Compoglass® F
Compoglass® Flow

Scientific Documentation

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Summary

Compoglass was introduced on the occasion of IDS 1995 in Cologne and was the second compomer available. It was well-accepted by the market. Various independent studies have rated Compoglass an excellent product superior to competitive materials. With Compoglass F, we are now offering a yet improved compomer version.

Compoglass F - what has been improved?

- The fluoride release has again been increased
- The surface is yet again smoother
- The marginal adaption has again been improved
- The matrix has been optimized

Advantages of Compoglass F over Compoglass

- The increased fluoride release reduces the risk of developing secondary caries. Compoglass F is thus used in cases with particularly high caries risk and where secondary caries often occurs, i.e. restorations in deciduous teeth and cervical defects.
- The extremely smooth surface features improved polishability and is less prone to palque accumulation.
- The improved marginal adaption results in tighter margins. Therefore, marginal discolouration and marginal caries are less likely to occur.
- The matrix has been optimized with regard to the influence on fluoride release and stability.

1. Introduction

Today's patients are no longer satisfied with the purely functional restoration of defective tooth structure. Patient requirements for tooth-coloured restorations cannot be adequately satisfied with glass ionomer cements. Although today's composites offer all the aesthetic possibilities desired, they frequently require more time-consuming working techniques by the dentist. Taking these aspects into account, the new compomer materials (Krejci, 1993) combine the desirable properties of the two restorative materials. Working with compomers is quick and easy. Furthermore, they satisfy the demand for outstandingly aesthetic, cosmetic restorations.

1.1 Requirements Placed on a Restorative Material

A restorative material must meet a variety of requirements (Janda, 1988, a, b, c):

1.1.1 Working requirements

- easy shade selection
- optimum consistency (handling)
- high polishability

1.1.2 Physical and chemical requirements

- good mechanical properties
- limited or no solubility
- limited or no shrinkage

1.1.3 Clinical requirements

- excellent resistance to oral conditions
- good shade matching with natural tooth structure
- good stability of shade
- wear resistance similar to that of tooth enamel
- sufficient radiopacity
- excellent adaptation to preparation margins and bonding with tooth substance
- fluoride release

1.1.4 Toxicological requirements

- lowest possible toxicological risk
- biocompatibility

1.2 Properties of Glass Ionomers

☺ direct adherence to enamel and dentin

☺ long-term release of fluoride ions, which are absorbed by the adjacent tooth structure

☺ biocompatibility

☺ easy working technique

☹ unsatisfactory wear resistance

☹ variations in the liquid/powder ratio influence properties

☹ sensitivity to moisture during curing

☹ weaker bond with dentin than materials combined with special dentin adhesives

☹ insufficient aesthetics

☹ mixing required

☹ highly limited clinical indication

1.3 Properties of Composites

☺ excellent physical properties

☺ high wear resistance

☺ polishability

☺ good aesthetics

☺ good resistance to oral conditions

☹ no direct bonding with enamel and dentin

☹ polymerization shrinkage of 2-5 % (volume)

☹ time-consuming, sensitive working technique

☹ rubber dam recommended

Ivoclar Vivadent has combined the favourable properties of both materials in one new restorative. The following detailed examination of the chemistry of the different restorative materials is intended to clarify the synthesis.

Summary:

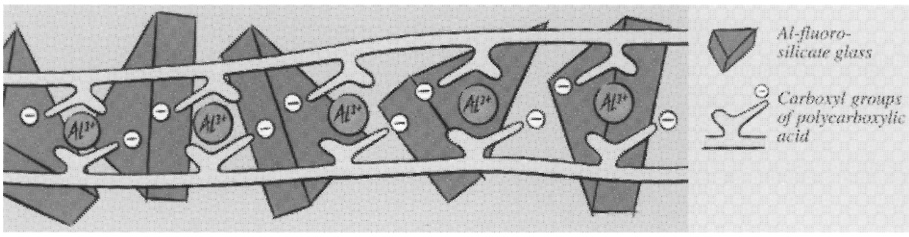
A new restorative material combining the favourable properties of glass ionomers and composites is desirable.

2. Chemistry of Restorative Materials

2.1 Glass Ionomers

Composition: **Aluminium fluorosilicate glass**
Polycarboxylic acid

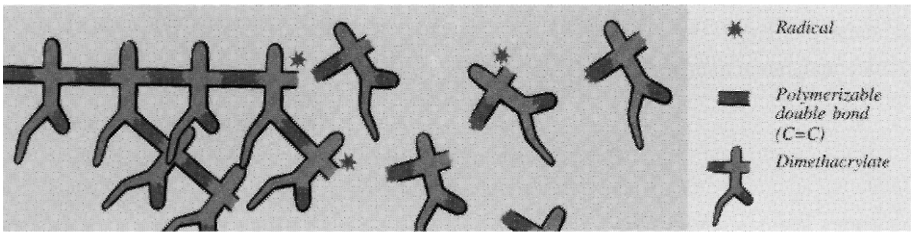
Curing reaction: Acid-base reaction, complex formation



