



**FRC Postec<sup>®</sup> Plus**

Glass-fibre-reinforced composite posts

## Scientific Documentation

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## 1. Introduction

### 1.1 Origin and function of post-retained restorations

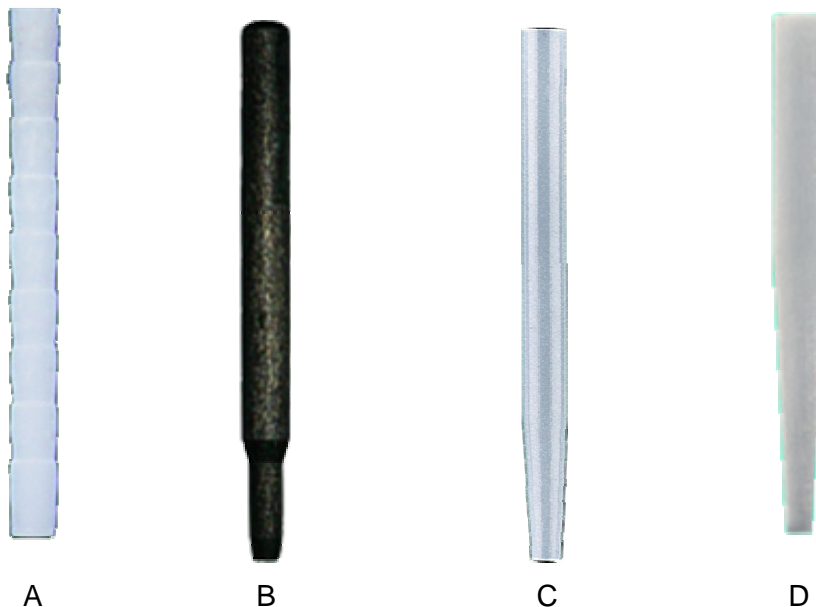
Post-retained restorations ("pin tooth" prostheses) were first fabricated at the beginning of the 20th century. At the time, root canal preparations were encircled with a gold band to balance out the pressure exerted on the root canal walls. This measure was supposed to prevent possible fractures of the root structure.

Root canal posts are used in endodontically treated non-vital teeth that demonstrate extensive coronal damage. This type of therapy is called post-endodontic treatment. While in the early days of endodontic treatment, root canal posts were thought to reinforce the pre-treated root canal structure, in our day root canal posts are regarded to provide a firm and reliable anchor for the core build-up. Teeth that show only minimal or moderate loss of tooth substance and offer enough remaining tooth structure for retention can be reconstructed with direct composites (e.g. Tetric EvoCeram) or, if necessary, core build-up materials (e.g. MultiCore) and indirect restorations. A root canal post is required if severe destruction of the coronal tooth structure is present.

## 2. Root canal post systems

Basically, a distinction is made between custom-made and prefabricated post build-ups. Custom-made build-ups are generally only used in indirect applications and most of them consist of cast dental alloys.

Prefabricated root canal posts can be categorized into active posts (screw posts) and passive posts. They can also be classified according to their geometrical shape. The following post shapes are available: cylindrical (A), two-stage cylindrical (B), cylindro-conical (C) and conical (D). Conical posts follow the taper of the natural root canal. In addition, the conical shape enables the luting material to flow more easily to the coronal region of the tooth.



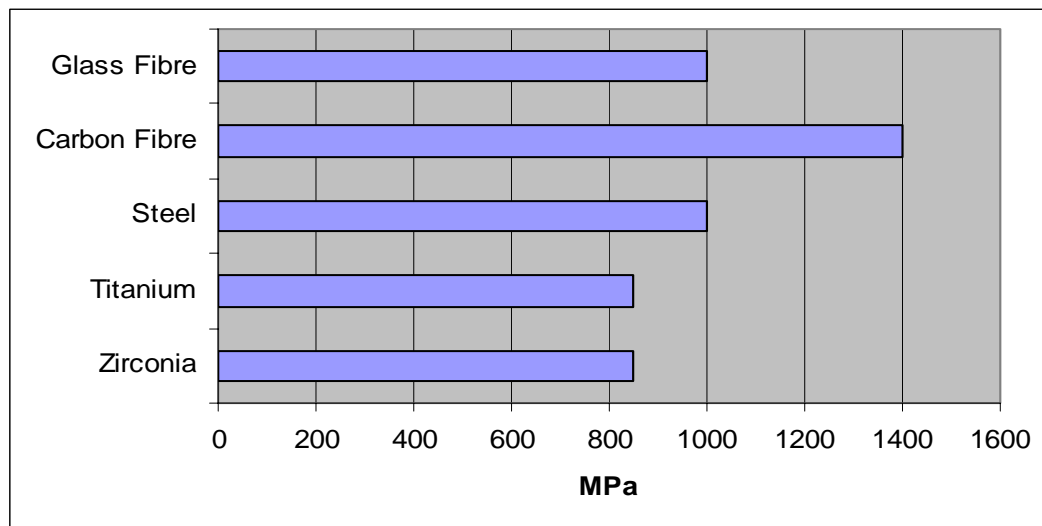
Geometrical shape of various root canal posts

Until recently, root canal posts have been made of stainless steel or titanium. As composite and ceramic materials are increasingly employed in the core build-up, aesthetic considerations have started to have an impact on the choice of the post material. Dark metal posts shine through composites and translucent ceramic materials, compromising the natural appearance of the restoration. This has led to the introduction of posts made of ceramic or fibre-reinforced composite.

Ceramic posts and zirconium oxide ceramic posts in particular exhibit a higher modulus of elasticity than composite posts. If force is applied at an angle of 45° to the axis of the composite fibres, the modulus of elasticity of glass fibre-reinforced composites is very similar to that of root dentin. Ceramic and metal posts are prone to causing canal wall fractures due to the difference in the elasticity between these materials and the natural dentin. As composite materials exhibit a modulus of elasticity that is very close to that of dentin, they hardly exert any stress on the tooth structure and consequently help prevent root canal fractures from occurring.

Root canal post material	Advantages	Disadvantages
Metal and metal alloys	Favourable mechanical properties Radiopacity	Unsatisfactory optical results Corrosion marks and deposits of decomposition products in the surrounding soft tissues High degree of rigidity
Titanium alloy	Favourable mechanical properties Good biocompatibility Radiopacity	Poor optical properties High degree of rigidity
Carbon fibre-reinforced composite	Easy to process Elasticity similar to dentin Easy to remove	Poor aesthetic properties Poor radiopacity
Glass fibre-reinforced composite	Favourable aesthetic properties Favourable biocompatibility Elasticity similar to dentin Easy to handle and remove Favourable retention in conjunction with the adhesive bonding technique	Posts introduced thus far only offer limited radiopacity
Zirconium oxide	Favourable optical properties Favourable biocompatibility Radiopacity	Very high degree of rigidity Difficult to remove / very brittle

Summary of the advantages and disadvantages of various root canal post systems



Fracture resistance of selected root canal post materials

Glass fibre-reinforced composite posts exhibit a similar fracture resistance as steel, titanium and zirconium oxide posts. The values given for steel and titanium represent their yielding points, i.e. the stress at which plastic deformation begins.

### 3. The development of FRC Postec Plus

The FRC Postec glass fibre-reinforced composite posts have been commercially available since June 2001. Excellent clinical experience has been gathered with these posts to date. Three-year study reports attest to the clinical success of FRC Postec. Nonetheless, FRC Postec does not escape the typical disadvantage of composite posts, i.e. poor radiopacity. FRC Postec Plus has been developed in an effort to overcome this disadvantage. The newly developed FRC Postec Plus offers the following advantages for the restoration of teeth that demonstrate extensive damage:

- Natural aesthetics due to high translucency
- High radiopacity
- High retention in conjunction with proven adhesives
- Compatibility with the root structure due to dentin-like elasticity
- Easy removal
- A clinically proven method

## 4. Technical data

### **Standard composition** (in wt %)

Dimethacrylates	approx. 21 %
Ytterbium fluoride	approx. 9 %
Glass fibres	approx. 70 %
Catalysts and stabilizers	< 0.5 %

