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ExciTE® F DSC



Scientific Documentation

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Table of Contents

1. Introduction 3
1.1 From ExciTE DSC to ExciTE F DSC 3
1.2 Properties 4
2. Technical Data 6
3. Material Science Investigations (*in vitro*) 7
3.1 Introduction 7
3.2 Shear bond strength 7
3.3 Bond strength in combination with root canal systems 9
3.4 Shear bond strength in combination with core build-up materials 10
3.5 Microleakage 11
3.6 The effect of the curing mechanism on the bond strength 12
4. Clinical Investigations (*in vivo*) 13
4.1 Introduction 13
4.2 Clinical trial of fibre posts luted with self-curing ExciTE DSC in combination with an experimental resin cement 13
4.3 Ivoclar cementation clinical trial 13
4.4 Clinical trial of Empress 2 inlays luted to vital abutments with self-curing ExciTE DSC and a self-curing resin cement 13
4.5 Empress inlays and overlays cemented with ExciTE DSC (self-cure or light-cure) and an experimental luting composite 14
4.6 Conclusion 14
5. Biocompatibility 14
6. Literature 15

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1. Introduction

Dentin adhesives enable exposed dentin surfaces to be sealed and thus prevent movement of fluid in the dentin tubules and reduce hypersensitivity caused by fluid movement. The adhesive bonding of composite materials to dentinal tissue allows minimally invasive preparation techniques to be used without having to provide mechanical retention. The combination of adhesives and modern composite materials produces highly esthetic restorations that are virtually indiscernible from the natural tooth structure at speaking distance. Tight margins without transitions and flexibility in the design of the preparation play a decisive role in this respect.

In an effort to streamline the application protocol, ever more one-bottle adhesives are available on the market. However, the dual-curing adhesives derived from these products usually continue to be two-bottle systems that are composed of the original, light-curing adhesive component and a catalyst liquid containing the chemical initiator components in a solvent. The dual-curing (light- and self-curing) adhesive solution is produced by mixing the two liquids.

These adhesives entail a few disadvantages. For instance, mixing and dosing errors may occur with them. Furthermore, the adhesive may become diluted by the activator liquid. In this case, the concentration of the functional monomers in the adhesive solution is reduced, which may inhibit the sealing and bonding properties of the adhesive.

Generally, these adhesives must be pre-cured with light to initiate polymerization. Consequently, excessively thick layers of the adhesive may be cured by accident and the accuracy of fit of the restoration may, as a result, be impaired. Furthermore, pre-curing with light is not feasible in some applications (e.g. root canals).

1.1 From ExciTE DSC to ExciTE F DSC

Light-curing adhesives can only be applied in situations that ensure sufficient access of light. For this reason, the dual-curing ExciTE F DSC version is offered alongside the purely light-curing ExciTE F for the insertion of root canal posts and for core build-ups with dual- or self-curing core build-up materials.

ExciTE F DSC is the successor product of ExciTE DSC. The new material contains a fluoride source, which allows the release of fluoride. Like its predecessor, ExciTE F DSC is a dual-curing adhesive for enamel and dentin bonding and is used in combination with the total etch technique (also known as etch-and-rinse technique).

Problems related to the limitations of earlier dual-curing adhesives were already overcome in the development of the original ExciTE DSC adhesive. The dual-curing adhesive version is based on the proven technology of purely light-curing products. However, it is somewhat less viscous to keep the layer thickness to a minimum when the material is applied for its main indication, i.e. cementation. The adhesive is supplied with a pre-mounted applicator brush which is especially coated with the initiators responsible for the self-curing action. The initiators contained in the coating are prerequisite for the dual-curing mechanism. They are dissolved upon contact with the adhesive liquid and upon application of the adhesive onto the tooth structure.

In addition, the self-curing mechanism of ExciTE F DSC requires an initiator component from a relevant dual- or self-curing core build-up material or luting composite to become effective. Only upon contact with this initiator is the self-curing process initiated.

