Scientific Manual

Surefil one™
Self-Adhesive Composite Hybrid

Dentsply Sirona

Research

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1 Preface by Mark A. Latta

Dear Colleagues,

The ever-increasing demand for clinically forgiving and durable esthetic restorative materials has resulted in an intense focus on the development of tooth colored restoratives that provide an esthetic alternative to silver amalgam. While modern resin composite restorative materials are a genuine alternative to silver amalgam, the clinical performance of these esthetic materials relies in large part on a meticulous adherence to clinical technique, especially moisture control and on the bonding procedure used to place the restorative.

Among the desired features for a directly placed esthetic restorative material are optical characteristics similar to mineralized tooth structure, strength and wear properties that can withstand masticatory forces, and the ability to bond to enamel and dentin. Restorations using a resin composite restorative typically require multiple steps related to the placement of the adhesive and the need to layer the restorative material to facilitate adaptation and complete visible light polymerization. As these polyacrylate materials are hydrophobic, field isolation is essential for successful placement and longevity.

Glass ionomer materials, based on polyalkenoic chemistry, are materials that have the potential to meet many of these characteristics. However, limitations in physical properties, handling characteristics and some esthetic limitations have hampered glass ionomer and resin modified glass ionomer materials from being a more prominent alternative to resin composite materials. A more ideal material would combine the features of both polyacrylate and polyalkenoic materials to achieve an esthetic, moisture tolerant, self-adhesive, durable and easy to place (i.e. dual cure and bulk fill) restorative. As the investigations documented in this manual suggest with the introduction of Surefil one clinicians now have a restorative material that can rival the performance of resin composite fillings and at the same time provide glass ionomer like handling characteristics.

One of the most unique features about Surefil one is its “self-adhesive” characteristic to mineralized tooth structure. The most common strategy for developing a self-adhesive material has been to modify the reactive diluent monomers with acidic functional groups to create an interaction with the inorganic components of enamel and dentin. However, materials that used this approach performed poorly clinically, in part due to the fact that they are hydrophobic and that they did not wet or interact effectively with hard dental tissues. Another approach is to modify structural monomers with acidic groups in order to facilitate bonding to enamel and dentin. Polyacids used in glass ionomers employ this strategy but are limited by the inability for these moieties to contribute to the structural integrity of the material as these polyacids do not contain polymerizable functional groups. Surefil one employs a Modified Polyacid System (MOPOS) that promotes bonding to tooth structure (self-adhesive) while also acting as a copolymerizing crosslinker between the covalent and ionic structural network in the set material. This merging of the polyacrylate and polyalkenoic strategies for self-adhesion and structural integrity has resulted in Surefil one being the first truly self-adhesive composite hybrid restorative.

To achieve an optimal bond to dentin and enamel a material should employ all three of the primary mechanisms of adhesion to tooth structure: 1) surface wetting, 2) micromechanical interlocking and 3) chemical covalent bonding. Consider the challenge of creating a high-quality bond with resin composites, which are hydrophobic when dentin consists of 25% water and enamel about 4%. Surefil one contains water and that is a critical component of self-adhesive bonding in that it can wet the surface without excess moisture and does not have to convert the hydrophilic tooth surface to a hydrophobic surface. Thus the “window of opportunity” for optimal bonding is widened compared to resin composite placement techniques. The acidic monomers in Surefil one modify the smear layer surface of both enamel and dentin promoting microretention and have the capability of forming a primary ionic bond with the hydroxyapatite in the tooth substrate.

The high level of mechanical properties including wear resistance are a result of the monomer systems and the reactive glass fillers used in the composition. Combined with the light cured and dark cure initiator systems the fully set and polymerized

Surefil one material results in a restorative material that can withstand the rigors of mastication in the oral environment.

I am excited for the introduction of Surefil one by Dentsply Sirona as it provides a valuable esthetic alternative to silver amalgam as well as being an attractive alternative to traditional resin composite materials. This high-quality restorative requiring fewer working steps for clinical success will undoubtedly be of great service to clinicians and patients alike.

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2 Path to a self-adhesive composite hybrid

In modern dentistry, permanent direct restorations of posterior teeth require the use of a resin composite material. Resin composites are composed of structural monomers as BisGMA or EBA which deliver strength, reactive diluents such as TEGDMA to facilitate paste flowability and to adjust handling properties, and fillers which contribute to strength and wear resistance but also influence handling properties (see Figure 1).

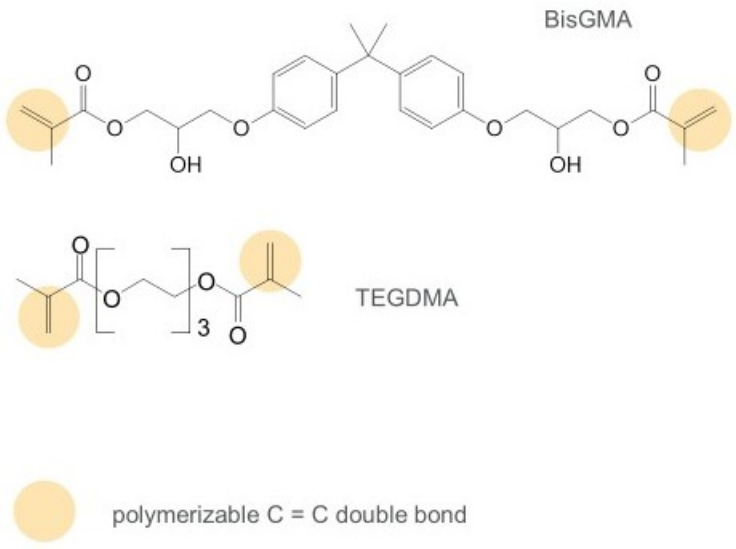

Figure 1 Structural monomer (BisGMA) and reactive diluent (TEGDMA) with terminal double bond for radical polymerization (yellow).

In the history of material development there were multiple approaches to make a resin composite material self-adhesive for simplifying its use and for increasing efficiency of the dental restorative treatment. The probably most prominent approach was modifying the reactive diluents with acidic moieties to facilitate interaction with dental hard tissue (see Figure 2). This was commercialized as the group of self-adhesive flowable composites but the clinical results obtained were often poor (Çelik EU et al. 2015).

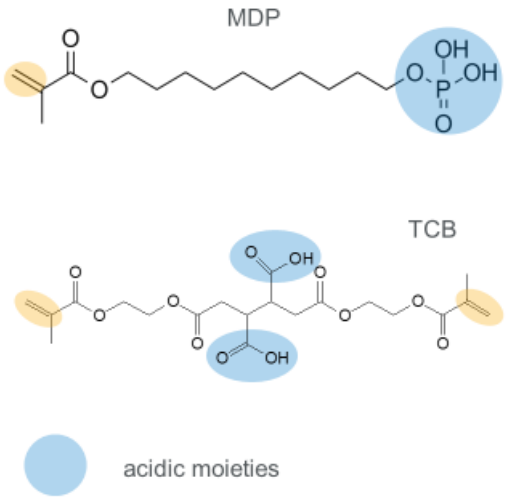

Figure 2 Examples of polymerizable (yellow) methacrylates modified with acidic moieties (blue).

Alternatively, the structural monomers can be modified with acidic groups to achieve sufficient adhesion to the tooth substrates. To its extreme this approach is realized in the polyacids used in glass ionomers whereas those polyacids cannot contribute to the radically polymerizing network due to lack of polymerizable groups. In order to overcome this deficiency of traditional polyacids, the radically polymerizable polyacid MOPOS was designed which contributes to strength via copolymerization with the reactive diluents merging the self-adhesive properties of classical polyacids with the crosslinking ability of structural monomers (see Figure 3).

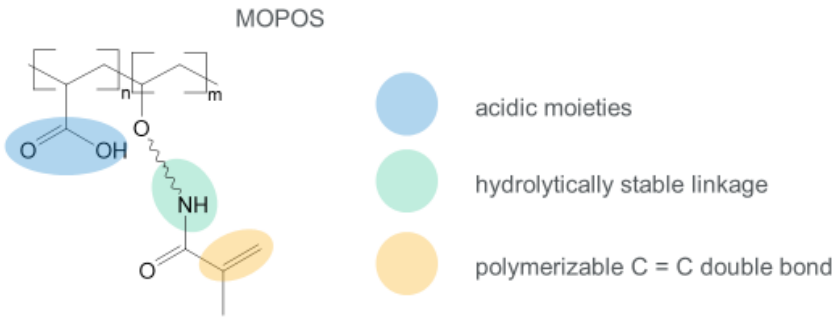

Figure 3 Structural unit of MOPOS: Numerous acidic moieties (blue) are integral part of the structural monomer and polymerizable double bonds (yellow) are hydrolytically stable linked (green).

Using polyacids in formulations requires the use of water in the formula due to insolubility in traditional composite resin compositions. Adding water to a formula has major consequences on the nature of the chemistry which can be applied in such a formula since every component needs to be compatible with water and stable in an

aqueous environment. Therefore, the classical reactive diluents need to be substituted by water soluble, hydrolytically stable molecules such as BADEP.

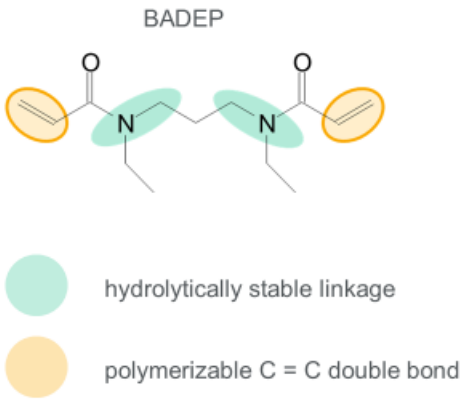

Figure 4 Water soluble and hydrolytically stable reactive diluent (BADEP).

To enable an esthetically sufficient outcome when restoring posterior teeth, the refractive index of the used filler system needs to be well below the refractive index of classical Ba-glasses used in resin composites. This can be achieved by using a reactive glass filler which additionally contributes to strength via copolymerization of the functional groups introduced by silane treatment.

Taking all this together results in **Surefil one a self-adhesive composite hybrid** which uses the principles of resin composite materials as structural monomers, reactive diluents and silanated glass fillers combined in a unique manner with the self-adhesive properties of polyacids known from glass ionomers.

3 New Chemistry for a self-adhesive restorative

3.1 Surefil one- product description

Surefil one is a self-adhesive composite hybrid offering the following features:

- Self-adhesiveness to enamel and dentin
- Bulk fill and dual-cure
- Fluoride release

Surefil one meets the requirements regarding flexural strength for direct composite restorations and is indicated for Class I to Class V restorations.
Surefil one is delivered in a pre-dosed mixing capsule for direct intraoral application with a minimal dispensable amount of 0.3 g.
After mixing the capsule in a capsule mixer, Capsule Extruder 2 is the device designed for extrusion and direct application of Surefil one restorative capsules.

3.1.1 General Composition

Surefil one is a self-adhesive composite hybrid restorative material. The liquid part contains newly developed hydrolysis stable, cross linkable poly acids, hydrolysis stable crosslinkers, reactive diluents and water. The reactive glass fillers of Surefil one contribute to strength and wear resistance of the material. For the bulk fill and dual-cure properties a unique initiator system is utilized. An overview of the composition and the general function of each component is given in the following Table 1.

Component	**General function**
Modified polyacid (MOPOS)	Etchant, adhesion promoter, crosslinker between covalent and ionic network
Bifunctional acrylate (BADEP)	Crosslinker in the covalent network
Acrylic acid	Reactive diluent, Primer, crosslinker between covalent and ionic network
Water	Solvent for polyacid and resins, etching aid
Reactive glass filler	Filler supporting wear resistance and mechanical strength
Non-reactive glass filler	Radiopacifier, rheology modifier
Initiator	Photo- and redox initiator system
Stabilizer	Stabilize monomers upon storage

Table 1 Composition of Surefil one, general function of components

3.1.2 What is needed to make a dental restorative material self-etching and self-adhesive?

Enamel as well as dentin are polar, hydrophilic substrates consisting of hydroxyapatite (enamel and dentin) and collagen (dentin). In order to generate adhesion to these substrates several chemical functionalities are essential. In contrast to classical resin based restorative materials which are typically highly hydrophobic materials, the interaction with hydrophilic substrates such as dentin and enamel requires a polar, hydrophilic chemistry to wet and to bond to these surfaces. Suitable for achieving these hydrophilic properties are e.g. acidic groups such as carboxylic, phosphoric, or sulphonic acids. At the time being, mainly carboxylic acids are used in dental restorative materials. In addition to hydrophilicity, a self-etching, self-adhesive restorative material needs to etch enamel to generate a certain level of microroughness to facilitate interaction by micromechanical interlocking. To achieve this etching effect on enamel a certain level of water is needed which can't be supplied by the very low water levels present in enamel.
In summary, the presence of acidic functions and water are the minimum requirements to achieve adhesion to enamel and dentin. Today this is achieved with Glass Ionomers and resin modified glass ionomers which unfortunately, due to their chemistry, lack the mechanical strength and wear resistance to act as permanent restorative materials for load bearing clinical situations.
To overcome these weaknesses Dentsply Sirona developed Surefil one.

3.2 MOPOS – Modified Polyacid system

The key component of Surefil one is MOPOS – a modified polyacid which, due to its unique structure and properties, allows new ways in formulating a self-adhesive restorative material. MOPOS contributes to the adhesion to tooth structure and to the network formation, thus the mechanical strength of the material. What makes MOPOS so special is the hydrolytically stable modification of the polyacid base polymer with polymerizable groups. Typically, polyacids used in resin containing materials are modified in a hydrolytically non-stable manner using HEMA (hydroxyethyl-methacrylate). As this linkage is not stable in an aqueous acidic

environment, an excess of HEMA must be used in the formulation to shift the equilibrium to the required level of functionalization of the polyacid (refer to Figure 5).

