ivoclar

Scientific Documentation

Helioseal® F Plus

Fissure sealant

Making People Smile

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1 Fissure caries

Fissure caries characteristically refers to the demineralization of tooth substance, beginning deep in the occlusal grooves of posterior teeth. Worldwide studies have shown that sensible eating plus good oral hygiene and fluoridation, can be insufficient at preventing fissure caries altogether.

Due to their morphology, fissures provide the ideal niche for food particles and microorganisms to settle in and grow. Even with excellent oral hygiene, plaque can often only be removed from the occlusal surface of the teeth up to the fissure entrance i.e., the bristles of a typical toothbrush may be unable to reach deeper areas of fissures (Fig. 1). Fissures therefore provide convenient retention areas for plaque / bacterial biofilms, enabling the development of carious lesions and cavities.

Fig. 1: Toothbrush bristles are unable to reach fissure bed. Prof. Dr Zimmer, University Witten/Herdecke, Germany

The teeth most at risk of fissure caries are molars, incisors with deep foramina caeca (pits or indentations that can occur on the buccal side of molars or palatal surfaces of maxillary incisors) and more rarely premolars. [1] The enamel depth in fissures is relatively thin, thus carious lesions in these areas are quickly able to penetrate through to 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] A 1988 study by 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]

2 Fissure sealing

2.1 Introduction

Fissure sealants were introduced to standard dentistry approximately five decades ago. [6] They are placed in high risk oral locations to provide a physical barrier to both microorganisms and food particles i.e., to seal off pits and fissures. Various materials and techniques have been advocated for preventing pit and fissure caries in children and high caries-risk adults. [7] Resin composites filled or unfilled, are the most popular fissure sealant materials. [7] Glass ionomer cements, compomers and resin modified glass ionomer materials may also be used. [6]

2.2 Properties of resin-based fissure sealants

Chemical and physical properties

Most fissure sealants on the dental market are filled or unfilled, one or two component methacrylate-based (e.g., Bis-GMA or UDMA or both) materials.

Fissure sealants may be self-cured or light-cured, fluoride-releasing or non-fluoride releasing. Self-cured (chemically cured) fissure sealants incorporate a catalyst, usually benzoyl peroxide, which initiates polymerization. Light-cured sealants are polymerized using an appropriate light source that activates a photoinitiator catalyst such as camphorquinone - which absorbs light within a specific wavelength range.

Fissure sealants contain various types of fluoride compounds, such as fluorosilicate glass, fluoridated methacrylic acid and sodium fluoride. The caries protective effect of fluoride is well-documented and accepted.[8,9] Fluoride is known to promote remineralization and hamper demineralization processes, increase enamel resistance and reduce plaque growth/activity (see section 2.3.2).

The physical properties of sealants are closer to those of unfilled direct resins than resin-based restorative composites,[7] and reports regarding physical properties tend to be scarce as specimen preparation with such low-viscosity materials is problematic. Also, as sealants tend to be completely circumscribed by enamel i.e., are not subject to occlusal stresses - their mechanical properties are less relevant than those of restorative composites.[10]

Shade

Unfilled resins are available as colourless or tinted transparent materials. Filled resins are opaque and are usually available either as tooth-coloured or white materials.[7] Often aimed at children, other colours such as red and colour-changing sealants are also available. Sealant application and evaluation at recall are better facilitated if a sealant is visible/pigmented e.g., white[11,2]. Transparent or tooth-coloured sealants offer invisible or chameleon-type esthetics, but may be difficult to differentiate from the enamel at recall. It may however be argued that transparent sealants offer a see-through surface through which any untoward changes in the fissure can be observed e.g., discoloration indicating incipient caries.

2.3 Means of protection

2.3.1 Mechanical

The principle means of protection provided by resin-based fissure sealants is mechanical. Fissure sealing is a non-invasive preventive measure which physically seals off pits and fissures with an impermeable resin layer. The picture below illustrates how applying a fissure sealant forms a smooth hygienic surface that is less susceptible to plaque build-up and aids oral hygiene.

The sealant prevents food and bacteria from entering the deep and narrow crevices of the fissure. The supply of substrates to bacteria that may already be below the sealant is also cut off – hampering bacterial metabolism and preventing bacteria from producing enough acid to cause further demineralization.[12, 13]

Fig. 2: Sealing of a tooth pit/fissure. Helioseal F Plus. Mag x 1.6. R&D Ivoclar, Liechtenstein

Fissure sealing not only protects those regions prone to caries, but can also stop the progression of initial lesions. [14] In a review of studies comparing bacteria-levels in sealed vs. unsealed teeth, Oong et al also found that sealants reduced the probability of viable bacteria by about 50%. [15]

2.3.2 Fluoride

Fluoride in sealants can also offer protection. Hydroxyapatite is the principal component of enamel, and when hydroxyapatite is exposed to fluoride ions, fluorapatite is formed:

$$[Ca_3(PO_4)_2]_3 \cdot Ca(OH)_2 \longrightarrow ([Ca_3(PO_4)_2]_3 \cdot Ca(F)_2)$$

Fluorapatite is far less susceptible to acid dissolution than hydroxyapatite. Numerous studies substantiate the fact that fluoride is incorporated into enamel, increasing its resistance when fluoridated materials are used on teeth. [16] Continual exposure to small quantities of fluoride is arguably optimal, thus fissure sealants, which are in long-term contact with the teeth and in a position to release small quantities of fluoride over time, can be highly beneficial. [17] *In vitro* studies have also shown that lesion depth is significantly lower after the application of a fluoride-sealant as compared to a non-fluoride sealant. [18] Furthermore, fluoride offers a protective effect at sealant margins, i.e., non-sealed enamel adjacent to sealants. Fluoride may therefore reduce the risk of caries development even if seals are broken or damaged. [19]

2.4 Patients and Timing

Fissure sealing is more commonly performed in children but is also suitable for adults, depending on their individual caries-risk profile. It is generally accepted that sealing is best performed early (after tooth eruption) as soon as the occlusal table is visible and free of soft tissue. [20] If applied too early, retention may be hampered by the tooth position or incomplete exposure of the occlusal surface. [12] The following photos from the Ivoclar internal clinic show the same tooth pre and post full eruption. Post full eruption, the tooth was sealed with Helioseal F Plus.

Fig. 3a-b: Maxilla: tooth 26. Left: Partially-erupted molar not yet suitable for sealing. Right: Fully-erupted molar (same tooth), now suitable for sealing. R&D Clinic, Ivoclar, Liechtenstein

In adults, sealing may be indicated in those with high bacterial (mutans streptococci / lactobacilli) counts. Lactobacilli, which are mainly responsible for the progression of caries, require retention sites and niches for their survival as they do not have the same ability of mutans streptococci to adhere to the smoother surfaces of the teeth. [10] A significant correlation between carious lesions and the lactobacilli count in both adults and children has been observed and a high lactobacilli count is also an indicator of high sugar intake. [1] Such patients could clearly benefit from the sealing off of bacterial retention sites. Patients unable to perform good oral hygiene due to old age or poor general health are also likely to benefit – in particular patients with diabetes or xerostomia (low salivary flow).

2.5 Rationale

It is generally accepted that fissure sealants can reduce the risk of developing occlusal caries as long as the sealant fully wets the surface of the pits and fissures, forms a strong and durable bond with the enamel and no mechanical, thermal or chemical stimuli are able to cause cracks in the sealant material. [15]

Overall about 90% of carious lesions are found in the pits and fissures of permanent posterior teeth, [23] thus the rationale for fissure sealing, remains just as relevant today.

The American Dental Association (ADA) and American Academy of Pediatric Dentistry released evidence based practice guidelines based on a systematic review, on the use of fissure sealants in 2016. They noted that although there has been a decline in the prevalence of caries in American adolescents and children in particular, the decrease in occlusal surface caries has not kept pace with the decrease in smooth surface caries. [6] Fissure sealing can therefore play a key role in caries prevention.

The 2016 ADA study [6] formulated three main conclusions that backed up the evidence from the previous 2008 ADA report that sealants can be used effectively to prevent the initiation and progression of dental caries: [22]

- Sealants are effective in preventing and arresting pit and fissure occlusal carious lesions of primary and permanent molars in children and adolescents - compared with the non-use of sealants or fluoride varnishes.
- Sealants could minimize the progression of existing initial lesions i.e., non-cavitated occlusal carious lesions.
- No specific type of material for fissure sealing is deemed superior due to a paucity of good data i.e., no statistically significant difference in superiority between could be established between resin-based sealants, resin-modified glass ionomer sealants, glass ionomer cements or polyacid-modified resin sealants. [6]

The first two conclusions above are also supported by and outlined in the guidelines (Leitlinien) of various German professional dental societies: (German Society for Paediatric Dentistry e.V. (DGKiZ), German Society for Dental Conservation (DGZ), and the German Society for Dental, Oral and Maxillofacial Medicine (DGZMK)). These guidelines however state an overall preference for the use of resin based sealants – however noting that glass ionomer cements may be useful as temporary pre-sealants in high caries risk patients where teeth may not have fully erupted but some preventive measure is necessary. [22]

Data from private dental insurance and Medicaid databases in the US has also shown consistent evidence that sealing the first and second molars of children and adolescents reduces future costs for restorative procedures. [21]

It should also be noted that although perfect long-term retention is the ideal, in a 2009 review, Griffin et al found that even in the case of lost or partially lost sealants, the caries risk in such patients was not higher than in patients without sealants. [23] This brings into question the commonly held view that a partially-lost sealant is a worse clinical situation than no sealant at all.

