the influence of enamel etching on the bonding values of Helioseal. This study showed that when the etching time was increased by a factor of three (20 s vs 60 s), higher bonding values were achieved (15.4 ± 4.8 MPa vs 20.9 ± 3.6 MPa) [30]. Other sealants tend to behave similarly, i.e. their bonding values also improve when the etching time is increased.

If the enamel is contaminated with saliva after etching, the bonding strength of the sealant may be impaired. It is therefore recommended to apply a rubber dam prior to applying the fissure sealant [31]. Another study, however, found that contamination with saliva did not have any effect on the bonding values of Helioseal F. Increasing the etching time (5 s vs 30 s) after saliva contamination did not result in improved bonding values [32].

3.3 Microleakage

Fissure sealants have to be tight to, for instance, prevent the ingress of bacteria through leaking margins and thereby to prevent bacteria from causing caries on the tooth surface under the sealant, where they are protected from mechanical cleaning measures. The tightness of sealants can be assessed by means of e.g. dye penetration tests.

Schoch *et al.* examined the marginal seal of Helioseal and did not detect any penetration of dye in the 24 slices cut from 8 sealed teeth; Helioseal therefore achieved 100% tightness. [33]. Furthermore, significant less marginal leakage was found in Helioseal than in Fluoroshield in a comparative study involving various products [34]. Generally, classic sealants such as Helioseal and Helioseal F were found to provide a tighter seal than flowables [35].

Two studies examined the effect of surface conditioning on the tightness of the seal. Conventional phosphoric acid etching proved to be superior to conditioning with no-rinse conditioners or abrasion with aluminium oxide particles [36; 37].

Contamination with saliva may also affect the tightness of the seal. Helioseal F provided a statistically significant tighter seal than the other materials in a comparative study involving three products (Helioseal F, Enamel Loc and Fuji VII) [38].

3.4 Wear

A study compared the wear of three sealants (Helioseal, Helioseal F, Concise) caused by brushing with tooth paste (My First Colgate and Colgate Total). Colgate Total caused more wear in all three materials than My First Colgate. Significant differences between the different materials were neither observed in the My First Colgate group nor in the Colgate Total group [39].

3.5 Conclusion

The laboratory investigations of the Helioseal sealants show that these products offer a favourable bond to the tooth structure, high tightness and a clinically desirable continuous fluoride release (Helioseal F).

4. Clinical Studies

Extensive scientific data are available on the clinical efficacy of fissure sealants in caries prevention. A metaanalysis showed that sealing with resin-based sealants can lead to a decrease in caries by 86% (12 months) to 57% (48 to 54 months) [40]. After nine years, only 27% of the sealed surfaces were affected by caries, while this figure was as high as 77% in unsealed teeth [41]. Fissure sealants therefore provide effective protection against occlusal caries. The same conclusion is drawn in a review article which considered studies that were published in the past 30 years or more. The writers of this article explicitly recommend fissure sealing as a measure that is safe and effective but, unfortunately, is not yet sufficiently widespread [42].

The Helioseal fissure sealants were also the subject of numerous studies. The table below provides an outline of the most important results of these investigations.

4.1 Retention

Retention of the sealant plays a decisive part in the success of fissure sealings. Only if the sealants permanently remain in the fissures can the development of caries be prevented in these areas. Numerous clinical studies investigated the retention of Helioseal in the past years. Table 1 provides an overview of the results found in these investigations.

Table 1: Retention of Helioseal fissure sealings. (Only the results for Helioseal are listed below. The results of possible comparable products can be found in the relevant publications).

Experimental	**Duration**	**Complete seal**	**Partial loss**	**Complete loss**	**Reference**
150 patients (aged 6 - 14) 920 molars Helioseal; sealing applied in tropical conditions (29 °C, 64.5% air humidity)	12 months	**94.1%**	2.3%	3.6%	[44]
52 patients (aged 8 - 19) 104 sealings Helioseal vs Tetric Flow (split-mouth design)	12 months	**100%**	0%	0%	[14]
74 patients (aged 6–8) 252 sealings Helioseal after tooth brushing or professional tooth cleaning	12 months	**97.6%** (PTC) **99.6%** (brushing)		0%	[45]
43 patients (aged 12±4 years) 86 sealings (pairs of molars) Helioseal vs Helioseal Clear Chroma (split-mouth design)	12 months	**76.7%**	23.3%	0%	[46]