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Fig. 1, 2: SEM images of a coated applicator in various scales of magnification

ExciTE F DSC is available in two applicator designs to suit different indications. The light-blue "regular" ExciTE F DSC applicator is suitable for standard preparations and the dark-blue “small/endo” applicator is designed for microcavities and root canals:



ExciTE F DSC can also be light-cured. If the adhesive is used in combination with light-curing materials (e.g. composites), light-curing is mandatory, as ExciTE F DSC does not cure by itself without exposure to light.

1.2 Properties

ExciTE F DSC is suitable for application in combination with light- and self-curing materials. As dual-curing single-component adhesive, it is characterized by the following properties:

- **Application in a single layer with a specially coated applicator**
  - → Easy, fast application
  - → Dilution of the adhesive by additional initiator liquid is prevented
  - → No mixing up of bottles and solutions
- **Suitable for direct and indirect restorations**
  - → Adhesive cementation of indirect, metal-free, translucent restorations with a dual- or self-curing luting composite (e.g. Variolink® II)
  - → Direct restorations and core build-ups with dual- or self-curing composites

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→ Direct restorations with light-curing composites (e.g. Tetric EvoCeram®)

- **Pre-polymerization with light is not necessary if the adhesive is used in conjunction with self- or dual-curing composites**

  → Accuracy of fit of the restoration is ensured

- **Single-dose delivery form for single use**

  → Pre-mounted coated applicator on single-dose vessel

  → Hygienic

  → Fresh material for each application

- **Nanofillers**

  → Optimum viscosity and layer thickness

  → Visible glossy layer during application

- **Phosphonate-based adhesive monomer**

- **High volume percent of hydrophilic monomers**

- **Acetone-free chemical composition**

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2. Technical Data

Standard composition		**(in wt%)**
Adhesive	Phosphonic acid acrylate, dimethacrylates, Hydroxyethyl methacrylate	72.0
	Highly dispersed silicon dioxide	0.5
	Ethanol	24.5
	Catalysts, stabilizers, fluoride	3.0
Applicator	Coated with initiators	

Physical property:

Shear bond strength on dentin	> 17 MPa

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3. Material Science Investigations (*in vitro*)

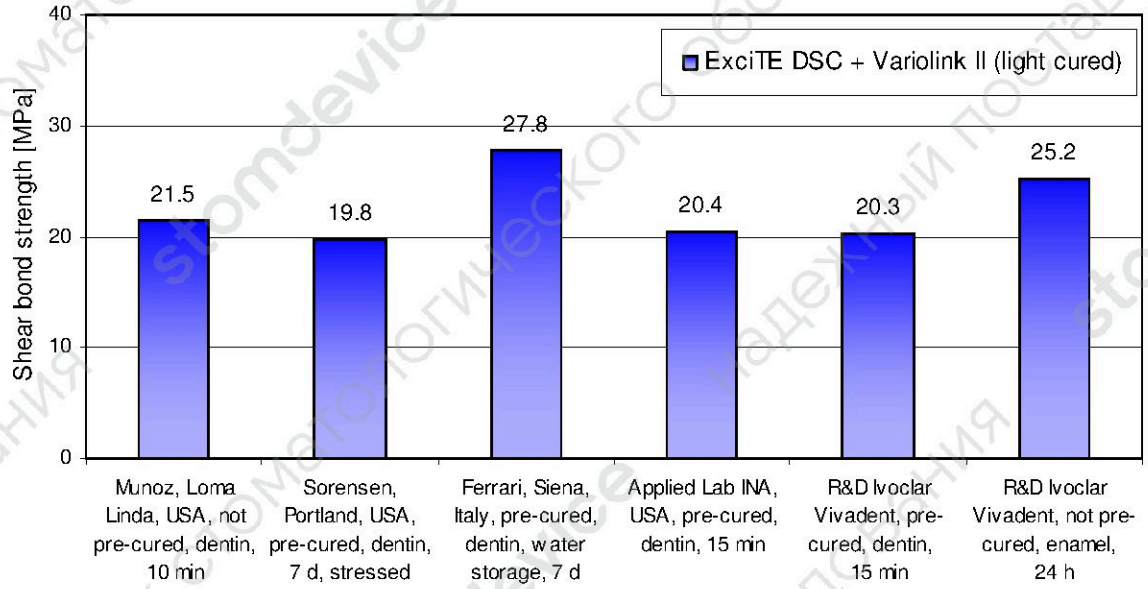
3.1 Introduction

ExciTE F DSC is the successor product of ExciTE DSC and contains a fluoride source, which enables the adhesive to release fluoride. Apart from this feature, the compositions of the two materials are identical and both products show a comparable performance as indicated by internal data. It is therefore reasonable to assume that the external data gathered on ExciTE DSC also apply to ExciTE F DSC.