This Scientific Documentation describes the resin based, white shaded, fluoride releasing fissure sealant Helioseal F Plus from Ivoclar and details the most important in vitro and clinical data.

3 Helioseal F Plus

Helioseal F Plus is a resin based, light-cured, white-shaded fissure sealant featuring fluoride release. It is used to seal pits, fissures and foramina caeca in posterior or anterior teeth, to protect them from caries. It is suitable for use in deciduous or permanent teeth in both children and adults. Helioseal F Plus is supplied in either a syringe or cavifil.

Fig. 4: Helioseal F Plus delivery forms : syringe and cavifils

The sealant is applied directly to the fissure, after cleaning the enamel to be sealed, achieving absolute or relative isolation and etching the area with a phosphoric acid etching gel such as Total Etch/Ivoclar. The sealant is light-cured for between 5 and 20 seconds depending on the power of the curing light used (see section 3.1.3). The sealant is white, esthetic and visible enough for checking retention at dental check-ups.

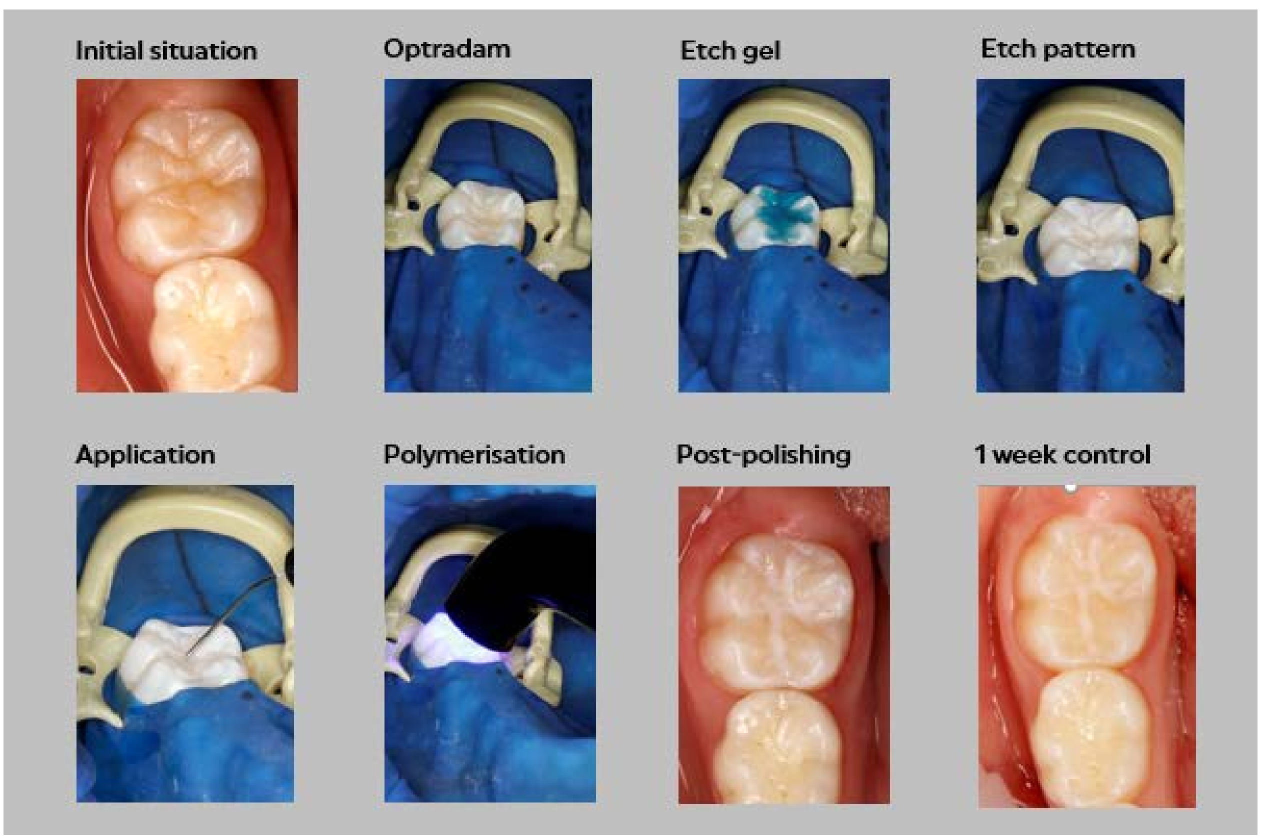


Fig. 5: Ideal step by step sealing of molar (46) with Helioseal F Plus. Ivoclar R&D clinic, Liechtenstein

3.1 Helioseal F Plus technologies

3.1.1 Monomer technology

Monomers together with initiators and other additives form the reactive part of a resin-based fissure sealant. Helioseal F Plus contains the following monomers:

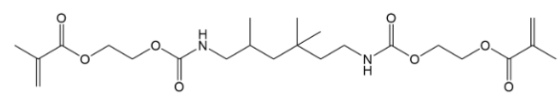
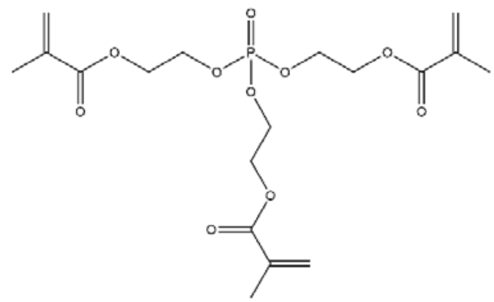
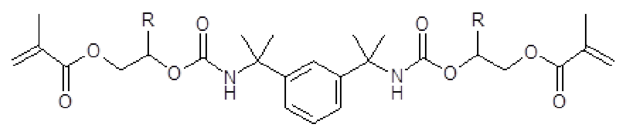
Helioseal F Plus Monomers	
UDMA / Urethane dimethacrylate	
HEMA phosphate	
Aromatic aliphatic UDMA	R=H oder CH_3 

Table 1: Structural formulae of Helioseal F Plus monomers

As with all resin composites, the monomers in Helioseal F Plus, are converted into a cross-linked polymer matrix during the light-initiated polymerization process.

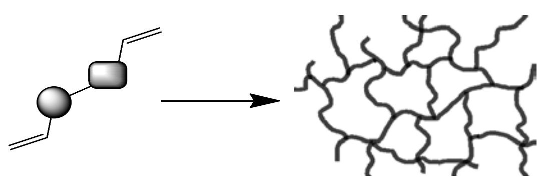


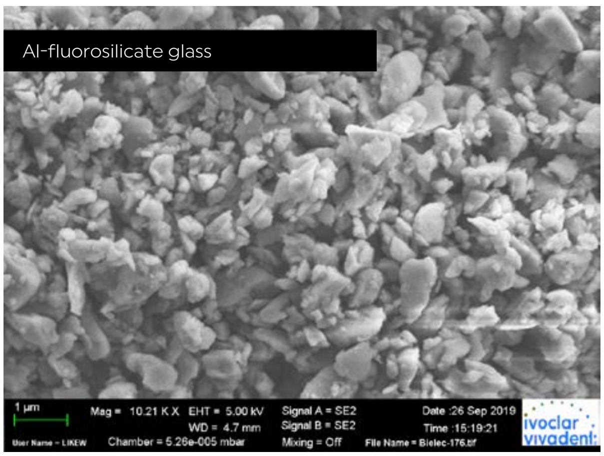
Fig. 6: Schematic representation of polymer matrix resulting from monomer polymerization

Helioseal F Plus has a relatively low viscosity in order to be able to flow into pits and fissures, and its organic matrix accounts for most (between 70 - 80%) of the mass . For comparison, flowable restorative composites have a lower organic matrix mass of approximately 25 – 40% and sculptable composites (with higher filler content) even lower at around 15- 20%.

Most sealants are based on BisGMA or UDMA. [10] Helioseal F Plus utilizes UDMA, an aromatic aliphatic UDMA and HEMA phosphate. UDMA and aromatic aliphatic UDMA exhibit moderate viscosity and yield strong mechanical properties as cross-linkers. As UDMA also has no hydroxyl side groups - it is hydrophobic and exhibits low water absorption. It also exhibits low polymerization shrinkage by volume due to its relatively high molar mass. HEMA Phosphate operates as a reactive diluent.

