

Scientific Documentation

Syntac[®]

**Research and Development
Scientific Service / April 1998**

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1. Introduction

Hardly any other area of restorative dentistry has seen such remarkable progress in recent years as in composite dentin bonding. This has led to the fact that composite and ceramic restorations are an integral part of today's dentin bonding agents. With improvements in retention and marginal quality in the forefront. New possibilities open up through dentin sealing with dentin adhesives, with pulp-dentin protection the reduction of post-operative pain and with the handling of overly-sensitive cervicals (Haller, 1994).

1.1. *Requirements on dentin adhesives*

An ideal adhesive should:

- lead to a good bond between dentin and restoration
- bonding strength and a seal which corresponds to natural dentin sealing layers (enamel and cementum)
- hinder fissures between tooth and restoration
- hinder secondary caries
- be durably stable
- hinder post-operative sensitivity
- be easy to use
- minimum proneness to non-ideal conditions of application
- biologically compatible, so that the adhesive can be used in deep cavities
- have storage stability

1.2. *Classification of dentin adhesives*

Whereas the dentin adhesives of the so-called first and second generations sought to achieve, with the help of bi-functional molecules, a chemical bond to the organic or inorganic dentin (Asmussen and Munksgaard, 1985), the adhesive systems of the latest generation are distinguished by the treatment of dentin prior to the application of the bonding agent. Based on the treatment of the smear layer (the dentin is covered by a layer after the preparation of the cavity) the adhesive systems can be classified. The smear layer is either kept and impregnated with resin, partially dissolved or dissolved and removed. The Syntac system works optionally with partial or complete removal of the smear layer.

Smear layer is kept (primer without conditioning)	Smear layer is removed (conditioning followed by primer)	Smear layer is partial removed (self-conditioning primer)
Probond Prisma Universalbond 3 XR-Bond	Scotchbond Multi-Purpose All Bond 2 Clearfil One Step Optibond FL Clearfil Liner Bond Prime & Bond 2.1 Gluma 2000 Syntac Single Component Syntac Sprint (Syntac)	A.R.T. Bond Denthesive II Scotchbond 2 Syntac

Haller, 1994; Van Meerbeek et al., 1992

1.2.1. Advantages / Disadvantages

Maintaining the smear layer

- ☺ Dentin permeability is not increased
- ☺ Compensation of contraction tensions conditioned by polymerization
- ☹ Independent strength of resin impregnated layer is minimal
- ☹ Water can continue to penetrate, which leads to long-term reduction of the bonding strength

Dissolving of the smear layer

- ☺ The labile layer is completely removed
- ☺ The monomers applied after conditioning fill the open dentin canals and constitute the retentive resin tags by polymerization
- ☺ The tags seal the dentin canals
- ☹ Dentin permeability is increased
- ☹ The dentin is demineralized and the collagen fibres can be denatured
- ☹ Decalcification can be lower than the penetration of adhesives es

Self-conditioning primer

- ☺ The labile smear layer is converted into a resin impregnated, stable hybrid layer
- ☺ The monomers applied with conditioning penetrate into the open dentin canals and through polymerization form retentive resin tags

- ☺ The tags seal the dentin canals
- ☺ The dentin is insignificantly demineralized and the collagen fibres hardly denatured
- ☹ Thinner peritubular hybrid layer than with adhesive systems which completely remove the smear layer
- ☹ Variability of the smear layer

2. Technical Data Sheet

Product: **SYNTAC**

Type of material: **Two-component adhesive system**

Standard - Composition:

(in weight %)

Primer:	Tetraethylenglycol dimethacrylate	25.0
	Maleic acid	4.0
	Dimethylketone	41.0
	Water	30.0
Adhesive:	Polyethylenglycol dimethacrylate	35.0
	Maleic acid	< 0.01
	Glutaraldehyde (50 %)	10.0
	Water	55.0

Physical properties:

Shear bond strength:

Etched enamel	after 1 minute	14 ± 2 MPa
	after 24 hours	22 ± 4 MPa
Dentin	after 1 minute	6 ± 2 MPa
	after 24 hours	14 ± 6 MPa
	after 6 months	15 ± 6 MPa
	after 12 months	12 ± 6 MPa
Refractive index n_D^{25}	Primer	1.3890
	Adhesive	1.3910

3. Processing

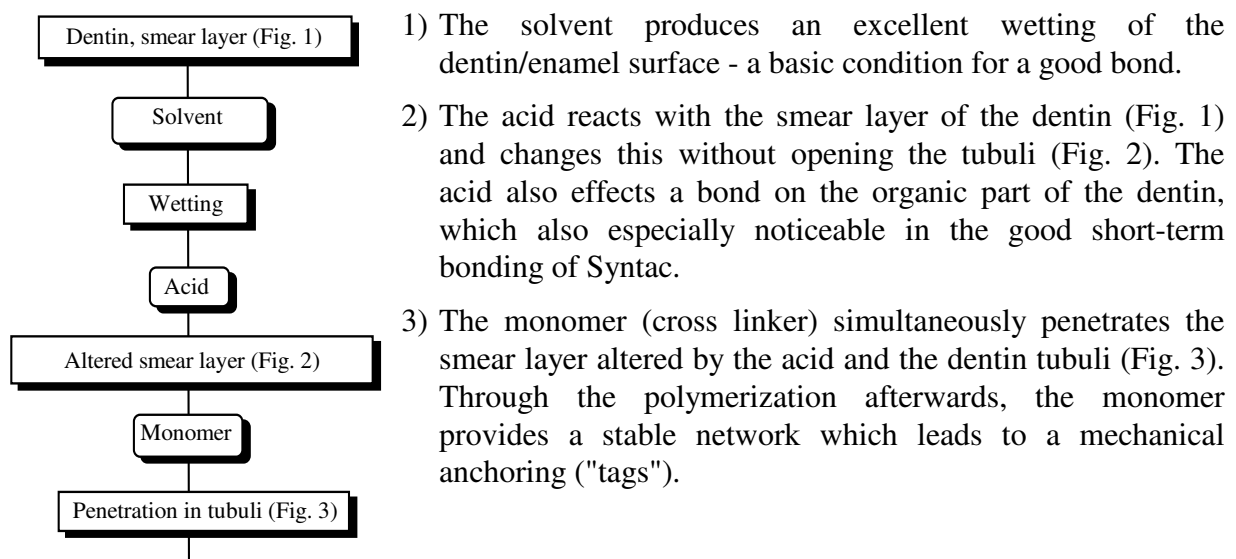
3.1. Recommendations for processing

- i. Etch enamel with 37 % phosphoric acid
- ii. Apply Syntac Primer to enamel and dentin, let work for 15 sec, dry with air
- iii. Apply Syntac Adhesive, let work for 10 sec, dry with air
- iv. Apply Heliobond, remove excess, light cure for 10 sec