3.2 Shear bond strength

To test the bond strength, composite test samples are bonded to ground smooth dentin and mounted on a universal testing machine to measure the shear bond strength.

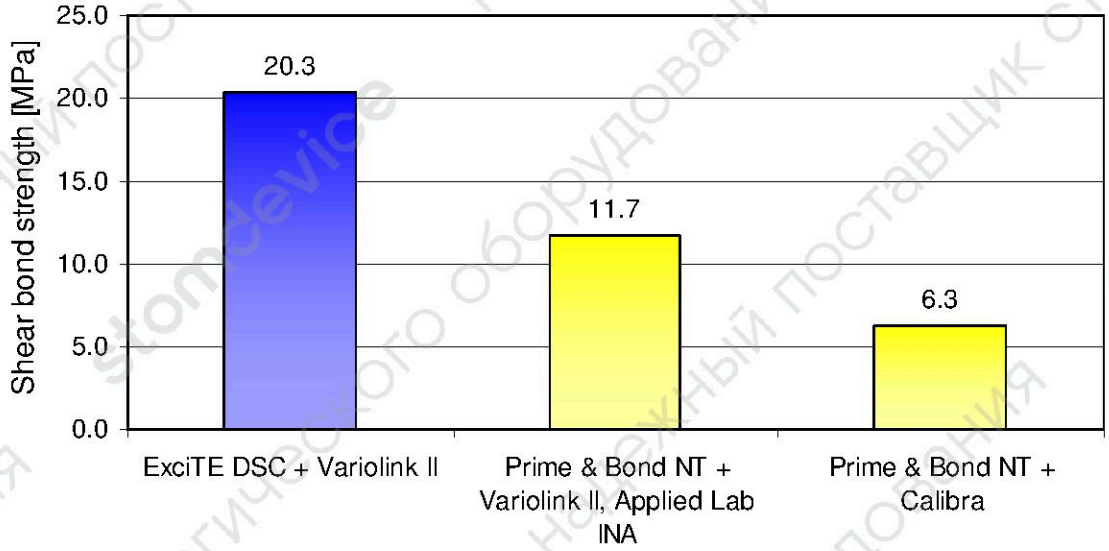
The bar chart below shows the shear bond strength values of bonding agent/luting composites in combination with ExciTE DSC/ Variolink II on dentin and enamel as measured and summarized by different test centres. Different examiners tested the shear bond strength of ExciTE DSC under different conditions. The results were found to be very good.



ExciTE DSC produced similarly favourable results in all test centres. The bond strengths measured are at least comparable to those of competitive adhesives.

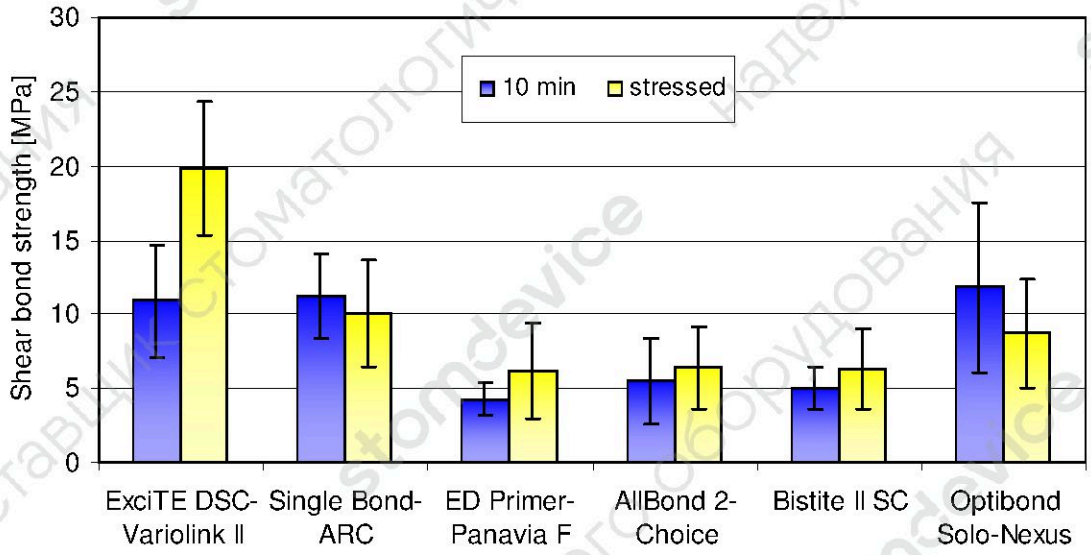
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R&D Ivoclar Vivadent, Schaan, Liechtenstein and Amherst AppliedTesting Center, Ivoclar Vivadent North America