3.1.2 Filler technology

As with resin-based restorative materials, inorganic fillers are also often added to resin-based fissure sealants - but in lower amounts to provide the desired stiffness and to improve overall wear. Helioseal F Plus has a filler content of 15-25%, made up of aluminium fluorosilicate glass and silicon dioxide.



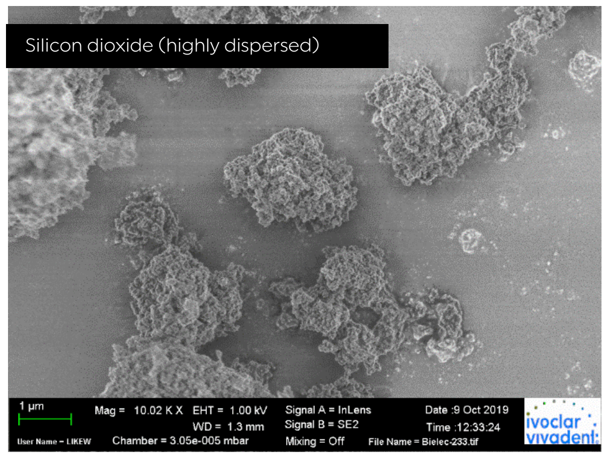


Fig. 7a-b : SEM photos of Al-fluorosilicate glass and highly dispersed silicon dioxide

The fillers together with the resin content, enable a wear-resistant, smoothly-sealed, visible sealant surface with the desired viscosity and thixotropic flow properties. Thixotropy refers to a time-dependent decrease in viscosity that occurs when stress is applied e.g. agitation of sealant with cannula during application allowing low viscosity (flowability) when needed and in turn higher viscosity when not (see section 5.2). The fluorosilicate glass also releases fluoride.

3.1.3 Polymerization Technology

Light cured fissure sealants such as Helioseal F Plus "set" by way of free radical polymerization. Incoming photons from the curing light are absorbed by photoinitiator molecules. The energy absorbed excites the molecules, and in their active state, radicals are formed (if one or several activators are present) and this triggers polymerization. Initiator molecules can however only absorb the photons of a specific spectral range. As customary resin materials are polymerized with visible blue light, the light-absorbing initiators used have an inherent yellow colour as this is the complementary colour to blue light. On curing, this yellow colour largely disappears.

In Helioseal F Plus, the initiator camphorquinone is used together with a tertiary aromatic amine (co-initiator for accelerated polymerization). Camphorquinone has a light absorption spectrum of approximately 410 nm to 500 nm, with a peak maximum of 470 nm within the blue wavelength range (Fig. 8).

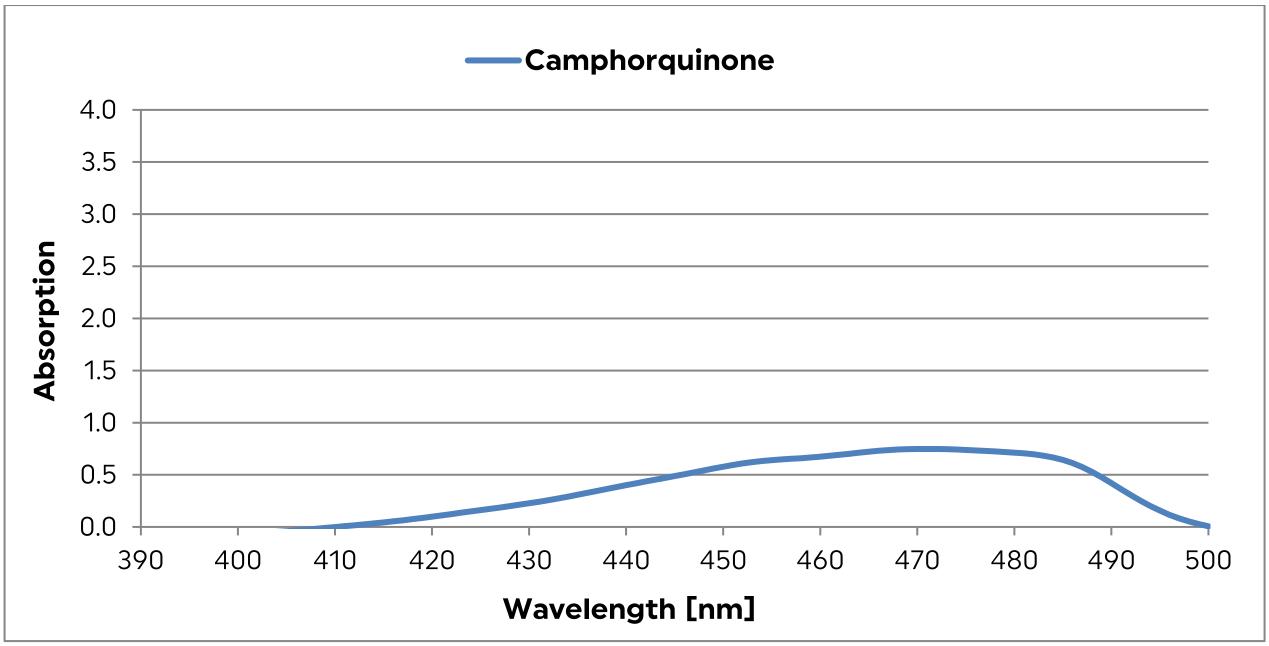


Fig. 8: Absorption spectrum of camphorquinone. R&D Ivoclar Vivadent 2012

Helioseal F Plus, can therefore be cured with all curing lights that emit blue light within the 400 - 500 nm range.

The necessary curing times, according to the light intensity of the polymerization unit are shown below.

Light intensity of Curing Light	Wavelength	Curing/Exposure time
>500 mW/cm^2	400-500 nm	20 s
>1000 mW/cm^2	400-500 nm	10 s
2000 mW/cm^2	400-500 nm	5 s

Table 2: Curing times necessary according to the light intensity of the polymerization lamp

The curing depth achieved with these light intensity and exposure time combinations has been shown to exceed 3mm. Shorter curing times of 5 seconds with e.g. the Bluephase PowerCure in Turbo mode, are especially helpful when treating children.

3.2 Advantages and Benefits of Helioseal F Plus

Features	Benefits
New formula with optimized consistency	Optimum sealing of pits and fissures with complex morphology
Precise dispensing and application	Efficient treatment
Reduced polymerization time	Quick, comfortable treatment of children
Fluoride release	Protection of enamel

Table 3: Principal features and benefits of Helioseal F Plus

Helioseal F Plus features optimized viscosity, is easy and precise to apply via syringe with optimized 0.4mm cannula tips or via cavifil. It can be cured in just 5 seconds with an appropriate curing light such as the Bluephase 20i or Bluephase PowerCure (Turbo mode) and it releases fluoride.

The material is the culmination of a wealth of research and market experience accumulated with Ivoclar "Helioseal" fissure sealants in general.

4 Technical Data

4.1 Chemical composition

Product: Helioseal F Plus		
Function	Substance/Component	Weight (%)
Monomer	Urethane dimethacrylate HEMA phosphate Aromatic aliphatic urethane dimethacrylate	70-80
Filler	Silicon dioxide, Al-Fluorosilicate glass	15-25
Additive	Polyacrylate	0-2
Initiator, Stabiliser, Pigment	Various	< 2

4.2 Characteristics and performance attributes

Product: Helioseal F Plus	Intended Purpose: Fissure sealant	
Characteristics[1]	Specification	Unit
Depth of cure	≥ 1.5	mm
Wavelength for curing	400-500 (blue light)	nm

The product meets the relevant performance criteria as defined in

EN ISO 6874:2015 - Dentistry – Polymer-based pit and fissure sealants (ISO 6874:2015)

[1] Physical and Mechanical properties

5 Materials Science investigations with Helioseal F Plus

Numerous *in vitro* investigations are carried out during the development phase of a dental product. Though not capable of predicting clinical success directly, they are useful indicators and e.g. allow comparisons with similar products of established clinical performance. The following section details the various materials science investigations carried out with Helioseal F Plus. Sections 5.1, 5.2 and 5.3 deal with the same group of fissure sealants: Helioseal F Plus/Ivoclar, Embrace WetBond/Pulpdent, Ultraseal XT Hydro/Ultradent, Fissurit F/Voco, Clinpro Sealant/3M Espe, Delton/Dentsply

5.1 Shear bond strength

The shear bond strength of the fissure sealants mentioned above was investigated. Bond strength values reflect the potential retention/adhesion of the sealant to the enamel. Five samples for each fissure sealant were prepared. In order to test adhesion - bovine enamel samples embedded in resin were etched for 30 seconds (on the basis of ISO 29022:2013), and the fissure sealants were applied. After 24 hours, the samples were then sheared from the surface with force, to measure bond strength - as shown schematically by the "F" arrow below.