2.2 Composites

Composition: **Monomer with curable double bonds**
Filler
Photoinitiator

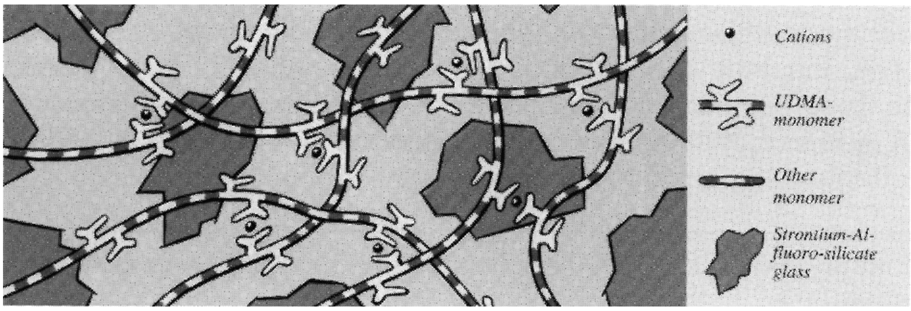
Curing reaction: Radical polymerization



2.3 Compomers[1]

Composition: **Aluminium fluorosilicate glass**
Dicarboxylic acid with curable double bonds
Photoinitiator
Monomer with free double bonds

Curing reaction:
1. Radical polymerization (composite reaction)
2. Acid-base reaction (glass ionomer reaction)

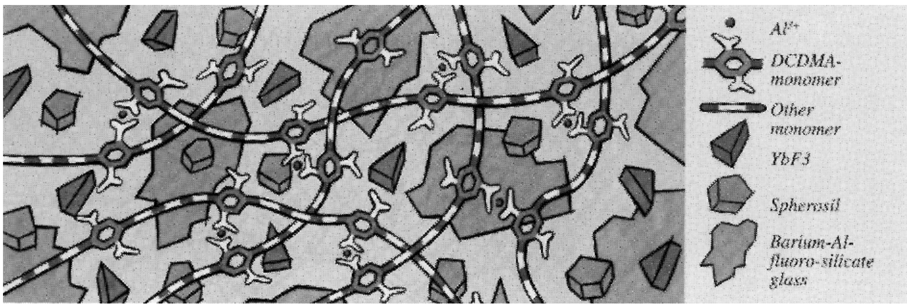


Various manufacturers have tried to combine the properties of both composites and glass ionomers. The development of light-curing glass ionomers and compomers (Photac Fil, Fuji II LC, Vitremer, Dyract) simplified the working techniques for this class of materials. Fluoride release, however, was significantly reduced (Torebzadeh et al., 1994) and the strength (Watts et al., 1994; Knobloch and Kerby, 1994) and wear resistance values (Peters et al., 1996) of composite materials were still not reached.

2.4 Compoglass™

Composition: **Aluminium fluorosilicate glass (∅ grain size 1.5 μm)**
Dicarboxylic acid with curable double bonds [2]
Filler based on composite technology
Photoinitiator
Monomer with free double bonds

Curing reaction:
1. Radical polymerization (composite reaction)
2. Acid-base reaction (glass ionomer reaction)



[1] Krejci, 1993

[2] Chemical strengthening of monomers (cycloaliphatic backbone = increased toughness), DCDMA monomer

2.5 Compoglass® F

Composition:	**Very fine aluminium fluorosilicate glass (Ø grain size 1.0 µm)** **Dicarboxylic acid with polymerizable double bonds** [3] **Filler based on composite technology** Photoinitiator Modified monomer with free double bonds
Curing reaction:	1. Radical polymerization (composite reaction) 2. Acid-base reaction (glass ionomer reaction)

The following requirements had to be met in the development of a new filler:

- Aluminium fluorosilicate glass with adequate physical strength and fluoride release
- A monomer with a tough backbone containing double bonds as well as supporting acid groups
- A filler mixture giving the material the desired physical properties

Compoglass F is the first restorative material to satisfy all these requirements. Compoglass F releases fluoride from three different sources: aluminium fluorosilicate glass, inorganic fluorides in the adhesive, and ytterbium trifluoride (ytterbium trifluoride, for which Ivoclar Vivadent owns a worldwide patent, has been clinically successful for more than 10 years). Wear resistance and strength have been achieved by chemically strengthening the monomers (cycloaliphatic DCDMA monomer; cycloaliphatic backbone = increased toughness) and adding an additional filler from the field of composite technology (spherosil).

Summary:

Compoglass F is the first real hybrid between glass ionomers and composites.

2.6 Compoglass® Flow

Compoglass Flow und Compoglass F are based on the same compomer chemistry. The flow properties of Compoglass Flow have been developed to meet the indications and requirements of compomers. As a result, Compoglass Flow features a new kind of flowability. The material is injected directly into the cavity. Given its flowability, Compoglass Flow easily adapts to the cavity walls without the use of additional instruments.