The bar chart above compares the shear bond strengths after 15 minutes of the following materials: ExciTE DSC with Variolink II, Prime & Bond NT with Variolink II and Calibra. The shear bond strengths were measured on dentin after 15 minutes and with pre-cured bonding agents. The combination of ExciTE DSC with Variolink II achieved the best performance.

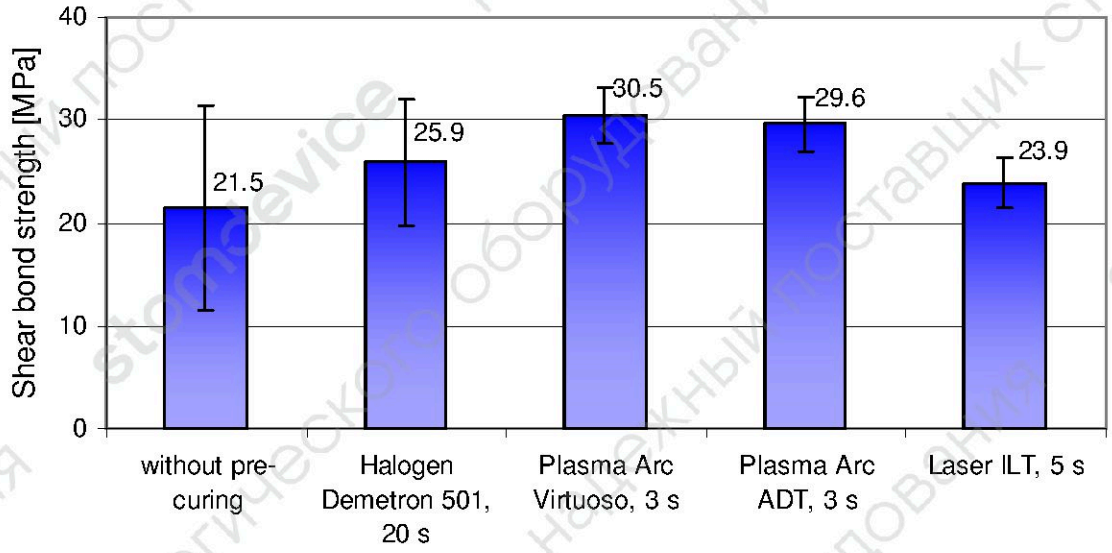


Sorensen JA, et al., J Dent Res 80 (2001) 102

The dentin bond strengths of various dentin adhesives and cementation systems (pre-cured adhesive) after 15 minutes as well as after 7 days of immersion in water at 37°C and subsequent thermal cycling (1000x 0°C-55°C), above shown as "stressed", were evaluated at the University of Oregon. The combination of ExciTE DSC and Variolink II achieved impressive results in the stress test in particular.