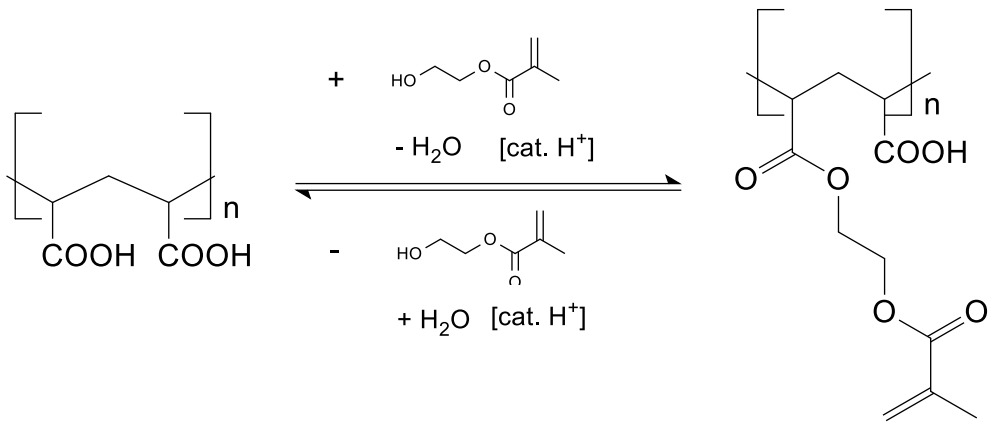

Figure 5 Equilibrium between unsubstituted poly acid and HEMA modified poly acid

Of course, the functionalization of the polyacid is not the only function of HEMA in such a formula, e.g. HEMA is an excellent dentin primer and contributes to the dissolution of the smear layer. On the other hand, HEMA as a monofunctional monomer, even when used in combination with bifunctional monomers such as TEGDMA, leads to a relatively weak network resulting in limited mechanical properties. Due to the hydrolytically stable connection of the polymerizable groups to the polymer backbone in MOPOS, the use of HEMA is no longer needed.

MOPOS is synthesized in a proprietary 3-step synthesis (refer to Figure 6) starting by polymerization of *tert. Butyl*-acrylate with an amino-functionalized vinyl ether in an organic solvent. This reaction leads to an amino-functionalized *tert.* butyl-ester protected polyacid. The amino groups are converted to methacrylic amides by reaction with methacrylic anhydride overnight. After deprotection of the ester moieties under acidic conditions MOPOS can be isolated as a crude product. In order to make it usable in a dental product, strict specifications on purity need to be met. These requirements are achieved by a unique, custom made purification process leading to the final functionalized polymer MOPOS.

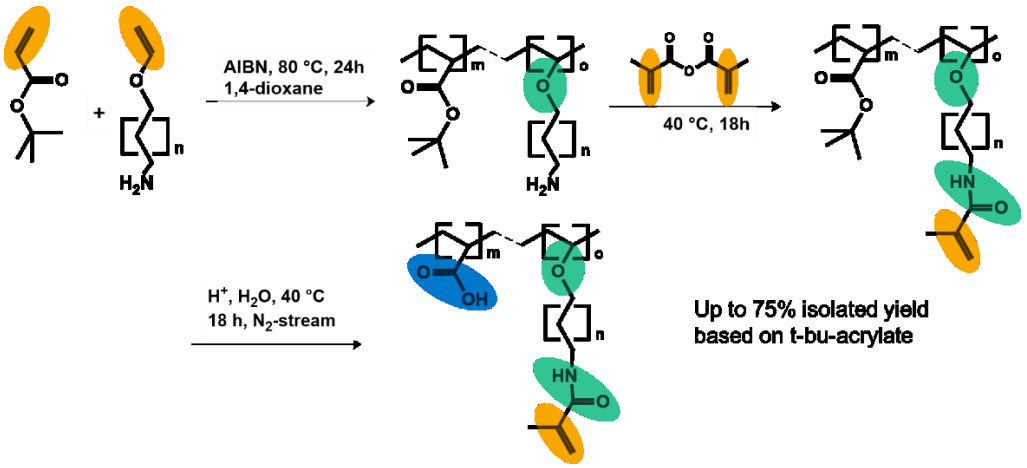

Figure 6 3-Step-Synthesis of the modified poly acid system MOPOS

3.3 Monomers

With MOPOS at hand there are new options for the use of different monomers to formulate the matrix system. One key monomer in Surefil one is acrylic acid which acts in multiple roles within the overall formula. While being an excellent primer for dentin, dissolving the smear layer and acting as a reactive diluent, it further contributes to etching of enamel and dentin and to the adhesion to these substrates. As a bifunctional monomer it contributes to the covalent polymer network through its polymerizable double bond as well as to the ionic network formed by cations released from the filler. Consequently, acrylic acid significantly contributes to strength and adhesion of Surefil one.

Beyond acrylic acid, more monomer chemistry is needed to meet the demanding chemical requirements of aqueous acidic systems and to achieve the desired mechanical properties. BADEP, a tailor-made component, used in multiple well-established dental self-etch and universal adhesives, turned out to be an ideal candidate. BADEP is a hydrolytically stable, low viscosity bis-acrylic amide which acts as a cross-linking molecule in the formula. Compared to e.g. TEGDMA (refer to Figure 7) which is a classical monomer for such applications, BADEP is not prone to acid catalyzed hydrolysis, assuring full cross-linking efficiency over the full product shelf-life.

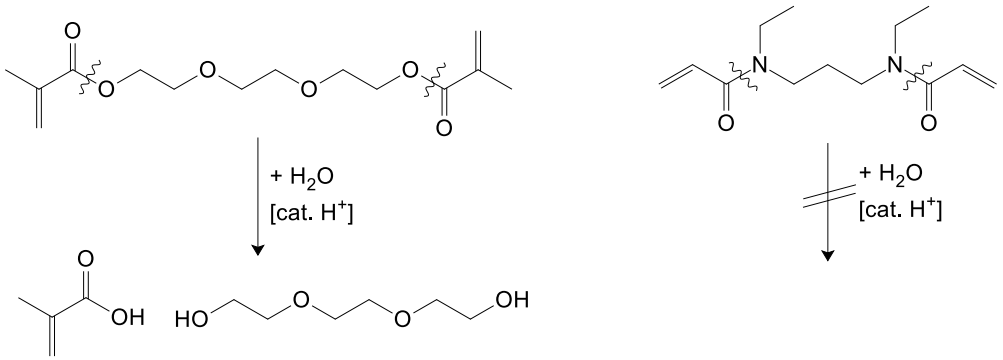

Figure 7 Structure and scheme of hydrolysis of TEGDEMA (left) and structure of stable crosslinker BADEP (right)

Upon polymerization, a dense network is formed which leads to the superior strength of Surefil one. In this network, the glass filler used to formulate Surefil one is strongly integrated by two mechanisms – 1. Through integration into the covalent part of the network by copolymerization of the adjacent methacrylate groups and 2. through interaction with the ionic parts of the network by formation of chelate complexes of the released cations.

3.4 Initiator System

Figure 8 Composition of the unique initiators system of Surefil one

The unique initiator system of Surefil one (refer to Figure 8) , which is responsible for the unlimited bulk-fill and dual-cure properties, consists of four different components: the photoinitiator Camphorquinone (CQ), a persulfate for redox curing and two different reducing agents, which are needed as co-initiators. The two reducing agents in this well-balanced initiator system are part of the light cure as well as the dark cure system.

The dual-cure mechanism, which is triggered by the ionomer reaction as well as a radical polymerization, starts directly with the mixing process of powder and liquid. During mixing, the liquid comes into contact with the powder and the solvation of the different initiator components starts, whose reaction then generates radicals throughout the whole paste. Thus, several MOPOS molecules can be linked to each other and to the various monomers in Surefil one. Simultaneously, the mixing also initiates the glass ionomer reaction between MOPOS and the reactive glass fillers starts. Consequently, it is essential to separate the reactive components within a two-component powder-liquid system to guarantee stability during storage. This can only be realized in a capsule, where the powder is separated by a thin membrane from the liquid.

After placing the restoration, its surface can further be light cured using a conventional light curing device. During this step, Camphorquinone is activated by the light, reacts with the reducing agents and forms additional radicals, which initiate a faster radical polymerization of the resin matrix in the upper millimeters of the restoration.

This combination of the two different initiator systems allows a fast and easy placement of the permanent restoration. Immediately after light curing, the surface can be finished and polished, while the bulk of the restoration underneath goes through the self-curing cycle. The presence of the dark cure initiator system in Surefil one provides the remarkable opportunity to use this material in the bulk fill technique without layering. In conclusion, the unique initiator system that was specifically developed for the use in Surefil one raises the efficiency and ease of use in clinical procedures to an unprecedented level.

3.5 Network

Based on all these specifically developed and carefully selected components like the modified poly acid MOPOS, the crosslinker BADEP, acrylic acid, water and the special filler and initiator system, a composite-like three-dimensional network (refer to Figure 9) is formed during the setting reaction, which significantly improves the mechanical strength of Surefil one. The presence of reactive double bonds and carboxylic acid groups in both MOPOS and acrylic acid generates a direct connection between the ionic- and the covalent network, resulting in an integrated, highly stable

molecular network. In this network the glass filler used to formulate Surefil one is strongly integrated by two mechanisms.

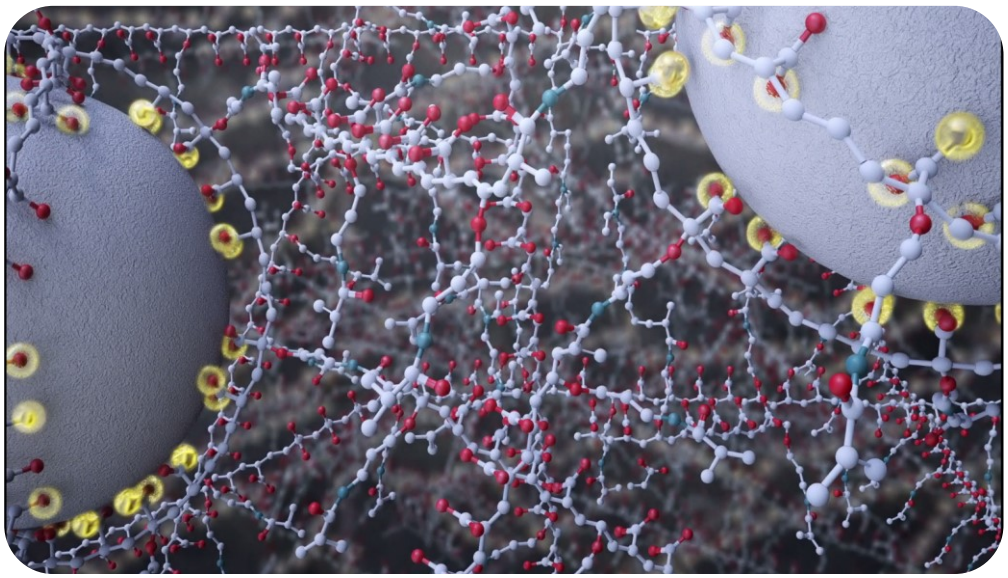

Figure 9 Scheme of the composite-like three-dimensional network of Surefil one (grey, red, green elements) and ionic interaction with glass filler (yellowish).

4 Material Properties and in vitro studies

When indicating a self-adhesive restorative for permanent fillings in posterior teeth, mechanical strength is of high importance to withstand chewing forces. Dimensional stability is also needed when indicating a material for larger fillings. Furthermore, wear resistance needs to be high enough to allow long-term stability of occlusion. As a hybrid material, fluoride release rate over a longer period of time is of interest, too. Finally, marginal integrity in class II restorations should be comparable to clinically proven combinations of adhesive and composite. On the other side, indicating a self-adhesive material for class V demands good adhesion to dentin and enamel to avoid retention failure.

In order to characterize Surefil one in these regards, the following properties were tested in vitro:

- Mechanical strength
- Dimensional Stability
- Wear resistance
- Fluoride Release
- Marginal integrity
- Adhesion to dentin and enamel

Following materials had be used as controls:

Product	Catgory	Adhesive / Conditioning
Activa	Resin modified glass ionomer (RMGI)	None
Ceram.X mono+	Hybrid composite	Xeno V+
Dispersalloy	Amalgam	None
Equia Forte	Glass ionomer (GI)	None
Filtek Supreme XTE	Nano composite	Scotchbond Universal
Fuji II LC	Resin modified glass ionomer (RMGI)	Dentin Conditioner or none
Heliomolar	Microfill composite	AdheSE Universal
Ketac Molar Quick	Glass ionomer (GI)	None
QuiXfil	Bulk fill composite; packable	Prime&Bond active
Spectra ST	Hybrid composite	Prime&Bond active Prime&Bond elect

4.1 Mechanical strength

Indicating a filling material for the use in stress bearing posterior teeth requires sufficient mechanical strength as a key property for clinical success. There are numerous ways finally leading to fracture. Therefore, mechanical strength testing needs to consider different scenarios regarding force initiation and stressing to simulate long-term behavior.

4.1.1 Flexural strength

Lohbauer U and Belli R, University of Erlangen (Germany)

Flexural strength represents the resistance to catastrophic failure upon maximum loading. For restorations this could be biting strongly on a very hard bolus that can’t be chewed (e.g. cherry stone).

15 specimens (2 x 2 x 25 mm) were made following ISO 4049 and ISO 9917 under calibrated conditions (23°C; 50% relative humidity). Light curing was performed with a halogen light curing unit (radiant exitance 750 mW/cm²) in an overlapping manner resulting in 5 exposures per specimen per side. Self-curing specimens were stored in a 37°C water bath for 10 minutes before removing from the mold. All specimens were stored in distilled water at 37°C for 14 days.

Flexural strength was tested with a crosshead speed of 0.75 mm/min in a four-point bending test as shown in Figure 10 with 10 and 20 mm distance between the upper and lower support, respectively. Four-point bending allows challenging a larger portion of the bending beam compared to three-point bending described in the ISO 4049. Therefore, the resulting values are typically lower.