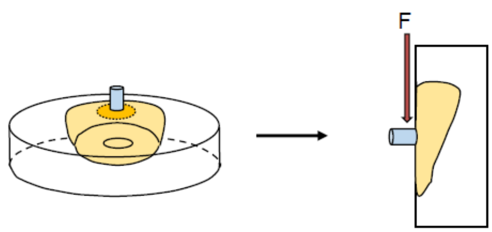


Fig. 9: Schematic representation of shear bond strength test for sealant samples

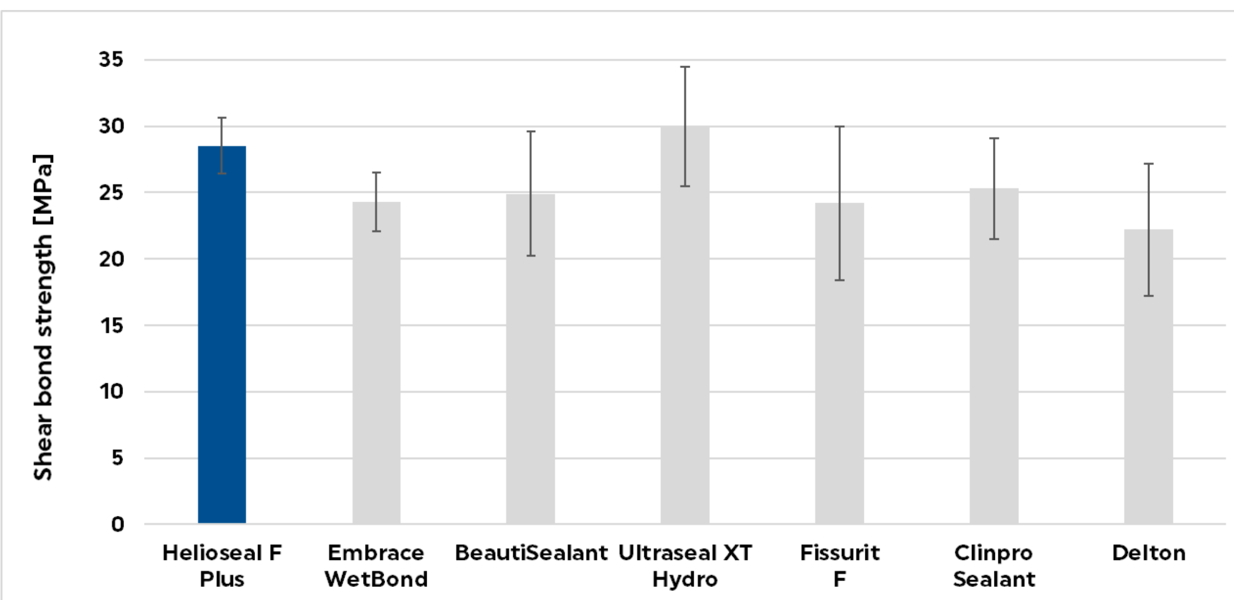


Fig. 10: Mean shear bond strength values of various fissure sealants [24]

Helioseal F Plus exhibited high average shear bond strength values, indicative of a good bond to the enamel surface i.e., adhesion and sealing.

5.2 Viscosity

The viscosity of a sealant needs to be carefully balanced. Low enough to wet surfaces and flow easily into narrow fissures but not so runny that it inconveniently flows off the teeth of the upper jaw, prior to polymerization. Helioseal F Plus exhibits two distinct thixotropic benefits here:

- Slightly higher viscosity before and after shear forces are applied
- Time-dependent low viscosity whilst shearing forces are applied

Thixotropy thus refers to a liquid being more flowable for a time-dependent period i.e. during shearing movements and otherwise exhibiting higher viscosity. The rheological properties, viscosity and shear-thinning behaviour (STB) of Helioseal F Plus and other commercially available fissure sealants were investigated. Thixotropic materials exhibit a structure break at the onset of shearing movements and structure recovery after they have ceased.

To investigate the handling properties, the rheological properties of the sealants were monitored in a controlled shear-rate test with different shear rates : ($\dot{\gamma}$) to represent the different phases of application from rest to application (involving shearing-movements) and recovery prior to light-curing.

- $\dot{\gamma}_1=0.1s^{-1}$ for 30 seconds
- $\dot{\gamma}_2=100s^{-1}$ for 2 seconds
- $\dot{\gamma}_3=0.1s^{-1}$ for 150 seconds

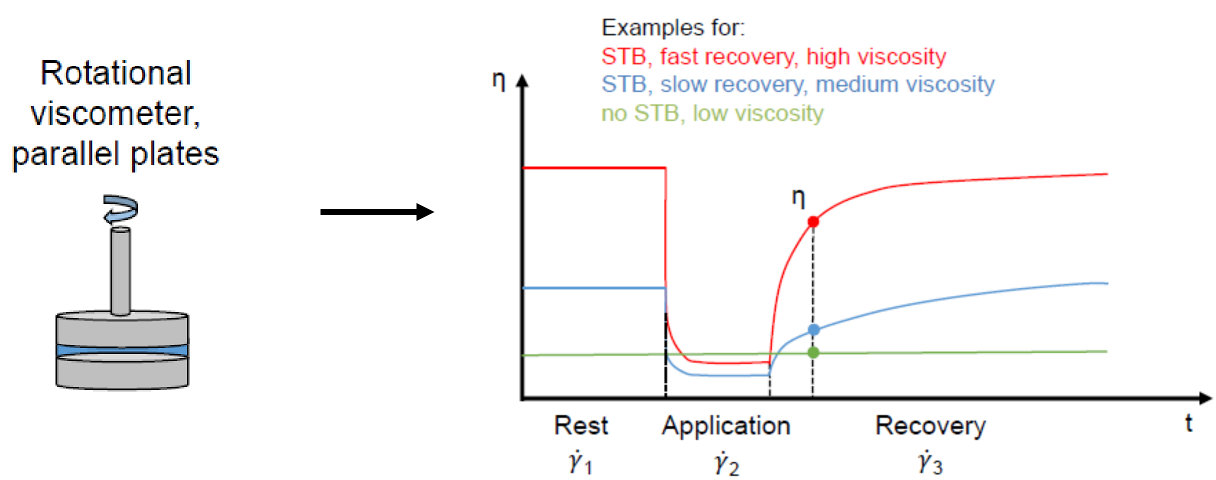


Fig. 11: Schematic representation of rheological testing and potential results [24]

The viscosity trajectory is indicated for different types of material whereby all exhibit relatively low viscosity during application but different levels before and after. The structure break and structure recovery points are indicated by the first and second (left to right) vertical black dotted lines in Fig. 11. The red line represents a material whereby a higher viscosity re-establishes itself quickly, 10 seconds (η) after the end of shearing movements (application) i.e. fast recovery.

The blue line shows medium viscosity after shearing ends i.e. a slower recovery to former viscosity. The green line represents a product with no shear thinning or thixotropic behaviour evident i.e. no change and low viscosity throughout.

The sealants' sheer thinning behaviour /structure recovery levels, measured 10 seconds after the start of structure recovery is indicated in the diagram below.

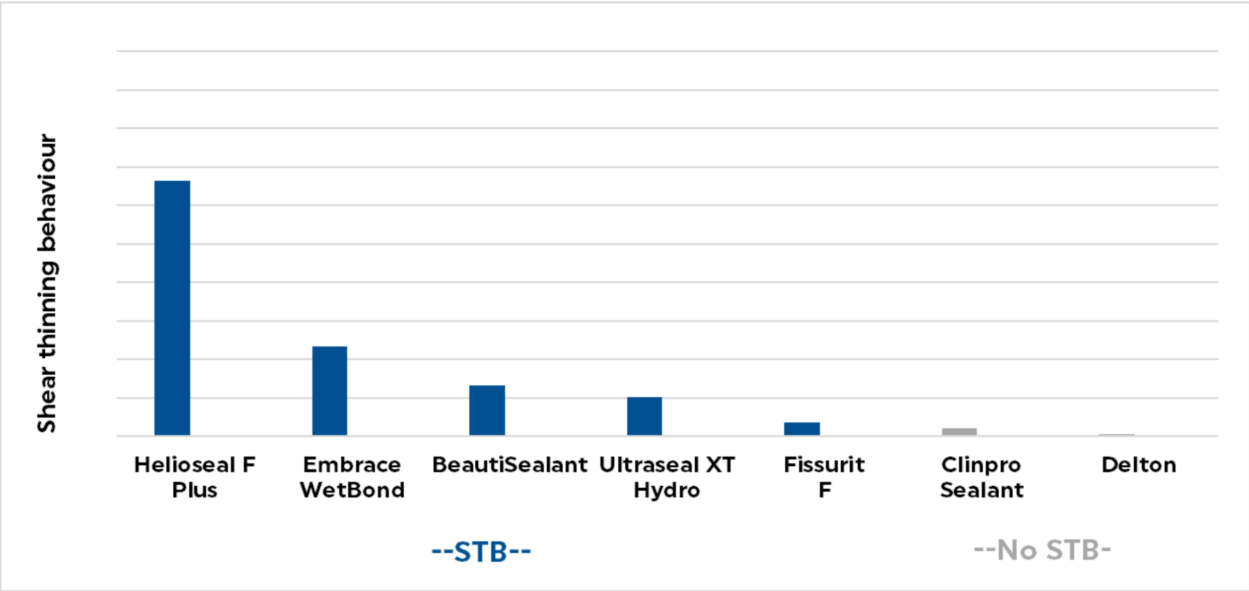


Fig. 12: STB / structure recovery of various fissure sealants after "application" [24]