### **Physical properties**

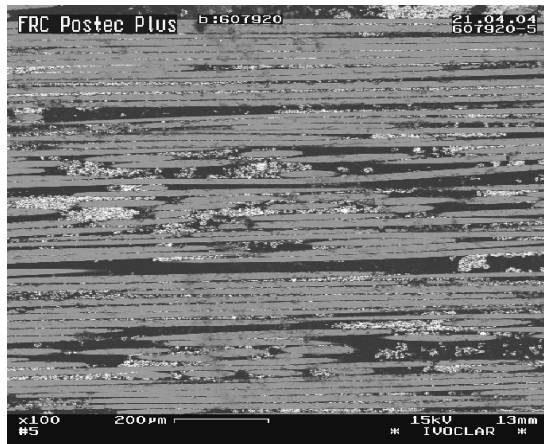
Flexural strength	$1050 \pm 50$ MPa
Modulus of elasticity	$48 \pm 2$ GPa
Water sorption	$17 \pm 1$ $\mu\text{g}/\text{mm}^3$
Water solubility	$2.5 \pm 0.25$ $\mu\text{g}/\text{mm}^3$
Radiopacity (Size 1 posts)	$330 \pm 10$ %Al
Radiopacity (Size 3 posts)	$510 \pm 20$ %Al

## 5. Laboratory investigations

### 5.1 Material

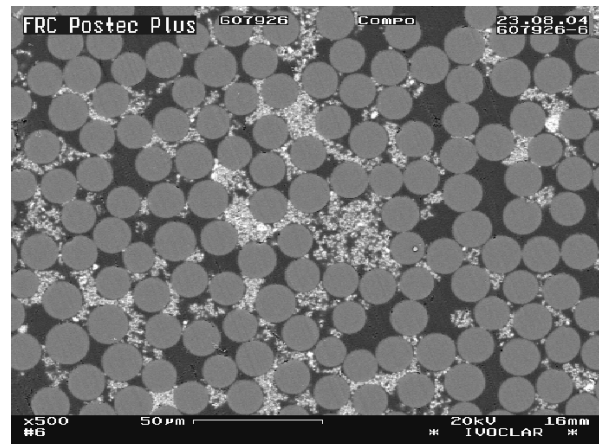
#### *FRC Postec Plus*

The cylindro-conical metal-free *FRC Postec Plus* root canal posts consist of glass fibres and a composite matrix, which contains dimethacrylate and ytterbium fluoride.



SEM image: Longitudinal section of FRC Postec Plus

Longitudinal direction of glass fibres embedded in a polymer matrix



SEM image: Cross section of FRC Postec Plus

Even distribution of the fibres in the matrix

### 5.2 Clinical application

The core build-up on FRC Postec Plus posts (Size 1 or Size 3) is in most cases fabricated with a mouldable composite (e.g. MultiCore or Tetric Ceram) directly in the dental office. This direct procedure helps save time. In addition, the adhesive bonding technique increases retention and thereby enhances the failure resistance of the reconstruction.

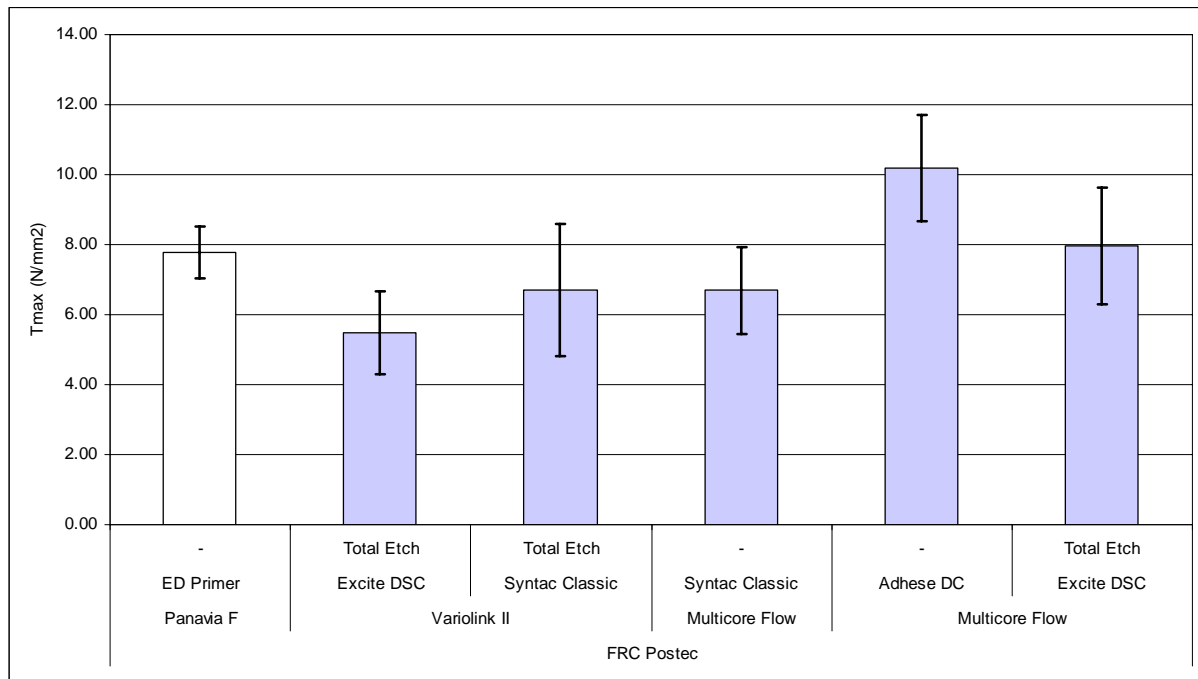
### 5.3 Suitable bonding systems for FRC Postec Plus

In addition to the properties, length, diameter and surface roughness of the post, the luting material or system used considerably affects the retention of the post in the root canal. Translucent composite posts offer an important advantage: they can be bonded in place using an adhesive luting composite. Adhesive bonding considerably increases the retention of the post in the root canal and decreases the risk of retention loss.

#### 5.3.1 Bond between the post and the inner surface of the root canal

Fibre-reinforced composite posts are adhesively bonded with a self- or dual-curing luting composite and a dentin bonding agent. Before the bonding procedure is started, FRC Postec Plus posts are cleaned with phosphoric acid gel. In the process, they are slightly etched. Subsequently, the surface of the post is silanized with a silane coupling agent. Adhesive bonding is generally associated with an increase in post retention. Composites also appear to reduce the risk of root fracture.

An *in-vitro* investigation was carried out to examine the bond of fibre-reinforced FRC Postec posts to the root dentin of human teeth in combination with selected luting systems. The bond strength was measured by means of a pull-out test and described in terms of the retention forces measured in the process.



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Bond of FRC Postec in the root canal of human teeth after having been bonded in place with various adhesive systems

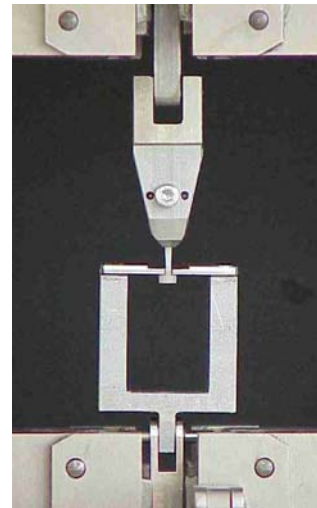
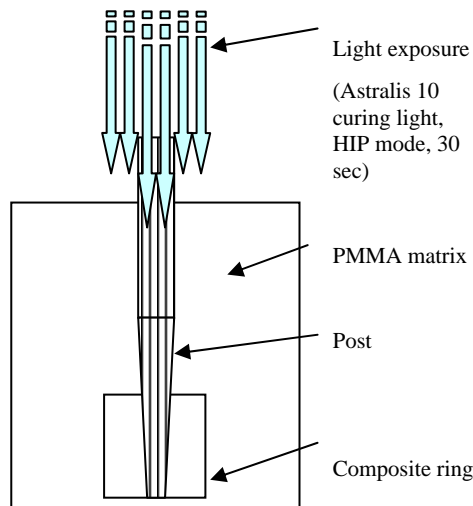
Adhesive bonding with appropriate composites provides sufficient bond strength. MultiCore Flow, applied in conjunction with a self-etching dual-curing adhesive system, produces the highest bond strength values. Panavia F and ED Primer were applied to conduct a competitive comparison. FRC Postec Plus is expected to produce similar bonding values as it contains a comparable composite matrix.

### 5.3.2 Bond between the post and luting material

The strength of the bond between various luting materials and FRC Postec Plus was examined by means of a pull-out test (see Graph). After the surfaces of the posts had been conditioned, a cylindrical body was cemented to the apical end of the post using selected luting materials. Dual-curing cements were light-cured with an Astralis 10 curing light for 30 seconds. Self-curing cements were allowed to cure for 10 minutes before the specimens were stored in water at 37°C for 24 hours. Subsequently, the specimens were subjected to thermocycling at temperatures from 5°C to 55°C. The retention force was measured by means of a Zwick testing machine.