3.2. Working mechanism of Syntac

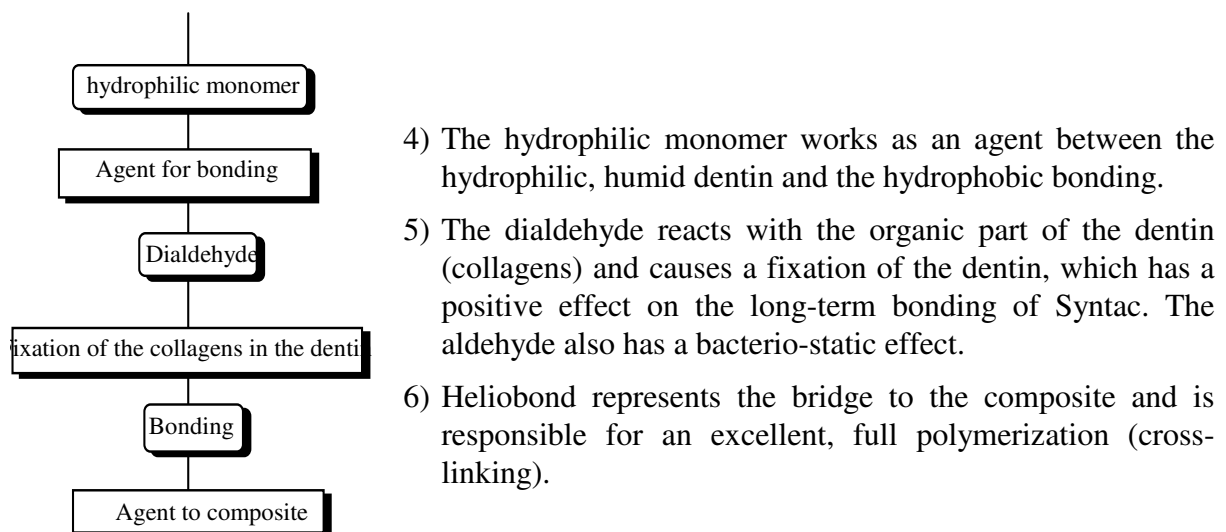
Syntac Primer principally consists of three components:

- a. solvent
- b. organic acid
- c. cross linker (monomer)



Syntac Adhesive consists of:

- a. hydrophilic dimethacrylate (monomer)
- b. glutaraldehyde (dialdehyde)



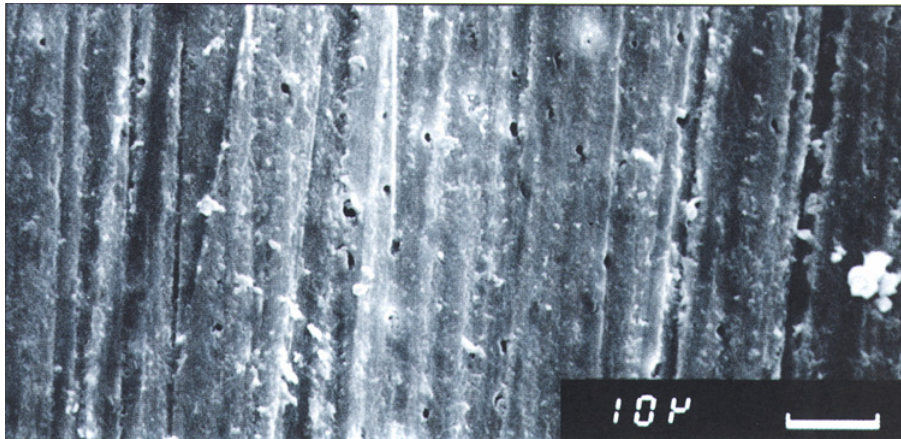


Fig. 1: Ground, otherwise untreated dentin (smear layer)

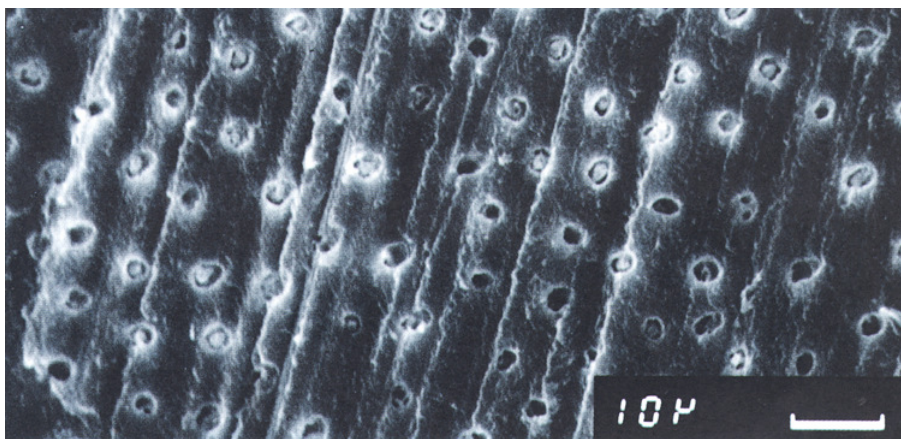


Fig. 2: Dentin treated with Syntac. The smear layer was changed without the tubuli being fully opened.

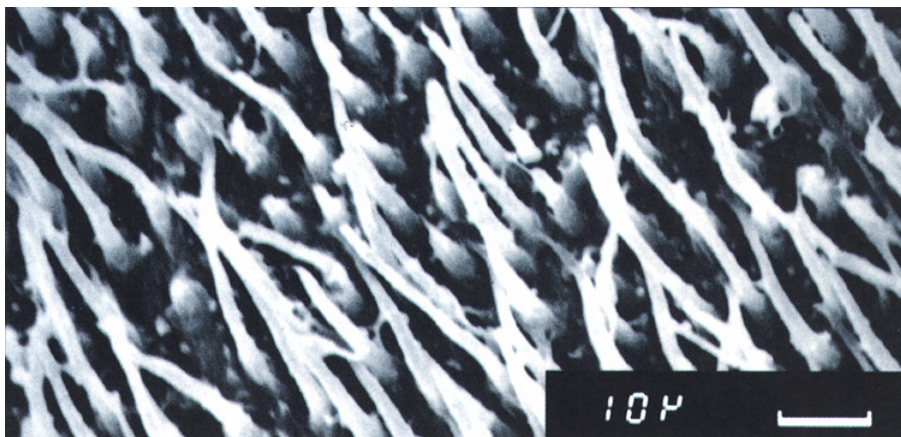


Fig. 3: Polymer "tags" from Syntac penetrated in the dentin. The dentin was dissolved before the exposure.

3.3. *Acid etching with Syntac*

Acid etching of the dentin is viewed by some scientists as critical technology, while others consider it as a prerequisite for the formation of a stable hybrid layer (Fusayama et al., 1978; Haller, 1994; Cox and Suzuki, 1994; Pashley, 1994). Objectively observed, there are arguments for its use, while others are against it. Gwinnett et al., (1992) have examined the dentin bond and the marginal seal of Syntac with relation to the processing technique. On the one hand, they have processed Syntac according to the manufacturer's requirements; on the other, they have processed it with the "total etch" technique (10 seconds 37% phosphoric acid

before applying the primer). It was observed that the bonding strength of Syntac was not affected by the etching, but that the marginal seal was improved.