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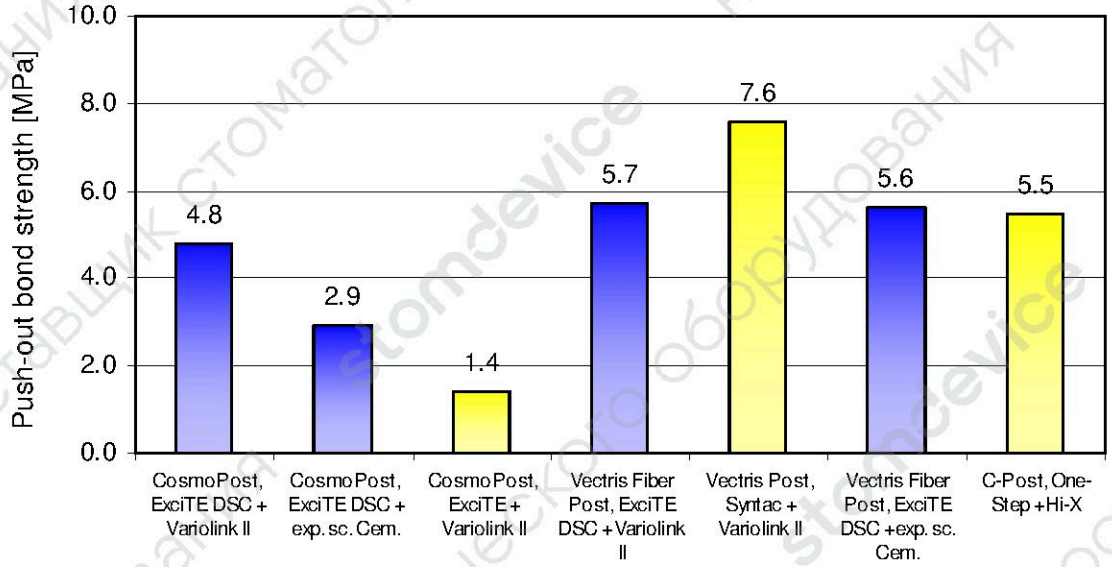


Dr Munoz, Loma Linda University, USA

The effect of different curing lights and times on the dentin bond strength of ExciTE DSC and Variolink II (light-cured) was investigated at the Loma Linda University, USA. Excellent bonding results were achieved irrespective of the curing light or exposure time chosen.

3.3 Bond strength in combination with root canal systems

The root retention of different esthetic posts in endodontically treated natural teeth was determined by means of a push-out test.

