3M ESPE

Sinfony

Indirect composite

Scientific Product Profile

Contents

1 Preface

Sinfony is the modern, light-cured, ultra-fine particle composite from 3M ESPE, with high strength for full veneering of fixed and removable prostheses on metal frameworks, for inlays/onlays, individual crowns, glass fibre reinforced bridges and for the customisation of prefabricated teeth.

2 Introduction

2.1 History

The use of Bis-GMA in dental materials was first described by Bowen in 1962. He was also the first to apply surface-modified glass fillers for the reinforcement of resins, thereby describing the first composites as we now understand them.

In the era before Bowen's pioneering work, only powder / liquid products based on PMMA / MMA had been used. The composite materials described before Bowen could only be polished to an inadequate degree because the fillers were, by today's standards, coarse-grained. From 1968 onwards, the use of microfillers meant that filled composites could also be given a high level of polish. This brought with it the use of microfilled composites in aesthetically demanding dental applications.

Further decisive leaps forward in development were achieved with the introduction of radiation hardening - initially with UV light - although the very limited polymerisation depth meant that a real breakthrough never occurred. From 1977 the first dental materials polymerising with visible light were introduced to the market.

After products based on MMA and Bis-GMA, which at first were either self-polymerising or heat polymerising*, the first light-cured microfilled composites for dental indirect composite techniques came onto the market in 1982. These were superior to MMA products because of their significantly higher degree of abrasion resistance and colourfastness as well as improved material characteristics.

* Initators required for the reaction are created by a chemical reactionthermolysis.

There follows an incomplete list of typical historical examples of differing classes of materials.

Self-curing polymers:	SR Ivocron PE (Ivoclar)	1970	Powder / liquid
Heat-cured polymers:	Biodent K+B Plus (DeTrey)	1979	Powder / liquid
	Biodent K+B Paste (DeTrey)	1990	Paste
	SR Chromasit (Ivoclar)	1992	Paste
Light-cured polymers:	Dentacolor (Kulzer)	1982	Paste
	Visio Gem (3M ESPE)	1983	Paste

The modern, light-cured indirect composite materials are easier and more efficient to use than the heat-cured materials. The high polish desired is made possible by using a micro-fine filler, generally in the form of fragmented polymer or agglomerates, whose primary particles are in the range < 0.05 µm.

So-called hybrid composites have been used for some considerable time as direct composite filling materials. These contain „macrofillers“, having a particle diameter < 10 µm, in addition to the „microfillers“. Since the rheological properties (flow behaviour) are better than those of purely microfilled composites, it was possible to increase the filler content and thereby further improve material properties with only a slight decrease in surface quality.

However, these hybrid composites were aesthetically unsuitable for indirect composite techniques and for the filling of anterior teeth because they could not be given a high polish. Only very recently have optimised grinding procedures achieved the manufacture of macrofillers with mean particle sizes of about 0.5 - 0.6 µm. The composites made in this way are known as ultra-fine particle hybrids. Regardless of the marketing names given by specific firms, all the indirect composite materials of the new generation are such ultra-fine particle hybrids.

2.2 Motivation

Sinfony, the new indirect composite material, was developed in accordance with the following premises:

The unique **thixotropic** consistency which distinguishes Visio Gem was to be improved, whilst retaining the layering technique with which technicians are familiar.

The tried and tested dispensers, which allow for **optimal handling**, and the light units needed for polymerisation would continue to be used.

A further important point to be mentioned is the full **compatibility** with the **Rocatec** system, which has won a firm place in modern indirect composite technology.

The following properties justify speaking of a new kind of composite technology. They were the motivation for the development of Sinfony.

With minimum layer thicknesses of 1 mm, Sinfony is perfectly suited for **full indirect composite**. This goal has been attained through a considerable improvement in material properties and in particular abrasion resistance.

The physical data, internal and external investigations and experience so far in the dental practice would even suggest broadening the range of indications to include **inlays/onlays, individual crowns** and **glass fibre reinforced bridges**.

The new filler technology allowed the **translucency**, in particular that of the incisal material, to be considerably improved. At the same time, all the other optical properties have improved, giving a natural appearance to Sinfony restorations: opalescence, fluorescence and transparency.

The tendency to accumulate plaque, common to all indirect composite composites, unlike PMMA and ceramic, was noticeably reduced through specifically influencing the surface potential* and achieving good

polishing characteristics. In laboratory tests the accumulation of typical oral bacteria was reduced by about 40%. In vivo, Sinfony performed markedly better when compared directly with Visio Gem and competitor products.

Behind all these aspects lies the effort to manufacture prostheses which are as long lasting and natural in appearance as possible.

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* Surfaces are primarily characterised by the factors of roughness, wettability and surface potential. According to their type of functional group (e.g. hydrophilic hydroxide groups, or hydrophobic carbohydrate groups) and their surface charge, they display a corresponding wettability and a specific surface potential (zeta potential). If the surface of a solid body is immersed in an electrolyte solution (saliva), surface charges are generated which depend on the chemical constitution of the materials, leading to a potential difference between surface and solution. A parameter associated with this is the so-called zeta potential (ζ). ζ is therefore one of the factors which determine the accumulation of proteins and cells on substrates. It should not however be forgotten that measurements both of wettability and of zeta potential are macroscopic methods which can only yield a generalised picture of a microscopically heterogeneous composite surface. The precise relationships are in no way trivial, and will therefore receive no further explanation here.

2.3 Indications

Because of its exceptionally good mechanical properties (elasticity, abrasion resistance, impact strength) and optical properties, Sinfony not only covers the entire spectrum of indications for the veneer technique but also goes beyond it.

Sinfony is suitable for the

- full indirect composite of crowns and bridges
- full crowns
- inlays/onlays
- glass fibre reinforced crowns and bridges
- direct bonded bridges
- telescopic and conical crowns
- attachments and implant work
- veneers
- long-term temporary work and its characterisation
- customisation of dentures and their teeth made of acrylic and ceramics
- intra- and extraoral repairs.

3 Chemical Background

3.1 General Overview

Dentine is an example of a natural composite. It consists in part of an organic collagen matrix with deposits of small inorganic hydroxyl apatite crystals. Dental composites always consist of an **organic matrix** in which **inorganic fillers** are deposited. In addition to monofunctional methacrylates, polyfunctional acrylates are mainly used as the organic base nowadays.

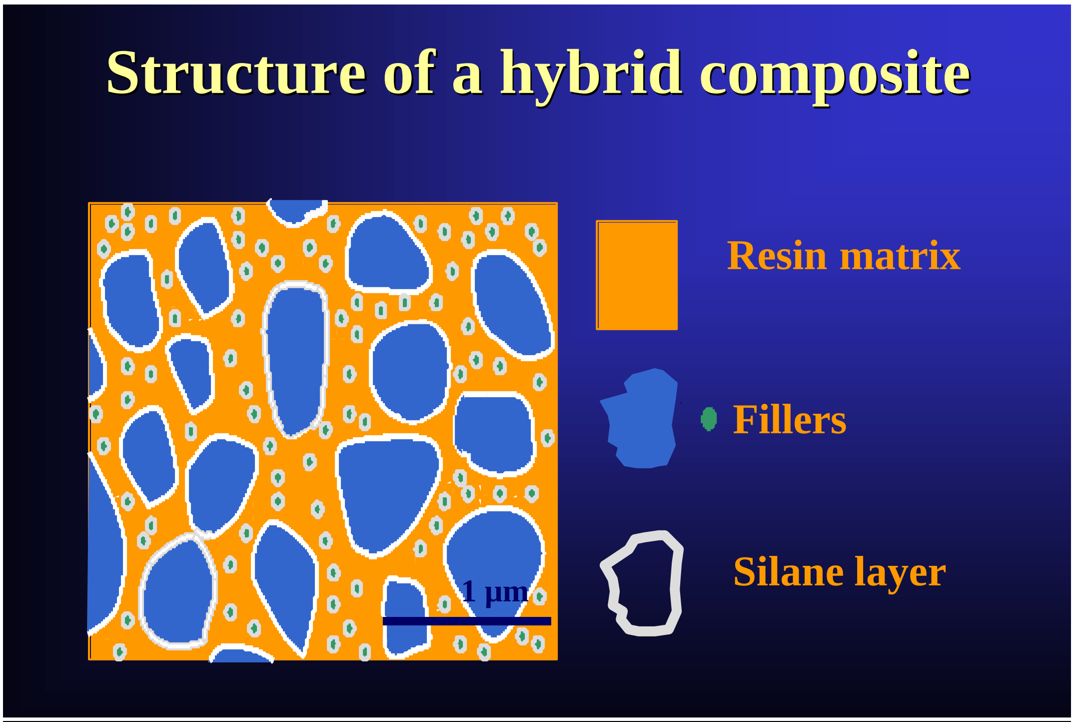

Fig. 1

Because of their generally known disadvantages, monofunctional monomers such as MMA are no longer state-of-the-art materials in the realm of composite veneering. The polymerisation of the bi-functional monomers used today leads to the formation of three-dimensionally cross-linked structures, meaning that in principle a single macromolecule is formed.

Since the double bonds in typical dental monomers represent only a small proportion of the molecule, polymerisation shrinkage is reduced in comparison with MMA (the majority of the monomer molecule remains unchanged during the reaction).

The absorption of water is also reduced by the generally very hydrophobic middle parts of the monomer chain.

The high molecular weights mean that the monomers no longer become volatile at room temperature.

A disadvantage of most of the commercially available dental monomers such as Bis-GMA is their extremely high viscosity, which make the use of so-called thinning monomers such as TEGDMA necessary. These thinning monomers partially cancel out the above-mentioned advantages.

The likelihood of both the double bonds of a bi-functional monomer failing to react during polymerisation is very small. Furthermore, the mobility of any monomers which do remain in the highly cross-linked matrix is also very low. The release of residual monomers is therefore greatly minimised in comparison with MMA. Normally, dental composites contain residual monomer levels of less than 2% and a residual double bond level of approx. 35%.

And now to the **inorganic** components:

Various kinds of glass, special glass-ceramics and quartz are used as so-called *macrofillers* in dental applications. Modern grinding technology can manufacture mean particle sizes of less than 1 µm without abrasion particles. Abrasion particles from grinding bodies or mill cladding lead to opaque powders which are not usable for dental applications.

The aggressive oral environment calls for dental fillers with exceptional hydrolytic stability. The refractive index of the materials used must agree with that of the monomers. A high proportion of silicon dioxide is desired in the glass matrix to allow for a lasting silanisation.