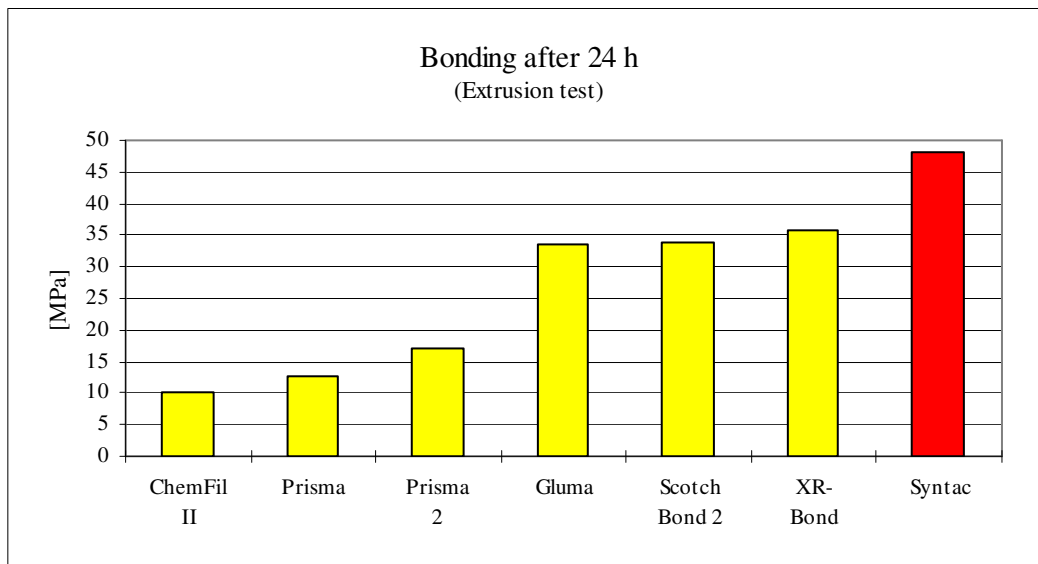
3.4. *Summary*

Syntac dissolves the smear layer and penetrates the dentin. After polymerization, Syntac leads to a solid bond between the tooth substance and the restoration. Syntac offers the dentist the possibility of applying a dentin adhesive corresponding to his personal experience and knowledge. Both with the conditioning of the smear layer, as well as through acid etching of the dentin, outstanding clinical results are achieved.

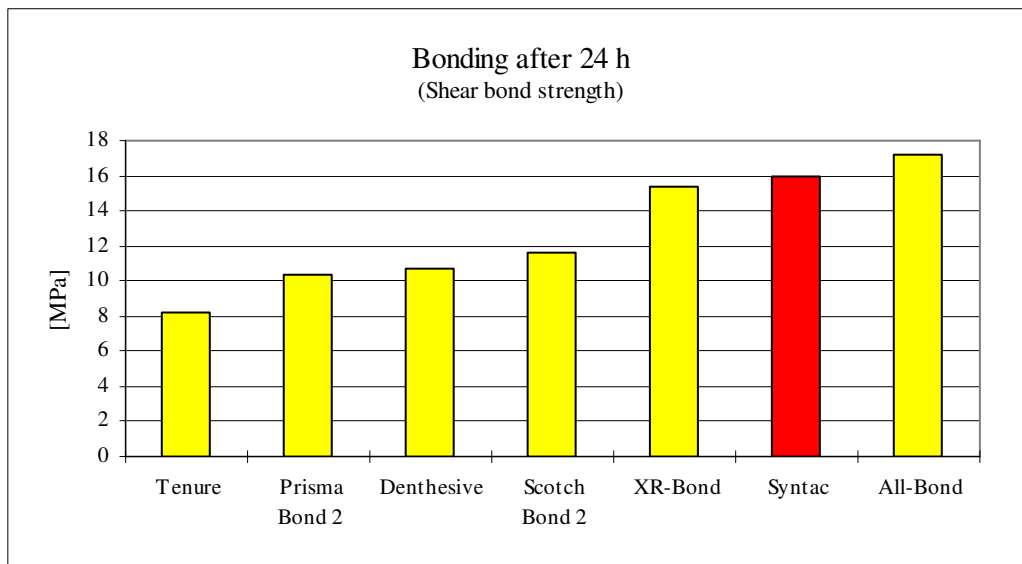
4. Physical Values

Here, the testing data of Syntac are summarized from tests conducted by independent scientists of renowned universities in Europe and the U.S. All results were published in international trade journals.