The structure recovery exhibited by Helioseal F Plus, 10 seconds after the start of the $\dot{\gamma}_3$ low shear section was highest (fastest) of all the sealants. This point in time represents the post application time when it is important that a sealant not flow off e.g. maxillary molars. Prior to this, the viscosity is lower during shearing activity (representing application) which aids flowability into narrow fissures. The pronounced shear thinning behaviour shown by the structure break and structure recovery of Helioseal F Plus, is represented schematically by the red line in Fig. 11. Two sealants showed no shear thinning behaviour (see Fig. 12).

5.3 Depth of Cure

The depth of cure for each sealant (see section 5), was tested according to the ISO 6874/ Dentistry – Polymer based pit and fissure sealants standard. The mean depth of cure was established, after curing three of each type of sealant according to their instructions for use with Bluephase Style/1100 mW/cm^2. Helioseal F Plus was cured for 10 seconds.

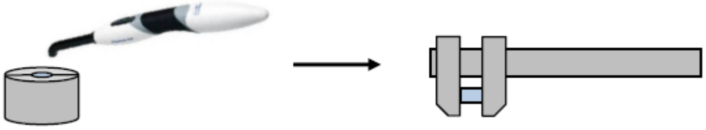


Fig. 13: Schematic representation of experiment to establish depth of cure

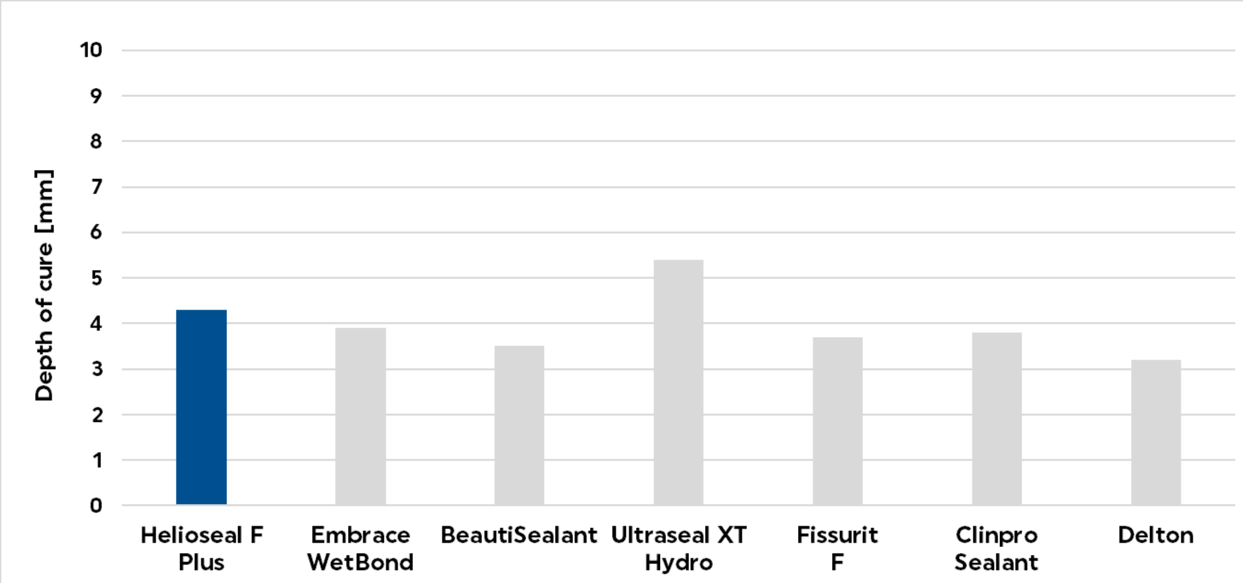


Fig. 14: Depth of cure values in mm for various fissure sealants [24]

Fissure sealants are applied in fissures in thin layers. All of the fissure-sealants fulfilled (and far exceeded) the ISO depth of cure requirement of >1.5mm. Helioseal F Plus exhibited a 4.3 mm depth of cure in this experiment.

5.4 Fluoride release

The principal protection offered by fissure sealants is mechanical in terms of providing a physical barrier to food and bacterial growth. Helioseal F Plus however also contains an Al-fluorosilicate glass. Sakaguchi [10] notes that the fluoride release in most fissure sealants is highest in the initial 24 hours following placement – tapering to a maintenance level thereafter. As previously noted (see section 2.3.2) continual exposure to low levels of fluoride is arguably optimal, thus fissure sealants, which are in long-term contact with the teeth and in a position to release small quantities of fluoride over time can be highly beneficial. [17]

The fluoride released from Helioseal F Plus was compared to that of the predecessor product Helioseal F. Polymerized discs (d=20 mm, h=1mm) of the materials were immersed in water at 37°C and the fluoride-ion release was measured over time. After one week the fluoride levels of both products were comparable at 0.7 and 0.4 mg/L for Helioseal F Plus and Helioseal F respectively.

5.5 Microleakage / Marginal adaptation

Fissure sealants should provide a tight seal to prevent bacterial penetration via leaky margins and to prevent any existing bacteria from causing caries on tooth surfaces under the sealant, where they may be inadvertently protected from mechanical cleaning measures. Sealant tightness / microleakage can be assessed by means of e.g. dye penetration tests.

5.5.1 In vitro evaluation of a new pit and fissure sealant – Helioseal F Plus [25]

Eliades G. Department of Biomaterials, School of Dentistry, University of Athens, Greece

Objective: To evaluate the in vitro performance of Helioseal F Plus in comparison with other commercially available products.

Method: Helioseal F Plus and four other fluoride releasing sealants (Clinpro Sealant/3M Espe, Embrace Wetbond/Pulpdent Corp, Fissurit FX/Voco, Ultraseal XT Hydro/Ultradent) were compared with regard to adaptation, microleakage and penetration into fissures.

100 sound premolars (n=20 per material), extracted for orthodontic reasons and kept in 0.5% chloramine solution at 8 °C for 2–6 months, were used in the experiment. The crowns of all teeth were cleaned with a rotary brush and a non-fluoride, oil-free pumice. They were then rinsed with water for 30 seconds and air dried with oil-free air for 30 seconds. For etching, a 37 wt% phosphoric acid gel (Total Etch/Ivoclar) was used for 60 seconds, rinsed with water and air-dried - except for Embrace Wetbond where the enamel surface was left slightly moist (shiny or glossy appearance) according to the manufacturer's instructions. The sealants were applied on the acid-etched enamel surfaces with the micro-cannulas provided by the manufacturers, left undisturbed for 10 seconds and then polymerized for 20 seconds using an LED curing light (Bluephase G2/Ivoclar), at 1200 mW/cm2 irradiance.

The teeth were stored in water at 37°C for 1 week, to obtain water saturation of the sealants. The roots were then blotted and air-dried and covered with two coats of a nail-varnish. After a 2 hour varnish-drying period, the teeth were immersed in 1.5 % neutralized fuchsine (dye) solution (pH=7.4) for 24 h at 37°C. The immersed tooth part included the crown up to the cervical area of the tooth (inverse crown immersion). After the immersion period, the teeth were rinsed with tap water, the crowns were removed from the roots and longitudinally sectioned in a microtome (Isomet, Buhler, USA) in a buccal-lingual direction, under continuous water cooling.

Sealant adaptation to the acid-etched enamel walls and microleakage at the enamel-sealant interface were assessed under reflected light stereomicroscopy at ≤50× magnification (M80 stereomicroscope, Leica, Germany) and reflected polarized-light microscopy with 90° crossed-polarizers, 200× magnification (DM 4000B, Leica).

The length of microleakage (IL%) and interfacial gaps (IG%) along the enamel-sealant interface, were linearly measured with the software of the microscopes and expressed as a percentage of the total interfacial marginal length of each section.