92 patients (aged 6–17) 656 sealings Helioseal	2 years	**96%**	4%	0%	[47]
95 patients (aged 5–15) 354 sealings (1st & 2nd permanent molars) Helioseal vs Ionosit Seal (split-mouth design)	3 years	**90.4%**	6.8%	2.8%	[48]
120 patients (test and control group of 60 patients each, aged 6–7) 161 sealings Helioseal vs unsealed control group	6 months	**98.6%**		1.4%	[49]
	1 year	**96.3%**		3.7%	
	2 years	**89.4%**		10.6%	
	3 years	**86.5%**		13.5%	
	4 years	**84%**		16%	
81 patients 429 sealings Helioseal	up to 8 years	**96%**	4%	0%	[43]
2415 sealed surfaces (1st molar) Helioseal / Delton / Microfill (retrospective)*	1 year	**91.5%***	4.8%*	3.7%*	[50]
	9 years	**58.2%***	15.4%*	26.4%*	

* Combined data of all three sealants used

Overall, Helioseal achieved excellent retention rates. After having been in place for 12 months, Helioseal showed retention rates of well over 90% in all but one study. Some studies also found excellent retention rates after Helioseal was in place for several years. For instance, Trummler *et al.* reported a retention rate of 96% after a study period of up to eight years [43]. The bar chart in Figure 10 shows the distribution of intact and partially intact sealings over a period of 2.5 to 8 years.

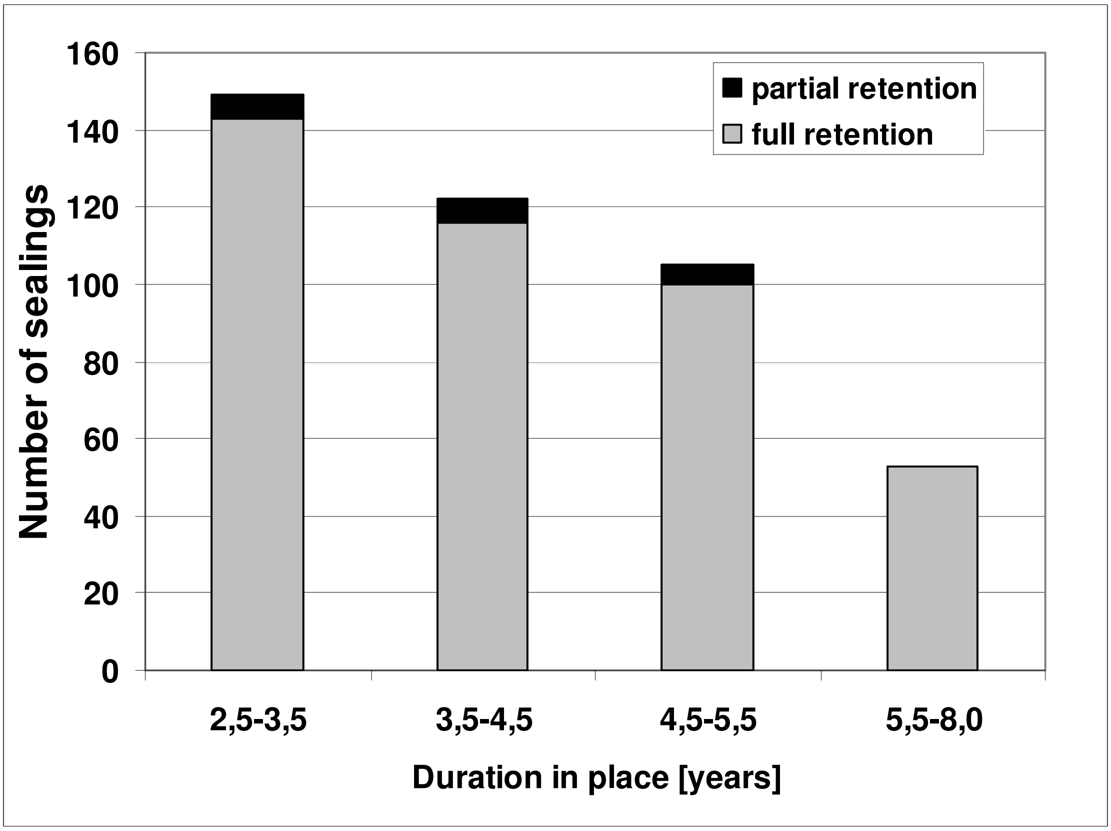

Fig. 10: Retention of Helioseal fissure sealings. The chart shows the number of intact seals (grey) and partially lost seals (black), broken down by the number of years of having been in place [51; 52].