4.1. Bonding after 24 hours

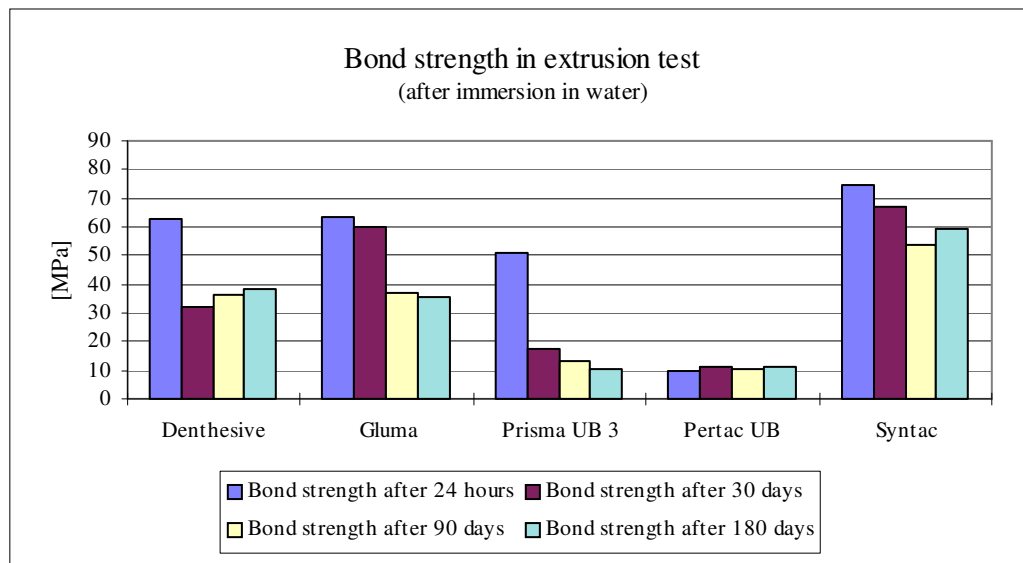


Haller et al., J Dent Res 70 (1991) 525

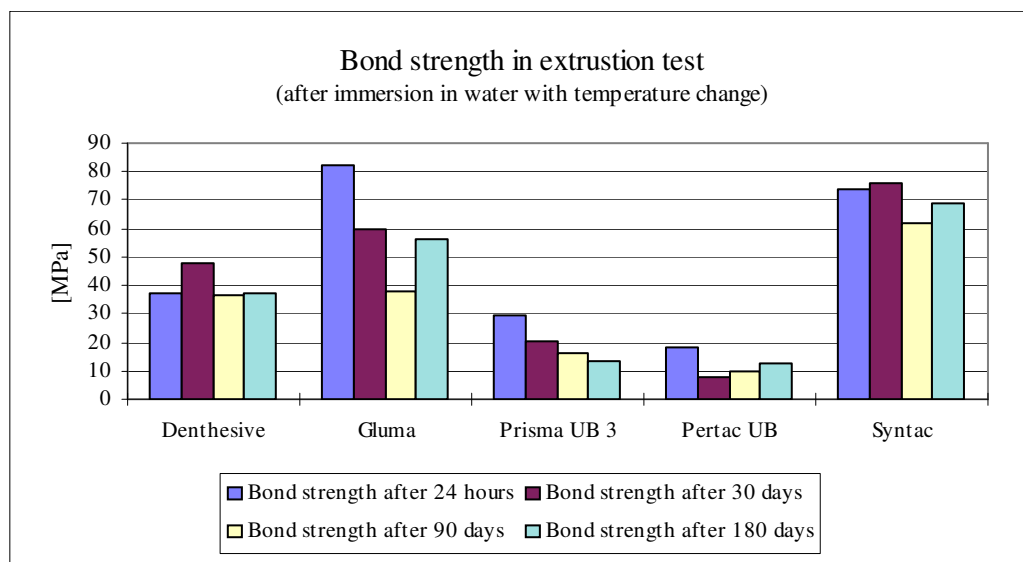


Retief et al., Am J Dent 7 (1994) 43-46

4.2. *Resistance of the composite dentin bond to artificial ageing*

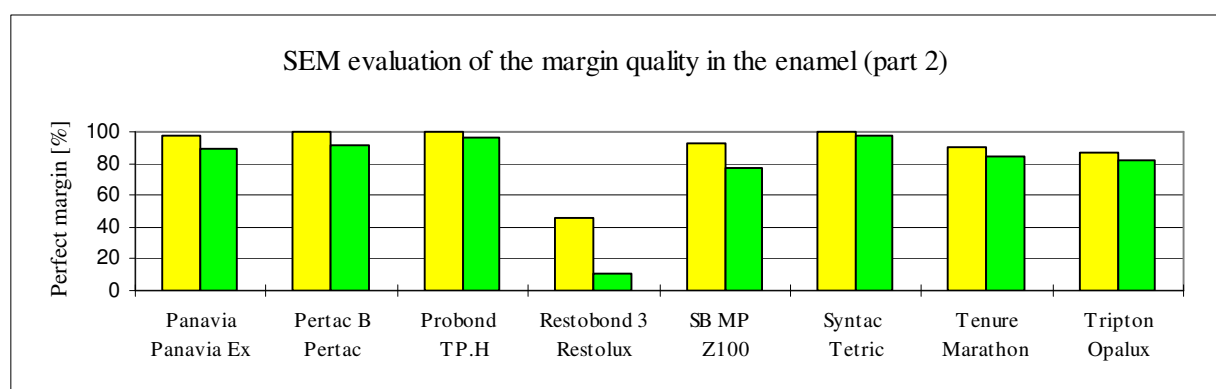
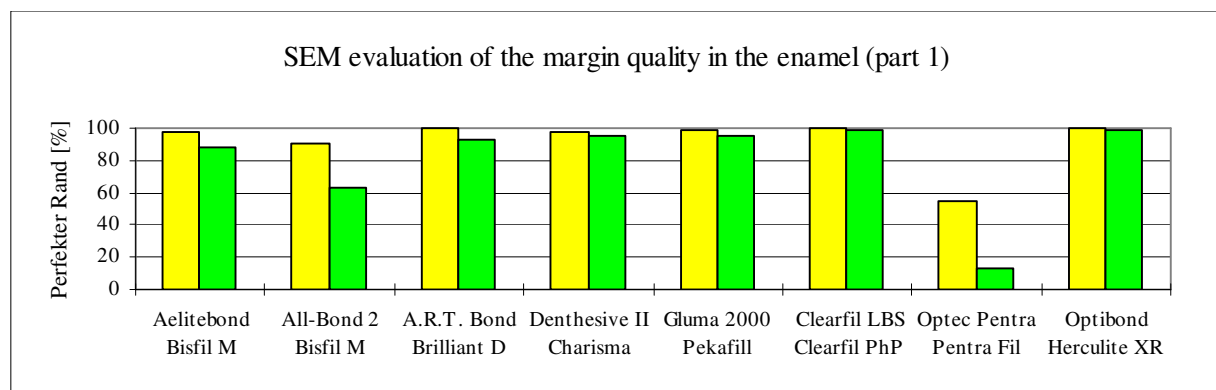
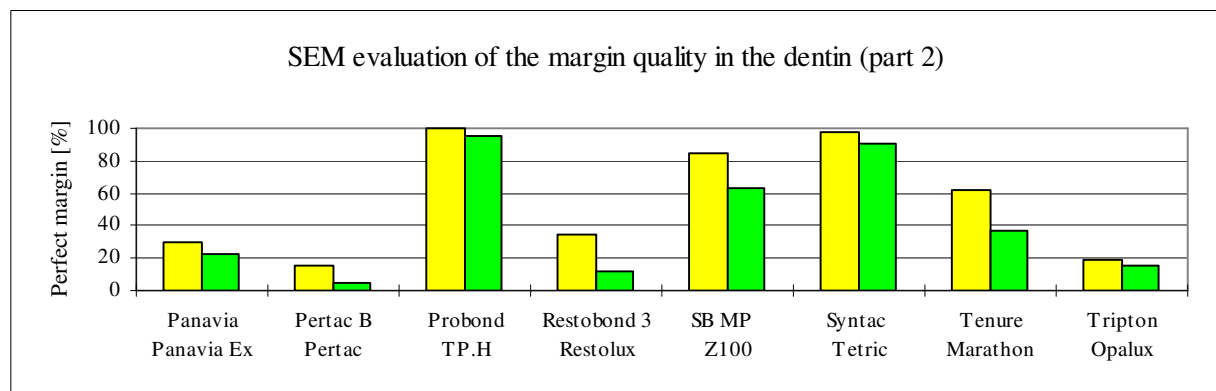
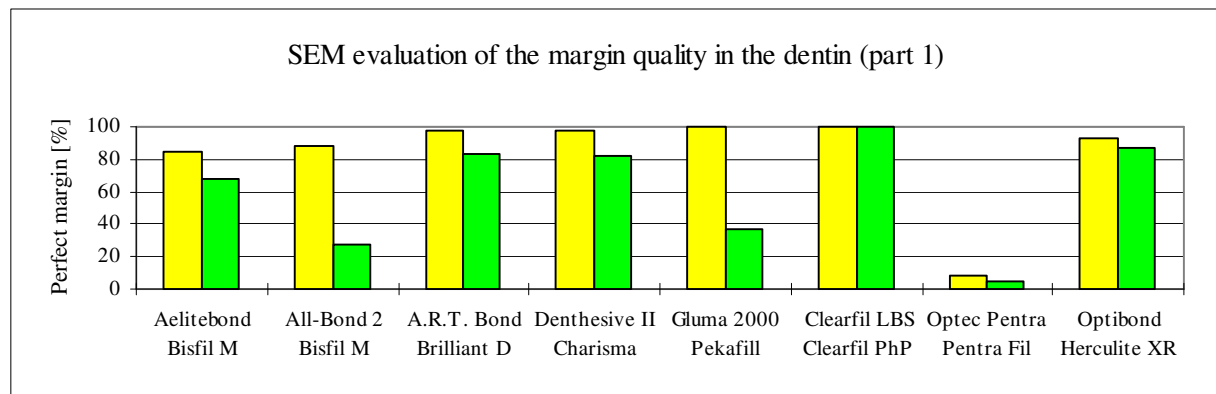