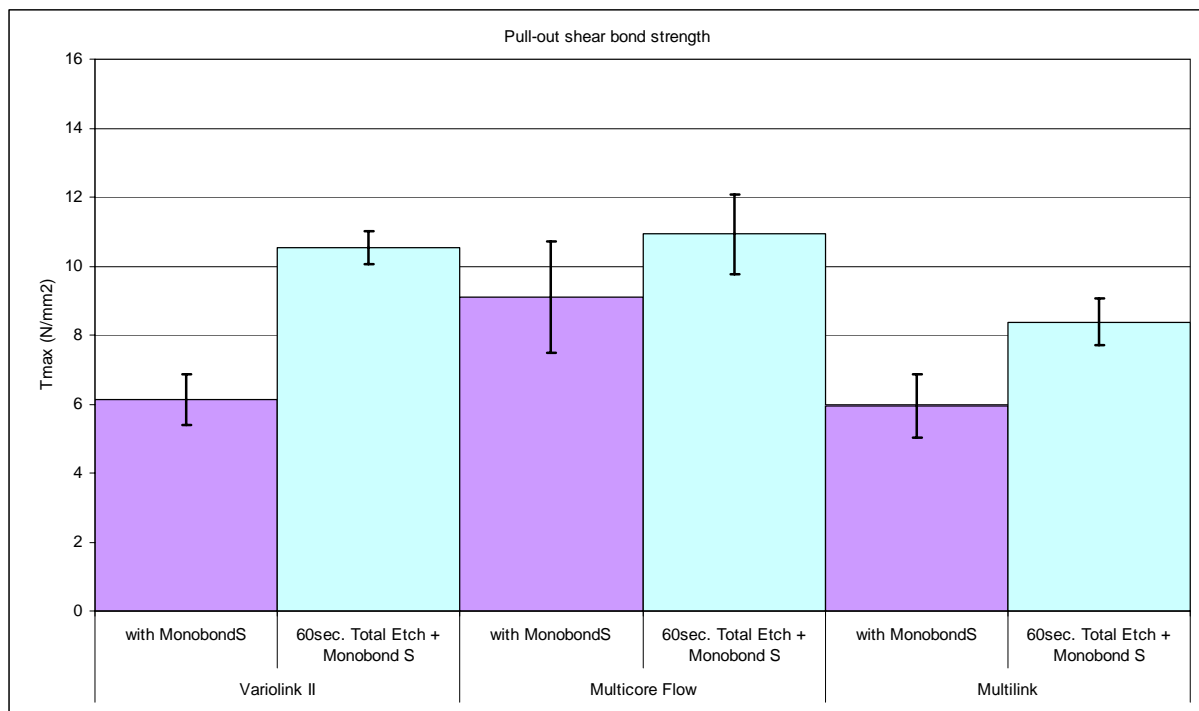
The pull-out shear bond strength was calculated by dividing the maximum retention force by the area of the conical bonding surface.





Preparation of specimens

Measuring equipment



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The above chart illustrates the shear bond strengths measured after the specimens were subjected to various pretreatment and luting methods (Multilink was the only self-curing luting material of all the composites used).

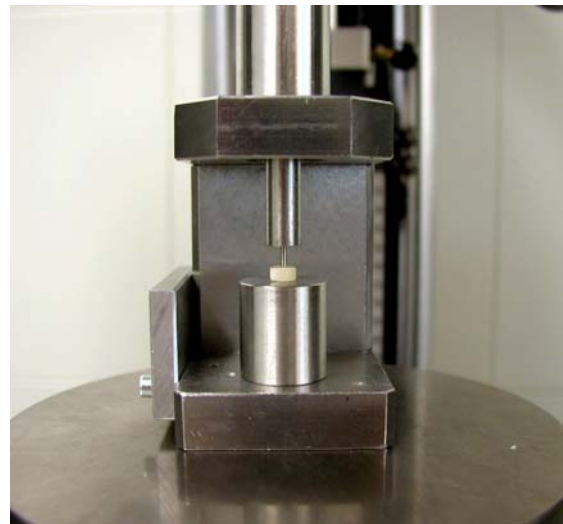
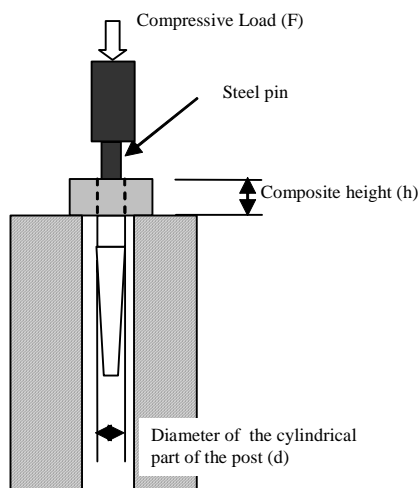
The results show that pretreating the posts with phosphoric acid and silane produced a strong bond to all luting composites tested. Phosphoric acid activates the surface of the FRC Postec Plus material. As phosphoric acid also cleans and disinfects the posts, the need to clean them with ethanol is eliminated.

### 5.3.3 Bond between the post and core material

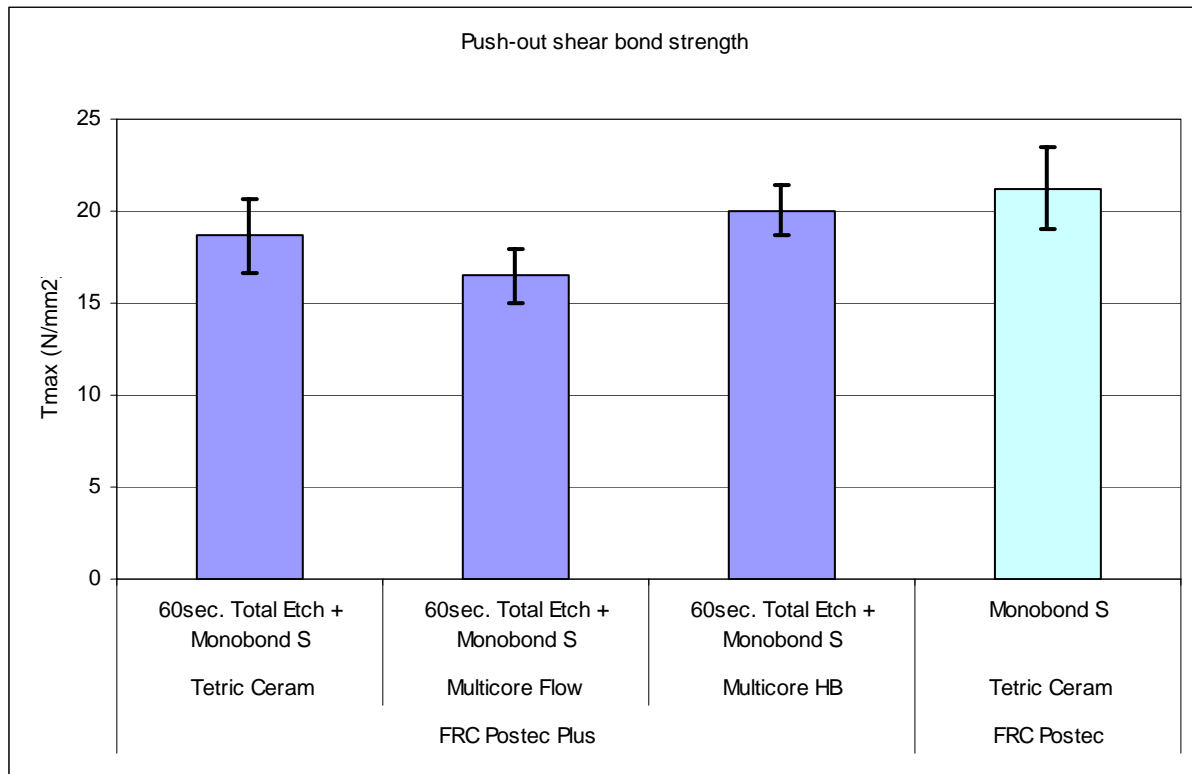
Core-build ups are created to reconstruct the retention and resistance form of teeth that have lost substantial amounts of coronal tooth structure, so that a final crown can be placed. A self- or dual-curing composite (e.g. MultiCore) is employed to create the core build-up and which is adhesively bonded to FRC Postec Plus.

The bond strength between selected core build-up materials and FRC Postec Plus was assessed by means of a push-out test. For this purpose, the post surfaces were conditioned and then a cylindrical body made of build-up composite (height: 3 mm; diameter: 3 mm) was luted to the cervical end of the post. The composite was illuminated from the occlusal surface for 40 s with an Astralis 10 curing light.