☺ reliable self-adaptation

☺ no material flowing away

☺ no trapping of air

☺ excellent marginal seal

[3] Chemical reinforcement of the monomers (Cyclo compound = increased stability), DCDMA monomer

3. Technical Data Sheet

Compoglass® F

Light curing, compomer-based restorative material

Standard - Composition:	**(in weight %)**
Urethane dimethacrylate	11.5
Polyethylene glycoldimethacrylate	4.6
Cycloaliphat. dicarbonic acid dimethacrylate	6.6
Mixed oxide, silanized	5.9
Ytterbiumtrifluoride	11.5
Ba-Al-Fluorosilikateglass, silanized	59.6
Catalysts, Stabilizers and Pigments	0.3

Physical properties:

In accordance with ISO 4049 and ISO 9917

Flexural strength	110	MPa
Flexural modulus	8200	MPa
Compressive strength	285	MPa
Vickers hardness	550	MPa
Water absorption	39	µg/mm^3
Water solubility	0.25	µg/mm^3
Radiopacity	275	% Al
Depth of cure (shade Universal)	> 4.5	mm
Sensitivity to ambient light	> 100	sec.

Compoglass® Flow

Light curing, compomer-based restorative material

Standard -Composition:	**(in weight %)**
Urethane dimethacrylate	20.6
Polyethylene glycoldimethacrylate	6.6
Cycloaliphat. dicarbonic acid dimethacrylate	5.7
Mixed oxide, silanized	5.1
Ytterbiumtrifluoride	10.0
Ba-Al-Fluorosilikateglass, silanized	51.7
Catalysts and Stabilizers	0.3
Pigments	< 0.1

Physical properties:

In accordance with ISO 4049 and ISO 9917

Flexural strength	95	MPa
Flexural modulus	5000	MPa
Compressive strength	325	MPa
Vickers hardness	310	MPa
Water absorption	35	µg/mm^3
Water solubility	Ø	µg/mm^3
Radiopacity	230	% Al
Depth of cure (shade Universal)	> 4.5	mm
Sensitivity to ambient light	> 95	sec.

4. Physical Properties of Compoglass F

Compoglass F stands out because of the following features:

☺ easy, quick working technique

☺ high degree of fluoride release

☺ minimal wear

☺ strong bond with dentin and enamel

☺ tight marginal seal

☺ low shrinkage

☺ impressive aesthetics

☺ radiopacity

☺ smooth, polishable surface

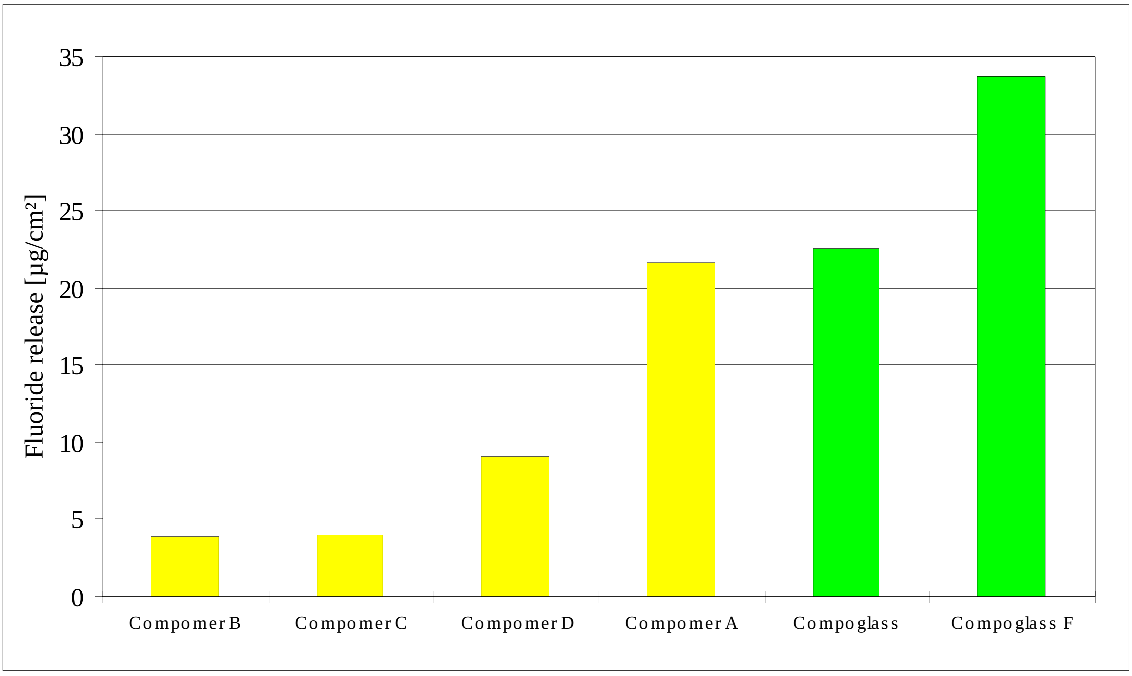
☺ easy-to-handle, watery adhesive free from acetone

The physical properties of different restorative materials are presented in the following pages to show the benefits of Compoglass F compared with other compomers and light-curing glass ionomers, as well as to give dentists a suggestion of where to position Compoglass with regard to composites and glass ionomers.