Haller et al., Dtsch Zahnärztl Z 48 (1993) 100-104



Haller et al., Dtsch Zahnärztl Z 48 (1993) 100-104

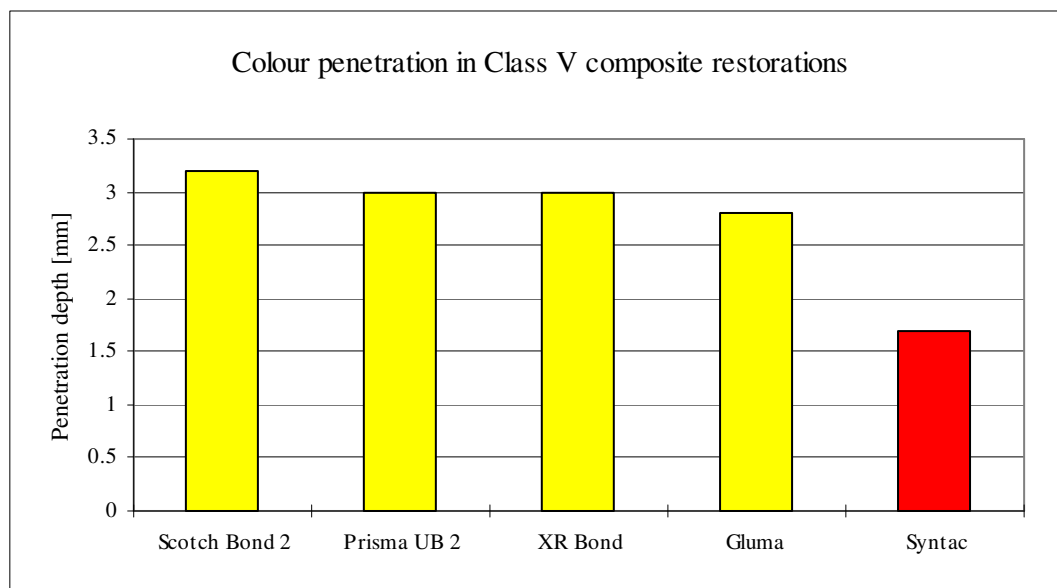
4.3. Margin quality in dentin and enamel



Krejci und Lutz, Eigenverlag PPK (1995) before thermocycling after thermocycling

Conclusion: The margin quality was also examined by Mehl et al. (1994) in which Syntac also achieved the best results.

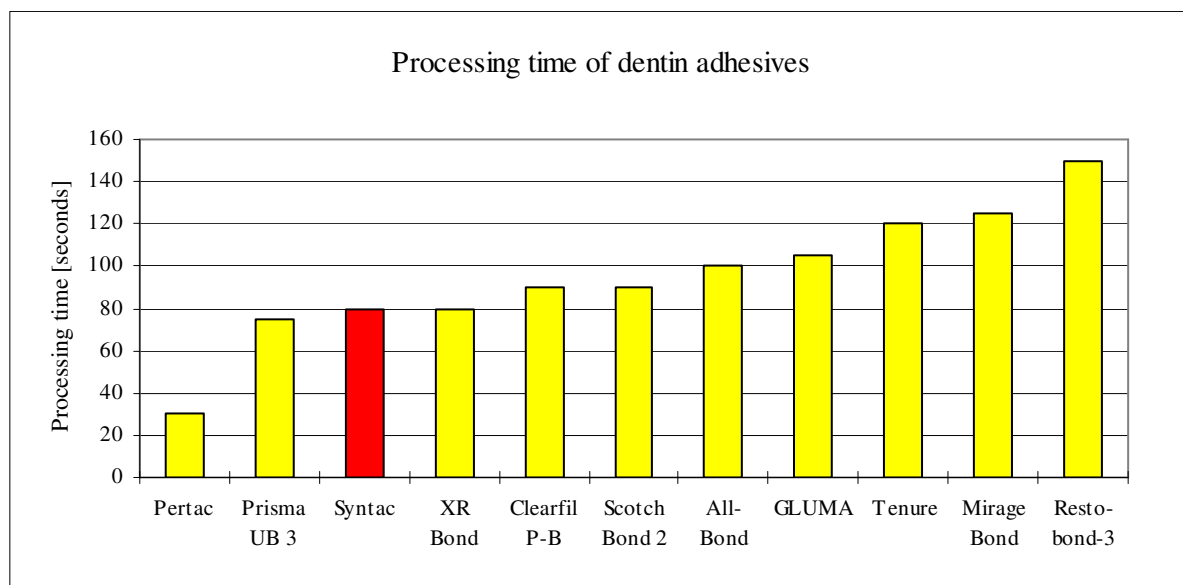
4.4. *Measurement of shade penetration as an indication of the marginal seal*



Haller et al., Dent Mater 8 (1993) 191-197

Conclusion: The marginal seal of Syntac was also examined by Crim et al., 1993. Syntac also showed the best sealing here. The influence of various storage conditions on the marginal seal of restorations affixed with adhesive was examined by Haller et al., 1993. Syntac demonstrated the best marginal seals.