The retention of Helioseal F was also investigated in clinical studies (see Table 2). This sealant also showed high retention rates of over 90% after as many as 3 years. In addition, the investigations revealed that there is no difference between the retention on deciduous and permanent teeth [53-55]. Another study concluded that rubber dam isolation resulted in significantly better retention rates than isolation with cotton rolls [56].

Table 2: Retention of Helioseal F fissure sealings. (Only the results for Helioseal F are listed below. The data for possible comparable products can be found in the relevant publications.)

Experimental	Duration	Complete seal	Partial loss	Complete loss	Reference
10 patients (aged 7–14) 10 pairs of teeth Helioseal F vs Dyract Seal (split-mouth design)	3 months	**100%**	0%	0%	[57]
50 patients 200 sealings Helioseal F vs Fluoroshield and Delton (split-mouth design; each	6 months	**87.3%**	4.8%	7.9%	[58]

combination included Delton and one of the other fluoride sealants)					
58 patients 203 pairs of teeth Helioseal F vs Fissurit F (split-mouth design, with and without rubber dam)	12 months	**68.3%** (rubber dam) **42.3%** (cotton rolls)	31.7% (rubber dam) 51.4% (cotton rolls)	0% (rubber dam) 6.3% (cotton rolls)	[56]
112 teeth (56 each with Helioseal F and glass ionomer cement respectively)	12 months	**80.4%**		19.6%	[59]
61 patients (aged 6–11) First molars Helioseal F vs Fissurit F (split-mouth design, rubber dam)	12 months	**83.3%**	16.7%	0%	[60]
	24 months	**40.5%**	59.5%	0%	
121 patients (aged 6–7) with high caries risk 83 patients with low caries risk (control group) Helioseal F	2 years	**76.6%**	22.0%	1.4%	[61]
797 sealings (1st molar) Helioseal F (n=293) vs Fluoroshield and Delton (split-mouth design; each combination included Delton and one of the other two sealants)	6 months	**89.8%**	5.8%	4.4%	[62]
	12 months	**95.7%**	3.3%	1%	
	18 months	**93.2%**	6.1%	0.7%	
	24 months	**86.3%**	12.6%	1.1%	
	30 months	**91.8%**	8.2%	0%	
132 patients 195 deciduous molars (36 children, 4.5 years old) 391 permanent molars (96 children, 10.5 years old) Helioseal F	12 months	**98.13%** (deciduous molars) **97.47%** (permanent molars)	1.87% (deciduous molars) 2.53% (permanent molars)	0% (deciduous molars) 0% (permanent molars)	[53]
	2 years	**97.11%** (deciduous molars) **96.85%** (permanent molars)	2.38% (deciduous molars) 2.61% (permanent molars)	0.51% (deciduous molars) 0.54% (permanent molars)	[54]

	3 years	**95.04%** (deciduous molars) **95.81%** (permanent molars)	3.12% (deciduous molars) 2.83% (permanent molars)	1.84% (deciduous molars) 1.36% (permanent molars)	[63]

Mainly resin-based materials are used for fissure sealing. However, it is also possible to utilize other materials for this purpose. If Helioseal is assumed to represent resin-based composites and compared with other types of materials, it becomes clear that the performance of Helioseal is superior to that of the compomer (combination of composite and glass ionomer cement) Ionosit Seal [48] and glass ionomer cement [59; 64]. The retention rate of these materials was well below 50% after one and three years respectively, while Helioseal achieved a more than 90% retention rate.

4.2 Surface quality

Surface quality constitutes one of the factors affecting the retention of fissure sealants. A sealing that contains air trappings or porosities or that does not enable a smooth transition to the enamel is more susceptible to wear and chipping and therefore protects the tooth less effectively than a smooth sealing that is well integrated into the tooth structure.

De Craene *et al.* describe a clinical study in which 656 Helioseal sealings were placed in 92 children. After the sealing had been in place for 24 months, a marginal adaptation of 93% was found, while 5% of the sealings showed air trappings [47].