The extent of resin penetration into fissures with narrow orifices (Ds%), was evaluated by linear measurements of the resin-filled fissure length (Ds), which was then expressed as a percentage relative to the total fissure length (Df). Measurements were performed only for fissures demonstrating an orifice of 100 µm in width.

Statistical analysis of the results of microleakage - IL%, interfacial gaps - IG% and sealant penetration - Ds% was performed by one-way ANOVA. Pearson's correlation coefficient was used to evaluate any correlation between IL% and IG% in the sealants tested.

Results:

Microleakage – IL%: Each sealant on each premolar was investigated and evaluated. The median percentage microleakage values were established, and no statistically significant differences were found between sealants.

Interfacial gaps – IG%: The median values for the percentage interfacial gaps were established and no statistically significant differences were found between sealants.

Sealant penetration – Ds%: Measurements were performed only for fissures demonstrating an orifice of ~ 100 µm in width – which was a maximum of 11 out of 20 samples across the board. The median percentage sealant penetration values for each sealant were then established and statistically analyzed using Dunn's Test for treatment groups of unequal size.

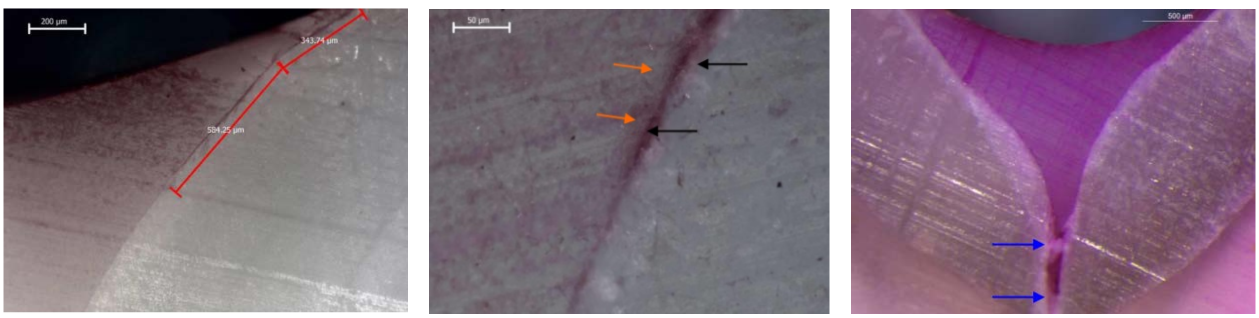


Fig. 15a-c: Example of linear measurement for microleakage; reflected polarized light microscopic image of microleakage (dye penetration shown by black arrows) and interfacial gaps (orange arrows); stereoscopic image of incomplete sealant penetration into fissure – blue arrows.

The only statistically significant differences found were between Helioseal F Plus and Embrace Wetbond and between Ultraseal XT Hydro and Embrace Wetbond with regard to sealant penetration whereby Embrace Wetbond exhibited lower (worse) sealant penetration - Ds% values than Helioseal F Plus and Ultraseal XT Hydro. Helioseal F Plus also exhibited the highest median percentage fissure-penetration value as shown in the following boxplot.

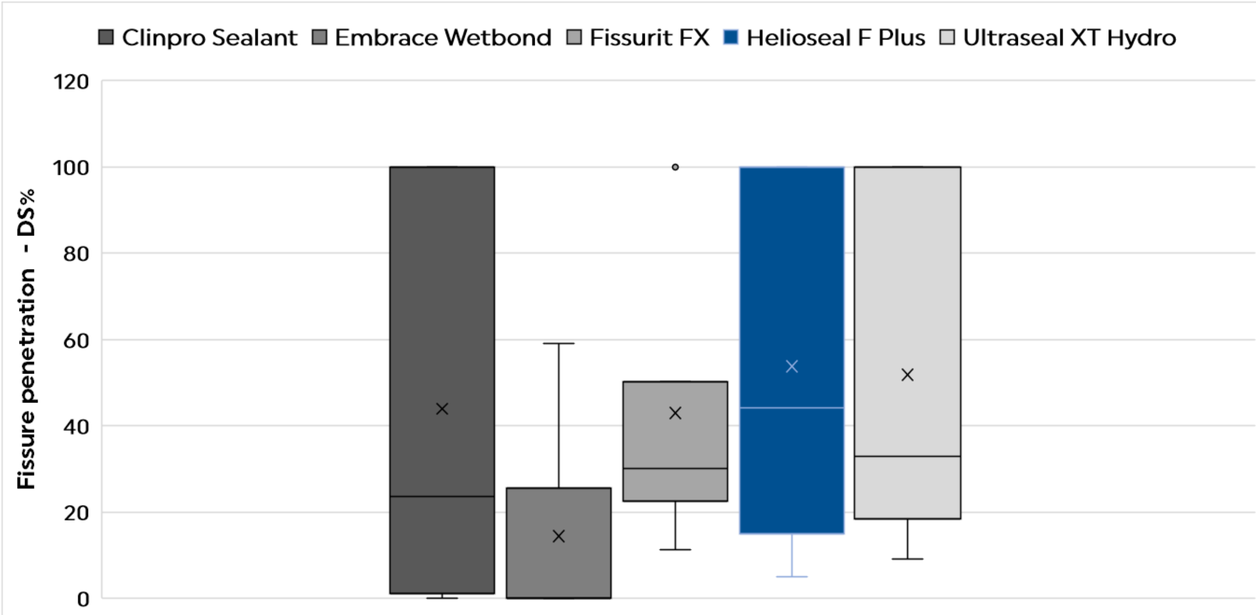


Fig. 16: Boxplot showing the percentage fissure penetration by sealant. [25]

Conclusion: Helioseal F Plus exhibited the highest median percentage fissure-penetration value and this was statistically significantly higher than that of Embrace Wetbond for narrow fissures. The other in vitro results showed no statistically significant differences between sealants regarding the extent of interfacial microleakage - IL%) or the extent of interfacial gaps - IG%. No statistically significant correlation was found between interfacial microleakage or interfacial gaps.

5.5.2 Marginal adaptation and 5s curing

Background: To establish the efficacy and equivalence of reduced curing times with higher intensity curing lights, natural molars were sealed with either Helioseal F (predecessor product for Helioseal F Plus) or Helioseal F Plus and cured for 5 seconds. Marginal adaptation results were compared to previous results obtained with Helioseal F when cured for 20s.

Method: Six molars per sealant were sealed following sandblasting to remove calculus, cleaning, drying and an application of Total Etch/Ivoclar etching gel. The sealants were applied to fissures with the narrow 0.4mm cannula and a fine probe was used to eliminate air bubbles and move material into para-fissures. After a penetration time of 15 seconds the Helioseal F sealants were light-cured for 5 seconds with Bluephase 20i /2000mW/cm and the Helioseal F Plus sealants were similarly light-cured for 5 seconds with Bluephase PowerCure in Turbo mode / 2000mW/cm^2. The sealed teeth were then subjected to thermal cycling (10,000 cycles, 5°C/55°C, 30s each) without further storage; followed by toothbrushing simulation for 5 hours using the Willytec toothbrush simulator with Signal Anticaries toothpaste and deionized water.

Photos (at 20x magnification) were taken of the occlusal surface at four time points: prior to sealing, after sealing, after thermocycling and after toothbrush simulation. Sealants were also evaluated by a clinician using 3.3x magnifying glasses and a fine probe. Dye penetration tests were performed using Fuchsin on the Helioseal F group and after sectioning the percentage dye penetration in relation to the fissure depth was measured. This group was compared to previous tests carried out when Helioseal F was cured for 20s with a Bluephase Style curing light / 1100mW/cm^2.

Results: After thermocycling and toothbrush simulation very few small partial fractures were detected at the margins of the Helioseal F group which was evaluated as a good result. In the Helioseal F Plus group, good to very good marginal quality was observed in all molars with only one sealant showing a small fracture.