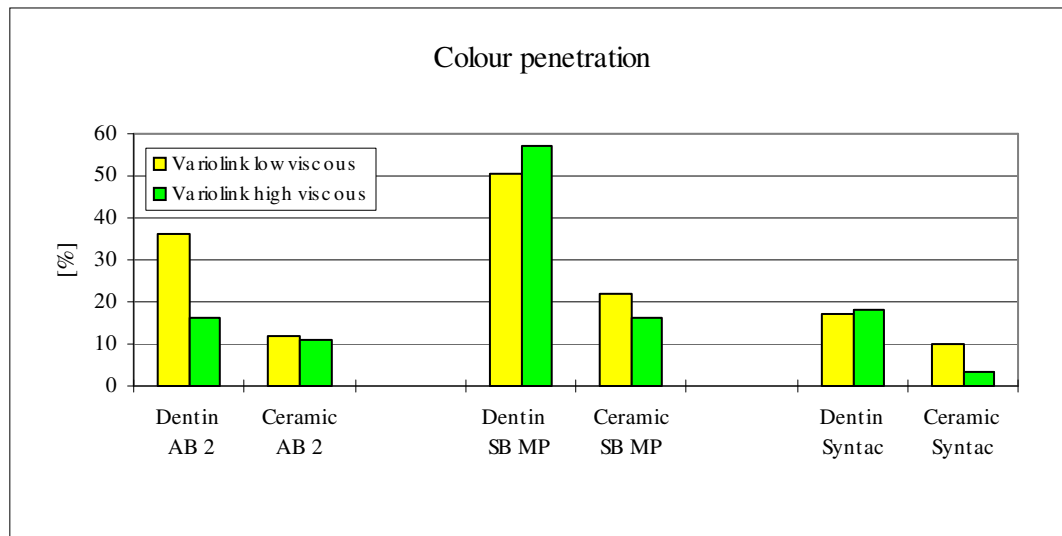
4.5. *Processing time of dentin adhesives*



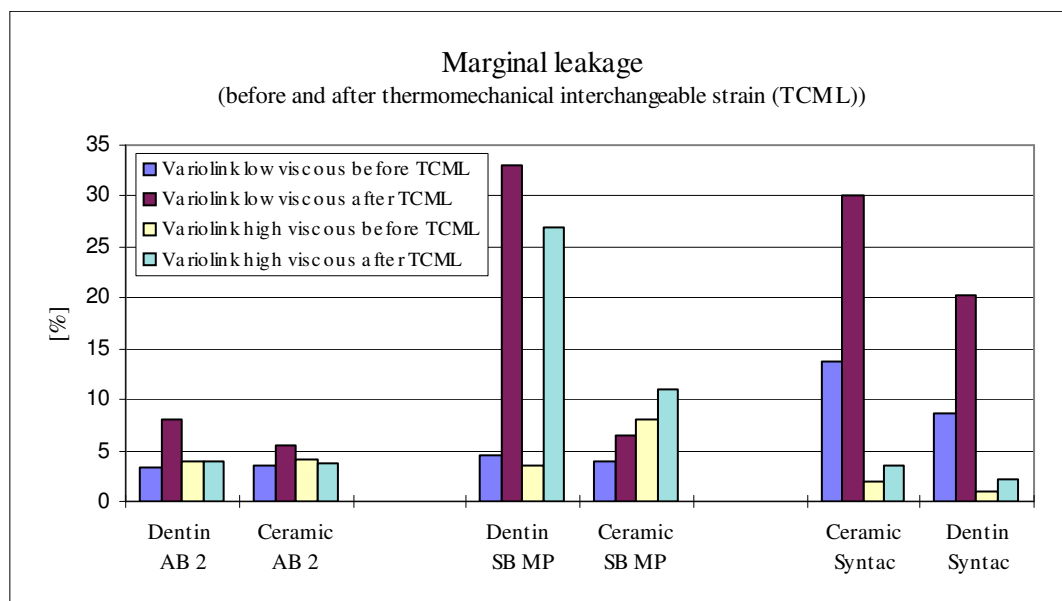
Johnson et al., J Am Dent Assoc 122 (1991) 34-41

4.6. Marginal seals of ceramic inlays with dentin adhesives

Syntac can be used for bonding indirect restorations as well as those that are direct.



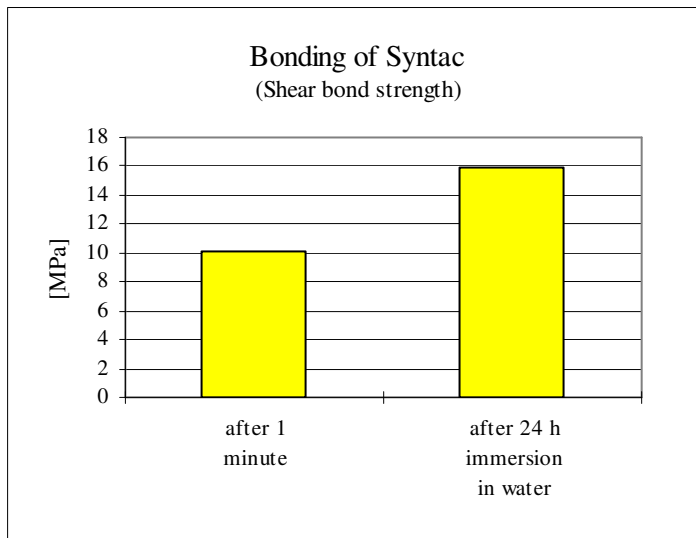
Thomemann et al., Dtsch Zahnärztl Z 49 (1994) 840 844



Thomemann et al., Dtsch Zahnärztl Z 49 (1994) 840 844

Conclusion: The best results in both tests were achieved by the combination Syntac/Variolink high viscous.

4.7. *Bonding regardless of time*



That bonding and a thick margin could be achieved is especially important, as the adhesive works so quickly, in order to counteract the shrinkage of the composite. If the adhesive bonds initially after the shrinking of the composite there is already leakage.

Retief et al., J Dent Res 71 (1992) 169

4.8. *Summary*

All scientific tests show that Syntac is a bonding system with extraordinary physical properties, which offer the dentist optimum prerequisites for the successful, durable restoration of teeth.

5. Clinical Studies

Syntac has proved itself successful in various clinical studies of up to four years conducted at European and American universities. The following table provides an overview of the clinical studies with Syntac. Subsequently, the most important studies and the results thereof are briefly summarized. Reference is given to the original literature to obtain further details.

	Duration	Head of study, place	Restoration examined	Special indications
5.1	4 years	Dr. Krejci, Dr. Oddera und Prof. Lutz University of Zürich, Switzerland	Syntac / Tetric	39 direct posterior restorations
5.2	4 years	Prof. Petschelt, Dr. Krämer, Dr. Frankenberger, Dr. Pelka University of Erlangen, Germany	Syntac / Empress	23 Onlays 73 Inlays
5.3	4 years	Dr. L. Pröbster University of Tübingen, Germany	Syntac / Empress	254 Inlays 49 Onlays
5.4	3 years	Dr. M. Fradeani Louisiana State University, USA	Syntac / Empress	144 crowns
5.5	3 years	Dr. Mazer und Prof. Leinfelder University of Alabama, USA	Syntac / Helio Progress	50 direct class V restorations
5.6	3 years	Dr. Loher, Dr. Mehl, Prof. Hickel University of Munich, Germany	Syntac / Tetric	33 direct class V restorations
5.7	1 years	Prof. Lasfargue Universite Paris V, F	Syntac / Tetric	30 direct class I 42 direct class II restorations

Overview of the clinical studies with Syntac

5.1. SEM and clinical study of Tetric/Syntac in posterior restorations

Head of study: Dr. Krejci, Dr. Besek and Prof. Lutz
Abteilung für Präventivzahnmedizin, Parodontologie und Kariologie
University of Zürich, Switzerland

Experimental setup: 39 conventional posterior restorations were placed with Tetric as the composite and Syntac as the adhesive. After 6, 12 and 48 months, the restorations were clinically evaluated with macrophotographs. Marginal analysis was taken of replicas in SEM.