In addition to these macrofillers, pyrogenic silica is also used as a microfiller. Pyrogenic silica is a form of amorphous silicon dioxide with a primary particle diameter of < 0.05 µm, produced in an oxy-hydrogen gas flame. Such particles have a very large surface area (up to 350 m^2/g) and have therefore a strongly thickening effect. They are used to control the rheological properties of the composite, in other words the flow properties. The microfiller particles can insert themselves into the gaps between the macrofillers. The thickening effect means that the filler must be introduced to purely microfilled composites in the form of fragmented polymer or agglomerates.

As **all new-generation light-cured indirect composite materials** contain *inorganic fillers* in the form of ultra-fine glass or glass-ceramic powders alongside a matrix consisting of *polyfunctional methacrylate monomers,* **all of these materials** match that description and must therefore still be described as composite or indirect composite materials.

Word creations such as Polyglass®, Ceromer® and such like do not represent new groups of materials from the material science point of view, but are at most marketing instruments used to differentiate these materials from previous-generation veneering materials.

3.2 Material Properties

Compared with non-filled plastics, filled composites display considerably better material properties:

An empty sack cannot stand !

The old chemist's adage "a lot helps a lot", i.e. the more filler, the better the material properties, applies only to a certain degree of filling and strictly speaking only if the resin matrix is identical. While some parameters, for example compressive strength, increase with the content of incompressible filler other parameters, for example flexural strength and impact strength, are more likely to be negatively influenced, i.e. the material becomes brittle.

Finally, abrasion resistance is not only influenced by the quantity of filler, but also by the shape and size of the particles.

Similarly the quality of the silanisation of the filler surfaces ultimately plays a decisive role for all of the criteria mentioned.

The fillers become permanently embedded in the resin matrix through their silane coating. This improves the mechanical properties and prevents the ingress of water etc. at the matrix/filler interface on the surface of the composite.

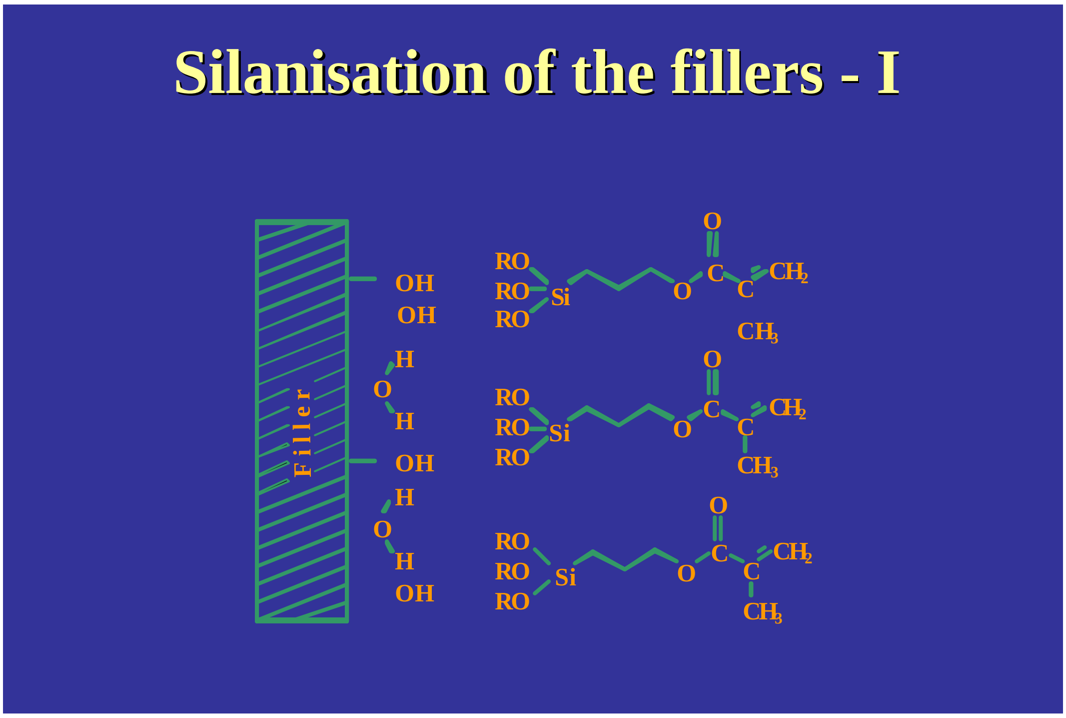

Fig. 2: Silanisation of the fillers I: The silane molecules (right) bond to the hydroxyl and oxygen functions of the filler surface.

The filler surfaces, which are actually hydrophilic (see diagram top left), are covered with a hydrophobic skin by the silanisation (see diagram, bottom), which then allows wetting by the „oily“ (i.e. hydrophobic) monomers to take place. Since, as a rule, methacrylic silane is used (see diagram top right), the filler particles are built into the synthetic matrix chemically and therefore irreversibly during polymerisation.

It is only on paper that this process appears simple. It must be perfectly controlled if the optimal material properties are to be achieved.

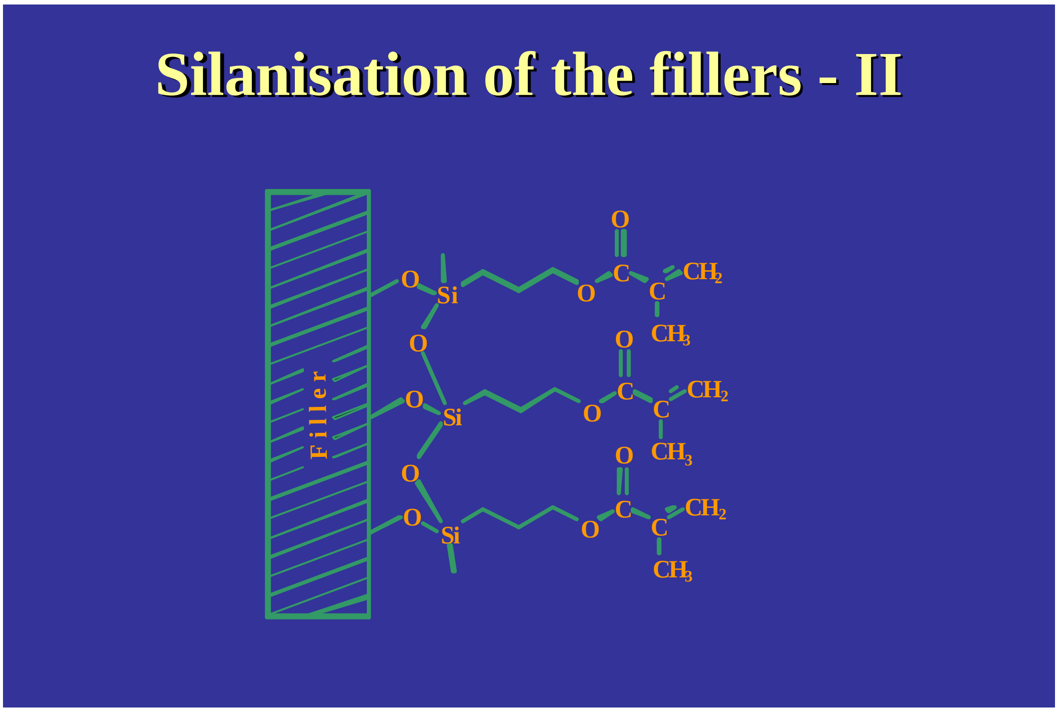

Fig. 3: Silanisation of the fillers II: After completion of the silanisation.

In comparison with unfilled synthetic materials, composites have generally higher abrasion resistance and higher mechanical strength.

It is generally true that the addition of fillers reduces polymerisation shrinkage. The coefficient of expansion, which is smaller than that of the resin matrix, also reduces thermal expansion and contraction. This reduces stress in the metal-resin bond when the temperature fluctuates. The inert fillers naturally also reduce the water absorption of the material.

The degree of polish attainable depends on the grain size of the filler used, since the filler grain size represents the minimum possible roughness of the surface.

4 Product Composition

4.1 Product Components

The Sinfony system consists of 16 dentine materials, corresponding to the Vita colour scale. Each colour has its own opaquer.
For the incisal area there are four incisal materials whilst two enamel effect materials, „polar“ and „sun“, are available for the incisal and occlusal areas. Additionally, there are four opalescent transparent materials and the range is extended with five opaque dentines. Nine intensive colours and five intensive opaquers are available for customisation.

4.2 Constituents

Sinfony, as an ultra-fine particle composite (or ultra-fine particle hybrid composite) contains of two kinds of filler:

The *macrofiller* (strontium aluminium borosilicate glass with a mean particle diameter of 0.5 - 0.7 µm; 40% by wt.) and the *microfiller* (pyrogenic silica; 5% by wt.) which can insert itself into the gaps between the macrofiller particles.

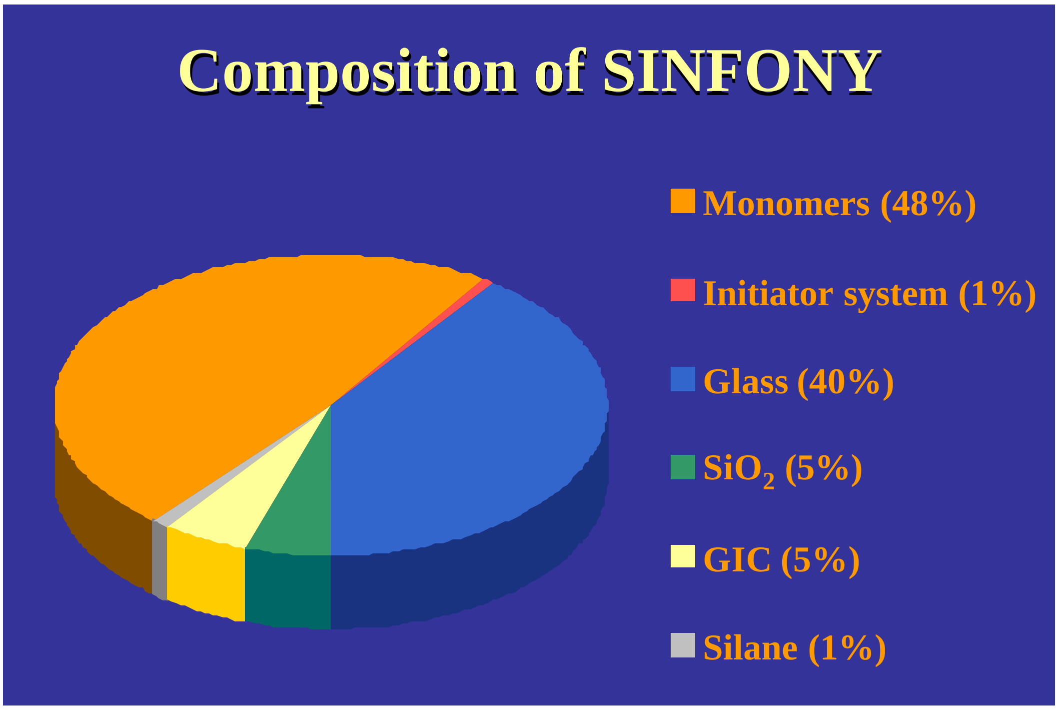

Fig. 4

In comparison with competitor materials, Sinfony has a lower filler content of about 50% (about 1% is accounted for by the silane layer), which is why the unique thixotropic consistency can be achieved.