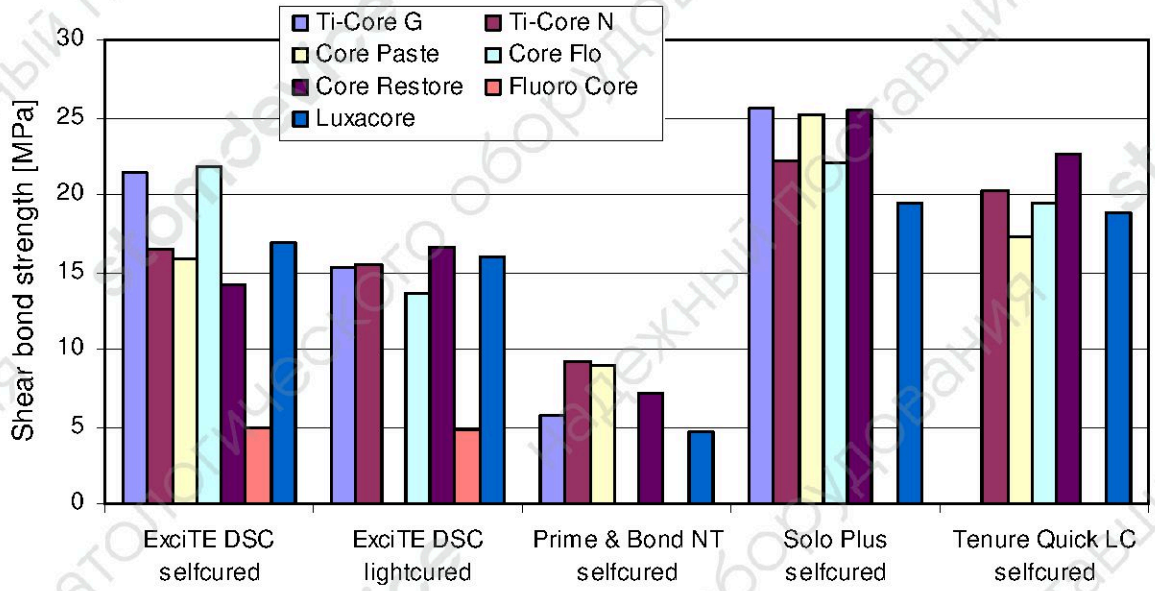


Dr Perdigao, University of Minnesota, USA

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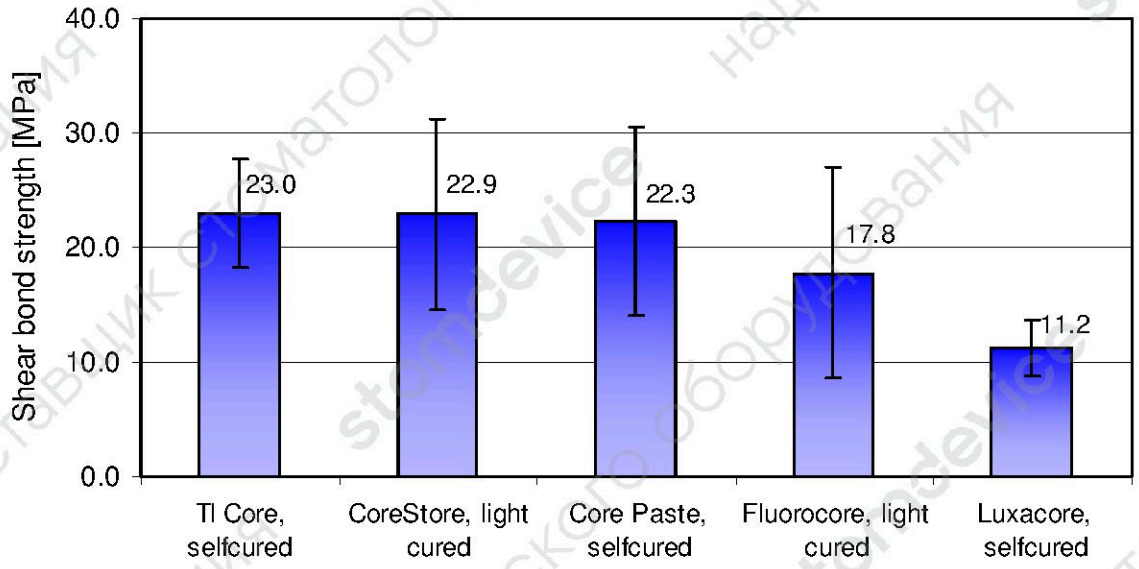
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3.4 Shear bond strength in combination with core build-up materials



Dr Munoz, Loma Linda University, USA

The effect of different adhesives on the shear bond strength (after 10 minutes) of several core build-up composites was examined by Dr Munoz, Loma Linda University. The composites were not cured with light.



Amherst Applied Testing Center, Ivoclar Vivadent North America

The shear bond strength of ExciTE DSC (self-cured) in combination with different core build-up composites is shown in the above bar chart.

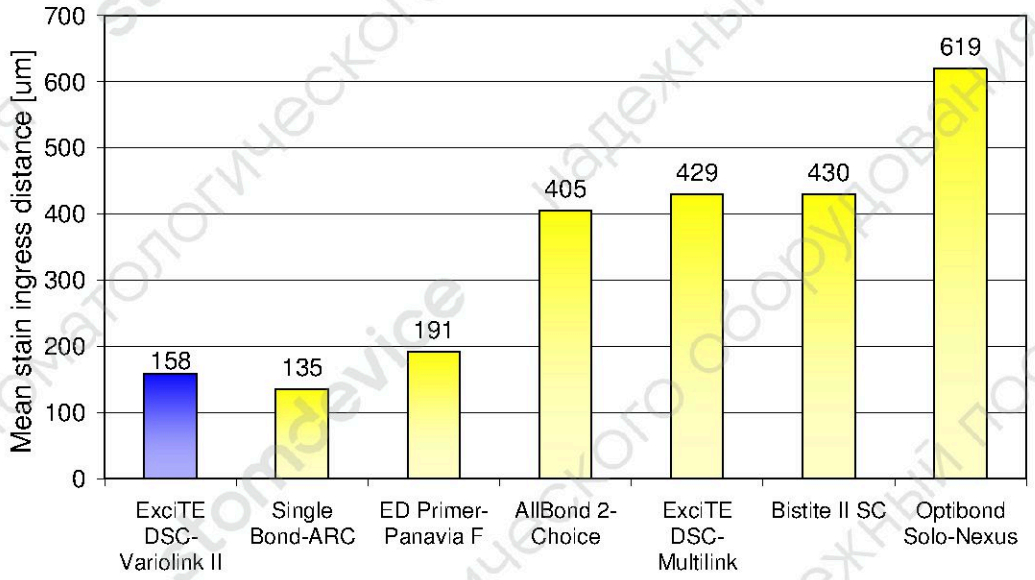
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3.5 Microleakage