Results: The results showed:

- 100 % were rated for highest to good clinical acceptability
- no restorations showed fractures after 48 months
- no recurrent caries after 48 months

Conclusion: The combination of Tetric/Syntac has proved to be clinically successful during 4 years.

- Publications: Krejci I, Besek M, Lutz F; Clinical and SEM study of Tetric resin composite in posterior teeth: 12-month results; Am J Dent 7 (1994) 27-30
- Boretti R, Krejci I, Lutz F; Clinical and scanning electron microscopic evaluation of fine hybrid composite restorations in posterior teeth after four years of wear; J Dent Res 76 (1997) 41

5.2. *Clinical evaluation of adhesively (Syntac) placed inlays and/or onlays in non-enamel-bordered teeth*

- Head of study: Prof. Petschelt, Dr. Krämer, Dr. Frankenberger, Dr. Pelka
Poliklinik für Zahnerhaltung und Parodontologie
University of Erlangen-Nürnberg, Germany
- Objective: Clinical evaluation of adhesively (Syntac) placed IPS Empress restorations in non-enamel-bordered teeth. Furthermore, the abrasion of IPS Empress restorations, the cementation joint, and the antagonist teeth were evaluated.
- Experimental setup: Twenty-three onlays with cusp reconstruction and 73 Class II inlays were adhesively placed (etching technique and dentin conditioning with Syntac; Tetric, Dual Cement, Variolink low, or Variolink Ultra were used as the luting composite).
- Results: After four years, only seven of the 96 restoration (7%) had to be replaced. Ninety percent of the restorations were "in good condition".
- Conclusion:** The fact that enamel is missing does neither influence the bonding strength nor the quality of the marginal gap. When used in combination with Syntac, IPS Empress inlays/onlays are clinically sound, even in severely damaged teeth.
- Publications: Krämer N, Frankenberger G, Dettenhofer J, Ebert M, Pelka M, Petschelt A; Clinical Evaluation of Ceramic Inlays and Onlays after Four Years; J Dent Res 76 (1997) 271
- Pelka M, Teinelt C, Krämer N, Fassbender U, Petschelt A; In-vivo-Abrasion bei IPS Empress Inlays; Dtsch Zahnärztl Z 50 (1995) 917-919
- Internal report for Ivoclar-Vivadent

5.3. *Clinical evaluation of adhesivly cemented IPS Empress inlays, onlays and crowns*

- Head of study: Dr. L. Pröbster
Abteilung für Prothetische Zahnheilkunde
University of Tübingen, Germany
- Objective: Clinical evaluation of the survival rate of adhesively placed IPS Empress inlays, onlays, and partial crowns in the posterior region.
- Experimental setup: After enamel etching, 254 posterior inlays and 49 posterior onlays or partial crowns were seated with Syntac, Dual Cement, or Variolink and Monobond S (all Vivadent, Schaan, Liechtenstein) in 50 patients.

- Results:** Calculated according to Kaplan-Meier, the survival rate after 41 months was $94 \pm 0.7 \%$. Postoperative sensitivity occurred in less than 1 % of all restorations. Within 41 months, a total of 4 fractures occurred.
- Conclusion:** Syntac/IPS Empress is excellently suitable for single restorations in the posterior region. Dentin conditioning seems to be an appropriate measure to prevent postoperative sensitivity.
- Publications:** Pröbster L, Ulmer HJ, Engel E; Four-year survival rate study of IPS Empress restorations; DGZPW (1996) 59
 Pröbster L; Clinical Experiences with the In-Ceram and IPS Empress Full Ceramic Restorative Systems; Budapest 1 (1992) 1

5.4. *Clinical evaluation of adhesivly cemented (Syntac/Variolink) IPS Empress crowns*

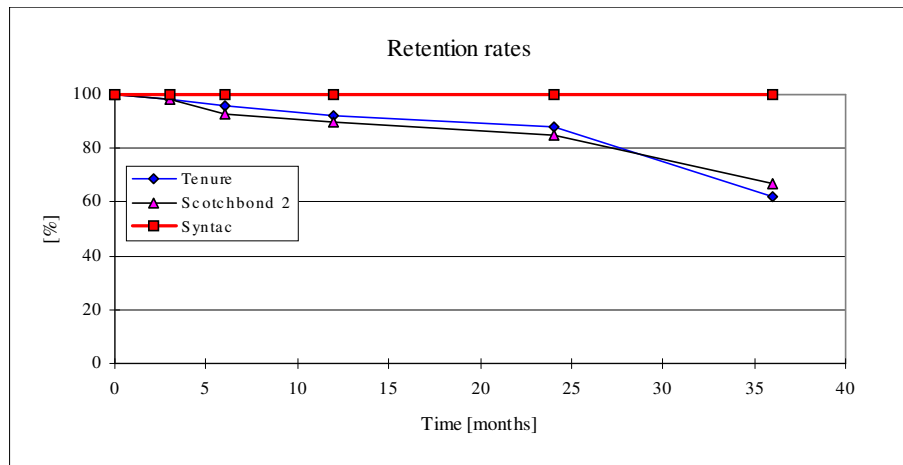
- Head of study:** M. Fradeani, MD DDS
 Special Lecturer, Department of Prosthodontics
 Louisiana State University, USA
- Objective:** Clinical evaluation of adhesivly cemented (Syntac/Variolink) IPS Empress crowns.
- Experimental setup:** One hundred and one anterior, 28 premolar, and 15 molar crowns were evaluated after an average of 37 months in-situ according to modified USPHS criteria.
- Results:** The estimated survival rate (Kaplan Meier) is 95.35 % after almost six years. Not more than 5 fractures occurred, two of which involved the composite bonding agent. In the other three cases, the minimum wall thickness of 1.5 mm had not been observed.
- Conclusion:** IPS Empress together with Syntac and Variolink is excellently suitable for the crown technique. The instructions of the manufacturer have to be observed.
- Publications:** Fradeani M, Aquilano A; Clinical Experience with IPS Empress Crowns; Int J Prosthodont 10 (1997) 241-247

5.5. *Clinical evaluation of Helio Progress / Syntac for restoration of class V defects*

- Head of study:** Dr. Mazer und Prof. Leinfelder
 Department of Biomaterials
 University of Alabama, USA
- Experimental setup:** 50 teeth with cervical erosions were restored with class V restorations. All mechanical retainers or pretreatments with tooth enamel were avoided. The restorations with Helio Progress (Vivadent) were affixed with Syntac. The restorations were critically evaluated immediately after the treatment, three months, six months, one year, two years, and three years later according to the USPHS method.