The main component of the filler mix in Sinfony is a special, ultra-fine strontium aluminium borosilicate glass in the sub-micron range. In addition it contains pyrogenic silica, also known as micro-dispersed silicon dioxide.

A completely new feature is the addition of a special glass ionomer (5% by wt.), which influences the surface potential of Sinfony, as described above, in such a way that plaque accumulation is minimised. At the same time, this additive does not change the other favourable composite properties. Even colour and acid stability are at the same levels as undoped Sinfony.

As will be shown below, Sinfony has exceptional material properties. These result from the perfect control of the filler pretreatment, as well as from the highly reactive monomer system (a mixture of aliphatic and cycloaliphatic monomers) in conjunction with the specifically optimised photo-initiator system.

Components developed and patented by 3M ESPE Research have been applied both to the monomers and the initiator.

The Sinfony monomer system has low viscosity and very high reactivity. Both parameters lead to the resin developing a very high density of cross-linking.

Low viscosity is the prerequisite for the monomers to be able to diffuse well to the active (i.e. radical) centres of the growing polymer.

The very hydrophobic character of the monomers used means that Sinfony one of the lowest water absorption amongst competitor products.

The newly developed Sinfony monomer system contains no Bis-GMA or TEGDMA.

The special monomer system, a mixture of aliphatic and cycloaliphatic monomers, permits the realisation of exceptional mechanical properties, such as compressive and flexural strength and abrasion resistance, whilst simultaneously retaining a satisfactory degree of toughness, and thereby high impact strength. These parameters are particularly important for a veneering material used for dentures.

5 Test Results

5.1 Physico-technical Data

All of Sinfony's material parameters, which are significant for the performance of a indirect composite material, are highly satisfying. The material therefore fulfils the demand for optimal physical properties.

The **compressive strength** of the majority of veneering materials tested are largely similar to Sinfony. In comparison with Visio Gem there is an improvement in compressive strength.

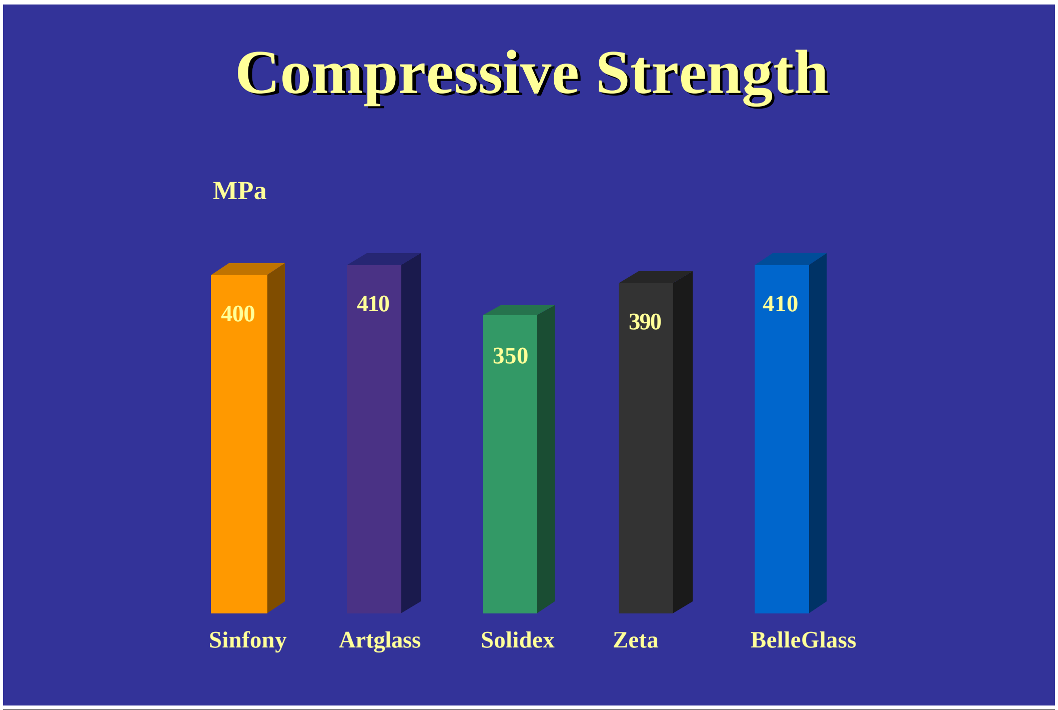

Fig. 5

Powers (J Dent Res, Vol 78, 1999) even demonstrated that Sinfony had much more significant advantages in compressive strength than competitor materials:

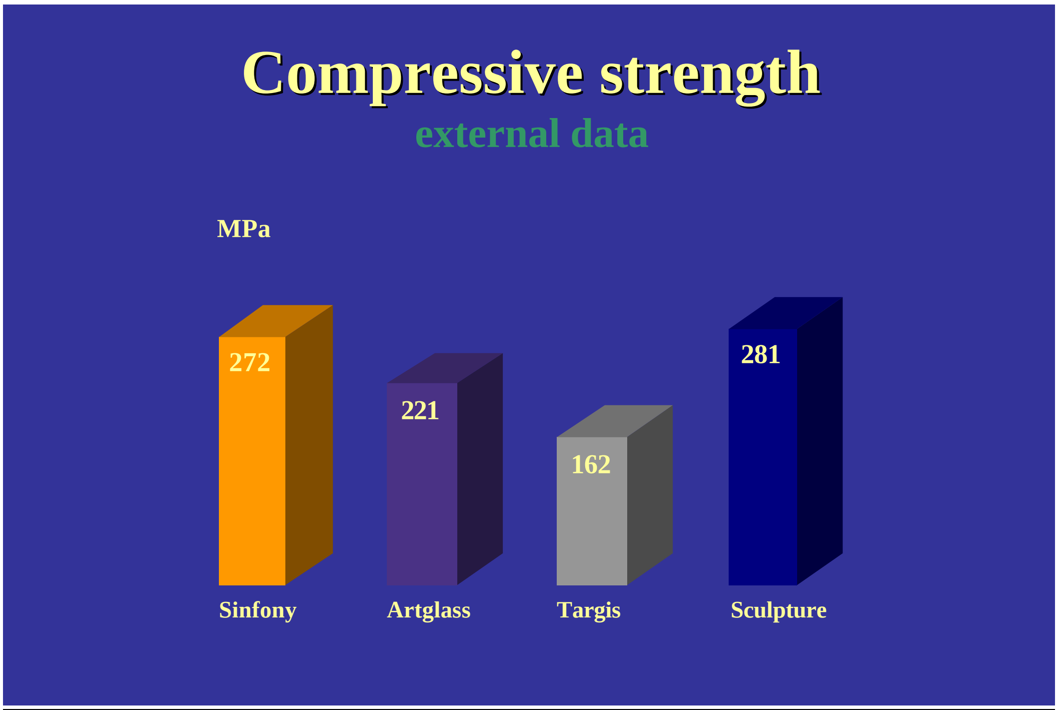

Fig. 6

In respect of **flexural strength** (according to ISO 10477, Polymer-based crown and bridge materials) the leap forward in the development of indirect composite materials is clear. Flexural strength is one of the most important material parameters for a veneering material. Tensile, compressive and shearing stresses occur simultaneously in the test specimen. At 105 MPa, Sinfony's flexural strength is some 40% greater than that of Visio Gem.

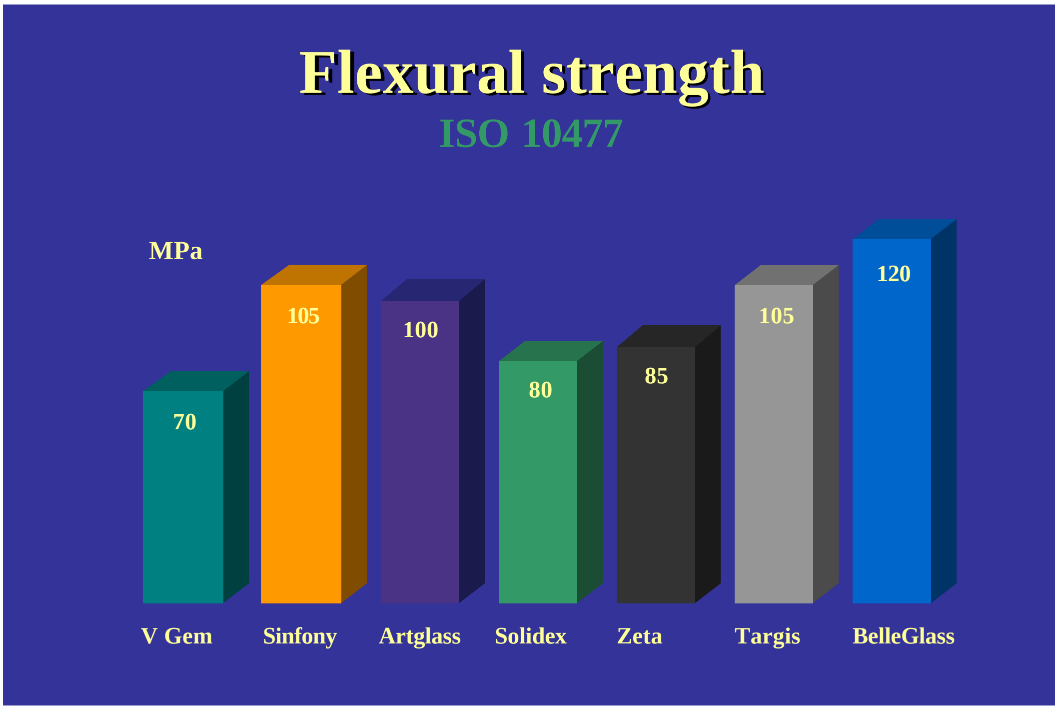

Fig. 7

To simulate the consistent quality of Sinfony, a long-term test was performed, whereby the test specimens were boiled for up to 30 days. No statistically significant changes were found.