The specimens were stored in distilled water at 37°C for 24 h. Subsequently, they were subjected to 5000 thermocycles from 5°C to 55°C. After that, the bond strength was measured by means of a Zwick testing machine. The push-out shear bond strength in MPa ( $T_{max}$ ) was calculated by dividing the maximum force of pressure by the area of the conical bonding surface.



Schematic of the test set-up



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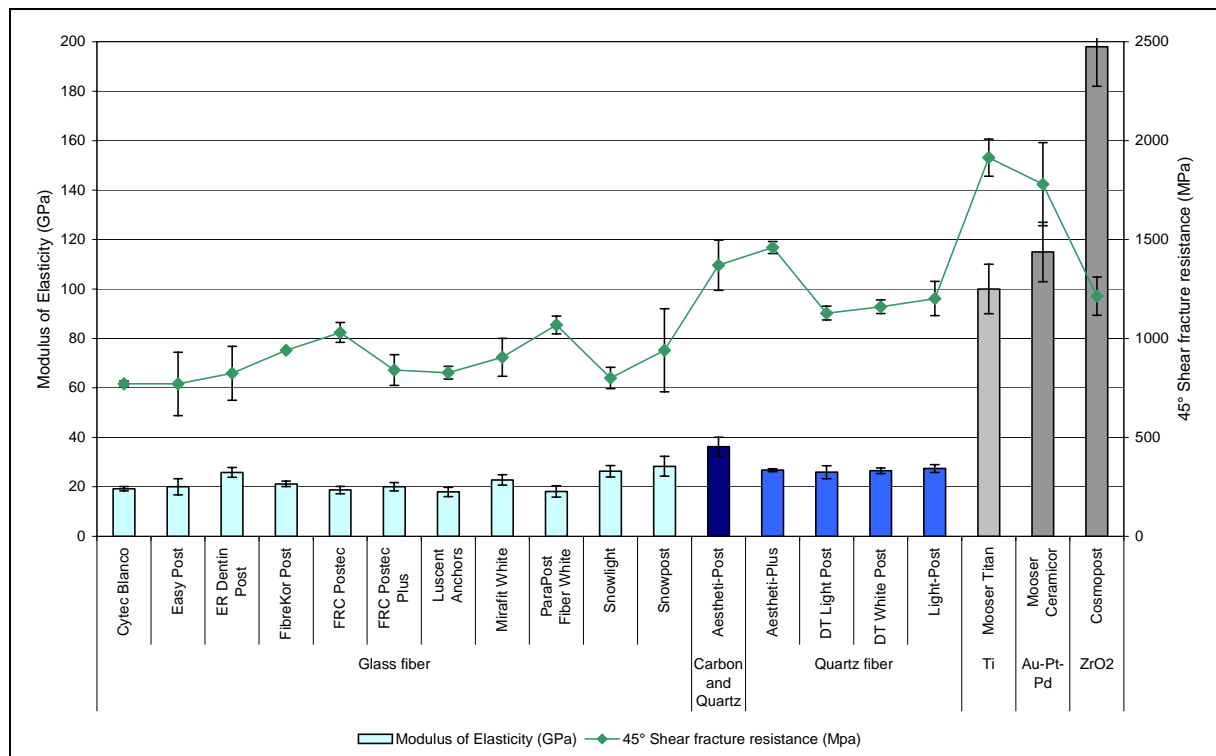
#### Bond strength between FRC Postec Plus and selected core build-up materials

The bond strength between FRC Postec Plus and the three core build-up composites tested is comparable to that between FRC Postec and Tetric Ceram – a combination that has been proven to provide long-term clinical success.

#### 5.4 Shear bond strength of selected root canal posts

During mastication, typical breaking loads are exerted on the post/core build-up at an angle of approx. 45° to the post axis. In a mechanical test, selected root canal posts were luted to a PMMA base using Variolink II. After the specimens had been stored in water at 37°C for 24 h, they were mounted on a Zwick testing machine and loaded to breaking point at an angle of 45°.

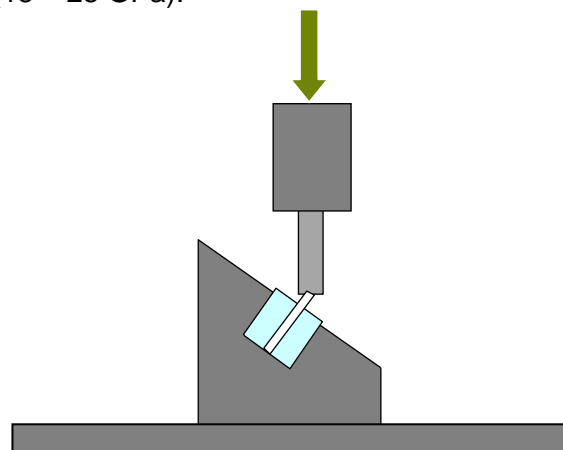
The fracture resistance and 'fictional' modulus of elasticity were calculated on the basis of the maximum breaking force and the course of the force/bending curve. The term 'fictional' is used here because the measuring set-up affects the modulus of elasticity. The modulus of elasticity of fibre-reinforced composites varies according to the direction of force due to their anisotropic properties.



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### Fracture resistance and modulus of elasticity of selected root canal posts

The results show that the fracture resistance of FRC Postec Plus is comparable to that of all the other fibre-reinforced posts tested. The modulus of elasticity of the fibre-reinforced posts is clearly lower than that of the ceramic and metal posts and closely matches the modulus of elasticity of dentin (15 – 25 GPa).



Set-up of the 45° shear bond test

## 5.5 Radiopacity

### 5.5.1 Measuring the radiopacity of FRC Postec Plus

Composite posts lack radiopacity, which is a significant drawback. It should be possible to assess previous endodontic interventions and the stability of core build-ups in the course of a radiographic examination. In most cases, radiopaque luting composites applied to the canal walls do not provide sufficient radiopacity because they are only applied in a thin layer thickness.

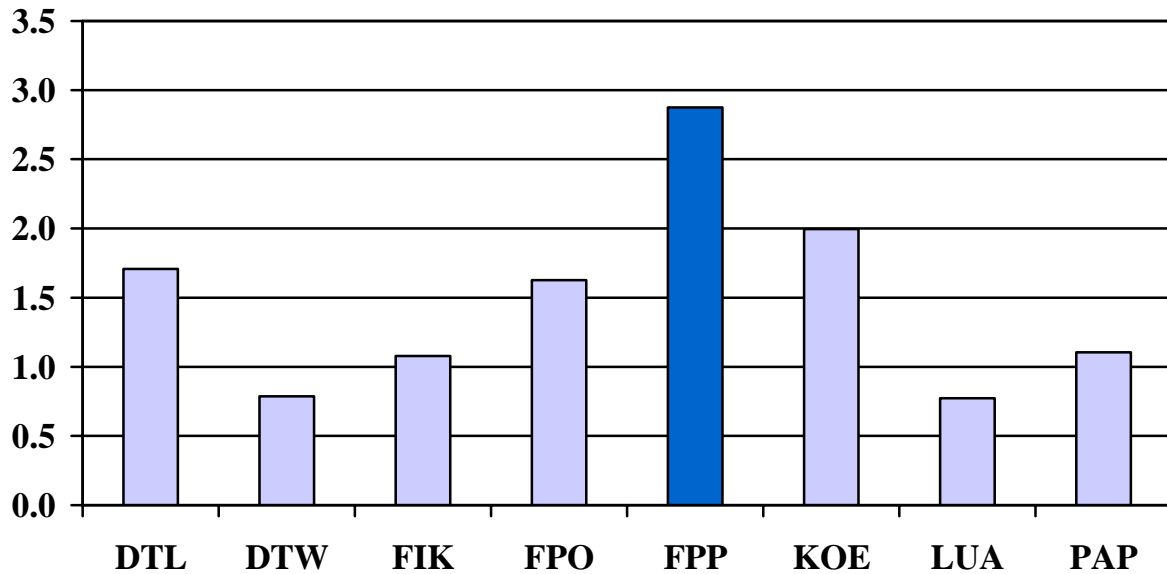
At the department of Dr. Finger / University of Cologne, Germany, the radiopacity of the new FRC Postec Plus was assessed and compared with the radiopacity of other commercially available composite posts.