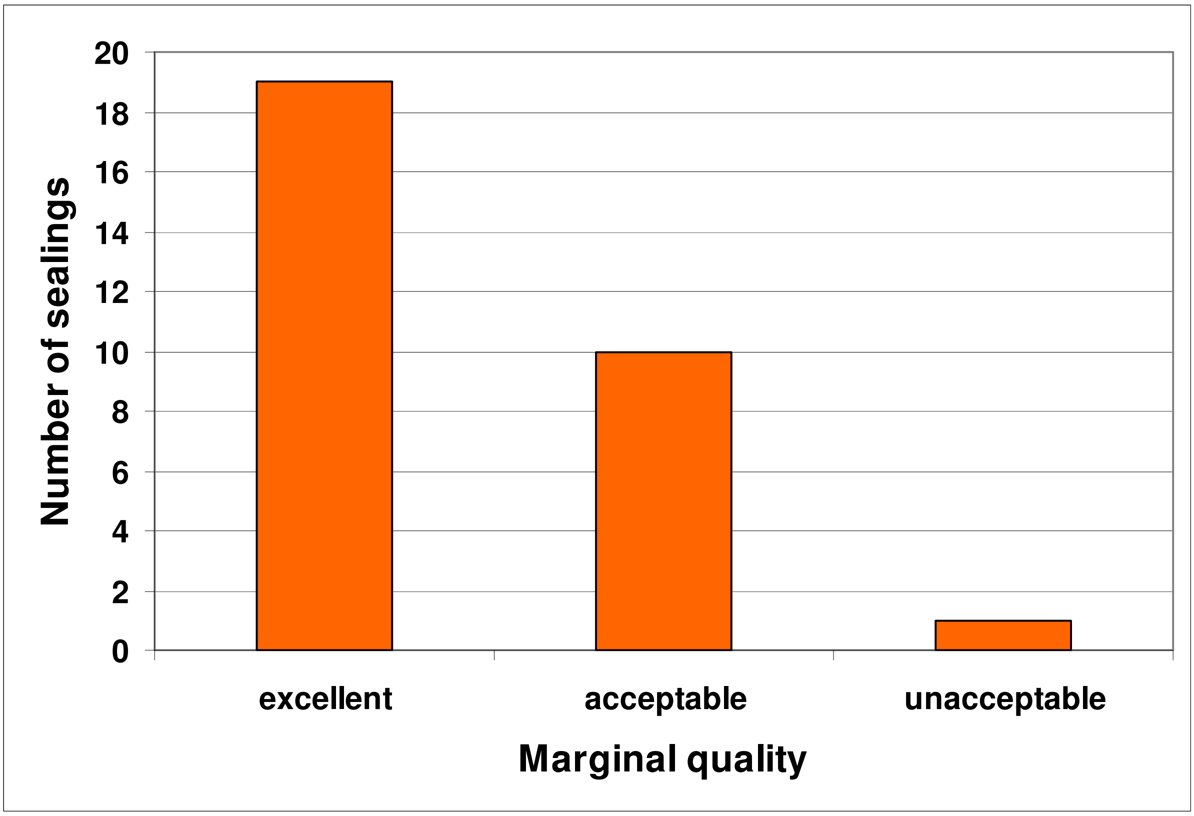

Fig. 11: Marginal quality of 30 Helioseal F fissure sealants after having been in place for 12 months [65]

Koch *et al.* carried out a study to compare the filled fissure sealant Helioseal F with the unfilled sealant Delton opaque. The study did not find any difference in the surface quality (porosities, marginal quality) between the two sealants. The results regarding the marginal quality are represented in Figure 11. The margins of almost two thirds of the Helioseal F sealings were rated “excellent” and one third was rated “acceptable”. Only one sealing was deemed “unacceptable” [65].

Likewise, the researchers did not find any difference in air trappings in another comparative study involving Helioseal F and Dyract Seal [57].

The performance of Helioseal F was superior to Fissurit F in a 24-month study. A significantly lower number of porosities and marginal defects was recorded for Helioseal F than for Fissurit F [60]. Furthermore, the surface of Helioseal was given better ratings than that of the flowable Tetric Flow in a comparison between these two materials. As can be seen in Figure 12, Helioseal exhibited significantly fewer surface defects than Tetric Flow (2.27% for Helioseal vs 13.84% for Tetric Flow) and a lower number of sealings with a marginal step were observed (1.96% vs 7.84%) [14].