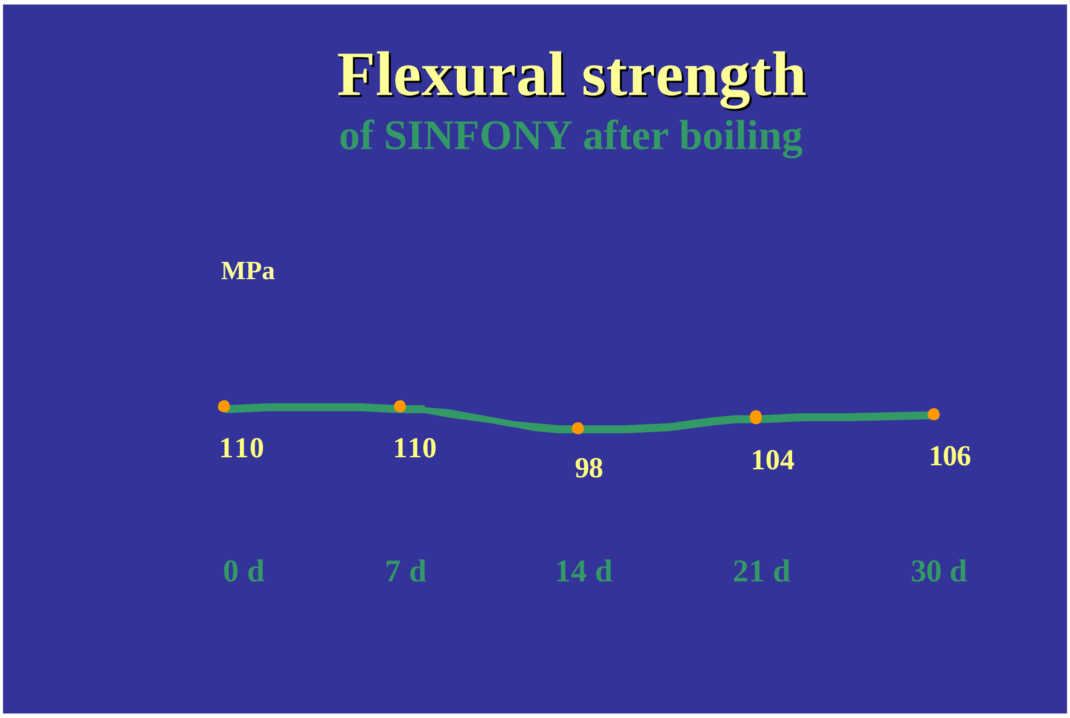

Fig. 8

In a bending test it is the modulus of elasticity which is determined in parallel. This is a measure of the rigidity of a material. A low modulus of elasticity means flexibility and a high modulus of elasticity means brittleness. Ideally a veneering material should have a high flexural strength and a relatively low modulus of elasticity. With removable dentures, for example, this prevents the veneer flaking off, although it may be subjected to stresses and strains and may even be deformed.

Sinfony offers just such an ideal combination of flexural strength and modulus of elasticity. Particularly for removable dentures, other materials have a modulus of elasticity which is too high and therefore too brittle.

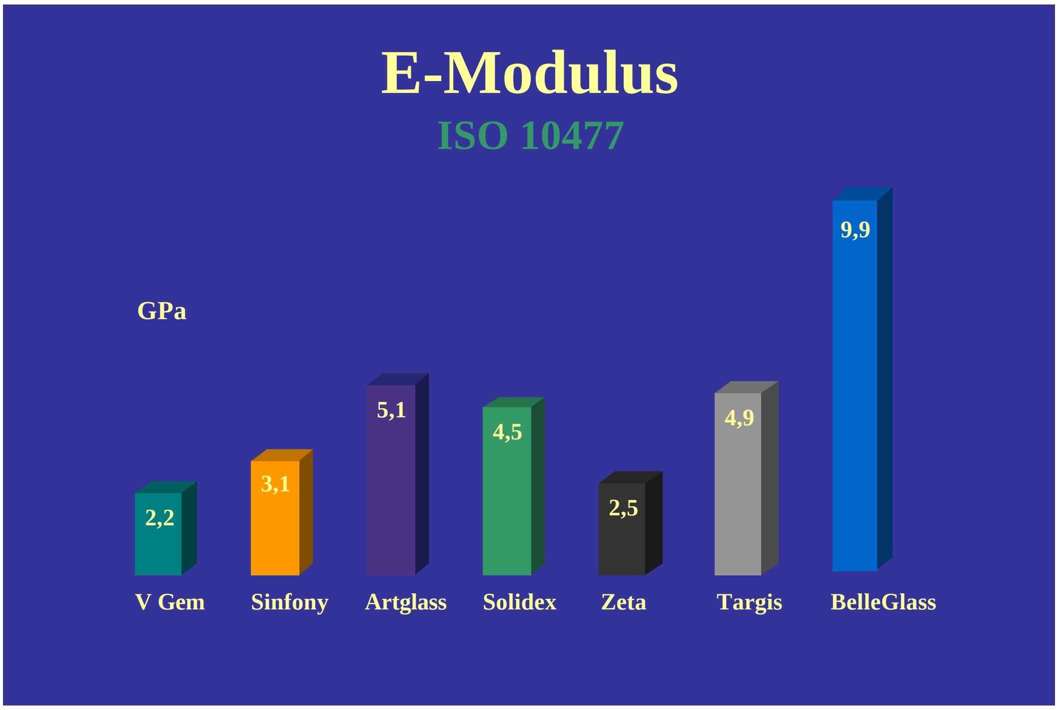

Fig. 9

While the tests on compressive and flexural strength are what are known as static methods, the **impact strength** (DIN 53 453, Transverse Impact Test) is a dynamic method. The test specimen, fitted in a pendulum impact tester, is fractured by a falling hammer and the energy required for this is measured. Such stresses occur in the mouth when, for instance, biting on a piece of nut shell in a cake, or through the effect of an external force (falling), or a malocclusion. As a result, increased chipping and fractures are clinically observed when materials with low impact resistance are used.

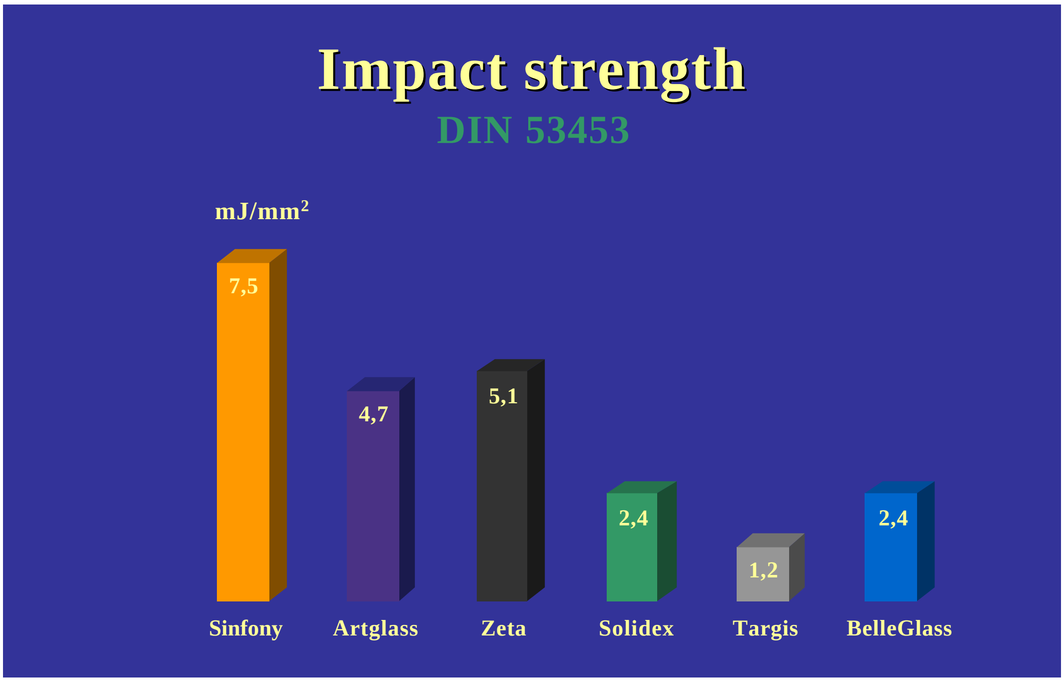

Fig. 10

At 7.5 mJ/mm^2, Sinfony clearly surpasses the other modern materials. Solidex, BelleGlass and Targis are relatively brittle and in this respect cannot satisfy the demands on a modern veneering material.

Abrasion resistance is another important requirement for indirect composite materials, particularly when these are used for occlusal veneers.

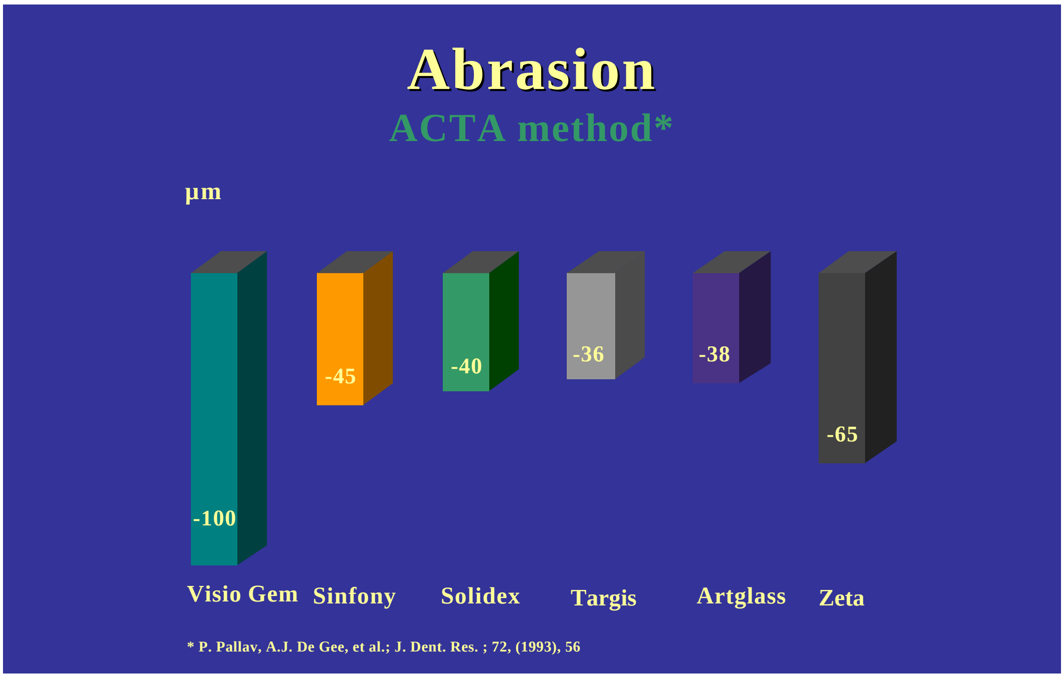

Fig. 11

The abrasion resistance of the new veneering materials was determined by the ACTA method (3-media abrasion: wheel with test specimen, antagonist wheel and a third medium simulating food) and compared with Visio Gem as a standard. The ACTA method, which uses millet husks as an abrasive medium, correlates well with clinical abrasion studies.