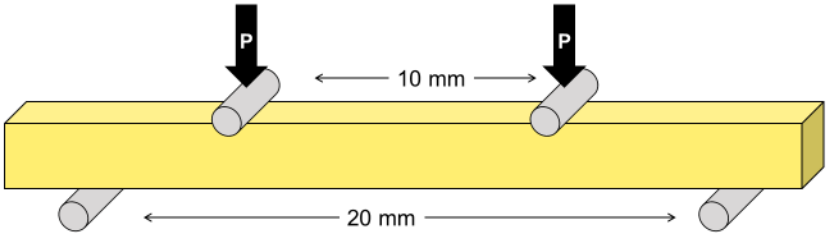

Figure 10 4-point bending test for flexural strength (P: force applied)

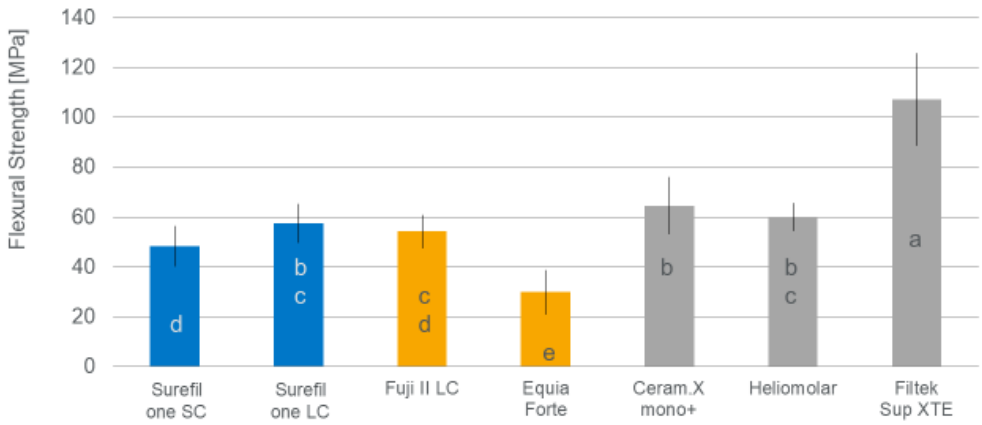

Figure 11 Initial flexural strength in four-point bending test (Lohbauer U and Belli R, 2020). Groups with same letter are not significantly different; n = 15.

When Surefil one is light cured (LC) (as described in the Instructions for Use, IFU) flexural strength was statistically comparable to Ceram.X mono+ and Heliomolar, both being composite materials with more than 10 years of clinical experience. When self-cured (SC), Surefil one was comparable to Fuji II LC and both surpassed Equia Forte (see Figure 11).

4.1.2 Flexural strength – long term testing

Dentsply Sirona, Research&Development, Konstanz (Germany)

Surefil one as self-adhesive restorative has hydrophilic properties in order to allow close interaction and wetting of wet surfaces (i.e. dentin). However, hydrophilicity may facilitate hydrolytic processes leading to decreased mechanical strength. Therefore, flexural strength was tested after storage in water up to 1 year.

Figure 12 shows measurements starting at 24 hours (day 1) up to day 360.

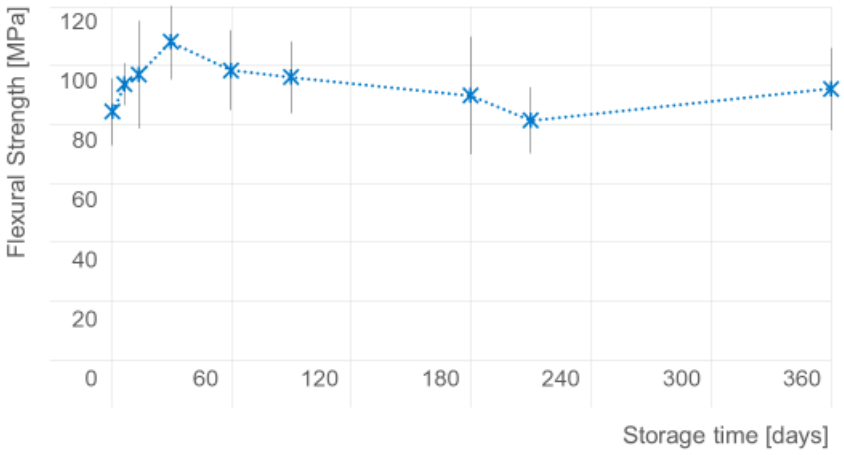

Figure 12 Flexural Strength (3-point according to ISO 4049) up to one year) with standard deviation (Dentsply Sirona R&D, Konstanz, Germany)

4.1.3 Flexural Fatigue Strength

Lohbauer U and Belli R, University of Erlangen (Germany)

In contrast to flexural strength, flexural fatigue strength represents the resistance to ongoing subcritical forces for a multitude of repetitions. In a review, it was concluded that assessment of fatigue resistance might be important when developing new formulations or attempting to predict clinical performance. (Ferracane JL, 2013).

25 specimens (2 x 2 x 25 mm) were made following the procedure described for flexural strength above in chapter 4.1.1.

To determine the flexural fatigue strength a staircase approach was used in which a given force is applied 10.000 times at 0.5 Hz. Starting value was 50 % of the initial flexural strength. If the specimen survived, the next specimen was tested under increased force. When a specimen fractured, the succeeding specimen was tested under decreased loading. Besides the calculated values for the (dynamic) flexural fatigue strength (FFS), the level of maintained (static) flexural strength was calculated and is shown in Figure 13 as well.

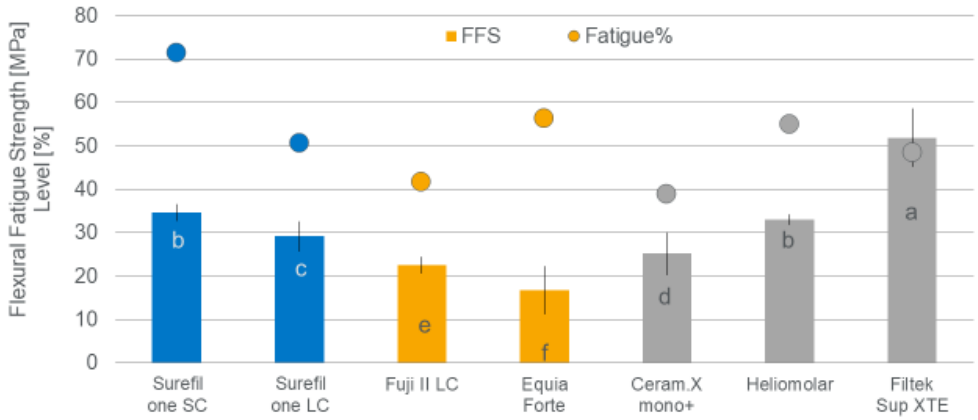

Figure 13 Flexural fatigue strength (FFS) and percentage compared to initial fatigue strength (Fatigue%) (Lohbauer U and Belli R, 2020).
Groups with same letter are not significantly different; n = 25.

In self-cure mode Surefil one showed the lowest reduction upon fatiguing (highest percentage of maintained strength). Light cured Surefil one specimens showed a flexural fatigue strength well above the tested glass ionomer and resin modified glass ionomer and one composite but lower compared to a micro- and a nano-filled composite.

Both, the absolute flexural fatigue strength and the maintained strength ratio puts Surefil one rather in the group of composites than current glass ionomer materials.

4.1.4 Fracture toughness

Lohbauer U and Belli R, University of Erlangen (Germany)

Fracture toughness (K_{Ic}) describes the resistance to catastrophic failure of an existing crack in a material. Following ISO 13856 15 specimens were prepared for the SENB (single-edge-notch beam) testing. Due to larger size of specimens compared to flexural strength testing, two capsules per specimen were needed for the respective materials. For notching, a diamond saw was used first before the notch was sharpened with a razor blade in a customized device (Figure 14) to control force and movement.

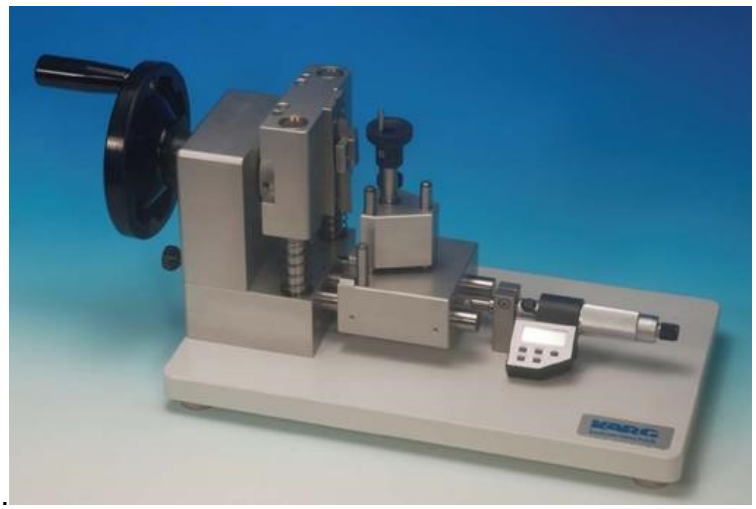

Figure 14 Notching device for parallel movement of the razor blade (Lohbauer U)

Specimens were loaded at a crosshead speed of 10 mm/min in a three-point bending test with an additional extensometer to precisely record strain during testing (see Figure 15).

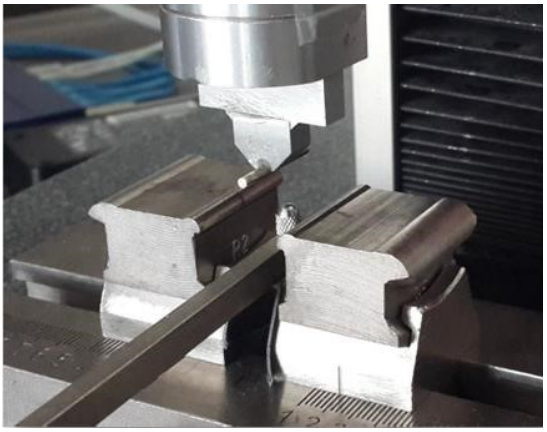

Figure 15 Three-point test set-up with extensometer (Lohbauer U)

It is of utmost importance to achieve a sharp notch as well as to precisely measure dimensions of the specimen/notch ratio after breakage to calculate K_{Ic} (I = mode I; c = critical).

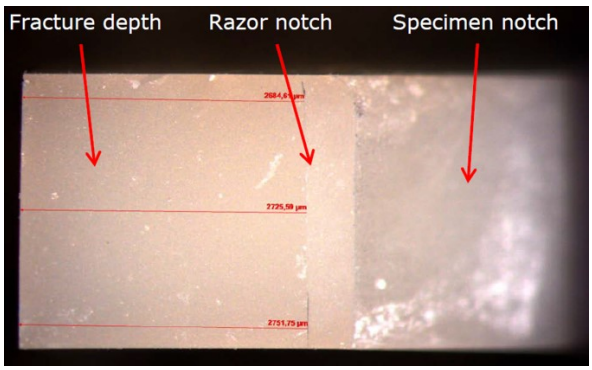

Figure 16 Determination of crack length (Lohbauer U)

Figure 16 shows a microscopic view of a cracked specimen with a clearly visible distinction between "fracture depth", "specimen-notch", and "razor notch" from sharpening with the razor blade, respectively.

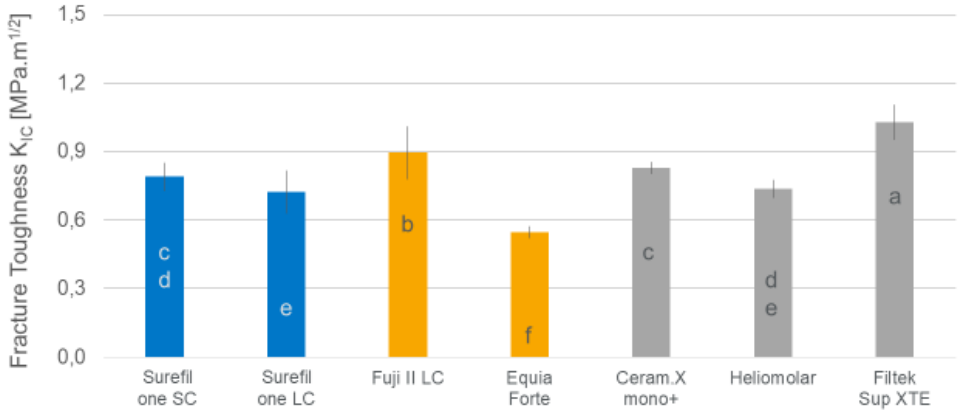

Figure 17 Fracture toughness (K_{IC}) after 14 days storage in water at 37°C (Lohbauer U and Belli R, 2020). Groups with same letter are not significantly different; n = 15.

Surefil one – either light cured or after self-curing – compares well to the composites Ceram.X mono+ and Heliomolar. Regarding fracture toughness the resin modified glass ionomer showed higher values compared to the latter and the traditional glass ionomer, known to be rather brittle and revealing the lowest fracture toughness as shown in Figure 17.

4.1.5 Fracture strength under chewing simulation

Frankenberger R et al., University of Marburg (Germany)

By using adhesively restored class II cavities in a chewing simulation marginal quality and wear as well as fracture resistance cam be evaluated in the same experiment (see chapter 4.5.1 for marginal integrity and chapter 4.3.3 for wear resistance).

Specifically, the load position of the artificial antagonist (see Figure 18) made of steatite onto the lateral ridges of two class II restorations positioned side by side and over the approximal box reaching into dentin are able to provoke marginal or bulk fractures known from clinical situations.

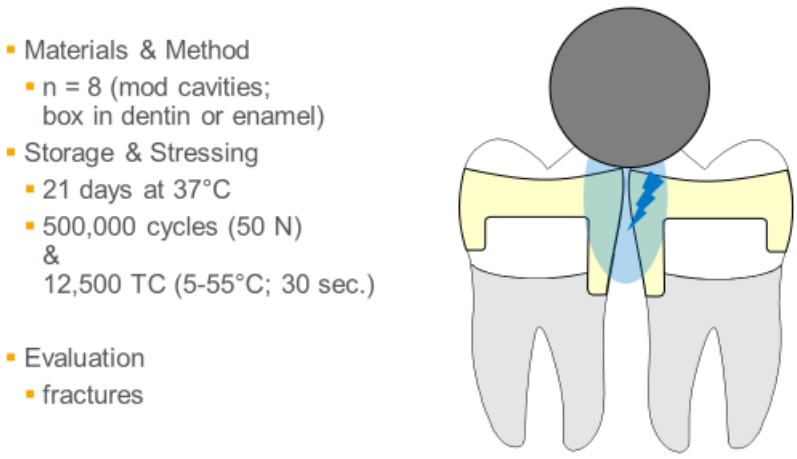

Figure 18 Parameters of chewing simulation in class II – fracture resistance (Frankenberger R)

Figure 19 illustrates the difference between marginal fractures defined as resulting in gaps smaller than 200 µm or dentin being exposed and bulk fractures when more than 50 % of the box volume is missing.