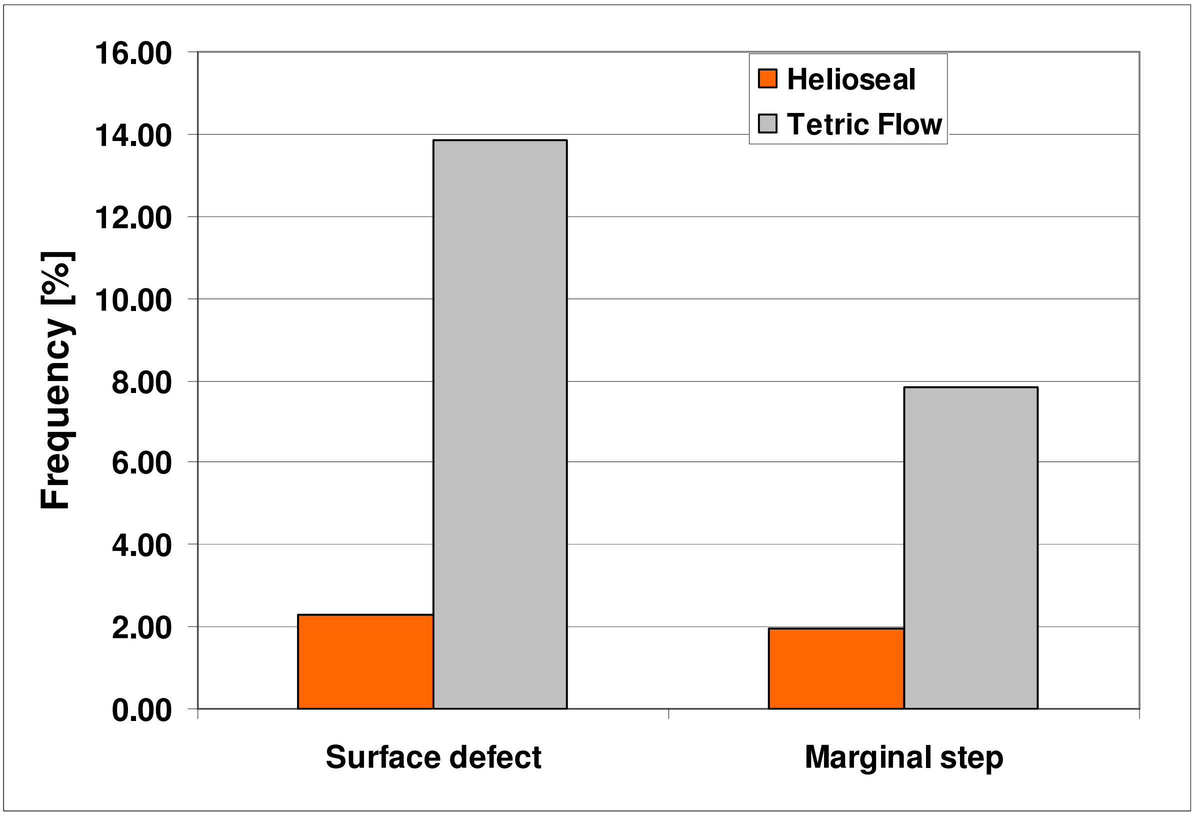

Fig. 12: Marginal quality and surface quality of 104 teeth sealed with Helioseal and Tetric Flow after the sealings have been in place for 10 months [14].

4.3 Reduction of caries incidence

The clinical objective of fissure sealing is to prevent the development of fissure and occlusal caries. For this reason, some of the studies listed in Table 1 and 2 also determined the caries incidence to appraise the clinical success of the sealings.

Three studies compared the caries incidence in teeth sealed with Helioseal and Helioseal F with that of unsealed teeth. Different caries incidence rates were found. However, the caries incidence was consistently lower in the sealed teeth than in the unsealed teeth [49; 50; 61].

For example, Wagner *et al.* found a caries incidence of 49.3% in the unsealed teeth of the control group and 7.3% in the sealed teeth.

Studies that did not involve unsealed control groups also reported very low caries incidence rates after sealing with Helioseal or Helioseal F. For instance, not a single incidence of caries was found after two years in a study involving 52 patients; the same result (no caries) was reported in an another study with 61 children [14; 60]. Two incidences of caries were identified in a larger study involving 354 sealings, while only one case of caries occurred in another study with 429 sealings [48; 51]. These results are of the same order as the outcome of a study that reported a caries incidence of 1% after sealing [47].