4.1 Fluoride release

Cumulative fluoride release from test samples was established in a Tris-lactate buffer (pH 7.2). Additional fluoride release from the Syntac Single Component adhesive was not taken into consideration.

Fluoride release of compomers during 4 weeks.

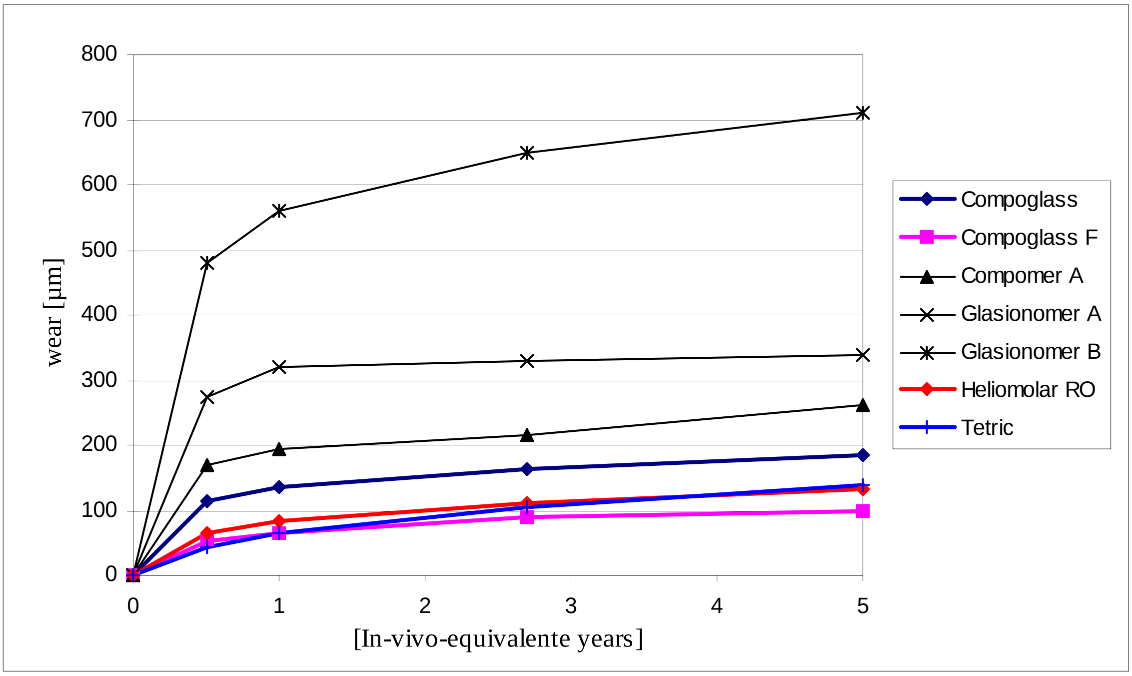


In-house investigation, R&D Ivoclar Vivadent Schaan, Liechtenstein

Conclusion: The fluoride release of Compoglass F was increased by 50 % compared with that of Compoglass.

4.2 Wear

The materials were subjected to a combined stress test that consisted of toothbrush and toothpaste wear, rapid temperature changes, and cyclical occlusal stress. The five-year values correspond to 300 minutes of brushing teeth, 1,200,000 masticatory cycles (49N / 1.7 Hz), and 3,000 thermal cycles (5-55°C).



In-house investigation , R&D Ivoclar Vivadent Schaan, Liechtenstein

Conclusion: The smaler particle size of the filler of Compoglass F (aluminium fluorosilicate glass 1.0 µm) improves the wear resistance compared to Compoglass (aluminium fluorosilicate glass 1.5 µm).

4.3 Bonding with Dentin and Enamel

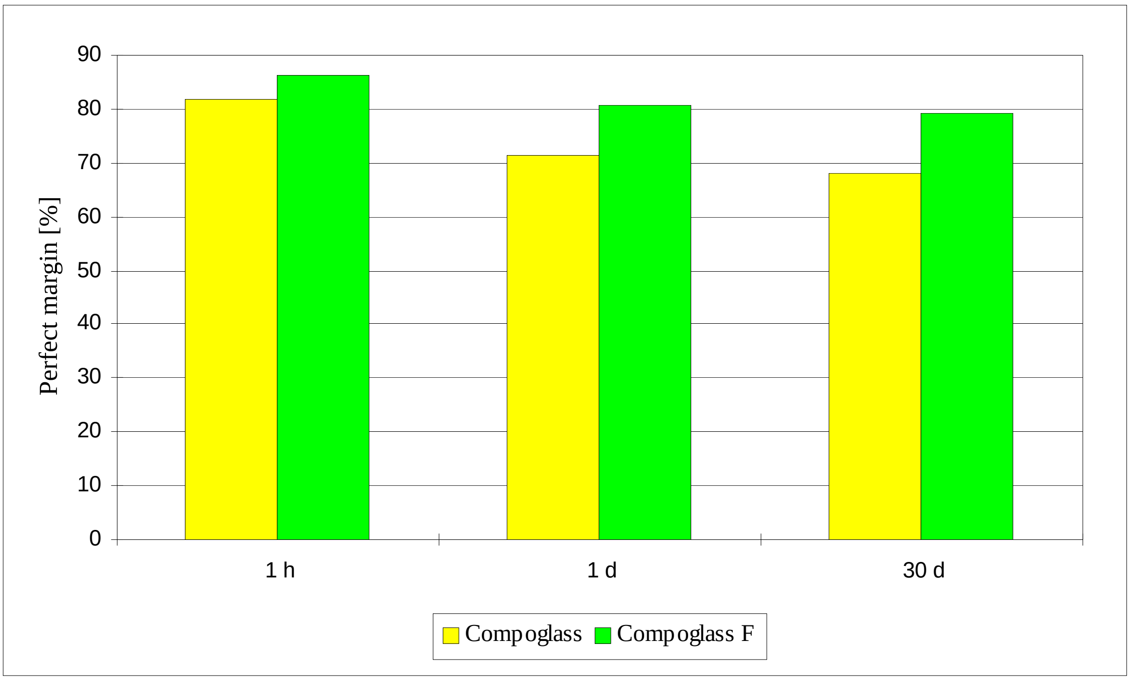
Shear bond strength was established with bovine teeth.