The following materials were included in the evaluation:

Root canal post	Abbreviation	Size	Manufacturer
DT Light Post	DTL	#1	RTD, St. Egrève, France
DT White Post	DTW	#1	RTD, St. Egrève, France
FibreKor Post	FIK	1.5 mm	Pentron, Wallingford, CT, USA
ER DentinPost	KOE	Size 090	Brasseler, Lemgo, Germany
Luscent Anchors	LUA	Size 5, medium	Dentatus, Hägersten, Sweden
ParaPost Fiber White	PAP	Size 5.5	Coltène, Altstätten, Switzerland
FRC Postec	FPO	Size 1	Ivoclar Vivadent AG, Schaan, Liechtenstein
FRC Postec Plus	FPP	Size 1	Ivoclar Vivadent AG, Schaan, Liechtenstein

Radiographs were obtained for three posts of each make by means of a Heliodent MD X-ray unit (70 kV, 7 mA) using an exposure time of 0.1 s at a distance of 250 mm. All radiographs were developed under identical conditions. A linear relationship between the photographic density and the aluminium thickness was established by means of aluminium standards. A calibration curve was computed on the basis of the data obtained in the process. The optical density was determined in the coronal third of the individual posts.

In a second test, upper human canines were used. The preparation depth of all canines was 15 mm. After the preparations had been completely cut, they were shaped with a reamer to provide the necessary space for the placement of the individual posts. The radiopacity was measured at the enamel-dentin junction.



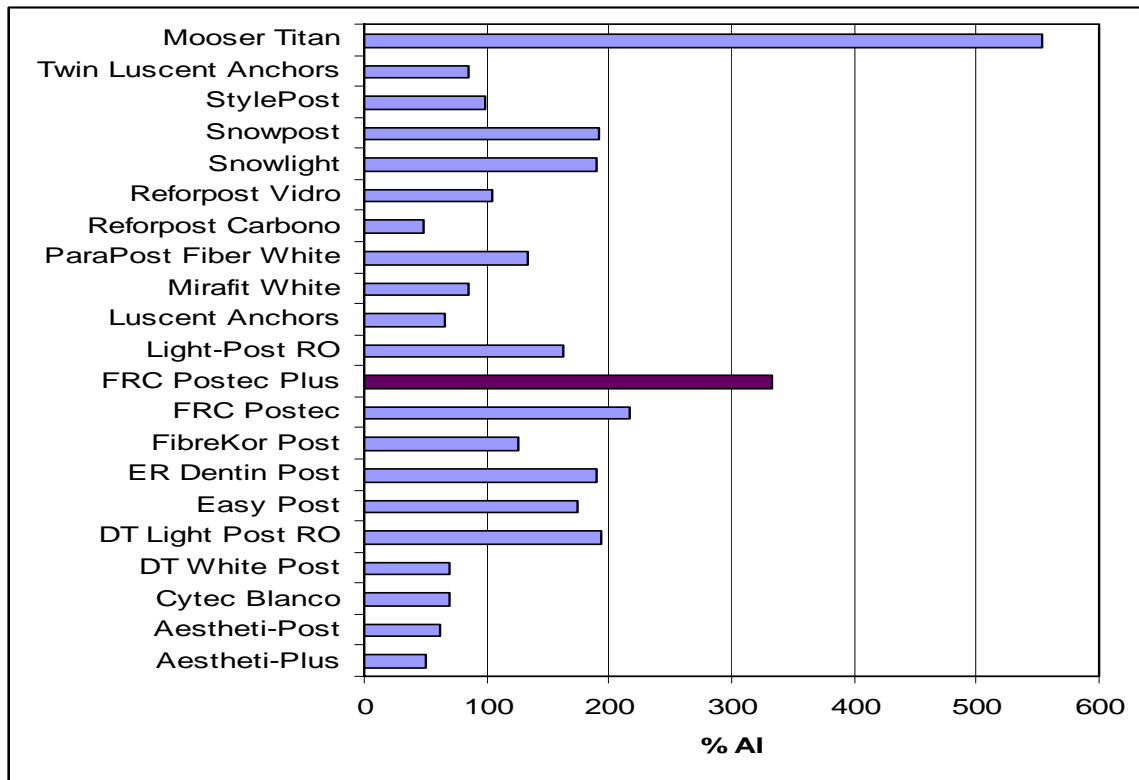
Finger, Cologne, 2004

Radiopacity of root canal posts (calculated for a post thickness of 15 mm)

The radiopacity of FRC Postec Plus (FPP) is considerably higher than that of the other composite posts tested. Given their high radiopacity, FRC Postec Plus posts can be distinguished from the surrounding structure on dental X-rays.

#### 5.5.2 Radiopacity of posts without surrounding material

The R&D Department at Ivoclar Vivadent measured the radiopacity of the posts with the help of two methods. In the first method, a post of each make was placed on an X-ray film and illuminated with an Oralix DC X-ray unit for 0.2 seconds. An aluminium stepwedge, which is graduated in incremental steps of 0.5 mm (from 0.5 to 5.0 mm), was radiographed together with the posts. The photographic density of the posts and each aluminium step was determined by means of a light transmission density meter. A diagram showing the relationship between the optical density of the aluminium steps and their thickness was created. In the process, a logarithmic calibration curve was obtained. With the help of this calibration curve, the optical density measured at the cylindrical section of the post was turned into the equivalent of aluminium thickness (e.g. 100 % Al = 1 mm aluminium). Three X-rays were taken of each product and the average value determined accordingly.



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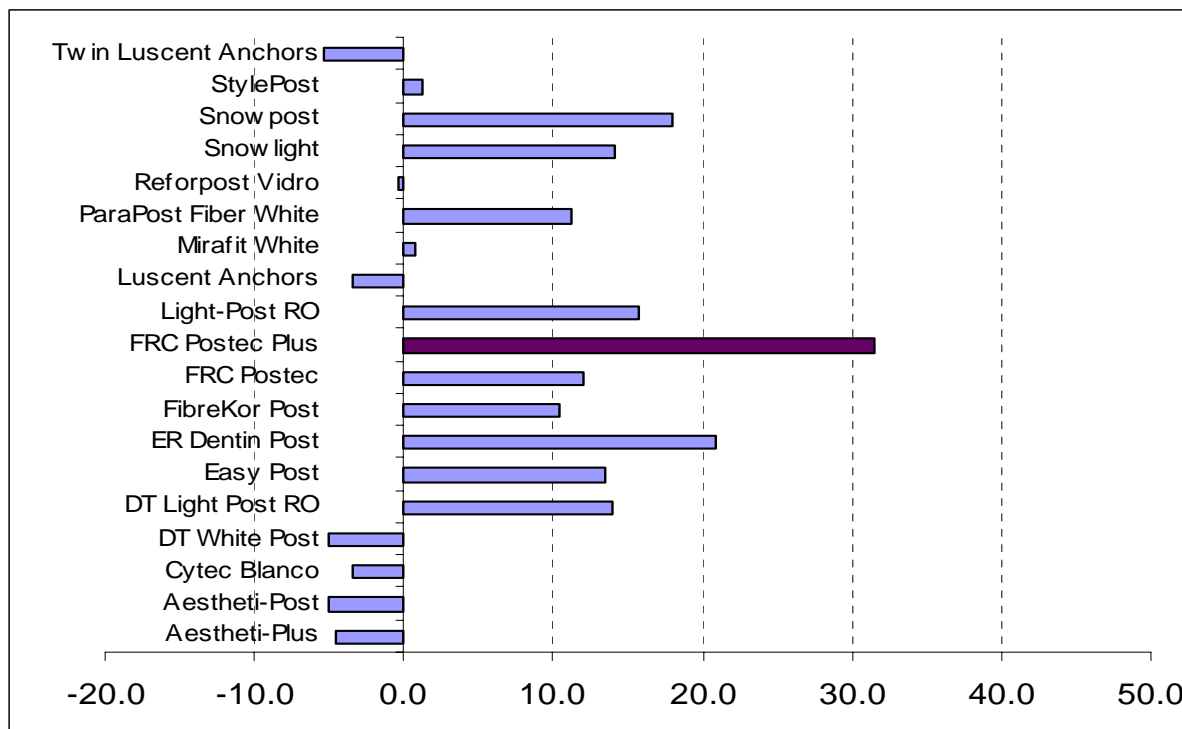
#### Radiopacity of different root canal posts

FRC Postec Plus shows a very high level of radiopacity compared to all the other composite posts examined. Only metal and zirconium oxide posts demonstrate a higher level of radiopacity.

#### 5.5.3 Radiographs – Posts in the root canal: grey scale contrast

To determine the grey scale contrast of the posts *in situ*, the root canals of three extracted human premolars were endodontically prepared and enlarged to create space for the posts. For this purpose, the reamer for the largest post was used. Subsequently, a post of each make was inserted into the prepared root canals and then the specimens were radiographed. The films were digitized and analyzed by means of AnalySIS version 3.1 software. The upper third of the root was selected for the digitized images (see Figure 1) and the grey scale values of the root dentin and post were determined. This procedure resulted in the curve shown in Figure 2. The difference between the grey scale values of the root dentin and the post provides an indication as to how easy a post can be identified on a radiograph.