The abrasion resistance of Sinfony is 55% higher than that of Visio Gem. The other indirect composite materials of the new generation also show improved abrasion resistance in comparison with Visio Gem.

Another method is toothbrush abrasion. Here too the enormous progress with regard to the abrasion resistance of the ultrafine particle composite becomes apparent.

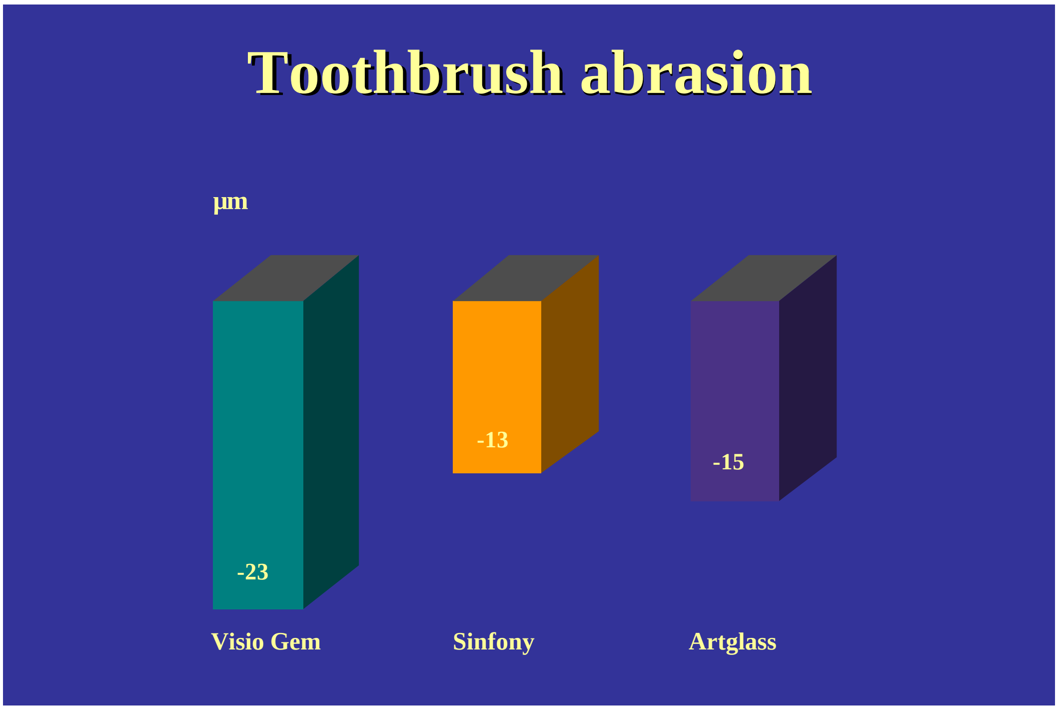

Fig. 12

These internal date were confirmed externally. The following two figures show the positive abrasion resistance of Sinfony in comparison to it's competitors.

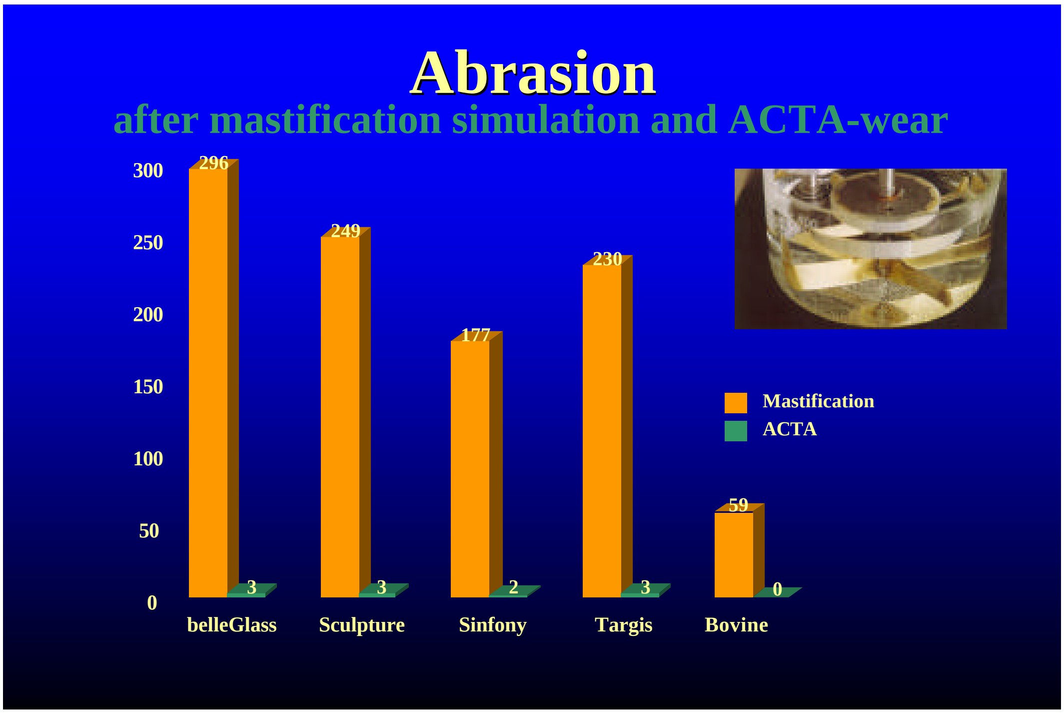

Fig. 13

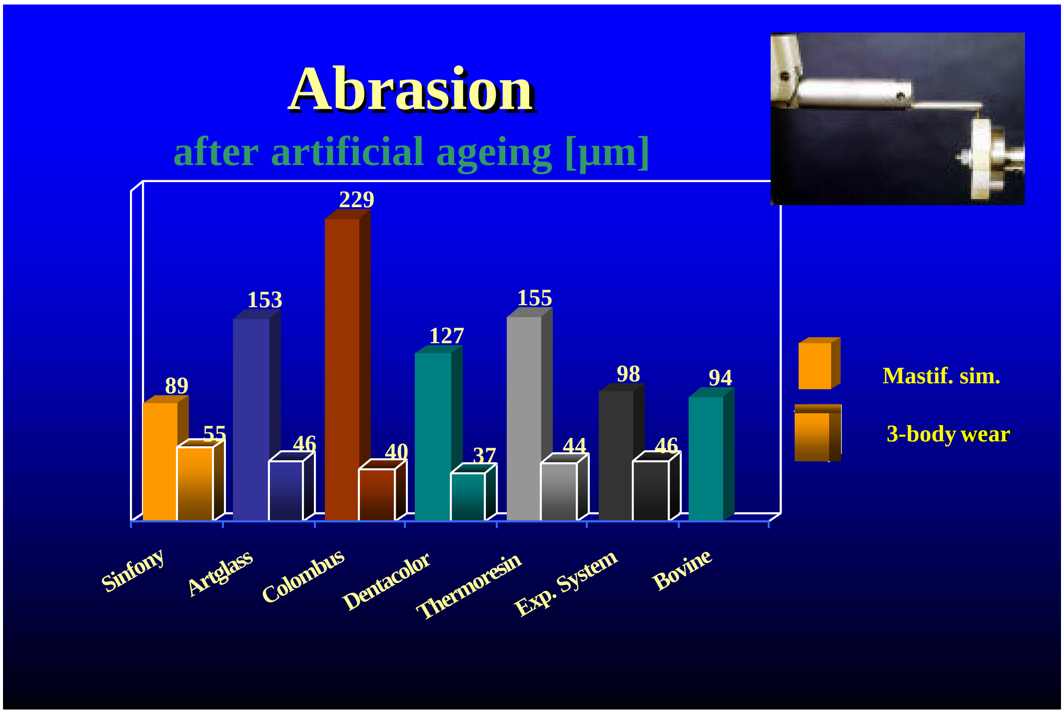

Fig. 14

Water absorption has been identified as the most important factor in physical and chemical decomposition of the polymer matrix.