In-house investigation, R&D Ivoclar Vivadent Schaan, Liechtenstein

[Compo=Compoglass / Compo F=Compoglass F / Syntac SC = Syntac Single-Component]

Conclusion: The high bonding values on enamel are a prerequiste for tight marginal seals. The values were achieved with acid etching.

4.4 Marginal Adaptation in Mixed Class V Cavity Preparations

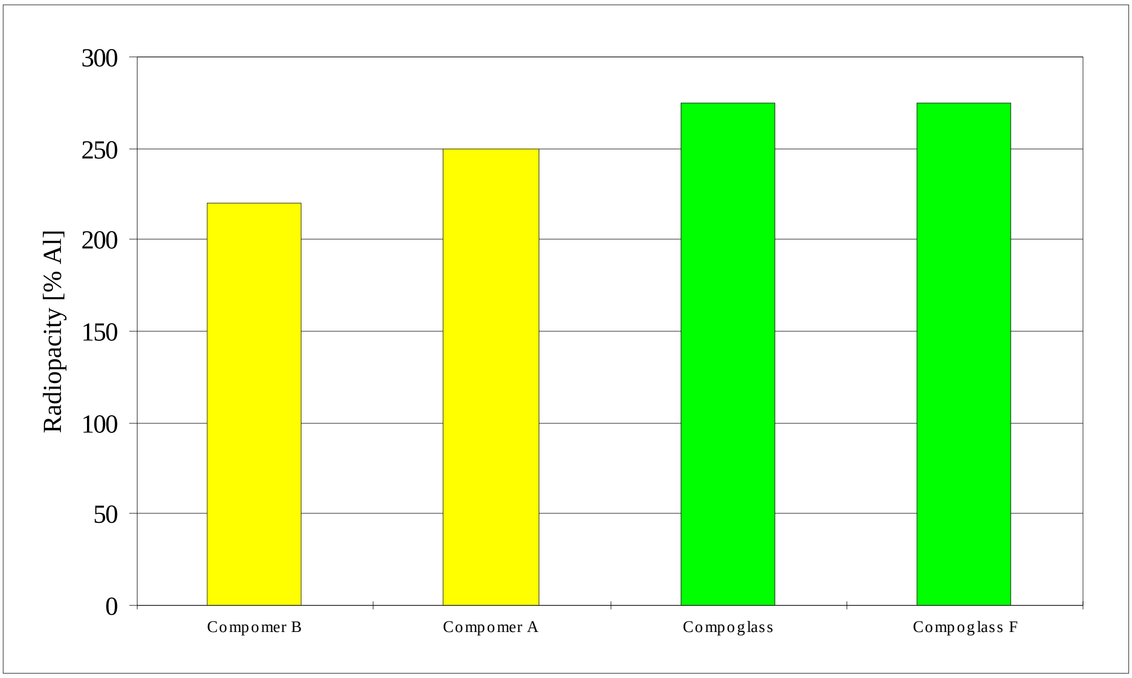


Interne Untersuchung, F&E Ivoclar Vivadent Schaan, Liechtenstein

Fazit: The modification of Compoglass F improves marginal quality. Close margins show less tendency for discolouration and caries.

4.5 Radiopacity According to ISO 4049

For restorations in areas that are clinically difficult to reach or even inaccessible, an X-ray of a radiopaque restoration is the only non-invasive means of diagnosing secondary caries. Radiopacity also offers an easy method for documenting the dentist's work.