Three radiographs were taken of each product and the grey scale values measured were averaged to obtain a mean value.



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#### Grey scale contrast between post and tooth structure on radiographs

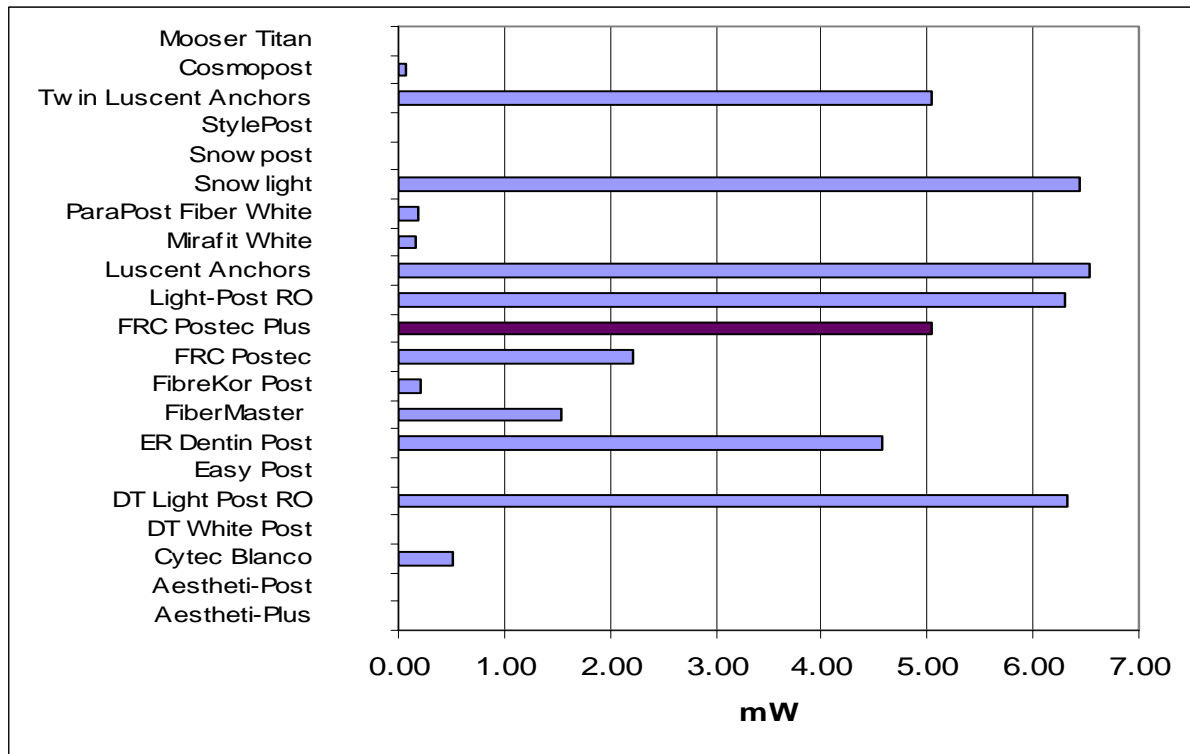
The grey scale contrast provides an indication as to how well the posts can be distinguished from the tooth structure. The higher the contrast is, the more easily the post can be told from the surrounding tooth structure. FRC Postec Plus outmatches all the other posts tested in terms of grey scale contrast.

### 5.6 Light transmission

Light transmission is measured by means of an Ulbricht sphere. For this purpose, a post of each brand was trimmed down on the coronal end to a standard length of 15 mm to eliminate any possible influence of the post length. Subsequently, the posts were embedded in an opaque silicone compound in a thickness of 3 mm. Only the coronal surface of the post was not covered with silicone material. The geometry of the silicone mould matched the aperture of the Ulbricht sphere. Consequently, it was possible to place the post exactly over the aperture. The light probe of the bluephase curing light (Ivoclar Vivadent) was held against the coronal end of the post (see Figure 3). As a result, the sensor connected to the Ulbricht sphere only measured the light (in mW) which was transmitted through the post when the curing light was switched on (the HIP program, which emits a light output of 1100 mW/cm<sup>2</sup>, was used in conjunction with bluephase).

The unit was calibrated by first guiding the light through the empty silicone mould (without the post) and measuring the resulting light transmission. The value measured was 0.0009 mW. This value was subtracted from the value measured when the post was inserted into the silicone mould. Three to six series of measurements were conducted for each post and then averaged to obtain the mean light transmission.





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Light transmitted through different posts when illuminated with a bluephase curing light

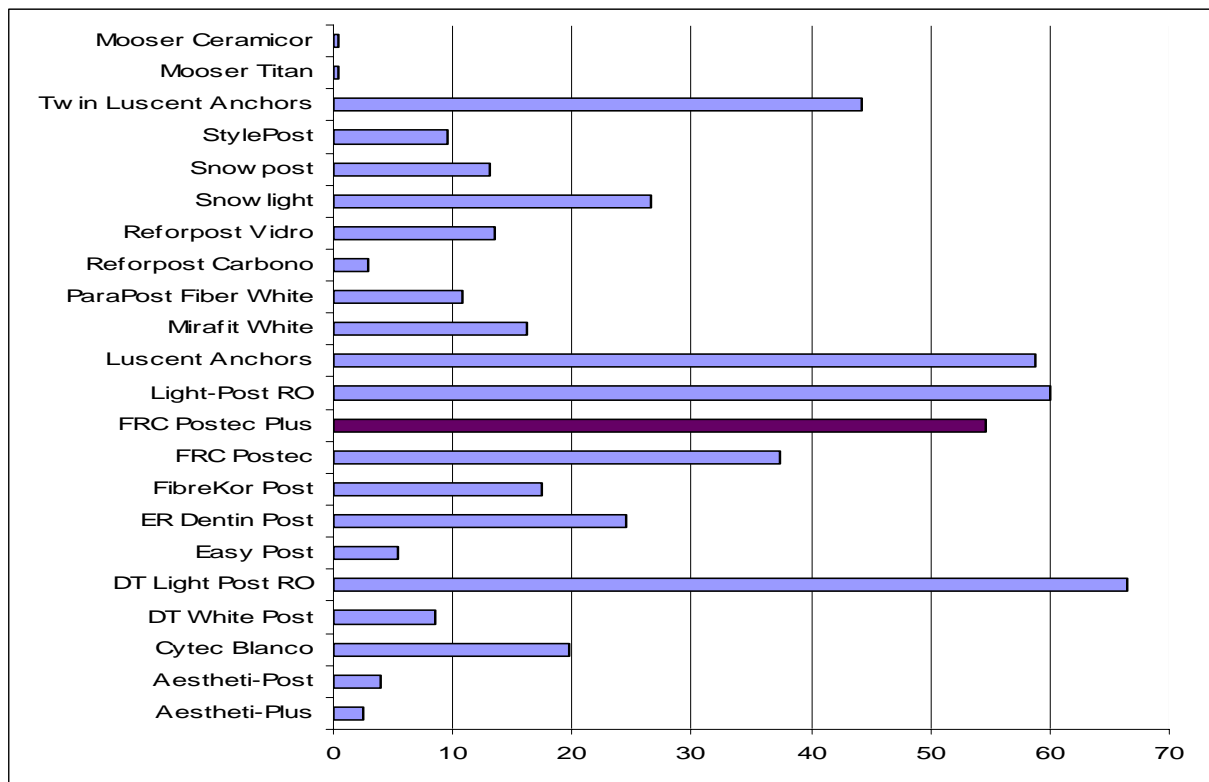
If posts that have favorable light transmitting qualities are used, dual-curing composites can be reliably and easily cured down to the apical region. In this context, FRC Postec Plus has been shown to provide excellent light transmitting properties.

### 5.7 Translucency - Posts on a black and white background: grey scale contrast

The translucency is best determined by measuring the contrast in grey scale values. For this purpose, one part of the root canal post is placed on a black background and the other part on a white background. Subsequently, a high-resolution digital image is taken. The grey scale values are determined by means of analySIS software and then the difference between the values obtained on the white and black background is calculated.



Grey scale measurement on a black and white background



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#### Differences in the grey scale contrast of selected root canal posts

Translucent root canal posts are particularly desirable in conjunction with translucent composite core build-ups because of aesthetic considerations. FRC Postec Plus demonstrates a high contrast in grey scale values, which is indicative of a high degree of translucency.