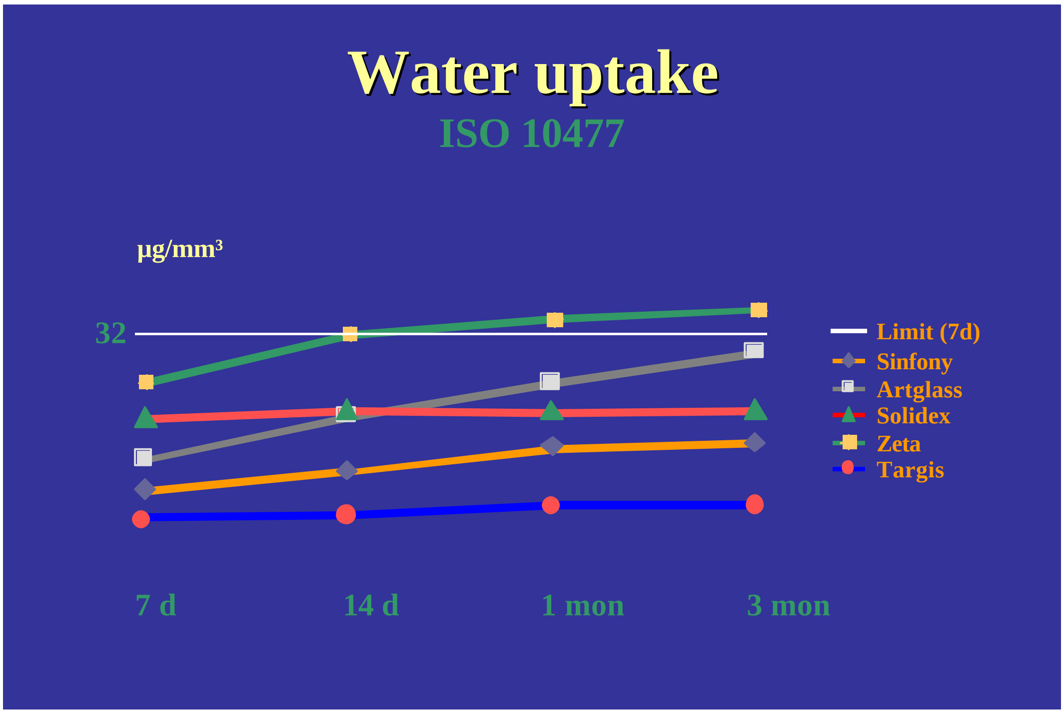

Fig. 15

The absorption of water correlates directly with the destruction of the boundary zone between filler and matrix. The result is the development of a plasticising effect on the material as well as a reduction in the tensile strength and lower abrasion resistance*.

At only 15 µg/mm^3 (measured according to ISO 10477, i.e. after seven days), Sinfony had nearly the lowest water absorption of all the materials tested. On the other hand, it is known that in the majority of products water absorption has not reached its equilibrium value after only a week. In four of the five veneering materials tested, water absorption is not complete until three months have passed. For Sinfony, the final value lies just under 20 µg/mm^3, and for Artglass nearly 30 µg/mm^3. The limiting value according to ISO 10477 is 32 µg/mm^3. This was exceeded by Zeta after no more than one month of storage in water.

In parallel with water absorption, **solubility** is also associated with the water repellence of the polymer matrix and, in addition, it is an indicator for completion of polymerisation. In this comparison Sinfony is clearly the best.

* Craig R. G., O'Brien W. I. and Powers J. M., Dental Materials: properties and manipulation, 6th ed., St. Louis, Missouri, 1996: Mosby, 55-78; Phillip R. W., Skinner's science of dental materials, 9th ed., Philadelphia, 1991: Saunders, 215-229

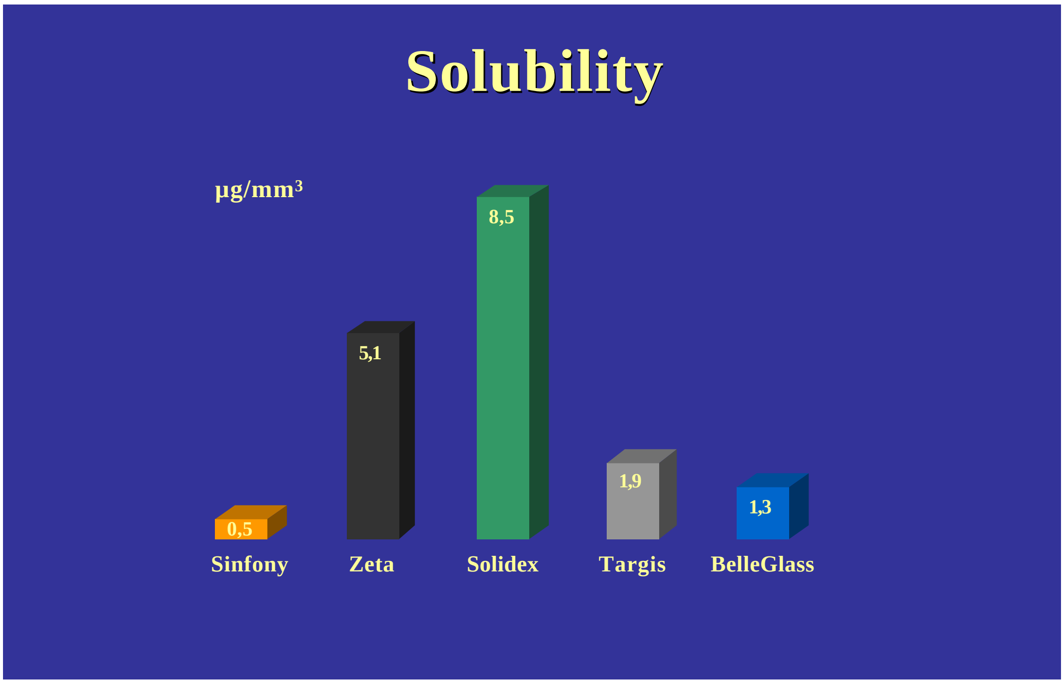

Fig. 16

Low water absorption and solubility are definitely major causes of the low tendency towards discoloration compared with competitors even under the most critical conditions (ageing when exposed to moisture, temperature and xenon light, immersion in highly staining fruit juice or tea solutions). Powers (J Dent Res Vol 78, 1999) investigated the corresponding influences. His results are shown here:

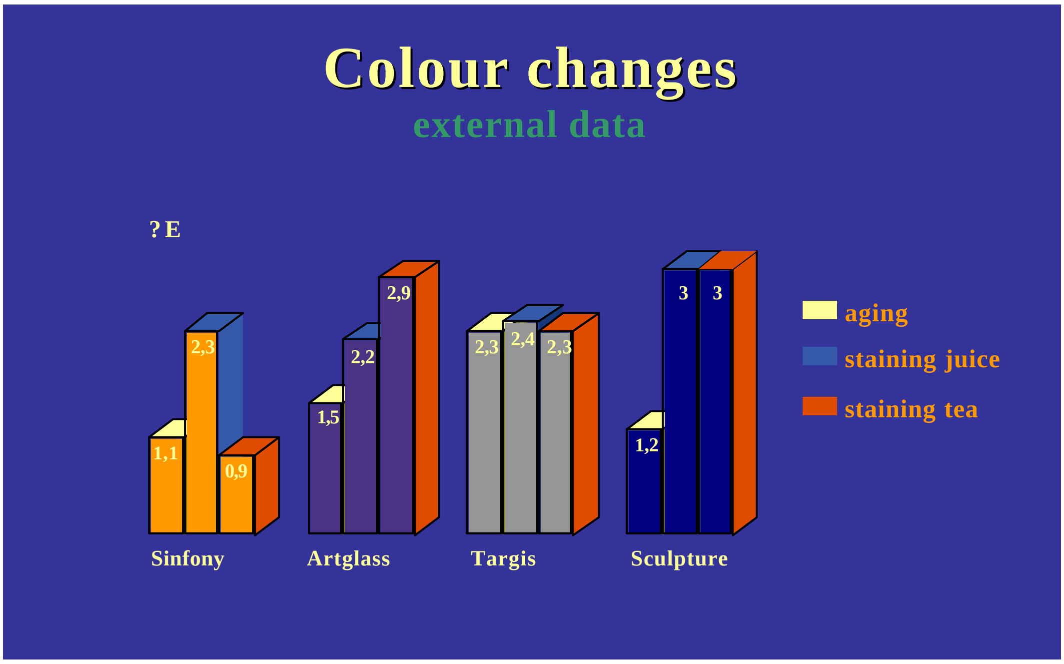

Fig. 17

Discolorations are usually given according to the L*a*b* scale. A change ?E of less than 1.5 cannot normally be perceived by the human eye.

In vitro plaque-adhesion experiments confirm in vivo experiences: Less plaque covered area and lower biofilm strength of attachment on Sinfony in comparison to other indirect composites (Visio Gem, Zeta LC, Solidex, Targis, Artglass).

Fig. 18

5.2 Bonding to metal

In contrast to ceramics, it is known that light-cured indirect composite materials have no natural tendency to bond with the metal framework. Sinfony therefore has been specifically adapted to the trusted **Rocatec** system and, when used in combination with Rocatec, reaches outstanding bond strengths. This has been achieved mainly by increasing the cohesion in the opaquer.

For the measurement of **bond strength** in a **tensile test**, the faces of moulded test screws were bonded together in an aligning device. Measurement took place after exposure to water and thermocycling. The **shear bond strength** was determined according to ISO 10477 (Amendment 1).

In all the systems investigated initial cohesive fracture takes place in the opaquer, i.e. in all cases the actual metal-to-resin bond was greater than the intrinsic strength of the resins. Sinfony achieves the highest bond strength, although the value is not significantly different from that of Visio Gem.

Siloc, the successor to Kevloc, is proving to be better, but it is still unable to achieve the excellent long-term bond strengths of Rocatec (Wöstmann, 1999).

In a tensile test on a high-gold alloy the excellent long-term strength of the Sinfony / Rocatec bond compared to a competitor system became evident.

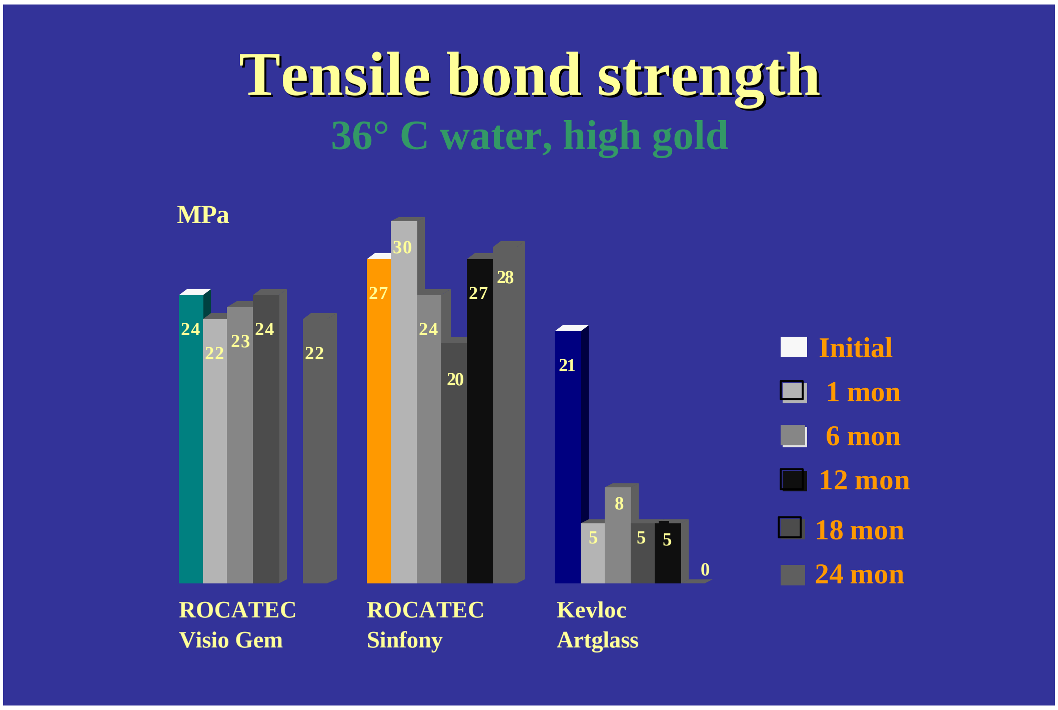

Fig. 19

In the shear test as well, the bond between Sinfony and Rocatec with various metals is superior to that of other products.