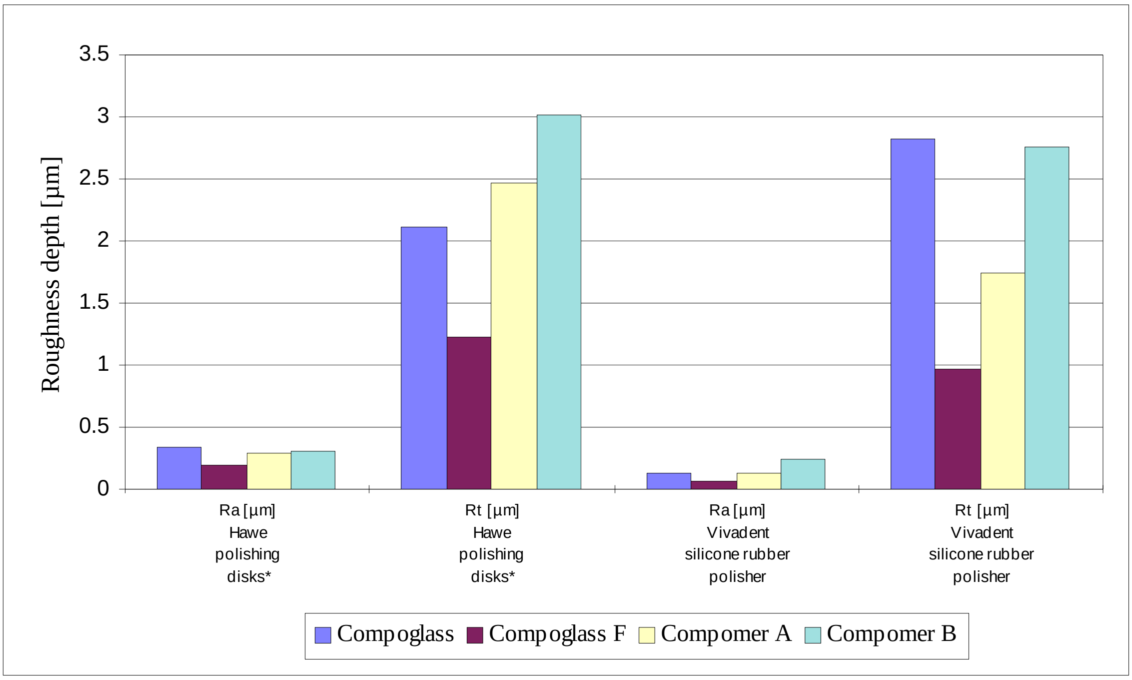
In-house investigation, R&D Ivoclar Vivadent Schaan, Liechtenstein

Conclusion: The radionpacity of Compoglass is achieved by adding ytterbium trifluoride (ytterbium trifluoride, for which Ivoclar Vivadent owns a worldwide patent, has been clinically successful for more than 10 years.

4.6 Surface Roughness

Smooth surfaces are a prerequisite for an aesthetic appearance. Furthermore, they are less susceptible to plaque accumulation than rough surfaces.

The compomers examined were polymerized under a foil and subsequently polished with the indicated instrument. The test samples were polished either with Hawe finishing and polishing disks, or with Politip P rubber polishers from Ivoclar Vivadent.



Rzanny and Welker (1997), University of Jena, Germany

* The test samples were treated with Hawe coarse, medium, fine and x-fine. The diagram indicates the average values.

R_a mean roughness depth / R_t maximum roughness depth

Conclusion: The smooth surface of Compoglass is achieved with the fine particle size of the filler. The mean grain size of the fluoro-aluminium silicate glass was reduced from 1.5 µm in Compoglass to 1.0 µm in Compoglass F.

4.7 Other Physical Data

	Compoglass F	Compoglass	Compomer A	Compomer B	Compomer C	Compomer D
Flexural strength*[1] [MPa]	110	105	115	135	160	133
Modulus of elaasticity *[1] [MPa]	8200	8700	7700	11400	17500	12900
Compressive strength * [MPa]	285	260	225	261		
Vickers hardness * [MPa]	550	510	470			
Water solubility *[1]	0.25 µg/mm^3					
Water absorption *[1]	39 µg/mm^3	0.33 %	0.47 %			

*=after 24h, H_2O, 37 °C / [1]=according to ISO 4049

5. Scientific Studies on Compoglass

A large number of independent studies have been conducted on Compoglass since its introduction at IDS 1995 in Cologne. It has been rated an excellent product superior to competitive products. These studies will be summarized below.

5.1 In Vitro Investigation (Physical Measurements)

5.1.1 Bonding strength

Title	Results [in MPa]	Reference
Long-term bond on dentin	• after 1h: Compoglass 29.5, Dyract 29.7 • after 6 weeks: Compoglass 31.4, Dyract 25.3	Jakob et al., 1996
Bonding strength on enamel	• without enamel etching: Dyract 11.2, Compoglass 17.9 • with enamel etching: Dyract 33.6, Compoglass 32.1	Moll et al., 1996
Bond on enamel and dentin	• Enamel: Dyract 13.5, Compoglass 18.2 • Dentin: Dyract 18.9, Compoglass 18.4	Leach and Aboush, 1996
Bond on dentin	• Compoglass 16.29, Fuji II LC 15.42, Dyract 15.33	Garcia-Godoy et al., 1996
Bond on dentin	• Photac Fil 0.5, Ketac Fil 3.0, Ketac Silver 3.1, Vitremer 7.9, Fuji II LC 8.2, Dyract 9.8, Compoglass 13.7	Peutzfeld 1996
Bond on deciduous teeth	• Herculite Optibond 6.07, Dyract 8.67, Compoglass 11.94	Jumlongras and White, 1997
Bond on enamel with and without acid etching	• Without acid etching: Compoglass 6.9, Dyract 4.5 • 20 s acid etching: Compoglass 22.4 Dyract 16.0 • 40 s acid etching: Compoglass 18.1, Dyract 14.8	Buchalla et al., 1997