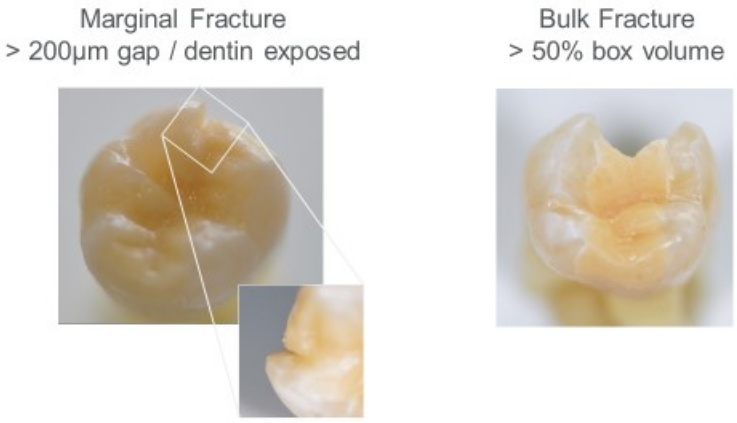

Figure 19 Illustration of “Marginal” vs. “Bulk” fracture (Frankenberger R)

Regarding fracture resistance to chewing forces amalgam and modern composites are considered as materials of choice for posterior teeth. However, other types of materials such as traditional and resin modified glass ionomers are used in practice as well despite their limited indications.

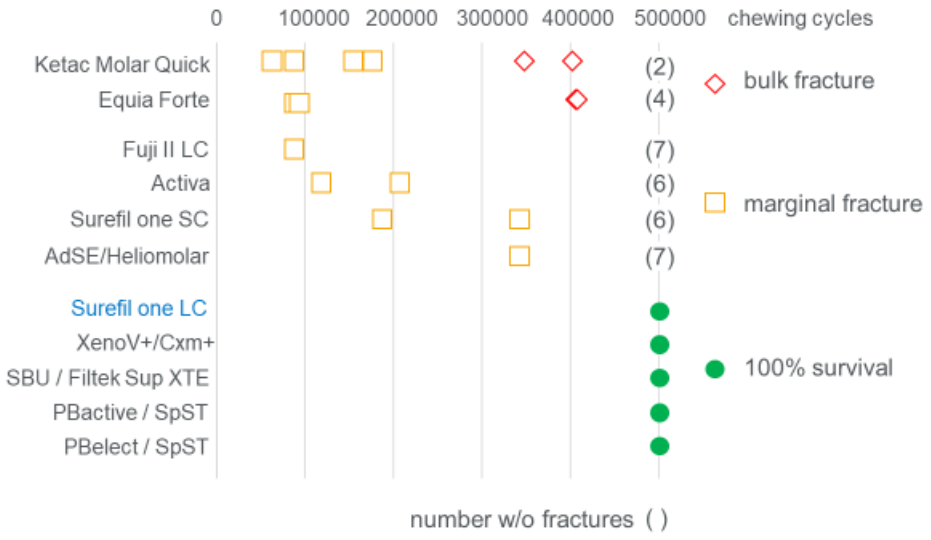

Figure 20 Marginal and bulk fractures as well as survival numbers vs. chewing cycles (excerpt from Frankenberger R et al., 2020)

The traditional glass ionomers showed bulk fractures (rhomb) towards the end of the chewing simulation. A mixed group of materials showed only marginal fractures (square). When the occlusal surface of Surefil one is light cured, no fractures occurred and all 8 specimens survived the 500,000 chewing cycles as it was found for the hybrid and nanofill composites, too. (see Figure 20)

4.2 Dimensional Stability

As mentioned in chapter 4.1.2, hydrophilic components are essential for self-adhesive materials to establish adhesion (see chapter 4.6) but should not be prone to hydrolysis. Furthermore, water uptake needs to be limited to guarantee dimensional stability. From the introduction of bulk-fill composites it became obvious that not the volume changes of unbonded material that may freely shrink is of importance, but that shrinkage stress inducing forces on the bonded interface is the key parameter to look for.

The same applies for expansion where the resulting stress towards the tooth cavity is the key parameter as it may affect tooth integrity. Following the method described by Falsafi A et al. (2015), cavities made of aluminum (E-modul ≈ 70 GPa; see Figure 21) were filled with a variety of restorative materials and dimensional changes were measured to simulate stress build-up in teeth.

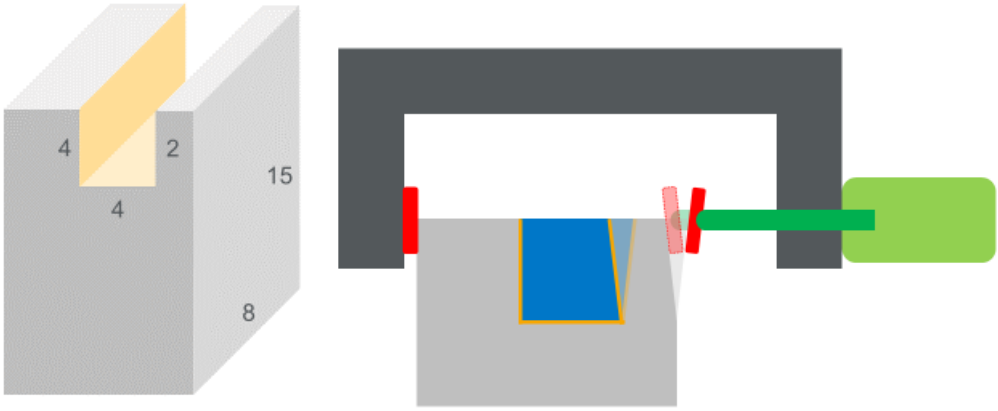

Figure 21 Aluminum cavity (left) and schematic drawing of measurement tool (right) showing deformation by shrinkage (towards left) or expansion (towards right). Modified from Falsafi A et al. 2015.

Two control materials were chosen that are indicated and used for core build-ups. A self-adhesive resin modified glass ionomer (RMGI) and a two-component composite material that needs to be bonded with an adhesive. Cavities were filled and stored in water at 37°C.

As shown in Figure 22 the composite leads to shrinkage forces (negative values) within the first days, whereas the RMGI rapidly starts to take up water and expands (positive values). Compared to these control materials Surefil one remains stable with only little deformation of the simulated cusp.

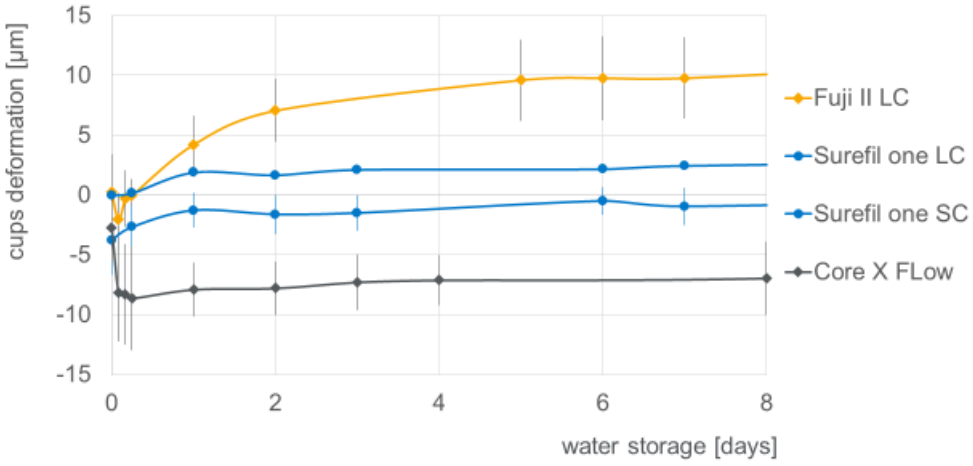

Figure 22 Cusp deformation in simulated cavities – short term measurements (Dentsply Sirona R&D, Konstanz, Germany); n = 10

After water storage for at least 7 months, Surefil one showed slight expansion being comparable or lower to the composite control, while the tested RMGI showed more than 3-fold higher cusp deformation (Figure 23).

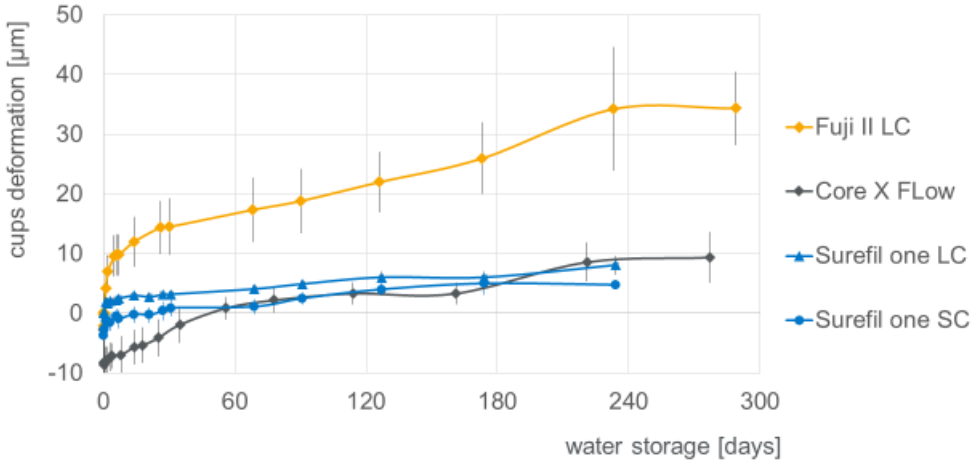

Figure 23 Cusp deformation in simulated cavities – long term measurements (Dentsply Sirona R&D, Konstanz, Germany); n = 10

This may lead to the conclusion that Surefil one, despite its hydrophilic nature of the used monomers, is highly polymerized to a dense and strong network, limiting the uptake of water.

4.3 Wear Resistance

Wear resistance is another key property for restorative materials used in stress bearing posterior restorations. To investigate different aspects of wear a variety of different methods had been employed to test the wear resistance of Surefil one.

4.3.1 "Enamel wear"

Eight sound human bicuspids per group were used as antagonist. Alteration and mounting in a pin-on-block design is shown in Figure 24. Materials were polished to 2000 grit and 33 % glycerin in water solution was used as saliva substitute. Chewing simulation was performed at 1 Hz and included a 2 mm slide onto the material. As chewing force 20 N was used. As controls a glass ionomer (GI), a resin modified glass ionomer (RMGI), a microfill composite, a hybrid composite, and a nanofill composite were included.

Figure 24 Antagonist preparation for “enamel wear” experiment. Bicuspids are altered with a diamond bur (left) and polished. Then mounted into a holder (middle). The enamel antagonist is than used in a pin-on-block design (right) with a sliding phase after initial contact.

Both, the lost volume and the depth of the wear facet were measured and are shown in Figure 25 and Figure 26, respectively.

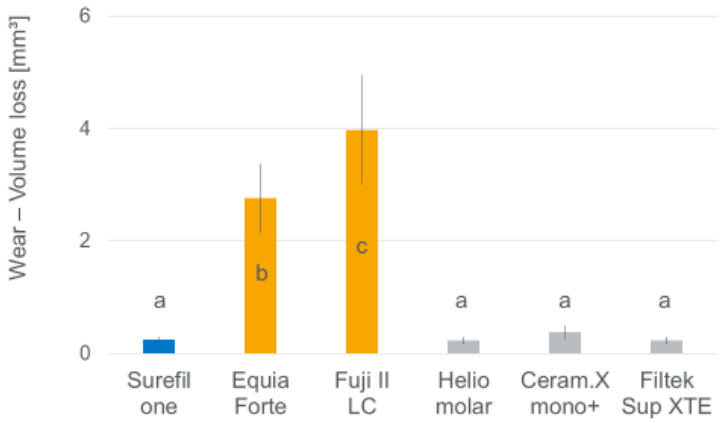

Figure 25 Volume loss after pin-on-block with enamel antagonist. (Lawson N and Burgess J, 2018). Groups with same letter are not significantly different; n = 8

Both, GI and RMGI, showed significantly higher volume loss compared to Surefil one and all composite types.

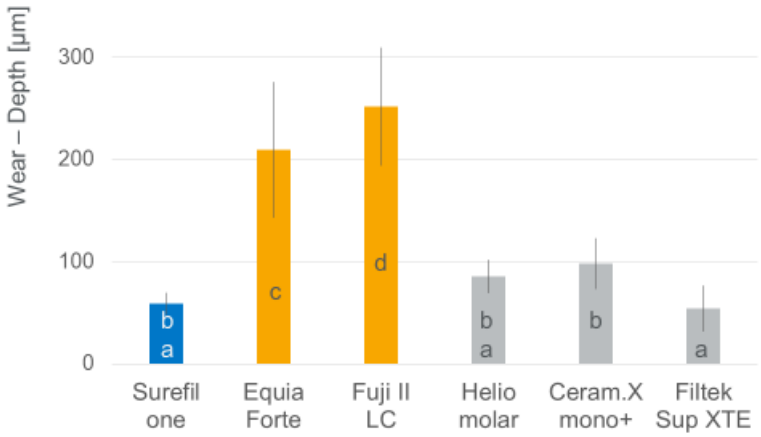

Figure 26 Depth of wear facet after pin-on-block with enamel antagonist (Lawson N and Burgess J, 2018). a-c: groups of no statistically significant difference; n = 8

Surefil one also showed significantly lower depth of wear facets after “enamel wear” compared to GI and RMGI but no difference to the different types of composites. Figure 27 shows examples of wear facets.

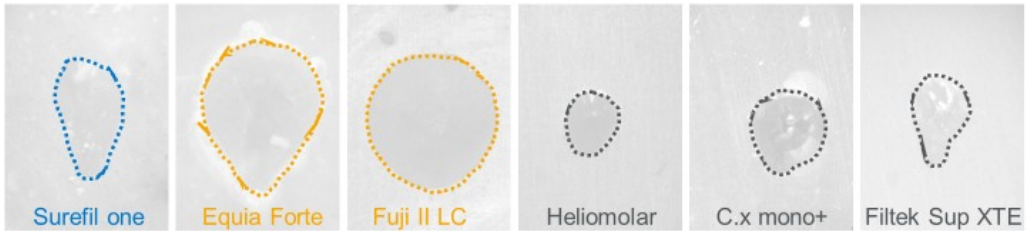

Figure 27 Examples of wear facets after chewing simulation (including sliding mode).

It is remarkable that both the GI and the RMGI showed not only significantly higher wear resistance in this set-up (rather low chewing force of 20 N) but also significantly lower flexural fatigue strength (see chapter 4.1.3). One may interpret these results, that GI and RMGI were loaded beyond their fatigue resistance and started to break down, whereas Surefil one and the composites did not reach that threshold.