## 6. Clinical investigations

FRC Postec has been the subject of a number of clinical studies that have been running for several years and therefore provide long-term clinical results. As FRC Postec Plus has been further developed and is based on the same material structure as its predecessor, the clinical experience gathered with FRC Postec also applies to FRC Postec Plus.

### 6.1 *Prospective study with FRC Postec in conjunction with the Syntac/Variolink II adhesive bonding system*

- Head of study: Dr. Andreas Rathke, R&D, Ivoclar-Vivadent AG, Schaan, Liechtenstein
- Objective: Evaluate the clinical performance of Syntac/Variolink II/Monobond S/FRC Postec on the basis of modified USPHS criteria (periapical lesion, retention, marginal leakage, marginal seal, shade stability, surface discoloration), radiographs (baseline and recall) and an SEM-based follow-up examination.
- Study set-up: Twenty silanized (Monobond S) FRC Postec glass fibre posts were placed in the anterior and posterior teeth of sixteen patients, using the dual-curing Syntac/Variolink II luting system. The post size (S or M) was chosen in accordance with the diameter of the root canal and the clinical indication given. The glass fibre posts were only used in teeth that demonstrated a nearly total loss of coronal tooth structure. The core build-ups were fabricated at the same appointment as the posts were placed, using Syntac/Tetric Ceram in the layering technique. The final restorations (crown or bridge), which were fabricated with Targis/Vectris, were cemented in place using a non-adhesive technique (zinc phosphate cement).
- Results: A report published after 12 months into the trial did not report any retention loss of the post/core build-up, periapical tissue damage or changes in the restoration's shade. The marginal criteria examined did not show any statistically significant difference between the situation at baseline and at the one-year recall.
- Publication: Rathke A., Buob D., Zappini G., Hagenbuch K., (2001). Preliminary results with adhesively placed translucent glass fiber posts. 37th Annual Meeting, Sept. 5-8, 2001, Rome, Italy; Abstract no. 138

### 6.2 *3-year study with FRC Postec bonded adhesively with the dual-curing Excite DSC bonding agent*

- Head of study: Dr. M. Ferrari, Department of Dental Materials, School of Dental Medicine, University of Siena; Research Center for Dentistry, Piazza Attias 19, Livorno, Italy
- Objective: Evaluate the clinical performance of the Excite DSC dual-curing single-component system when used for luting FRC Postec glass fibre posts.
- Study set-up: After endodontic treatment, the root canals of 40 patients were restored with a post-retained composite core build-up restoration involving FRC Postec glass fibre posts. The posts were adhesively bonded using the 'one-bottle' system Excite DSC and Multilink (self-curing). The core build-up was fabricated with Tetric Ceram. All restorations were placed between March and April 2000 and were evaluated in terms of stability-related and clinical criteria (retention in relation to the core and core build-up, post fracture, marginal criteria, periapical lesions, discoloration, crack formation). The

restorations were also examined by means of radiographic images. The control group consisted of 40 patients, who received a glass fibre post that was inserted using the 3-component adhesive All-Bond 2 and C&B luting composite.

**Results:** To date, the restorations have been examined at five recalls (after 1 month, 6 months, 12 months, 24 months and 36 months). Thirty-five cases were available at the recall after 36 months. No failures have been observed in terms of retention, shade stability and crack formation. A periapical lesion requiring endodontic treatment was diagnosed in a patient after 6 and 12 months respectively. After 12 months, an incidence of each of the following was noted: slight marginal discoloration, slight ledging and surface staining.

**Publication:** Ferrari M., Mannocci F., (2000). A 'one-bottle' adhesive system for bonding a fibre post into a root canal: an SEM evaluation of the post-resin interface. *Int. J. Endodont.* **33**, 397.

Ferrari M., Vichi A., Grandini S., Goracci C., (2000) Efficacy of a self-curing adhesive resin-cement system on luting glass-fiber posts into root canals: a SEM investigation. *Int. J. Prosthodont.* **14**, 543

Monticelli F., Grandini S., Goracci C., Ferrari M., (2003) Clinical behavior of translucent-fiber posts: a 2-year prospective study. *Int. J. Prosthodont.* **16**, 593

### **6.3 2-year study involving FRC Postec, Excite DSC (dual-curing single-component adhesive), Variolink II and Tetric Ceram HB – a single-matrix system**

This study was conducted with a view to assessing the post, dentin adhesive, luting composite and core build-up material as an integrated system that involves a single-matrix system, which is contained in all components of the system (i.e. post, cement, composite).

**Head of study:** Dr. P. Gianetti, Odontoiatra, Via Fosso della Castelluccia 146/6, 00134 Rome, Italy

**Objective:** Examine the long-term performance of FRC Postec root canal posts.

**Study set-up:** Ninety-four FRC Postec posts were placed in 57 patients in the course of six months in a direct chairside procedure. Fourteen of these restorations were placed in the anterior region and the others in the posterior region. After the post had been bonded in place and the core reconstructed with Tetric Ceram HB, the post-core foundations were evaluated by means of a radiograph. The final crown restorations were evaluated with regard to debonding, aesthetic appearance, and discoloration and assessed radiographically (after 3, 6, 12 and 24 months). Comprehensive photographic documentation will be produced for ten cases.

**Results:** The clinical recalls (after a total period of observation of 48 months) did not produce any signs of failure or any other clinically striking features, neither on the radiographs nor in the visual examinations. The aesthetic properties of the restorations have been rated 'excellent'.

**Publication:** Giannetti, F: (2004) Un nuovo sistema per la ricostruzione del dente trattato endodonticamente; 48 mesi di controllo su 66 denti privi di corona clinica. Congresso Nazionale SIE (Verona 2004)

#### **6.4 FRC Postec reinforced composite posts – The challenge of the art in pediatric dentistry**

- Head of study: Prof. D. Beloica, Prof. Z. R. Vulicevic; Fac. Stomatology; University of Belgrade, Yugoslavia
- Objective: Prospective clinical study with FRC Postec
- Study set-up: In this study, a total of 104 FRC Postec posts were placed in 93 patients, of which 51 were adults and 42 were adolescents. One half of the posts were bonded in place using Variolink II / Excite DSC and the other half using Multilink. The core build-up was created with Tetric Flow.
- Results: No posts were broken two years into the study. Root fractures and debonding did not occur.

#### **6.5 Clinical Investigation of a new radiopaque fibre-reinforced post**

In this clinical study on FRC Postec Plus, half of the superstructures were fabricated in all-ceramic and the other half in composite.

- Head of study: Dr. P. Gianetti, Odontoiatra, Via Fosso della Castelluccia 146/6, 00134 Rome, Italy
- Objective: Examine the long-term clinical performance of FRC Postec Plus root canal posts.
- Study set-up: Thirty endodontic post build-ups were fabricated in the course of this study. Variolink II / Excite DSC was used as the luting system. The core build-ups were fabricated using Tetric Ceram. The superstructures for one half of the reconstructions were created with Vectris/Adoro and for the other half with IPS Empress.
- The restorations will be assessed with regard to their clinical performance, aesthetic appearance and handling properties. The recalls will also involve radiographic examination.
- Results: To date, i.e. after all restorations have been placed, the handling and aesthetic properties of the restorations have been rated 'excellent'.

## **7. Biocompatibility**

### **7.1 Toxicological risk due to emissions of glass fibre dust**

The glass fibres contained in the FRC Postec Plus posts are biologically inert. As the dental pulp is removed in the course of preparing the tooth for post placement, the glass fibre framework and living tissue do not come into contact with each other (adhesive bonding with luting composite). Direct exposure and any particular effect of harmful substances are unlikely to occur.

When the posts are handled (trimmed) by the dentist in the direct method or by the dental technician in the indirect method, small glass fibre particles may be released. Glass fibre dust is potentially carcinogenic and is classified as a category 2 carcinogenic material [1]. However, when the glass fibre-reinforced FRC Postec posts (diameter of fibres 14 µm) are manipulated in the dental laboratory, the dust concentration and geometrical dimensions of the dust particles are below the levels that are internationally recognized as involving an increased risk [1,2,3].