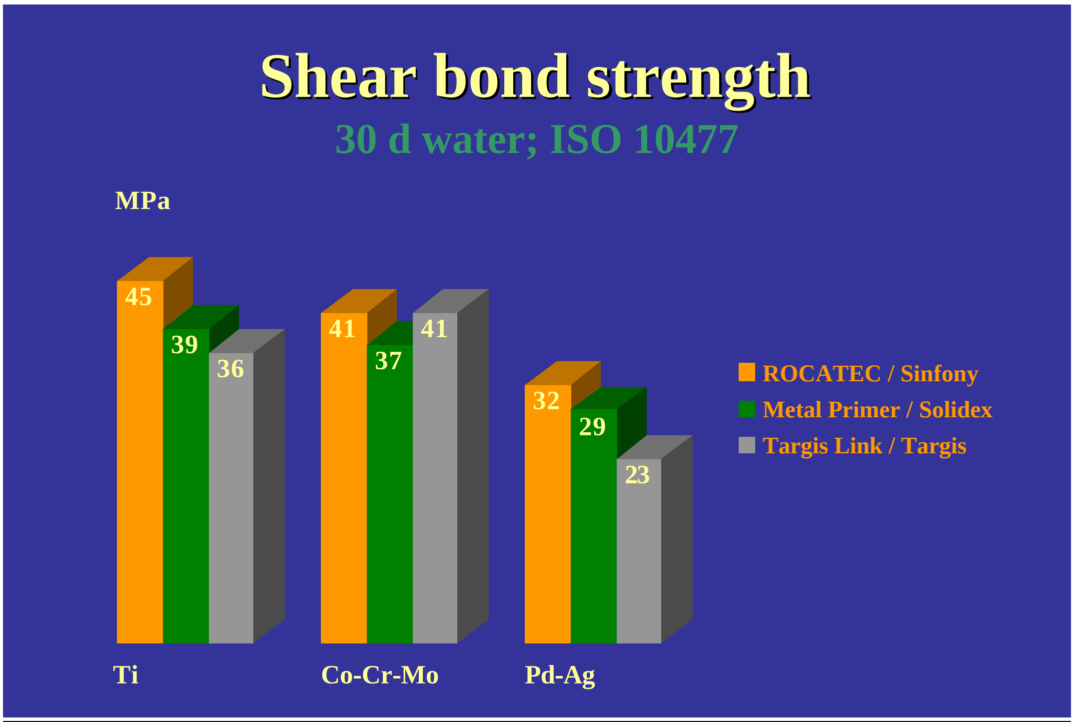

Fig. 20

Absorption of water in the bonding zone is only completed after one to three months depending on the material. The weakening of the bonding layer saturated with water after thermocycling then leads to the low bond values described above although initially after load cycles (without water saturation of the bonding layer) adequate bond strengths are measured.

5.3 Fibre reinforcement

Sinfony is ideally suited to fibre reinforcement in order to make aesthetically perfect, metal-free, multi-part composite bridges as long-term temporary work. With the glass fibre systems from Stick Tech (Stick, Stick Net), Jeneric Pentron (Fibrekor) and Ivoclar (Vectris) extremely stable restorations can be made.

Judging from the results of the bending test illustrated below one can clearly recognise the increase in strength as the quantity of glass fibre increases, but also the better compatibility of Sinfony with Vectris than Targis with Vectris.

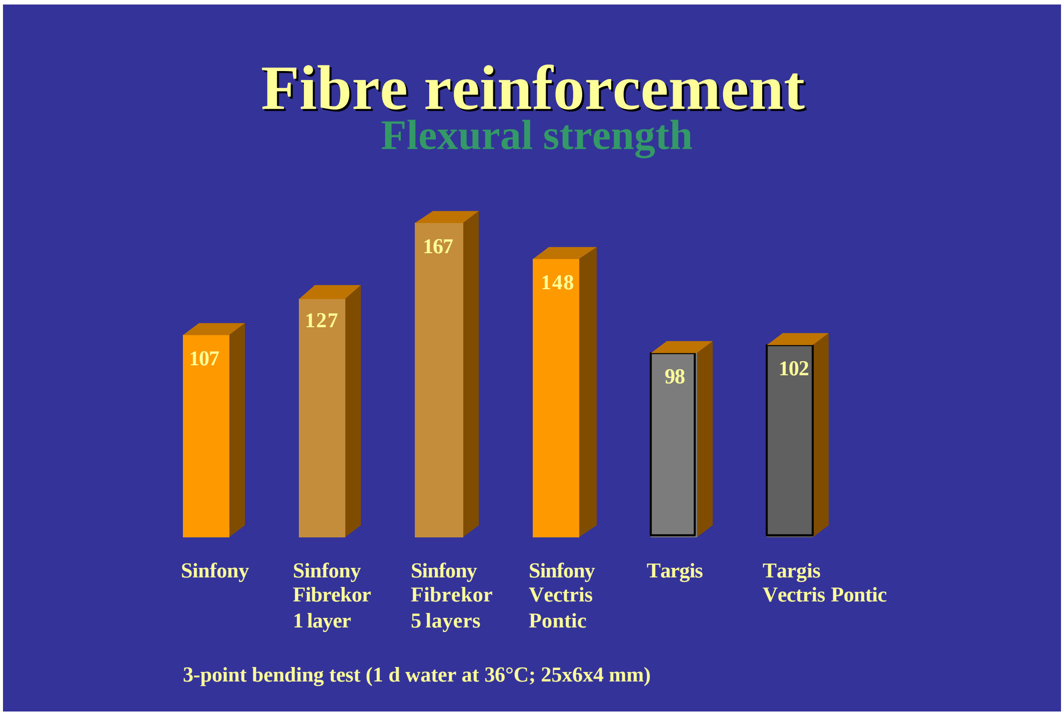

Fig. 21

In a study published in 1998 the fracture strength of standardised single crowns was described. Here too the Sinfony/Vectris system proved to be a highly attractive alternative to Targis/Vectris because after thermocycling there was even found to be an increase in resistance to fracture.

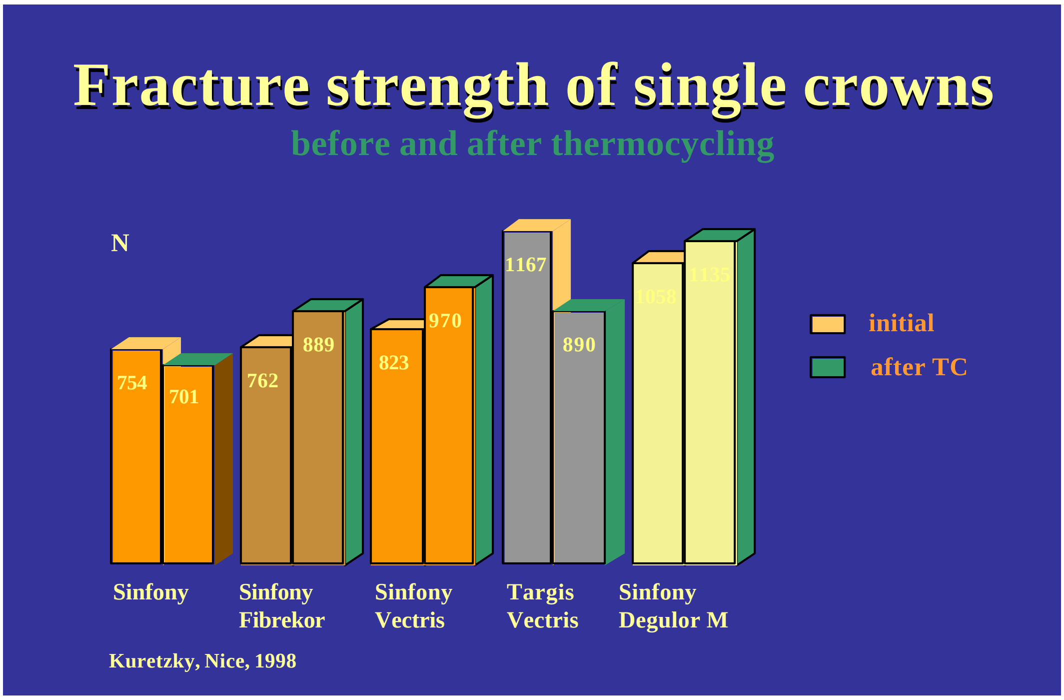

Fig. 22

At the same time, a study from Regensburg was presented which confirms the above findings and demonstrates that Sinfony achieves a good bond to Vectris not just initially, but also after repair (aged Vectris).