4.3.2 Leinfelder wear (generalized and localized)

Latta MA, Creighton University Omaha, NE (United States)

Wear in the oral cavity is a multifactorial process. Besides abrasion during grinding movements different wear patterns are generated during forceful occlusal contacts. Furthermore, localized wear in the occlusal contact area (OCA) might be different from generalized wear induced by chewing food bolus without direct contact to the antagonist.The so called "Leinfelder Wear Machine" allows testing both situations – localized and generalized wear.

In the generalized wear mode a steel piston is pressed through a slurry of PMMA beads onto the specimen while rotating 30° without touching its surface. Parameters for the experiment including a typical wear pattern are shown in Figure 28.

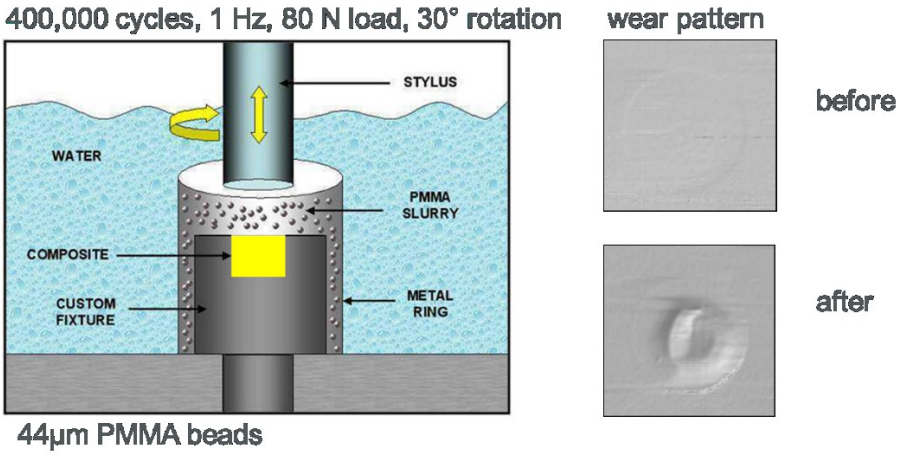

Figure 28 Generalized wear mode and typical wear pattern (Latta MA)

Figure 29 shows the volume loss of the total surface under generalized wear.

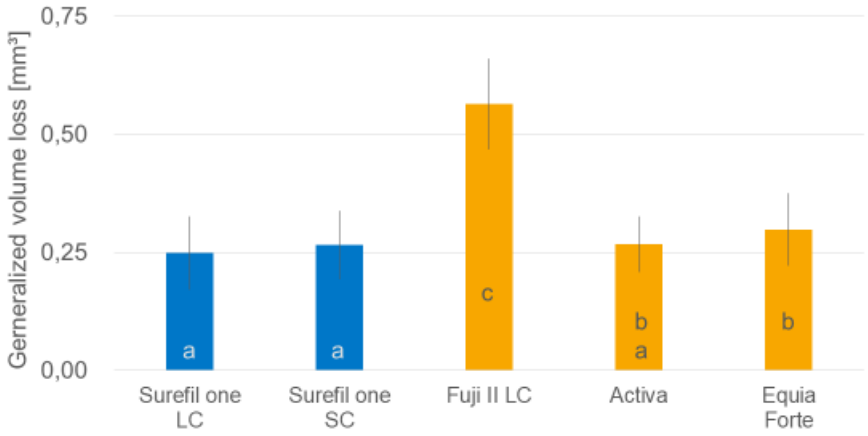

Figure 29 Volume loss under generalized wear. (Latta MA, 2020). Groups with same letter are not significantly different; n = 12.

Surefil one - in both curing modes - showed very good resistance to simulated generalized wear (i.e. without occlusal contact to the antagonist) as shown in Figure 29.

To simulate wear in the occlusal contact area the stylus is modified as shown in Figure 30. The shape of the resulting wear pattern differs from the generalized wear test (see Figure 28).

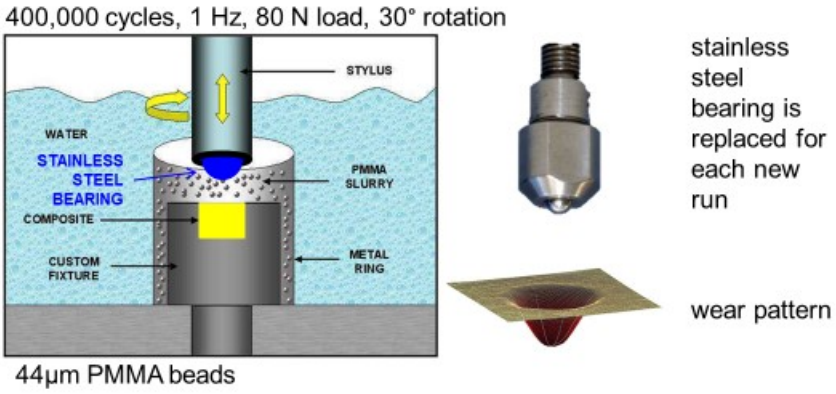

Figure 30 Localized wear mode and typical wear pattern (Latta MA)

Under the harsh conditions of localized wear Surefil one showed the highest resistance to volume loss among the tested self-adhesive materials when the occlusal surface is light cured as shown in Figure 31. Both resin modified glass ionomers showed significantly higher wear than the other groups.

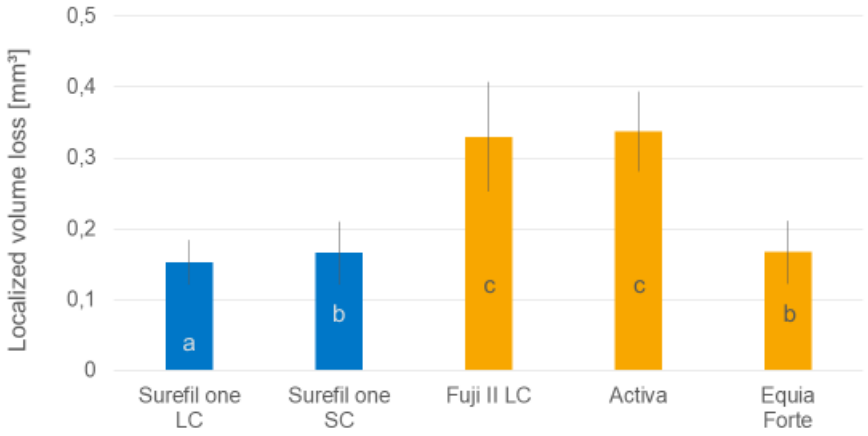

Figure 31 Volume loss under localized wear (Latta, 2020). Groups with same letter are not significantly different; n = 12.

4.3.3 Chewing simulation – wear

Frankenberger R, University of Marburg (Germany)

As explained in chapter 4.1.5 (Fracture resistance), chewing simulation allows to evaluate several parameters in the same set-up (see chapter 4.3.1 for marginal integrity). Figure 32 shows the positioning of two class II restorations and the load position of the artificial antagonist made of steatite onto the lateral ridges over the approximal box reaching into dentin to evaluate wear.

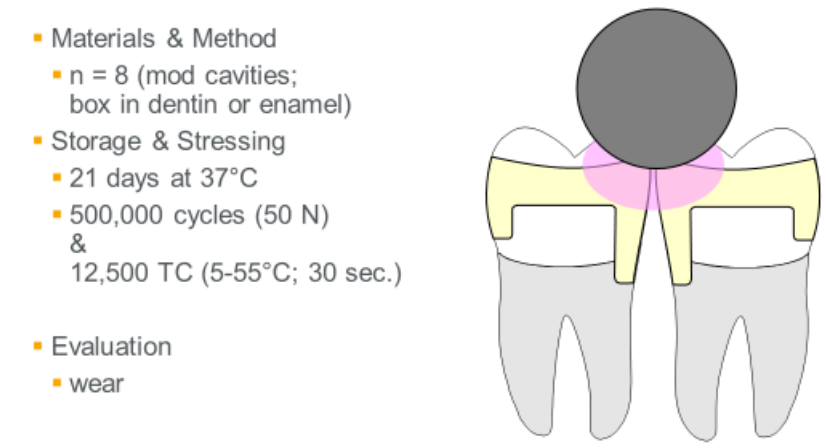

Figure 32 Parameters of chewing simulation in class II – wear (Frankenberger R)

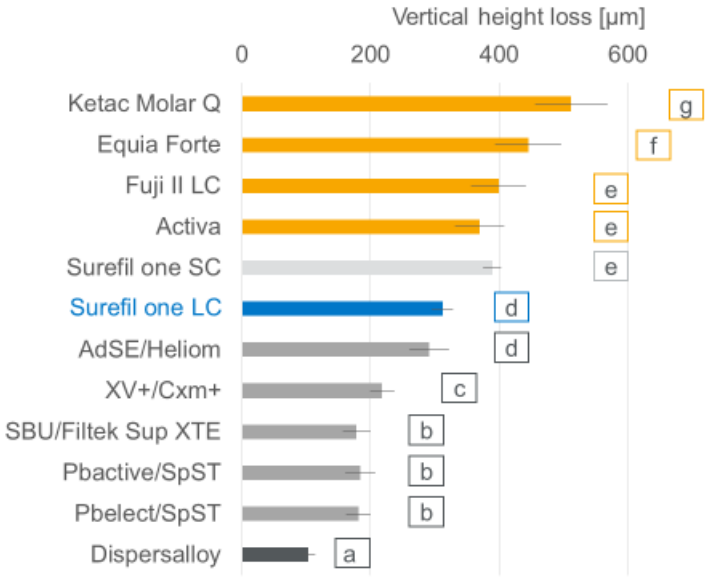

Figure 33 Wear as vertical height loss in contact areas on lateral ridges (Frankenberger et al., 2020). Groups with same letter are not significantly different; n = 8.

Vertical height loss on the marginal ridge after 500,000 cycles of thermo mechanical loading revealed lower wear for light cured Surefil one (LC) compared to all other self-adhesive materials tested as shown in Figure 33. Furthermore, light cured Surefil one showed comparable wear resistance to a microfill composite. However, modern composites showed lower and amalgam (i.e. Dispersalloy) lowest height loss in this chewing simulation on lateral ridges.

4.4 Fluoride Release

As described in Table 1 reactive glass fillers are used in Surefil one. Furthermore, acid groups are available in the formulation as well. Therefore, fluoride release based on an inherent acid-base reaction is expected.

Over decades the importance of fluoride release for the clinical success has been debated. It is well known that glass ionomers provide an initial fluoride burst that significantly decreases over time. In vitro measurements showed that compomers (i.e. Dyract) provide fluoride release rates comparable to traditional glass ionomers on a long-term base (Asmussen E and Peutzfeldt A, 2002). A recently published retrospective clinical study in non-caries cervical lesions revealed that none of the recalled Dyract restorations showed signs of secondary caries after 20 years (Alonso de la Peña V et al. 2017). On the other hand, an in-situ study comparing Dyract extra with a non-fluoride releasing composite (i.e. Spectrum TPH) in simulated approximal contact areas of class II restorations resulted in less caries (i.e. enamel demineralization) compared to both – the composite as well as the enamel control. This significant difference in early caries development was found despite all probands using fluoridated tooth paste twice a day being applied on the in-situ appliances (Lennon AM et al. 2007).

Considering the above, fluoride release rates of Surefil one were compared to compomers, resin modified glass ionomer, and glass ionomers. Three specimens per material were stored in water and storage media was exchanged after each measurement point. Fluoride was measured with a fluoride sensitive probe. Figure 34 shows the current status of measurements up to 450 days storage.

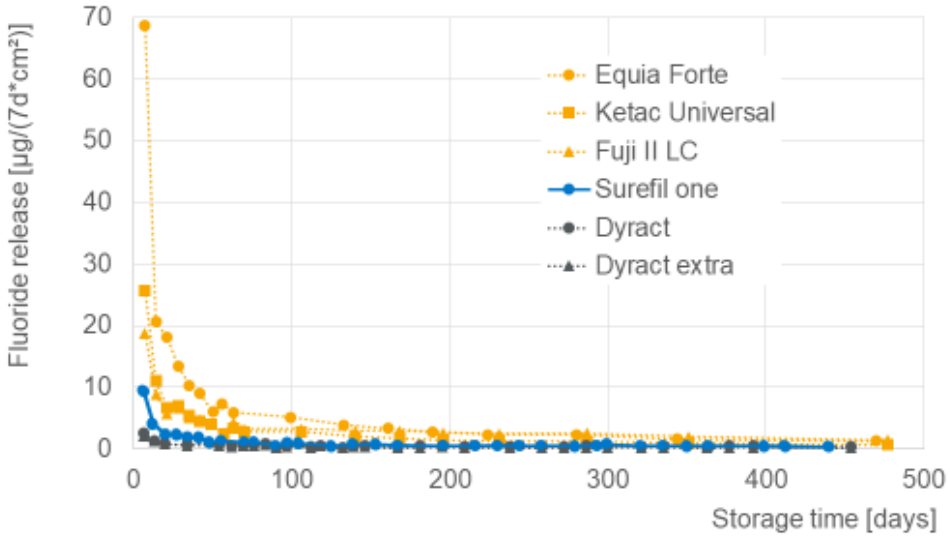

Figure 34 Fluoride release rates comparing glass ionomer, resin modified glass ionomer, compomer, and Surefil one up to approximately 450 days (Dentsply Sirona R&D, Konstanz, Germany); n = 3.

Glass ionomers showed as expected a high boost at the very beginning followed by an immediate sharp drop in release rate. As mentioned above, the fluoride release rate of these different material types approximate each other from a long-term perspective.

4.5 Marginal Integrity

Marginal integrity of adhesive restorations is an indirect measure of the bonding performance (adhesive or self-adhesive) challenged by simulated occlusal forces as well as thermo cycling and allows – in contrast to bond strength testing – measurements at several stages of stressing of the same specimen. Chewing simulation allows measuring fracture rates and wear simultaneously as described in chapter 4.1.5 and 4.3.3, respectively.

4.5.1 Class II – chewing simulation and SEM evaluation

Frankenberger R, University of Marburg (Germany)

Standardized class II cavities with boxes reaching into dentin or ending above the enamel/dentin junction were prepared and restored before thermo-mechanical loading was applied using parameters shown in Figure 35.