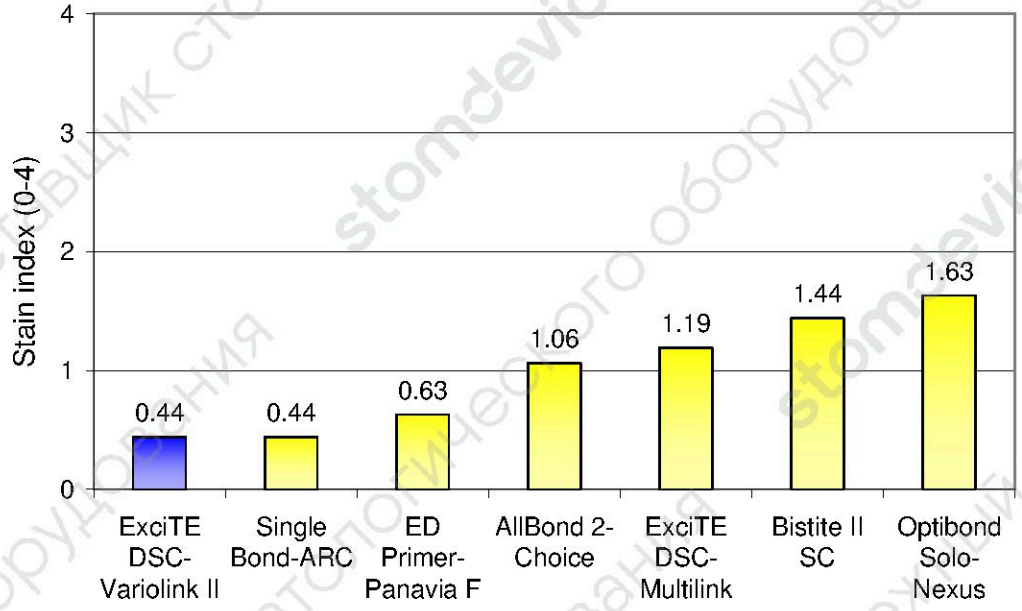
Leaking margins encourage microleakage. Microleakage is defined as a clinically imperceptible passage of microorganisms, fluids and molecules between the tooth and the restorative material applied to it (Kidd, 1976). Leaking restorative margins may cause sensitivity, marginal discolouration and secondary caries.

At the University of Oregon, Dr Sorensen examined the marginal seal of various adhesive/luting composite systems after the cementation of ceramic inlays using stain ingress testing. The adhesives were light cured.



Sorensen JA, et al., J Dent Res 80 (2001) 102

The graph below shows the stain index (0 to 4) of the combinations of materials shown above. ExciTE DSC and Variolink II show a close-to-perfect marginal seal.



Sorensen JA, et al., J Dent Res 80 (2001) 102

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3.6 The effect of the curing mechanism on the bond strength

An investigation was carried out to determine if the curing mechanism (light- or self-curing) affects the bond strength. For this purpose, ExciTE F DSC was used in combination with MultiCore Flow on bovine dentin.