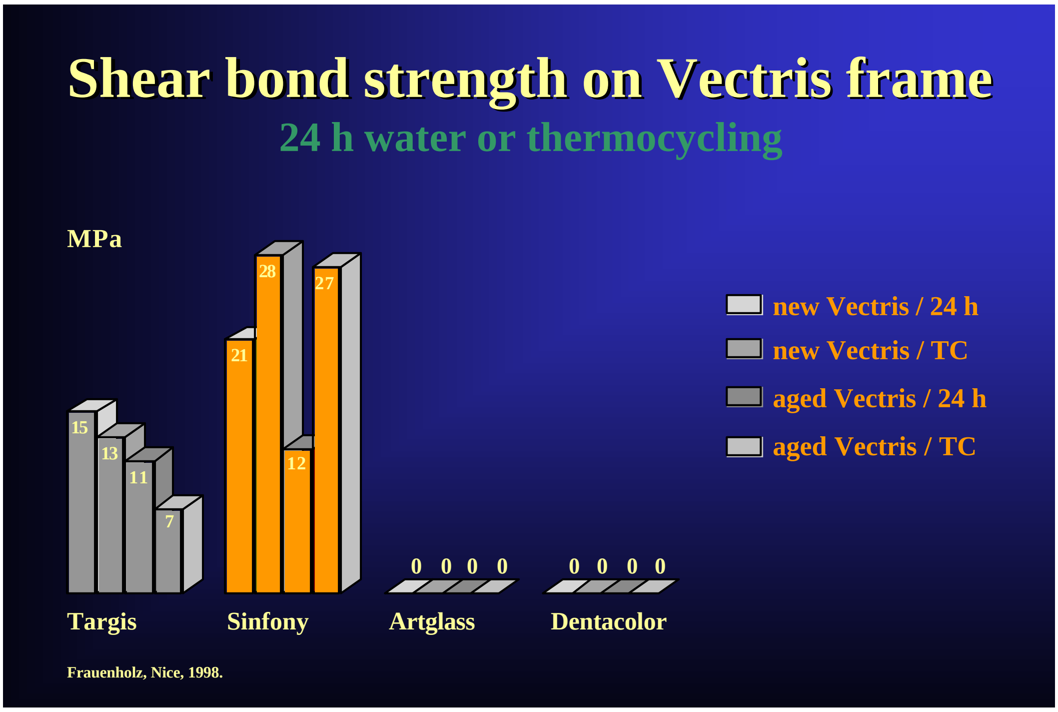

Fig. 23

5.4 Clinical Data

5.4.1 Telescopic crowns

Prof. Wöstmann, Gießen published so far his 18 months data about his experiences on composite veneering of telescopic crowns (Denta color, Artglass and Sinfony).
The Sinfony / Rocatec combination was obviously more successful than Artglass / Siloc.
The so far unpublished 3 years results are even more positiv for Sinfony / Rocatec

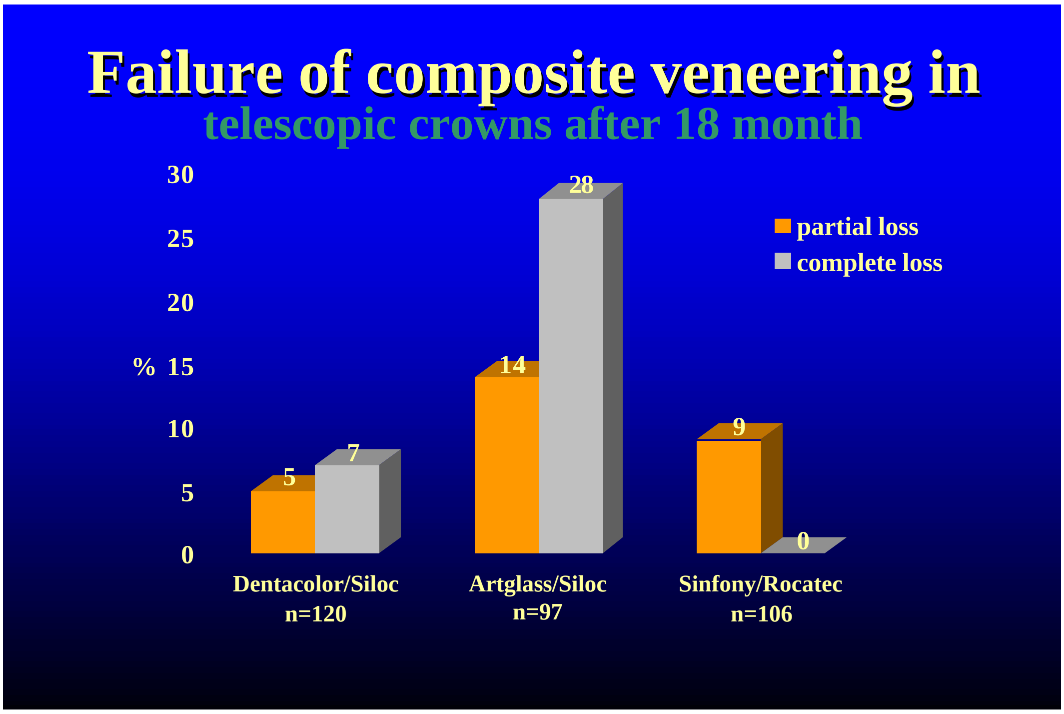

Fig. 24

5.4.2 All composite crowns and Inlays

The Dental Advisor reports about the excellent results of the 1 year recall of a 5 year study.

Fig. 25

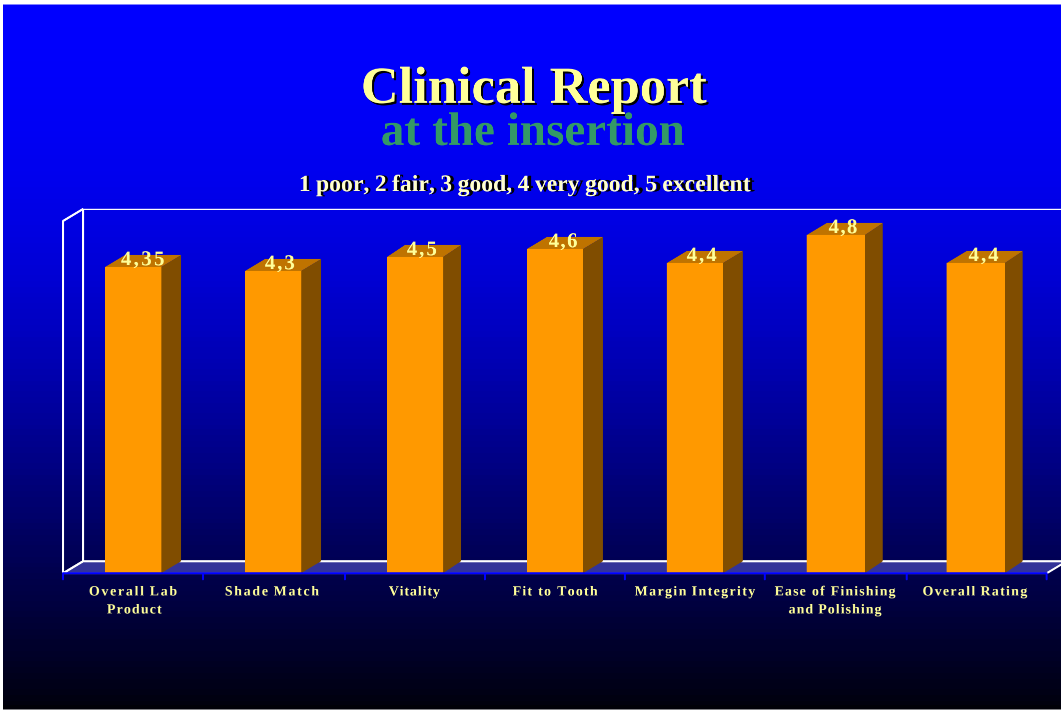

Fig. 26

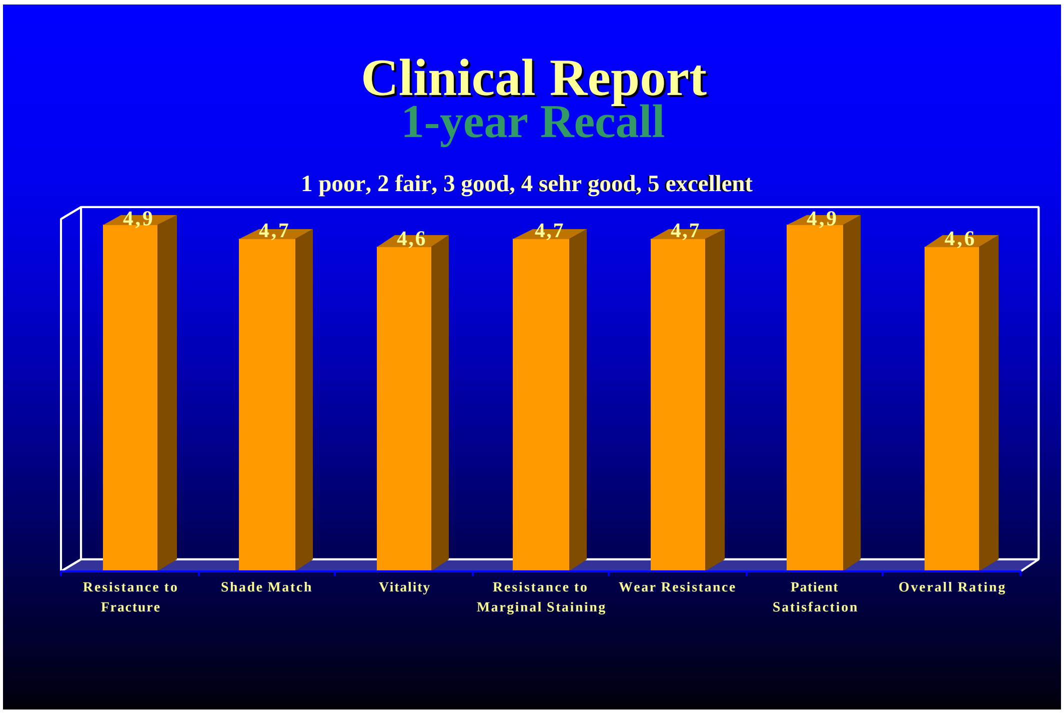

Fig. 27

A comparable positive conclusion was published in 2000 from another US-study in Reality:

Fig. 28

5.4.3 Fibre-Reinforced Bridges

Very promising results after the 2 years recall of 31 bridges were published by Pekka Vallittu.

Fig. 29

6 Summary

Sinfony meets all the requirements for a modern indirect composite. The enhancement of the tried and tested Visio Gem system has been a complete success. The positive aspects of this Sinfony predecessor have been retained or further improved, and its weaknesses eliminated. In the meantime, Sinfony has become established on the market and is now the leading indirect composite in Germany.

Special mention should be made of the successful combination of improved material properties and optimised aesthetics, while still retaining the easy handling. Improved thixotropic consistency has made Sinfony even more pleasant to use.

Sinfony is not only 100% compatible with the Rocatec adhesive system, but its bond strength has been increased still further.

Sinfony clearly outperforms competitor products in terms of the important properties of impact resistance and water absorption. As regards the other properties, Sinfony is either comparable or better.

The outstanding material properties and excellent market experience have led to the range of indications for Sinfony being broadened. These now also include individual crowns, fibre-reinforced crowns and bridges as well as inlays and onlays.

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