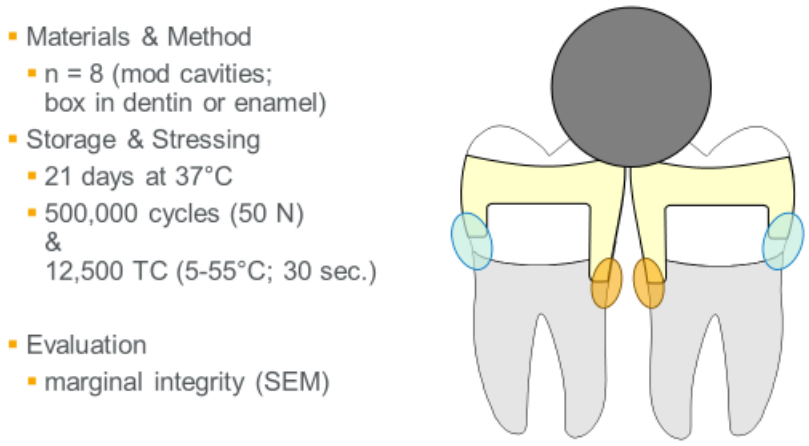

Figure 35 Parameters of chewing simulation in class II – marginal integrity of dentin (orange) and enamel (light blue) margins (Frankenberger R).

In this chewing simulation a very broad array of restorative materials, reaching from amalgam to composite, was tested (Table 2).

Restorative	Adhesive	Notes
Dispersalloy	N/A	Harvard Cement lining
Ketac Molar Quick	self-adhesive	Self-curing
Equia Forte Fil		Self-curing
Fuji II LC Improved		1.8 mm increments; light cured
Activa		4 mm increments; light cured
Surefil one		SC: Self-curing
		LC: Occlusal surface light cured
Ceram.X mono+	Xeno V+ (XV+)	Self-etch adhesive
Heliomolar	AdheSE U (ASU)	Universal adhesive; self-etch mode
Filtek Supreme XTE	Scotchbond U (SBU)	
Spectra ST	P&B elect (PBe)	
	P&B active (PBa)	

Table 2 Restorative systems used in chewing simulation (Frankenberger R et al., 2020)

Marginal integrity as seen under SEM at x200 magnification and expressed as percentage of gap-free margins before and after thermo mechanical loading (TML) is shown in Figure 36 for enamel and in Figure 37 for dentin.

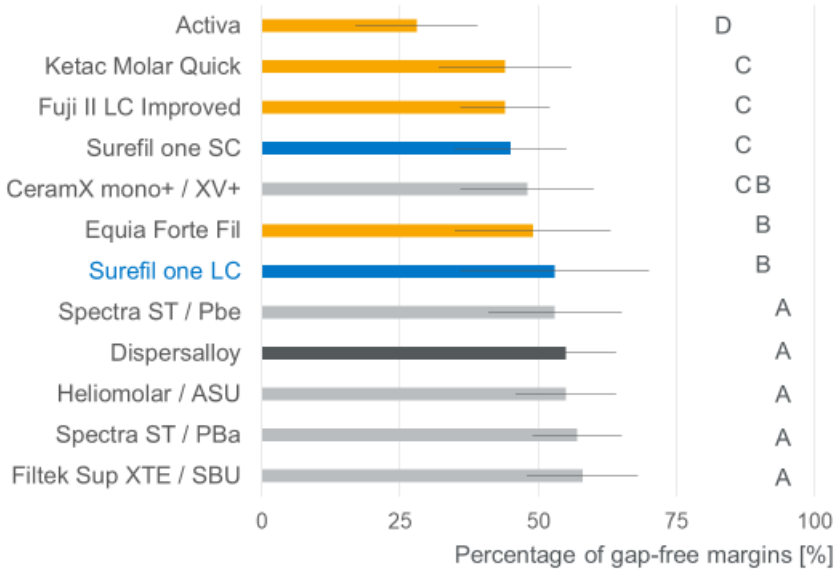

Figure 36 Percentage of gap-free margins in enamel after 500,000 Thermo Mechanical Loadings (TML) (Frankenberger R et al., 2020). Groups with same letter are not significantly different; n = 8.

After 500,000 cycles of TM, four groups showed no statistically significant difference in enamel. When the occlusal surface of Surefil one class II restorations are light cured, percentage of gap-free margins in enamel was comparable to a composite bonded with a self-etch adhesive for which 5-year clinical data is available (Figure 36).

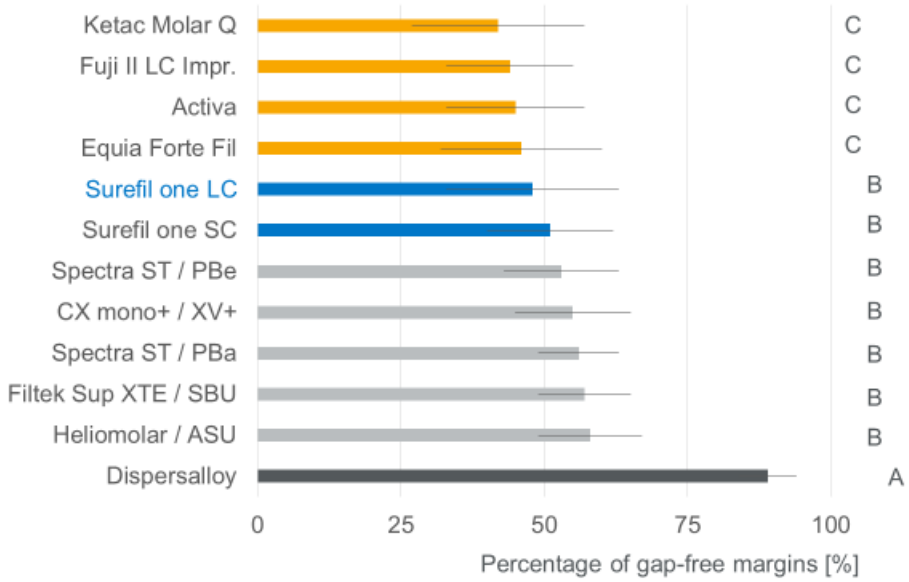

Figure 37 Percentage of gap-free margins in dentin after 500,000 Thermo Mechanical Loadings (TML) (Frankenberger R et al., 2020). Groups with same letter are not significantly different; n = 8.

In dentin, three groups showed no statistically significant. Surefil one – either after light curing the occlusal surface or in self-cure mode – was comparable to adhesively bonded composites in self-etch mode and superior to glass ionomers or resin modified glass ionomers (Figure 37).

4.6 Adhesion to Dentin and Enamel

Mechanical strength is a key parameter of filling materials used for restoring stress bearing class I and II cavities in posterior teeth. However, adhesion – close interaction between adhesive or self-adhesive material and the tooth substrate – is regarded as important to prevent gap formation which might increase the risk of (secondary) caries and to seal dentin towards the pulp (e.g. to avoid post-operative hypersensitivity). Furthermore, adhesion is the key parameter for retention in class V cavities having no undercuts.

While establishing adhesion, contamination needs to be avoided. The longer the application of a dental adhesive takes (e.g. spreading onto all surfaces, scrubbing, time for infiltration, solvent evaporation) the more likely contamination before light curing could occur and impair long-term success.

Simply by replacing the adhesive with all its application steps by a self-adhesive material reduces the time needed to keep surfaces clean and free of contamination and therefore, potentially increases clinical success in cases where contamination control is challenging.

Despite the advantage in process time, self-adhesive materials need to provide adhesion to dentin as well as enamel on a sufficiently high level. Therefore, Surefil one was tested under a number of different test protocols and conditions in comparison to other self-adhesive materials as well as adhesive-composite combinations.

4.6.1 Shear Bond Strength – Robustness

Latta MA and Radniecki SM, Creighton University Omaha, NE (United States)

Since the introduction of etching dentin with phosphoric acid followed by rinsing with water, the way how to establish afterwards the ideal degree of moisture and to what extend that may interfere with adhesion has been investigated. It was found that

depleting collagen from its mineral surroundings not only let it collapse but may lead to agglutination of the collagen fibrils which blocks adhesive molecules from infiltration and chemical interaction with the underlying solid dentin substrate.

Clinical protocols to leave the right amount of water or to re-wet a dry dentin surface with water are not easy to follow. Blowing away rinsing water with an air stream from an air-water-syringe is much easier but could result in over-dried dentin and decreased adhesion.

Therefore, shear bond strength to enamel and dentin was tested to evaluate whether the generally easier protocol to blow away rinsing water (dried for 10 seconds) is also applicable for the self-adhesive restorative Surefil one and compared to a more technique sensitive blot-dry approach (moist surfaces).

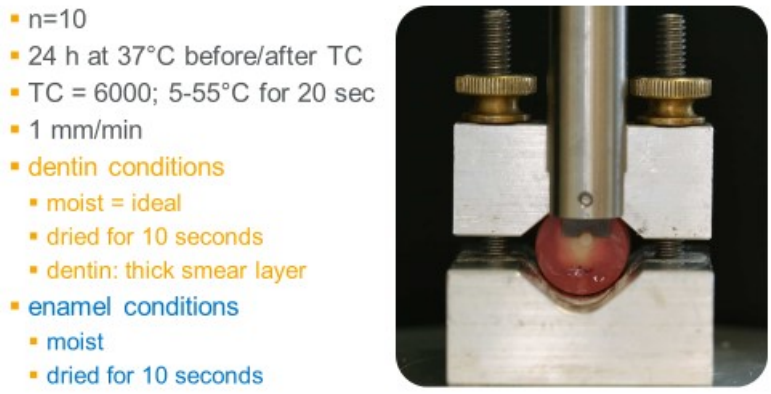

Figure 38 Shear bond strength testing set-up and parameters (Latta MA).

Specimens were stored 24 hours before and after thermocycling (6000 x) and sheared to failure at 1 mm/min crosshead speed.

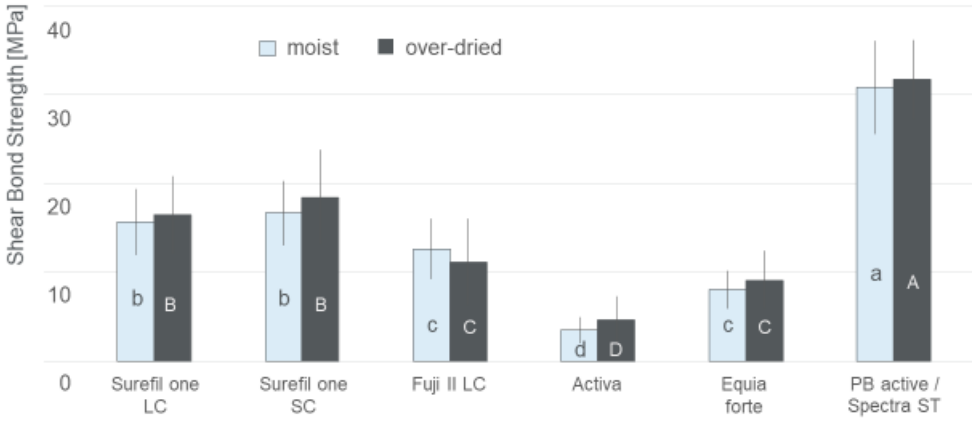

Figure 39 Shear bond strength after 6,000 thermo cycles to enamel – either moist (light blue) or dried for 10 seconds (grey) (Latta MA and Radniecki SM, 2020). Groups with same letter are not significantly different; n = 10.

Surefil one showed higher enamel bond strength compared to all other included self-adhesive materials. Using a universal adhesive in self-etch mode in combination with a light cured composite provided highest bond strength. The degree of moisture did not significantly affect enamel bond strength.

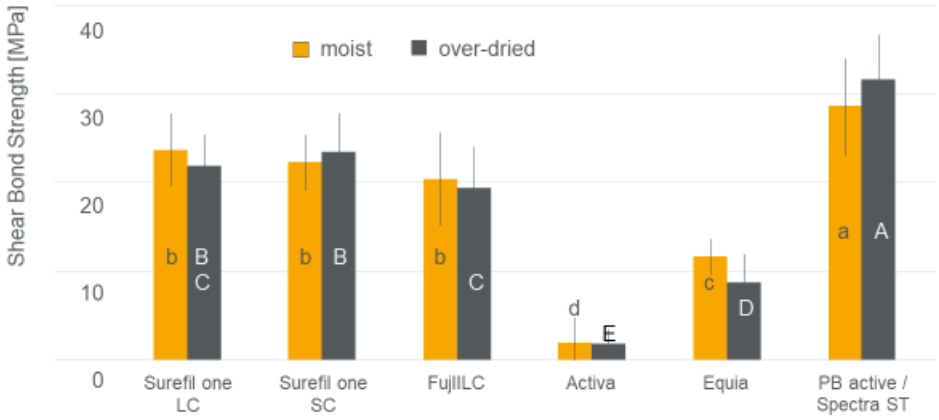

Figure 40 Shear bond strength after 6,000 thermo cycles to dentin – either moist (yellow) or dried for 10 seconds (grey) (Latta MA and Radniecki SM, 2020). Groups with same letter are not significantly different; n = 10

On dentin, Surefil one showed equal or better bond strength than Fuji II LC and both outperformed the traditional glass ionomer. Lowest bond strength values on dentin and enamel were found for Activa for which the manufacturer nowadays recommends the use of an adhesive. Again, the degree of moisture did not significantly affect bond strength showing comparable performance on dentin dried for 10 seconds compared to ideally moist dentin.

As described above, collagen fibers depleted from minerals may collapse and hinder adhesive molecules from reaching solid dentin. Cavity preparation using coarse diamond burs may result in thick smear layers also hindering adhesive molecules from reaching underlying dentin. In the study, differences in smear layer thickness on dentin were evaluated comparing 600-grit to 180-grit ground surfaces.

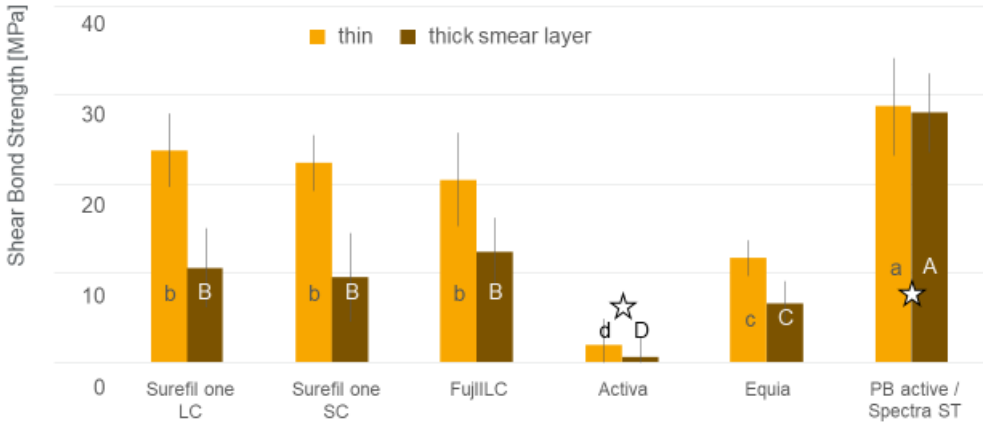

Figure 41 Shear bond strength after 6,000 thermo cycles to dentin – either thin (yellow) or thick (brown) smear layer (Latta MA and Radniecki SM, 2020). Groups with same letter or connected via asterisks are not significantly different; n = 10.