Curing mechanism	Bond strength [MPa]	Type of fracture
ExciTE F DSC (LC) + MultiCore Flow (SC)	21 ± 4.9	cohesive: 5/5, adhesive: 5/-
ExciTE F DSC (SC) + MultiCore Flow (SC)	21 ± 6.3	cohesive: 5/5, adhesive: 5/-
ExciTE F DSC (LC) + MultiCore Flow (LC)	22.5 ± 3.6	cohesive: 5/5, adhesive: 5/-

LC = light-curing, SC = self-curing

As can be seen in the above table, a significant effect on the dentin bond strength was not observed. Moreover, all fractures were cohesive, suggesting that the bond between dentin, adhesive and composite is more stable than the bond within the dentin.

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4. Clinical Investigations (*in vivo*)

4.1 Introduction

The composition of ExciTE F DSC and ExciTE DSC are identical, except for the fact that ExciTE F DSC includes an additional source of fluoride. Consequently, the results of the clinical studies conducted on ExciTE DSC also apply to ExciTE F DSC.

Clinical studies were conducted at the in-house clinic of Ivoclar Vivadent as well as at various European and American universities. The clinical results confirm the favourable results of the *in vitro* investigations.

4.2 Clinical trial of fibre posts luted with self-curing ExciTE DSC in combination with an experimental resin cement

Dr M. Ferrari, University of Siena, Italy

Forty FRC Postec posts were placed using ExciTE DSC and an experimental self-curing luting composite.

Results after 12 months

Periapical lesion:	4 %
Retention:	100 %
Marginal seal:	96 %
Marginal adaptation:	96 %
Shade stability:	100 %
Surface discoloration:	4 %
Surface microcracks:	0 %

4.3 Ivoclar cementation clinical trial

Dr J.A. Sorensen, University of Oregon, USA

In the course of this study, sixteen all-ceramic restorations (crowns and bridges), among others, were cemented using ExciTE DSC and Variolink II. After two weeks, two patients were diagnosed with postoperative sensitivity.

4.4 Clinical trial of Empress 2 inlays luted to vital abutments with self-curing ExciTE DSC and a self-curing resin cement

Dr M. Ferrari, University of Siena, Italy

In this clinical study, the marginal quality of the self-curing bonding/cementation system ExciTE DSC and an experimental luting composite was examined and the results were compared with those achieved with ExciTE LC and Variolink II.

Results after 6 months

Postoperative sensitivity:	0 %
Retention:	100 %
Marginal seal:	100 %
Marginal adaptation:	100 %
Shade stability:	100 %
Surface discoloration:	0 %
Surface microcracks:	0 %

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4.5 Empress inlays and overlays cemented with ExciTE DSC (self-cure or light-cure) and an experimental luting composite

Ivoclar Vivadent Clinic, Liechtenstein

IPS Empress inlays and overlays were seated in eight patients using ExciTE DSC in combination with an experimental self-curing cement. The clinical reliability of ExciTE DSC was confirmed for both application techniques (self-curing and light-curing).

4.6 Conclusion

The studies on ExciTE DSC have shown that unjustifiable side effects or risks did not occur in clinical situations and the material can be successfully used for clinical applications. It is reasonable to assume that the same is true for ExciTE F DSC due to the comparability of these two materials. On the basis of the currently available data and the current level of knowledge, ExciTE F DSC does not involve an increased risk for patients and is suitable for clinical application if it is used for its intended use.

5. Biocompatibility

ExciTE F DSC contains ingredients that are known to be used in dental materials.

On the basis of the existing data on toxicology as well as the long-term clinical experience with comparable products and the current level of knowledge, it can be assumed that the application of ExciTE F DSC for the intended indication is justified. There is no indication of an increased or unacceptable risk for patients.

As most composite-based dental materials, ExciTE F DSC contains methacrylate and acrylate derivatives. In rare cases, these ingredients may cause a sensitizing reaction. This may cause allergic contact dermatitis. These reactions can be prevented by clean working conditions and by avoiding skin contact with the uncured material. Commercially available medical gloves do not provide effective protection against the sensitizing effect of these ingredients.

The Instructions for Use should be strictly followed. ExciTE F DSC does not involve a risk if it is used correctly and in accordance with the Instructions for Use. Dentists and their staff are not at an increased risk if they use ExciTE F DSC in comparison with existing practice, as the working techniques used with these materials are part of the state of the art.

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