5.1.2 Release of Fluoride Ions

Title	Results	Reference
Fluoride release in an acidous or neutral environment	• neutral pH [µg/cm^2] Vivaglass Base 49, Dyract 52, Compoglass 98 • acidous pH [µg/cm^2]: Vivaglass Base 54, Dyract 87, Compoglass 113	Attin et al., 1996
Fluoride release during 6 months	• [µg/mm^{2}d] Ketac Fil 0.11, Compoglass 0.05, Chem Fil Superior 0.03, Dyract 0.02	Shaw and McCabe, 1997
Fluoride release of glass ionomers, compomers, and composites	• After 1 day [ppm]: Fuji II LC 63.8, Fuji II 54.6, Vitremer 54.4, Compoglass 30.9, Dyract 27.2, Heliomolar 13.6 • After 44 days [ppm]: Fuji II LC 16.7, Fuji II 11.3, Vitremer 12.2, Compoglass 17.0, Dyract 6.2, Heliomolar 3.5	Nunez et al., 1997
Fluoride release of compomers and flowable composites	• After 1 week [ppm]: Compoglass 9.77, Dyract 1.84, Crystal 7.71, Ultraseal XT 0.71, Flow It 0.42 • After 1 month [ppm]: Compoglass 2.56, Dyract 1.07, Crystal 1.03, Ultraseal XT 0.20, Flow It 0.00 • After 8 months [ppm]: Compoglass 0.98, Dyract 0.93, Crystal n/t, Ultraseal XT n/t, Flow It 0.00	Rasmussen et al., 1997

5.1.3 Wear Simulation

Title	Results	Reference
Abrasion of silicophosphate and glass ionomer cements	• Drala stone cement (highest abrasion) > Drala steel cement >Cupro Dur > Trans Lit > Ketac Silver > Fuji IX > Dyract > Compoglass > Valiant (least abrasion)	Bauer et al., 1996

5.1.4 Hardness

Title	Results	Reference
Surface hardness of glass ionomers and compomers	• Rockwell hardness: Vitremer 14.1, Photac Fil 14.4, Fuji II LC 27.7, Fuji IX 35.5, Dyract 38.9, Compoglass 44.4, Z100 62.6	Peutzfeld et al., 1997
Microhardness	• Vickers hardness: Compoglass 68.8, Fuji II LC 62.7 Dyract 57.7, Vitremer 50.0	Ellakuria et al., 1996

5.2 In Vivo Investigations (Clinical Investigations)

5.2.1 Class V

Head of Study	Subject	Experimental	Status/Results
Dr. U. Blunk, T. Richter, ZA / Prof. J.F. Roulet Centre for Dentistry at the Charité Humboldt University, Berlin, Germany	Clinical testing of Compoglass and a comparable product (Product A) for the restoration of **cervical cavities**	One hundred teeth with non-carious cavities are being studied. The cavities were cleaned with a polishing paste. Subsequently, they were isolated and restored with one of the materials tested. Immediately following their placement and after 6, 12, 24, and 36 months, the restorations are evaluated with direct clinical methods and the quality of the margins are examined with the help of SEMs.	All restorations have been placed and were examined after 6 months. A corresponding publication is being prepared..
Prof. R.D. Perry/ Prof. G. Kugel Department of Restorative Dentistry Tufts University, Boston, USA	Evaluation of the clinical performance of Compoglass in **Class V restorations**	The cavities are prepared without mechanical retention. A total of 63 restorations are placed. The teeth are evaluated according to clinical parameters after 6, 12, 24, and 36 months. In addition, close-up colour photographs and X-rays will be used to conduct indirect evaluations	Initially, 100 % of the restorations were rated A with regard to all criteria. The 6-month examination was already conducted on 19 restorations. All of them scored A ratings.
Dr. A. Abdalla Dr. H. Alhadainy Dr. F. Garcia-Godoy, Tanta Egypt and Department of Pediatric and Restorative Dentistry University of Texas, San Antonio, USA	Clinical investigation on glass ionomers (Fuji II LC and Vitremer) and compomers (Dyract and Compoglass) for the restoration of **carious Class V defects**	30 Class V cavities each were restored with 4 different materials. After 1 and 2 years, the restorations were evaluated according to USPHS criteria.	After 1 year, the shade match of Vitremer was significantly weaker than that of the other materials tested. After 2 years, the compomers demonstrated clearly better results than Fuji II LC, which was rated higher than Vitremer. Abdalla et al., 1997