4.4 Fluoride concentration in the oral cavity

In addition to mechanical protection, fluoride-containing fissure sealants offer the additional benefit of localized fluoride release, strengthening the enamel and increasing its resistance to acid attacks.

Two studies investigated the influence of fluoride-containing Helioseal F on the fluoride concentration in saliva and plaque. No increase in the fluoride concentration in the saliva was found following the placement of the sealing in a study involving 121 children [61]. The same result was found in another study, where the four first molars in 18 children were sealed and then the fluoride concentration measured. However, this study reported an increase in the fluoride concentration in the plaque 24 hours after the sealing had been placed [66].

4.5 Conclusion

The Helioseal fissure sealants have proven to be effective in many years of clinical use. Studies show that these sealants achieve high retention rates and an advantageous surface quality, even if they are placed without rubber dam isolation. Helioseal sealings demonstrably reduce the caries incidence rate to a very low level and present therefore a valuable prophylactic measure.

5. Biocompatibility

5.1 Toxicity and genotoxicity

Helioseal and Helioseal F exhibit no acute toxicity. An LD50 of >5000 mg/kg of body weight was reported for Helioseal [67]. Likewise, the fluoride contained in Helioseal F does not pose any toxicological risks.

The cytotoxicity of Helioseal F was evaluated by means of an agar diffusion test. No cytotoxic potential was found [68].

The only possible source of a chronic toxicological risk could arise from the wear of cured sealing material in the oral cavity. However, the sealant is applied in very small amounts and is, as mentioned above, not toxic. A chronic toxicological risk can therefore be ruled out [68].

Helioseal F did not show any mutagenic potential in a bacterial assay for gene mutation (AMES test) [69].

5.2 Irritation

Uncured Helioseal was classified as “non-irritant” in a rabbit eye irritation test [70] [68]. These results are also applicable to Helioseal F.

5.3 Sensitization

Helioseal F did not show a sensitizing effect in a skin sensitization test in guinea pigs. [71]. However, methacrylates are known to have a certain allergenic potential and may lead to contact allergies in persons who are sensitive to this chemical compound. This risk exists with all fissure sealants containing methacrylate.

5.4 Release of bisphenol A and monomers

The possible health risks associated with bisphenol A (BPA) have become a recurrent debate. The harmful effect of bisphenol A is related to the hormone-mimicking activity of this compound. This means that bisphenol A may possibly have a disrupting effect on the human hormone system and may therefore affect fertility or the development of hormone-dependent tumours.

Bis-GMA and other bisphenol-based monomers may contain bisphenol A as an impurity and traces of the impurity (in the ppm range) may be found in dental materials. With the exception of bis-DMA, bisphenol-based monomers do not release bisphenol A when they degrade in the physiological environment of the oral cavity. The Ivoclar Vivadent products, including Helioseal, do not contain bis-DMA.

Several studies investigated the BPA release of fissure sealants. Three studies (*in vitro* as well as *in vivo*) did not find any BPA in Helioseal or Helioseal F, i.e. no BPA was detected in the bodily fluids of the test persons exposed to these materials [72-74]. Another study did find traces of BPA, but being at a level of 5.5 µg, the dosis was negligible [75]. In comparison, the application of Delton LC resulted in a dosis of 110 µg BPA – a level that is several times higher than that of Helioseal.

A review of the effects that may be caused by a possible exposure to BPA through fissure sealants drew the conclusion that fissure sealants do not pose any risks because only very small quantities of BPA, if any at all, are released. In addition, the inhibition layer, which is most likely to release chemical compounds from the sealing material, can be removed by cleaning with water or a water-pumice mixture after the sealant has been applied [76].

With regard to the release of monomers, traces of TEGDMA were found in Helioseal. However, the quantities found in Helioseal were again smaller than those found in other sealants [72; 74; 77]. One study detected bis-GMA in extracts of Helioseal [74], while another study did not [78].

5.5 Conclusion

Helioseal sealants are neither toxic nor irritant. The risk of sensitization is in the range of other dental materials containing methacrylate. The exposure to oestrogen-mimicking bisphenol is considered to be very low, if present at all. The caries protective advantages that fissure sealants offer to patients prevail over a possible minor health risk.

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