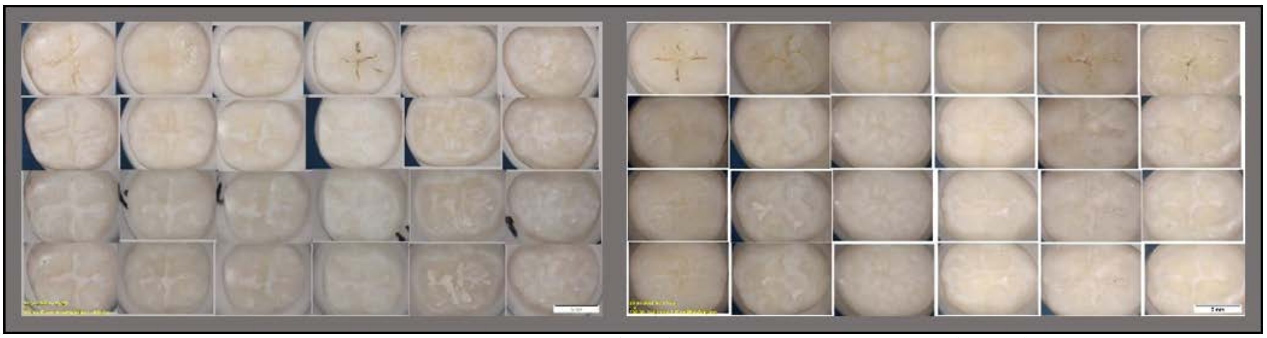


Fig. 17: Light microscope images of Helioseal F (left) and Helioseal F Plus (right) sealed teeth - all polymerized for 5s at 2000mW/cm^2. Top to bottom in rows (n=6): Before sealing, after sealing, after thermocycling and after toothbrush simulation. [26]

Only the Helioseal F group was exposed to the dye penetration test after thermocycling and toothbrush simulation. Comparing the 5s cured group to the previous 20s cured group, the test confirmed the clinical visual evaluation above. Very low dye penetration was observed and the difference between the differently polymerized groups was not statistically significant (5s/2000mW/cm^2 = 4.96% and 20s/1100mW/cm^2 = 4.83%)

Fig 18 : Section through a tooth sealed with Helioseal F showing no dye penetration in the fissure

Conclusion: There was no significant difference after artificial aging, between sealants sealed for 5 seconds or 20 seconds at different light intensities. Helioseal F Plus behaved similarly if not slightly better than Helioseal F in the clinical evaluation. It can be assumed that Helioseal F Plus would also behave equivalently with respect to the dye penetration.

5.6 Surface roughness

The surface texture of a restorative material or fissure sealant has a clear influence on plaque accretion, discoloration and wear.

The texture after polishing was measured using an FRT MircroProf optical device after the manual removal of the inhibition layer with an ethanol soaked lint-free cloth. Eight pre-cured disc specimens of the sealants were prepared by roughening with 320 grit sandpaper, followed by storage and polishing with OptraPol NG.

Helioseal F Plus surface roughness values are shown below as compared to the predecessor fissure sealant Helioseal F. In general, a mean surface roughness of <0.1 µm indicates excellent polishability, <0.2 µm suggests good polishability, a value between 0.2 - 0.4 µm corresponds to a medium polishability and >0.4 µm suggests poor polishability.

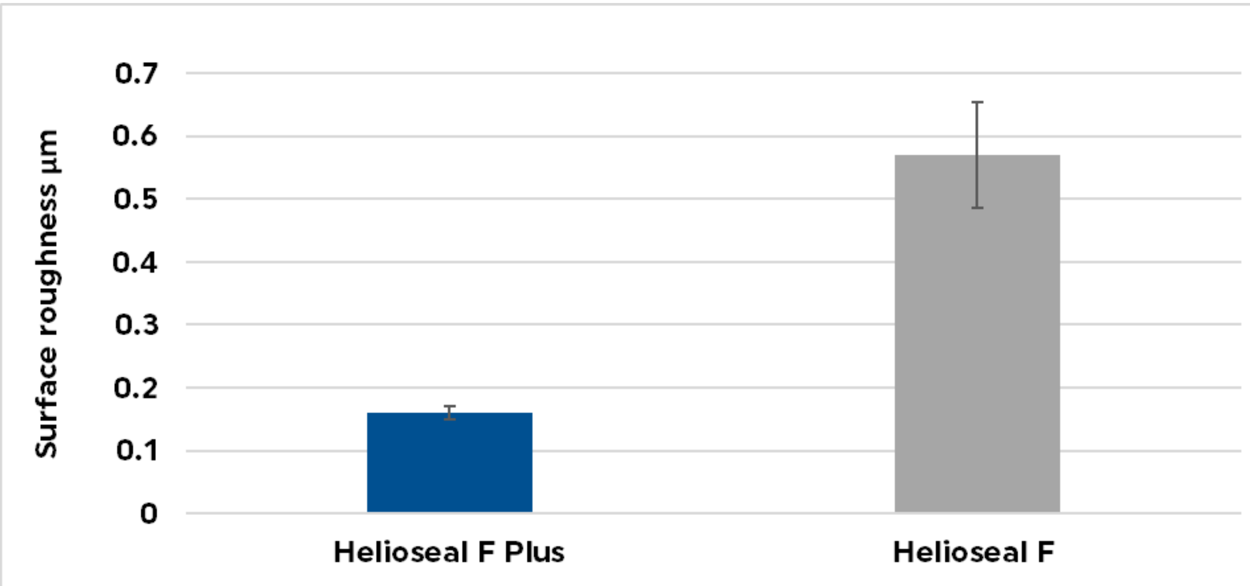


Fig. 19: Surface roughness of Helioseal F Plus and Helioseal F

Helioseal F Plus utilises very fine-grained filler particles and demonstrates good (low) surface roughness i.e., polishability levels.

5.7 Conclusion

Overall the laboratory investigations with Helioseal F Plus show that the product bonds well to tooth structure, exhibits high depth of cure, good microleakage and favourable surface smoothness, it releases fluoride and exhibits good handling with regard to its flow properties.

6 Clinical experience with Helioseal F Plus

Helioseal F Plus was launched in 2019, optimizing the predecessor product Helioseal F. As the sealant is relatively new, there are few finalized clinical studies. In general however Helioseal fissure sealants have proven effective over many years of clinical use and Helioseal F Plus is the culmination of Ivoclar sealant technology and experience.

6.1 In vivo investigations with Helioseal F Plus

6.1.1 Clinical performance of a new fissure sealant – Results from a 2-year randomized clinical trial [27, 32]

Kühnisch J. University Hospital, Ludwig Maximilians-University Munich, Germany; Dental practice Wädenswil, Switzerland

Objective: To explore the clinical survival of Helioseal F Plus in comparison to the established fissure sealant Helioseal F.

Method: A clinical, prospective randomized control trial, utilizing two centres and a split-mouth design was planned. Patients were treated by three clinicians: two (LMU 1 and LMU 2) at the University of Munich Polyclinic (n= 51) and one (Wädenswil 1) at a private practice in Wädenswil (n=41). The initial study population consisted of 92 children/adolescents with an average age of 11.7 years (SD 2.8 years). Patients with suitable pairs of permanent first or second molars were included in the study. Both caries-free and teeth with non-cavitated caries lesions were accepted. Patients received both Helioseal F and Helioseal F Plus sealants in one or more pairs of teeth. Relative isolation with cotton rolls was carried out at LMU and absolute isolation with rubber dam at the dental practice in Wädenswil. The Helioseal F Plus sealants were cured for 10 seconds with Bluephase Style (1200mW/cm^2) and the Helioseal F sealants were cured for 20 seconds with the same curing light. At the outset, 164 sealings with each of the sealants (n= 328), were carried out. Patients were followed up after one month (n=89), six months (n= 88), one year (n= 85) and two years (n=82). As 82 patients could be evaluated after 2 years, this resulted in an overall attrition rate of 10.9%.

	Recall				
	Baseline	1 month	6 months	1 year	2 years
No. patients	**92**	**89**	**88**	**85[a]**	**82[a]**
♀/♂	51/41	49/40	49/39	47/38	45/37
Munich/Wädenswil	51/41	48/41	49/39	48/37	47/35
No-shows	-	3	2	3	6
Drop-outs	-	-	2	2	-
	Sealants applied				
All sealants	**328**	**322**	**315**	**305[b]**	**297**
Helioseal F Plus	164	161	158	153	149
Helioseal F	164	161	157	152	148

Table 4: Overview of study population, location and sealants

[a] The total patient numbers at 1 and 2 years also take account of all dropouts recorded to date.
[b] One case cannot be evaluated as an orthodontic bite block remains

At each recall, sealant retention and the presence of caries were recorded.

Results:

Retention

No adverse events during application or any of the follow-up visits were documented. After 2 years, the proportions of completely intact sealants or with different kinds of loss, showed a very similar distribution in both sealant groups.