A thick smear layer reduced shear bond strength to dentin for all self-adhesive restoratives. Therefore, it is recommended to avoid coarse diamond or carbide burs for cavity preparation and to finish with fine instruments. Following this recommendation, Surefil one showed higher shear bond strength compared to a traditional glass ionomer and the RMGI Activa.

4.6.2 Microtensile Bond Strength (MTBS)

Yao C et al., BIOMAT, KU Leuven, (Belgium)

Shear bond strength testing as described in the previous chapter 4.6.1 allows to test a high number of specimens in a reproducible manner leading to low standard deviations. However, specimen preparation is typically limited to bonding onto flat surfaces.

MTBS testing, on the other side, allows using a more versatile approach to specimen configuration. Furthermore, thermo cycling of the typically small sticks allows much faster hydration of specimens to test whether hydrolysis has a significant effect.

After one week of water storage, 8 teeth per group were further processed resulting in a total of 32 sticks per group. MTBS to mid-coronal dentin was tested either immediate or after 50,000 thermo cycles comparing bond strength to flat dentin and bottom dentin in class I cavities (see Figure 42).

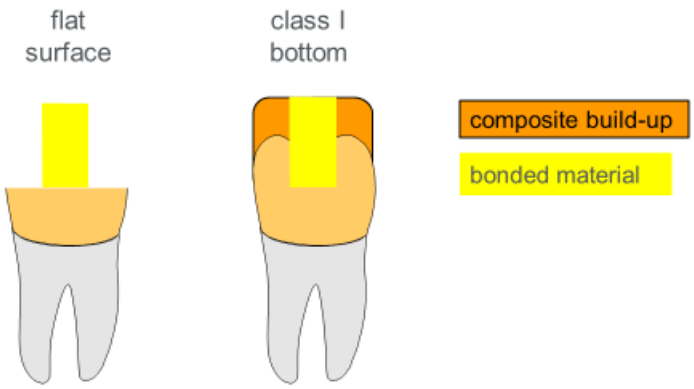

Figure 42 Configurations for “flat surface” and “class I bottom” bond strength testing; not in scale. (Van Meerbeek B, 2018)

There were remarkable differences between MTBS on flat dentin versus bottom dentin in 4-mm deep class I cavities. On flat dentin surfaces, Surefil one (when light cured; LC) achieved MTBS comparable to RMGI combined with its conditioner or a bulk-fill composite bonded with the respective universal adhesive in self-etch mode (see Figure 43).

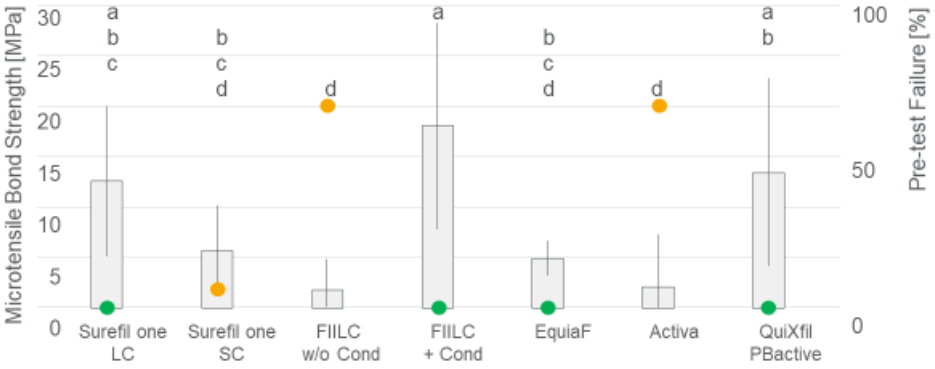

Figure 43 Microtensile Bond Strength to flat dentin before thermo cycling. Green dots indicate no occurrence of pre-test failure. Yellow dots indicate percentage of pre-test failures (calculated with 0 MPa). Groups with same letter are not significantly different. (Yao C et al., 2020 a/b). n = 16 (8 teeth).

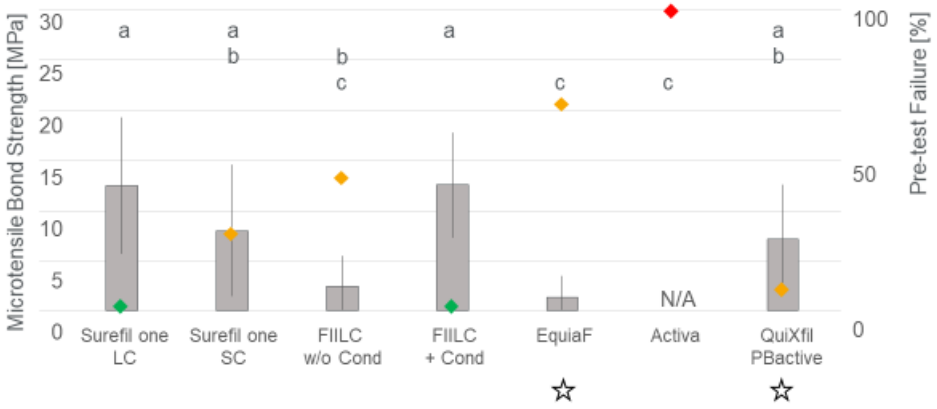

Figure 44 Microtensile Bond Strength to flat dentin after 50,000 thermo cycles. Green rombs indicate no occurrence of pre-test failure, yellow rombs indicate percentage of pre-test failures (calculated with 0 MPa), and red romb indicate pre-test failing of all specimens. Groups with same letter are not significantly different; asterisks indicate statistically significant differences to MTBS before thermo cycling (Yao C et al., 2020 a/b). n = 16 (8 teeth).

Surefil one when light cured (LC) did not show any pre-test failure and MTBS remained stable over 50,000 thermo cycles. Combined with its Dentin Conditioner, Fuji II LC also had no pre-test failures. However, without using the conditioner almost half of the specimens failed during thermo cycling. All specimens of Activa[1] failed during thermo cycling. MTBS of GI and the packable bulk-fill composite bonded in self-etch technique significantly decreased after thermocycling (see Figure 44).

Compared to flat dentin with only one bonded surface, class I cavities have 5 bonded surfaces resulting in a much higher configuration factor (c-factor). The higher the c-factor, the more stress might be build-up during bonding.

To test adhesion to class I cavity floor, teeth where build-up with composite so that bottom dentin of 4 mm deep cavities (3.5 x 3.5 mm width) reached the same level of mid-coronal dentin as in the “flat-surface” testing described above (see Figure 42).

In 4 mm deep class I cavities, all groups showed pre-test failures calculated as 0 MPa leading to a lower level of bond strength (see Figure 45 and Figure 46).

[1] When the study protocol was designed, Activa was described by the manufacturer as self-adhesive material. Meanwhile, the manufacturer revised its instructions for use by recommending the use of an adhesive.

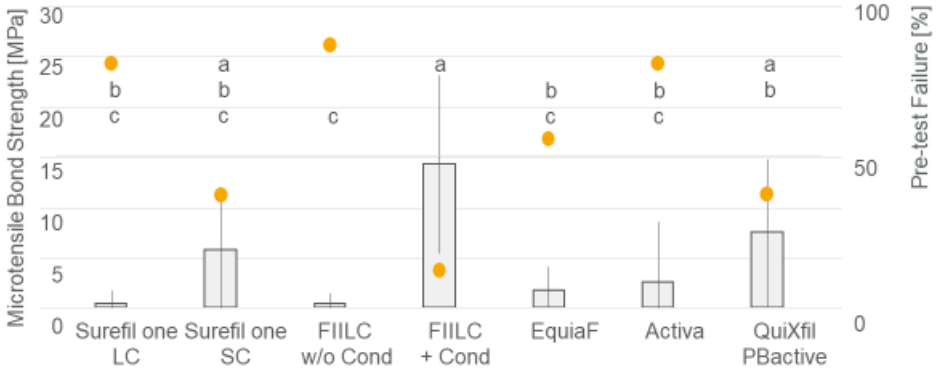

Figure 45 Microtensile Bond Strength to bottom dentin of 4 mm deep class I before thermo cycling. Yellow dots indicate percentage of pre-test failures (calculated with 0 MPa). Groups with same letter are not significantly different. (Yao C et al., 2020 a/b). n = 16 (8 teeth).

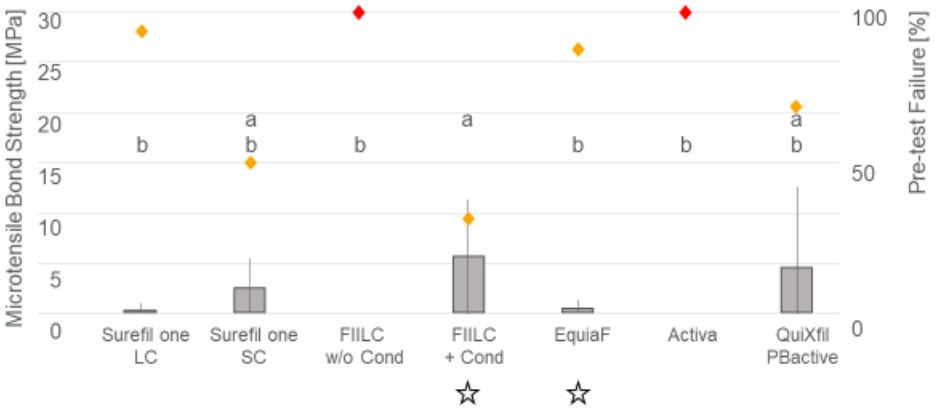

Figure 46 Microtensile Bond Strength to bottom dentin of 4 mm deep class I after 50,000 thermo cycles. Yellow rombs indicate percentage of pre-test failures (calculated with 0 MPa) and red rombs indicate pre-test failing of all specimens. Groups with same letter are not significantly different; asterisks indicate statistically significant differences to MTBS before thermo cycling. (Yao C et al., 2020 a/b). n = 16 (8 teeth).

The current investigation showed a high number of pre-test failures in class I cavities even with restorative materials that showed good clinical success. In a previous study using the same set-up different types of composite were bonded with the same adhesive. While on flat dentin surfaces no pre-test failures occurred, in class I cavities up to 100% pre-test failures were shown. SDR was the only composite that did not cause pre-test failures at the cavity floor (Van Ende et al. 2016). It might be concluded that MTBS to bottom dentin in class I cavities is sensitive to identify materials with low stress build-up following a worse-case pre-clinical scenario. Comparable performance of Surefil one to clinically successful self-adhesive materials (i.e. Fuji II LC and Equia Forte) was achieved.

A clinical trial was initiated using Surefil one focusing on post-operative hyper sensitivity which could be a clinical symptom when no bonding to bottom dentin is established (see chapter 5 Clinical data).

4.6.3 Shear Fatigue Strength

Latta MA et al., Creighton University Omaha, NE (United States)

When introducing a new approach to permanently adhere to tooth structure, simulation of long-term behavior is essential before even starting a clinical trial. Water storage itself may help to discover pure hydrolysis driven degradation. Thermo cycling adds a mechanical component to this challenge mediated through the different coefficients of thermal expansion of the materials bonded to each other. A mechanical challenge reflecting the subcritical mechanical loading through the life-span of a filling is to apply control forces over defined amplitudes in a defined frequency.

In this study, metal rings filled with the restorative were bonded (self-adhesively or with an adhesive) to finely ground dentin and aligned in a testing machine for fatigue testing under water (see Figure 47).

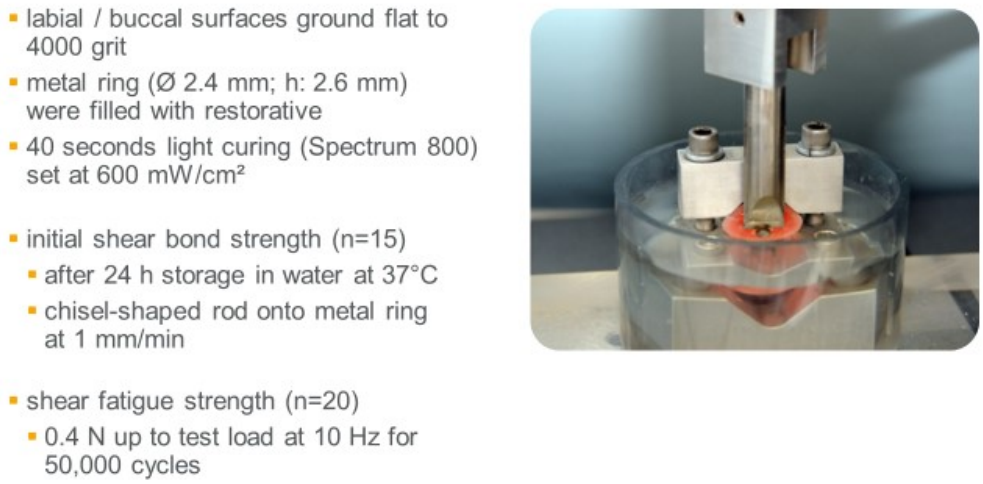

Figure 47 Shear fatigue strength test set-up with a bonded specimen in water and aligned chisel-shaped rod (Latta MA 2018).

After measurement of the initial shear bond strength (SBS), a staircase method was used starting at 50-60% of the initial strength level applied at 10 Hz up to 50,000 cycles. When the specimen survived the load was increased or decreased when the specimen failed.

Figure 48 shows results for SBS and shear fatigue strength (SFS) to enamel. Furthermore, the ratio SFS to SBS is shown. When light cured (LC), Surefil one showed higher shear fatigue strength to enamel compared to all other self-adhesive materials.