Inhalation of fibre dust should generally be avoided. The risk of adverse health effects, inhalation exposure or local irritation can be minimized by implementing measures such as [3]:

- Rubber dam isolation
- Use of water spraying and suction system
- Use of suction equipment
- Use of rubber gloves
- Use of protective mask

### **7.2 Biocompatibility of the polymer matrix**

The polymer matrix consists of monomers that have been used in dental products for many years. The toxicological evaluation of these monomers is comparable to products such as Vectris [4], Heliobond and Helioseal/Helioseal F, which have been extensively screened, tested and clinically examined:

- Primary eye irritation study in rabbits (RCC Project 034604)
- Salmonella Typhimurium Reverse Mutation Assay/Ames Test (In-vitro; Chromosomenschädigung) (RCC Project 427206)
- Contact Hypersensitivity in Albino Guinea pigs (RCC Project 347095)
- Cytotoxicity Test In-vitro: Agar Diffusion Test (CCR Project 109904)
- Toxicological investigation and specialist report according to the German Drug Law (AMG § 24, Section 1, No. 2)

### 7.3 Cytotoxicity of root canal posts

Fluid extracts of FRC Postec Plus were examined in a culture medium according to ISO 10993-5. The extracts showed no cytotoxic potential [5].

The toxicological risk of the individual ingredients [6-9] was also assessed. These ingredients are unlikely to involve any health risk due to the optimal degree of polymerisation provided by the manufacturer and the consequently minimal elutability *in vivo* and low water solubility (see Technical Data Sheet).

The current level of knowledge and data as well as the experience gathered with FRC Postec do not indicate any signs of a heightened or unacceptable risk if FRC Postec Plus is used according to the manufacturer's instructions.

### 7.4 Literature on toxicity

[1] Deutsche Forschungsgemeinschaft DFG, Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe **MAK- und BAT-Werte-Liste 2001**, Mitteilung 37, WILEY-VCH Verlag GmbH, D 69451 Weinheim

[2] Glasfaserbelastung im zahntechnischen Labor bei der Verarbeitung von Vectris. Interner Bericht DVS 96000939, Ivoclar Vivadent, Schaan Liechtenstein 1996

[3] Gutachterliche Stellungnahme betreffend das gesundheitliche -inhalative Risiko beim Verarbeiten vom Gerüstwerkstoff Vectris der Fa. Ivoclar AG. RCC Project 620280

[4] In-vitro cytotoxicity test evaluation of materials for medical devices (direct cell contact assay) with Vectris Single, Pontic and Frame. RCC Project 652770

[5] Determination of Cytotoxicity; Assay Report 2002-DJF517-7; Laboratoire L.E.M.I..

[6] Acute oral toxicity evaluation of aliphatic urethane dimethacrylate in the rat. Consultox Laboratories Ltd, London, Bericht an die Fa Ivoclar AG, Schaan Liechtenstein, August 1977

[7] In vitro cytotoxicity assay: evaluation of materials for medical devices (XXT-test) with five monomers: EM113, EM62, Bis-GMA, Urethandimethacrylat, Triethylenglycoldimethacrylate. RCC Project 652768, Mai 1997

[8] Toxicity of Ytterbium trifluoride in Heliomolar radiopaque. Sciserv AG, CH-Liestal, Bericht an Ivoclar/Vivadent AG, Juli 1985

[9] Acute oral toxicity (LD50) study with Ytterbium trifluoride, anhydrous in rats. RCC Project 048881

## 8. Literature

- Bruchmann KS (2001). **Der Kronenstumpfaufbau – Teil 3 Therapiekonzepte zum Aufbau devitaler Zähne mit Stiften.** Team Work, J. Multidisciplinary Collaboration in Prosthodont. 2, 208-216
- El-Mowafy OM, Milenkovic M (1994). **Retention of Paraposts cemented with dentin-bonded resin cements.** Oper. Dent. 19, 176–182
- Fernandes AS, Dessai GS (2001). **Factors affecting the fracture resistance of post-core reconstructed teeth: A Review.** Int. J. Prosthodont. 14, 355-363
- Ferrari M, Grandini S, Bertelli E (2001). **Current situation and future prospects in the use of fiber posts.** Proceedings from the V International Symposium *Adhesion and Reconstruction in Modern Dentistry*, S. Margherita Ligure, 2001, 2-9
- Ferrari, M., Grandini, S., Bertelli, E. (2001) **Current situation and future prospects in the use of fiber posts.** Odontoiatria 2-9
- Ferrari, M., Vichi, A., Grandini, S., Goracci, C. (2001) **Efficacy of a self-curing adhesive-resin cement system on luting glass-fiber posts into root canals: An SEM investigation.** Int. J. Prosthodont. 14, 543-549
- Fischer H, Edelhoff D., Marx R. (1998). **Mechanische Beanspruchbarkeit von Zironoxid-Wurzelstiften.** Dtsche Zahnärztl. Z. 53, 854-858
- Fredriksson M, Astbäck J, Pamenius M, Arvidson K (1998). **A retrospective study of 236 patients with teeth restored by carbon fiber-reinforced epoxy resin posts.** J. Prosthet. Dent. 80, 151-7
- Grandini, S., Balleri, P., Ferrari, M (2002) **Scanning electron microscopic investigation of the surface of fiber posts after cutting.** J. Endodont. 28, 610-612
- Grandini, S., Ferrari, M., Balleri, P., Vichi, A. (2002) **Clinical trial of fiber posts luted with self-curing Excite in combination with an experimental resin cement.** J. Dent. Res. 81, A52
- Grobler, D.G. (2003) **Interface integrity of core material bonded to intra-radicular posts.** Ph.D. thesis
- Gutmann JL (1992). **The dentin-root complex: anatomic and biologic considerations in restoring endodontically treated teeth.** J. Prosthet. Dent. 67, 458-467
- Guzy GE, Nicholls JI (1979). **In vitro comparison of intact endodontically treated teeth with and without endo-post reinforcement.** J. Prosthet. Dent. 42, 39-44
- Hill G, Zidan O, Duerst L (1986). **Retention of etched base metal dowels with resin cement and bonding agent.** J. Prosthet. Dent. 55, 691-693
- Junge T, Nicholls JI, Phillips KM, Libman WJ (1998). **Load fatigue of compromised teeth: a comparison of 3 luting cements.** Int. J. Prosthodont. 11, 558-64
- Krasteva K (2001). **Clinical Application of a Fiber-Reinforced Post System.** J. Endodont. 27, 2, 132-133
- Mendoza DB, Eakle WS (1994). **Retention of Posts cemented with various dentinal bonding cements.** J. Prosthet. Dent. 72, 591–594
- Mendoza DB, Eakle WS, Kahl EA, Ho A (1997). **Root reinforcement with a resin-bonded preformed post.** J. Prosthet. Dent. 78, 10-4
- Meyenberg KH, Luthy H, Schärer R (1995). **Zirconia posts: a new all-ceramic concept for non-vital abutment teeth.** J. Esthet. Dent. 7, 73-80
- Paul SJ, Schärer P (1996). **Plastische Aufbauten in der Kronen- und Brückenprothetik.** Quintessenz 47, 1519-1531
- Rathke, A., Buob, D., Zappini, G., Hagenbuch, K. (2002) **Preliminary results with adhesively placed translucent Glass Fiber Posts.** J. Dent. Res. 81, B-248
- Rosentritt M, Furer C, Behr M, Lang R, Handel G (2000). **Comparison of in vitro fracture strength of metallic and tooth-coloured posts and cores.** J. Oral Rehabilitation 27, 595-601
- Scotti R, Monaco C, Malferrari S (2000). **Pre-prosthetic rebuildings using quartz fiber posts: clinical experience after 18 months.** Proceedings from the IV International Symposium *Adhesion and Reconstruction in Modern Dentistry*, S. Margherita Ligure, 2000, 21-26
- Seitner T, Gläser R (1997). **Vollkeramische Restaurationen bei stark zerstörten Seitenzähnen.** Quintessenz 46, 1085-1101
- Sidoli GE, King PA, Setchell DJ (1997). **An in vitro evaluation of a carbon fiber-based post and core system.** J. Prosthet. Dent. 78, 5-9
- Simon MHP, Paffrath J (1995). **Neue Perspektiven zur vollkeramischen Stabilisierung und zum Aufbau devitaler Zähne.** Quintessenz 46, 1085-1101
- Sornkul E, Stannard JG (1992). **Strength of roots before and after endodontic treatment and restoration.** J. Endodont. 18, 440-443



Stecher T, Munack J, Schwarze T, Geurtsen W (2001). **Keramische Versorgungen endodontisch behandelter Front- und Seitenzähne.** Quintessenz 52, 7, 705-717

Stiefenhofer A, Stark H (1992). **Wurzelkanalverankerung von Kronenaufbauten.** Phillip Journal 9, 375-380

Wirz U, Christ R (1982). **Korrosionserscheinungen an Schrauben und Stiften bei Zahnaufbauten – eine in-vitro-Studie.** Schweiz. Monatsschr. Zahnheilk. 92, 408

Zalkind M, Hochman N (1998). **Esthetic considerations in restoring endodontically treated teeth with posts and cores.** J. Prosthet. Dent. 79, 702-705

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