5.2.2 Deciduous Teeth

Head of Study	Subject	Experimental	Status/Results
Dr. A. Trummler Director of the School Dental Service of the City of St. Gallen Switzerland	Clinical evaluation of Compoglass as a restorative material for **deciduous teeth**.	103 Compoglass restorations were placed in 64 patients and evaluated over a period of 2 years.	Initially, all restorations were rated A (A=good; B = clinically acceptable; C=unacceptable). One hundred restorations were examined after 12 months. 97 % were rated A and 3 % B. The shade was considered as good in all cases. Neither postoperative sensitivity nor secondary caries were noted. After 24 months, 93 restorations were examined (94.6% A, 5.4 % B / shade 99% A, 1% B / postoperative sensitivity 0% / secondary caries 0%).
Prof. F. Garcia-Godoy Department of Pediatric Dentistry and Restorative Dentistry University of Texas, San Antonio, USA	Clinical investigation of Compoglass as a restorative for **Class I and II cavities in primary molars**	Sixty restorations were inserted in deciduous molars. The teeth are evaluated after 6, 12, 18, and 24 months according to clinical parameters (USPHS). In addition, close-up colour photographs and impressions will be made for the indirect evaluation of the restorations.	After 6 months, the restorations were rated perfect (marginal quality (100% A), discolouration (100% A), anatomic shape (100% A), shade match 100% A). After 12 months, only the ratings for marginal quality (98% A) and discolouration (98% A) were slightly different. Neither postoperative sensitivity nor secondary caries were noted.

5.2.3 Long-Term Temporaries

Head of Study	Subject	Experimental	Status/Results
Prof. E. Reich/ A. Zamani, ZA Department for Periodontology and Operative Dentistry University of Saarland, Homburg, Saar, Germany	Clinical evaluation of Compoglass, with and without the acid etch technique, in **stress bearing occlusal Class I and II cavities**	Patients with at least two similar cavities (Class I or II) were selected to participate in the study. In general, the cavities were prepared according to the adhesive technique. One cavity for each patient was restored with Compoglass, according to the Instructions for Use and without using the acid etch technique. In 20 patients, the second cavity was restored with a comparable material (Dyract) and in 20 patients with Compoglass using the acid etch technique. The teeth will be evaluated according to clinical parameters after 6, 12, 18, and 24 months. In addition, close-up colour photographs will be taken. Impressions will be made of some of the restored teeth to determine abrasion.	After 6 months, the restorations were examined according to modified Ryge critera. All restorations were functional. Neither discolouration of the restorations, nor secondary caries were noted. After 6 months, 75 % of the Dyract restorations and 73 % of the Compoglass restoration showed slight negative steps, but no marginal gaps. When seated with acid etching, Compoglass restorations did not demonstrate any changes of marginal quality. 33 % of the Dyract restorations and 7 % of the Compoglass restorations evidenced marginal discolouration after 6 months. Restorations seated with acid etching did not show any marginal discolouration (Balz et al., 1997).

6. Biocompatibility

Compoglass F consists of the same component as the existing Compoglass. Only the ratio of the components has been optimized. Furthermore, the fluorosilicate glass was finer ground. Toxicological data are available for the individual components. Given the extremely similar composition, the toxicological data of Compoglass may be used for the toxicological evaluation of Compoglass F. Additionally, a cytotoxicity test was conducted on Compoglass F.

The following examinations are necessary for evaluating the biocompatibility of dental materials:

1. Acute oral risk: The patient accidentally swallows the entire amount of adhesive and restorative material
2. Local tolerance with surrounding tissue that comes in contact with the material
3. Possible sensitizing reactions
4. Mutagenic potential of eluted low-molecular components
5. Cytotoxicity: Damage to cultivated cells

6.1 Acute Oral Risk

Acute oral toxicity is established from the relationship between dose and effect, tested on rodents. The measure for the toxic effect was established as the lethal dose (LD_{50} value).

The following LD_{50} values can be calculated from the experimental data:

Compoglass	> 5000 mg / kg
Syntac Single-Component	> 5000 mg / kg

Acute toxicological risk of Compoglass and Syntac Single Component can thus be virtually excluded.

6.2 Histology

Local tolerance with surrounding tissue was tested on monkeys. The restorative was placed in Class V cavities using the adhesive technique. The effect on vital pulp tissue was examined. Infections or inflammations were not observed at any time (Tarim et at., 1996, 1997).

This study proves that Compoglass, used together with Syntac Single Component, does not harm the pulp. Rather Compoglass effectively protects the pulp against bacteria and inflammation.

6.3 Sensitization

Sensitization means that heightened sensitivity or allergic reactions to the chemical substance are induced. The sensitizing potential of a chemical substance was tested on the skin of albino guinea pigs.

No allergic reactions toward Compoglass were observed under the given test conditions. Compoglass can thus be considered non-sensitizing.

6.4 Mutagenicity

Mutagenicity of a substance can be easily and reliably determined with a bacterial test (Ames Test, Ames et al., 1975).

No mutation of Salmonella typhimurium could be determined in an Ames Test conducted under the selected experimental conditions. In these tests, Compoglass was demonstrated to be non-mutagenic.

6.5 Cytotoxicity

The toxicity of eluted low-molecular substances can be determined with cultivated cells of mammals.

No cytotoxicity was determined for Compoglass F.

7. Literature

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