Results: The result of the three-year study can be summarized as follows:

- three years later, 100% of the restorations were in situ
- all restorations were still intact three years later and 93% showed no leakage
- 90 % of the margins showed no stain
- no irritation of the pulp occurred during the whole time



Conclusion: After 3 years Helio Progress/Syntac performed clinically extremely well.

Publications: Mazer RB, Cury C, Teixeira L, Leinfelder K; Influence of maleic acid on the retention of abraded lesion restorations; J Dent Res 73 (1994) 275

5.6. *Investigation of clinical suitability of different restorative materials for class V defects*

Head of study: Dr. Loher, Dr. Mehl, Prof. Hickel
University of Munich, Germany

Objective: Investigation of clinical suitability of different restorative materials for class V defects

Experimental setup: In 37 patients a total of 197 fillings were placed. The teeth were randomly assigned to four groups for filling either with Tetric/Syntac, Dyract, Fuji II LC or Photac Fil. The restorations were reevaluated in accordance to USPHS system at 8, 15, 24 and 36 months after placement.

Results:

	clinical acceptable (total of α and β)
Tetric/Syntac	93.0 %
Dyract	83.3 %
Fuji II LC	66.7 %
Photac Fil	60.0 %

Conclusions:

After a period of 3 years the clinical study demonstrates superior quality of Tetric/Syntac and Dyract class V restorations in comparison to the fillings with light curing glass ionomer cements.

Publications:

Loher C, Kunzelmann KH, Hickel R; klinische Studie mit Hybrid-ionomerzement-, Kompomer- und Kompositfüllungen in Klasse-V-kavitäten; Dtsch Zahnärztl Z 52 (1997) 8

Folwaczny M, Loher C, Mehl A, Benz C, Hickel R; Class V fillings with four different light curing materials: three years results; J Dent Res 77 (1998) 190

5.7. Clinical performance of Tetric/Syntac in class I and II defects**Head of study:**

Prof. Lasfargues
University of Paris V, France

Objective:

Investigation of clinical performance of Tetric/Syntac in class I and II defects

Experimental setup:

72 Tetric restorations were placed with the adhesive Syntac (total etch technique) to restore class I and II defects in 36 patients. After 12 months the restorations were evaluated by radiography, intra-oral direct examination and indirect replicas observations.

Results:

After 12 months all restorations were present without loss, fracture or other failures. According USPHS criteria, the large majority after restorations were scored *Alpha*.

The average occlusal loss of the replicas were ranked in the category of $\leq 25 \mu\text{m}$.

Publications:

Lasfargues J, Bonte E, Bnebot D, Pujol F, Bachelard B; Clinical performance of a microhybrid posterior composite resin restorative material: a one-year clinical report; J Dent Res 76 (1997) 1117

5.8. Summary

Syntac enables the achievement of perfect margins in the dentin and enamel, guarantees a high rate of retention, hinders post-operative sensitivity and can effectively protect the pulp from bacterial infection. Syntac is probably the adhesive with the longest term clinical experience still on the market today.

6. Toxicological Data

Syntac consists of a primer, an adhesive, and a bonding agent. The adhesive of Syntac contains 5% glutaraldehyde, for which there is a known toxicological potential.

6.1. Toxicity of glutaraldehyde

The toxicity of glutaraldehyde is known and has been well examined (summary article of O. Beauchamp, 1992).

6.2. Toxicity of Syntac

In the correction application, the adhesive is applied to the pretreated dentin, whose open collagen fibres are on the surface. The amino groups of the collagen fibres react with glutaraldehyde molecules in an N-(hydroxyalkyl)-bond that then further reacts with the acrylate under dehydration to O, N-Acetal (Munksgaard and Asmussen, 1987). This procedure is extremely fast and bound with a polymerization of glutaraldehyde monomers, which includes a large number of free glutaraldehyde molecules (Nimni et al., 1987). The fixation of collagen fibres by glutaraldehyde is irreversible and endangerment through bonded glutaraldehyde is thus excluded (Hopwood, 1970). How far this reaction includes all glutaraldehyde molecules can not be evaluated.

The diffusion of glutaraldehyde molecules in the dentin is especially slow (diffusion of 2% glutaraldehyde solution in dentin requires more than a week for a distance of 200 µm (Wemes et al., 1982). Watson and Wilmot, 1992 have examined the interphase between Syntac and the tissue of the tooth. It showed that the adhesive was only diffused in the direction of the pulp extremely little (< 30 µm). Possibly free glutaraldehyde molecules diffuse only very slowly through the dentin to the pulp, where they produced a mutagene effect on the living cells. On the way to the pulp, the diffusing molecules were extremely thin (up to 25,000 times, personal communication, Dr. Bouillaguet, School of Dental Medicine, Geneva, Switzerland).

The amounts involved are extremely small. In an application a maximum 20 mg of each component is applied, i.e. for glutaraldehyde max, 1 mg, normally only 0.1 mg.

In an unprofessional application of Syntac, the adhesive fluid can come in contact with oral mucosa. When this contamination is immediately treated with water (glutaraldehyde is soluble in every relationship with water) there are no damages to tissue. If, however, unforeseen contaminations of the mucosa occur, they can lead to local tissue damage. The data on acute oral toxicity with rats range from 250-2400 mg/kg. This range is based on the fact that glutaraldehyde is especially aggressive in the alkali region (pH > 7.5), whereas the low toxicity values for tests in the weak acid area were observed. As the formulation to be evaluated has a pH value of 3.0, the upper LD-50 region (low toxicity) is determinative in this case.

Syntac was examined in vivo at various universities and was observed in all studies to have extremely low post-operative sensitivity, as well as a good marginal seal.

- Krejci & Lutz, Zürich, Switzerland
- Leinfelder, Alabama, USA
- Petschelt & Krämer, Erlangen, Germany

6.3. *Pharmacological-toxicological professional expertise*

A toxicological expertise from Dr. R. Leimgruber, RCC, Switzerland, confirms Syntac as justified general preparation for the use foreseen.

6.4. *Histology*

Farmer et al., (1992) have tested the histological compatibility of Syntac. In three days, there was no pulp reaction observed, or only an extremely small one, which came from the operative trauma of cavity preparation - and not from Syntac. On the basis of observing the pulpa more than 80 days, the authors exclude irritation of the pulp by Syntac.

6.5. *Summary*

The toxicity of Syntac can with correct application be considered extremely low, as:

1. The amounts used is very small;
2. The glutaraldehyde reacts with the collagen;
3. Eventual excess are hardly diffused, and are greatly thinned during diffusion;
4. Accidental contamination can be easily removed with water.

6.6. Literature

Hopwood D

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