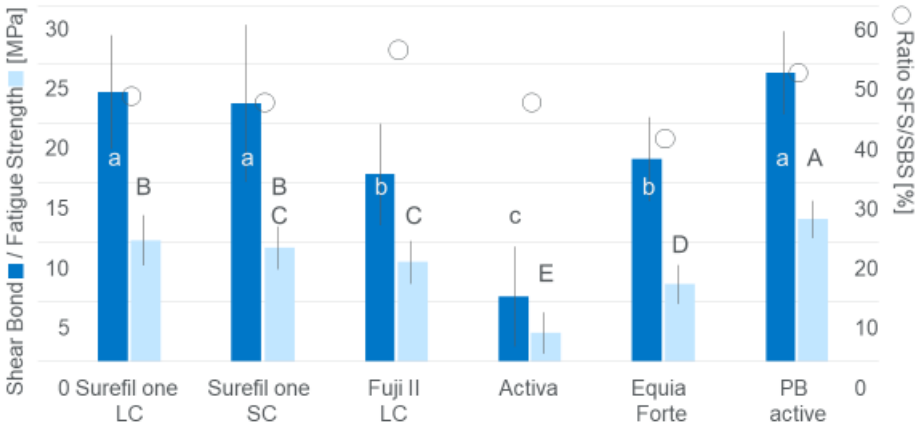

Figure 48 Shear Bond Strength (SBS) and Shear Fatigue Strength (SFS) to enamel. Circles indicate ratio SFS / SBS (Latta et al., 2020). Groups with same letter are not significantly different; n = 15 SBS; n = 20 SFS.

Surefil one achieved similar values of bond strength and ratio SFS to SBS on enamel and dentin (Figure 49).

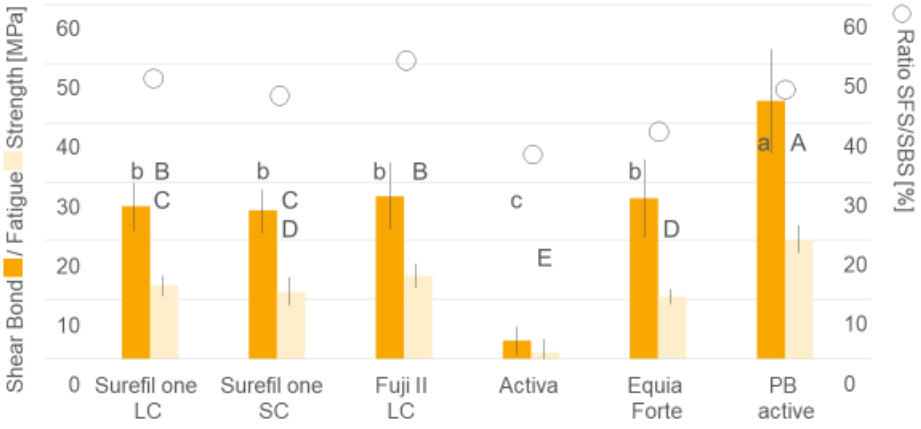

Figure 49 Shear Bond Strength (SBS) and Shear Fatigue Strength (SFS) to dentin. Circles indicate ratio SFS / SBS (Latta et al., 2020). Groups with same letter are not significantly different; n = 15 SBS; n = 20 SFS.

When light cured (LC), Surefil one showed no significant difference to Fuji II LC while after self-curing Surefile one was not significantly different to Equia Forte.

Again, bonding performance of Surefil one seems to be comparable to self-adhesive restoratives being successfully used in clinical practice.

5 Clinical data

When developing a new restorative material, an important step is to evaluate data gained in vitro and compare the results with those from materials that had been used successfully in clinical practice. Laboratory studies are often focused to test one aspect of a complex procedure and therefore allow to highly standardize testing – at least when performed at one site by calibrated operators. Furthermore, in vitro testing allows to accelerate aging processes that may need years in a clinical setting. Therefore, parameters such as mechanical strength and adhesion are best investigated in vitro.

As mentioned in chapter 4.6, it was important to ensure Surefil one adheres to enamel and dentin as well as known from successfully used other self-adhesive materials such as GI and RMGI. This was verified in a variety of in vitro studies as described in chapters 4.6.1 to 4.6.3. However, one typically observed unwanted effect with adhesive procedures – post-operative hypersensitivity (POHS) – is difficult to evaluate in vitro. Therefore, it was concluded that a clinical study focusing on this aspect is needed to validate the positive data gained in vitro.

As placing dental restorations in a clinical setting requires manual skills and therefore highly depends on the dentist, user evaluations are needed to exploit acceptance of handling properties and other aspects in daily practice.

5.1 Clinical study on post-operative hypersensitivity (POHS)

Data from in vitro studies showed a high tolerance of Surefil one to dried dentin. However, it was also found that thick smear layers may reduce bond strength (chapter 4.6.1). As both parameters – moisture degree in dentin and smear layer thickness – depend on operator skills and procedures, it was decided to use a practice-based research network (PBRN) to study occurrence of POHS.

Six dental practices in Houston (TX, United States) were selected to cover a broad range of general dental practitioners. Seven operators placed a total of 60 restorations in 41 patients in class I, II and V cavities. See Figure 50 and Figure 51 for further details.

- 6 sites (7 dentists)
  - 10 restorations per site (class I,II, V; max. 2 restorations per patient)
- Patient feedback on POHS
  - up to 4 weeks
- Recall visit after 3 months
  - evaluation of simplified criteria by operator

Figure 50 Set up of clinical PBRN based study

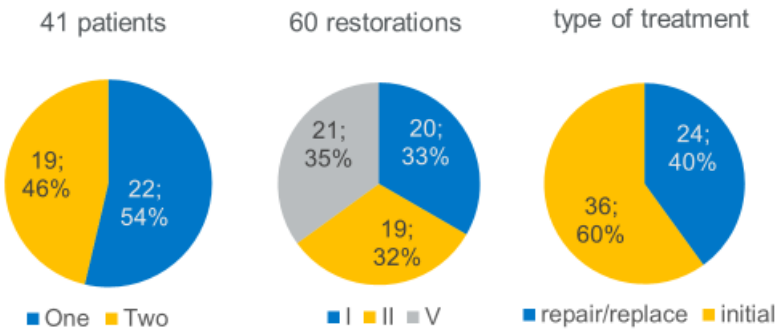

Figure 51 Number of patients (with one or two restorations), distribution among cavity classes, and distribution of either initial caries treatment or repair/replacement of existing restorations

POHS was categorized in four levels as shown in Table 3 of which level 2 was considered a typical short-term sensation after any type of interaction in sensitive patients, but level 3 and 4 as signs of unwanted effects if persisting.

POHS level	Description
1	No sensitivity is experienced at any time
2	Slight sensitivity is experienced occasionally but it is not uncomfortable
3	Moderate sensitivity is experienced intermittently and it is noticeably uncomfortable
4	Severe discomfort is noted routinely with cold or pressure stimulation

Table 3 Post-operative hypersensitivity (POHS) levels

Table 4 shows POHS levels starting at week 1 up to 3 months.

POHS level	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
week 1	4	4			8	2			10				4	2	1		9				2	2			5			
week 2	7	2	1		10				10				1				7				4	1			5			
week 3	4	2	1		10				9								4				5				5			
week 4	7	3			10				9				8			1	4											
3 months	9			1	10				9*				10				10				5				5			

Table 4 Distribution of POHS level among operators from week 1 to 3 months.
* one patient was lost to follow-up at 3 months.

During the first four weeks, not all patients provided feedback. Patients of three dentists didn't report any sensitivity at any time point. One patient, who had reported POHS level 3 at week 2 and 3, specified level 4 at the 3-month recall and was scheduled for treatment. However, the dentist reported in the respective form that this sensitivity might not have been caused by the restorative measure.

One patient was lost to follow-up at 3 months. The overall POHS rate at 3 months was 1.7 % (1/59).

Besides POHS shade match was recorded immediately after placement and at the 3-month recall.

Comparing scores for shade fit (not all shades were available at the time of the study) after placement and at three-month recall, revealed a high percentage of improvements (see Table 5).

Baseline		3 months					
Total (BL)	Score	5	4	3	2	1	improvements
3	Perfect - 1		2			1	
6	2			1	4	1	17%
24	3		2	9	11	2	54%
17	4	1	6	2	5	3	59%
9	Not at all - 5	3		1	2	3	67%
		4	10	13	22	10	
		Total (3 months)					

Table 5 Scores for shade fit (1 = perfect / 5 = not at all) at baseline (left column) compared to outcome after 3 months (line at bottom). Grey fields indicate worse shade fit and green fields indicate improved shade fit after 3 months.

From the shade fits being scored 3 or worse immediately after placement, 54-67 % cases were scored better after 3 months.

5.2 Long-term user evaluation

When handling aspects (including technique robustness) need to be evaluated, treatments during daily practice allow the best judgement.

5.2.1 User evaluation after 3 months

24 general dental practitioners (GDP) in Germany received Surefil one to be integrated in their routine treatment of patients. After 3 months using the material, participants received a questionnaire to collect feedback on handling and immediate outcome.

1294 restorations had been placed in 1051 patients at this time, primarily in posterior teeth. The median number of placed restorations per dentist was 40. (see Figure 52)

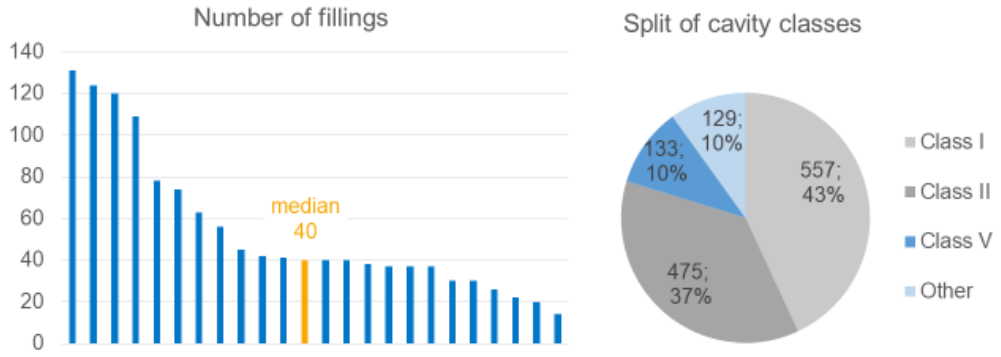

Figure 52 Distribution of number of fillings placed within 3 months (left) and split of cavity classes/type of restoration (right)

10 cases of post-operative hypersensitivity (POHS) were reported by 4 (17%) dentists of which 2 rated the occurrence as less frequent and 2 as equal compared to what they are used to from their routine treatments.

All other participating dentists did not observe any POHS after treatment with Surefil one. The overall POHS rate with 10 cases out of 1294 restorations is 0.8 %.

5.2.2 User evaluation after 6 months

After 6 months a total of 2628 restorations had been placed in 2160 patients. The type of treatment that were performed by the participants in the last 3 month are shown in Figure 53.

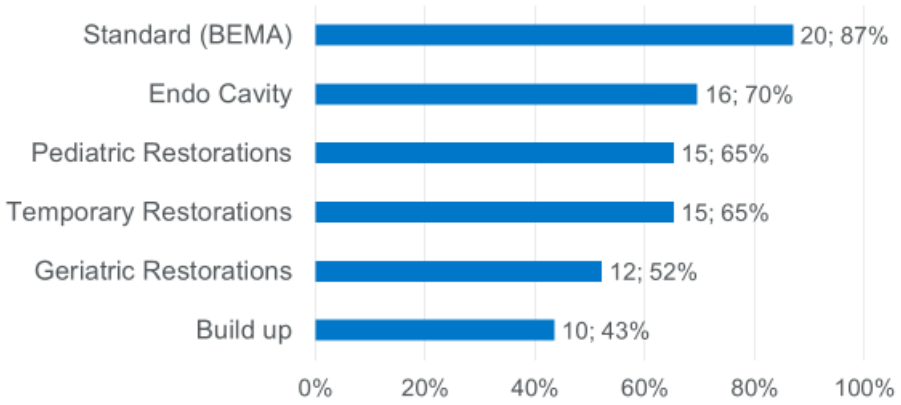

Figure 53 Distribution of treatment types between 3 and 6 months within the user evaluation. (Note: BEMA stands for standard restorations paid by the public health insurance system in Germany.)

In summary, following insights regarding handling were gained:

- To fully use the working time that starts upon activating the capsules, triturator should be placed in the operatory close to the treatment center
- Light sources (operatory light, loupes, …) should be dimmed or switched to “composite mode”
- Cavities need to be “actively” filled by distributing the material with the nozzle to all cavity aspects – the material will not flow
- Best technique is to slightly overfill the cavity and to shortly adapt using hand instruments with movements always towards the margins or by pressing with a foam pellet
- After light curing the final layer, fillings should be kept moist while contouring and finishing

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7 Glossary and Abbreviations

BADEP	N,N´-Bis-acrylamido-N,N´-diethyl-1,3-propandiamine
BisGMA	bisphenol A-glycidyl methacrylate; 2-Propenoic acid, 2-methyl-, (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] ester
CQ	Camphorquinone
EBA	ethoxylated bisphenol-A-dimethacrylate
HEMA	Hydroxyethyl-methacrylate
IFU	Instructions for Use
KPS	Pottasium persulfate
LC	Light cured
MDP	10-Methacryloyl-oxydecyl-dihydrogenphosphat
MOPOS	Modified polyacid system
MTBS	Micro Tensile Bond Strength
OCA	Occlusal Contact Area
PBRN	Practice Based Research Network
SBS	Shear bond strength
SC	Self cured (cured in dark mode)
SEM	Scanning Electron Microscope
SFS	Shear fatigue strength
TC	Thermo Cycling / Cycles
TCB	Butane-1,2,3,4-tetracarboxylicacid-di-2-hydroxyethylmethacrylate
TEGDMA	Triethylene glycol dimethacrylate
TML	Thermo Mechanical Loading

8 List of Figures

9 List of Tables

Brands of Dentsply Sirona and their abbreviation(s):

Ceram.X mono+ (Cxm+)
Ceram.x Spectra ST (SpST)
Dyract, Dyract extra
Dispersalloy
Prime&Bond active (PBactive, PBa)
Prime&Bond elect (PBelect, PBe)
SDR flow+ (SDR)
Xeno V+ (XV+)

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Brand (abbreviation(s); Manufacturer):

Activa (Pulpdent)
AdheSE (AdSE, ASU; Ivoclar Vivadent)
Dentin Conditioner (Cond.; GC)
Equia Forte (EquiaF; GC)
Filtek Supreme XTE/Ultra (Filtek Sup XTE, Filtek Sup; 3M)
Fuji II LC (FIILC; GC)
Heliomolar (Ivoclar Vivadent)
Ketac Molar Quick (3M)