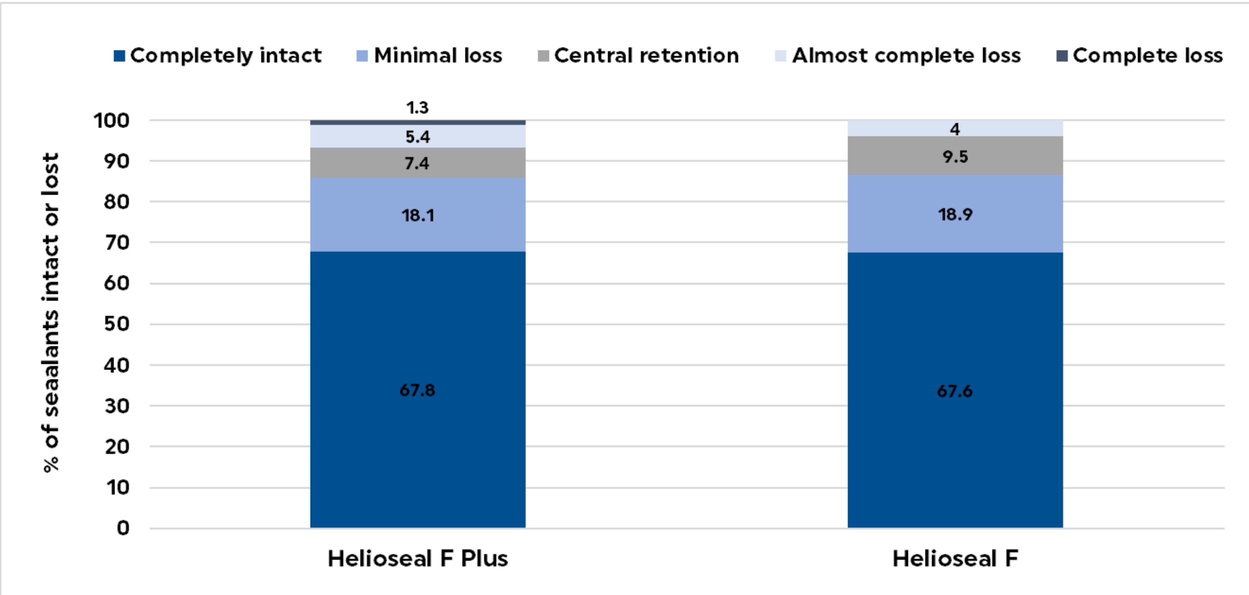


Fig. 20: Comparison of sealant retention behaviour from both centres

According to internationally accepted criteria for the success of fissure sealants – minor retention losses are considered unproblematic, thus if the "completely intact" percentages are added to the "minimal loss" percentages – the percentages for "intact" sealants remains almost identical in both groups at 85.9% for Helioseal F Plus and 86.5% for Helioseal F. No statistically significant differences were found with regard to sealant retention.

Interestingly, quite stark differences regarding retention were found between operators. With one operator (LMU 1) incurring far higher percentages of loss as shown in the diagram below. This may have been due to the relative difference in seniority/experience with children of the practitioner in question. Importantly no differences between the sealants for each operator were evident. Slightly better retention was also evident in older patients compared to younger.

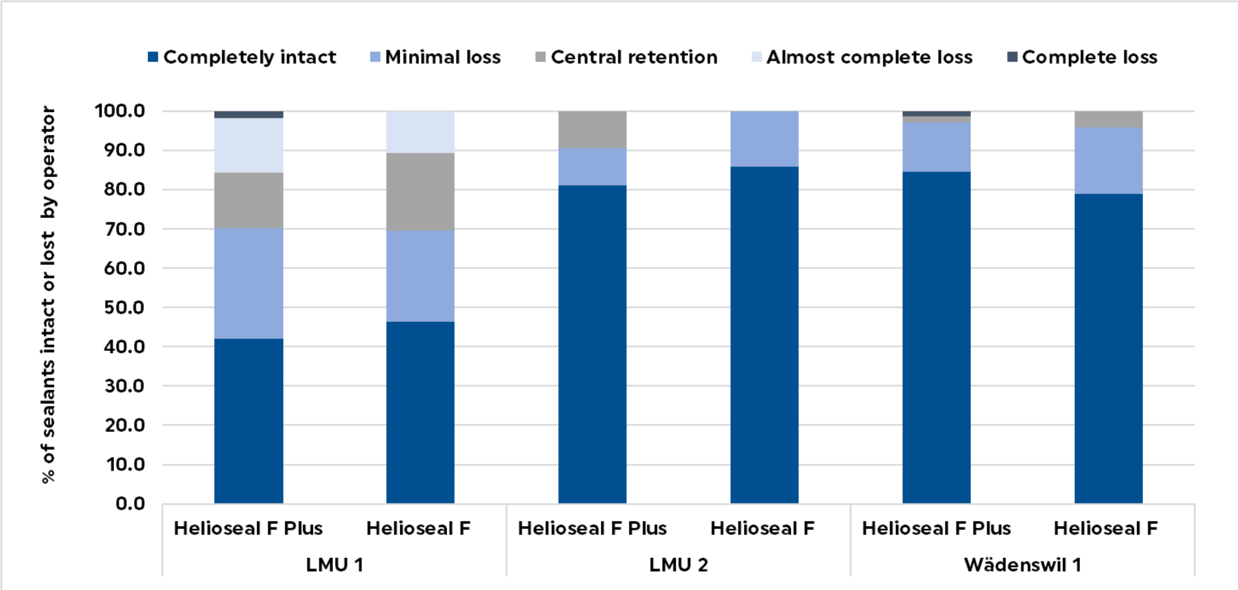


Fig. 21: Comparison of sealant retention by operator

Marginal Discoloration and Integrity

The sealants were also compared in terms of marginal discoloration and marginal integrity. After 2 years, marginal discoloration that could not be polished away was present in two Helioseal F Plus sealants and three Helioseal F sealants. The discoloration observed was not connected to any cavitation. 96.6% of the Helioseal F Plus sealants showed no discoloration at all, similarly to 97.9% of the Helioseal F sealants. Similarly, 100% of the Helioseal F Plus sealants showed good/sufficient marginal integrity and 99.3% of the Helioseal F sealants from both test centres.

Conclusion: There were no material-related adverse clinical events during the study. Helioseal F Plus exhibited equivalent clinical behaviour to the established sealant Helioseal F in terms of survival, retention, marginal discoloration and integrity. This study flagged up the issue of operator-dependency but otherwise there were no significant differences found between the two sealants, study centres, chosen isolation technique, patient age or sex.

7 Conclusion

State of the art modern dentistry is an ongoing effort to simplify and improve clinical practice by creating ever more esthetic, durable, safe materials that are easier and quicker to use. This is true for preventive dentistry as much as curative. Helioseal fissure sealants have proven to be effective over many years of clinical use. Helioseal F Plus – an efficient, esthetic, fluoride releasing sealant, is the culmination of Ivoclar sealant technology and experience accumulated over recent decades.

8 Biocompatibility

Biocompatibility can be defined as the ability of a substance/material to be in contact with a living system without producing an adverse effect. When developing new products, Ivoclar strives to use well-established raw materials that have already proven safe *in vivo,* in order to minimize any biocompatibility risks from the outset

Medical device standards
Medical devices are subject to very strict requirements, which are designed to protect patients and operators from any potential biological risks. ISO 10993 "Biological evaluation of medical devices" defines how the biological safety of a medical device is to be evaluated. Furthermore, dental medical devices are subject to ISO 7405 "Evaluation of biocompatibility of medical devices used in dentistry" and standard risk management requirements as set out in ISO 14971 "Medical devices – Application of risk management to medical devices".

The biocompatibility of Ivoclar medical devices and in this case Helioseal F Plus, was examined according to these standards.

Testing regime
Tests are carried out with individual product ingredients however resin materials usually also undergo extraction/leaching tests in their polymerized state as this is the state in which they remain long term in the human body.

Cured discs of the products are produced and testing is carried out with regard to e.g. cytotoxicity, hypersensitivity/sensitization, acute or sub-chronic systemic toxicity – oral/inhalation and genotoxicity. Tests indicate the reactivity or tolerance of cells (often mouse fibroblasts) to soluble compounds of a material.

Various biocompatibility assessments were carried out with Helioseal F Plus. Polymerized Helioseal F Plus exhibits very low water solubility of 0.24 µg/mm^3 and according to the data available it can be concluded that the sealant does not cause adverse reactions when implanted in teeth and according to the data available:

- The cured product does not exhibit any cytotoxic potential (toxicity to cells).
- The sealant exhibits no acute or subacute systemic toxicity
- Subchronic or chronic systemic toxicity is not expected
- Helioseal F Plus is neither genotoxic nor carcinogenic
- In its uncured state, the sealant may cause sensitization to methacrylates, which is entirely typical for all resin-based dental materials.

Sensitization/Irritation
Like almost all dental composite materials, Helioseal F Plus contains (di)methacrylates. Such materials may cause sensitization to methacrylates, which can lead to allergic contact dermatitis. These reactions can be minimized by clean working conditions and avoiding contact of the unpolymerized material with the skin. [28-31] In its uncured state, the sealant may have a slight irritant effect on skin, eyes and mucous membranes. Cured Helioseal F Plus can be considered non-irritant when used according to the instructions for use.

Conclusion

Helioseal F Plus is neither toxic nor irritant for patient or user, when used as intended and according to the instructions for use. The risk of sensitization is similar to that of other dental materials containing methacrylates. Although allergic reactions can never be completely excluded, on the basis of the toxicological evaluation of the product, its predecessor products and longstanding worldwide clinical use of very similar materials, it can be concluded that the benefits provided to patients by the final product exceed any potential risks produced by the device materials.

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